Exhibit 192

Pfizer Finding as of 8-12-22

https://www.dropbox.com/scl/fi/9g918lxdeuqdggtomb2o8/Pfizer-Findings-as-of-8-12-22.xlsx?dl=0&rlkey=mmhra071dgpbqviuwi0lv8326

Pfizer's Documents

https://phmpt.org/pfizers-documents/

Timestamp	Document Name - the name of the PDF as downloaded from phmpt.org/pfizers-documents/ (example: Bates-FDA-CBER-2021-5683-0002379_te.xpt)	Page Number(s)	Paragraph Number	What type of issue did you find?	Explanation – what about the above referenced page and paragraph deserves attention? If you selected "Other" for the "type of issue" above, please start your Explanation by providing a name/short description for the issue.
3/7/2022 20:29:16	125742_S1_M5_5351_c4591001-fa-interim-protocol	1-1413		Study Protocol	
3/7/2022 20:47:03	FDA-CBER-2021-5683-0000054 / 5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021	20	Table 7. AESIs Evaluation for BNT162b2	Adverse Effects - Other	Encephalitis was listed among the 'Most frequently reported relevant PTs' within the 'Immune-Mediated/Autoimmune AESIs' section. It also features throughout the report, various different types of Encephalitis. This could be nothing, but something to keep eyes on. In Australia right now we are going through a Japanese Encephalitis outbreak, they say due to the floods. Despite the fact we have had floods in recent years, it is usually just the general ross river fever. JEV is usually asymptomatic but now it is hospitalising people with brain swelling. It is found at the tip of QLD, in Australia, not all over. It is normally detected in pigs. You would have to check with an immunologist whether or not those who have been vaccinated, and are bitten with a mosquito carrying Encephalitis could be at higher risk of being highly symptomatic due to the vaccine response. As no cases of JEV have been detected in the state of QLD for years.
3/7/2022 20:54:46	5.3.6-postmarketing-experience.pdf	11	Table 5	Fatality	Table analysis. • Page 11 VAED. 138 Serious Cases, 38 deaths, 27.5% of the reported cases resulted in death
3/7/2022 20:56:53	5.3.6-postmarketing-experience.pdf	12	table 6	Fatality	Table 6. Description of Missing Information Death (28) is the second most frequent outcome in pregnant or lactating mothers in the time period only trailing Headache (33). Total Deaths: 23+1+2+1+1{death neonatal in second section}=28 (did not count the 5 pending). spontaneous abortion (23), outcome pending (5), premature birth with neonatal death, spontaneous abortion with intrauterine death (2 each), spontaneous abortion with neonatal death, and normal outcome (1 each). And 4 serious foetus/baby cases reported the PTs Exposure during pregnancy, Foetal growth restriction, Maternal exposure during pregnancy, Premature baby (2 each), and Death neonatal (1). Trimester of exposure was reported for 2 cases (twins) as occurring during the 1st trimester. Death (28) is the second most frequent outcome in pregnant or lactating mothers in the time period only trailing Headache (33). Trimester data only collected in 22 of 124 cases.
3/7/2022 20:57:58	5.3.6-postmarketing-experience.pdf	17	Table 7	Fatality	Page 17. Infection fatality rate as calculated in the COVID-19 AESIs. 3067 cases with 136 confirmed deaths is 4.43% which is much higher than is typically reported.
3/7/2022 20:58:48	5.3.6-postmarketing-experience.pdf	20	Table 7	Fatality	Page 20. Immune-Mediated/Autoimmune AESIs. 12 fatalities out of 1050 reports 1.14% of the known cases resulted in death
3/7/2022 20:59:32	5.3.6-postmarketing-experience.pdf	21	Table 7	Fatality	Page 21. Neurological AESIs. Median time of onset 1 day. 16 fatalites out of 501 event 3.19% of the known cases resulted in death
3/7/2022 21:00:18	5.3.6-postmarketing-experience.pdf	22		Fatality	Page 22. Renal AESIs. 69 cases, median 4 days (renal failure in 4 days?), 23 known fatalities 33.33% of the known cases resulted in death
3/7/2022 21:01:32	5.3.6-postmarketing-experience.pdf	23		Fatality	Page 23. Thromboembolic Events. 151 cases,median onset 4 days (seems incredibly fast), 18 known fatalities 11.9% of the known cases resulted in death.
3/7/2022 21:02:19	5.3.6-postmarketing-experience.pdf	24		Fatality	Page 24. Stroke. 275 cases all serious,median onset of symptoms 2 days, 61 known fatalities 22.18% of the known cases resulted in death.
3/7/2022 21:02:58	5.3.6-postmarketing-experience.pdf	26		Study Protocol	Page 26. The US outperforms Medication errors by a wide margin. Horrific.
3/7/2022 21:16:03	5.3.6-postmarketing-experience	15 and beyond		Efficacy	16 cases of "vaccination failure", lack of efficacy in preventing covid infection, seriousness level is: all serious.
3/7/2022 21:19:48	CRFs-for-site-1096	146		Adverse Effects - Other	lower extremity paralysis was documented as AE.
3/7/2022 21:23:04	CFRS-FOR-SITE-1081	420 - 425, and 449 - 455		Adverse Effects - Other	several entries on "anemia," and a series of notes debating back and force on if the anemia should be counted as AE. The final conclusion is it should be counted as AE, as the patient's anemia has worsened after receiving the vaccine.
3/7/2022 21:24:52	CFRS-FOR-SITE-1081	437		Adverse Effects - Other	There were a series of unusual discussions on "serious abdominal pain" -- On page 437, "SAE RECON: lower abdominal pain(Onset date:11Oct2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF."
3/7/2022 21:39:47	Adverse Events	16	Table 7	Adverse Effects - Miocarditis	Cardiovascular # of cases 1403 including 136 fatalities. The conclusion on p. 17 was as follows "Conclusion: this cumulative case review does not raise new safety issues. Surveillance will continue." I noted that on the following pages through p. 23 of the different body systems, the conclusion was always the same re "not raise new safety issues despite the listing of fatalities." I don't think I know how to upload screen shots.
3/7/2022 23:32:08	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	40; 115; 160-161; 162; 82-113	1; 6 - 7; Table 9; Table 10; Table 6	Adverse Effects - Other	See screenshot upload
3/7/2022 23:36:48	125742_S1_M2_26_pharmkin-tabulated-summary.pdf	whole document		COVID Testing	The whole document is on trials on rats and shows the spike moved to every major organ
3/7/2022 23:44:52	125742_S1_M2_26_pharmkin-written-summary.pdf	whole Document		COVID Testing	The animals injected by IV the spike did not remain, injected by needle It remained in the body and spread into more organs
3/7/2022 23:54:34	125742_S1_M5_5351_c4591001-fa-interim-excluded-patients	1, 3, 4	charts	Adverse Effects - Other	Substantial "protocol" issues in Phase 1 and test subject no-shows for Phase 2. Were the no-shows due to negative side effects from the first shot? If so, how were these drop-outs recorded, i.e. were their negative side effects lost as far as the data is concerned?
3/8/2022 0:04:11	125742_S1_M4_4223_185350.pdf	page 29	6	Adverse Effects - Other	Hazard warning- Chemical in drug known to cause Cancer
3/8/2022 9:54:06	125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf	1407	2	Study Protocol	Just wondered why liver function tests were not required as a safety monitoring procedure.
3/8/2022 9:57:44	test	4344	333	Adverse Effects - Other	test
3/8/2022 10:05:09	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy.pdf	13	2.7.3	Efficacy	"Proposed indication: Active immunization to prevent COVID-19 in individuals 16 years of age and older" Off the bat, they were studying efficacy in preventing Covid-19, THE DISEASE, not infection by SARS-Cov-2 virus. This makes it at best a PROPHYLACTIC THERAPY, not a vaccine. Exactly this discredits the entire vaccination program and mandates. They never intended to study efficacy in preventing infection or transmission, only actual disease, as far as I can tell! I could be wrong. Just an observation. The simplest things are often overlooked.
3/8/2022 13:10:17	5.3.6 postmarketing experience.pdf	7	Table 1	Study Protocol	For cases listed as "Not recovered at the time of report" is there any follow up in future reports? The Methodology section says "only those having a complete workflow cycle in the safety database (meaning they progressed to Distribution or Closed workflow status) are included in the monthly SMSR". What condition are these "not recovered" individuals in that their case can be considered closed? If someone is in a coma at the time of the report and dies later, does that fatality not get counted since their case was reported closed?
3/8/2022 14:19:47	STN 125742_0_0 Section 2.7.4	14	2	Study Protocol	The study was unblinded. They gave the placebo group the vaccine on a certain date. Thus no comparison group.
3/8/2022 14:21:58	5.3.6-postmarketing-experience.pdf	13	Table 6, Row 4	Adverse Effects - Other	Misadministration-In pediatric individuals <12 years of age, there are 34 cases (24 of which were considered serious) having 132 reported events. 27 events were categorized as "product administered to patient of inappropriate age." So 27 events/34 cases means 79% of these children were given wrong medication? Seems incredibly high.
3/8/2022 15:47:31	5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021	12	4 bullet point	Adverse Effects - Other	270 mother cases, 238 of them no outcome provided
3/8/2022 15:50:59	125742_S1_M1_waiver-req-designated-suffix	3 and 4	Conclusion	Adverse Effects - Other	Pfizer asserted that VAERS and VSD were adequate systems to ensure safe dispensing to obtain a waiver but later depreciated the effectiveness of the VAERS system when adverse effects where reported in high numbers
3/8/2022 16:39:16	Pfizer-Japan-PK-study-2.6.4-not-disclosed-with-disclosure	7	Table 2.6.5.5b PK Organ Dist. cont.	Adverse Effects - Reproductive Issues	Pfizer Japan PK module 2.6.4. It appears to be a bit more granular than the disclosed 2.6.4 as it is one of the studies that make up the disclosed 2.6.4. It was made available early in the vaccine roll-out by a source I cannot recall. At the time, reports of bleeding caused me to zero in on the biodist in the ovaries. There are some interesting data around the rate at which the expression medium was concentrating in the ovaries. It seems to have a higher overall concentration, but also at a higher rate over the first 48 hours. It does not appear that this study or its findings are included at this granularity in the disclosure.
3/8/2022 17:00:51	125742_S1_M2_24_nonclinical-overview	1 - 31	numerous	Adverse Effects - Miocarditis	See one-page "summary" PDF re. possible liver damage, evidence for a "cytokine storm," elevated fibrinogen, etc. I'm also uploading the original document with highlights and comments correlated with the line items in the "summary."
3/8/2022 17:10:42				Efficacy	I am a nurse practitioner with experience in gastroenterology and primary care. Please include me with medical group.

3/8/2022 17:25:18	BTN 162b2 5.3.6 Cumulative Analysis Post-Authorization AER's	5 & 6	2. Methodology	Adverse Effects - Other	The "Methodology" stated in this document is seriously flawed and begins with excuses as to why AE type events may occur and the level of difficulty associated with attempting the establishment of a cause and effect relationship between vaccine and event. Pfizer appears to have dismissed its role or ability to correlate cause and effect of any given event based upon some identified hurdles that may be encountered during any type of investigation of an AE. At the outset, Pfizer positions this document as some minimal effort to look at or review AE events, even though this entire trial exercise was being done under an emergency authorization and knowing that there were insufficient clinical trials associated with the development and release of the vaccine for distribution and application. They essentially dismissed this effort in light of the waiver of liability and the fact that they were not going to be held accountable for any AE's, whether in the short term or long term. Indeed the brevity of the "Methodology" section is an indication of their lack of attention towards details surrounding AE's, which is further exacerbated by the fact that there is reportedly nine pages of adverse effects or potential side-effects from the vaccine that were not generally in the public domain.
3/8/2022 17:38:46	I have 30 years experience working for FDA inspecting Clinical Investigators, Sponsors, Contract Research Orgs plus drug manufacturers both foreign and domestic. I wanted to volunteer if you need someone with my background.				
3/8/2022 18:24:01	5.2 listing of clinical sites and cvs pages 1-41.pdf	redactions on pgs., 4, 5, 15, 20, 28, 31, 32, 38			Clinics included locations of: Germany, Turkey, Brazil, South Africa and Argentina but most were in the U.S.; approx. a dozen email addresses redacted and a (b)(6) designation was inserted (presumably the personal privacy statutory exemption under the Freedom of Information Act). All other clinics included email addresses.
3/8/2022 18:30:34	5.3.6 Cumulative Analysis of Post Authorization AER's	6	2. Methodology	Adverse Effects - Other	There is no discussion over the "Methodology" surrounding the classifications of AER's. It appears that Pfizer underestimated the amount of AER's that they were going to receive because they did not have enough people to process them. They go on at length describing the flowrate of AER's, their lack of personnel, and intimate that this was a data management problem and NOT a health safety issue. Thousands of cases were filed, and awaited processing for what they reported as 90 days. This obviously means that people and medical personnel dealing with the filed AER's got no help in dealing with patient issues and were on their own. There is no "Methodology" described here, it is just excuse after excuse.
3/8/2022 18:47:54	5.3.6 Cumulative Analysis Post Authorization AER's	6	Methodology	Adverse Effects - Other	There is no statement regarding how many days passed before serious cases were uploaded, while the Non-serious was within 4 days; then there is a statement that Non-serious cases were posted within 90-days. There is no definition of "serious" versus "non-serious" AER's although there is a distinction in Table 1 on page 7. There is no mention as to what the basis is for the categories chosen in Table 1. There is no discussion regarding the report of the AER and when it occurred relative to the receipt of the injection. If there is a "Serious" category, there is no discussion as to how many days past before it was assigned to a medical tech/assistant for response or follow-up. They are missing an important time element here. Who were the qualified individuals involved in reviewing "Serious" AER's and responding to patient care givers? Did all caregivers or administrators of the shot get the 9 pages of potential side effects and corresponding treatments?
3/8/2022 18:51:14	5.3.6 postmarketing experience.pdf	6	2	Adverse Effects - Other	text states limitation in listing adverse effects; "only those having a complete workflow cycle" are in monthly SMSR; states large numbers of spontaneous adverse event reports were received, the MAH (marketing authorisation[sic] holder) prioritized reporting serious cases to meet expedited reporting timelines; non-serious cases could be processed up to 90 days from receipt; 3 redactions of info under asserted (b)(4) basis, presumably the FOIA trade secret/commerical/financial data statutory exemption; in context these redactions appear to have been numbers; through 28 feb 21 there were 42,086 case reports containing 158,893 events. most cases were in U.S.; descending order: UK, Italy, Germany, France, Portugal, Spain and 56 other countries.
3/8/2022 18:59:41	5.3.6 postmarketing experience.pdf	7	table 1	Adverse Effects - Other	Data chart of Selected Characteristics of All Cases Received During the Reporting Interval; Gender, Age, Case Outcome; text below Table 1 refers to Figure 1 and notes SOS system order classes contained greatest number of events: "Nervous system disorders (25,957), Musculoskeletal and connective tissue disorders (17,283), Gastrointestinal disorders (14,096), Skin and subcutaneous tissue disorders (8,476), Respiratory, thoracic and mediastinal disorders (8,848), Infections and infestations (4,610), Injury, poisoning and procedural complications (5,590), and Investigations (3,693)"
3/8/2022 19:21:01	test	3	3	Data Missing	test
3/8/2022 21:20:48	STN 125742_0_0 Section 2.7.4 summary-clin-safety.pdf	299	274612	Study Protocol	My issue is with the clinical trial design. In the visit schedule for a patient they didn't measure heart or stroke activity post vaccination. I am sure they knew at least post second dose these vaccines might cause strokes and heart issues. Why didn't they observe patients at least post 3rd vaccine? Since this was not tested adequetly during phase 1 why weren't there more safety tests like these performed at each visit?
3/8/2022 21:31:29	FDA-CBER-2021-5683-0022618-to-0022691_125742_S1_M5_c4591001-A-P-adsl-demo-7d-eval-eff-sas.txt	Whole Document (file is computer code for an app or program)	Whole Document (Notes skimming computer code 119 pages)	Subdivided Data (to make the numbers smaller)	This file needs to go to a programmer for review, if necessary. Text file was computer code for program or app. 119 pages reviewed for any language or significance and notes added in .rtf file for review with code copied and pasted for a computer coder to search for more thoroughly. The suggestion is to refer the data to a computer coder to see if there is anything here such as for "kurtosis", "co-morbidities" section, etc. Not happy that I am loading something up on Google. I understand this is a work in process, but.... Google? Really. :-)
3/8/2022 22:48:41	2.5 Clinical Overview	P. 126	2.5.4.4.3.1	Adverse Effects - Other	2.5.4.4.3.1. Immunogenicity Populations Disposition and Data Sets Analyzed The 360 participants enrolled in Phase 2 were randomized 1:1 to the BNT162b2 and placebo groups (180 participants each). Among participants randomized to the BNT162b2 group, 88 participants were in the younger age group (18 to 55 years of age) and 92 participants were in the older age group (56 to 85 years of age) (Table 45). All 360 participants received both doses of study vaccine, except for 1 participant in the younger age group who was withdrawn from the study after Dose 1 of BNT162b2 but before Dose 2 because of an SAE of gastric adenocarcinoma 23 days after receiving Dose 1.
3/8/2022 22:54:31	2.5 clinical overview	page 151	4	Data Discrepancy	The Clinical overview document stated that " There were NO Phase 1 participants ...who died through the data collection cut off date of 3/13/2021." This is in contradiction to document 5.3.6 Cumulative analysis of Post authorization AERs Table 1 which reports 1,223 deaths from 12/1/2020-3/13/2021.(the reporting period).
3/8/2022 23:17:16	Clinical Overview	p. 146	STN-125742-0--0-Section 2.5 BNT162b1	Data Missing	Among the BNT162b2 groups in the Phase 1 portion of Study BNT162-01, 53/60 younger and 30/36 older participants completed the study (ie, through end of treatment visit). Two premature discontinuations have occurred. One younger participant in the 10 µg group discontinued prematurely due to AEs after Dose 1; these AEs were assessed as not related to study treatment. One younger participant in the 1 µg group discontinued prematurely due to withdrawal by the participant after Dose 1. No older participants have prematurely discontinued the study; most have completed the study the others remain in follow-up.
3/9/2022 0:12:44	FDA-CBER-2021-5683-0014176	123	4?	Study Protocol	Pfizer set up an "independent" Data Management Committee (DMC) who report exclusively to Pfizer staff who then decide whether to advance any issues raised to appropriate authorities.
3/9/2022 0:56:41	FDA-CBER-2021-5683-0000069	17	2	Study Protocol	The Adverse Events Table 7 acknowledged 136 fatalities after two months, from cardiovascular events. Pfizer concluded that this "does not raise new safety issues". This implies that these risks were already known if they were not "new". If a serial killer murdered 136 people in two months, would it not be a a serious "issue" worthy of disclosure and consideration? Pfizer separately stated that they wanted to "assure" safety, NOT "ensure" safety.

3/9/2022 8:58:37	STN-125742_0_-Section-2.7.4-summary-clin-safety.pdf	14, 16, 17	pg. 14, para. 2; pg.16, para. 1; pg. 17, para. 1	Study Protocol	pg. 14, text states protocol 10 amendment, on 14 December 20, participants >16 who originally received placebo were unblinded and could receive the BNT162b2; thus, placebo participants can no longer be used for comparison with those originally randomized to BNT162b2. The change was following "local or national recommendations" or following completion of the active safety period. pg. 16 data chart Table 1. Cutoff Dates for Safety Data Presented in Summary of Clinical Safety indicates in phase 2 (post dose 2) of study 360 people had reactogenicity within 7 days after doses, that is AEs (adverse events) and SAEs (serious adverse events). Pertinent data cutoff date was 02 Sept 2020. pg.17 Data table for Phase 3 summary of clinical safety date with cutoff date 13 Mar 2021; blinded AEs (adverse events)and SAEs (serious adverse events) included 43,847 "HIV positive subset(s)"
3/9/2022 9:08:21	STN-125742_0_-Section-2.7.4-summary-clin-safety.pdf	19	5	Adverse Effects - Other	endpoint summary data was noted to have been acquired through "subject paper diaries". This would seem to mean that there are additional documents which subjects kept and which were not wholly incorporated into Pfizer's record keeping but rather summarized by the corp. Although this may be far down in the weeds information, conceivably if the diaries exist, and could be obtained, there could be examination/comparison to the Pfizer released docs to determine whether Pfizer minimized subjects reported adverse events, ignored them or accurately reported them.
3/9/2022 9:29:07	STN-125742_0_-Section-2.7.4-summary-clin-safety.pdf	29	7	Study Protocol	In phase 1 individuals at high risk of getting Covid 19 and high risk occupations were excluded from the study (Hypertension, Diabetes mellitus, Chronic pulmonary disease, Asthma, Current vaping or smoking, History of chronic smoking within the prior year, Chronic liver disease, Stage 3 or worse chronic kidney disease, Resident in a long-term facility, BMI >30 kg/m[overweight], Anticipating the need for immunosuppressive treatment within the next 6 mo.) Occupation high risk excluded from phase 1: health care workers and emergency response personnel. These general categories seem to include categories of people who ended up dying from Covid 19. One possible way of viewing these exclusions from the phase 1 study is that Pfizer avoided looking at vaccines for the most vulnerable in order to minimize adverse event data and win FDA approval - though this may be medically myopic.
3/9/2022 9:48:08	STN-125742_0_-Section-2.7.4-summary-clin-safety.pdf	39-40	11 (last para.)	Data Missing	The note states that 4 participants were excluded from all efficacy and safety analyses due to their "significant misconduct" having "compromised the integrity of the study data." There was no elaboration/explanation. Continuing to pg. 40, the note says these 4 were discontinued from vaccination, although it says they are "listed separately."
3/9/2022 10:04:00	STN-125742_0_-Section-2.7.4-summary-clin-safety.pdf	40	3, 4	Data Missing	Note says 105 participants were withdrawn from the study, most due to the participant or "protocol deviation." Additionally, safety analysis data from HIV participants were summarized separately. Reviewer is not versed in the intricacies of medical pharmaceutical study but this information raises the question of whether or not conclusions from data are skewed due to these facts. Might this be considered missing data, sanitized in order to achieve acquiring FDA approval?
3/9/2022 10:17:34	125742_S1_M5_5351_c4591001-fa-interim-protocol.pdf	34-39	2. Introduction	Study Protocol	BNT162b1 & BNT162b2 immature technology in development. Risk-Potential for COVID-19 enhancement. Disease enhancement has been seen following vaccination with respiratory syncytial virus (RSV), feline coronavirus, and Dengue virus vaccines.
3/9/2022 10:25:52	STN-125742_0_-Section-2.7.4-summary-clin-safety.pdf	63, 64, 66, 69, 70, 72	1 (data bar graphs)	Data Discrepancy	Uncertain whether there is data discrepancy. However, these bar charts purport to visualize the mild, moderate and severe adverse events. Thus far, within the document, I did not see how those characterizations are defined, so the assessments may be inherently questionable. There may be a known standard or these terms may be defined elsewhere but the visual graphs following the texts of details seems to deliver a powerful impression of general safety, which may or may not be justified depending how one defines mild, moderate and severe.
3/9/2022 10:52:02	STN-125742_0_-Section-2.7.4-summary-clin-safety.pdf	116	1	Data Discrepancy	Table 7. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date – Phase 2/3 Subjects ≥16 Years of Age – Safety Population. I merely question the data on deaths. The size of the group which was vaccinated, or at least the number of their adverse events was 6947. The placebo group, or the number of its adverse events was 3568, close to half the amount of the vaccinated group. Deaths among the vaccinated group were 15 and among the much smaller placebo group was 14. This leaves the impression that deaths among the vaccinated were practically the same as the general unvaccinated population. Are the 2 groups really mathematically comparable due to the difference in size? As a nonmedical person, I think it appears suspicious that 15 vaccinated people died in a larger group, yet in a much smaller placebo group almost the same number of people died. These appear to me to be striking numbers, so much so as to raise questions of whether or not they were jiggered or falsified to show the vaccine was as safe as the ordinary placebo group of people going about their lives. This should be discussed with medical and/or statistical specialists. It's just my initial impression.
3/9/2022 10:54:44	125742_S1_M5_5351_c4591001-interim-mth6-oversight-committees.pdf	29,30	Appendix 3. Key Contacts	Study Protocol	Shanghai, China - EXTERNAL DATA MONITORING COMMITTEE
3/9/2022 11:03:17	125742_S1_M5_5351_c4591001-fa-interim-compliance.pdf	1-49	16.2.5.2.1 - 16.2.5.4	Adverse Effects - Other	Listing of Physical Examination With Abnormal Finding – Phase 1, 2 Doses, 21 Days Apart & Listing of Medication Errors – All Subjects
3/9/2022 11:34:34	STN-125742_0_-Section-2.7.4-summary-clin-safety.pdf	257	1-8	Data Discrepancy	Text section: 2.7.4.2.4.3.3.1. Blinded Placebo-Controlled Follow-Up Period From Dose 1 to 1 Month After Dose 2 (Phase 3, Study C4591001, Safety-Related Participant Withdrawals). This section states that 32 participants in the vaccine group withdrew from the study: 6 were due to adverse events from general disorders (injections site pain, chills, swelling but also 1 death); 5 were due to poisoning & procedural complications; 3 were due to nervous system disorders (dizziness, amnesia, cerebral infarction, hemorrhagic stroke, paraparesis, and Parkinsonism; 3 were due to gastrointestinal disorders; 3 from Neoplasms Benign, Malignant and Unspecified (adenocarcinoma gastric, lymphoproliferative disorder, and metastases to central nervous system). The section also notes these study participate withdrawals from the placebo group totaling 36. Do the withdrawals from the vaccinated group ultimately remove those adverse actions from the conclusions for this phase 3? If so, I am thinking that it necessarily skews the final data analysis, essentially rendering these AEs from not having occurred. If that is the case, does it follow that faulty data would have been used in the ultimate determination of safety and approval?
3/9/2022 11:35:32	STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	pg.295	2.7.4.3.4. Use in Pregnancy and Lactation Study BNT162-01 There were no pregnancies reported through the data cutoff date of 13 August 2020.	Efficacy	Study C4591001 data inconclusive/risks admitted/50 pregnant in study, general public many pregnant women took the innoculation
3/9/2022 11:43:32	CRFs-for-site-1055.pdf	42	Form line item 1	Adverse Effects - Other	Urinary Tract Infection
3/9/2022 11:46:46	CRFs-for-site-1055.pdf	42	Line item 2	Adverse Effects - Other	Injection site pain
3/9/2022 11:46:51	STN-125742_0_-Section-2.7.4-summary-clin-safety.pdf	261-262	pg.261, para. 3, pg. 262, 1-	Data Discrepancy	Notes say 45 vaccine participants withdrew from BNT162b2 vaccine study; 9 were from cardiac disorders including 4 cardiac arrests and cardiac failure congestive, cardio-respiratory arrest, coronary artery disease, hypertensive heart disease and tachycardia. pg. 262 Notes 3 withdrew from vax study due to gastrointestinal disorders; 7 from general disorders including sudden cardiac death; 4 withdrew due to infection/infestation (COVID-19 pneumonia, emphysematous cholecystitis, sepsis, septic shock and Shigella sepsis). The same question arises for similar other observations. Does withdrawal from the study due to these adverse events remove them from the final statistical analysis? Is the end result erasure of these adverse events from the stats considered by the FDA for vaccine approval? If yes, isn't that deceptive to the public?
3/9/2022 11:48:37	CRFs-for-site-1055.pdf	42	Form line item 3	Adverse Effects - Other	chills
3/9/2022 11:50:21	CRFs-for-site-1055.pdf	42	Form line item 5	Adverse Effects - Other	fatigue
3/9/2022 11:51:55	CRFs-for-site-1055.pdf	42	from Line item 6	Adverse Effects - Other	lymph node swelling
3/9/2022 11:56:37	BNT162b2 2.7.4 Summary of Clinical Safety	pgs 10 -12	ABBREVIATIONS	Study Protocol	helpful resource / definitions of terms
3/9/2022 11:59:21	CRFs-for-site-1055.pdf	184	Form line item 2a	Adverse Effects - Other	Fever
3/9/2022 12:01:46	CRFs-for-site-1055.pdf	185	Form line item 2e	Adverse Effects - Other	Headache

3/9/2022 12:02:12	STN-125742_0_-Section-2.7.4-summary-clin-safety.pdf	284	2	Data Discrepancy	Note text says there under the header of acute myocardial infarctions in vaccine group BNT162b2, there were a total of 17 events (1 in the placebo group). Note says more than half of occurred more than 30 days after vaccine or placebo. "None of these events were assessed by the investigator as related to study intervention . Outcome was resolved in all participants in the BNT162b2 group; outcome in the placebo group was fatal in 2 and resolved in the other participants." The 30 day marker seems to be an arbitrary cutoff point after which adverse events are not considered related to the vaccine. Not counting these suggesting ultimate safety data may have been skewed.
3/9/2022 12:03:50	CRFs-for-site-1055.pdf	188	Form line item 2e	Adverse Effects - Other	vomiting
3/9/2022 12:05:04	CRFs-for-site-1055.pdf	188	2f	Adverse Effects - Other	Diarrea
3/9/2022 12:06:52	CRFs-for-site-1055.pdf	189	2.g	Adverse Effects - Other	new or worsened muscle pain
3/9/2022 12:08:14	CRFs-for-site-1055.pdf	189	Form line item 2h	Adverse Effects - Other	new or worsened joint pain
3/9/2022 12:10:02	CRFs-for-site-1055.pdf	191	Form line item a5b	Adverse Effects - Other	Injection site swelling
3/9/2022 12:11:48	CRFs-for-site-1055.pdf	192	Form line item 5e	Adverse Effects - Other	Pain at injection site
3/9/2022 12:12:03	AESIs Evaluation for BNT162b2	page 20	Table 7 under musculoskeletal AESIs	Adverse Effects - Other	3600 cases (8.5%) would like to add that each section has a relevant event outcome, many list unknown in regards to surveillance. Also, there are fatalities in each of the sections I looked at. Would that not indicate a concern and shouldn't patients have been given this criteria? This isn't informed consent is it?
3/9/2022 12:16:55	CRFs-for-site-1055.pdf	298 (page 49 of sub-document)	Form line item 1	Adverse Effects - Other	Left supraclavicular adenopathy
3/9/2022 12:18:26	CRFs-for-site-1055.pdf	198 (page 49 of sub document)	Form line item 2	Adverse Effects - Other	shingles
3/9/2022 12:18:58	BNT162b2 2.7.4 Summary of Clinical Safety	page 33	2.7.4.1.1.3. Narratives Narrative summaries were written for the following participants in Study BNT162-01:	Study Protocol	Death/SAE's/AE's withdraw/Covid-19 available in Module 5.3.5.1 BNT162-01 CSR Section 12.6.
3/9/2022 12:24:27	STN-125742_0_-Section-2.7.4-summary-clin-safety.pdf	287 - 288, 291	1 -. 291, para.1	Subdivided Data (to make the numbers smaller)	In serial text sections discussing more serious adverse effects, it seemed convenient that the vaccine group event numbers were the same or nearly the same as the placebo group, which strains credulity. pg. 287, Pulmonary embolism in both groups was 8; stroke and hemorrhage in vaccine group 4; in placebo group 3. pg.287- 288 Ischemic stroke in both groups was 8. thrombocytopenia in vaxed group 2 and placebo, 1. Venus thromboembolism was 9 in each group. Not a medical specialist reviewer and the numbers may be legitimate but they look like there was an effort to even-up the serious adverse events by recording similar numbers among the placebo group. The numbers appear uncannily similar for the vax and placebo groups. pg. 291 conclusions "The incidence of SAEs (serious adverse events) and deaths were low in the context of the number of participants enrolled and comparable between BNT162b2 and placebo groups. The incidence of discontinuations due to AEs was also generally low and similar between BNT162b2 and placebo groups." The issue of comparability and similarity even regarding deaths seemed awfully convenient. Also, the method of the conclusion section discussion sounds entirely conclusory. It does not site logical specific points leading up to the conclusion.
3/9/2022 12:26:24	CRFs-for-site-1055.pdf	488 (page 40 of sub document)	Form line item 1	Adverse Effects - Other	Warm feeling of neck and head
3/9/2022 12:27:44	CRFs-for-site-1055.pdf	488 (page 40 of sub document)	Form line item 2	Adverse Effects - Other	fatique
3/9/2022 12:29:08	CRFs-for-site-1055.pdf	488 (page 40 of sub document)	Form line item 3	Adverse Effects - Other	Low grade fever
3/9/2022 12:40:53	CRFs-for-site-1055.pdf	659 (page 40 of sub document)	Form line item 1 and 2	Adverse Effects - Other	injection site pain
3/9/2022 12:42:19	CRFs-for-site-1055.pdf	659 (page 40 of sub document)	Form line item 3	Adverse Effects - Other	headache
3/9/2022 12:43:07	STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	page 33	2.7.4.1.1.3. Narratives /in Study C4591001:	Efficacy	Deaths, SAE's/AE's requested by FDA/AESI numerical imbalance/COVI9 19
3/9/2022 12:51:08	STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	33	2.7.4.1.1.3. Narratives (Death, SAE's, AE's)	Study Protocol	Study BNT162-01: Module 5.3.5.1 BNT162-01 CSR Section 12.6. (deaths, SAE's,) Study C4591001: Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR Section 14 Subject Narratives
3/9/2022 12:51:42	CRFs-for-site-1055.pdf	837 (page 58 of sub document (	Line item 1 and 4	Adverse Effects - Other	injection site pain
3/9/2022 12:53:34	CRFs-for-site-1055.pdf	837 (page 58 of sub document)	Form line item 2	Adverse Effects - Other	headache
3/9/2022 12:55:47	CRFs-for-site-1055.pdf	837 (page 58 of sub document)	Form line item 3	Adverse Effects - Other	injection site soreness
3/9/2022 12:57:39	CRFs-for-site-1055.pdf	page 837 (page 58 of sub document)	Form line itme 5	Adverse Effects - Other	headache
3/9/2022 13:00:05	CRFs-for-site-1055.pdf	page 838 (page 59 of sub document)	Form line item 6	Adverse Effects - Other	Left Axillary Adenopathy
3/9/2022 13:28:00	CRFs-for-site-1055.pdf	page 1260 (page 36 of sub document)	Form line item 1	Adverse Effects - Other	injection site soreness
3/9/2022 13:30:21	CRFs-for-site-1055.pdf	page 1260 (page 36 of sub document)	Form line item 2	Adverse Effects - Other	chills
3/9/2022 13:38:42	CRFs-for-site-1055.pdf	page 1446 (page 42 of sub document)	form Line item 1	Adverse Effects - Other	Dysphagia
3/9/2022 13:40:23	CRFs-for-site-1055.pdf	1446 (page 42 of sub document)	Form line item 2	Adverse Effects - Other	Right upper extremity pain
3/9/2022 13:43:05	CRFs-for-site-1055.pdf	Page 1446 (page 42 of sub document)	Form line item 3	Adverse Effects - Other	Cerebral Capillary telangiectasia
3/9/2022 13:53:50	CRFs-for-site-1055.pdf	Page 1594 (page 40 of sub document)	Form line item 1 and 2	Adverse Effects - Other	Perforated appendicitis (appendicitis DELETED ?)
3/9/2022 13:55:11	CRFs-for-site-1055.pdf	Page 1594 (page 40 of sub document)	Form line item 3 and 4	Adverse Effects - Other	Injection site pain
3/9/2022 13:57:26	CRFs-for-site-1055.pdf	Page 1594 (page 40 of sub document)	Form line item 5	Adverse Effects - Other	fatigue
3/9/2022 14:03:54	CRFs-for-site-1055.pdf	Page 1743 (page 44 of sub document)	Form line item 1	Adverse Effects - Other	Coronary vasospasm
3/9/2022 14:07:31	CRFs-for-site-1055.pdf	Page 1890 (page 34 of sub document)	Form line item 1	Adverse Effects - Other	Melanoma
3/9/2022 14:10:04	CRFs-for-site-1055.pdf	Page 1890 (page 34 of sub document)	Form line item 2	Adverse Effects - Other	skin lesion of scalp
3/9/2022 14:36:08	Adverse Events: 5.3.6 post-marketing experience.pdf (38 pages long) Date: 11/7/2022	12	2	Adverse Effects - Reproductive Issues	

3/9/2022 14:44:59	FDA-CBER-2021-5683-0000069	16-23	na	Adverse Effects - Other	
3/9/2022 15:13:54	STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	page 296-297	2.7.4.5. Overall Conclusions	Study Protocol	From December 2020 until April 2021, >100 million doses of BNT162b2 have been administered to individuals ≥16 years of age in the US under EUA.3,4 It is reassuring that the most commonly reported AEs in the post-authorization review (which includes global safety reporting) reflect the same profile observed in the blinded placebo-controlled reactogenicity events. Overall, the risk-benefit of BNT162b2 30 µg remains favorable (Personal COMMENT: Is there other internal/external data resources contradicting this position?)
3/9/2022 15:20:25	PF-07302048	42	1	Adverse Effects - Other	I'm a licensed clinical psychologist, retired from full-time work but still doing clinical work on a project-by-project basis. My training allows me to comprehend the effects of such actions as separating people from each other, closing off access to visitors, taking away facial expression through masking, etc. (The document, page and paragraph cited above are just included in the placeholder spots so I could Submit this form to you, and you'd see this message.) Overlooking the way the pandemic was managed, I see as likely significant harms to children and the elderly, and want to be of assistance in pointing out how those came about. (That will also require being able to formulate plausible/likely chain reactions of both pandemic managers' actions and the people who were likely harmed, which I can also do, having worked in public bureaucracies.) If this doesn't make sense, please ask for clarification. If it makes sense, may I please be directed to the documents that include how the vaccines were directed toward children and the elderly, as well as adverse reactions? Thanks, and please confirm you received this message.
3/9/2022 15:22:33	STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	page 284	Acute Myocardial Infarction	Adverse Effects - mYocarditis	Acute myocardial infarctions were searched with the PTs of acute myocardial infarction, acute coronary syndrome, coronary artery occlusion, and myocardial infarction. A total of 6 acute myocardial infarctions, 4 myocardial infarctions and 1 acute coronary syndrome (total of 11 events) were identified in the BNT162b2 group, and 4 acute myocardial infarctions, 8 myocardial infarctions, 4 acute coronary syndrome, and 1 coronary artery occlusion in the placebo group (total of 17 events), respectively. Slightly more than half of these events had onset distant to (ie, >30 days following) receipt of vaccine or placebo . None of these events were assessed by the investigator as related to study intervention . Outcome was resolved in all participants in the BNT162b2 group; outcome in the placebo group was fatal in 2 and resolved in the other participants
3/9/2022 15:22:52	BNT162B2. https://acrobat.adobe.com/link/review?uri=urn:aaid:scds:US:0707295f-999a-370d-9e0d-87b26765c8d9	7-38	All paragraphs	Adverse Effects - Other	What's interesting in reviewing the Adverse Events from these vaccines is a categorical comparison of VAERS to CDC comorbidities caused by zinc deficiencies. Hmm, seems like both vaccines and virus- spike protein prions maybe causing zinc deficiencies - inhibiting zinc zip protein ionophores from delivering zinc to various organs, tissues, blood and nervous systems. Hypothesis :non protein zinc ionophore drugs and nutraceuticals plus zinc are effective against viral RNA transcription and could also be effective against vaccine mRNA transcription- inhibiting spike protein, prion production via inhibiting RdRp transcriptase enzymes. https://factcheckedorg.files.wordpress.com/2020/12/covid19-problem-analysis.pdf https://acrobat.adobe.com/link/track?uri=urn:aaid:scds:US:b5339f43-2bc1-3c02-9067-e977e5716774
3/9/2022 15:26:42	https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	page 6, page 9, page 12 to page 15	3.1 Safety, 3.12 Safety Concerns, Table 6	Data Discrepancy	I am including information from the federal register also, as I do work for the government, I do legal research for our union and do agency work as well. I have lots of research experience, and the Federal Register is an important source to use, as it annotates federal discussions, and input by HHS meetings, or "commenters" [the public] regarding the covid-19 vaccines and the concern of their inclusion in the Vaccine Injury Compensation Program. Many have gotten injured from the covid -19 shots. The federal register is public information. It has references to CFR codes which you can click on. The Pfizer data in section - 5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021. I believe this safety data was put together based on what the Federal Register finalized on February 22, 2021. But the "commenters" had concerns on many safety issues that the host of the meeting[HHS] just blew off in that government way. For example in the this Pfizer data it states in 3.12 Safety: Missing information Use in Pregnancy and lactation Use in Paediatric Individuals <12 Years of Age Vaccine Effectiveness 090177e196ea1800\Approved\Approved On: 30-A pr-2021 09:26 (GMT) FDA-CBER-2021-5683-000006 But in the Federal Register it states: The Department previously issued a notice of proposed rulemaking that proposed to remove SIRVA, vasovagal syncope, and Item XVII from the Vaccine Injury Table found at 42 CFR 100.3. The Department did so for the reasons set forth in the proposed rule.[6] In other words, the following chart information from 42 CFR 100.3 below per Federal Register would exclude the data for Vaccine Injury Table: XVII. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children and/or pregnant women, after publication by the Secretary of a notice of coverage So, that is why information is missing because the Federal Register finalized the revised with out it. And Shoulder injuries were excluded too as they knew should injury results for these vaccines. A. Shoulder Injury Related to Vaccine Administration B. Vasovagal syncope
3/9/2022 15:32:16	STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	261	2.7.4.2.4.3.3.2. Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date (Phase 3, Study C4591001, Safety-Related Participant Withdrawals)	Adverse Effects - Other	9 participants in the BNT162b2 group and 8 participants in the placebo group withdrew from the study due to AEs in the SOC Cardiac Disorders (BNT162b2 group: cardiac arrest [4 participants]; cardiac failure congestive, cardio-respiratory arrest, coronary artery disease, hypertensive heart disease and tachycardia [1 participant each]; placebo group: atrial fibrillation and myocardial infarction [2 participants each]; cardiac arrest, cardiac failure congestive, cardio respiratory arrest, and coronary artery occlusion [1 participant each]).

3/9/2022 15:34:49	FDA-CBER-2021-5683-0022793-to-0022866_125742_S1_M5_c4591001-A-P-adsl-s005-demo-all-p3-saf-sas.txt	Document is Computer Code	Document is Computer Code	Study Protocol	Document is computer code that I reviewed, and I wanted to point out the following section of computer code below (see .rtf attached) where the following items are mentioned to be part of the research: a. Safety Population b. “SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.” c. HIV d. “Positive N-binding antibody result at Visit 1, positive NAAT result at Visit1, or medical history of COVID-19.” e. “Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.” Don't know what it means, but it seems as if they were "looking" for these things (planning them as part of the computer code), but I don't know how the code fits into the larger picture.
3/9/2022 15:49:41	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy.pdf	18	First complete paragraph	Study Protocol	2.7.3 Summary of Clinical Efficacy on p. 18 first full graf says: "Also included were individuals with previous clinical or microbiological diagnosis of COVID-19 or with evidence of current or prior infection based on serology or nasal swab." Shouldn't people with prior covid infections be excluded? How many in this group? If it's a large enough part of the total population, wouldn't this skew the data? How do they separate out the impact of natural immunity from vax-induced immunity? They appropriately excluded immunocompromised individuals; it seems that people who had already had covid infections would be the flip side of the same coin.
3/9/2022 16:05:36	STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	pages 244-145	2.7.4.2.4.3.2.4. Blinded Placebo-Controlled and Open-Label Follow-Up Periods to 6 Months After Dose 2 – Original BNT162b2 Participants (Phase 3, Study C4591001,Serious Adverse Events)	Adverse Effects - Other	Serious Adverse Events increased: From Dose 1 to 6 months after Dose 2, during the blinded and open-label follow-up periods,190 (1.6%) participants in the BNT162b2 group reported at least 1 SAE (Table 20). .Comparison of SAEs reported from Dose 1 to 1 month after Dose 2 to SAEs reported from 1 month after Dose 2 to 6 months Dose 2 shows that the frequency of SAEs increased from 0.5% to 1.1%, respectively.
3/9/2022 16:14:11	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy.pdf	18	First full paragraph	Study Protocol	I jumped the gun on the question I raised -- why did the study include subjects who had already had covid cases? The answer came on the next page, sort of: they separated out these pre-infected people into a group that includes both pre-infected and not pre-infected subjects. So at least theoretically that is legitimate -- but I still mistrust their process. It would be easy to "accidentally" conflate data from the mixed group with data from the subjects who had no prior covid infections.
3/9/2022 16:58:41	FDA-CBER-*sas.txt	all	all	Data Discrepancy	All those files are COMPUTER PROGRAM SOURCE CODE, they should not be counted towards "document limit" but released separately. Source code is always digital. In data processing, the same output can be achieved with a small program (in lines of code) as with a badly written one (lots of lines of code). PFIZER DUPED YOU AGAIN.
3/9/2022 17:18:49	STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	50	2.7.4.2.1.5	Data Discrepancy	Lab results show an increase in CPR (C Reactive Protein) in young age groups. CRP indicates inflammation, (especially arteries of the heart). This finding was considered insignificant and was mentioned in the safety summary on page 56.
3/9/2022 17:27:49	FDA-CBER-2021-5683-0022867-to-0023006_125742_S1_M5_c4591001-A-P-adsl-sas.txt	Over 140 pages of computer code--see 10 pages of attached notes in .rtf	Computer Code (see attached .rtf)	Other	Computer Code: Age within software app: 12-15 years; 16-55 years... (minors) List of official comorbidities List of various impact of disease: pneumonia, sepsis, viraemia, and "Multisystem inflammatory syndrome in Children". (Yes, that's in the code!) List of phrases such as "Severe Acute Resp Syndrome Coronavirus 2", "Immunochromatography", "Cepheid RT_PCR Assay", "Reverse Transcriptase PCR", "Severe Acute Resp SYndrome Coronavirus 2".... List of "Respiratory Illness" Formal list of signs and symptoms in code. Additional list of the following: Severe COVID-19 Illness, Significant Acute Renal Dysfunction, Significant Acute Hepatic Dysfunction, Significant Acute Neurologic Dysfunction. CDC is mentioned in the document. Phrase "Central Lab" used. Two individuals you may want to find the last names for (Xla/James) as they seem to be familiar with the study. Odd note: *Shanghai 23Feb2021 add BDCSRDT/X1CSRDT; See 10 pages of notes attached in .rtf document.
3/9/2022 17:28:57	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy.pdf	21	2nd graf following Table 1, near bottom	COVID Testing	They used the Cepheid and Roche PCR tests to confirm diagnosis. I searched the document for Cepheid, PCR, NAAT and Roche and nowhere did they say what kind of settings they used -- same number of amplification cycles for both vaxed and unvaxed? Or different number of cycles for vaxed and unvaxed per FDA standards? They mention FDA approval right after listing the PCR test. They only speak of "NAAT-positive." As the CDC itself has said, PCR testing is very unreliable.
3/9/2022 20:12:00	BNT162b2 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	1-10	2, partial 3	Adverse Effects - Other	Highlighted the adverse reactions on a PDF -
3/9/2022 21:02:33	125742_S1_M5_5351_c4591001-fa-interim-lab-measurements.pdf	193	N/A	Adverse Effects - Other	Life threatening toxicity (Level 4 on the FDA Toxicity Grade scale) in a subject's Lymphocytes (lymph nodes). This document appears to contain breakthrough covid cases, often after a second dose, but also concerning lab measurements at various phases of the study - between doses and after doses. It includes BNT162b1, BNT162b2 and Placebo.
3/9/2022 22:39:35	Document for first names N-R	14	2.4.2.3	Study Protocol	No safety pharmacology studies were conducted with BNT162B2.
3/10/2022 0:34:37	BNT162b2 5.3.6 Cumulative Analysis of Post authorization Adverse Event Report	23,16,18,22,	Table 7	Other	On Table 7 (pg 23) Thromboembolic events represent 0.3% of the total PM dataset however, there are several embolic and bleeding events on the Table that occur under the Haematological , Pregnancy, Respiratory, Stroke, and Cardiovascular categories. The presentation of embolic and bleeding events in this manner appears to dilute, undercount or minimize the number of these important events. If these counts are combined, thromboembolic and other bleeding events could be the most frequently occurring events.
3/10/2022 1:02:01	BNT162b2 5.3.6 Cumulative Analysis of Post authorization Adverse Event Reports	13	Table 6	Other	According to the EUA, product was authorized for emergency use in the US on 11 Dec 2020 for individuals > = 16 years of age (EUA 27034). On Table 6 under the Topic of Use in Pediatric Individuals < 12 years of age, it is indicated that children who ranged in age from 2 months to 9 years were administered product (n=34). Twenty 27 of these reports of patient of inappropriate age were coded to the MedDra Preferred Term (PT) of medication error. What were the other 7 reports coded to? Aren't they all considered a medication error? Did all of these children experience an adverse event concurrently with the event of medication error?
3/10/2022 1:33:43	BNT162B2 5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports	7	Table 1	Data Discrepancy	On Table 1 the total Fatal report count is 1223. When counting the outcomes of Death under each category on Table 1, the total number of fatalities do not add up to 1223. No information is provided concerning the cause of death for these 1223 reports. No discussions of the death reports are provided in the document. Why is this important topic omitted from the report?

3/10/2022 2:02:08	BNT162b2 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	24	Table 7 roll over from the AESI of Stroke, Subject age group reports a child (1) with a footnote of m. Footnote m indicates that a UK MHRA describes a 7 y.o. female subject who received the vaccine and had a stroke (outcome unknown). No follow-up is possible for clarification.	Adverse Effects - Other	Case was burried in the data. This 7 year old UK female does not appear to be counted under the Use in Pediatric Individuals section of < 12 Year of Age on page 13. Therefore I am not sure if the total pediatric cases are undercounted. Her event of unclarified stroke is not listed under the events for Ped cases either. Under the Stroke category she is counted as a child (1), but it is not clear what type of stroke she had, and where it was counted. This case was not flagged up or discussed which is unusual. They only statement regarding the case was a footnote on pg 25 commenting she had a stroke and that follow-up was not possible. Outcome is unknown.
3/10/2022 7:55:52	FDA-CBER-2021-5683-0014054	355-358	multiple	Study Protocol	Legal Hypothesis: If in fact, FDA (and other global agencies) emergency use authorization and corresponding vaccination mandates were based on trial results that excluded participants for multiple criteria, then would not this be the legal basis for granting exemptions and/or cause for uninformed consent litigation? Also, under certain conditions, would not the potential for class action suit for long term liability regarding forced exposure to excluded groups? Would it not also be basis for wrongful termination or denial of care suits?
3/10/2022 8:03:05	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.5-Clinical-Overview.pdf	15	1	Other	"healthy participants ≥12 years of age." - minors included in experimental study?
3/10/2022 8:26:03	STN-125742_0_0-Section-2.5-Clinical-Overview.pdf	21	4	Adverse Effects - Other	"Note: the SRC recommended that a second dose of BNT162b1 at 60 µg not be administered due to reactogenicity after the first dose." - Safety Review Committee noted adverse reaction?
3/10/2022 8:51:57	STN-125742_0_0-Section-2.5-Clinical-Overview.pdf	25	2	Data Missing	(b) (4) - redacted/missing text
3/10/2022 10:23:13	https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	6	3	Data Missing	AE events are not included in this report where not "fully processed". Therefore the total number of AEs reported, their seriousness and their outcomes, is unknown.
3/10/2022 10:32:39	https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	7	Table 1	Study Protocol	Pfizer makes a distinction between 19,582 cases "recovered or recovering" and 11,361 "not recovered." The "recovering" should be in the "not recovered" group. Or - does "not recovered" mean permanently injured? Also - the recovery status of 9,400 cases is "Unknown." Why were they not followed up?
3/10/2022 10:38:07	https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	8	Table 2	Adverse Effects - Other	Pfizer note "Lymphadenopathy" as accounting for 4.7% of AEs - but they do not note whether it was localized or generalized. They also do not list lymphadenopathy as a potential risk (Pp. 10 & 11) although it is a condition which can lead to cancer.
3/10/2022 10:42:37	https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	9	Table 2	Adverse Effects - Other	"Headache" is listed here as accounting for 24.1% of AEs. Yet no potential risks are listed as possibly arising from this AE though we have seen strokes associated with the vaccine.
3/10/2022 10:49:01	https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	11	Table 5	Adverse Effects - Other	Pfizer refer to VAED as a "theoretical risk." But they list multiple deaths from severe Covid/VAED. They KNEW this had happened. Three quarters of the cases they report were severe after 1 or 2 doses. They led to - variously - "hospitalizations", "disability", "life-threatening" consequences or "death".
3/10/2022 10:52:31	https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	12	Table 6	Adverse Effects - Reproductive Issues	26 out of 32 pregnancies ended in miscarriage or neonatal death. Pfizer refer to 270 pregnancies but 238 were ongoing. So the fatal outcomes represent 26 out of 32.
3/10/2022 10:54:44	https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	12	Table 6	Adverse Effects - Reproductive Issues	Breastmilk given after vaccination harmed 17 babies - 3 seriously. Pfizer comment that this raised "no safety signals" for use in pregnancy in breastfeeding.
3/10/2022 10:58:25	https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	13	Table 6	Adverse Effects - Other	Pfizer note here (2nd Box in the Table) that of 34 cases of AEs in children, 24 were "serious."
3/10/2022 11:38:45	#3 - 5.3.6 postmarketing experience.pdf	13	1 -- conclusion paragraph (top portion of page)	Other	Invalid conclusion -- Table 6 (Use in Pregnancy and lactation) described several serious outcomes such as spontaneous abortion, neonatal death, fetal growth restriction, fever, rash, diarrhea, etc) but drew the conclusion there were "no safety signals..emerged"
3/10/2022 12:31:03	125742_S1_M5_5351_c4591001-interim-mth6-oversight-committees.pdf	40	5.1.3.	Study Protocol	Surveillance of Events That Could Represent Enhanced COVID-19 Disease - "cytokine storm"
3/10/2022 12:47:09	125742_S1_M5_5351_c4591001-fa-interim-lab-measurements.pdf	N/A	N/A	COVID Testing	If I understand correctly, this documents contains 350 accounts of people who received 2 doses of shots yet got COVID. Among the cases, you have 88 counts of people reported loss of smell or taste, and 99 counts of fever, 133 accounts of increased cough; and 30 counts of diarrhea. (from key word search)
3/10/2022 12:56:41	CRFs for site 1128.pdf	6, 67, 98	n/a	Fatality	several accounts of documented death.See screenshots below.
3/10/2022 13:05:52	125742_S1_M2_26_pharmkin-written-summary.pdf	5	1 right after charts	Study Protocol	No absorption studies done because of WHO protocols
3/10/2022 13:22:45	125742_S1_M2_24_nonclinical-overview.pdf	10	1 and 2	Adverse Effects - Other	The paragraphs explain that the vaccine protects the virus and beats up the T cells so the spike can be delivered.
3/10/2022 13:31:03	125742_S1_M2_24_nonclinical-overview.pdf	23	2	Adverse Effects - Reproductive Issues	The vaccine was carried into the babies
3/10/2022 13:38:14	125742_S1_M2_24_nonclinical-overview.pdf	29	2.4.4.4. Genotoxicity 2.4.4.5. Carcinogenicity	Study Protocol	Testing was not done do to WHO protocol
3/10/2022 13:42:49	CT02-GSOP Clinical Protocol Template Phase 1 2 3 4 (05 December 2019)	4 and 5	Protocol Amendment 10	Study Protocol	Tony Paunicka

3/10/2022 14:09:51	CRFs for site 1055	1 - 320	I reviewed the first two participants and need to know if this is the type of detail you want. Our Team 5 has not, as yet, made decisions about what roles and what docs we will review, so I need to know if this is too much for you. I'm coming from a faculty perspective and reviewed the submitted data with adherence to study design. If this is a true experiment, then parameters are missing (i.e., inclusion and exclusion data). I see problems with their design (true experiments do not omit important criteria) and that is reflected in my four pages of comments for this 320 pages review.	Study Protocol	I have detailed by page and associated questions within the document I am uploading rather than screenshots.
3/10/2022 15:04:18	BNT162b2	37-38	2.7.4.1.2.3.2.	Adverse Effects - Other	A younger trial participant was withdrawn from the study 23 days after 1st dose due to a SAE (serious adverse even) of diagnosis of gastric adenocarcinoma. Very unusual in young people.
3/10/2022 15:10:18	phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	10; 16-25	Tables 4 & 7	Fatality	inconsistencies in safety issues/concerns when fatalities are involved
3/10/2022 15:52:08	BNT162b2 2.7.4 Summary of Clinical Safety	13	2.7.4	Study Protocol	Summarized as BNT162b2 as best vaccine candidate, it is defined as an 'investigational vaccine' upon registration and application for approval. Was not the investigation already completed? Final selection based upon lung response
3/10/2022 17:40:19	FDA-CBER-2021-5683-0002985	89	bottom of list	Adverse Effects - Other	it just struck me oddly that there is a category for "sensation of foreign body" at the injecton site. is this normally on all vaccines?
3/10/2022 18:05:16	www.cdc.gov/vacines/acip/meetings/downloads/slides-2021-10-20-21/07-COVID-Su-508.pdf	7 & 8	slide p8	Adverse Effects - mYocarditis	the slide/table indicated shows ~15 to 24 y/o males have a significant percentage of vaccine related development of myocarditis: enough to end the continued enrollment of this cohort and all people under 24. With a near negligible risk for the young who develop covid, the further use in children is beyond immoral. Further on page 83 of the list of Ads Myocarditis cases the incidents in the "vaccinated" is marked as 0 (zero)
3/10/2022 18:52:41	BNT162b2 2.7.4 Summary of Clinical Safety	page 295	2.7.4.3.4. Use in Pregnancy and Lactation	Efficacy	Data was inconclusive regarding pregnant women taking the inoculation. Many pregnant women were pushed to have the vaccine
3/10/2022 18:57:10	125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf	59	2	Other	False claim/assumption. While this document was written in March 2021, clearly by then it was known that monoclonal antibodies, Ivermectin, Hydroxychloroquine, ZPack, Fenofibrate and Vitamin D were all effective therapeutic options. Of course, none of these would make money for Pfizer despite the last sentence in paragraph 2 of page 57 in this pdf.
3/10/2022 19:04:11	125742_S1_M5_5351_c4591001_fa_interim excluded patients sensitive	1 & 643 and 645-656 & 1448	No paragraph, this document is just 1448 pages of excluded patients	Data Discrepancy	From page 1 to 643 there are between 5 - 7 patients per page. Let's say average 5 = 3220 patients excluded. The same patients show up starting from page 645 to 1448. However, there are many patients in the second group that are not listed in the first group. In the 12-15 age group for instance, only 1 patient shows up in the first grouping, and 90 show up in the second group. That is a difference of 89 teenagers who did not get the second dose. Zero detail. Same reason for everyone: Did not complete 2 vaccination doses. Same applies to older age grouping.
3/10/2022 20:02:38	125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf	199	5	Study Protocol	Pfizer claims to be committed to transparency "regardless of the outcome of the study" so then why did they want to wait SEVENTY FIVE years to release their study results?!?!?! They also say results are reported in "complete manor". If true, why was part of this initial data dump redacted? (See intro video for new participants.)
3/10/2022 22:36:55	125742_S1_M2_24_nonclinical-overview.pdf	Page 20, 29 and 30	2.4.3.7. Pharmacokinetic Drug Interactions, 2.4.4.4. Genotoxicity, 2.4.4.5. Carcinogenicity, 2.4.4.8.3. Immunotoxicity	Data Missing	I am not in this field, so not sure if this is ok or standard procedure when verifying new vaccines, but all paragraphs listed above were not tested. There was no testing of the vaccine done for any pharmacy drug interactions, no testing for genotoxicity, no testing for carcinogen related effects and nothing done for immunotoxicity or immune system related issues. Seems to me that these things should be included tests when something like this is going out to the whole world.
3/10/2022 22:57:50	#43 - 125742_S1_M2_24_nonclinical-overview.pdf - "NON CLINICAL OVERVIEW - needs thorough review"	12	3	Efficacy	For the study in rhesus macaques, it was demonstrated that titers showing efficacy of the Pfizer vaccine waned significantly by day 56, approaching the efficacy of the control group on trend. This was known despite the health community stating that the public would need just 1 or 2 doses of the original vaccination to have immunity from the virus permanently.
3/10/2022 23:05:47	STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	13	1 - second sentence," intended to prevent COVID-19,"	Other	this is a lie because they used the word "prevent"
3/10/2022 23:18:59	#43 - 125742_S1_M2_24_nonclinical-overview.pdf - "NON CLINICAL OVERVIEW - needs thorough review",	15	1-4	Adverse Effects - Other	When Wistar Han Rats were given the Pfizer vaccine, lipid nanoparticles of the vaccine were only mostly anchored at the injection site and not completely anchored at the injection site as told to the public. This study shows that these particles spread throughout tissues in the body, most notably to the liver with approximately 50% of ALC-0159 remaining unmetabolized. Pfizer admits that these particles are only slowly metabolized. Expression of the particles took place only 6 hours from injection in this study.
3/10/2022 23:38:06	#43 - 125742_S1_M2_24_nonclinical-overview.pdf - "NON CLINICAL OVERVIEW - needs thorough review",	22	1	Adverse Effects - Other	Injection site injuries made worse by repeated booster shots in Wistar Han rats - adverse effects at the injection site worsen with each additional booster received.
3/11/2022 0:03:16	#43 - 125742_S1_M2_24_nonclinical-overview.pdf - "NON CLINICAL OVERVIEW - needs thorough review"	26	6	Adverse Effects - Other	2.49x fibrinogen levels over control group up to at least day 17 after vaccination in both male and female Wistar Han Rats - Increased fibrinogen indicates a greater chance for blood clots to arise. Fibrinogen is produced by the liver. According to the research conducted by Pfizer, the most common place for spike proteins to anchor outside the injection site was the liver where fibrinogen is made. When the liver is harmed, in this case by the lipid nano particles anchoring in the liver or in other tissues, additional fibrinogen is released which can lead to increased incidents of blood clots. This can be one of the primary causes of blood clotting associated with these vaccines since the vaccine induced spike proteins do not stay at the injection site.
3/11/2022 3:03:26	STN-125742_0_0-Section-2.5-Clinical-Overview.pdf	36 or 334	Table 1. Efficacy Populations – Interim Analysis 1	Other	Subjects excluded from Dose 2 efficacy analysis: vax arm 2785 (12.9%); placebo arm 2795 (12.9%); TOTAL Excluded patients 5580 (12.9%); Such a high number of excluded patients indicates major problems with sites following the protocol, which in tern is indicative of lack of controls during study conduct

3/11/2022 3:23:44	STN-125742_0_0-Section-2.5-Clinical-Overview.pdf	p36/334	Table 1	Other	Subjects excluded from efficacy population (7 Days): vax arm 3273 (15.1%); placebo arm 3054 (14.1%); TOTAL Excluded from Efficacy analysis: 6327 (14.6%) These high numbers indicate major problems with sites following the protocol, which in tern is indicative of lack of controls during study conduct NOTE: this is different entry as it is exclusion fro the overall efficacy analysis; the other entry was for Dose 2.
3/11/2022 8:36:56	BNT162b2 2.7.4 Summary of Clinical Safety	page 23	Table 3. Safety Objectives, Estimands, and Endpoints for Study C4591001	Data Missing	no reference source provided for later update of data for children >12 where to find this information?
3/11/2022 8:51:33	STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	214	Table 15	Study Protocol	Adverse Event Incident Rates for Unblinded Safety Population Table appears to have limited value. The number of subjects followed is N = 19524 persons. The total exposure time is TE = 23.8 100 person-years. To determine the average amount of time each person was followed, divide TE by N equals TE/N = 23.8 100 person years * 100 / 19524 persons = .12 years = 43 days The amount of time following each person would not allow detection for longer-term health effects. Further, based on limitations discussed above, the Confidence Interval values also have limited values.
3/11/2022 9:07:32	BNT162b2 2.7.4 Summary of Clinical Safety	page 59	2.7.4.2.3.3.1. Adverse Events by System Organ Class and Preferred Term (Phase 2, Study C4591001)	Other	Younger participants receiving vaccine have higher % of AE's as compared to older participants; and placebo participants have the highest % of AE's. (phase 2)
3/11/2022 15:09:15	https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	13	Whole page	Other	The definition of Vaccination Failure dramatically minimizes the number of "failures". Positive lab tests for covid infection were required. This allowed Pfizer to list only 16 Vaccination Failures. But there were 1649 "Drug Ineffective Cases". What did they gain by minimizing Vaxx Failure while listing many Drug Ineffective Cases? And why did they not obtain lab tests for all the apparent infections which they classed as "Drug Ineffective"?
3/11/2022 15:23:35	090177e19668af9a\Approved\Approved On: 02-Mar-2021 14:41 (GMT)	page 80	number 6 on page	Other	it states people at risk for virus that we were never told!
3/11/2022 15:24:28	https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	16	Table: Cardiovascular AESIs	Adverse Effects - Other	Of the serious cardiac problems, 1078 were in people aged 18-64; 266 were in people over 65 and 2 were in children between 2 years old and 18. Pfizer clearly knew serious heart problems were occurring in all age groups - the large majority in people of working age. And the 18-64 age group figures high in the excess mortality figures for the second half of 2021.
3/11/2022 15:31:42	https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	18	Para. Haematological AESIs	Adverse Effects - Reproductive Issues	Pfizer buries 2 fertility issues in the Haematological category: Vaginal haemorrhage (29 cases) & menorrhagia (27 cases).
3/11/2022 15:47:02	https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	23	Table 7 Respiratory AESIs	Subdivided Data (to make the numbers smaller)	Pfizer break down 137 respiratory AES as being: Fatal (41); Resolved or resolving (47); Not recovered (18); Unknown (31). This entirely obscures the total number of those who were not recovered which may have been 86.
3/11/2022 15:55:12	#20 - STN 125742_0_0 Section 2.7.3 Summary of Clinical Efficacy	135,137,159,161	no paragraphs - tables	Data Missing	Obesity (a known risk factor for severe C19) is not listed as a comorbidity, and yet, it is broken out for Covid occurrences (Tables 41,42 and 55,56) If we do not know the overall incidence of obesity in each group, the high numbers in the placebo group have little meaning. Maybe they stacked the placebo group with a known comorbidity.
3/11/2022 15:56:52	https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	24	Table 7, Stroke	Adverse Effects - Other	The outcome of 275 was appalling: 61 Fatal; 10 had Sequelae; 85 were Not Resolved; 83 outcomes were Unknown; 61 were Resolved/resolving. (The last category is evidently misleading as Resolving could, equally, be classed in Not Resolved.)
3/11/2022 16:08:49	https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	26	Footnotes	Study Protocol	Evidence of incompetence in the administration of the injections is listed here but also evidence of problems with the product, including: "poor quality product"; "product preparation error"; "underdose"; "overdose"; "incorrect dose"; "expired product";
3/11/2022 16:16:04	https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	29	Summary & Conclusion	Other	After 28 pages of fatalities, serious & less serious AEs Pfizer blithely concludes they confirm a favorable benefit/risk balance. For a treatable virus with an approximate 97% natural recovery rate and with an average age of death of 83, their data actually confirms the opposite.
3/11/2022 17:26:58	5.3.6 postmarketing experience.pdf	6	4	Other	Early Evidence of Huge Number of Adverse Reactions; In the first half of 2021 there were so many adverse reactions Pfizer was hiring extra full-time employees each month just to keep up with the reports coming in.
3/11/2022 17:34:22	5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	11	5	Adverse Effects - Other	75 severe cases of Covid19 following vaccination, yet they conclude none could be definitively considered VAED or VAERD. What is the means for determining whether or not a post vaccination infection is the result of VAERD? Is there a clinical definition?
3/11/2022 18:09:55	5.3.6 postmarketing experience.pdf	Page 7	Table 1. General Overview: Selected Characteristics	Adverse Effects - Other	71% Total Cases = Female. 29914 / 42086
3/11/2022 18:13:17	#19 - STN 125742_0_0 Section 2.5 Clinical Overview.pdf - "Clinical Overview"	17	last bullet on pg 17	Other	In the Clinical Overview section(2.5), section 2.5.1.2.1.1 Current Therapies, the last bullet under Current Therapies in the Clinical trail setting the drug ivermectin (anti-parasitic) is listed. Ivermectin has been banned as a treatment by the Agency due to no FDA approval for COVID treatment. However, here in this document they are recognizing ivermectin as a current treatment therapy.
3/11/2022 18:58:07	125742_S1_M2_24_nonclinical-overview	12	2.4.2.1.4.1. Immunogenicity in Rhesus Macaques	Other	Immunized macaques compared with humans The 38 humans were "asymptomatic 14 days after positive SARS-CoV2 PCR test" Did they ever have symptoms or COVID-19 ? Did they compare immunized macaques (unstated number) with 38 people with false positive PCR tests?
3/11/2022 18:58:07	125742_S1_M5_CRF_c4591001-1085-10851246.pdf	129 and on	4th column	Adverse Effects - Reproductive Issues	The client was on birth control and got pregnant during trials
3/11/2022 19:10:23	125742_S1_M2_24_nonclinical-overview	6	2	Study Protocol	It says " only BNT162b2(V9)...is the subject of this BLA application " Why is variant (V8) often used as a reference ?
3/11/2022 19:57:59	The One for first name a-c was to read	21	Table 7	Other	Over 2000 neurological reported symptoms yet not enough to change safety data. And more than 1000 excluded cases a-f. . Also most neurological reports are high tech and would require hospitalization to detect. Eg increased intracranial pressure. Under-reported because most people don't go to the hospital, or even if they do, the do not get such high tech interventions. Eg they get it Tylenol for head ache. I also question the frequent 2:1 or 3:1 reporting for women:men. I think men just complain less or stay home and die. In my personal acquaintances I would say the deaths among men outnumbers females. There is no comment on whether spike proteins cross the blood brain barrier. I believe the reported neurological adverse events suggest they do. Both from the vaccine and from the virus. By my personal symptoms I suspect the same. There is also no warning to individuals who may have had pre-existing neuropathy , or deficiencies in blood brain barrier from, for example, chemotherapy, that would make them more vulnerable to these events. Thus there is no ability to make an informed consent to protect themselves since this information was withheld. I am commenting primarily on neurological AE since by my training as psychiatrist we take the same board exam as neurologists. Or at least I am commenting on this first.
3/11/2022 19:58:11	125742_S1_M2_24_nonclical-overview	8	bottom section	Data Missing	In vitro metabolism: 01049-20010 is listed then it skips the numbers 01049-20011 - 19 01049-20020 is listed next Is this normal, or does this suggest missing or cherry-picked data ?

3/11/2022 20:27:44	#43 - 125742_S1_M2_24_nonclinical-overview.pdf - "NON CLINICAL OVERVIEW - needs thorough review"	23	1	Adverse Effects - Other	(from a non-scientist) are these truly anticipated macroscopic and microscopic effects of the vaccine? "increased size of draining iliac lymph nodes and increased size and weight of spleen." "increased size of draining iliac lymph nodes and increased size and weight of spleen."
3/11/2022 20:55:37	#43 - 125742_S1_M2_24_nonclinical-overview.pdf - "NON CLINICAL OVERVIEW - needs thorough review"	23	2	Other	Regarding the DART study - -Is this significant? - - Apparently, vaccinated females pass the antibodies to their offspring. Specifically, "neutralizing antibodies were also detectable in the F1 offspring (fetuses and pups)." ?
3/11/2022 20:57:19	BNT162b2 - 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	12, 13	Table 6	Adverse Effects - Reproductive Issues	Pregnancy and Lactation issues
3/11/2022 20:58:35	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy.pdf	18, 20	18 - 2nd paragraph; 20 - last full paragraph	Study Protocol	On page 18 regarding participant selection it states: "Also included were individuals with previous clinical or microbiological diagnosis of COVID-19 or with evidence of current or prior infection based on serology or nasal swab." So it sounds like people previously infected were potentially included in the study. Then on page 20, it states: "Only first occurrences of COVID-19 with onset of symptoms at least 7 days or 14 days after Dose 2 were included in the analyses." So this potentially sounds to me like someone with prior infection could be enrolled in the study, but perhaps if they test positive during the study they would not be counted as a positive case since it is not their "first occurence of COVID-19?" - If that is correct, it could dishonestly increase their effectiveness rates if that is in fact what it's stating. Additionally I jumped ahead to the sited section 5.3.5.1 & it notes that Exclusion Criteria should include: "Previous clinical (based on COVID-19 symptoms/signs alone, if a SARS-CoV-2 NAAT result was not available) or microbiological (based on COVID-19 symptoms/signs and a positive SARS-CoV-2 NAAT result) diagnosis of COVID-19." So it's stating that individuals with prior infection should not be included in the study, but it is noted that they were allowed to be included.
3/11/2022 20:59:55	BNT162b2 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	16 to 25	Table 7	Adverse Effects - Other	NOTE 2 - Adverse Events of Special Interest [AESI's] Evaluations, Table 7,pages 16 to 25
3/11/2022 21:02:05	BNT162b2 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	30 to 38	Appendix 1	Adverse Effects - Other	Appendix 1. Full List of Adverse Events of Special Interest [AESIs] - at time of document submission
3/11/2022 21:04:43	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy.pdf	16	7	Study Protocol	It states at the very end of the paragraph: "To facilitate rapid review of data in real time, sponsor staff were unblinded to vaccine allocation for the participants in Phase 1." This unblinding of staff sounds potentially problematic. I also noted in a referenced table 6.1 that the experimental vaccines were given all in glass, and the placebos were given in glass OR PLASTIC - I would think this too could be problematic, making it easier for people involved to know when they are giving a placebo and potentially for participants to find out as well.
3/11/2022 21:05:27	#43 - 125742_S1_M2_24_nonclinical-overview.pdf - "NON CLINICAL OVERVIEW - needs thorough review"	26-27	7	Adverse Effects - Other	Are these truly "non-adverse effects" as the document concludes? "The vaccine elicited a robust antigen-specific immune response and produced nonadverse macroscopic changes at the injection sites, spleen, and the draining lymph nodes; increased hematopoiesis in the bone marrow and spleen; liver vacuolation; and clinical pathology changes consistent with an immune response. The findings in this study were either fully recovered or showed evidence of ongoing recovery at the end of the 3-week recovery phase, and were consistent with those typically associated with the IM administration of LNP-encapsulated mRNA vaccines"
3/11/2022 21:09:08	BNT162b2 - 2.5 Clinical Overview.pdf	18,19,22,142,227 to 250, 255 to 268, 272 to 273..	Tables 64, 66, 67, 70, 71, 74	Other	Multiple issues from study discrepancies to LNPs, Pregnancies, study stopping rules, Acs [full range] and more, including HIV issues
3/11/2022 21:11:36	125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf	85	Last paragraph	Study Protocol	It states: "Participants ≥16 years of age who originally received placebo and accept the offer to receive BNT162b2 at defined points as part of the study will receive 1 dose of BNT162b2 at each additional vaccination visit (Visits 101 and 102) in accordance with the study's additional SoA (Section 1.3.3)." So it sounds like the placebo group was allowed to switch to the experimental group if they chose to, which seems like an issue as they are not supposed to know what they are receving, nor is the person administering it supposed to know as far as I can tell. Further, it eliminates, at least partially, your control group and makes it more difficult to honestly compare the two groups.
3/11/2022 21:15:06	BNT162b2 2.6.5 Pharmacokinetics Tabulated Summary.pdf	3-14	As Highlighted	Other	LNPs and Luciferase infiltrating and lodging in the itemized organs of the human body — Liver, hepatocytes, blood, spleen, uterus, ovaries, adrenal glands
3/11/2022 21:26:15	#43 - 125742_S1_M2_24_nonclinical-overview.pdf - "NON CLINICAL OVERVIEW - needs thorough review"	27	2, 3	Adverse Effects - Other	HIGHER BODY TEMPERATURE FOLLOWING VACCINATION - - "Test article- related higher mean body temperature (maximum increase post each dose) compared with control animals was noted on Day 1 (up to 0.54°C), Day 8 (up to 0.98°C), and Day 15 (up to 1.03°C) postdose." HIGHER INCIDENCE AND SEVERITY OF EDEMA AND ERYTHEMA - - "BNT162b2 (V9)-related injection site edema and erythema were noted on Days 1 (up to slight edema and very slight erythema), 8 (up to moderate edema and very slight erythema), and 15 (up to moderate edema and very slight erythema). The incidence and severity of the reactions were higher after the second or third injections compared with the first injection."
3/11/2022 21:27:43	BNT162b2 Module 2.4. Nonclinical Overview	7, 10, 29, 6	As highlighted in document	Other	Luciferase, page 7, with resources; Carcinogenicity, pages 10 & 29, with resources; LNPs (lipid nanoparticles), page 6; LNPs [lipid nanoparticles] distribute to/and reside in the liver, spleen, ovaries, and adrenal gland
3/11/2022 21:30:19	FDA-CBER-2021-5683-0015529; 5530, 5531	Page 3-5	Table section Protocol amendment 13 12 February 2021, Summary and Rationale for Changes	Study Protocol	As a lay person, certain statements caught my attention as highlighted in screenshots in regards to unblinding of study participants, knowing who was getting placebo and using telehealth protocols instead of in-person data collection, not sure if that's proper procedure?
3/11/2022 22:00:55	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	page 1-20	i have a word document to submit page 1-20	Other	2 in phase of trial, PCR test use when PCR was overcalculated, many other issues. i can only work with submitting word doc
3/12/2022 2:00:08	125742_S1_M5_5351_c4591001-fa-interim-compliance.pdf	1-49	All	Other	Reference to age of subjects "16-55" (minor subjects?) Reference to substantial medication storage, wrong dosage and wrong product administration. I have provided a one-page summary of the entire 49-page document in lieu of screenshots.
3/12/2022 3:28:29	125742_S1_M2_24_nonclinical-overview.pdf	10	3	Efficacy	The claim is that modRNA vaccines result in "particularly strong, long lived, high affinity antibody responses" and yet there is minimal, if any, data in the paper suggesting tests >30 days.
3/12/2022 4:03:54	125742_S1_M2_24_nonclinical-overview.pdf	15, 16, 17, 18	(1,2,3); 3; 2; 1	Adverse Effects - Other	These issues all appear to affect the liver
3/12/2022 4:12:08	125742_S1_M2_24_nonclinical-overview.pdf	12	3	Efficacy	Not 100% sure of this para, but they took sera from adults from 18-83 (wide range?) and efficacy in Macaques apparently declining after 56 days (not a long time!)
3/12/2022 4:18:43	125742_S1_M2_24_nonclinical-overview.pdf	13	3, 4, 5	Adverse Effects - Reproductive Issues	Not sure if this is an 'adverse' effect, but offspring also had immunity. Also, rats had 3 and even 4 doses of vaccine.
3/12/2022 4:22:29	125742_S1_M2_24_nonclinical-overview.pdf	29	4	Data Missing	There were no tests done for carcinogenicity
3/12/2022 4:25:27	125742_S1_M2_24_nonclinical-overview.pdf	22	3	Data Missing	There were no apparent tests for vaccine going to male sperm
3/12/2022 4:30:56	125742_S1_M2_24_nonclinical-overview.pdf	28	2	Adverse Effects - Other	The report only talks of "partial recovery of enlarged drainage nodes" but with rider "Suggesting recovery in progress"
3/12/2022 5:32:50	125742_S1_M5_5351_c4591001-fa-interim-compliance-sensitive.pdf	2-3	all	Other	Confirmed minor test subjects as young as 16 years old.
3/12/2022 7:49:05	STN 125742_0_0 Section 2.7.4 summary-clin-safety.pdf	27 & 28	Last Paragraph & 1st Paragraph	Study Protocol	Phase2/3 included plans to also study a vaccine prototype BNT162b2-VOC which is specifically identified as BNT162b2-SA for the South African variant. This subset of participants would receive the 1st prototype shot 5-7 months after the 2nd dose of the original vaccine.
3/12/2022 10:42:58	STN-125742_0_0-Section-2.5-Clinical-Overview	many	Tables 58 - 74	Other	I am not a medical professional but I do have experience in managing and interpreting data. The experimental results versus the placebo results are at least superficially reasonable in support of the efficacy and safety of the vaccine. I do question whether this test vaccine is the same composition as the vaccine actually used under the EUA to immunize millions, among whom there are many thousands who have experienced adverse side-effects.
3/12/2022 12:05:06	5.3.6 postmarketing experience.pdf	28	Table, Row 8	Study Protocol	Product administered to patient of inappropriate age. 44 total, 4 with harm. I think this means 44 children under the age of 12.

3/12/2022 12:14:37	5.3.6 post-marketing experience.pdf	Page 38 of 38	FDA-CBER-2021-5683-0000091	Adverse Effects - Other	Listed Adverse Effect: "Toxic Oil Syndrome"; Did research on this, found that Toxic Oil Syndrome was an epidemic in 1981 isolated to Spain (how could this possibly be an adverse effect of a current covid vaccine?) Interestingly, it involved people getting sick and dying of pneumonia like symptoms which was investigated and was attributed to poisoned cooking oil sold in the street markets of Madrid, but certain doctors and health officials started questioning the validity of this explanation; they found there was no way the illness could have anything to do with oil, as people were dying who had no contact with oil, and many who used the oil were fine. According to the attached Guardian article, "The disaster is historically important not just because of its scale and the number of victims. It was the prototype contemporary scientific fraud. It marked the first time that multinational interests successfully contrived a major cover-up in international science. For the one thing that is certain about the Spanish "cooking oil" disaster is that it had nothing to do with cooking oil." Those who spoke out were silenced, harassed, and fired from their medical or government posts, and the only victims counted in reports were those who claimed to have consumed cooking oil. Any victims who didn't meet the government narrative were excluded from the official reports. It was ultimately determined that the real cause of the epidemic was ORGANO-PHOSPHATE PESTICIDES on tomatoes. All official reports on this have never been updated with the truth, and the governments and WHO have always continued to officially refer to the illness as "Toxic Oil Syndrome" despite having nothing to do with oil. And in 2021 it was listed by Pfizer as one of the adverse effects of its Covid 19 vaccines. So, I did more research trying to find any logical explanation for the presence of organo-phosphates in vaccines, as well as researching any correlations between OP pesticides and SARS Cov 2. And I was again shocked from what I found: An NIH medical article titled "Immunotoxic role of organophosphates: An unseen risk escalating SARS-CoV-2 pathogenicity" Stated in the Abstract of this article: Organo-phosphates "fuel oxidative stress to impair antiviral immune response in living entities. Aside, organophosphates promote cytokine burst and pyroptosis in broncho-alveolar chambers leading to severe respiratory ailments. At present, we witness COVID-19 outbreak caused by SARS-CoV-2. Infection triggers cytokine storm coupled with inflammatory manifestations and pulmonary disorders in patients. Since organophosphate-exposure promotes necroinflammation and respiratory troubles hence during current pandemic situation, additional exposure to such chemicals can exacerbate inflammatory outcome and pulmonary maladies in patients, or pre-exposure to organophosphates might turn-out to be a risk factor for compromised immunity."
3/12/2022 12:52:25	1257_S1_M2_24 NonclinicalbOverview	23	1st full patagraph	Adverse Effects - Other	It mentions hepatocyte vacuolation in the liver. Copy below. Vaccine-related microscopic findings at the end of the dosing phase consisted of edema and inflammation in injection sites and surrounding tissues; increased cellularity in the draining (iliac) lymph nodes, bone marrow, and spleen; and hepatocyte vacuolation in the liver.
3/12/2022 14:37:56	#20 - STN 125742_0_0 Sec 2.7.3 Summary of CE	112,121,122,144,145	these are tables	Data Discrepancy	Numbers do not make sense. Created a table of main entries - someone with CT experience will need to look and see if there is a good explanation for this. Increasing number of subjects and declining numbers of exclusions. Where did those people go?
3/12/2022 15:03:28	BNT162b2 5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports	6	Bullet #3	Data Missing	It was noted in this report that there was a back log of cases to be entered into the database. The serious reports were entered however, not all non-serious reports were entered. This means the case and event counts for this period of 3 months is not completely accurate because not all non-serious cases are in the database/this output. This does not appear to be an intentional omission, it appears that they could not keep up with the volume of incoming reports. They noted they hired additional help. However, this omission of reports gives an underinflated count of reports/events. Question for Pfizer would be did they include these missing reports in their next monthly surveillance report? They should have made sure the cases were accounted for in the next report.
3/12/2022 15:34:14	https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	6	3rd Bullet Point	Data Missing	p. 6 2. METHODOLOGY "Due to the large numbers of spontaneous adverse event reports received for the product . . ." Pfizer is acknowledging extensive safety problems with their vaccine. "Entrance into the database includes the coding of all adverse events; . . ." The public needs a list of those codes and the number of cases reported for each. "Pfizer has taken multiple actions to help alleviate the large increase of adverse event reports." Another admission by Pfizer of extensive safety problems. "To date, Pfizer has onboarded approximately REDACTED additional full-time employees (FTEs). More are joining each month with an expected total of more than REDACTED additional resources by the end of June, 2021." Yet another admission, with the redaction of numbers indicative of cover-up attempt. 3. RESULTS 3.1.1. General Overview "It is estimated that approximately REDACTED doses of BNT162b2 were shipped worldwide from the receipt of the first temporary authorization for emergency supply on 01 December 2020 through 28 February 2021." The redacted number of doses shipped is another concealment of the extent of the safety issues.
3/12/2022 15:39:04	https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	9-29	Tables 2 through 8	Other	After detailing deaths and serious non-recovered adverse events as well as recovered with sequelae, Pfizer repeatedly states after each Table their conclusion: No NEW safety information was identified. The implication is that they were already aware of all these safety issues prior to this report.
3/12/2022 15:45:13	https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	11	Table 5, Important Potential Risk	Other	Pfizer Minimizing Harm Vaccine Associated Enhanced Disease (VAED), including Vaccine-Associated Enhanced Respiratory Disease (VAERD) Of the 138 cases identified, 38 were fatal, 13 life-threatening, 9 serious for disability, yet in their conclusion, Pfizer states "VAED/VAERD remains a THEORETICAL (emphasis added) for the vaccine. I doubt the victims are "theoretically" dead or disabled. This conclusion typifies Pfizer's minimizing of serious adverse events from their product.

3/12/2022 15:48:37	https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	12	Table 6	Study Protocol	Table 6, Description of Missing Information Of 274 Pregnancy Cases, 28 babies died. Pfizer conclusion: “No new significant safety information was identified . . .” 28 dead babies are significant. Pfizer should be sounding the alarm that pregnant mothers should not receive the vaccine. Vaccine Effectiveness: “The coding conventions for lack of efficacy in the contest of administration of the COVID-19 vaccine were revised on 15 February 2021.” Pfizer’s report does not state what the prior coding convention was, why the change was made, and how the change affected the number and type of adverse events reported. The question arises of whether Pfizer was attempting to minimize the AE’s by changing coding conventions not just mid-stream, but toward the very end of the reporting period. Was the change applied retroactively to exclude adverse event cases?
3/12/2022 15:50:19	https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	15	Table 6 Explanatory Notes	Data Missing	59 cases excluded because Pfizer determined height and weight were not consistent with pediatric patients. It would be good to drill down on those 59 to see if they were in fact pediatric and should have been included, and whether those 59 had serious outcomes Pfizer was attempting to hide.
3/12/2022 15:54:31	https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	16	Table 7	Data Missing	Table 7, AESIs Evaluation for BNT162b2 Cardiovascular AESIs Number of cardiovascular cases reported was 1403 of which 136 were fatal. Relevant event onset latency median onset time was less than 24 hours. In light of such potential lethality, why are vaccine clinics being held in churches, schools and other non-medical facilities, and are these institutions informed of the deadly risk they are exposing others to? Are they liable for the harm done? Facial Paralysis One INFANT and one child suffered this vaccine injury. Pfizer says “[t]his cumulative case review does not raise new safety issues,” facial paralysis is highly significant to these children and their families. If this was not a NEW safety issue, where is the data already on hand of these AESIs? Pfizer should warn every parent of the risk of facial paralysis and other potential injuries to their children.
3/12/2022 15:58:36	https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	16	3.1.3 Table 7	Adverse Effects - Other	p. 16, 3.1.3 Review of Adverse Events of Special Interest (AESIs) Table 7 AESIs Evaluation for BNT162b2 This table includes serious, life-threatening events such as anaphylactic reactions, cardiovascular and hematological events, liver damage, immune and auto-immune and neurological events. Are vaccine recipients warned of the extensive number of serious risks? Should employees and other agencies/entities who require vaccination be required to warn? Has informed consent been given to anyone? Should those who mandate vaccines be liable for damages? The vaccine producers have prematurely been given liability protection, but those who FORCE/COERCE the jab should be held liable. Legislation needs to be passed to remove mandating power from all sectors. Public health is best served when the individual can make the best-informed decision for himself and his children. Stopping a huge public health policy takes time, while the individual can react quickly to threats and new information of risk. While citizens wait for a governing entity to become informed and act properly, millions are irreparably harmed.
3/12/2022 16:07:27	https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	Appendix 1, p. 1	97th entry in adverse event list	Adverse Effects - Reproductive Issues	Appendix 1 LIST OF ADVERSE EVENTS OF SPECIAL INTEREST The shear number of adverse events reported is staggering – over a thousand. Of note is recurrence of disease previously in remission (e.g., multiple sclerosis). Are such patients warned not to vaccinate? Also, there are a large number of autoimmune disorders reported, as well as antibody test abnormalities. Of grave concern is “anti-sperm antibody." All women of child-bearing age should be informed of this risk and given an opt-out. This would also be a justification for a religious exemption for employees/students if they were aware of this potential risk.
3/12/2022 16:22:50	5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	multiple	multiple	Adverse Effects - Other	I am uploading 2 files. A Doc file with explanation & an excel file that reformats the data to make it more meaningful
3/12/2022 17:22:04	STN 125742_0_0 Section 2.7.4	81	2.7.4.2.4.2.1.2.1	Data Discrepancy	On page 81, in the narrative, they point out the number of subjects (mostly in the younger group) who had night sweats or hyperhydrosis. This data was entered into the summary table of adverse events under "Disorders of the Skin" on page 110. Hyperhydrosis can accompany skin disorders, but in this context and without an underlying skin condition, it should have been considered a symptom of underlying system disorder. This is not a specific finding, but can indicate underlying cardiac disorder (including endocarditis), or endocrine disorder.
3/12/2022 17:48:37	125742_S1_M2_24_nonclinical-overview.pdf	17 and 18	both paragraphs in sections 2.4.3.4	Other	Study shows LNP in organs: We were told the vax stayed in the deltoid muscle, but these animal tests show the LNPs were distributed to the liver, spleen, adrenal glands and ovaries.
3/12/2022 18:00:24	125742_S1_M2_24_nonclinical-overview.pdf	29	2.4.4.5 entire paragraph, two sentences	Study Protocol	Carcinogenicity studies were NOT conducted....none at all.
3/12/2022 19:25:47	STN-125742_0_0-Section-2.5-Clinical-Overview	21	2.5.1.2.3.2.1. Phase 1/2 Study BNT162-01	Data Missing	1) In the ongoing dose level finding study, ("BNT162-0... FIH, Phase 1 dose level-finding study") safety review committee recommended against the second 60ug dose, Why??? the quote is "Note: the SRC recommended that a second dose of BNT162b1 at 60 µg not be administered due to reactogenicity after the first dose." then further said not available at time of submission quote"Note that at the time of BNT162-01 Interim CSR preparation, data for BNT162b2 dose levels of 50 µg and 60 µg were not available." So, safety data not available even though the SRC said stop, seems like missing important data 2) The data for "other platforms" not relevant. If you wanted to understand the safety of platforms (LNP) vs antigens (Spike, RBD, etc) this should be relevant, and FDA should decide relevance, Not Pfizer. quote"Dosing with other candidates on different platforms, BNT162a1 (uRNA) and BNT162c2 (saRNA), is not discussed as it is not relevant to progression with modRNA candidates." A subject matter expert should review this IMO
3/12/2022 19:29:42	#19 - STN 125742_0_0 Section 2.5 Clinical Overview.pdf - "Clinical Overview"	17	2.5.1.2.1.1	Study Protocol	Under “Current Therapies” (Section 2.5, pg. 17) There is a glaring lack of interest in proven and effective therapies being used around the world.
3/12/2022 19:40:29	STN-125742_0_0-Section-2.5-Clinical-Overview	22	2.5.1.2.3.2.2. Phase 1/2/3 Study C4591001 sub par. "Phase" 1	Study Protocol	The dose finding study went up to 60ug (and safety committee recommended against the second 60ug dose), but phase 1 went up to 100ug for BNT162b1, I realize that they used BNT162b2 for the vaccine they got approved, but why would it make sense for a protocol to dose higher in Phase 1 than in the dose finding study (especially when that study did not proceed to a second 60ug dose for safety reasons). Doesn't sound right?
3/12/2022 19:52:38	STN-125742_0_0-Section-2.5-Clinical-Overview	22	2.5.1.2.3.2.1. Phase 1/2 Study BNT162-01, Sub Par. "Study Eligibility Criteria"	Study Protocol	They excluded from participation people who based on occupation were likely to be exposed to infection. They excluded quote "Occupation with high risk of SARS-CoV-2 exposure (eg, healthcare, emergency response)" Wouldn't this deliberately reduce the 'statistical power' of the study to determine efficacy (better confidence, more quickly, with less participants, etc.). What could the reason be? Did they worry that vaccinating shortly before, during, or shortly after exposure would produce results that would not support approval? How do I tell if a vaccine prevents COVID 19 unless participants get exposed to SARS CoV2? Isn't this the whole point of the study... Seems to raise questions

3/12/2022 20:13:11	FDA-CBER-2021-5683-0015532, 5533, 5534, 5535, 5536	6 -10	paragraphs in multiple table sections	Study Protocol	Please note, I'm not a scientist, dr, etc - these things caught my eye: 5532(p6) discusses unblinding, medication errors, discontinuation of study interventions, & Added that 2 periods of potential COVID-19symptoms within 4 days will be considered as a single illness; 5533(p7) are considered...due to vaccine reactogenicity, Amended scope of analyses of safety data, less than 18 years of age will not be enrolled in the EU., Removed the need to have safety data reported for participants to be included in the safety objective assessment, Removed exclusion criterion, Decreased the lower age limit and removed the upper age limit for inclusion in Phase 2/3; 5534(p8) Removed reference...P2 mutant, prefusion spike glycoprotein (P2 S) being "heads up.", ...definition should not be recorded as AEs., Clarified the AE reporting requirements for potential COVID-19 illnesses, Moved the immunogenicity objectives, Modified exclusion criterion 5...excluded from all phases of the study; 5535(p9) 2 all-available efficacy populations., AEs will only be performed in Phase 2/3...only the first primary objective will be evaluated., the need to demonstrate VE as soon as possible, the protocol has been amended to be powered to meet new efficacy objectives, nonclinical data are available to support the study, 6-month safety follow-up telephone contact has been changed, permit a remote or in-person visit, AEs that occur between consent and dosing will now be reported on the AE (rather than Medical History); 5536(p10) added to outline the stopping and alert rules to monitor for potential enhanced COVID-19, Not to study the BNT162a1 and BNT162c2 vaccine candidates at this time, BNT162b3 vaccine candidate has been removed from the protocol until further nonclinical data are available to support study in humans,. increase flexibility enrolling participants, an extended screening window (increased from 14 to 28 days), number of doses that can be obtained from available vaccine vials, not all dose levels will result in a dosing volume of 0.5 mL
3/12/2022 20:45:08	https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf	Page 80 5.2. Exclusion Criteria Participants are excluded from the study if any of the following criteria apply:	5.2 and following	Study Protocol	For starters, I would be concerned about the subject selection and exclusion criteria. The researchers would only be able to generalize their findings to subjects similar to those in the study. The study subjects seem to be different than the general population. For example, no individuals with prior allergic reaction to a vaccine were excluded as were those with hypertension or asthma. Also those in "Receipt of medications intended to prevent COVID-19" were excluded which is an interesting exclusion criteria. I would like to see tables that detail the study participants including those that withdrew and why given that if they withdrew consent no further data was collected. What is the attrition rate? Also, three variations of the vaccine were studied. Were the results reported separately for each. More to review in this document.
3/13/2022 7:05:45	2.7.4 Figure 4 graph	69	Graph - Figure 4 :	Adverse Effects - Other	Severe side effects of vaccine after 7days of each dose by age group 16-55 Increased severity of fatigue, headache, chills, muscle pain and joint pain after 2nd vaccine dose
3/13/2022 8:05:37	https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	highights are provided through the whole document	the number of fatalities, serious and unresolved events recorded and yet their conclusion: Conclusion: No new significant safety information was recorded"	Fatality	again-there are so many fatalities, serious adverse events, unresolved and unknown outcomes and yet they conclude there are no safety concerns. And these events were often occurring within 24 hrs of dosage administration. One would think a handful of fatalities and SAEs would have shut this down immediately.
3/13/2022 10:20:35	5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	7	Table 1	Adverse Effects - Other	Table shows all cases post authorization adverse events and also demonstrates female: 29914, male: 9182. Maybe females self report at higher frequency however this is a large difference and is worth looking into. Also for case outcomes there is no outcome for just "recovered" it is best outcome "recovered/recovering." Maybe this is typical reporting but again seems an easy way to technically hide ongoing issues. I also question the outcome of 9400 "unknown" as "unknown" would be an easy place to hide fatalities. If Pfizer as the initial info of the adverse event they should at the very least be able to state this outcome as "unknown but no fatality" at time of report they could find records of death (to at least eliminate that as part of the unknown field).
3/13/2022 11:08:49	https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	10, 16-24	Multiple tables throughout document	Adverse Effects - Other	When reviewing the Adverse Events of Special Interest (AESIs) listed by country and gender etc. Besides also noticing that most adverse events are in female population, I noticed that in a vast majority of areas such as Anaphylactic Reactions, Cardiovascular AESIs, Dermatological AESI, Haematological AESI, Hepatic AESIs, Immune-Mediated/Autoimmune AESIs, Musculoskeletal AESIs, Neurological AESIs, Other AESIs, Renal AESIs (Germany first), Respiratory AESIs, Thromboembolic Events, Stroke, Vasculitic Events that numbers show UK reporting higher numbers than any other country. USA was first in only COVID-19 AESIs, Facial Paralysis and Use in Pregnancy and lactation. This caught my attention as the data is only up to 2/28/21 and I remember although initially Pfizer was authorized early in the UK I believe a the early population was primarily receiving the AstraZeneca vaccine. I would love to know how many persons in the USA per population received the Pfizer vaccine vs how many persons in the UK per population received the Pfizer vaccine up to the data cut off of 2/28/21. If it is found that the UK had a much smaller segment given Pfizer up to 2/28 per population however they report most of the adverse events this would demonstrate that either USA has vastly underreported Adverse Events or that the UK received vaccines that would be causing greater Adverse Events. As the USA had three different vaccines distributed and the UK was distributing two different vaccines this information may be difficult to determine, however, if we could find it it might show some important signals. As a nurse, I have already suspected that the Adverse Reporting process in the USA has been confusing, unmandated and has a great potential to miss and under report many adverse events. The graphs reflecting this are from https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf pages 10-24. I do have screen shots of all of it however it would be many different files so I am going to post only a few examples to show it as these tables are scattered and easily identifiable in pages 10-24. I am happen to upload them all if that is necessary but wanted to not confuse this.
3/13/2022 11:08:49	5.3.6	11	2, 4 & conclusion	Fatality	out of 138 cases: 71 were medically significant of which 38 died, of the 317 relevant events drug ineffective (135)
3/13/2022 11:20:39	STN-125742_0_0-Section-2.5-Clinical-Overview	27	2.5.2.2. Biopharmaceutical Studies	Other	Potentially false statement (omission of material information from a statement) To me, material information was left out that "any competent professional following standard professional work practices" would have included. So, although technically accurate as is, statement may be considered deliberately misleading (if there is a requirement/expectation for submission to be complete). Pfizer knew that activation of cells took place throughout the body, not just "at the site of injection (ie, muscle)" Excerpt, then paragraph for context: Excerpt: "Vaccine induced activation of antigenpresenting cells takes place at the site of injection (ie, muscle) which is rapidly followed by antigen-presenting cell migration via lymphatic vessels towards the draining lymph node where vaccine antigens activate specific B and T cells." Full Paragraph for context "2.5.2.2. Biopharmaceutical Studies Bioavailability and bioequivalence assessments are not relevant to vaccine antigenicity and have not been measured. The major pharmacodynamic effect of a vaccine, unlike a drug, is to elicit an immune response to the antigens included in the vaccine. Vaccine induced activation of antigenpresenting cells takes place at the site of injection (ie, muscle) which is rapidly followed by antigen-presenting cell migration via lymphatic vessels towards the draining lymph node where vaccine antigens activate specific B and T cells. There is no specific vaccine antigen blood level required to elicit the immune response."
3/13/2022 12:05:07	5.3.6	12	1, 2 (entire section) 3 Breast feeding	Adverse Effects - Reproductive Issues	84 serious cases out of 413 cases (20%), 23 spontaneous abortions out of 270 pregnancies (8.5%) out of 124 mother cases 75 were considered serious (60%) which were in the vaccinated mothers. In the 124 mother cases there were 25 spontaneous abortions (20%) Out of 133 breast feeding baby cases 116 cases reported exposure to vaccine during breast feeding.
3/13/2022 13:24:28	#19: STN 125742_0_0 SEc 2.5 Clinical Overview	79-80	Table 28	Data Missing	I made a submission yesterday with a chart I made showing the discrepancy between 3 tables (in Doc #20) re the number of subjects who did not receive Dose 2. In this document: (Doc #19)Table 28 shows the lower numbers presented from Doc #20 - which makes it appear (if you only bothered to read the Overview document) that the numbers were not that bad, and the reasons rather benign. Furthermore, a submission I made a few days ago re document: '125742 S1 M5 5351 fa interim excluded patients sensitive c459101' shows 1448 pages of excluded subjects. There are 2 sections there: page 1-643 and 645-1448, with some discrepancies between these sections as well as detailed previously. I have not added all the subjects up in totality - only the teenagers as submitted. There is a difference of 89 teenagers between the 2 sections of excluded patients for not receiving the second dose.

3/13/2022 15:08:02	Clinical efficacy		@12-15	Unsure	Efficacy	Throughout the section they never refer to Absolute Risk Reduction or even Relative RR. It's just efficacy which they don't define to my satisfaction. I'm not familiar with Bayesian analysis so I can't comment on the stats associated with it. Their initial testing only decreased ARR by 0.05% even though they claimed it to be 95% effective!
3/13/2022 15:19:13	FDA-CBER-2021-5683-001387		Pages 16, 17, 18	Table 2.4.3-1./ Figure 2.4.3-1., page 17 Distribution, page 18 paragraph 1	Adverse Effects - Other	My understanding is the injection was to remain in the injection site.
3/13/2022 15:56:31	Bates-FDA-CBER-2021-5683-0002398		18	4	Other	Misleading statements: "RNA-based vaccines do not carry risks associated with infection". This is contradicted by the list of adverse events in other documents and the VAERS reporting. "RNA occurs naturally in the body, is metabolized and eliminated…." There are studies showing that the RNA remains in the body and a recent study suggesting it can transcribe to the genome in liver cells.
3/13/2022 16:10:09	FDA-CBER-2021-5683-2403		23	1 & 5	Efficacy	This document is dated April 2021. This page shows that Pfizer was already contemplating the need for third and fourth booster shots before the shots were even made available to the whole population.
3/13/2022 16:14:21	FDA-CBER-2021_0002404		24	1	Study Protocol	Pfizer unblinded participants, meaning there is no clinical way to measure safety and efficacy of the vaccines against the unvaccinated.
3/13/2022 16:15:00	FDA-CBER-2021-5683-0002897		16-17	Table 1	Adverse Effects - Other	Phase 3 Data looks to me to state: 43,847 - Blinded AEs/SAEs; 20,309 - Open-label AEs/SAEs; 12,006 - Blinded and open-label AEs/SAEs; 19,525 - Open-label AEs/SAEs. This seems like a High overall number of AEs for less than 10k participants.
3/13/2022 16:21:09	FDA-CBER-5683-0002407		27	2.5.2.2	Data Discrepancy	"Vaccine induced activation of antigen-presenting cells takes place at the sire of injection…." This statement contradicts data presented in the Organ Distribution Chart found at 2.6.5.5B pp 6 and 7.
3/13/2022 16:32:28	125742_S1_M2_24_nonclinical-overview.pdf		12-13	2.4.2.1.4.2	Study Protocol	The dosage given to the non-human primates was much higher than given to people (100ug), even before considering bodyweight. They timed the SARS-CoV-2 challenge to peak immunogenicity (55d after dose 2, see previous paragraph), which is when it would show the largest effect. The non-human primates given saline didn't exhibit any signs of COVID-19 illness, so there's no clear effect on illness outcomes. How do we know that the vaccine didn't simply rend rtPCR unable to return a positive result, perhaps due to competitive binding? I've been having trouble finding quantitative analyses of disease severity with and without BNT162b2 vaccination in an animal model. The closest I've found is this paper: https://www.biorxiv.org/content/10.1101/2021.12.27.474282v1.abstract They provided no data and only said that the booster reduced disease. The lung inflammation score differences appear to not be statistically significant. They openly admit that their conclusions are based mostly on "trends" and not significant differences. Back to Pfizer... "In summary, BNT162b2 provided complete protection from the presence of detectable viral RNA in the lungs compared to the saline control with no evidence of vaccine-elicited disease enhancement." Seems it would have been best to look for viral plaques, rather than relying on rtPCR. No disease at all, so impossible to make conclusions.
3/13/2022 16:44:22	FDA-CBER-2021-5683-0002915		19	The safety review committee (SRC) recommended that a second dose of BNT162b1 at the 60 µg dose level not be administered due to the reactogenicity after the first dose.	Other	Safety Review Committee recommendation regarding 2nd dose reactogenicity issue. What was/were the issue(s), what were the guidelines to determine there was/were issue(s), how were the guidelines developed/determined, and were they applied in the same way across all dose administrations?
3/13/2022 17:05:06	FDA-CBER-2021-5683-0002438		58-59	Table 14	Study Protocol	Table 14 shows 100% efficacy among black and South Africans. This suggests a flaw as 100% efficacy in any treatment seems impossible.
3/13/2022 17:07:47	FDA-CBER-2021-5683-0002448		70	2.5.4.2.2.1.3.2	Efficacy	There was no statically significant benefit to vaccine in preventing severe COVID.
3/13/2022 17:21:19	FDA-CBER-2021-5683-2461		81, 82	Table 29	Study Protocol	Demographics seem disproportionately white, disproportionately young, and lacking in co-morbidities.
3/13/2022 17:34:11	FDA-CBER-2021-5683-0002479		99	Table 35	Study Protocol	This may be an anomaly, but the chart doesn't look right. No statistical differences between vaccine and placebo group on positive tests. But it shows negative efficacy in two categories and significantly more negative tests among placebo group.
3/13/2022 18:37:34	FDA-CBER-5683-0002397		17	2.5.1.2.1.1	Other	In April 2021, Pfizer acknowledged that Ivermectin (anti-parasitic) was a possible therapeutic that could be studied clinically.
3/13/2022 18:50:46	FDA-CBER-2021-5683-0002495 and 2496		115, 116	2.5.4.4.1.1.1 and Figure 3	Efficacy	Pfizer acknowledged "protein-specific" T cell response (leaving open the question of efficacy against variants). Also acknowledged T cell response was decreased by Day 85 and illustrated the same in Figure 3. So in April 2021, there was evidence of waning efficacy within three months of getting a shot.
3/13/2022 19:04:04	FDA-CBER-2021-5683-0002499		119	4 on the page	Study Protocol	Impact of COVID infection on the persistence of vaccine induced response was not measured because participants were not routinely monitored for infection.
3/13/2022 20:52:12	FDA-CBER-2021-5683-0002501		121	2.5.4.4.1.2	Efficacy	In April 2021, Pfizer was already acknowledging a booster would be needed. ". . . A booster does is necessary to increase functional antibody titers."
3/13/2022 21:22:32	FDA-CBER-5683-0002530		150	2.5.5.3.3	Adverse Effects - Other	Adverse events were higher among younger people than older
3/13/2022 21:26:29	125742_S1_M2_24_nonclinical-overview		16	2.4.3.3. Absorption	Adverse Effects - Other	They say no absorption studies conducted because the jab is in the muscle. If 60% goes to the liver and is later expelled through feces, then it is moving in parts of the digestive tract that conduct absorption.
3/13/2022 21:31:00	FDA-CBER-5683-00025		152-153	2.5.5.4.2.2	Adverse Effects - Other	Adverse events listed, higher among younger participants than older
3/13/2022 21:49:44	125742_S1_M2_24_nonclinical-overview		20	2 and 2.4.3.6. Excretion	Study Protocol	They say no excretion studies were done because proteins are "expected" to be degraded like others. Then in 2.4.3.6. they say they found none of one and 50% of another and no need to study because prior section "expected" - (assumption)
3/13/2022 21:59:30	125742_S1_M2_24_nonclinical-overview		18	1	Adverse Effects - Other	"Outside the injection site, low levels...detected in MOST TISSUES, ...PLASMA...1-4 hours post dose.
3/14/2022 1:53:15	125742_S1_M2_24_nonclinical-overview		22	2.4.4-1. (last)	Study Protocol	The last paragraph and first of next page(23) suggest that there were problems with V8 and V9 but only V9 reversed- the variant submitted for approval.
3/14/2022 2:36:08	125742_S1_M2_24_nonclinical-overview		29	2.4.4.4. Genotoxicity	Study Protocol	In this paragraph and the next (2.4.4.5 Carcinogenicity) - They say toxicity isn't "expected" - So no studies are planned. don't look = won't find
3/14/2022 2:57:28	125742_S1_M2_24_nonclinical-overview		31	2.4.4.9. Target Organ Toxicity	Adverse Effects - Other	This paragraph says some problems were "partially reversed" and "reversible" - sounds meaningless. It also says elevated levels in one study were not in another study so they "were not associated" - Are they saying they picked the answer they liked best?
3/14/2022 3:39:43	125742_S1_M2_24_nonclinical-overview		15	2.4.3.1. Brief Summary	Study Protocol	"...as a surrogate reporter." Was luciferase used WITH a complete vaccine, or was it used IN PLACE of parts of the vaccine? If it replaced a part, then it could only show where it MIGHT go - Not that missing parts actions, reactions, and effects on its way.
3/14/2022 10:17:57	CFT for Site 1128 FDA-CBER-2021-5683-0010385		103-175	Multiple	Fatality	Thea Sonnier is part of Texas Case 1:21-cv-00008-MJT for false claims and has witnesses that observed Sonnier changing quality control document relating to blood pressure.

3/14/2022 12:50:27	STN-125742_0_0	36	2.7.4.1.2.2.2.	Other	Re: Naomi's appearance on Warroom and multiple dosages. The phase 1 clinical study tested at 10, 20, 30 and 100 ug dosage. The 100 ug subjects were only given 1 jab at that dosage due to adverse events. Their second jab was at 10ug. In the phase 2 trials, only dosages of 30ug are noted. There is a BIG difference between 30 and 100 ug. According to what I have read so far, phase 2 only tested at 30ug.
3/14/2022 13:37:25	STN-125 742_0_0-Section-2.7.4-Summary-Clinical-Safety.pdf	page 49	paragraph 1	Adverse Effects - Other	on pages 22 and 23 table 3/phase 1 and table 3 phase 2/3 under the study safety profile of the third dose new and/or worsening joint and muscle pain are considered systemic events. However, the CDC website re the Pfizer vaccine defines serious adverse events as ...life threatening.... or resulted in persistent disability. On page 49 P1 myalgia is reported in the younger group. Given the CDC guidelines this should be characterized as a serious adverse event in this age group as it could be an indication of future serious and permanent muscle damage (caused by the vaccine) that first presents as myalgia and ultimately results in autoimmune anti-HMGCR myopathy. Muscle damage is progressive. It can take years or decades to be diagnosed. A lawsuit was brought against Pfizer in June of 2006 by atty Mark Jay Krum claiming their bestselling drug Lipitor caused lasting debilitating muscle and nerve problems. I have researched this extensively after being diagnosed with this 1 1/2 years ago. In the vaccine study on page 51 Pfizer concludes the vaccine is safe and well tolerated in healthy adults 18-85. The same was said about Lipitor. A March 8,2017 summary by (Johns Hopkins Rheumatology) Erika Darrah indicates among other things that younger patients have more severe disease and worse prognosis. To put a darker face on this an April 16, 2015 Allied Market Research report titled Global Intravenous Immunoglobulin (IVIG) Market-Size Industry Analysis, Trends, Opportunities, Growth and Forecast, 2014-2021, forecasts the IVIG market to grow at a CAGR of 6.8% between 2015 and 2021. IVIG is considered the treatment for this. It is required once a month at a cost of $10-20,000 per month for life. (I am not drawing any conclusions.) On page 51 of the Pfizer report they conclude that BNT162b2 is safe and well tolerated in healthy adults ages 18-85. In 2006 Pfizer referred to Lipitor as among the world's safest drugs. A Dovepress Review titled Statin-Associated Autoimmune Myopathy: Current Perspectives dated March 30,2020 page 1 introduction second paragraph "...given the projected increase of statin use, we expect similarly an exponential rise in even the rarest side effects." One can only imagine this future autoimmune response and need for treatment from the vaccines. That would be for the doctors and lawyers to sort.
3/14/2022 14:11:10	STN 125742_0_0	117	2.7.4.2.4.2.2.2.1.	Fatality	This death, in a vaccinated subject was eliminated from the data because of an unapproved COVID test used. It does not show up in subsequent tables as a death during the trial.
3/14/2022 14:16:55	STN 125742_0_0	160	2.7.4.2.4.2.3.1. Table 9	Fatality	3 vaccinated subjects died between the unblinding and the cut-off date of 3/13/21. These would not be included in the postvaccine data.
3/14/2022 14:23:17	STN-125742_0_0	171	Table 12	Adverse Effects - Other	The number of SAE (Serious Adverse Events) is increasing during the 2-6 month follow-up period.
3/14/2022 14:33:09	2.7.3 Summary of Clinical Effacacy. FDA-CBER-2021-5683-0002731	17	3	Adverse Effects - Other	This is in regards to Dr. Wolf's AMA document findings on March 14, 2022 about the dosages of different lot numbers being different. Some of these doses were 100 micrograms. I noticed for the efficacy trials for BNT162b1 that the IRC recommended that a second dose of 100 micrograms not be administered due to reactogenicity after the first dose. I realize the trials were on 30 micrograms of BNT162B2, but I thought it may be significant in some way if the two vaccines were likely similar. For example they knew 100 micrograms was not safe and administered it anyway to the public.
3/14/2022 17:43:02	Document from AMA related to vax codes/dosage differences	pages 1 and 2 of document	https://www.ama-assn.org/find-covid-19-vaccine-codes	Other	CPT Codes related to 2nd paragraph of codes Naomi mentioned on War Room. These codes can be sorted by dosage in the left column. Clear evidence that these codes are demonstrating dosing differences from 3mcg, 10mcg and 50mcg for Pfizer.
3/14/2022 19:48:44	https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	10	Notation below Table on Anaphylaxis	Adverse Effects - Other	day they were vaccinated. Although these patients experienced adverse events (9) that are potential symptoms of anaphylaxis, they all had serious underlying medical conditions, and one individual appeared to also have COVID-19 pneumonia, that likely contributed to their death." I want to link this with information given by Pfizer about the Study Eligibility Criteria. Pfizer explains away same day deaths like this stating this is due to their serious underlying medical conditions. However, it is important to note when reviewing the following documents which includes the study eligibility criteria: https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.5-Clinical-Overview.pdf (Page 21) https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy.pdf (page 18) There is clear documentation of the study eligibility criteria for phase 2/3 of trial. Documentation states "Inclusion criteria allowed for preexisting stable disease defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks prior to enrollment. Individuals with medical conditions considered to possibly confound evaluation of vaccine safety or immunogenicity were excluded." I am tying this back to dismissals of deaths noted by Pfizer (the 4 same day deaths listed above) and also the dismissal of other adverse events throughout. This vaccine was clearly pushed out to and in many cases mandated only a population that would be considered "unstable" disease process not a "preexisting stable disease." I could not find that the trials ever included persons that would be deemed as "unstable" preexisting disease (unless it is included elsewhere?). Is this normal in a trial like this that was planned to be pushed out to the entire population? Many Americans exist in the "unstable" disease process based on Pfizer's definition. This could greatly impact the reported adverse events and efficacy reported pre to post emergency authorization. If Pfizer only included a mostly healthy population (stable preexisting disease being no change in 6 weeks prior to administration of trial/vaccine) how can they then blame same days deaths on a person's preexisting condition?
3/14/2022 20:46:21	5.3.6-postmarketing-experience.pdf	7	Row 9 in table	Data Discrepancy	The total number of fatalities is 1223. I searched on the term "fatality" and counted the total number per condition throughout the document. There are 586 fatalities accounted for (including cardiovascular, renal, stroke, medication error, etc.). Where are the other 637 fatal events documented?
3/14/2022 22:53:18	STN-125742_0_0-Section-2.5-Clinical-Overview.pdf	160	2.5.5.5.1.2. Disposition	Study Protocol	In this study the: Number of subjects Originally randomized to placebo 20,948 After un-blinding the numbers below Received Dose 3 (first dose of BNT162b2 [30 µg]) 19612 (88.8) Received Dose 4 (second dose of BNT162b2 [30 µg]) 15986 (72.4) I couldn't find the dates when the vaccine was administered to the placebo group and don't know if it is standard or good practice to give a vaccine being tested the placebo group
3/15/2022 0:40:19	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy	13	5	Other	Studies BNT162-01 and C4591001 included subjects as young as 12.
3/15/2022 0:41:34	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy	16	2	Adverse Effects - Other	Second paragraph after bullets. Note re. "tolerability profile" issues at 60 micrograms of BNT162b1 that precluded a second dose
3/15/2022 0:42:56	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy	16	4	Study Protocol	States immunity was checked up to 162 days after second dose. Were adverse effects also checked?
3/15/2022 0:44:16	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy	17	5	Adverse Effects - Other	Second dose of BNT162b1 at 100 mcg not administered due to "reactogenicity." Another "tolerability profile" issue?
3/15/2022 0:45:16	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy	17	6	Study Protocol	Immunogenicity evaluated as far as 24 months after second dose. Were adverse effects also checked?
3/15/2022 0:46:15	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy	18	2	Study Protocol	Participants were a mixture of people infected and not infected with Covid. ???

3/15/2022 0:47:10	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy	20	6	Study Protocol	"Only first occurrences of COVID-19... were included in the analyses." Does this bypass the more severe adverse effects from the vaccine on those who've already have COVID?

3/15/2022 6:07:48	https://phmpt.org/wp-content/uploads/2021/11/BATES-92_adc19ef-ve-cov-7pd2-wo-eval-sas.txt	1	Second group of text string below three lines of ****	Other	The following string of code is included in the second grouping on page 1:
					
					proc datasets library=WORK kill nolist
					nodetails;
					quit;
					
					Definition of “kill” pursuant to Base SAS(R) 9.2 Procedures Guide:
					KILL deletes all SAS files in the SAS
					library that are available for processing.
					The MEMTYPE= option subsets the
					member types that the statement
					deletes.
					
					The following example deletes all the
					data files in the WORK library:
					
					proc datasets lib=work kill
					memtype=data;
					run;
					quit;
					CAUTION:
					The KILL option deletes the SAS
					files immediately after you submit
					the statement. [cautionend]
					(Base SAS(R) 9.2 Procedures Guide, https://support.sas.com/documentation/cdl/en/proc/61895/HTML/default/viewer.htm#a000247753.htm)
					
					Full code grouping with KILL prior to “run” command;(Located on page 1 of referenced doc, https://phmpt.org/wp-content/uploads/2021/11/BATES-92_adc19ef-ve-cov-7pd2-wo-eval-sas.txt)
					Full code grouping with KILL prior to “run” command;
					
					proc datasets library=WORK kill nolist nodetails;
					quit;
					
					%let prot=/Volumes/app/cdars/prod/sites/cdars4/prjC459/nda2_unblinded_esub/bla_esub_adam/saseng/cdisc3_0;

3/15/2022 7:16:05	125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf	1313	8.3.1.1	Study Protocol	It states that "all report SAE's must be reported to Pfizer "Safety." My question is, do we know this has happened and are there documents backing up that any SAE's were, in fact reported?
3/15/2022 10:59:08	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	340 through 342	Table 36 & Table 37 -- Country	Other	Phase 2/3 study was conducted in 6 countries. After unblinding the participants, ** NONE ** of the participants who received the vaccine were from Germany, South Africa or Turkey. Granted, these study groups were small, but a truly randomized trial would have seen at least a few of these participants vaccinated. ??
3/15/2022 17:30:41	FDA-CBER-2021-5683-0013897	Page 4 and page 5	Page 4 paragraph 2, page 5 paragraph 1 below fig. 2.6.4-1.	Study Protocol	Pharmacokinetic animal study (mice and rats) of novel lipid excipients used in the Pfizer shots indicates intramuscular injection of mice and rats led to bio distribution to the liver at about 6 hours after injection. Up to 18% of the administered dose was found in the liver. I believe these lipid nano particle formulations are the protection/carriers for the spike proteins. We were told this remained in the shoulder muscle. I do not know when these animal studies were done. Page 5 below the graph states that no absorption studies were conducted for BNT162b2 as administration is intramuscular and generally not considered necessary….etc. Yet they knew that the LNP moved to the liver of mice and rats with intramuscular injection. Also, is polyethylene glycol itself an issue (toxic)??
3/15/2022 17:49:49	FDA-CBER-2021-5683-0013902	6	2 and 3	Study Protocol	“Bio distribution of the antigen encoded by the RNA component of BNT162b2 is expected to be dependent on LNP distribution” LNP distribution is to the liver (up to 18%), spleen (less than or equal to 1%), adrenal glands (less than or equal to .11%) and ovaries (less than or equal to .095%). When did they have this information from these animal studies? Is this a real document? I found it online but did not find this data in your listed documents.
3/15/2022 23:31:58	#19 - STN 125742_0_0 Section 2.5 Clinical Overview.pdf - “Clinical Overview”	203	Table 59	Adverse Effects - Other	Although Pfizer did not indicate that they identified a signal, the number of cancer cases (21 total of the following: skin (9), ovarian (1), prostate (3), testicular (1), colon (2), gastric (1), biliary (1), adrenal (1), thyroid (1), and unspecified CNS (1) appears to be unusual to me. These counts are among the BNT162bb2 30 mcg group, from Dose 1 to 1 Month after Dose 2. There are some additional cases that do not indicate whether the events were cancerous therefore, this number could be larger.
3/16/2022 0:19:16	#19 - STN 125742_0_0 Section 2.5 Clinical Overview.pdf - “Clinical Overview”	181	5	Adverse Effects - Other	The frequency of lymphadenopathy in the BNT162b2 group (0.4%) was higher than the placebo group (0.0%). The lymphadenopathy group was assessed by the Investigators as "related to study intervention". Using the CIOMS frequency categories, Lymphadenopathy was assigned the Common frequency (>or = 1% and < 10%) . Although this is a sign and not an actual disease, it sometimes can be a sign of infection or cancer. It is one of the most frequently reported adverse events in the study
3/16/2022 1:37:10	#19 - STN 125742_0_0 Section 2.5 Clinical Overview.pdf - “Clinical Overview”	153	Last paragraph	Adverse Effects - Other	A subject in the BNT162b2 "younger age group" who reported an SAE (Serious Adverse Event) of Gastric adenocarcinoma was discontinued from the study on Day 23, after dose 1 of BNT162b2. Investigator assessed the event as not related to study intervention.

3/16/2022 3:03:53	#19 - STN 125742_0_0 Section 2.5 Clinical Overview.pdf - "Clinical Overview"	159	Table 54	Fatality	This table (54) reports Deaths and Pregnancies among subjects who were discontinued or withdrawn from the study. There were 3 Deaths among the BNT162b2 group and 4 among the placebo group in the "Discontinued from original blinded placebo-controlled vaccination period". Under this same group there were 6 pregnancies among the BNT162b2 group and 6 pregnancies under the placebo group. Under the "Withdrawn after 1 month post Dose 2 visit there were 16 Deaths among the BNT162b2 group and 15 Deaths among the placebo group. Under this same group there was only 1 pregnancy in the placebo group Under the "Open label period" there were 3 Deaths among the BNT162b2 group and 2 Deaths among the placebo group. Under this same group there were 4 Pregnancies under the placebo group Under the Completed 1 month post-Dose 4 visit, there 2 Deaths in the placebo group and no pregnancies This table is vague and lacks clarity. There may be some overlap in the patients/groups, but I am unsure. Sometimes subjects are lost to follow-up as they do not return to the study center or lose touch with Investigator however, some of these patients received study vaccination and their Deaths could be due to the vaccine. I don't agree to withdrawal them from the study. I would count them in the study as a valid patient (they should have all the patients demographics, medical history etc because they are in the clinical trial) with an outcome of death, cause unknown. To be transparent they could be coded to the term Death, and in their Case Report Forms (CRFs) document cause of death unknown. In the "Withdrawn after 1 month post Dose 2 visit there were 15 Deaths alone! Pregnancies are not adverse events unless the subject experiences an adverse event while they are pregnant. However, Drug companies are required to follow the pregnant patient to her delivery to determine if the baby was born healthy or had congenital or other issue. They usually obtain the due date and contact the patient around her due to obtain the outcome of the pregnancy.
3/16/2022 8:24:06	BNT162b2 2.7.4 Summary of Clinical Safety	p.119.	Paragraph 5.	Adverse Effects - Other	Deafness, Deafness unilateral, Deafness neurosensory, Hypoacusis, and Sudden hearing loss
3/16/2022 8:29:53	BNT162b2 2.7.4 Summary of Clinical Safety	p.272	Paragraph 7.	Adverse Effects - Other	There were 14 cases of appendicitis and 1 case of appendicitis perforated in the BNT162b2 group, and 9 cases of appendicitis, 2 cases of complicated appendicitis, and 1 appendicitis perforated in the placebo group
3/16/2022 8:39:21	BNT162b2 2.7.4 Summary of Clinical Safety	p. 279	Paragraph 7.	Adverse Effects - Other	Optic neuritis. Optic neuritis was observed in 2 participants in the BNT162b2 group and none in the placebo group; 1 case occurring in a male participant and 1 case occurring in a female participant. Both participants were in the younger age group.
3/16/2022 8:53:10	BNT162b2 2.7.4 Summary of Clinical Safety	p.172	Paragraph 3.	Adverse Effects - Other	musculoskeletal and connective tissue disorders (905 [7.5%])
3/16/2022 9:00:21	BNT162b2 2.7.4 Summary of Clinical Safety	p.216	Last paragraph	Fatality	A Grade 4 life-threatening SAE of cardio-respiratory arrest was reported in one participant in the older age group. The event occurred 25 days after Dose 3 and the outcome was fatal.
3/16/2022 15:53:18	STN-125742_0_0-Section-2.5-Clinical-Overview.	pg 254	2.5.5.5.3.5.2. Analysis of Adverse Events Adverse Events by System Organ Class and Preferred Term	Adverse Effects - Other	DVT and PE reported - participant with multiple high risk comorbidities- resolved within 3 days? deemed not related? One participant with a past medical history significant for deep vein thrombosis, hypertension, pulmonary arterial hypertension, right ventricular enlargement, hypercholesteremia, atherosclerosis and bilateral peripheral neuropathy reported a grade 2 SAE of deep vein thrombosis (lower right extremity) and grade 1 SAE of pulmonary embolism, which both occurred 2 days after Dose 3, had both resolved with a duration of 3 days; both SAEs were assessed by the investigator as not related to the study intervention.
3/16/2022 16:10:49	STN-125742_0_0-Section-2.7.4-	182 and 190	Table 13	Data Discrepancy	On page 182, they report 22 exposures during pregnancy. In the same table, page 190, they report 2 spontaneous abortions and 1 exposure during pregnancy. If 22 exposures resulted in 2 spontaneous abortions, the risk is 9%. There is no explanation for the difference in the number of exposures during pregnancy.
3/16/2022 18:35:49	BNT162b2 Module 2.4. Nonclinical Overview 2.4 NONCLINICAL OVERVIEW	14	2.4.2.2., 2.4.2.3, 2.4.2.4	Study Protocol	No secondary pharmacodynamics studies were conducted with BNT162b2. No safety pharmacology studies were conducted with BNT162b2 ..... Nonclinical studies evaluating pharmacodynamic drug interactions with BNT162b2 were not conducted.
3/16/2022 20:27:39	FDA-CBER-2021-5683-0002916	20	Table	Study Protocol	"The screened set is defined as all subjects who signed informed consent" Interested to know what was written in the consent subjects signed and if all consents were equal?
3/16/2022 20:32:25	FDA-CBER-2021-5683-0002933	37-38	Para 8 - 2.7.4.1.2.3.2. Exposure (Phase 2, Study C4591001)	Adverse Effects - Other	The participant in the BNT162b2 younger group was withdrawn from the study 23 days after receiving Dose 1 (after Dose 1 but before Dose 2 because of an SAE of gastric adenocarcinoma (Section 2.7.4.2.3.4.2).
3/16/2022 20:34:41	https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-oversight-committees.pdf	pg. 6, 29-30	pg. 6 (para 2.2), pg. 29 (para. 3-6). pg. 30 (para. 2-3)	Other	pgs 29-30. It seemed strange that 6 Chinese individuals with Shanghai, China addresses were listed as "statistical programming" personnel on the External Data Monitoring Committee. I did not recall China study locations or China involvement with the vaccine studies, so it appeared quite unusual. Cross-reference to other documents may enlighten why these 6 persons were receiving all of the study data. Or, should there ever be litigation, that may be an area of inquiry for depositions. on pg. 6 provides that "members" of the External Data Monitoring committee will sign confidentiality agreements. [:No communication, either written or verbal, concerning the deliberations or recommendations of the committee will be made outside of the committee without approval of Pfizer, except as provided for in this charter (refer to Section 6 Communication Plan Between Pfizer and the Committee).''] It is unclear whether the Chinese statistical programming personnel are "members" of the committee but it seemed as though they were. If that is the case, it would be difficult to obtain information from them.
3/16/2022 20:36:42	FDA-CBER-2021-5683-0003092	196-197	1st paragraph	Fatality	The IR for discontinuations because of related AEs was 0.5 per 100 PY, and 2 participants died (Section 2.7.4.2.4.3.1).
3/16/2022 20:49:40	FDA-CBER-2021-5683-0003116	220	2nd paragraph	Fatality	"...[2] deaths were reported as of the cutoff date, and none of these deaths were assessed by the investigator as related to study intervention:" Unsure of importance, since narrative does state investigators did not relate deaths to vaccine study.
3/16/2022 20:53:30	https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-oversight-committees.pdf	pg. 14-15	5.1.3	Adverse Effects - Other	The text states that Pfizer recognized that after the vaccine there could be an "exaggerated adaptive immune response and containment of viral replication in some instances is associated with a "cytokine storm" that accompanies clinical deterioration, patient profiles of all nucleic acid amplification test (NAAT)-confirmed cases will be reviewed contemporaneously by the committee during Phase 1 of the study." Further down the narrative paragraphs, it comments about severe Covid 19 illness: "Indicators of severity may include accelerated deterioration, need for hospitalization, need for ventilation, death. the date of the approval of this document is 6 Nov 2020, recorded vertically in the left margin. The document seems to concede that Pfizer had knowledge of or some expectation of the possibility of very severe adaptive immune response (cytokine storm). Also, they knew of the possibility that there could be accelerated deterioration in which a participant ay need hospitalization, ventilation and may even suffer death. (is this akin to knowledge of a "leaky vaccine"? The text raises the question of whether or not that was revealed to the public as possible side effects (i.e. were participants given informed consent?). If there is data of such severe events, it also raises the question of whether Pfizer legitimately met the approval criteria.
3/16/2022 20:54:47	FDA-CBER-2021-5683-0003137	240-241	last paragraph and 1st paragraph	Fatality	SAE resulting in death
3/16/2022 21:02:25	FDA-CBER-2021-5683-0002972	76	AE Table	Fatality	3 deaths reported in this table from individuals who received vaccine
3/16/2022 21:08:07	FDA-CBER-2021-5683-0003012	116	Table 7	Fatality	15 deaths - received BNT162b2 (30 µg) But investigators did not assess deaths related to investigational product. What were the causes of death??

3/16/2022 21:12:39	FDA-CBER-2021-5683-0003025	129	Table 8 - Sudden cardiac death	Fatality	
3/16/2022 21:16:51	FDA-CBER-2021-5683-0003056	160	Table 9	Fatality	3 Deaths - investigators do not relate to investigational product...
3/16/2022 21:18:47	FDA-CBER-2021-5683-0003094	198	Table 14	Fatality	2 Deaths - investigators do not relate to investigational product...
3/16/2022 21:20:26	FDA-CBER-2021-5683-0003128	232	Table 18	Fatality	1 - Sudden cardiac death
3/16/2022 21:23:43	FDA-CBER-2021-5683-0003153	257	1st bullet	Fatality	1 death
3/16/2022 21:26:08	FDA-CBER-2021-5683-0003157	262	2nd bullet	Fatality	1 sudden cardiac death
3/16/2022 21:27:22	FDA-CBER-2021-5683-0003160	264	Table 23	Fatality	1 Sudden cardiac death
3/16/2022 21:34:43	FDA-CBER-2021-5683-0003182	333	Table 31	Fatality	Multiple deaths reported
3/17/2022 11:54:15	BNT 162b2 2.7.4 summary of clinical study	29	Key exclusion criteria	Other	They mentioned use of meds used to prevent Covid-19 excluded some from being in study but I thought there were no meds to prevent Covid-19?
3/17/2022 14:10:20	The Pfizer Document	7	chart	Fatality	On page 7, it states that between Dec 2020 and Feb 2021 they received 42,086 complaints with 158,893 adverse events. 1,223 of these reported complaints were fatal. This represents 2.9% of the total people reported.
3/17/2022 14:13:52	Pfizer Report	12	whole page	Adverse Effects - Reproductive Issues	On page 12 they mention 270 pregnancies .. the majority (238) there was no outcome reported. But of the ones that were reported, 85% resulted in miscarriage, spontaneous abortion, or premature birth resulting in death. Strange that the 238 had no outcomes.. given that 85% were horrific, they may have buried the other 238 events reported.
3/17/2022 14:16:09	Pfizer Document	16	Whole page	Adverse Effects - mYocarditis	On page 16 it mentions that 3.3% of the 42,086 reports resulted in cardiovascular issues
3/17/2022 21:08:13	I'm sorry, I am confused at what you need. My name starts with an M and so I am reviewing: BNT162b2 2.7.4 Summary of Clinical Safety	25	Phase 1 - First two paragraphs but specifically the second paragraph that starts: The Internal Review Commitrr (IRC) recommended that a second dose....and last paragraph about testing a 3rd shot (booster)	Study Protocol	It states that the "second dose" of BNT162b1 at 100ug NOT be administered to the younger age group due to reactogenicity. And that the second dose should be 10ug. ----- I did not receive the vaccine so I had to do some online research. It says that the second and first dose is the same. So in real life, if you got 100ug and was in the younger age group you would get 100ug at the second dose?? In last paragraph the "third" shot could also be different. They would give you 30ug but you could have gotten 10, 20, 30 ug at Dose 1 and 2.
3/18/2022 9:03:55	STN-125742_0_0-Section-2.5-Clinical-Overview.pdf	26	2.5.2.1. Formulation Development	Other	Pfizer claims: "The BNT162b2 vaccine is provided in a multi-dose vial that contains a frozen concentrated solution that is preservative-free and must be thawed and diluted prior to administration. The BNT162b2 concentrate must be diluted in its original vial using 0.9% Sodium Chloride Injection, USP, resulting in an off-white suspension. The 0.9% Sodium Chloride Injection, USP is not packaged with the vaccine and must be sourced separately." Questions: 1) In practice, are the Pfizer vaccines really "preservative-free"? 2) In practice, are the Pfizer vaccines really diluted with 0.9% sodium chloride only?
3/18/2022 9:12:23	STN-125742_0_0-Section-2.5-Clinical-Overview.pdf	27	2.5.2.2. Biopharmaceutical Studies	Study Protocol	Pfizer states: "Bioavailability and bioequivalence assessments are not relevant to vaccine antigenicity and have not been measured." Question: Are bioavailability and bioequivalence assessments really irrelevant?
3/18/2022 9:17:46	STN-125742_0_0-Section-2.5-Clinical-Overview.pdf	27	2.5.3. Overview of Clinical Pharmacology	Study Protocol	Pfizer states: "Pharmacokinetic studies are not usually required for vaccines. Measurement of the plasma concentration of the vaccine over time is not feasible." Questions: 1) Are pharmacokinetic studies really not required? 2) Is plasma concentration of the vaccine over time really infeasible? 3) What findings would pharmacokinetic studies and vaccine plasma concentrations reveal?
3/18/2022 9:47:44	STN-125742_0_0-Section-2.5-Clinical-Overview.pdf	39	2.5.4.3.1.2. Primary Efficacy – Interim Analysis	Other	Pfizer claims: "VE of BNT162b2 was 95.5% with a >99.99% posterior probability for the true VE being >30% conditioning on available data, to overwhelmingly meet the prespecified interim analysis success criterion (>99.5%)." Questions: 1) Are there any other vaccines currently on the market with 95.5% VE? 2) How realistic are claims of 95.5% VE? 3) Is Pfizer's 95.5% VE true? 4) If Pfizer's 95.5% VE claims are not true, does this constitute fraud?
3/18/2022 13:07:51	STN-125742_0_0-Section-2.5-Clinical-Overview.pdf	303 to 304	7	Adverse Effects - Other	Hypersensitivity to the vaccine in a participant with history of severe allergies: During the open-label follow-up period, 1 participant who received BNT162b2 as Dose 3 (after originally being randomized to placebo and unblinded to receive BNT162b2) had an Severe Adverse Event of anaphylactoid reaction, which was assessed as related to study intervention. She was a female adolescent with a medical history significant for multiple allergies since infancy. Two days after Dose 3, she experienced hives on the left arm (deltoid) and self-administered an epinephrine pen 24 minutes later (given the history of anaphylaxis tomultiple allergens). Six minutes after injection, she experienced shortness of breath. Hives and shortness of breath resolved within 10 and 30 minutes, respectively, of epinephrine treatment. The participant did not seek additional medical attention. As a result of the anaphylactoid reaction, the participant was permanently withdrawn from the study. This adolescent had a history of severe allergies and was included in the study. After this adverse event she was removed from the study due to the adverse event. It seems logical that the research and science outcome of this would be to inform parents of children with a history of severe allergies to not take a Covid19 vaccine, or to study further, and share this adverse event with the public. I have an adolesent niece who has had severe food and other allergies since birth, and she received a Covid19 vaccine. Her mother might have used the above information from Pfizer to determine to not vaccinate her daughter. Furthermore, if there is a risk of the Covid19 vaccine triggering an episode, has this information been shared at pop up vaccine clinics and do those clinics have an epipen ready on site? This is extremely important because given this Severe Adverse Event to this child, potentially every child with a history of severe allergies is put at risk of death upon vaccination, either as a result of the vaccine adverse reaction or as a result of not having access to an Epipen at the place and time the child is administered the vaccine.

3/18/2022 17:12:02	#43 - 125742_S1_M2_24_nonclinical-overview.pdf - "NON CLINICAL OVERVIEW	Page 6 Section 2.4.3	One	Study Protocol	"The dose selected for BNT162b2 ... is 30 micrograms administration IM as two doses given 21 days apart." As explained by Ronald Kostoff in an excellent December 8, 2021, Trial Site News article, "COVID-19 'Vaccines': The Wrong Bomb Over the Wrong Target at the Wrong Time": "An effective vaccine would focus on cellular immunity in the respiratory and intestinal tract, in which secretory IgA is produced by your lymphocytes that are located directly underneath the mucous membranes that line the respiratory and intestinal tract. The antibodies produced by these lymphocytes are ejected through and to the surface of the linings. These antibodies are thus on site to meet air-borne viruses and they may be able to prevent viral binding and infection of the cells. Unfortunately, the main inoculants used presently for COVID-19 focus on antibodies (IgG and circulating IgA) that occur in the bloodstream. These antibodies protect the internal organs of the body from infectious agents that try to spread via the bloodstream." When you are injected with the COVID jab, your body will only induce IgG and circulating IgA — not secretory IgA, and these types of antibodies do not effectively protect your mucous membranes from SARS-CoV-2 infection. So, as noted by Kostoff, the breakthrough infections we're now seeing "confirm the fundamental design flaws" of this gene transfer technology. "A natural infection with SARS-CoV-2 (coronavirus) will in most individuals remain localized to the respiratory tract," Kostoff writes. "The vaccines used presently cause cells deep inside our body to express the viral spike protein, which they were never meant to do by nature. Any cell which expresses this foreign antigen on its surface will come under attack by the immune system, which will involve both IgG antibodies and cytotoxic T-lymphocytes. This may occur in any organ, but the damage will be most severe in vital organs. We are seeing now that the heart is affected in many young people, leading to myocarditis or even sudden cardiac arrest and death. In other words, we are dropping the wrong bomb on the wrong target at the wrong time!" In the end, your body will essentially believe that your innate immune system has failed, which means it must bring in the backup cavalry. In essence, your body is now overreacting to something that isn't true. You're not actually infected with a virus and your innate immune system has not failed, but your body is forced to respond as if both are true.
3/18/2022 18:04:22	#43 - 125742_S1_M2_24_nonclinical-overview.pdf - "NON CLINICAL OVERVIEW	Page 14 Section 2.4.2.3 Safety Pharmacology	One	Study Protocol	"No safety pharmacology studies were conducted with BNT162b2 as they are not considered necessary for the development of vaccines according to the WHO guidelines (WHO, 2005)." "Worse Than the Disease: Reviewing Some Possible Unintended Consequences of mRNA Vaccines Against COVID-19," published in the International Journal of Vaccine Theory, Practice and Research by Stephanie Seneff in collaboration with Dr. Greg Nigh, is one of the best, most comprehensive descriptions of the many possible unintended consequences of the mRNA gene transfer technologies incorrectly referred to as "COVID vaccines. As noted in her paper, many factors that lacked precedent were being implemented at breakneck speed in its development and administration. Yet Pizer determined that no safety pharmacology studies were necessary? Stephanie writes: The reason we're seeing all these problems from the COVID shots is because they program your cells to continuously produce SARS-CoV-2 spike protein, which we now know is the most dangerous part of the virus. Many experts noted this from the start, wondering what the vaccine developers could possibly be thinking, selecting this as the antigen for their shots. While the mRNA injections can cause harm in many different ways, one basic problem is that they can overstimulate your immune system to the point of failure. In summary, as your cells start producing the viral spike proteins, your immune cells rally to mop up the proteins and dump them into your lymphatic system. (This is why many report swollen lymph nodes under the arms.) The antibody response is part of your humoral immunity. You also have cellular immunity, which is part of your innate immune system. Your innate immune system is very powerful. If you're healthy, it can clear viruses without ever producing a single antibody. Antibodies are actually a second-tier effect when your innate immune system fails. The problem is that your innate immune system will not be activated and likely will fail to protect you if you get a COVID-19 shot, because it's bypassing all of the areas where your innate immune system would be brought to bear. Normally you breathe the virus in and stimulate the production secretory IgA antibodies that protect your respiratory system. When you bypass that route of exposure with a jab in the arm, no secretory IgA antibodies are produced, leaving you susceptible to the infection. Maybe inhalers are needed to prevent SARS-CoV-2. Safety, safety, safety is the most important thing!
3/18/2022 19:16:29	#43 - 125742_S1_M2_24_nonclinical-overview.pdf - "NON CLINICAL OVERVIEW	Pages 22-23 Section 2.4.4.1	Paragraph one (under Table 2.4.4.1)	Adverse Effects - Other	Througout the Toxicity Testing Phases, the recovery phase for all changes in clinical pathology parameters was a mere three weeks which seems insufficient. I understand the researchers were under incredible pressure with Operation Warp Speed (OWS) to produce a vaccine, but so much was at stake Seems reckless. In her article, Worse Than the Disease? Reviewing Some Possible Unintended Consequences of the mRNA Vaccines Against COVID-19, Stephanie Seneff writes: "We still don't know how long the effects last. Manufacturers initially guessed the synthetic RNA might survive in the human body for about six months. A more recent investigation found the spike protein persisted in recovered COVID patients for 15 months.This raises the suspicion that the synthetic and more persistent mRNA in the COVID shots may trigger spike protein production for at least as long, and probably longer. What's more, the number of spike proteins produced by the shots is far greater than what you experience in natural infection." As explained by Dr. Peter McCullough, this means that after your first shot, your body will produce spike protein for at least 15 months. But, when you get shot No. 2 a few weeks later, that shot will cause spike protein production to go on for 15 months or longer. With shot No. 3 six months after that, you produce spike protein for yet another 15 months. With regular boosters, you may never rid your body of the spike protein. All the while, it's wreaking havoc with your biology. McCullough likens it to "a permanent install of an inflammatory protein in the human body," and inflammation is at the heart of most if not all chronic diseases. There's simply no possible way for these gene transfer shots to improve public health. They're going to decimate it. Personally, I think we should abort usage of these vaccines until proper trials have been conducted and we KNOW they're safe. I believe that as my Pfizer vaccine efficacy waned after 5-6 months, I exhibited symptoms of a compromised immune system (i.e. GI issues, dermatologic irritations requiring steroid cream, and finger infection requiring two antibiotics). Lasted four months and resulted in weight loss. The symptoms seem to have resolved, but who knows for how long? I declined the booster shot and instead resigned from my career as a nurse anesthetist where the shots were required. I converted to Ivermectin if/when necessary. For sure, the vaccines should not be mandated and the EUA should be lifted. .
3/19/2022 13:43:33	FDA-CBER-2021-5683-0002715	17	2.7.3.1.1.2.1	Study Protocol	Document say blood for immunogenicity WAS collected at 24 months after dose two.
3/19/2022 14:14:04	5.3.6	13	2 (2nd section)	Other	34 children in study 24 of which had serious events
3/19/2022 15:08:01	5.3.6	16-17	5 and Table 7 Cardiovascular	Other	There were 946 serious Cardiovascular AESI's out of 1403 cases (1441 events) and 136 Deaths - that's 9.69%, yet the conclusion was it does not raise new safety issues. Also, I wasn't clear Pg 16 Paragragh 5, if this study was included in SMSR. It reads, 'This is distinct from safety signal evaluations which are conducted and included, as appropriate, in the Summary Monthly Safety Reports submitted regularly to the FDA and other Health Authorities'
3/19/2022 17:05:19	5.3.6	17	8th bullet point	Data Discrepancy	the numbers don't add up. Also, 136 people died in this section (Covid) as well as 136 in the section above (Cardiovascular) Coincidence? It could be nothing, but at first glance I thought the Cardiovascular deaths were part of the Covid deaths, not in addition to the Covid deaths.
3/19/2022 18:22:37	FDA-CBER-2021-5683-0002381	26	2.5.1.4.	Other	Ethical Considerations states that all studies in the clinical development program were conducted in compliance with the ethical principles originating in or derived from the Declaration of Helsinki and in compliance with all International Council on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines. The Bill and Melinda Gates Foundation was added as Observer on International Council on Harmonisation, also found ties to Good Clinical Practice. Research into the Declaration of Helsinki implies weakening of Nuremburg Code.
3/20/2022 6:27:37	2.7.3 SUMMARY OF CLINICAL EFFICACY	112	Table 26	Other	The background infection rate is 20.1%. At 20.1%, lockdowns are totally ineffective.
3/20/2022 6:33:45	2.7.3 SUMMARY OF CLINICAL EFFICACY	112	Table 26	Data Missing	For Dose 2, 2785 out of 18868 patients did not take the second dose. There is no explanation given.

3/20/2022 6:41:20	2.7.3 SUMMARY OF CLINICAL EFFICACY	pp 144-145	Table 48	Study Protocol	Follow up period 4.4% of background population is infected prior to Dose 1. Lockdowns are ineffective.
3/20/2022 6:46:10	2.7.3 SUMMARY OF CLINICAL EFFICACY	pp 144 to 145	Table 48	Study Protocol	Subjects excluded from Dose 2 or did not receive 2 vaccinations. insufficient explanation. Data unreliable and 21 unblinded. This will impact the vaccine efficacy.
3/20/2022 6:51:35	2.7.3 SUMMARY OF CLINICAL EFFICACY	p141	Table 45	Efficacy	only 181 patients out of 37234 patients were evaluated for vaccine efficacy. As a large number of patients were unblinded or did not receive two doses of vaccine, the efficacy evaluation could be markedly altered by the results of these patients. It suggests tha patients were pre-screened and taken out of the study.
3/20/2022 6:55:35	2.7.3 SUMMARY OF CLINICAL EFFICACY	p134	Table 40	Efficacy	The vaccine does not prevent disease. 9 patients after Dose 2 after day 7 developed disease.
3/20/2022 7:03:21	2.7.3 SUMMARY OF CLINICAL EFFICACY	p18, p 122	2.7.3.1.1.2.2. Phase 2/3 of Study C4591001; Study Population; Table 32	Study Protocol	HIV patients on retroviral were initially excluded and then included. This raises a confounding issue of the synergistic effect of retrovirals.
3/20/2022 7:27:58	2.7.3 SUMMARY OF CLINICAL EFFICACY	18	2.7.3.1.1.2.2. Phase 2/3 of Study C4591001; Vaccine Administration	Study Protocol	The administrator of the vaccine is unblinded. This can easily bias results.
3/20/2022 7:32:40	2.7.3 SUMMARY OF CLINICAL EFFICACY	21	2.7.3.1.2. Methods for the Evaluation of Efficacy – Study C4591001, Phase 2/32.7.3.1.2.2. Surveillance/Definitions /Case Determination for Confirmed COVID-19	Study Protocol	Patients were to self-report if they developed symptoms instead of active surveillance. This means the reporting data is likely to incomplete.
3/20/2022 12:06:38	2.7.3. SUMMARY OF CLINICAL EFFICACY	13	2.7.3.	Study Protocol	caused by the virus, SARS-CoV-2. (V-2) 1. CoV-2 comes from the family of negative-sense RNA viruses which include seven genera only 4 genera contain virus that cause influenza in birds and mammals and humans. They are Alphainfluenzavirus, Betainfluenzavirus, Deltainfluenzavirus, Gammainfluenzavirus Negative sense (single strand) RNA, means a virus can be alive and dead at the same time. Since they created a segmented genome sequencing from the 1918 Avian virus which was not the parent virus. Without the parent virus you will never cure a virus. What genera virus did they use? What delivery vehicle did they use, a living cell, did they use bird or human or cellulose like tomatoes or lettuce currently in research? What is in the second stand of RNA so it energizes and stabilizes the negative sense RNA virus so it can transmit to the DNA for viral replication? What ethnic groups are they targeting? V-2 a missile delivery system used to kill people in WW2 a targeted strike.
3/20/2022 12:47:34	2.7.3 Summary Clinical Efficacy	55	Table 17	Data Missing	No details of regarding severity of COVID occurrence in either vaccine or placebo group c
3/20/2022 13:04:17	2.7.3 Summary of Clinica Efficacy	57	Table 19	Efficacy	VE ratio starts at 87.8% increases to 96.2% after 2nd dose then drops to 83.7. Also note infection spikes in the vaccine group after the 2nd dose. No explanation for these increases late in the study period
3/20/2022 13:14:31	2.7.3 Summary of Clinical Efficacy	59-60	Table 20	Study Protocol	Age Group from 18-64 appears to have largest number of COVID 19 infections for vaccinated group. No analysis as to why this group is prevalent. Recent studies show a large increase in mortality for this group. Further breakdowm of ages may be revealing.
3/20/2022 13:16:45	2.7.3 SUMMARY OF CLINICAL EFFICACY	17, 18, 25, 26-34, and 66-70	6, 3, 2	Study Protocol	How is it possible to do immunogenicity evaluation at 24 months after dose 2 when we have not had it in effect for 24 months? (pg. 17 π 6) What primate studies were used in comparison if this was a newly created vaccine? Were the primate studies for the MRN technology or the vaccine? In previous primate studies with MRN technology all primates died within two years of the studies. (pg. 18 π 3) Noted: That T cell responses were evaluated at later time points for only a small number of participants for the BNT162b at doses 10, 20 and 30 µg. Why only a small number used and who did they determine would be evaluated? (pg. 25 π 2) Interesting note: There were 311 participants in the BNT162b2 group and 60 participants in the placebo group excluded for having important protocol deviations on or prior to 7 days after Dose 2.In the BNT162b2 group, most of these deviations were related to improper administration of the investigational product (263 participants, as compared with 20 participants in the placebo group); among these, most exclusions in the BNT162b2 group were due to dosing/administration errors (105 participants) or administration of investigational product that was deemed not suitable for use by the contractor who distributed the vaccine to study sites (144 participants). Is this exclusion considered high for a study? (pgs. 28 π 6) Footnote in table 24 and 25 - unblinded/C4591001. (pgs. 66-67 ππs 1) Noted throughout pgs. 66-70 the placebo group always had higher reported cases of symptoms of COVID 19 vs. BNT162b2 group. FDA and CDC have different defined COVID-19 protocol definitions, why? The VE rates are different based, so they obviously have different protocol definitions. (pg. 68 π 6 and pg. 69 π 1) VE appears to decrease after 7 days of dose 2 and greater than 4 months after dose 2. (pg. 68 ππs 3, 5, 6) (Study C4591001) VE 87.88% after dose 1 (Study C4591001). (pg. 68 π 4) The comorbidities specified are interesting since the side effects currently being reported effect the heart, lungs, spleen, cancers, blood clotting. (Pg. 69, π7)
3/20/2022 13:28:26	2.7.3 Summary of Clinical Efficacy	59-60	last para. - pg 59	Efficacy	"VE are considerably higher in participants who were positive for N-binding antibody only" Is the vaccine providing extra protection OR are prior infection antibodies? The herd immunity may be at work here.
3/20/2022 13:35:52	STN 125742_0_0 Section 2.7.3 Summary of Clinical Efficacy.pdf	135-143	Pages 135, 137, 138, 140, 142, 143 data	Study Protocol	Surprising large number of co-morbidities in trial with low efficacy in 2 major co-morbidities; short temporal limitation on efficacy with no longitudinal studies prior to EUA submission; unreliably overbroad definition of COVID-19 infection; and unreliable diagnostic technique (the PCR test)

3/20/2022 20:47:47	In Study 20256434, female rats were administered 4 total IM doses of BNT162b2 (V9) 21 and 14 days prior to mating and on GD9 and GD20. Serum samples were collected from females prior to vaccine administration, just prior to mating (M0), at the end of gestation (GD21), and at the end of lactation (LD21) and offspring (fetuses on GD21 and pups on PND21). Sera were analyzed for SARS-CoV-2 neutralizing antibodies. After immunization, SARS-CoV-2 neutralizing titers were detected in all maternal females as well as in their offspring (fetuses and pups). SARS-CoV-2 neutralizing antibody titers were not observed in animals prior to vaccine administration or in saline-administered control animals. CONFIDENTIAL Page 13	Page 13	2.4.2.1.5. Immunogenicity Testing After Weekly Immunization of Rats	Other	BNT162b2 vaccinated rats passed the neutralizing titers and were detected in all maternal females as well as in their offspring (fetuses and pups). meaning they vaccinated the offspring as well in the birth and breastmilk of the female rat.
3/20/2022 21:22:45	#3 - 5.3.6 postmarketing experience.pdf - "Analysis of Adverse Events to end Feb 2021"	multiple	multiple	Other	multiple, please see Word doc
3/20/2022 22:02:53	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy.pdf	17	3	COVID Testing	It appears that during testing that Pfizer recommends that people who were dosed with 100 micrograms of the vaccine were not recommended to receive an additional dose due to the retrogenitcy of the first dose administered. Since there were missing dosage amounts on the Pfizer viles administered, it was possible the public received doses of 100 microgram vaccines and then received the additional vaccines afterwards, which is something that Pfizer is recommending against in their own research model.
3/21/2022 9:23:18	BNT162b2 Study C4591001-Efficacy-Updated Analysis	Pgs 144-152	Table 48-52	Efficacy	Short synopsis
3/21/2022 13:21:31	STN-125742_0_0-Section-2.5-Clinical-Overview.pdf	325 to 326	6	Other	of any such protection is currently unknown." The date of this conclusion appears to be at latest March 13, 2021, which was the end date of updated analysis contained in the document (prior analysis date was November 14, 2020 from what I can see). 2.5.6. Benefits and Risks Conclusions 2.5.6.1. Benefits COVID-19 is a serious and potentially fatal or life-threatening human infection. Based on clinical data to date, it is expected that BNT162b2 (30 µg) will elicit an immune response that is likely to protect against COVID-19. The total duration of any such protection is currently unknown (pg. 325). Simply put, in this document, Pfizer does NOT claim that Pfizer has determined a duration of effectiveness and protection of its Covid19 vaccine based on its vaccine trials. Yet as soon as July 2021, The Washington Post publishes an article assuring the public that the vaccine provides 6 months of protection. The link to The Washington Post article below. The article states that Pfizer's data found the vaccine to provide 6 months of protection, and proceeds to state that Pfizer executives have "predicted" that boosters will be needed by all fully vaccinated persons in 6 months. This duration of protection statement is not what Pfizer wrote in the document, yet this inaccurate statement is contained in The Washington Post article. It was published in other news outlets at the time as well, and it forms the basis upon which the "everybody is going to need a booster" recommendation began. https://www.washingtonpost.com/health/2021/07/28/pfizer-data-shows-vaccine-protection-remains-robust-six-months-after-vaccination-even-company-argues-that-boosters-will-be-needed/ The Washington Post article is only one of many that stated at that time that the vaccine duration of protection lasted 6 months. Since Pfizer wrote that the duration of their vaccine's effectiveness was unknown, that means that the statement that the duration of the vaccine's protection last 6 months was inaccurate. Yet the mainstream press began publishing this information about duration as if it were fact, and Pfizer leadership does not appear to ever have corrected it. From this inaccurate statement about the vaccine protection lasting 6 months many departments of health ran with the idea that a 3rd shot would be needed after 6 months. Pfizer did not know with certainty that their vaccine "waned" after 6 months. It is likely that if that booster recommendation had not been amplified in the press, and if Pfizer had corrected the press outlets, that millions of people might have waited to get a third shot.
3/21/2022 16:07:51	First name begins with M (this is where I grabbed my papers for review. This is under Trial C4591001- Study Population	28 through 32	All of it!	Study Protocol	People who were included in the "Population Study"were: Key inclusions = only extremely healthy people were included - page 28 Key "EXCLUSIONS" = people high blood pressure, diabetes, BMI greater than 30, smokers, asthma, pregnant women, people with autoimmune disorders, residents in long-term facilities, etc!!! Pages 29 an 30. (Weren't these the very people they said should get the vaccine ??? Yet, they did not include them in the study called POPULATION STUDY. Page 31 - Bullet point 1: Physical examination was not required Page 31 - Bullet point 4: The only AE's that were recorded was acute reactions within the first 4 hours for the first 5 participants vaccinated in each Phase 1) - and for the remainder of participants it was only within the first 30 minutes!!!!!! Page 32 - After last bullet point, 1st paragraph, No adverse events of special interest were defined for Study C4591001. Again, look at who did NOT get included in the study!!! ** To note, this study was mentioned on GETTR regarding how many people were in the study. On that note of participants in study. On page 26, 27 (sorry no photo), last paragraph on pg 26 states "first 360 enrolled in the BNT162b2 trial - and then on pg 27, first paragraph it states: It was "planned" for the Phase 2/3 part of the study to comprise of approximately 21,999 vaccine participates. Planned and never executed????
3/21/2022 16:35:03	FDA-CBER-2021-5683-0000065	12	3	Fatality	Pregnancy Outcome
3/21/2022 21:02:20	https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf	2021 and 1007	8.3.1.2 Recording Nonserious AEs and SAEs on the CRF	Study Protocol	On May 27 2020 at 8.3.1.2, Recording Nonserious AEs and SAEs on the CRF, it states, in part, AEs and SAEs will be recorded on the Medical History/Current Medical Conditions section of the CRF, not the AE section of the CRF. A subsequent amendment to the protocol on June 30, 2020 removed the language stating the AEs and SAEs should be recorded on the Medical History/Current Medical Conditions section of the CRF and not the AE section of the CRF. The question is why would a researcher not annotate AEs and SAEs on a participant's Medical History/Current Medical Conditions file. What if the person died while in the program, but adverse reactions or events weren't documented in the person's Medical History/Current Medical Conditions file? Initially, I found no reference for recording such Medical History/Current Medical Conditions events elsewhere in the Protocol...the 8.3.1.2 section does not refer a researcher to a different location for recording any AEs and SAEs in a Medical History/Current Medical Conditions. No history of an event or events in the Medical History/Current Medical Conditions...no blame on vaccine?

3/21/2022 23:40:21	STN 125742_0_0 Section 2.7.3 Summary of Clinical Efficacy.pdf	45-54	table 14	Efficacy	For pages 45-54 Nothing specific, in the sense the numbers are what they present. In table 14, in "preventing " severe COVID with an efficacy of 88.9 %...the true absolute risk reduction is 0.00036 (ie risk of severe covid in placebo was 0.0004- in intervention group of 0.00004) the risk of severe COVID in itself is very small. But this was Pfizer's conclusion "In conclusion, the final efficacy results show that BNT162b2 at 30 µg provided protection against COVID-19 in participants who had no evidence of prior infection with SARS-CoV-2, including across demographic subgroups, with severe cases observed predominantly in the placebo group. "
3/22/2022 4:15:48	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy.pdf	24	1	Data Missing	"The analyses... ≥14 days after Dose 2 were not updated." WHY? Are they saying VE is < 2 weeks?
3/22/2022 4:17:20	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy.pdf	25	2	Data Missing	Later data (Day 43 through Day 184) were analyzed in ways "not specified in the protocol" for "general research purposes." Why weren't they interested in (or documenting?) immunity over time?
3/22/2022 4:18:18	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy.pdf	26	7	Data Missing	Third bullet point. Why wasn't the ≥4-fold rise in cytokine response measured in Study C4591001 after Phase 1?
3/22/2022 16:41:43	https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	16-26	Multiple	Subdivided Data (to make the numbers smaller)	The first time I went thru I only looked at their subsection of neurology aesi. Now I went back and looked again pg 16-26. Things that should have been included in neurological were facial paralysis, strokes -bleeds and clots or embolism to brain, neuropathy and polyneuropathy, if these were all included in neurology the category swells and might even become the most prevalent . Suggests to me that spike proteins cross the blood brain barrier. The encephalopathy cases may not even be counted yet, because there are cases of unknown etiology.
3/22/2022 21:48:27	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	Page Number 14	Second Paragraph	Other	Convoluted statement: C4591001 protocol amendment 10 allowed participants ≥16 years of age who originally received placebo the opportunity to receive BNT162b2 following local or national recommendations, Who exactly were these local and national recommendations from? They destroyed clinical trials control groups based on what? Were these local groups grocery stockers unions (local-national)? Were they teachers unions (local-national)? Were they political groups (local-national)? Were they medical groups (local-national)? Were they the companies performing the trials on behalf of the drug companies? I have been struggling with this for a couple weeks. As a former Paramedic, I have read enough medical information to know when I am being lied to. I will forge forward because I believe America is worth saving.
3/23/2022 0:07:49	#58 - 125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf - "Pfizer protocol double blind study amendment 3/2/21 (2346 pages)"	multiple (59 times), first instance is on page 132	8.11.2.1 and follows 58 more times in various paragraphs	Study Protocol	This key term appears 59 times in this document "For participants who are HIV-positive, record HIV viral load and CD4 count...." Is it normal for a vaccine study to be so concerned with HIV positive participants in their studies to include HIV viral load and CD4 counts? Do other vaccine studies have this requirement? This statement appears 89 times in the document. There are several sources that say the COVID vaccines are laden with materials that could quite possible cause someone to become HIV positive.
3/23/2022 0:18:47	#58 - 125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf - "Pfizer protocol double blind study amendment 3/2/21 (2346 pages)"	Page 77 and 14 other instances that followed	14.2 and various that follow	Study Protocol	This statement appears 15 times in the document: "Human reproductive safety data are not available for BNT162 RNA-based COVID-19 vaccines, but there is no suspicion of human teratogenicity based on the intended mechanism of action of the compound. Therefore, the use of a highly effective method of contraception is required (see Appendix 4)." How did doctors come to the conclusion that this was safe for pregnant people if the study protocol specifically says contraception must be used.
3/23/2022 0:30:55	#58 - 125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf - "Pfizer protocol double blind study amendment 3/2/21 (2346 pages)"	112 and 29 other instances	8.3.5.1 and 29 other instances	Study Protocol	This statement appears 30 times in the document "Pregnant Partner Release of Information....." If this is perfectly safe for pregnant women, why in the world would a pregnant partner release of information be necessary?
3/23/2022 0:41:56	#58 - 125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf - "Pfizer protocol double blind study amendment 3/2/21 (2346 pages)	213	Appendix 4 - all	Study Protocol	This appendix says that men may not donate sperm for 28 days and must agree to be absinent or use a condom during intercourse. Women must agree to abstinence for 28 days or be on approved birth control. Women must not be breastfeeding.
3/23/2022 7:28:16	BNT162b2 Module 2.4 Nonclinical Overview	25	1	Adverse Effects - Other	With fibrinogen being a part of the clotting process, I thought this may explain at least part of the clotting issues that have occurred with vaccination. In the paragraph I am citing, on Day 17 "Fibrinogen was higher in the vaccine-administered group (up to 3.1x controls), consistent with an acute phase response."
3/23/2022 11:49:18	https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf	p. 94	Section 7.2	Other	There should be results reported that document the number of subjects that withdraw or discontinue to capture reasons for declining further participation.
3/23/2022 11:57:47	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy.pdf	104	Bottom 4 paragraphs	Adverse Effects - Other	SAE 23 days post dose 1 - Gastric Adenocarcinoma
3/23/2022 12:10:17	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy.pdf	109 and 110	last paragraph on 109 and underlined on 110	Efficacy	they knew it doesn't work yet continue to mandate and claim its protecting against C19
3/23/2022 12:15:50	125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.	1448 pages of excluded participants !!!!	all 1448 pages	Adverse Effects - Other	participants excluded without explanation why and what happened to them not being able to continue .....most answers is not getting second dose ! WHY?????
3/23/2022 16:43:41	FDA-CBER-2021-5683-0002926	page 30	3	Study Protocol	In the Key exclusion criteria they excluded women who are pregnant or breastfeeding from the study,
3/23/2022 16:51:13	This is a research question	See below	See Below	Other	I am wondering if you and your team have a way of scanning the documents for terms or words. I am very curious if any of the documents recorded the LOT #'s given to the test subjects. It would be illuminating to compare them with the data being compiled byTeam Enigma- at https://howbad.info/
3/23/2022 16:56:28	FDA-CBER-2021-5683-0002915	19	4	Study Protocol	"The SRC recommended that a second dose of BNT161b1 at the 60ug not be administered do to the reactogenicty after the first dose." what were the reactions and why were they not documented.
3/23/2022 17:06:20	FDA-CBER-2021-5683-0002930	34	2-3	Study Protocol	In phase 1 of the study, 80/84 younger participants and 11/36 older participants completed the BNT162b1 trial with 4 premature discontinuation In phase 2 of the BNT162b2 53/60 younger and 30/36 older participants completed the study with two premature discontinuations. There is no explanation as to why the participants did not complete or discontinued the study.
3/24/2022 5:43:10	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy	13	2.7.3.1. Background and Overview of Clinical Efficacy/Immunogenicity	Other	modRNA ability to suppress innate immunity. I'm not an immunologist, and so I could be understanding this incorrectly, but does this not say that the modRNA has the ability to suppress the body's innate immune response. When a cell is infected, the CD8+ T cells recognise this by recognising the changed cell membrane which is no longer "self". Does this mean that the cells infected with modRNA can go undetected?
3/24/2022 6:19:34	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy	P16	2.7.3.1.1.2.1. Phase 1 of Study C4591001	Study Protocol	Those who were excluded from the study: 1. Perons at high risk of covid 19, immunocompromised, and those with autoimmune disorders: where these ever studied later, especially since the vaccine was first promoted to those at high risk of sever COVID-19, including those who are immunocompromised? This was and still is the case here in Australia. 2. Those with IgM and IgG antibodies were excluded.In other words, those with natural immunity were excluded, which included immunity to other covids. IgM is non-specific immunoglobulin. If I'm not mistaken, its presence would indicate that the person had previously encountered a different strain of covid. Therefore, this study did not look at the safety of vaccinating people with pre-existing natural immunity. Should this then not be a caution when vaccinating people?
3/24/2022 6:42:14	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy	p18	paragraph 2 of 2.7.3.1.1.2.2. Phase 2/3 of Study C4591001	Study Protocol	Further to a previous comment. Phase 2 appears to include people at high risk of covid 19 and people with previous infection with covid 19. However, immunocompromised were still excluded, as well as those immunodeficient conditons. (However, later some people with immunodeficiency were included.) Therefore, question again is, was the vaccine ever trialed on immunocompromised. If not, why was it promoted especially to the immunocompromised?

3/24/2022 10:17:32	#58 - 125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf	2268-2346	8-10	Study Protocol	in Paragraph 8 they discuss e-dairy. I could not find that in my pages. The pages I reviewed discuss protocol. So no results. Would be curious if we can get access to the e-dairy data. Paragraph 10 discusses ethical principles like the declaration of helsinki ea (page 2321). I will go of that as well.
3/24/2022 10:17:43	Protocol C4591001	0	0	Other	
3/24/2022 11:16:53	/home/robin/Downloads/125742_S1_M2_24_nonclinical-overview.pdf	23, 29	2.4.4.1, 2.4.4.6	Study Protocol	DART test includes no male vaccine subjects, only females. Quick survey of online DART studies showed if both sexes are going to take the drug/product, both sexes appear to be tested.
3/24/2022 14:04:22	2.7.3 Summary of Clinical Efficacy	Appendix Table 32 "Efficacy Population"	Table 32	Study Protocol	1 person excluded due to not being provided "informed consent". QUESTION: Can we see the Informed Consent document? What did it say? Did everyone sign one? Why the huge predominance of white race (approx. 83%) versus only under 9% black, 4.5% Asian? Conflicting percentages for Hispanics: 10% vs 26.5%?
3/24/2022 14:10:02	2.7.3 Summary of Clinical Efficacy	101	Fig 20 Mean Titers 95% CI	Efficacy	Data shows 2 doses of 30mcg vaccine had declined about 6 months, though still higher than pre-vax levels. So, they KNEW this "vaccine" started to lose efficacy after 6 months. Traditionally, a vaccine is supposed to PREVENT future disease by sufficiently educating a person's immune system. This 6-month decline set up from the beginning the need for further doses. QUESTION: What were the objectives of the study in terms of prevention that were considered as success?
3/24/2022 14:20:34	FDA-CBER-2021-5683-0002818	104	6	Adverse Effects - Other	Possible vaccine side affect of gastric carcinoma after dose 1 with 1 person out of 360. Unclear if related to vaccine.
3/24/2022 14:31:03	FDA-CBER-2021-5683-0002826	112	Table 26	Other	Amount of people excluded in subjects without evidence of infection prior to 7 days after dose 2
3/24/2022 15:37:45	FDA-CBER-2021-5683-0003112	216-217	9 onwards	Fatality	Fatality was put down as "considered unrelated to vaccine as assessed by the investigator" even though the four cases described here all fit a major thrombo-embolic event (one of the main reasons the J&J vaccine had it's use suspended
3/24/2022 17:22:02	Adverse Events 5.3.6	page 12	table 6 Pregnancies	Adverse Effects - Reproductive Issues	They reported 270 pregnancies with vaccination. Of those 270, 238 had no outcome provided. They knew the result of 36 pregnancies only. Of these 36, 28 resulted in spontaneous abortion or death. That is 77.7% abortion or death of the known outcomes. They cannot assume that the "unknowns" resulted in a normal birth.
3/24/2022 17:58:25	https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf	22	Paragraph 2 Under Rationale	Efficacy	The rationale given for the study was the fact that as of March 2, 2021 there was no licensed vaccine to prevent infection of SARS-CoV2. Given the rapid transmission, the rapid development of an effective vaccine is of utmost importance. As of today, March 24, 2022 we know that there is still no vaccine that prevents infection. That we are still under pressure from the FDA and CDC to vaccinate using an ineffective, even harmful vaccine makes no sense. The goal posts have been moved.
3/24/2022 18:39:08	Adverse Events 5.3.6	pages 16 to 25	Table 7 AESI	Other	SAFETY: We have been told repeatedly that this vaccine is safe and effective. Table 7 lists the percentage of patients experiencing SERIOUS adverse events. 3.3% cardiovascular, 7.3% Covid, 2.2% Hematological, 1.07% Facial paralysis, 2.5% autoimmune disease, 1.2% neurological events, 0.3% thromboembolism, 0.6% stroke. These are all very serious events and equal 18.5% of all patients. Very few would have taken this drug if they had known it was this harmful!
3/24/2022 20:58:29	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.5-Clinical-Overview.pdf	ABBREVIATIONS-PAGE 13	C4591001 Efficacy Final Analysis Interim CSR	Data Discrepancy	USE OF THE TERM "PRESPECIFIED" 'Study C4591001 interim clinical study report including prespecified final analysis of efficacy and available immunogenicity and safety data up to data cutoff date of 14 November 2020.' According to Reader's Digest Great Encyclopedic Dictionary including Funk and Wagnalls Standard College Dictionary 1966 Edition, there is NO applicable scientific term "prespecified". "SPECIFICATION" [page 128]: 3- In patent law, the detailed statement of the nature of an invention and the method of constructing and applying it. In addition, the term "SPECIFIC" [page1286] 5-medicine: curing or alleviating a special disease or pathological condition: said of a remedy or medicine. 5b-Caused by a particular condition, germ, ect....said of a disease.
3/24/2022 23:11:30	FDA-CBER-2021-5683-0015537 -5538	11-12	highlighted sentances in tables	Study Protocol	FDA-CBER-2021-5683-0015537 - changes in doses, Removed hemoglobin change-from-baseline abnormalities from the laboratory abnormality grading scale...Removed time frames for stopping rules...Clarified safety data requirements to permit dose escalation. RE FDA-CBER-2021-5683-0015538 - Amended text so that the stopping rules apply to an RNA platform rather than a specific vaccine candidate
3/24/2022 23:34:02	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.5-Clinical-Overview.pdf	Abbreviations page 13 ICH International Council on Harmonisation	2.5.1.4 Ethical Considerations	Study Protocol	Ethical Considerations- All protocols are being approved through international committees of which the International Council for Harmonization is pivotal in making protocol rules. The Bill and Melinda Gates Foundation as well as members of the FDA are paid members of this organization that includes all the health authorities of all major countries including China, North Korea and Japan. They decide what information is gathered and what criteria is used in trials. And how the information is released. https://www.ich.org
3/25/2022 10:34:41	BNT62b2 2.7.3 Summary of Clinical Efficacy	17	2	Study Protocol	A total of 15 participants were selected for both clinical trials (12-55 year old age group and 56-85 year old age group) with 12 participants receiving the vaccine and only 3 participants receiving the placebo. The study groups should have equal numbers of participants to minimize the risk for sample bias.
3/25/2022 12:11:30	BNT162b2 Summary of Clinical safety	P. 169	2	Adverse Effects - Other	The paragraph states that a younger participant had a myocardial infarction deemed by the investigator to be study related. The paragraph goes on to say that the issue resolved in one day. Never in my 30 years of nursing did I see an MI resolve in one day. This sounds very curious.
3/25/2022 12:51:37	BNT162b2 Summary of Clinical Safety	216	Bullet points 2, 3, and 5.	Adverse Effects - Other	These were all unblinded original placebo participants who then took the shot, so dose 3 and 4 should be considered 1 and 2. Bullet point 1- severe Covid pneumonia 8 days after first injection deemed not study related. Bullet point 3- older participant had a severe CVA 16 days after dose 2. Deemed not study related. Bullet point 4- younger participant who had a pulmonary embolism 5 days after dose 2. Investigator claimed it resolved the following day. Again, in my experience resolution of a PE takes much longer than1 day. Bullet point 5- An older participant had a pulmonary embolism and an occlusive thrombus in the right calf. Again the study claims that these two adverse events resolved the next day and were not related to the study. An occlusive thrombus and PE's take extensive anticoagulant therapy to resolve.
3/25/2022 13:01:57	BNT162b2 Summary of Clinical Findings	p. 309	Point e. Under table	Other	It was noted that an optional blood draw of around 170 ml was taken from willing participants for further Covid-19 research. It does not mention how many gave blood and what the focus of the research would be and when the results from said research would be available.
3/25/2022 13:51:07	STN-125742_0_0-Section-2.7.3Summary of Clinical Efficacy	29	Table 2	Efficacy	The interim efficacy of the vaccine was documented only 7 days after the second dose of the vaccine, which was 95% on 4 November, 2020. The vaccine was beginning to be rolled out in late November, into December while quoting an efficacy rate only 7 days after a second dose?
3/25/2022 14:02:42	Case 1:21-cv-00008-MJT Document 2-3 Filed 1-8-21 P 1-74 PageID #: 425	Entire Document is Highlighted where BIG errors are noted for correction	Whole document riddled with errors (highlighted for your review)	Data Missing	74 Page document highlighted for general REVIEWER-NOTED ERROR, missing and erroneous data, including missing INFORMED CONSENT documentation, dates, etc.
3/25/2022 14:41:08	STN-125742_0_0-Section-2.7.3Summary-of-Clinical-Efficacy	47	1 and Table 12	Efficacy	Among participants without evidence of SARS-CoV-2 infection before and during vaccination regimen, the estimated VE against severe COVID-19 occurring at least 7 days after Dose 2 was 66.4%, with 1 and 3 cases in the BNT162b2 and placebo groups respectively (Table 12). The posterior probability for the true vaccine efficacy greater than 30% is 74.29%, which did not meet the prespecified success criterion of >98.6% for this endpoint due to the small number of severe cases observed after Dose 2 in the study.
3/25/2022 15:15:10	Signed-F21-5683 CBER Dec132021 Response letter. Pdf	1	1, 2, 3	Other	Mr.Siri is asking for Freedom of Information Act (FOIA). There are 2,890 pages of records that we may want to get our hands on.
3/25/2022 15:34:33	BNT 162b2 2.5 Clinical Overview	27	1	Study Protocol	Study protocols, the vaccine concentrate is diluted with 0.9%Sodium Chloride which is not packaged with the vaccine and is sourced separately. This would not be considered a controlled study.
3/25/2022 16:02:26	125742_S1_M5_5351_c4591001-interim-mth6-protocol	59	2	Study Protocol	"There is an ongoing global pandemic of COVID-19 with no preventative or therapeutic options available." Is this true? Was hydroxychloroquine tested to ameliorated the symptoms of Covid-19?
3/25/2022 16:21:53	125742_S1_M4_4223_R-20-0072.pdf	see below	see below	Data Missing	This document recorded test results of 3 different RNA platforms. Luciferase was used to 'see' where the RNA traveled in mice. The majority of the data is redacted-including the graphs, as well as the other RNA products they were comparing results. I guess I am wondering why the results are redacted. I read through the document and just highlighted what I thought might be of interest. Looking for more to read.
3/25/2022 16:23:08	BNT 162b2 2.5 Clinical Overview	27	2.5.2.2	Study Protocol	The major pharmacodynamic effect of a vaccine is not like a drug. A drug goes through out the body. The vaccine concentrate stays within the injection site, the muscle then is released into the lymph nodes, the antigen causes the antibodies to form for the protection from the virus. But after hearing the vaccine is found in the blood stream, liver and other organs it is performing more like a drug than a vaccine.

3/25/2022 18:19:30	125742_S1_M1_priority-review-request-1	10	6	Efficacy	This is an update letter to the FDA (released 3/24/22) asking the FDA for renewed EUA for >16 yr olds. 1.4.2.2.1. Phase 2/3 Efficacy Final Analysis (Evaluable Efficacy Population) shows that the expected vaccine efficiency (VE) was only 66.3% vs the expected >98%. The problem is that in the summary paragraphs on VE on page 12, they tell the FDA that it is >90%
3/25/2022 19:55:05	https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	5	Intro & parag.6	Other	premise of FDA/CDC/DHHS colluding w/ Pfizer for guaranteed approval - Conspiracy
3/25/2022 19:59:25	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy.pdf	82	2	Study Protocol	I believe this is a very important find. The paragraph states: "For benchmarking, GMTs of the dose level groups were compared with those of a panel of human convalescent sera (HCS) comprising samples obtained from 38 individuals 18 to 85 years of age at least 14 days after confirmed diagnosis of COVID-19." So this comparison group of naturally infected individuals consisted of only 38 people total, & NOT broken down into equivalent age groups like the study groups, which had age categories. That is an issue. But most importantly I believe is that the study groups (those that received the vaccines) had their antibodies measured at: baseline, 8 days, 22, 29 &43 days. While the HCS (the naturally infected comparison group) was checked only once "at least 14 days after confirmed diagnosis..." According to the CDC's own website, they note it can take 1-3 weeks to develop antibodies after infection, so checking at 14 days they may not have given this comparison group enough time to reach appropriate or peak levels of antibodies - therefore, measuring their product against an unfair comparison group! When looking at the graphs on page 82 & 83 you can see that basically none of their vaccine groups had detectable antibodies above the level of detection at day 22, and they only increased to detectable levels after that (which they themselves note on these pages) - & of note, the HCS group had what appears to be entirely detectable levels already at that time ("of at least 14 days from diagnosis); none of the HCS group appears to be under the level of detection. So if they were given until at least 21 days after confirmed diagnosis as it appears according to the CDC they should have given at least that much time, they may have had even higher levels of antibodies, which may have shown these vaccines to not be superior as they claim in this study. Lastly, they note consistently that older adults had lower levels of antibodies or "decreased neutralization responses" when compared to the younger age groups; the HCS group contained individuals 18-85! They did not break them down - so this bias may have also added to faulty data if the same holds true for the HCS group (were most the 38 older/closer to 85 or were they closer to 18)?? Please email me if you want me to clarify any of this - I find this to be important. Thank you.
3/25/2022 19:59:31	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy.pdf	16	2.7.3.1.1.2.1.	Other	individuals with certain medical conditions or situations that could affect participant safety or evaluation of vaccine safety or immunogenicity were excluded.
3/25/2022 20:13:00	STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	40	2.7.4.1.2.4.1.2. Open-Label Follow-Up Period	Other	I find it interesting that 105 study participants from the vaccine group withdrew from the study, yet only a few from the placebo group. No reasons were given for the withdrawals.
3/25/2022 20:37:34	STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	40	2.7.4.1.2.4.2. Exposure (Phase 3, Study C4591001)	Study Protocol	14 different protocol deviations of giving the wrong injection to participants, placebo to someone assigned to the vax group, or vice versa, depicting very sloppy work.
3/25/2022 21:16:17	STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	47	2.7.4.2.1.1.2. Systemic Events (Phase 1, Study BNT162-01)	Adverse Effects - Other	Pfizer states that they saw systemic events occur in a dose dependent fashion and increased with the number of doses given, though they do say they were mild to moderate and short lived. These were in people receiving 10, 20 or 30 ugs though, not the 100 ug dose some people are getting with the vax
3/25/2022 21:45:31	STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	51	2.7.4.2.2. Phase 1 (Study C4591001)	Adverse Effects - Other	BNT162b1 at 100 µg, was discontinued after the first dose due to the reactogenicity profile, even though this is not the product that was used under the EUA, I feel it is significant, since they are both pretty similar
3/25/2022 21:51:44	STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	52	C4591001 Efficacy Final Analysis Interim CSR Section 12.1.1. 2.7.4.2.2.1.2. Systemic Events (Phase 1, Study C4591001)	Adverse Effects - Other	Headaches and fatigue as common AEs, though these were not severe in nature, I think they could be significant findings at these lower doses since so many people have experienced migraines, strokes, brain hemorrhaging etc that have taken the vax under EUA.
3/25/2022 22:02:39	STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	54	after any dose of BNT162b2. 2.7.4.2.2.3.4. Severe Adverse Events (Phase 1, Study C4591001)	Adverse Effects - Other	These adverse effects were considered unrelated by the investigator, but could possibly be related.
3/25/2022 22:21:29	STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	57	2.7.4.2.3.1.2. Systemic Events (Phase 2, Study C4591001)	Adverse Effects - Other	More acknowledgement of the dose response nature of these adverse events. Keep in mind that these are lower doses and fewer injections than what many received under the EUA.
3/25/2022 22:27:50	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	33-34	2.7.4.1.1.3. Narratives	Other	"Missing Narratives" in documentation - Section 2.7.4.1.1.3 refers to narratives for all participants that died, had AE's that required removal from the study, SAE's, etc. See screenshot. I looked through all the https://phmpt.org/pfizers-documents/ documents that made sense to look for this info, and I did not find. Seems to me these narratives would be VERY informative. If this was not part of the data release, I would think it should be requested.
3/25/2022 22:30:45	STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	58	2.7.4.2.3.2. Summary of Adverse Events (Phase 2, Study C4591001)	Adverse Effects - Other	Two severe events were reported for 2 participants in the BNT162b2 younger age group: myalgia(AE) and gastric adenocarcinoma (SAE), Both were considered unrelated by investigator, but were they? Both of these types of SAEs have been reported in VAERS.
3/25/2022 22:42:24	125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf	All	N/A	Adverse Effects - Other	"Subject Dropouts?" Adverse effects or "cold feet"? If I recall correctly, I have heard Naomi talk about something like 10,000 folks that "disappeared". When looking for a reference from my "assigned" section, I ran into the doc listed above on the https://phmpt.org/pfizers-documents/ site. I estimate there are about 10,000 individuals in this documentation that basically dropped out or were dropped. All the ones I saw said did not get the second dose, or on time or something similar. Makes one wonder why... There is another similar one for "final". Did not estimate the # in that doc. Maybe already known. Just sayin'
3/25/2022 23:04:54	STN 125742_0_0 Section 2.7.4 summary-clin-safety.pdf	28	2.7.4.1.1.2.3.	Other	"Gap in participant age group". When doing the Phase 1 trials to determine dosage, the age groups are 18-55 and 65 to 85. I do not understand why they would skip 10 years when looking for volunteers? 65 is Medicare age. Seems odd.
3/26/2022 1:17:08	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy	16	7	Study Protocol	"To facilitate rapid review of data... sponsor staff were unblinded..." Conflict of interest?
3/26/2022 1:18:37	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy_Screenshot	18	5	Study Protocol	Vaccines administered by unblinded staff. Another conflict of interest/revelation of substance administered through behavior or accidental remarks?
3/26/2022 1:19:53	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy	23	3	Study Protocol	Intermin analyses performed by an unblinded statistical team. Why? Does tallying results require unblinding?
3/26/2022 1:21:15	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy	28	9	Study Protocol	Intermin analysis of VE 7 days after second dose of vaccine. Was/is any monitoring taking place to determine the duration of the VE over time?
3/26/2022 1:35:44	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy	P17	Paragraph 3 of section: 2.7.3.1.1.2.1. Phase 1 of Study C4591001	Study Protocol	For deciding on the appropriate dose, 12 people aged between 18 and 55 were split into four groups. This means that there were 3 persons per group. In other words, they appear to be comparing 18 year olds with 55 year olds to determine dose levels for those aged 18-55 years. A 20 year old has a different body and health status to a 50 year old. How is this even comparable? Three people per group is hardly a standard, especially if the age range is so vast.
3/26/2022 4:30:39	125742_S1_M5_5351_c4591001-interim-mth6-protocol	71	1	Study Protocol	"Up until the final efficacy analysis, this protocol will use a group of internal case reviewers to determine whether certain investigator-reported events meet the definition of disease-related efficacy endpoints, using predefined endpoint criteria." Shouldn't this to done by a external neutral party.
3/26/2022 5:13:42	125742_S1_M5_5351_c4591001-interim-mth6-protocol	76	3	Study Protocol	I thought that the vaccine was developed in 10 months. How does 26 months fit into this equation?
3/26/2022 6:06:02	STN 125742_0_0 Section 2.5 Clinical Overview.pdf	page 30	Table 1 - Had other important protocol deviations on or prior to 7 days after Dose 2	Efficacy	From day 1 to day 7 of the vaccine of dose 2- 302 participants were excluded because of protocol deviations. vs.52 from Placebo. The study only counts reactions after day 7 of the dose. The study never clearly defines what 'protocol deviation' is in great detail. I suspect it is an adverse reaction within the first 7 days.

3/26/2022 9:26:08	STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	35, 36, 37	2.7.4.1.2.1.4. Demographic and Other Characteristics of Study Population (Phase 1, Study BNT162-01) and 2.7.4.1.2.2.4. Demographic and Other Characteristics of Study Population (Phase 1, Study C4591001)	Study Protocol	The demographics of both Phase 1 dosage studies, BNT162-01 and C4591001, were comprised of essentially ALL white people. In BNT162-01, it says 2% Hispanic (probably a single individual) in the younger age group and older age group ALL white. No blacks, Asian, etc. In C4591001, it just says most were white in younger age group and older ALL white again. For what is a "gene therapy" that they intend to use as a one-size-fits-all on ALL races, it seems CARELESS to me to limit the dosing study to one race - white, non-Hispanic. Am an engineer and not a geneticist, so maybe much ado about nothing, but... See screenshots
3/26/2022 10:41:27	STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	69-70	Figures 4 and 5	Adverse Effects - Other	Even though they do not show any statistics, just looking at this graph shows that there is increased systemic adverse events with the increased number of doses. It also clearly shows that increases do not exist with injecting placebo multiple times. Clearly these events are due to the vax. Again, these may not be extremely serious events in themselves, but this is at 30 ug injections and only 3 injections. under the EUA they have injected up to 100 ug 3-4 times which would greatly increase these AEs which may very well be indications of internal damage occurring that they did not check for.
3/26/2022 13:51:07	STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	48	2.7.4.1.2.4. Phase 3 (Study C4591001)	Data Missing	Often what is most important about FOIA releases is what is missing. First off, the (b)(4) FOIA exemptions (basically trade secret exemptions) are always something to which medical experts should pay attention, as although pfizer may be claiming this exemption, only litigation and a decision by the judge can validate it as meeting this exemption. Second, the summary of clinical safety (2.7.4) references underlying data (5.3.5) which has conveniently not been released (they want you trust their analysis), although it seems perhaps one ore more tables of 5.3.5. data have been included in the Ad Hoc Tables document 125742_S1_M5_5351_c4591001-ad-hoc-label-tables.pdf. 5.3.6 has been released, but not 5.3.5, which should be a huge red flag. Perhaps its release is forthcoming, but perhaps it will never come...
3/26/2022 14:11:04	FDA-CBER-2021-5683-0000063	10	CONCLUSION	Fatality	In the conclusion: 4 individuals in the anaphylaxis evaluation who died the SAME DAY they werevaccinated
3/26/2022 14:19:04	FDA-CBER-2021-5683-0000060	6	3RD BULLET POINT	Data Discrepancy	Pfizer has taken multiple actions to help alleviate the LARGE INCREASE of adverse event reports - WHAT DOES THAT MEAN? nefarious actions?
3/26/2022 14:40:06	FDA-CBER-2021-5683-0000064	11	Table 5 Important Potential Risk	Fatality	*out of 138 cases from Dec.2020 to Feb.2021- 38 Died. Then in the conclusion: VAED/VAERD remains a theoretical RISK for the vaccine (yet they said it is safe and effective?)
3/26/2022 14:59:57	BATES-92_adc19ef-ve-cov-7pd2-wo-eval-sas.txt	0	0	Other	I didn't find anything but I wanted to let you know that I have a friend who is a manager for a clinical research firm that worked on these trials and I'm willing to ask him any questions you would like to relay if that would be helpful. I should mention that he himself doesn't think there is anything wrong the trial and is vaccinated.
3/26/2022 15:16:42	5.3.6-postmarketing-experience	12	Table 6	Adverse Effects - Reproductive Issues	Premature birth and spontaneous abortion
3/26/2022 15:25:45	5.3.6-postmarketing-experience	12	Table 6	Adverse Effects - Other	Problems in infants from breastfeeding
3/26/2022 15:29:46	5.3.6-postmarketing-experience	20	Table 7	Adverse Effects - Other	The number of musculoskeletal AESIs reported seems higher than other categories
3/26/2022 15:32:26	STN-125742_0_0 Section 2.5 Clinical Overview.pdf	pp. 204, 243, 265, 280, 289, 292-3	Tables 59, 64, 66, 68, 69, 70	Adverse Effects - Other	Many of the Nervous System Disorders referred to in these tables, e.g. Paraesthesia, Hypoaesthesia, Transient ischaemic attack, Peripheral nerve lesion, Brachial plexopathy, "Balance disorder", "Dizziness", etc. are symptoms of Multiple Sclerosis. I have M.S., my mother had M.S., and my older daughter and possibly my younger daugher as well have M.S. All of the above disorders are those that we all have experienced, especially at the onset of, and before the official diagnosis of, M.S. My concern is that these AEs are not only potenially far more serious than this study would have us believe but also that these AEs will not be so easily resolved. There are too many instances within this study where its concluding language states something like "most AEs were considered by the investigator--who, by the way, is this investigator? only one person?--as not related to study intervention and mild to moderate in severity, and all AEs were reported as resolved." (see e.g. the uploaded screenshot of page 147) My experience as an M.S. patient is that these symptoms come and go (esp. in relapsing/remitting M.S.) and vary widely in severity. The idiosyncratic nature of M.S. (within the experience of a single patient as well as those of M.S. patients collectively) cannot be overlooked when evaluating nervous system disorder-related AEs. Finally, it is essential that a long term approach to the study of these AEs is employed. For many M.S. patients it takes years to get the official diagnosis of M.S. My opinion is that this study is laughably too short to justify the vaguely worded and misleading language in the conclusion sections of this document. The sponsors of this study are banking on the assumption that only its conclusions will be read since the body of the report is so lengthy and dense that no one will want, or have time, to read it. How manipulative is it to insinuate that just the sheer amount of data justifies the conclusion when often the data itself shows a completely different conclusion?
3/26/2022 19:46:01	FDA-CBER-2021-5683-0000069	16-24	All theTables under GENDER	Other	Why does it seem that there are so many more females than males that are included in all of these tables - are females more at risk for injury? I don't know if this is a relevant question but I just noticed much higher numbers for women.
3/26/2022 19:54:23	FDA-CBER-2021-5683-0000077	25	Table 7	Adverse Effects - Other	m. This UK case report received from the UK MHRA described a 7-year-old female subject who received the vaccine and had stroke (unknown outcome); no follow-up is possible for clarification j. This UK case report received from the UK MHRA described a 1-year-old subject who received the vaccine, and had left postauricular ear pain that progressed to left-sided Bell's palsy 1 day following vaccination that had not resolved at the time of the report; WERE THEY EVEN ALLOWED TO GIVE BABIES AND CHILDREN THIS EXPERIMENTAL VACCINE?
3/27/2022 8:14:49	STN 125742_0_0 Section 2.7.4 summary-clin-safety.pdf - "Safety Profile of vaccine and adverse events"	27	2.7.4.1.1.2.2. Overall Design (Study C4591001) Bullet point at bottom of page 27 under "Planned Analyses"	Data Discrepancy	Hi, I watched the video introduction about the Pfizer documents and it said the data was thru Feb 2021. I have been reviewing section 2.7.4, Summary of Clinical Safety. At the bottom of page 27 there is reference to the "South African variant". That is a relatively new phenomenon (Nov. 2021?). I could find no title page to provide a date and title of what all the section I am reviewing is supposed to be from. I thought were suppose to be the clinical trial data when they sought the EUA and approval for the Pfizer and than the Bio-N-Tech mRNA therapies. That was Sep-Oct 2021? So my question is, just what are these docs supposed to represent and is there an as-of date? Trying to provide myself some context. I spent many years reviewing Engineering and Valuation reports and was always looking for inconsistencies with dates, times, amounts, along with evaluating what was presented. Anything that made me think "Huh?". Seeing reference to the South African variant made me do that.
3/27/2022 13:00:11	STN-125742_0_0-Section-2.5-Clinical-Overview.pdf	17	2.5.1.2.1.1. Current Therapies	Other	Current Therapies includes Ivermectin in hospital or clinical setting Despite media frenzy against treatments like Ivermectin - this therapy is included as a current therapy
3/27/2022 13:07:05	STN 125742_0_0 Section 2.5 Clinical Overview.pdf	24	2.5.1.2.3.2.3. Planned Studies	Study Protocol	study for pregnant women taking 'vaccine' was planned for 2021 However the vaccine was commonly available for those over 16 before this date. Were pregnant women warned that a study had not yet been made?
3/27/2022 13:14:21	STN 125742_0_0 Section 2.5 Clinical Overview	19	2.5.1.2.2. Vaccine Product Information	Adverse Effects - Other	An adverse effect is mentioned but made to sound like a feature not a bug Blunts immune system - some platform(s) blunts innate immune system sensor activating capacity.

3/27/2022 13:36:51	FDA-CBER-2021-5683-0013861 Nonclinical Overview	Pg. 6	Paragraph 1 last sentence and paragraph 2	Other	A: Although the heading references NONCLINICAL TESTING STRATEGY my question would be: Why would the notation "The dose selected for BNT162b2. with efficacy demonstrated in Phase 2/3 clinical evaluation and intended for commercial use etc." be included in this particular document? Namely "demonstrated in Phase 2/3 clinical evaluation". B: Paragraph 2. NONCLINICAL TESTING STRATEGY- "Only BNT162b2 (V9) has been evaluated in the clinic" etc Same question as in above example A I referenced the attached FDA Bioresearch Monitoring Information (definition) Comparison of FDA, EPA ,OECD GLP under FDA Column pg.2 Nonclinical Laboratory Study 58.3 (d) sentence 2 of particular interest. C: According to FDA-CBER-2021-5683-0000004 Table 1. on pg. 4 The phase 1/2/3 Start date was April 2020 and ongoing, with no start date distinction between the clinical trials 1,2 and 3. in the table. When would the actual preclinical phase studies have been done? On page 8 of FDA_CBER-2021-5683-0013868 Table2.4.1-2 Nonclinical Studies, the date Jul. 06 2020 references the Test Item "modRNA encoding luciferas formulated in LNP comparable to BNT162b2" and Pg.9 the date of Aug.5 2020 is referenced ....these dates don't jive with the start date for phase 1/2/3 of clinical trials with subjects starting in April 2020 found in Table 1 Pg. 4 FDA-CBER-2021-5683-0000004 Since this document references Approval Feb 8 2021, and is NONCLINICAL OVERVIEW, I have not been able to find another reference to original nonclinical study material for comparison from 2020. In order to authorize the EUA it must have been included? An OVERVIEW is sufficient for a Biologics License application? Since these were the assigned pages for my name I hope I have not wasted your time. I am not familiar with scientific study. i can only reference that which jumps out at me.
3/27/2022 16:17:25	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.5-Clinical-Overview.pdf	p.36	Table 1	Data Discrepancy	I hope I am not getting too much in the weeds here, but when you are dealing with small efficacy numbers of injection versus the placebo, I thought it was worth mentioning. The numbers listed in Table 1 do not add up to me. I will just address the vaccine column but the same analysis is true for the placebo column. - the subjects w/o evidence of infection before Dose 1 is considerably less than the Dose 1 all-available efficacy population. What is the explanation for this discrepancy? - the subjects w/o evidence of infection prior to 7 days after Dose 2 plus the Subjects excluded from Dose 2 all available efficacy population do not add up to the Dose 2 all-available efficacy population. What is the reason for the discrepancy? - subjects w/o evidence of infection prior to 7 days after Dose 2 plus subjects excluded from evaluable efficacy population does not add up to the evaluable efficacy population (7 days) do not add up to the evaluable efficacy population (7 days). What is the reason for this discrepancy?
3/27/2022 19:40:43	#19 - STN 125742_0_0 Section 2.5 Clinical Overview.pdf - "Clinical Overview"	17	2.5.1.2.1.1. Current Therapies	Other	Ivermectin is listed as a current therapy under "Clinical trial setting". Were they aware of data of Ivermectin use? If Ivermectin was proven to work and they were aware of success with this treatment then emergency authorization of the vaccine is not warranted (if therapeutics are available.)
3/27/2022 19:50:37	https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	11	5	Adverse Effects - Other	vax'd increase in positive covid19 diagnosis - manipulation of timeline by CDC to reduce causality Pg 11 Conclusion: VAED may present as severe or unusual clinical manifestations of COVID-19. Overall, there were 37 subjects with suspected COVID-19 and 101 subjects with confirmed COVID-19 following one or both doses of the vaccine; 75 of the 101 cases were severe, resulting in hospitalisation, disability, life-threatening consequences or death. None of the 75 cases could be definitively considered as VAED/VAERD. …COVID-19 following vaccination, based on the current evidence, VAED/VAERD remains a theoretical risk for the vaccine. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect.html It takes time for the body to build protection after any vaccination. Most people are considered fully vaccinated 2 weeks after the second dose of the Pfizer-BioNTech
3/27/2022 20:04:24	5.3.6-postmarketing-experience.pdf	10	b) at very bottom of page	Fatality	b There were 4 individuals in the anaphylaxis evaluation who died on the same day they were vaccinated. Although these patients experienced adverse events (9) that are potential symptoms of anaphylaxis, they all had serious underlying medical conditions, and one individual appeared to also have COVID-19 pneumonia, that likely contributed to their deaths Question: If a patient has serious underlying conditions, should they really be taking an experimental vaccine who's side effects are more dangerous than the disease it's supposed to protect against?
3/27/2022 20:13:06	BNT162b2 Summary of clinical safety 2.7.4	Pages 59 and 60	Pg 59 last paragraph and pg 60 first paragraph	Data Missing	Inadequate documentation on both events. Incomplete documentation on gastric adenocarcinoma symptoms. NO documentation as to how the investigator assessedor determined these 2 events were not related to the study intervention.
3/27/2022 20:21:57	STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	82	Table 6.	Adverse Effects - Other	The incidence of adverse effects for the 30 ug dose was more than double those that received placebo. Of these AEs, blood and lymphatic system disorders were more than 5 times higher in the experimental group over the placebo, most of which was attributed to lymphadenopathy. Surprisingly, cardiac disorders were about the same for both groups! It seems that the placebo group was high. It would be interesting to see the ages of those affected. Makes one wonder how healthy these 'healthy volunteers' really were.
3/27/2022 20:33:44	STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	85	Table 6	Adverse Effects - Other	It appears that GI disorders were significantly higher in the vaccinated groups, in particular nausea, diarrhea and vomiting. Again this is 30 ug dose level.
3/27/2022 22:29:27	STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	89-90	Table 6	Adverse Effects - Other	Significant increases in General Disorders and Administration Site Conditions were found in the vaccinated groups. The main increases were found to be injection site pain, fatigue, pyrexia (fever), chills, injection site pain, erythema (redness), pruritis (itching) and edema (swelling), malaise, and asthenia (weakness, debility). Some of these increases were huge.
3/27/2022 22:39:56	STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	100	Table 6	Adverse Effects - Other	Large significant increases in musculoskeletal and connective tissue disorders were found in the vaccinated group over the placebo group, especially myalgia (muscle pain), arthralagia (joint pain) and pain in extremity were several fold higher.
3/28/2022 6:21:43	STN 125742_0_0 Section 2.7.4 summary-clin-safety.pdf - "Safety Profile of vaccine and adverse events"	34	2.7.4.1.2.1.1. Disposition (Phase 1, Study BNT162-01)	Adverse Effects - Other	Questionable Narrative - Under "Disposition", it says they had 36 participants in the older age group. It goes on to say that only 11/36 completed the study, yet only 4 "premature discontinuations" and NONE in the older age group??? They do not define the causes of "premature discontinuations". So less than 33% of the older age group completed the study, but none of the dropouts were a result of some problems they were having? If you lose over 2/3's of ur group, what use is it? You will note also that they attempted a 60 microgram dosage in the younger cohort, but did not give the second dose due to reactogenicity. There is no explanation of what that reactogenicity consisted of. First hint of heart issues? Does not say. This was for BNT162b1. They did not attempt the 50 and 60 microgram doses for BNT162b2. See Screenshot.
3/28/2022 6:33:44	STN 125742_0_0 Section 2.7.4 summary-clin-safety.pdf - "Safety Profile of vaccine and adverse events"	33, 34 and others	2.7.4.1.1.3. Narratives and 2.7.4.1.2.1. Study BNT162-01 and others	Data Missing	Missing? Documents - The section I am reviewing keeps referring to Final and Interim, Final and Update CSR's (Clinical Study Reports) for both studies discussed in this section, BNT162-01 and C4591001, to locate data on Phase 1 of the trials. I have have looked and cannot locate anywhere.
3/28/2022 6:56:34	STN 125742_0_0 Section 2.7.4 summary-clin-safety.pdf - "Safety Profile of vaccine and adverse events"	5 thru 9	N/A	Data Missing	No Tables for Phase 1 Studies - The section I am reviewing discusses Phase 1 of the trial (in addition to Phase 2/3). When I look through the tables, they all apply only to Phase 2/3. When reading the parts on the Phase 1 study, it always refers to to other documents (CSR's, Clinical Study Reports) that we do not appear to have. Seems to me they should have been included in this section. Why would they not be? If not suspicious, it certainly is annoying.

3/28/2022 9:03:22	20 stn125742-00		12	2.7.3.1	Other	"Which has blunted innate sensor activating capacity "
3/28/2022 10:57:50	2.7.3. Summary of clinical efficacy		13	2.7.3.1	Other	BioNTech has developed multiple RNA-LNP platforms, including nucleoside-modified RNA (modRNA), which has blunted innate immune sensor activating capacity and thus augmented antigen expression. Two modRNA vaccine candidates were evaluated in both the FIH dose-ranging study, conducted in Germany (BNT162-01), and in the Phase 1, dose-ranging portion of Study C4591001, conducted in the United States. The
3/28/2022 12:34:42	125742_S1_M5_5351-c4591001-interim-mth6-protocol.pdf	61, 80-81, 118, 132-133, 2328		2.3.1; 5.2; 8.11.1.2; 8.11.2.1; 11.	Study Protocol	While hypertension and diabetes are considered high risks for Covid, Pfizer's protocol stopped measuring blood pressure in phase 2/3 and has never performed blood glucose test . However, the protocol refers to FDA guidance for evaluation toxicity(page 61). Pfizer followed FDA recommendations only for checking vital signs in phase 1, which didn't include people with high blood pressure, diabetes, chronic kidney diseases,etc.(page 80-81).In phase 2/3 Pfizer measured only body temperature and weight.(pages 132-133). As for blood chemistry(page 2328), the protocol didn't include coagulation, glucose, electrolytes, and the urine test which were recommended by FDA (screenshots).In Pfizer preclinical trials on mice (p.2345 ,#6:5.3.1.7)the fibrinogen level was increased after injections but went to normal by 23 day of experiment. Also electrolytes and the urine test are important for 2/3 phase because it included 65+ group that is in high risk of developing kidney failure.
3/28/2022 12:51:04	STN 125742_0_0 Section 2.7.4 summary-clin-safety.pdf - "Safety Profile of vaccine and adverse events"	38-39		2.7.4.1.2.4. Phase 3 (Study C4591001) and 2.7.4.1.2.4.1. Disposition (Phase 3, Study C4591001)	Data Missing	"Missing Documentation" - Hi, last time I bring this up. The section I am reviewing keeps referring to Clinical Study Reports (CSRs) that we do not appear to have. For the BNT162-01 and C4591001 studies. By referencing those reports, I believe them to be part and parcel of the section I am reviewing. If the information in those reports is available in some form or known to be in future materials, please advise. Thanks!
3/28/2022 14:48:47	other	other		other	Other	Please see my FDA Citizen's Petition and denial response. I think the FDA lawyer's response may be helpful in determining further strategy.
3/28/2022 15:07:25	STN 125742_0_0 Section 2.7.3 Summary of Clinical Efficacy.pdf - "Effectiveness of Vaccine - how much protection from COVID"		13	1st paragraph under section 2.7.3.1.	Adverse Effects - Other	Paragraph mentions "blunted innate immune sensor activating capacity". Is this potentially what is causing so-called VAIDS such as what appears to have affected professional golfer Steve Stricker? See https://www.essentiallysports.com/golf-news-steve-stricker-health-update-what-caused-his-illness-and-how-is-he-doing-now/
3/28/2022 15:26:44	STN 125742_0_0 Section 2.7.3 Summary of Clinical Efficacy.pdf - "Effectiveness of Vaccine - how much protection from COVID"		17		5 Study Protocol	From the report: "Blood for immunogenicity evaluations was collected immediately before Dose 1 and at visits taking place approximately 7 and 21 days after Dose 1; at 7, 14, and 28 days after Dose 2, and at 6, 12, and 24 months after Dose 2". If this report was issued 4/30/21, how could they claim to have collected blood "24 months after Dose 2"? When did the trial start?
3/28/2022 16:24:16	STN 125742_0_0 Section 2.7.3 Summary of Clinical Efficacy.pdf - "Effectiveness of Vaccine - how much protection from COVID"		18	1st full paragraph	Study Protocol	Third sentence from the end of the paragraph: ""Immunocompromised individuals were excluded, including those receiving immunosuppressive therapy or systemic corticosteroids (inhaled/nebulized corticosteroids were permitted)" Immunocompromised people were strongly encouraged to take the vaccine after the EUA was approved? Were they informed that such people were excluded from the studies?
3/28/2022 16:36:14	5.3.6. 2 of 2	all		all	Other	Uploaded doc to Craig
3/28/2022 16:51:57	FDA_CBER-2021-5683-0002944		48	4 and 6	Adverse Effects - Other	Paragraph 4: In Phase 1 of the administration of BNT162b1 2 younger participants and one older participant discontinued from the study due to SAE. Paragraph 6: BNT162b1 most frequently reported included nervous system disorders (most headache) and cough and oropharyngeal pain. Older adults reported thoracic and mediastinal disorders most cough, and oropharyngeal pain.
3/28/2022 17:11:12	FDA-CBER-2021-5683-0002948		52		7 Adverse Effects - Other	Phase 1 Clinical study, Dose 1 older adults who had AE were 8.3%-25% as opposed to younger who had AE at the rate of 41.7%-50% which is significant especially with what we are seeing now in younger people and their health issues.
3/28/2022 17:27:28	FDA-CYBER-2021-5683-002954		58		1 Data Discrepancy	It seems odd that systemic events would be the same for younger participants after dose 1 and 2 and the placebo group? as well as the older group with similar results.
3/28/2022 18:55:37	2.4 NONCLINICAL OVERVIEW		6		1 Other	Design of modified mRNA by Pfizer was cited in literature as likely to be a poor immunogen and cause pathogensis in the process. Motivated by financial ties?
3/28/2022 19:56:10	2.7.3 SUMMARY OF CLINICAL EFFICACY		13	11 under 2.7.3.1. Background and Overview of Clinical Efficacy/Immunogenicity	Efficacy	Quote - "BioNTech has developed multiple RNA-LNP platforms, including nucleoside-modified RNA (modRNA), which has blunted innate immune sensor activating capacity and thus augmented antigen expression." This above BioNTech statement is interesting to me because it indicates that BioNTech have synthetically modified the nucleoside molecule of RNA composition (modRNA) in such a way that the modRNA would pass through body circulations without being detected by innate or primary immune defense mechanisms. IN OTHER WORDS, modRNA is designed to bypass the human primary immune system to get into cells by fooling the body into not defending against it. THEREBY; allowing the modRNA to be taken up by cells for initiation of manufacturing pathogenic molecules, ostensibly the Spike Protein of the SARSCOV-2 virus (Toxic), inside the human body.
3/28/2022 20:19:41	125742_S1_M5_5351-c4591001-interim-mth6-protocol.pdf	210-211		10.3.3	Adverse Effects - Other	There aren't objective criteria to establish a causality of AE.The protocol states that the decision about that is on the site investigator personal judgment. Also the protocol refers to the investigators brochure BNT162/PF-07302048 that is composed by Pfizer.(page 227, #7 : pages 80-81[7.8.1, 7.8.2] According to the brochure there are only a few AE related to the vaccine: injection site pain, headache, fever, chills, fatigue,and muscle pain. "No serious adverse reactions are considered expected by the sponsor for regulatory reporting purpose."
3/29/2022 4:51:36	STN 125742_0_0 Section 2.7.4 summary-clin-safety.pdf - "Safety Profile of vaccine and adverse events"		55	2.7.4.2.2.5. Clinical Laboratory Evaluations (Phase 1, Study C4591001)	Adverse Effects - Other	Decreases in lymphocytes and neutrophil - In Phase one of C4591001 there were reports of decreases in lymphocytes and neutrophil after Dose 1. (Immune suppression?) The decreases are described as "transient". There is no other detail in this section of just what they were seeing. There is no mention of results after a Dose 2. There is no mention of what the dosage was. 30 micrograms? With what we know now (the apparent suppression of immune systems), this reduction in white cells may have been the first clue - and only after a single dose. Once again, the section refers you to a CSR (Clinical Study Report) that we do not appear to have for the details. The more I read, the more apparent it is that there is more Reactogenicity in the "Younger" age group. However, since the younger cohort is 16 thru 55 and grouped together, cannot tell if reactogenicity increases in general as ages decrease.
3/29/2022 5:03:37	STN 125742_0_0 Section 2.7.4 summary-clin-safety.pdf - "Safety Profile of vaccine and adverse events"		56	2.7.4.2.2.8. Conclusions (Phase 1, Study C4591001)	Adverse Effects - Other	Reduced Lymphocytes - I reported this prior from interpreting another paragraph. The conclusions here reiterate my findings. What bothers me is that the reduced lymphocytes are only discussed after a SINGLE dose and they state "was not considered clinically relevant". Would seem to me that ANY effect on the immune system would be "clinically relevant". Particularly since subsequent doses were envisioned at the time. Surely they could envision "cumulative" effects?
3/29/2022 9:44:24	Clinical Overview		15		1 Study Protocol	Why is original research question for 12 years old and greater but study was conducted on 16 years old and greater?
3/29/2022 9:48:39	Clinical Overview		18		7 Study Protocol	States that RNA does not integrate into the genome and is transiently expressed. Did they have proof of this?
3/29/2022 9:51:48	Clinical Overview		22		5 Data Missing	Why was the 100 ug dose discontinued? Should the reason have been added to side effects to look for in the study groups?
3/29/2022 9:53:03	Clinical Overview		22		6 Data Missing	Safety follow up for 2 years? Where is more current data?
3/29/2022 9:56:20	Clinical Overview		23		5 Data Missing	Was geographic area where postitive cases occurred identified and accounted for? Since there are only a small number of positive cases to begin with, where the participant lived could have been an issue as there were dramatic spikes in cases in different communities.
3/29/2022 9:58:41	Clinical Overview		24		6 Data Missing	Do we have the results on the 2021 study of lot consistency?
3/29/2022 10:00:54	Clinical Overview		27		4 Data Missing	Did the difference in manufacturing process to increase production cause any issues?
3/29/2022 10:03:26	Clinical Overview		28	5 and 8	Efficacy	Why was the endpoint criteria changed from 7 days after dose 2 to 14 days after dose 2?
3/29/2022 10:08:38	Clinical Overview		43		3 Other	Why did investigators not reveal that there were zero covid recovered participants who contracted severe covid? the FDA and CDA would have been aware of this.
3/29/2022 10:11:23	Clinical Overview		48	4 and 5	Data Discrepancy	Was is 162 cases or 165 cases?
3/29/2022 10:15:47	Clinical Overview		66		1 Study Protocol	Why exclude patients with any illness??

3/29/2022 10:18:29	Clinical Overview		68		4	Other	Why was the extremely low number of severe covid cases not public at this time? If all cause mortality was included risk vs benefit it would change decision making by public as per informed consent.
3/29/2022 10:22:34	Clinical Overview		77		1	Other	Why was efficacy against severe covid advertised as almost perfect? This is not what the data shows (66%)
3/29/2022 10:24:56	Clinical Overview		80		1	Data Discrepancy	why 240 protocol deviations in the experimental group vs placebo? 240 vs 60. Was it related to administration errors?
3/29/2022 10:27:03	Clinical Overview		88		4	Data Discrepancy	Why such a difference in efficacy for South Africa, Germany and Turkey
3/29/2022 10:28:39	Clinical Overview		88		6	Other	Why mandatory vaccination Covid recovered if data should be interpreted with caution?
3/29/2022 10:55:32	5.3.6 Cumulative Analysis of Post Authorization Adverse Events Reports :Appendix 1. List of Adverse Events of Special Interest	Page1 of Appendix 1. Note-:Page 30 of 38		Appendix 1. First entry of first line		Adverse Effects - Other	1p36 deletion syndrome is a chromosome disorder that causes sever intellectual disability.
3/29/2022 11:40:37	Clinical Overview		89		1	Data Discrepancy	Were the patients with a medical history of Covid actually tested? Early in the pandemic patients were assumed to be covid positive my physicians because they didn't want to have contact with pateints.
3/29/2022 11:41:38	FDA-CBER-2021-5683-0023007-to-0023031_125742_S1_M5_c4591001-A-P-adsympt-sas.txt	30 pages of computer code		NA Computer Code		Other	Code has phrase "Multisystem inflammatory syndrome in children"
3/29/2022 11:42:17	Clinical Overview		89		2	Data Discrepancy	Prior covid showed efficacy of only 58.9% so why vaccine mandates in covid recovered?
3/29/2022 11:45:49	Clinical Overview		99		1	Adverse Effects - Other	Subjects with previous covid had negative efficacy with vaccination this was not publicized.
3/29/2022 11:48:56	Clinical Overview		113		3	Data Discrepancy	Why 100% estimated efficacy in 12-15 year olds?
3/29/2022 11:51:23	Clinical Overview		115		5	Data Discrepancy	Decreased levels of CD4 and CD8 after 2 month were not released to the public.
3/29/2022 11:54:32	Clinical Overview		119		1	Study Protocol	Did the participants with preexisting CD* and C-terminal have previous covid or similar corona virus that imparted immunity vs the vaccine imparting immunity?
3/29/2022 11:56:20	Clinical Overview		119		7	Data Discrepancy	Investigators knew that IL-4 was reduced but this was not made public knowledge which negates informed consent.
3/29/2022 11:59:17	Clinical Overview		121	2, 5 and 8		Data Missing	Where is the data for the older age group?
3/29/2022 12:01:10	Clinical Overview		123,124,125	tables		Other	Decreases were not made public.
3/29/2022 12:05:00	Clinical Overview		136	table		Other	Are titers dangerously high in recovered covid participants?
3/29/2022 12:08:40	Clinical Overview		147		5	Adverse Effects - Other	Systemic events increase with dose amount and frequency should question use of boosters?
3/29/2022 12:12:39	Clinical Overview	182-213		adverse events data		Subdivided Data (to make the numbers smaller)	Adverse events should have been grouped to flag areas of interest as many conditions have more than one specific name.
3/29/2022 12:14:05	Clinical Overview		216		2	Data Discrepancy	why are there 31 more in the intervention group than the placebo group?
3/29/2022 12:15:44	Clinical Overview		222	chart		Data Discrepancy	How was it determined that adverse events were not related to vaccination?
3/29/2022 12:17:08	Clinical Overview		237	chart		Data Missing	22 exposures during pregnancy, how many births?
3/29/2022 12:19:12	Clinical Overview		251	chart		Adverse Effects - Other	Only 1 serious event considered study related out of 65? This is not logical
3/29/2022 12:22:45	Clinical Overview		326		3	Efficacy	VE of 66.3% against sever covid was not made public
3/29/2022 14:27:09	https://fb.watch/c35wnw2sdZ/		1		1	Adverse Effects - Other	I discovered this many months ago and it was removed from anywhere I could find it it is now since been reposted if the link is unavailable I do have it saved I haven't figured out how to put it on a page yet or if I even should. But I'm rather concerned that the aluminum not in a particles that created mimicry in the virus that is causing the aluminum nanoparticles to bind to the spike proteins and delivering them to the brain amongst other areas I'm having some difficulty finding the information in the study because I believe they're using a different vernacular instead of aluminum or nanoparticle. Is anyone doing research on this area I'd appreciate knowing and I can concentrate my efforts elsewhere sorry to use this form for submission of a question that wasn't sure where else to put it without being made public.
3/29/2022 15:16:54	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy	page 25			3	Other	They did an ELISPOT assay on only vaccinated to see if cytokine cells Were they expecting a cytokine storm after vaccination?
3/29/2022 15:22:51	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy.pdf	Pages 50, 55, 57		Tables		Other	The number of people in the study keeps changing and it doesn't explain why On page14 they explained 21999 started the study in each of vaccine and placebo groups and other tables have different participant numbers
3/29/2022 15:27:55	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy.pdf	Pages 64-67		p 64 paragraph 2 - page67		Other	Seems like the emphasis changed from a vaccine preventing Covid-19 to one that prevented severe covid since the first endpoint didn't work
3/29/2022 15:30:19	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy.pdf	pages 69-71		Graphs		Other	Mostly white participants very few blacks and hispanics. Does it not work on blacks and hispanics?
3/29/2022 15:32:55	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy.pdf	p 81			3	Other	All T cells decreased after 100 days. Does this mean participants can't respond to other infections?
3/29/2022 15:36:35	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy.pdf	p101-104			1	Efficacy	Geometric mean titers went down significantly from day 52-202 especially in the 65-85 age group
3/29/2022 15:39:13	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy.pdf	p104			6	Adverse Effects - Other	Serious adverse event gastric adenocarcinoma 23 days after dose 1 in younger age group - withdrawn
3/29/2022 17:16:12	125742_S1_M2_24_nonclinical-overview.pdf		6		1	Other	Basic design of mod-mRNA as described by Pallesen 2017 is flawed (unstable) and use of spike protein as an immunogen is already known to cause disease (Wang 2008).

3/29/2022 17:53:22	#43 - 125742_S1_M2_24_nonclinical-overview.pdf - "NON CLINICAL OVERVIEW - needs thorough review" https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf	13, 18, 23, 29.	20256434, female rats were administered 4 total IM doses of BNT162b2 (V9) 21 and 14 days prior to mating and on GD9 and GD20. Serum samples were collected from females prior to vaccine administration, just prior to mating (M0), at the end of gestation (GD21), and at the end of lactation (LD21) and offspring (fetuses on GD21 and pups on PND21). Sera were analyzed for SARS-CoV-2 neutralizing antibodies. After immunization, SARS-CoV-2 neutralizing titers were detected in all maternal females as well as in their offspring (fetuses and pups). SARS-CoV-2 neutralizing antibody titers were not observed in animals prior to vaccine administration or in saline-administered control animals. Page 18 The distribution of a	Adverse Effects - Reproductive Issues	My concerns are regarding: 1- Passage of BNT162b2 to test animal offspring (fetuses and pups), 2- Systemic distribution to many organs including liver, adrenals, spleen and ovaries, and 3-Lack of genotoxicity and carcinogenicity studies according to the ?? "WHO, 2005". 4- Follow was very short, for a few weeks, not months or years. Note all bold and underlined findings from the 4 pages enclosed. I hope this helps. Cheers. Ronald M Gemberling, MD, FACS.
3/29/2022 18:42:38	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy.pdf	16, 18	p16, last paragraph. p18, main paragraph	Other	Discrepancy between CDC public statement and trial data. As the vaccine mandates were being handed down in Aug and Sep 2021, the CDC website said "People with autoimmune conditions may receive a COVID vaccine. However, they should be aware that no data are currently available on the safety of COVID-19 vaccines for people with autoimmune conditions." Page 16 of this document states that people with autoimmune disease were excluded from the Phase 1 of the study. Page 18: "Enrollment criteria for Phase 2/3 were defined to ensure a broad study population representative of the "real-world" populations expected to receive the registered vaccine. Healthy participants with preexisting stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment, were eligible for the study." Was Pfizer including patients with autoimmune conditions in phases 2 and 3 but not recording or disclosing what they learned? How could anyone with an autoimmune condition - and these are conditions that many, many people suffer from - have informed consent when forced by an employer to receive these injections? (I also recall that during the hearings for full approval, they dodged multiple questions about autoimmune conditions. I will continue to try to find this video or transcript.)
3/29/2022 19:09:58	5.3.6	9 & 17	pg 9 Covid 19, Page 17 under Covid 19 1st paragraph	Data Discrepancy	Table 2 said there were 1927 Covid-19 MedDRA PT's, page 17 said there were 3067 cases, 2587 serious relevant events of Covid-19
3/29/2022 20:19:19	STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	103	table 6	Adverse Effects - Other	Significant differences found in Nervous system disorders, most were headaches and migraines. Vaccinated was 1338 incidences of headache compared to only 424 in placebo group.
3/29/2022 20:49:52	STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	106	Table 6	Adverse Effects - Other	There is an increase in the category of Psychiatric Disorders in the vaccinated group over the control group. Not sure if it is significant or not. Mostly it seems to be Insomnia and a few cases of disorientation and abnormal dreams.
3/29/2022 21:10:19	STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	110	Table 6	Adverse Effects - Other	Definite increases were found in the category of Skin and Subcutaneous Tissue Disorders with vaccinated compared to placebo. The largest differences were found in pyritis (itching), hyperhidosis (excessive sweating), night sweats and erythema (redness).
3/29/2022 21:14:26	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.5-Clinical-Overview.pdf	page 24	5	Study Protocol	The BioNTech and Pfizer trials started in April 2020 and are to be tracked for 2 years which means the entire world population has been the "lab rats" for the trials instead of the noted "40,000" subjects listed. The trials are not effectively completed until April 2022. All injections given have been part of the study.
3/29/2022 21:17:02	STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	115	2.7.4.2.4.2.1.2.4.	Other	I find it strange that in just a 6 month period that 21 (vaccinated group) and 26 (placebo group) participants had a life threatening adverse event. They do not state the how many were in the older groups vs. younger groups. How healthy were these participants in the first place? Were they trying to hide AEs in a background of people with bad health already? Just seems strange to me. Normally healthy people are used for phases 1 and 2.
3/29/2022 21:35:31	STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	116	Table 7	Other	Maybe this is OK, but it just seems to be a high number of severe adverse events in the placebo group if these are healthy volunteers. Also the number of severe adverse events in the placebo group that are related to the investigational product (saline) is 1313! Why should this be?
3/29/2022 22:01:02	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.5-Clinical-Overview.pdf	27	2.5.2.2 Biopharmaceutical Studies	Study Protocol	Both bioavailability and bioequivalency seem to me to be relevant because it has been demonstrated that the injection does not stay in the muscle, but enters the blood stream. Further, the injections have their effects when they enter the circulation and become active in organs, blood cells and tissue. They do not stay in the muscle at injection site.
3/29/2022 23:28:06	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.5-Clinical-Overview.pdf	330	1 and 2	Study Protocol	[paragraph 1:[Expansion of vaccine via licensure would ultimately improve the prospect of achieving population herd immunity to bring the pandemic under control.[paragraph 2:] 'are balanced in favor of the potential benefits to prevent COVID-19 in immunized individuals. {It is my view that the study participants are misrepresenting how herd immunity is achieved and they are purposefully presenting the findings in such a way as to obfuscate the danger of the bioengineered inoculation for profit through licensure and for reasons other than public health. In addition, it has been irrefutably proven that the inoculation does nothing to prevent immunized individuals from getting Covid and even repetitively}
3/30/2022 0:26:58	STN-125742_0_0-Section-2.7.3-summary	Pgs 47, 48	1	Efficacy	
3/30/2022 0:47:54	STN-125742_0_0-Section-2.7.3-Summary	53 and 54	Pg 53 para8, pg 54 para 1	Other	Pfizer claims they had large deviations due to dosing administrative errors (76 participants). I can not prove it but this could be a false flag because of it does not give the demographic of the 76 participants and the efficacy could have been very low and they wanted to hide that

3/30/2022 9:39:29	FDA-CBER-20215683-0000054-91	7 also shows in all the individual tables of outcomes. Page 7 is the total.	Table 1 - Bottom Line - Relevant cases (N-42086)	Data Missing	The high percentage of Unknown results? For something being forced on people and people being lied to about its safety the outcomes of the unknown could be very deadly or catastrophic.
3/30/2022 9:47:43	FDA-CBER-2021-5683-0013862	13	6- last sentence	Adverse Effects - Reproductive Issues	After immunization, SARS-CoV-2 neutralizing titers were detected in all maternal females as well as in their offspring (fetuses and pups).
3/30/2022 11:37:16	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.5-Clinical-Overview.pdf	325	2.5.6.1	Efficacy	[Based on clinical data to date, it is expected that BNT162b2 (30 µg) will elicit an immune response that is likely to protect against COVID-19. The total duration of any such protection is currently unknown-Study quote] ME: This disclaimer invalidates the study's final analysis on efficacy since there is no data supporting ANY implied protection. It is unknown and no data exists to confirm injection-induced protection for any duration period. Period.
3/30/2022 12:00:09	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.5-Clinical-Overview.pdf	324	2.5.5.9	Data Discrepancy	"Aside from addition of anaphylaxis and hypersensitivity, the analyses of cumulative post- authorization safety data, including a review of AESIs, are consistent with the analysis of the pivotal clinical study (C4591001). Review of post-authorization data has not revealed any novel safety concerns except for anaphylaxis and has confirmed the favorable benefit-risk profile of the vaccine." [quote from study] Me- There is concrete evidentiary proof of discrepancy between their report and the actual vaers numbers during the mandated EUA in the current chart from the openvaers.com report. There should be two files with supporting evidence. Thank you for your diligence.
3/30/2022 17:08:03	https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf	p 111	8.3.5.1	Other	Need to explain environmental exposure by inhalation or skin contact.
3/30/2022 21:11:02	https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	12	4 - all....	Data Discrepancy	dropbox added "pt info sheet" correlate with all AE please. Highlight pregnancy, info sheet 0 disclosure of spontaneous abortions
3/31/2022 3:16:23	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy	31	1	Data Discrepancy	Surveillance time was much higher for whites and for U.S. residents. Also, blacks, "all-other" races and/or Brazilians showed negative CI combined with "100%" effectiveness rates. If I understand CI correctly, this means the data is unreliable, but showing "great" VE results? This contradicts, or at least challenges, the claim on Page 33, Paragraph 2 that the VE was consistent "...across race/ethnic groups, and on the basis of geographic location..."
3/31/2022 3:17:52	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy	34	3	Study Protocol	"There were 311 participants in the BNT162b2 group and 60 participants in the placebo group excluded for having important protocol deviations..." Since this involves so many more vaccine recipients than placebo, what were the issues? Temperature & storage? Improper injection techniques? ??? What are "dosing/administrative" errors?
3/31/2022 3:19:22	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy	35	5	Study Protocol	"Cases were counted...or from 14 days after Dose 2." This is the longest efficacy evaluation period I've seen referenced in this paper so far -- not even an entire month after dosage.
3/31/2022 3:20:40	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy	39	1	Data Discrepancy	Figure One shows monitoring up to 112 days after first dose. Note slow but consistent increase in Covid-19 infection in BNT162b2, with jumps at ~57 and ~97 days. The report describes this as "virtually flat," but did these results continue to deteriorate over time? Or, increase exponentially?
3/31/2022 3:21:51	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy	58	1	Data Discrepancy	Cf. P. 39. Similar slow but consistent increase in infections in vaccinated group. Did these results continue to deteriorate over time?
3/31/2022 3:22:52	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy	60	1	Data Discrepancy	Large differences seen here and throughout these results in VE for "Asian," "Hispanic/Latino" and "multiracial" groups, and nationally for Argentina and Brazil.
3/31/2022 3:24:45	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy	74	1	Data Discrepancy	Decrease in T cell responses up through Day 184. (Finally, a reporting time longer than two weeks!)
3/31/2022 3:26:01	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy	76	3	Adverse Effects - Other	Discussion of 11-fold higher cytokine response as a justification of boosters, but no discussion of adverse effects.
3/31/2022 3:27:10	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy	79	1	Data Discrepancy	Decrease in T cell reponses up through Day 184.
3/31/2022 3:29:01	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy	81	1	Data Missing	Talks about responses "persisting" for up to 6 months after second dose, but at what level? And, what about a year later? Or two?
3/31/2022 3:29:58	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy	91	3	Adverse Effects - Other	Acknowledgement of a stronger response in the "younger" (18-55) age group. I wish we had this data broken out for people 18-30.
3/31/2022 3:31:16	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy	94	5	Adverse Effects - Other	Acknowledgement of stronger responses in younger people. "GMCs in the older age group were generally lower than the GMCs in the younger age group at the same dose level."
3/31/2022 3:32:23	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy	99	6	Efficacy	Breakdown of decrease in VE factors over six months (and beyond???) Also see Figure 20 on Page 101.
3/31/2022 3:33:20	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy	104	7	Study Protocol	"...results for later time points will be reported when available." Let's hope so.
3/31/2022 11:21:21	FDA-CBER-2021-5683-0002381_2.5 Clinical Overview	Page 117-119	2.5.4.4.1.1.2	Efficacy	P. 119 - T cell responses contracted by Day 43 and plateaued at a lower level toward Day 85. See Figures 4 and 5 on Page 118.
3/31/2022 11:28:34	FDA-CBER-2021-5683-0002381_2.5 Clinical Overview	P. 121	2.5.4.4.1.2	Efficacy	Booster dose necessary at 60 microgram initial dose to increase functional antibody titers.
3/31/2022 11:43:06	FDA-CBER-2021-5683-0002381_2.5 Clinical Overview	P. 126	2.5.4.4.3.1	Adverse Effects - Other	1 member of younger age group withdrawn after SAE of gastric adenocarcinoma.
3/31/2022 11:49:40	FDA-CBER-2021-5683-0002381_2.5 Clinical Overview	P. 127-128	2.5.4.4.3.1	Study Protocol	7 participants excluded from Dose 2 all-available immunogenicity population because they did not have at least one valid immunogenicity result after Dose 2. See Table 45.
3/31/2022 11:55:09	FDA-CBER-2021-5683-0002381_2.5 Clinical Overview	P. 144	2.5.5.1.2.3	Study Protocol	Safety evaluations conducted through a data cutoff date of 13 March 2021.
3/31/2022 12:50:08	FDA-CBER-2021-5683-0002381_2.5 Clinical Overview	P. 146	2.5.5.2.1	Data Missing	For the BNT162b1 group in Phase 1, 80/84 younger and 11/36 older participants completed the study.
3/31/2022 13:11:45	FDA-CBER-2021-5683-0002381_2.5 Clinical Overview	P.147	2.5.5.2.2.1	Adverse Effects - Other	Local reactions increased in frequency and/or severity with increasing dose levels and number of doses. Most local reactions were mild or moderate in severity, and resolved within several days of onset.
3/31/2022 13:22:15	FDA-CBER-2021-5683-0002381_2.5 Clinical Overview	P. 147	2.5.5.2.2.2	Adverse Effects - Other	Systemic events generally increased in frequency and/or severity with increasing dose level and number of doses for BNT 162b1 and BNT 162b2. Most systemic events were mild or moderate and were short-lived. The incidence of any systemic events were the same for the younger and older age groups. The incidence of severe systemic events was similar in the younger and older BNT 162b2 groups, and were substantially less frequent than the severe events reported for younger and older BNT 162b1 groups.
3/31/2022 13:53:37	FDA-CBER-2021-5683-0002381_2.5 Clinical Overview	P. 147-148	2.5.5.2.3	Adverse Effects - Other	45% of participants across all age groups and dose levels who received BNT 162b1 and BNT 162b2 reported one or more adverse events from Dose 1 through 28 days after Dose 2. Most adverse events were considered by the investigator as not related to study intervention and mild to moderate in severity, and all adverse events were reported as resolved. No deaths occurred in the Phase 1 part of Study BNT 162-01.
3/31/2022 14:07:33	FDA-CBER-2021-5683-0002381_2.5 Clinical Overview	P. 149	2.5.5.3.2	Adverse Effects - Other	For BNT 162b1, reactogenicity (particularly systemic events) increased after Dose 2 compared to Dose 1.
3/31/2022 14:20:04	FDA-CBER-2021-5683-0002381_2.5 Clinical Overview	P. 150	2.5.5.3.2.2	Adverse Effects - Other	Prompted systemic events generally increased in frequency and/or severity with increasing dose level and number of doses of BNT 162b1 and BNT 162b2. Most systemic events were mild or moderate , arose within 1-2 days of dosing, and resolved within several days of onset. No potentially life threatening events were reported.
3/31/2022 14:43:04	FDA-CBER-2021-5683-0002381_2.5 Clinical Overview	P. 150-151	2.5.5.3.3	Adverse Effects - Other	Adverse events were generally lower in the older age groups compared with the younger age groups. Across BNT 162b1 dose levels, 42% to 50% 0f younger participants and 25% to 58% of older participants reported adverse events. Across BNT 162b2 dose levels, 33% to 42% of younger participants and 8% to 25% of older participants reported adverse events. The investigator did not consider the adverse events to be related to study intervention. For the BNT 162b2 study, 6(50%) participants in the younger age group and 3(25%) participants in the older age group reported at least one adverse event. No deaths were reported in either the younger or older participants in the BNT 162b2 group.

3/31/2022 15:19:10	5.3.6 Cumulative Analysis of Post-Authorization adverse event reports of PF-0730202048 (BNT162b2) Received through 28-FEB-2021	11	Not sure if I'm supposed to count? I don't see a number in the document...	Adverse Effects - Other	COMMENT 2: The Vaccine Associated Enhanced Disease (VAED), including Vaccine Associated Enhanced Respiratory Disease (VAERD) section in the Pfizer document 5.3.6 Cumulative Analysis of Post-Authorization adverse event reports of PF-0730202048 (BNT162b2) Received through 28-FEB-2021 on page 11 states "No post-authorized AE reports have been identified as cased of VAED/VAERD, therefore there is no observed data at this time. An expected rate of VAED is difficult to establish so a meaningful observed/expected analysis cannot be conducted at this point based on available data. The feasibility of conducting such an analysis will be re-evaluated on an ongoing basis as data on the virus grows and the vaccine safety data continues to accrue." It is my comment that there was plenty of data to support vaccine adverse events related to VAED and VAERD at that time, as implicated in the screenshot below:
3/31/2022 15:40:30	FDA-CBER-2021-5683-0023032-to-0023065_125742_S1_M5_c4591001-A-P-adva-sas.txt	Computer Code	NA	Other	Nothing. See document but not much in this. After review, someone can cross off.
3/31/2022 16:32:02	FDA-CBER-2021-5683-0002381_2.5 Clinical Overview	P. 149-150	2.5.5.3.2.1	Adverse Effects - Other	For both BNT 162b1 and BNT 162b2, the frequency of local reactions was lower in the older group than the younger group. 2 (16.7%) participants in the BNT 162b2 thirty (30) microgram younger group and 1 (8.3%) participant in the BNT 162b2 thirty (30) microgram older age group reported at least one (1) severe adverse reaction. No deaths were reported in either group. Adverse events were most commonly reported in the system organ class (SOC) of nervous system disorders (3 [25%] participants in the younger age group and 1 [8.3%] participant in the older age group), followed by musculoskeletal and connective tissue disorders (1 [8.3%] participant in each age group). No deaths of Phase 1 participants were reported in the BNT 162b2 Study through the March 13, 2021 cutoff date.
3/31/2022 17:18:59	FDA-CBER-2021-5683-0002381_2.5 Clinical Overview	P. 152-153	2.5.5.4.2.2	Adverse Effects - Other	List of adverse events and percentage of participants affected, including fatigue, headache, muscle pain, chills, diarrhea, joint pain, fever, and vomitting. Younger group suffered more adverse events than older group. Severe systemic events occurred only after the second dose of BNT 162b2, and were reported for fever, fatigue, headache, chills, and muscle pain. No grade 4 events were reported.
3/31/2022 17:31:54	FDA-CBER-2021-5683-0002381_2.5 Clinical Overview	P. 153	2.5.5.4.3	Adverse Effects - Other	Adverse events - Phase 2. For BNT 162b2, only two (2) serious adverse events reported for myalgia and gastric adenocarcinoma. Both not attributed to the study.
3/31/2022 17:37:35	FDA-CBER-2021-5683-0002381_2.5 Clinical Overview	P. 159-161	2.5.5.5.1.2	Adverse Effects - Other	Table 54 provides disposition of all randomized subjects for Phase2/3 for subjects > 16 years of age, including the number of deaths and adverse reactions.
3/31/2022 17:54:23	FDA-CBER-2021-5683-0002381_2.5 Clinical Overview	P. 161-164	2.5.5.5.1.3	Study Protocol	Table 55 gives demographic characteristics of participants. 75% of participants were either overweight or obese. 68.9% of the placebo group were overweight or obese. P. 164 - 20.7% of the participants had any comorbidity. The most frequently reported comorbidities were diabetes (7.7%), chronic pulmonary disease (8.1%), and any malignancy (3.6%). In the younger age group, 13.3% had any comorbidity, the most frequent being diabetes ((3.7%) and chronic pulmonary disease (7.4%). In the older age group, 31.6% of the participants had any comorbidity, the most frequent being diabetes (13.6%) and chronic pulmonary disease (9.1%).
3/31/2022 18:01:51	FDA-CBER-2021-5683-0002381_2.5 Clinical Overview	P. 164-166.	2.5.5.5.1.3.2	Study Protocol	P. 164 - Table 56 shows demographic characteristics of subjects with at least 6 months of follow-up time after Dose 2. P. 165 - 69.4% of subjects were either overweight or obese.
3/31/2022 18:09:22	FDA-CBER-2021-5683-0002381_2.5 Clinical Overview	P. 168-170	2.5.5.5.2.1	Adverse Effects - Other	This section pertains to reactogenicity in Phase 2/3. Pain at the injection site, including severe pain, was reported more frequently in the younger group than the older group, and substantially more frequently than in the placebo group. Local reactions resolved within 1-2 days in both age groups.
3/31/2022 18:39:25	5.3.6 Important Potential Risk	25	Table 7 AESIs Evaluation of BNT162b2	Adverse Effects - Other	h subjects with age ranged between 1 (28 days) and 23 months e subjects age range 2 and 11 years
3/31/2022 18:44:59	#19-STN 125742-0-0 Section 2.5 Clinical Overview	30	2.5.4.1.2.1	Efficacy	Study intended to evaluate safety and efficacy of vaccine BNT162b1 and b2. Yet, "Efficacy was not evaluated in Phase 1." Evaluation of efficacy does not start until when? Phase 2? No clarification is offered. I find this troublesome.
3/31/2022 19:12:29	STN-125742_0_0-Section-2.5-Clinical-Overview.pdf	182	Table 59	Other	Event terms were not lumped together using synonymous terms and counting all of the terms in the group as a whole, thus lymphedema has very slight lower count. Not carefully identifying disease concepts and MedDRA dictionary codes that fall under that concept can be misleading. It doesn't appear to me that safety surveillance was done for signal terms and the concepts they fall under. A comprehensive medical review doesn't appear to be done. There is not explanation of case reviews and whether the cases contained alternative etiologies such as medical history of the adverse event, concomitant meds that could have contributed to the event, the latency period etc.
3/31/2022 19:16:09	FDA-CBER-2021-5683-0000079, to 0000081	pages 26 to 28	5.3.6 3.1.4	Adverse Effects - Other	Medication Error Medication error case outcomes fatal(7) with comment at end of paragraph indicating relationship between medication error and death is weak page 26 0000079; Not recovered (189 0f which 84 are serious); Unknown (1498 of which 84 are serious)
3/31/2022 19:32:26	FDA-CBER-5683-0000078 AESIs Evaluation for BNT162b2 Table 7	page 25	" h. subjects with age ranged from 1 (28 days) and 23 months"	Adverse Effects - Other	"h. subjects with age ranged from 1 (28 days) and 23 months'
3/31/2022 19:45:46	FDA-CBER-5683-0000065	page 12	Table 6 Description of missing information	Adverse Effects - Reproductive Issues	See Table 6 use in Pregnancy and lactation for adverse events that occurred
3/31/2022 19:49:53	FDA-CBER-5683-0000062	page 4	Table 2 Events reported in greater than 2% cases	Adverse Effects - Other	Total number of events-93473; COVID-19 1921 (4.6%)
3/31/2022 20:24:52	BNT162b2 2.7.4 Summary of Clinical Safety	114	2.7.4.2.4.2.1.2.1.1. P	Adverse Effects - Other	They state "few AEs were reported" but some do look significant such as: general disorders and administration site conditions (19.0% BNT162b2 vs 2.0% placebo), musculoskeletal and connective tissue disorders (6.0% BNT162b2 vs 3.0% placebo), and nervous system disorders (5.0% BNT162b2 vs 0.0% placebo).
3/31/2022 20:41:21	STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	119	5th paragraph on page 119	Adverse Effects - Other	I find the hearing loss AEs to be high in these age groups, but in addition to that, the investigator even felt that 2 of them were related to the vaccine. No reasons were given for the other losses.
3/31/2022 20:49:51	STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	120	Table 8.	Adverse Effects - Other	Blood and lymphatic system disorders are much higher in vaccinated group (118) than placebo (32). The majority of these were lymphadenopathy (87 vs 8), but iron deficiency anemia may also be noteworthy (9 vs 5).
3/31/2022 21:13:04	STN-125742_0_0-Section-2.5-Clinical-Overview	238	Table 64	Adverse Effects - Other	Cases of varying degrees and types of burns (first, second, and third degree burns, thermal burns, oral cavity burns and chemical burn of eyes)
3/31/2022 21:51:28	STN-125742_0_0-Section-2.5-Clinical-Overview	239-240	Table 64	Adverse Effects - Other	A number of diabetes reports and diabetes related events/complications under Metabolism and Nutrition Disorders (T2DM, DM, Glucose tolerance impaired, Hyper and Hypoglycemia, DM inadequate control, Diabetic ketoacidosis, Insulin resistance, Metabolic syndrome, Polydipsia, Investigations: Blood glucose increased, Blood glucose abnormal
3/31/2022 23:54:13	Summary of Clinic Safety	Pages 82-113	2.7.4	Adverse Effects - Other	The System adverse event data count does not match the tally numbers in the report. I will attach the data I found. Cardiac adverse events are very disturbing. Surprisingly Myocarditis was not listed as an adverse event, but others cardiac adverse events were also disturbing. Summary attachment included.
4/1/2022 0:24:54	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	p.25	6	Other	Follow-up visits are to last from 1 week to 24 months after Dose 2. How were these vaccines approved without all the follow-up visits?
4/1/2022 0:27:44	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	25	7	Other	There's mention of a 3rd dose. Was a booster always in the plan?

4/1/2022 0:33:07	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	27	3	Other	Placebo group became eligible to receive vaccine after 6 months. Study loses its control group.
4/1/2022 0:36:53	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	27	last paragraph	Other	A potential 4th dose is mentioned. Was a 2nd booster planned?
4/1/2022 8:36:37	Definition of SAE, 10.3.2	155	10.3.2	Data Missing	The definition of SAE is a serious adverse event. Each SAE MUST be recorded and determined causality by an investigator. How many SAE were recorded? Was the recorded cause the vaccine? Since all SAE's HAVE to be recorded, where is that data?
4/1/2022 10:23:59	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy.pdf	104	2nd paragraph under "Disposition"	Adverse Effects - Other	They note a participant was withdrawn after the first dose because of a severe adverse event (I believe SAE stands for) of gastric cancer. It states: All 360 participants received both doses of study vaccine, except for 1 participant in the younger age group who was withdrawn from the study after Dose 1 of BNT162b2 but before Dose 2 because of an SAE of gastric adenocarcinoma 23 days after receiving Dose 1."
4/1/2022 10:36:44	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy.pdf	105	4	Efficacy	The paragraph states: "Of note, 50% neutralizing GMTs at 1-month post Dose 2 for both younger (GMT = 399.4) and older participants (GMT = 255.0) in the evaluable immunogenicity population were similar to the GMTs of a comparative panel of HCS (GMT = 319).8 The HCS is the same panel described in Section 2.7.3.1.3.4 except that 5 sera from the N=38 serum panel had been depleted." I found this elsewhere as well. The HCS panel are the naturally infected control group of only 38 people that had a positive covid diagnosis "at least 14 days prior" to being tested. Some issues with this that I already submitted in another report is they only tested this control group ONCE (they tested the vaxx group at multiple points and they did not have detectable antibody levels until after day 22; this control group all had detectable levels already at their one time test date), they had a wide age range in this small group 18-85 year olds and they note that all the older groups have consistently lower antibodies (and they don't describe the breakdown of the ages of these 38 people anywhere that I have found yet so was it one 18 year old and 37, 85 year olds which would drive down the antibody levels of the control group)? Further according to the CDC website it takes 1-3 weeks after infection to have detectable antibodies and they note that some of these people could have been only 2 weeks post-infection so they don't even give them the full time to reach peak antibody level. Still with all of that factored in at one month out post dose 2 the vaxx group had "comparitive" levels to the naturally infected HCS group - in fact the HCS group had higher levels than the older participants. So I believe this really calls the efficacy of the vaccine, given the study design and the what seems to be a very poor control group of 38 people and they ended up with comparible levels of antibodies. And I do not believe the set up is intellectually honest.
4/1/2022 11:15:02	FDA-CBER-2021-5683-0013861	7	3	Study Protocol	Throughout the document reference is made (Study design is based on the WHO guidelines for vaccine development 2005) is used. Question: Given newer technology MRNA, LNP, Spike and a "Novel Vaccine" of 2020 and 2021, the WHO has no updated study design to cite? (In consideration of request for full authorization) My concern for example, would be with toxicology studies , considering the short 21day recovery period sited throughout the document. (With the exception of 1- 55 day observation period in another section of the paper).
4/1/2022 12:07:49	Nonclinical overview FDA-CBER-2021-5693-0013861	7 and 14 examples	Pg.7 Parag 3 and Pg 14. 2.4.2.3 an 2.4.2.4	Study Protocol	A. Question: Using WHO guidelines of 2005, not necessary to study or additional studies? A. Toxicology B. Safety Pharmacology C. Pharmacodynamics Given the general population at large are being mandated to take the vaccines, and given the fast-track EUA was implemented, there would be no understanding as to issues that may surround possible/probable adverse interactions to those required to take any number of Phamaceuticals. I personally find the unethical. B. Keeping in mind this is a preclinical overview and recovery phase of 21 days after dosage is referenced, the verbiage used throughout this paper ie: Not considered necessary, typically associated with, proposed, anticipated, expected to be, considered incidental, generally not used, partially recovered/reversed, suggesting recovery, recovery in progress etc. doesn't exactly exude safety especially when seeking full authorization of a Novel Vaccine with new MRNA technology and LNP and this particular Spike protein.
4/1/2022 13:22:54	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy.pdf	137	Table #42	Study Protocol	This table shows the breakdown of comorbidity status of vaxx vs. placebo participants that contracted covid after 7 days from dose #2 (and the data is a little confusing as the numbers don't seem to add up to me), but what is clear is when looking at the breakdown the vaxx group had a total of 4 for "any comorbidity" and the placebo group had a total of 86 for "any comorbidity." So it seems clearly that the placebo group was much sicker or immunocompromised when compared to the vaxx group, and again seems to be a clear study error or intellectually dishonest representation.
4/1/2022 13:47:09	FDA-CBER-2021-5683-0023455-to-0023486_125742_S1_M5_c4591001-A-define-2-0-0.xsl	Computer Code (approx 50 pages)	NA	Other	XML Stylesheet (XSL document) really no content.
4/1/2022 17:05:15	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	29	last line on page	Other	The immunocompromised were to be EXCLUDED from the study. Why were they the 1st targeted to receive the vax. The 2nd booster was just approved for those over 50 & THE IMMUNOCOMPROMISED.
4/1/2022 17:10:28	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	34	2.7.4.1.2.1.1. Disposition	Other	The group of 12 who received 60mg didn't not receive Dose 2 because of Dose 1 reactogenicity. What were those reactions & how many of the 12 were affected? No link provided.
4/1/2022 17:14:54	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	34	2.7.4.1.2.1.1.Disposition	Other	11/36 older participants didn't complete study. 2/3 of group in study drop out without any explanation?
4/1/2022 17:20:15	https://docs.google.com/forms/d/e/1FAIpQLSefx2Lh1cMQHbp-rIXG_Yr5mM1c9akRdXt9nRVANoFFXIe1Sw/viewform?pli=1&pli=1	36	4	Other	All participants...randomized to placebo group received both doses.... There were no control groups at the 6 month period?!
4/1/2022 17:24:31	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	36	2.7.4.1.2.2.2.Exposure	Other	Mention is made of the group that received 100mg. On p34 where the dosage amounts are listed, there was nothing about 100mg; the max was 60mg. Why did only the younger group receive the 100mg?
4/1/2022 18:47:16	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	48	3	Other	MOST AEs were consider....not related to study. MOST AEs were mild to... How did the investigator determine that? No definition of MOST.
4/1/2022 18:51:07	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	49	4	Other	...(NO severe TEAEs were assessed as related). What was the criteria to assess that?
4/1/2022 18:56:05	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	50	1 & 2	Other	...(considered NOT related to study...) What was the determining factor?
4/1/2022 19:01:20	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	51	6	Other	All doses...safe & well tolerated except for BNT162b1 @ 100mg... Did those who received 100mg at Dose 1 then go on to get Dose 2? On p34 those who received 60mg at Dose 1 weren't allowed to receive Dose 2.
4/1/2022 19:08:11	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	57	2.7.4.2.3.1.2.	Other	...systemic events....higher severity in younger groups. The age groups were divided between 18-55-yr-old & 65-85-yr-old. If the younger group experienced more AEs, why was this approved for younger than 18-yr-olds?
4/1/2022 19:12:32	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	58	1	Other	...events ....reported less frequently in placebo groups.... The next sentence says that AEs were reported with similar frequencies in both placebo & BNT162b2. Which is it?
4/1/2022 19:17:23	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	58	last	Other	...at least 2 months of follow-up... How many more months than was there follow-up after an AE? Was it by phone?
4/1/2022 19:21:04	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	60	3	Other	...had SAE...not related to study intervention. Why is it labeled SAE if it's not related to study?
4/1/2022 19:26:42	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	67	all of them	Other	Again, the younger group experienced more AEs than the older group. And there were more AEs after Dose 2 than after Dose 1. Why was the vax given to those of younger age and why a 2nd dose?
4/1/2022 19:34:47	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	77	last	Subdivided Data (to make the numbers smaller)	Those who received BNT162 had much higher AEs compared to the placebo group. Rather than comparing them 1 for 1, they made the AEs as a percentage of each group. Which, of course, makes the stand alone pecentages seem much smaller in comparison.

4/1/2022 19:38:59	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf		79		1	Subdivided Data (to make the numbers smaller)	Again, AEs compared to total in each group rather that BNT162b2 to placebo.
4/1/2022 19:41:49	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf		79		2	Subdivided Data (to make the numbers smaller)	This time the comparison is between the older & younger group. If the raw numbers were compared, a much higher rate would be seen.
4/1/2022 19:44:57	STN-125742_0_0-Section-2.5-Clinical-Overview		16	3.4		Data Missing	Sections 2.5.1 and 2.5.11 are place holders only... Mission rational for product development and context for this therapeutic...
4/1/2022 19:52:09	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf		241	last		Adverse Effects - mYocarditis	...life-threatening SAE of myocardial infarction...lasted 1 day & resolved the same day. Is it even possible to have such a life-threatening SAE & resolve it in the same day? Dr. Peter McCullough might disagree with that assessment.
4/1/2022 19:57:05	STN-125742_0_0-Section-2.5-Clinical-Overview		17	last		Other	ivermectin presented as a recommended treatment in clinical studies
4/1/2022 20:28:33	STN-125742_0_0-Section-2.5-Clinical-Overview		18	3-8		Other	P 3 - Formulation of the RNA in the presence of lipid nanoparticles creates a synthetic antigen producing molecule with unknown stability and active life in the host. P 4-8 are likely true for RNA without lipid nanoparticles. Lipids are hydrophobic and, therefore, likely to migrate to areas with increased lipid concentration i.e. the blood stream and fatty tissues. Lipids form non-ionic bonds in and around the RNA stabilizing their tertiary and quaternary structures, and extending their active life within the host.
4/1/2022 20:50:36	STN-125742_0_0-Section-2.5-Clinical-Overview		19	11-13		Other	Vaccine is designed to enter the cell, but not the nucleus of the cell. Therefore the antigenic response that occurs in the cytosol, and is synthetic and foreign to cell and body as the nucleus was not involved in creation of the antigenic response. It is this adaptive "immune response" that required redefinition of the term "vaccine" to replace immunity with a stimulated immune response.
4/1/2022 22:25:35	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf		256	2.7.4.2.4.3.2.5.1.		Adverse Effects - Other	Page 28 mentions that the participants were healthy based on medical history & physical exam. Two participants had past medical history of conditions (listed on p29) which excluded them from the study (i.e. covid-19 & hypertension). When both experienced SAEs the investigator determined they weren't related to the study.
4/1/2022 22:30:42	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf		28	2.7.4.1.1.2.3. Study Population		Study Protocol	In Phase 1 the age groups are divided 18-55 yr-olds & 65-85 yr-olds, inclusive. Why was the age group 56-64 yr-olds not tested? In Phase 2/3 the age group is >/= 12-yr-old. Were there 12-yr-olds in the study?
4/1/2022 22:37:00	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf		256	2.7.4.2.4.3.2.5.1.		Adverse Effects - Other	An older participant had 3 Grade 3 & 1 Grade 2 SAEs & all were assessed as NOT related to the study. Two of the Grade 3 SAEs developed day 7 after Dose 3 & was still administered Dose 4 & suffered 2 more SAEs! NONE related to study!
4/1/2022 22:42:23	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf		257	2nd bullet point		Study Protocol	A disqualifying condition was pregnancy. What does it mean that 2 participants who received BNT126b2 had exposure during pregnancy?
4/1/2022 22:45:59	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf		262		2	Fatality	A person in the placebo group died. Was it related to the study? If not, shouldn't that be mentioned so that the illusion isn't that it was due to the placebo?
4/1/2022 22:53:10	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf		271		3	Adverse Effects - Other	Participant was an adolescent (how old was she?) female who had multiple allergies since infancy (a disqualifying condition on p29). Participant was withdrawn from study. Why was she in it when she'd had history of anaphylaxis to multiple allergens?
4/1/2022 22:59:01	https://docs.google.com/forms/d/e/1FAIpQLSefx2Lh1cMQHbp-nIXG_Yr5mM1c9akRdXt9nRVANoFFXIe1Sw/viewform?pli=1&pli=1		271	2.7.4.2.4.3.4.1.2.		Other	Why are AEs of 40-70 yr-olds in vaxxed group being compared to 71-73 yr-olds in placebo group?
4/1/2022 23:07:44	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf		290		1	Adverse Effects - Other	5 ADRs are added to the CDS but won't affect the safety profile?! The ADRs will be PROPOSED for the BNT162b2 labels.
4/1/2022 23:25:00	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	292-293		last		Adverse Effects - Other	Former placebo participant received BNT162b2 & experienced an anphylactoid reaction who had a medical history of drug hypersenitivity & other allergies. According to p28 participant should NOT have been in the study. The paragraph recommends that clinics take precautions for allergic reactions. WHY WERE THESE VAXXES GIVEN AT DRIVE-THRUS IF THAT WAS A RECOMMENDATION?
4/1/2022 23:32:03	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf		293	after 2nd bullet point		Study Protocol	Disqualifying condition (p29) was known infection w/HIV. 2 participants who died had confirmed stable HIV disease.
4/1/2022 23:38:00	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf		295		5	Other	It is admitted that there is INSUFFICIENT data to determine if the BNT162b2 is safe for pregnant women. WHY WAS IS RECOMMENDED FOR THEM THEN?
4/1/2022 23:41:46	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf		295	2.7.4.3.5 OVERDOSE		Other	It's mentioned that any dose over 30mg was considered an overdose. What about those that received 50mg, 60mg or 100mg?
4/1/2022 23:47:46	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf		296		5	Adverse Effects - Other	The novel safety concern is anaphylaxis is added but there's still a favorable risk-benefit profile. Anaphylaxis can be life-threatening if one isn't near a hospital or in possession of a epi-pen. How does that qualifiy as favorable?
4/1/2022 23:51:13	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf		318	Table		Other	Vaccine 3?! Vaccine 4?! Was a 2nd booster already planned?
4/1/2022 23:56:41	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf		334	Table 31		Study Protocol	Only 1% returned for 1-month follow-up after Dose 2. Only 29% returned for 6-month follow-up after Dose 2. Not a lot of data to go on if so few return for follow-ups.
4/2/2022 0:12:53	125742_S1_M1_priority-review-request-1.pdf		6	1.3 point 2		Study Protocol	These documents were printed in May 2021, The points blames end of lockdowns and restrictions which didn't start till the end of May 2012.
4/2/2022 0:25:56	125742_S1_M1_priority-review-request-1.pdf	most of them		most of them		Efficacy	Their percentages are on people who never had COVID. After dose 2 the numbers went down on people with medical conditions.
4/2/2022 0:34:51	STN 125742_0_0 Section 2.7.4 summary-clin-safety.pdf - "Safety Profile of vaccine and adverse events"		295	2.7.4.3.4. Use in Pregnancy and Lactation		Other	Reproductive Issues - This subsection section states that women who were pregnant or breastfeeding were to be excluded from the trials in this section. On page 295 where the subsection is located, it mentions a DART trial in regards to reproductive issues. DART meaning Developmental and Reproductive Toxicology. Did not provide any details. Simply states "In a DART study, no vaccine-related adverse effects on female fertility, fetal development, or postnatal development were reported." See screenshot. I searched on DART and Pfizer and located a document located at https://www.icandecide.org/wp-content/uploads/2022/03/125742_S1_M1_priority-review-request-1.pdf titled "REQUEST FOR PRIORITY REVIEW, COVID-19 Vaccine (BNT162, PF-07302048), BLA 125742, MAY 2021" This date not long after the cutoff date of 13 March 2021 for the data we are looking at in this section. The Request document provides some explanation of the DART test they had performed. In section 1.4.1 on page 6 of the Request it stated in part: "A developmental and reproductive toxicity (DART) study was completed in rats." There is more about it in the section. See screenshot. I may be remembering wrong, but as soon as the "vax" came out, they were letting anyone over 65, certain comorbidities and emergency/Dr, nurses, etc. get this. And by May 2021, anyone could get it. I do not recall anyone saying "Full disclosure, if u are pregnant or nursing, we have only tried this on a few RATS!!"
4/2/2022 0:35:30	125742_S1_M5_5351_c4591001-fa-interim-publications.pdf	3 bottom portion			3	Data Discrepancy	The paragraph says with this drug the vaccine can dampen the immune system and build up the mrna.

						I know this has been discussed numerous time. I still have other issues to address, but when I got to the end of the report, I read (Under "Overall Conclusions") the last sentence and it says "Overall, the risk-benefit of BNT162b2 30 µg remains favorable." I can only guess they mean "We are not killing or REALLY SCREWING UP too many people at present..." Maybe in another section that would support this statement, but WHAT RISK AND WHAT BENEFIT?? Not in this section. If you are going to say this, CITE SOMETHING!!! By the end of March or April 2020, long before the EUA, it was well known that younger folks up to 55 or more without comorbidities had little to no problems dealing with COVID-19. Feel like crap? Welcome to the flu! I recall March being kinda hairy cuz China and WHO were obviously lying. The PCR tests were so screwed up (can't tell the difference between COVID-19 and the flu) and so prone to false positives/negatives and/or not identifying the underlying infection no one even knew the true risk of either the disease or the "Vax". We DID know over 99% survival rate - phew. If there were no studies done by Pfizer to determine the "TRUE" risks of the disease and the "TRUE" benefit of the "Vax" with REAL, KNOWABLE numbers, that statement is ludicrous, not to mention dangerous...in my opinion, a total LIE - CUZ THEY DID NOT KNOW - COULD NOT KNOW!!! The only TRUE risk I knew of was following the Fauci/CDC protocol indemnifying hospitals/doctors if they followed "The Protocol". Wait til u turn blue, come back, Remdesivir that destroys ur organs, vent and die...
4/2/2022 1:15:20	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	295, 296		2.7.4.5. Overall Conclusions	Data Missing	I cannot help but think of the joke of one rat to another "Rat 1: Did u get the vax yet? Rat 2: NO! I am waiting for the human trials to end!" Some joke huh...BUT TRUE!!!
4/2/2022 9:34:54	125742_S1_M5_5351_c4591001-fa-interim-publications.pdf		4		1 Adverse Effects - Other	everyone (100%) who received 30 and 100 units had a reaction to the vaccine.
4/2/2022 9:39:49	125742_S1_M5_5351_c4591001-fa-interim-publications.pdf		4	Safety and Tolerability para 2	Study Protocol	The people who received the 100 units in dose 1 were only given 30 units in dose 2
4/2/2022 9:44:32	125742_S1_M5_5351_c4591001-fa-interim-publications.pdf		4	Safety and Tolerability para 4	Adverse Effects - Other	4 of the 12 people who were given the 100 unit dose had a grade 3 reaction
4/2/2022 10:59:58	125742_S1_M5_5351_c4591001-fa-interim-publications.pdf		10	Safety assessments para 1	Study Protocol	Only 5 people were watched for 4 hours for AE, the rest were only watch for 30 mins.
4/2/2022 11:32:27	Pdf		16	Neurology	Adverse Effects - Other	
4/2/2022 12:01:58	#43 - 125742_S1_M2_24_nonclinical-overview.pdf		14	2.4.2.3	Other	No safety pharmacology studies were conducted.
4/2/2022 12:10:50	#43 - 125742_S1_M2_24_nonclinical-overview.pdf		16	2.4.3.3.2 and chart 2.4.3-1	Adverse Effects - Other	2.4.3.3.2: study conducted to determine results based on IM administration but IV route used in study. I'm not sure if this is a problem or not; Figure 2.4.3-1 shows lingering concentration of luciferase RNA in liver for ALC-0159 beyond 14 days
4/2/2022 12:14:47	#43 - 125742_S1_M2_24_nonclinical-overview.pdf		33		1 Adverse Effects - Reproductive Issues	Last sentence states that immune response was also detectable in offspring.
4/2/2022 13:12:26	125742_S1_M5_5351_c4591001-fa-interim-publications.pdf		29		1 Study Protocol	They said here and in another spot all subjects were healthy. They used people with compromised immune systems. 100% had some kind of AE and they were healthy, what would the jab do to people with low to no immune systems
4/2/2022 13:41:23	https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	30-38			1 Adverse Effects - Other	Amyloid related issues are mentioned 14 times in pages 30-38 as adverse events of special interest and may induce many horrible effects before causing death. Amyloidosis is a group of diseases in which abnormal proteins, known as amyloid fibrils, build up in tissue. There are several non-specific and vague signs and symptoms associated with amyloidosis. These include: fatigue, peripheral edema, weight loss, shortness of breath, palpitations, and feeling faint with standing.
4/2/2022 14:43:47	STN 125742_0_0 Section 2.7.3 Summary of Clinical Efficacy.pdf		135	Table 41	Study Protocol	Dementia patients included in study. This population cannot give adequate informed consent.
4/2/2022 14:45:24	STN 125742_0_0 Section 2.7.3 Summary of Clinical Efficacy.pdf		159	Table 55	Study Protocol	Dementia patients included in study. These participants are unable to give adequate informed consent.
4/2/2022 14:54:11	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy.pdf		14	3-5	Data Missing	For operational reasons, the first planned IA was not performed. Amendment 9 to the C4591001 protocol eliminated the planned interim analysis at 32 cases and provided for 3 interim analyses to be performed after accrual of at least 62, 92, and 120 cases
4/2/2022 14:54:41	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy.pdf		14	3 , 4 and 5	Data Missing	For operational reasons, the first planned IA was not performed. Amendment 9 to the C4591001 protocol eliminated the planned interim analysis at 32 cases and provided for 3 interim analyses to be performed after accrual of at least 62, 92, and 120 cases.
4/2/2022 14:54:42	STN 125742_0_0 Section 2.7.3 Summary of Clinical Efficacy.pdf		104	2.7.3.2.2.2.1	Adverse Effects - Other	A young participant was withdrawn due to SAE (serious adverse event) of gastric adenoma 23 days after Dose 1.
4/2/2022 14:57:28	PF-07302048 (BNT162 RNA-Based COVID-19 Vaccines) Protocol C4591001 Protocol Amendment 14, 02 March 2021		2	Protocol Amendement Table - Summary and Rationale for Changes	Other	*Protocol Amendment 14, 02 March 2021 Approximately 600 people in the Phase III of the trial will receive an additional dose of BNT162b2 5 to 7 months after their second dose (of BNT162b2 or BNT162b2SA) to determine if the vaccine is effective against variants. 30 of those who got BNT162b2SA, will get a further dose of the SA shot. So this suggests that 600 subjects were expected to get a third shot. It is not clear how many doses the group of 30 were expected to get. The 3rd main paragraph or bullet mentions 'booster vaccination'. *Protocol Amendment 13, 12 Feb. 2021(page 3) Talks about 'boostability' of BNT162. Phase 1 subjects will get an additional dose of BNT162b2 in 6 to 12 months after their second dose of BNT162b1 or BNT162b2. It seems to me that booster shots of several of the vaccine candidates were planned for during different phases of the Phasel/II/III trials.
4/2/2022 21:38:17	FDA-CBER-2021-5683-0013883		23		2 Other	Organ weight changes; inflammation response and increased size of iliac lymph nodes and increased size and weight of spleen.
4/2/2022 21:50:27	reissue_5.3.6-postmarketing-experience.pdf		6		3 Study Protocol	Pfizer had their marketing team set the priority of the AEs
4/2/2022 22:00:25	FDA-CBER-2021-5683-0013878(125742_S1_M2_24_nonclinical-overview.pdf)		18	2.4.3.5 (or paragraphs 2 & 3)	Other	Metabolism: This may be adverse, but I don't know. The paragraph discussed lipids and metabolism.
4/2/2022 22:02:45	reissue_5.3.6-postmarketing-experience.pdf		10	b	Fatality	They claim 4 people died the same day of the jab, but it was due to ill health, but in document 125742_S1_M5_5351_c4591001-fa-interim-publications.pdf page 29 they stated all participants were healthy.
4/2/2022 22:16:28	reissue_5.3.6-postmarketing-experience.pdf		11	a	Adverse Effects - mYocarditis	Small list of side effects including AEs on children
4/2/2022 22:27:46	reissue_5.3.6-postmarketing-experience.pdf		12	Pregnancy cases	Fatality	31 babies died in the womb
4/2/2022 22:30:21	reissue_5.3.6-postmarketing-experience.pdf		13	Paediatric individuals <12 years of age	Adverse Effects - Other	34 peds jabbed 24 serious AE
4/2/2022 22:35:21	reissue_5.3.6-postmarketing-experience.pdf		13	Vaccine Effectiveness	Data Discrepancy	They said in the note after 14 days if the patient gets covid considered a potential lack of efficacy even if the vaccination course is not complete
4/3/2022 9:16:31	BNT162b2 2.7.4 SUMMARY OF CLINICAL SAFETY		20	First paragraph -chart	Data Missing	Questions about the population. What is the number of people in the population who were in the screened set and in the safety set (SAF)? Did researchers pre-determine who would be excluded, what outliers would be excluded, and how outliers would be treated? Are the excluded cases outliers available to review?
4/3/2022 14:24:31	125742_S1_M2_24_nonclinical-overview.pdf		25	2.4.4.3.1	Fatality	"The most common macroscopic observation in the BNT162b2 (V8) group was a thickened injection site and/or induration noted for nearly all animals (16/20) at necropsy." There's 20 animals, however in Table 2.4.4-1 (page 22), referring to this study #38166, there should have been 30 animals (15/sex). I noticed when they discussed the next study, they explicitly stated that no animals died but that similar text was missing for this particular safety study. I'm guessing that 10 of the 30 animals died.
4/3/2022 17:30:04	125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf		32		6 Adverse Effects - Reproductive Issues	The dosing and schedule is extreme (100ug per week for 3 weeks). They state if pregnant or planning on you can not be in the study

4/4/2022 18:17:02	STN-125742_0_0-Section-2.5-Clinical-Overview.pdf		50 Table 9 "Note: Subjects"	Data Missing	Evidence of infection between the vaccine and controls uses a N-binding antibody test. If you had the vaccine, you will not generally generate Nucleocapsid binding antibodies against infection. This would suggest that the 8 vs 165 rate that they are looking at could not have been relevant since the vaccine group when infected would not have been generated the antibodies that they are testing for. This is the difference between the 8 and 165. My guess would be that you would see roughly the same nasal swab results between the groups and that the unvaccinated folks developed antibodies to a wide variety of the parts of the virus and that the vacinnated folks were predisposed to only produce S-binding antibodies.
4/4/2022 18:28:04	STN-125742_0_0-Section-2.5-Clinical-Overview.pdf		54 Figure 1	Study Protocol	The definition of sickness with C19 included the presence of N-binding antibodies. The divergence in the graphs would seem to suggest that 10 days after dose 1, the intervention group could not longer develop the N-binding antibodies since they would only make spike antibodies post vaccination.
4/4/2022 18:36:08	STN-125742_0_0-Section-2.5-Clinical-Overview.pdf		18 6, second bullet "RNA-based vaccines can mimic antigen expression"	Study Protocol	Their statement: "RNA-based vaccines can mimic antigen expression during natural infection by directing expression of a pathogen antigen with high precision and flexibility of antigen design." Shows that their study design of that determines infection based (in part) on the presence of N-antibodies was done so that the S-antibodies developed in the vaccine arm of the trial would not be detected since their immune system was already trained to develop antibodies angainst the spike and not the nucleocapsid.
4/4/2022 18:40:02	STN-125742_0_0-Section-2.5-Clinical-Overview.pdf		20 2	Other	The study claims "in A SARS-CoV-2 rhesus challenge model, BNT162b2 provided complete protection from the presence of detectable viral RNA in the lungs compared to the saline control with no clinical, radiological, or histopathological evidence of vaccine-elicited disease enhancement.". Since we know that humans can pass on the disease and carry the virus in the lungs, this claim is impossible
4/4/2022 18:42:07	STN-125742_0_0-Section-2.5-Clinical-Overview.pdf		22 6	Adverse Effects - Other	100 ug dose was known to be damaging
4/4/2022 18:44:13	STN-125742_0_0-Section-2.5-Clinical-Overview.pdf		23 6 (last one)	Study Protocol	Describes selection of a subset. How are these folks selected? Did they select themselves? Since their data is not included in this submission it would be a good way to eliminate folks that you don't want to report on.
4/4/2022 18:47:42	STN-125742_0_0-Section-2.5-Clinical-Overview.pdf		24 6 (last one)	Study Protocol	Two of the planned studies (Lot consistancy, and Process 1 and Process 2 comparison) show that Pfizer did not know how their manufacturing processes worked. Where did the second process come from? Could be the reason behind the how bad is my batch phenomenon?
4/4/2022 18:51:11	STN-125742_0_0-Section-2.5-Clinical-Overview.pdf		27 4	Study Protocol	How could informed consent work unless they disclose that they are evaluating two different manufacturing processes with suspected lot to lot deviations?
4/4/2022 18:53:46	STN-125742_0_0-Section-2.5-Clinical-Overview.pdf		27 2.5.3	Study Protocol	They state that "Measurement of the plasma concentration of the vaccine over time is not feasible." Doesn't seem like they wanted to know what it did.
4/4/2022 18:56:22	STN-125742_0_0-Section-2.5-Clinical-Overview.pdf		30 2.5.4.1.2.1.	Study Protocol	Not much of an pandemic with a 1.3% per year illness rate. Why would the sample size assume a VE of 60%? WOuld this allow the study to end early?
4/4/2022 18:58:30	STN-125742_0_0-Section-2.5-Clinical-Overview.pdf		31 3	Efficacy	"the true VE of BNT162b2 is >30% using a beta-binomial model"
4/4/2022 19:02:42	STN-125742_0_0-Section-2.5-Clinical-Overview.pdf		36 2.5.4.3.1.1.	Study Protocol	6x dropout rate (vax v unvax) "There were 302 participants (1.4%) in the BNT162b2 group and 52 participants (0.2%) in the placebo group excluded for having important protocol deviations on or prior to 7 days after Dose 2."
4/4/2022 19:08:02	STN-125742_0_0-Section-2.5-Clinical-Overview.pdf		46 Table 6	Study Protocol	5x dropout rate vax vs unvax.
4/4/2022 19:29:33	#21 - STN 15742_0_0 Section 2.7.4 Summary - clin - safety.pdf	Page 25 Phase 1	paragraph 2	Other	IRC recommended 2nd dose of 100mg not be administered due to reactogenicity after first dose in younger age group - participants instead received a second dose at 10mg. There is no discussion as to the process for evaluating the safety of a 2nd dose being given at all. On page 51 par. 4, there is a mention that 11 of 12 participants received dose 2 of 10mg but results were not yet available at time of this report.
4/5/2022 11:07:32	5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021	NA	NA	Data Missing	"Other" issue explanation: This Pfizer report does not appear to comply with the FDA's Guidance for Industry for Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines. Page 18, lines 528 through 546 provides this listing of expected actions to be taken when vaccine adverse events are reported and the Pfizer summary report does not contain any of this information: b. Section 2: Narrative discussion of actions taken A narrative discussion of actions taken must be provided, including any labeling changes and studies initiated since the last periodic report. This section should include: • A copy of current U.S. product labeling • A list of any labeling changes made during the reporting period • A list of studies initiated • A summary of important foreign regulatory actions (e.g., new warnings, limitations in the indications and use of the product) • Any communication of new safety information (e.g., a Dear Doctor letter) c. Section 3: Index line listing Note: I performed a word search in the Pfizer report using the word "action' and it returned just 2 hits on that word. The only reported action was Pfizer staffing up to manage the influx of adverse event reports. None of the above FDA-required actions were listed.
4/5/2022 11:47:14	NA	NA	NA	Other	I do not see how to submit this question to the team any other way. Today I submitted a finding that my assigned document, BNT162b2 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports, does not comply with the FDA Guidance for reporting actions taken in the event of adverse events. However, I realize that the action reporting MAY have been submitted by Pfizer in a separate document. May I review that document if it exists? My background and education include FDA compliance auditing. Thank you. Anne Woods
4/5/2022 14:22:12	STN-125742_0_0-Section-2.5-Clinical-Overview.pdf		83 2.5.4.3.3.3.	Efficacy	They commonly claim "The posterior probability for the true VE being >30%, given the available data, was >99.99%." A posterior probability, in Bayesian statistics, is the revised or updated probability of an event occurring after taking into consideration new information. The posterior probability is calculated by updating the prior probability using Bayes' theorem. In statistical terms, the posterior probability is the probability of event A occurring given that event B has occurred.
4/5/2022 16:57:00	Internal Review Committee Charter (CT22-GSOP-RF02 6.0) dated 01-Nov-2019 FDA-CBER-2021-5683-0017873.	25-35 list;6 sec 3.2;15 sec 6.2;10 sec 4.5;19;23	25-35 list;6 sec 3.2;15 sec 6.2;10 sec 4.5;19;23;24	Study Protocol	oversight committee members list who cleared continuance of the study. Depose them. Missing "Safety Surveillance Review Plan" that committee followed. Missing committee filled out forms CT22-GSOP-RF11 used to report AE's, SAE's and death along with committee decision to continue or stop study. Committee decides when next higher dose is given and to which groups/prime candidates. Also tasked to look for covid like symptoms in participants at various dosing levels. Response options provided on form CT22-GSOP-RF11are so vague as to essentially guarantee no stoppage of the project/study despite AE's. p 6. A voting quorum is required to stop a study. Pfizer can overrule/remove any stoppage (p. 10 sec 4.5). Missing charter data, meeting minutes from routine meetings and required AE meetings, who left committees and who was assigned as replacement. Oversight committees also tasked with dissemination of information (p. 23. Appendix 2). Conclusion: All committee members KNEW of the AE's, SAE's and Deaths and directed the study to continue or were overruled by Pfizer if they suggested a stoppage. Need complete forms CT22-GSOP-RF11 to see who recommended what or if they even acknowledged the AE's. Smoking Gun of directly responsible oversight committee members.
4/5/2022 19:23:17	STN-125420_0_0-section-2.7.4-summary		180 table 13	Other	Infection and Infestations
4/5/2022 19:29:40	STN-125742_0_0-SECTION-2.7.4-SUMMARY	P.28	1st paragraph	Other	acute myocardial infarction
4/5/2022 23:46:32	FDA-CBER-2021-5683-0000066	page 13-14	Table 6 Description of Missing Information related to vaccine effectiveness	Efficacy	"Note: after the immune system has had sufficient time (14 days) to respond to the vaccine, a report of COVID-19 is considered a potential lack of efficacy even if the vaccination course is not complete." Pt "vaccination failure" one criteria is considered to be "the subject experiences SARS-CoV-2" So what was the purpose of being injected???

4/5/2022 23:57:08	FDA-CBER-2021-5683-0000075	22	Table 7 Renal AESIs AESIs Evaluation for BNT162b2	Adverse Effects - Other	"number of relevant events-70 all serious: relevant event outcome: fatal (23),resolved/resolving(10), not resolved(15), and unknown(22)" Their " Conclusion: This cumulative case review does not raise new safety issues" This is the response to all the adverse events in each body system
4/6/2022 1:23:10	FDA-CBER-2021-5683-0013766 125742-S-1-M1-trans-of-oblig.pdf	page 1 and 2	Table 1 Sponsor Obligations Transferred to Pfizer	Other	Many concerns regarding training, safety, and monitoring during the study. "21CFR 312.56 (d) Ensure discontinuation of the study if the drug presents an unreasonable and sinificant risk to study subjects; notification to FDA and IRB of discontinuation." " In compliance with 21 CFR 312.52 Table 1 below lists the Sponsor responsibilities that were transferred from BioNTech SE to Pfizer Inc in the conduct of the C4591001 clinical study"
4/6/2022 1:41:31	FDA-CBER-2021-5683-0013738 to 41	page 1-4	2.1 and 2.2	Data Discrepancy	2.1 Vaccination record keeping and monitoring. informing individuals about VAERS and VIS and safety monitoring.
4/6/2022 17:54:35	19STN125742-0-0 SECTION 2.5 Clinical Overview	36	Table 1	Subdivided Data (to make the numbers smaller)	It appears that if participant contracted infection during trial AFTER Dose 1 they were excluded from efficacy evaluation. Result is a upwardly slewed level of efficacy since those for which the vaccine failed were not included in the group total for which vaccine was at least partly effective.
4/6/2022 19:58:35	STN-125742_0_0-Section-2.5-Clinical-Overview	119	3, 4, and 7	Adverse Effects - Other	Immune response, including inflammation continued for 6 months after second injection. P3... "the cell mediated immune responses were detectable until Day 184 (approximately 6 months after Dose 2). P4... "The impact of SARS-CoV-2 infection on persistence of vaccine induced immune response could not be evaluated since participants were not routinely monitored for infection in Study BNT162-01." P7... "BNT162b2 induced poly-functional and pro-inflammatory CD4+ and CD8+ T cell responses in nearly all participants and persisted in the majority of participants for up to approximately 6 months."
4/6/2022 20:05:33	FDA-CBER-2021-5683-0013766	1-2	bottom of Table 1 page 2	Study Protocol	"Table 1 Sponsor Obligations Transferred to Pfizer Related to the Conduct of Study" At bottom of Table 1 " Where applicable, contractors who performed clinical supplies, manufacturing, packaging, labeling and/or testing are noted in Module 3 Section P.3.1 of the IND and are, therefore, not included in Table 1" Does this mean Pfizer has no responsibility or liability and it falls on the contractors?
4/6/2022 20:33:59	FDA-CBER-2021-5683-0013900	4	2.6.4.1 Pharmacokinetics Written Summary	Other	"evaluation of the PK and metabolism of two novel lipid excipients (ALC-0315 and ALC-0159) in the LNP and potential biodistribution using luciferase expression as a surrogate reporter or a radiolabeled lipid marker. Th PK study showed the LNP distibutes from the blood to the liver, approx 1% of ALC-0315 and approx 50% of ALC-0159 were excreted unchanged in feces,and there was no detectable excretion of unchanged ALC-0315 and ALC-0519 in the urine." "2.6.4.3 Absorption. The liver appears to be the major site of drug uptake from the blood
4/6/2022 20:42:22	Reissue 5.3.6 Post Marketing Experience	7	Table 1	Adverse Effects - Reproductive Issues	In general it seems strange that most adverse events, serious or not, occur in females. Reproductive issue?
4/6/2022 21:01:11	FDA-CBER-2021-5683-001983 pdf	22	1	Other	"Conclusions I M 50 mcq injection of male and female Wistar rats observed blood.plasma. and selected tissues over 48 hrs using a radiolabeled material similar to BNT162b2. "Total recovery of radioactivity outside of the injection site was greatest in the liver, with much lower total recovery in the spleen, and very little recovery in adrenal glands and ovaries." See FDA-CBER-5683-0013986 page 25 Table 2 for concentration distribution throughout the body of Wistar Hans rats.
4/6/2022 21:23:02	FDA-CBER-2021-5683-0000065	12	2	Adverse Effects - Reproductive Issues	Use in Pregnancy and lactation Table 6 Description of Missing Information " Pregnancy outcomes for the 270 pregnancies were reported as spontaneous abortion(23), outcome pending (50, premature birth with neonatal death, spontaneous abortion with intrauterine death (2 each), spontaneous abortion with neonatal death, and normal outcome (1 each). no outcome was provided for 238 pregnancies. Information in other paragraphs of Table 6 describes other adverse events. There were 116 cases reported exposure to vaccine during breastfeeding babies
4/6/2022 21:28:04	Reissue 5.3.6 Post Marketing Experience	7	Table 1	Subdivided Data (to make the numbers smaller)	126,212,580 doses shipped between 12/01/2020 and 2/28/2021. 158,893 total (reported) events. Female 29,914. Male 9,182. Unknown 2990. (42,086 [26.5%] of total) Age breakdown: =<17 - 175. <16 = 46. <12 = 34. 18 - 30 = 4,953. 31 - 50 = 13,886. 51 - 64 = 7,884. 65 - 74 = 3,098. 75 + =5,214. Unknown = 6,876. Fatal result = 1,223 (0.076%). Note: 19,014 aged 50 and under. 16,196 aged 51 and greater. No indication of death expressed by age. Of the 158,893 evens charted, 116,807 are missing. Is there a reason for omitting information concerning these? If so, what is the rational? It would be edifying and useful to know where in the listed categories those 116 thousand people fit.
4/6/2022 21:36:40	Reissue 5.3.6 Post Marketing Experience	28	Appendix 1 List of Adverse Events of Special Interest	Adverse Effects - Other	I note that this is nine pages of ailments that range from 1p36 deletion syndrome through Zika virus associated Guillian-Barre syndrome. Is this simply a copied list of human conditions or is this actually a listing of all known adverse events reported by the test subjects? It seems to me that clarity and completeness of information and any reasoning behind its inclusion would serve to eliminate subjective and perhaps alarmist readings of this reporting.
4/6/2022 21:59:02	FDA-CBER-2021-5683-0000081- pdf	28	4	Adverse Effects - Other	4.Discussion "this cumulative analysis to support the Biologics License Application for BNT162b2, is an integrated analysis of post-authorization safety data, from the U. S. and foreign experience focused on Important Identified Risks, Important Potential Risks, Important Missing information, Pharmacovigilance Plan, Adverse Events of Special Interest and medication errors. The data do not reveal any novel safety concerns or risks requiring label changes and support a favorable benefit risk profile of the BNT162b2 Vaccine. Hard to believe the companies can state this after 9 pages of adverse events and how many deaths that they have identified themselves in all these documents.
4/7/2022 5:24:40	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf	34, 26	2.7.4.1.2.1.1. Disposition (Phase 1, Study BNT,.7.4.1.2.1.2. Exposure (Phase 1, Study BNT162-01), 162-01), 2.7.4.1.2.2.2. Exposure (Phase 1, Study C4591001)	Data Missing	High dose reactogenicity. Was not sure what to put this under. There were two studies in Phase 1. BNT162-01 and C4591001. They appear to have been running concurrently based on cutoff dates, but difficult to tell. In the BNT Study, they went up to a 60 microgram dose of the b1 version. It is stated that these people were not given another dose due to a decision by the SRC (Safety Review Committee). They do not explain what the problem(s) was. In the C4591001 study, they attempted a 100 microgram dose, also of the b1 and dropped it to 10 micrograms for the second dose due to reactogenicity (these participants received BNT162b1 at 10 µg as their second dose). There is no explanation other than that. Looking at the cutoff dates for the two studies, it would appear that the C4591001 study was begun sooner than the BNT study. If that was the case, then that might explain only going to 60 micrograms in the BNT study. However, they determined that 60 was too much. They certainly did not provide any details on what the adverse events were that caused them to drop those doses. Might have provided from insight in what to expect down the road.
4/7/2022 15:21:29	125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf	4412	1	Other	HIV positive patients were added late into the study after pressure from activist groups, Latino Commission on AIDS and the National Minority AIDS Council. It seems strange that Pfizer would want immunocompromised people in the study and would bend to the pressure of such small advocacy groups.
4/7/2022 15:57:10	125742_S1_M5_5351_c4591001-interim-mth6-invest-signature.pdf - INVESTIGATOR DECLARATION - Clinical Study Report	1	Paragraph 1	Data Discrepancy	I find it extremely problematic that this is the 6 month report on how the vaccine works. My question is this: how did the CDC or NIH permit a vaccine that was not already fully vetted to be used en masse? How does this compare to the normal protocols for vaccine development?

4/7/2022 17:09:52	https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M1_exclusivity-claim.pdf	1	B.	Other	Pfizer is contending that the licensure of "Pfizer-BioNTech- COVID-19" constitutes the first licensure under section 351 (k)(7)(C) of the Public Health Service Act (PHS). Section 351 of the PHS Act defines a biological product as a “virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, … applicable to the prevention, treatment, or cure of a disease or condition of human beings.” Biological products are generally derived from living material--human, animal, or microorganism-- are complex in structure, and thus are usually not fully characterized. A 351(k) application must show that the biological product to be licensed is "biosimilar or interchangeable" to a reference product and uses the same "mechanism of action". The PHS Act defines the “reference product” for a 351(k) application as the “single biological product licensed under section 351(a) against which a biological product is evaluated. Questions: It is unclear whether Pfizer is contending that the reference product is COVID-19 and that the "biosimilar" product is their COVID-19 vaccine. They are referring to "COVID-19" as their product and not "COVID-19 Vaccine" in this Notice of Claimed Exclusivity. Was COVID-19 or COVID-19 vaccine already licensed under 351(a)? There is a clear argument that COVID-19 and also COVID-19 vaccine is not derived from any living material thus is not a biological product. I am not very familiar with the section 351(a) or (k) pathways to regulatory approval, but it would be worth a lawyer looking over this.
4/7/2022 17:25:12	125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf	all	na	Study Protocol	It is unknown from looking at this document which standard was applied for Informed Consent. FDA CFR50.20, Informed Consent Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors, should apply unless the 21st Century Cures Act overrode this guidance. The Guidance document states these components of Informed Consent: 1) Explain to study participant that the vaccine is research with no assurance of safety or efficacy, 2) Risks divulged and not minimized. Risk explanation should include package labeling and previous research study reports for the vaccine, 3) Benefits of the vaccine explained and not overstated; 4) Disclosure of alternative courses of treatment, including off-label medication use (and a footnote on Page 9 of the Guidance states "As FDA has recognized in prior guidance, "[O]ff-label uses or treatment regimens may be important and may even constitute medically recognized standard of care." (So were Hydroxychloroquine, Ivermectin or any other zinc ionosphore with zinc, Vitamin D3 and Vitamin C explained as an alternative course of treatment for COVID19 during the Informed Consent process?); 5) Method of maintaining participant confidentiality to be explained; 6) Explain to participant whether compensation or medical treatments are available in case of vaccine injury. This team needs to understand how much of this Informed Consent Guidance was followed and I cannot tell from this document.
4/7/2022 19:50:06	2022/04/125742_S1_M5_5351_c4591001-fa-interim-sample-crf.pdf	138, 145	N/A	Study Protocol	Instructions for TrialMaxApp only allow reporting of a limited set of symptoms, 11 for the Vaccination Diary which are mostly non-serious, and 9 for the COVID-19 Illness Diary. How were symptoms that did not appear on this list to be recorded and reported?
4/7/2022 21:34:15	Table 16.2.4.1 Listing of Demographic Characteristics – Phase 1, 2 Doses, 21 Days Apart; Table 16.2.4.1.1 Listing of Demographic Characteristics – Phase 1 – BNT162b1 (100 µg); and 16.2.4.4 Listing of Demographic Characteristics – All Subjects	1-21	No paragraph - n/a.	Data Missing	This table reports subject demographics for Phase 1, with various vaccine doses and placebos, for two age groups: 18-55 and 65-85. I do not see the 55-65 group.
4/7/2022 21:38:25	5.3.6 postmarketing experience	17- 50	All the Adverse Events	Study Protocol	In this document of adverse events (some very serious), the conclusion was ALWAYS: "This cumulative case review does not raise new safety issues. Surveillance will continue" It was like they were rubber stamping all the adverse events with the same exact conclusion. Like they were sweeping the adverse events under the carpet and didn't want to acknowledge them. The fact that they reached the same conclusion for all those events doesn't make sense.
4/7/2022 21:42:31	Table 16.2.4.1 Listing of Demographic Characteristics – Phase 1, 2 Doses, 21 Days Apart; Table 16.2.4.1.1 Listing of Demographic Characteristics – Phase 1 – BNT162b1 (100 µg); and 16.2.4.4 Listing of Demographic Characteristics – All Subjects	22, 1858, 1864	N/A	Other	Table 16.2.4.4 Subject demographics start on page 22 for ages 16-55. On page 1858, there is a group of subjects only for ages 65-85. None of them have a BMI over 30. Then on page 1864, there is a lengthy list of subjects that include all those >55 (including ages 65-85). Many of these people have BMIs >30. I am unclear why they separated the 65-85 in one section and then included more subjects within that age range later on in the >55 section. May be nothing.
4/7/2022 21:46:36	Table 16.2.4.1 Listing of Demographic Characteristics – Phase 1, 2 Doses, 21 Days Apart; Table 16.2.4.1.1 Listing of Demographic Characteristics – Phase 1 – BNT162b1 (100 µg); and 16.2.4.4 Listing of Demographic Characteristics – All Subjects	Example: 1346, 2166, 2167	N/A	Data Missing	Subject numbers followed by a cross symbol indicate HIV positive subject - for some reason they do not include these subjects' height, weight and BMI. I am unsure why that data is excluded for that specific health condition. No other symbol is used to distinguish subjects with any other health condition. I do not understand why they felt the need to identify the subjects with HIV specifically in this data set.
4/7/2022 22:19:05	https://phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf	20	Na	Study Protocol	Document shows dosing trials of 10ug, 20ug and 30ug and then it goes on to a 100ug study. May be nothing but a 10X variance in dosings (100ug vs 10ug) seems like a lot.
4/7/2022 23:51:06	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf	20, 21	100 µg columns	Study Protocol	It appeared that there were only 3 subjects in the placebo group for 100 µg. For all age groups in BNT 162b1 and BNT 162b2, they studied 10 µg, 20 µg, and 30 µg. Why the jump to 100 µg? Could this correlate to the more toxic batches noticed in VAERS?
4/8/2022 9:00:11	STN-125742_0_0-Section-2.7.4-summary-clin-safety	57, 67, 77, 79	2.7.4.2.3.1.2. Systemic Events (Phase 2, Study C4591001)2.7.4.2.4.1.2. Systemic Events (Phase 3, Study C4591001), 2.7.4.2.4.2.1.2.1. Adverse Events by System Organ Class,	Data Discrepancy	When looking thru the sections reporting systemic events for Phase 2 and Phase 3, the results were first reported in percentages (See pages 57 and 67). There are results reported in numerical as well as percentage (%) on page 77 and repeated on page 79. The numbers on page 79 are the same as the numbers on page 77 except on page 79 "headache" is included. (The missing "headache" on page 77 not the issue. When u review the percentages of events on pages 57 and 67, they are pretty consistent between Phase 2 and phase 3, pages 57 and 67 respectively. When u look at the reporting in actual numbers on pages 77 and 79, they are no where close! Also see table 6 where the numerical values reported are repeated. For a couple of examples: On page 67, a ballpark percentage for both age groups for headache is about 40%. (On page 57, is about 35%) and chills about 20%. However, when u look at the reporting in numbers on page 79, the percentages reported are 6.1% for headache and 6.2% for chills. In table 6, the reported "headaches" was 1,339 or 6.1% of the Population Number of 21, 926. 1,339/21,9126 = 0.061. If u apply the 40%, that would be 21,926 * 0.40 = 8,770 instead of the 1,339. Hmmm. I considered that the overall population studied and reported on was much greater, but if there are these significant differences, something is bad wrong in the study. Just taking headaches, go from 40% (almost half) to 6%? Huh? Many of the later tables are reported in IR (Incident Rate) as opposed to percentages, but is easy to convert the reported numbers to percentage. Table 6 happens to be in %. Maybe I am missing something and might not be exactly apples to apples, but the differences are certainly stark.

4/8/2022 11:39:14	STN-125742_0_0-Section-2.7.4-summary-clin-safety	68, 69, 70	2.7.4.2.4.1.2. Systemic Events (Phase 3, Study C4591001)	Subdivided Data (to make the numbers smaller)	Not really making numbers smaller, but this is an issue with data presentation. Throughout this section I have been reviewing, they mentioned numerous times reactogenicity and AE (Adverse Events) being reported more in the "Younger age group" than the "Older age group". When the data is presented graphically in Figures 4 and 5, each figure is for a separate age group. The graphic presentation should be able to illustrate visually the differences in reactions from each age group. The purpose of having two separate age groups? Duh. Separating them as they did (separate pages also), the ability to easily discern the difference is taken away. Note, one other observation in reviewing the section is that the "younger" age group covers a large span. 16 thru 55. There is no discussion as to whether the reactions grew as age went down. Seems like something they would be VERY interested in, but did not want to know or report?
4/8/2022 12:32:28	https://docs.google.com/forms/d/e/1FAIpQLSefx2Lh1cMQHbp-rIXG_Yr5mM1c9akRdXt9nRVANoFFXle1Sw/viewform	28	1, 3, 7	Other	text states twice that the study dated 30 April 2020 is to see if a vaccine to "PREVENT* Covid 19 is safe and can help" prevent" CHILDREN and adults from getting Covid 19. These statements conflict with other public statements that the vaccines were intended merely to slow infection, lessen the effects, and/or reduce hospitalization of Covid 19; the study will include children age 16 and up and also children age 12 to 15 years old.
4/8/2022 12:40:43	https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-oversight-committees.pdf	31	6-7	Adverse Effects - Other	This is an explanatory text for a study dated 30 April 2020 in which subjects will get Covid vaccines. The text is addressed to "you" the reader-subject volunteers. It advises ONLY that "The injection could cause pain, tiredness, increased body temperature (fever), chills, headache, and muscle aches. Other side effects could include redness, swelling and itching; loss of appetite, joint aches and sweating." I believe other Pfizer documents which have been reviewed indicate Pfizer was aware of other much more severe possible side effects in April 2020. Thus, this document in conjunction with others may indicate intentional failure to provide informed consent to children and adult participants.
4/8/2022 12:59:06	https://phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf	47	4	Study Protocol	Text of the study (April 2020) for children & adults to see if vaccine prevents covid 19 are instructed what to do if they get a positive nasal swab result after receiving the vaccine. If not experiencing any symptoms they will continue in the study and receive the second dose. If they have a positive swab and are experiencing symptoms, they will not get the 2nd dose but will "be requested to remain in the study." In a common sense manner this sounds as though it would undermine the plan or design of the study.
4/8/2022 13:08:27	https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-oversight-committees.pdf	48-49	pg. 48 para 8, pg. 49 all	Other	text of April 2020 study to see if vaccine prevents Covid 19, notes within paragraph that "risks, which may include negative effects that could make your child unwell or uncomfortable and EVEN POTENTIALLY BE SERIOUS OR LIFE-THREATENING". (emphasis added) When referencing adverse effects or side effects pages earlier in the document it merely mentioned very minor symptoms such as redness, swelling at injection site,itching, pain, tiredness, increased body temperature (fever), chills, headache, and muscle aches, loss of appetite, joint aches and sweating.; The next page does not list any specific serious or life-threatening reactions except to mention possible allergic seizure.
4/8/2022 13:53:43	16.2.4.1 Listing of Demographic Characteristics Phase1,2 Doses, 21 Days Apart	1-15	chart each page	Other	180 test subjects ages 19-82, 103 female, 77 male; only 1 obese or .005%; 90% white; .06% Asian; .03% African American. Lacks diversity of test subjects.
4/8/2022 14:08:14	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf	0-600	N/A	Study Protocol	Barring human error in the 1st 5000 doses of 162b, 2384 placebo (2616 biontech) 2 dose were scheduled with 4 no shows, 93 didn't receive 2nd placebo, 99 didn't receive 2nd biontech. I don't see any obvious pattern but will forge on.
4/8/2022 14:38:39	FDA-CBER-2021-5683-0024763	All pages 14 pages	No paragraph	Study Protocol	This entire document is from the Phase 1, 2 dose trials, Randomized Clinical Trial (RCT) It does not denote Phase 1a or Phase 1b. In a Phase 1a trial the protocol should be for only a small number (3) of subjects to be given the same dose to be given to determine if there are any significant adverse events. In a Phase 1b trial ascending doses can be given to determine the safety of the drug for it's stated purpose. Usually, 20 to 100 test subjects. In this documentation, as a summary, there were 196 subjects, 41 placebos, 49 at 10mcg, 48 at 20mcg, 47 at 30mcg, and 12 at 100mcg.
4/8/2022 14:42:06	FDA-CBER-2021-5683-0032396	All	All	Other	No issues
4/8/2022 14:44:16	FDA-CBER-2021-5683-0029224	1	None	Other	None
4/8/2022 15:54:17	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy-1	13	1	Data Missing	No mention of graphene hydroxide listed in ingredient list. If this is ever confirmed, will be criminal omission.
4/8/2022 16:00:53	STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy-1	13	1	Other	The IRB that approved the studies listed is liable to suits and discovery, and prosecution. It does not have the blanket exemption that Pfizer has, especially in approving studies involving vulnerable populations like elderly, pediatric, and pregnancy.
4/8/2022 16:05:07	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf	Following page 21	Not applicable	Data Missing	Following page 21, why is there not a breakdown of Vaccine Group (10 µg, 20 µg, 30 µg, placebo, 100 µg) for Phase 2 as there was for Phase 1 on pages 1 through 21?
4/8/2022 16:19:45	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf	pages 1-21	Not applicable	Study Protocol	Why is the placebo group smaller than the experimental groups for each age group of BNT 162b1 and BNT 162b2 (each vaccine group of 10 µg, 20 µg, and 30 µg had 12 subjects each for a total of 36, while the placebo group had 9).

4/8/2022 16:25:51	125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf	all	all	Study Protocol	published studies discussing alternative treatment results as required by 21 CFR 50.25(a)(4)? Here is the relevant excerpt from the FDA's Informed Consent Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors DRAFT GUIDANCE Below this guidance excerpt is a reference to a published retrospective study on the effectiveness of alternative treatments for COVID19. Review the previous studies in the footnotes for similar studies published prior to this Pfizer study (which should have been provided to study participants.) Guidance: 4. Alternative Procedures or Treatments A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject. (21 CFR 50.25(a)(4).) To enable an informed decision about taking part in a clinical investigation, consent forms must disclose appropriate alternatives to entering the clinical investigation, if any, that might be advantageous to the subject. (21 CFR 50.25(a)(4).) Prospective subjects must be informed of the care they would likely receive if they choose not to participate in the research. This includes alternatives such as approved therapies for the patient's condition, other forms of therapy (e.g., surgical), and when appropriate, supportive care with no disease-directed therapy.16 This disclosure must include a description of the current medically recognized standard of care,17 particularly in studies of serious illness. Standard of care may include uses or treatment regimens that are not included in a product's approved labeling (or, in the case of a medical device cleared under the 510(k) process, in the product's statement of intended uses).18 FDA believes that treatment options lacking evidence of therapeutic value do not need to be discussed. 15 See the FDA Information Sheet "Payment to Research Subjects," available at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126429.htm, for further information. 16 FDA notes that OHRP may hold a different interpretation of "appropriate alternative procedures or courses or treatment" as noted in their regulatory correspondence. 17 For the purposes of this guidance only, medically recognized standard of care is one evidenced by publication in a peer reviewed journal or recognition by a professional medical society. 18 As FDA has recognized in prior guidance, "[O]ff-label uses or treatment regimens may be important and may even constitute medically recognized standard of care." FDA Guidance, "Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses
4/8/2022 17:52:03	BETA-FDA-CBER-2021-5683-0029230		1 NONE	Study Protocol	Clinical Review of Pfizer Documents Susanne Esch RN BSHCA Sussiq58@gmail.com I initially looked at document BETA FDA-CBER-2021-5683-0024763, I noted that this was a Listing of Randomization Scheme and Actual Vaccine Received – Phase 1, 2 Doses, 21 Days Apart. I noted and submitted my review on Apr., 8 2022 noting that there was no indication if this was a Phase 1a or Phase 1b trial. In a Phase 1a Randomized Clinical Trial (RCT), according to accepted standards only a small sample of about 3 people should be done with the minimal dose of drug given to assess any toxic or adverse effects. If none are found then another small sample of subjects, again 3, with a higher dose to test for adverse reactions, increasing doses are then again tested to determine adverse effects, before moving on to Phase 1b. In Phase 1b, standard practice allows for testing of those doses from Phase 1a on a larger sample size with varied doses to check again for safety and tolerance. This is what I noted in my initial review of this document. It is unclear if a Phase 1a was done first before moving to a larger sample size. • After my review was completed noting the above, I decided to look at some of the documents that are not part of my letter assignment and found some areas of concern regarding subjects that were to be excluded per the below information. 5 subjects were identified because of screening hematology and/or blood chemistry lab values in the Phase 1 trials. It would seem then that these subjects should have been excluded from the trials/and or reporting because of this, but I did not find this to be the case. See below: In reviewing document BETA FDA-CBER-2021-5683-0029230, I noted that the below subjects were included in the trial, per document BETA FDA-CBER-2021-5683-0024763. Inclusion/Exclusion Participant met exclusion criterion #19 (Phase 1 only: any screening hematology and/or blood chemistry laboratory value that meets the definition of a >=grade 1 abnormality) 1 C4591001 1002 10021053 - Subject was included in the trial and given 10mcg dose, twice 21 days apart Inclusion/Exclusion Participant met exclusion criterion #19 (Phase 1 only: any screening hematology and/or blood chemistry laboratory value that meets the definition of a >=grade 1 abnormality) 1 C4591001 1003 10031021 - Subject was included in the trial and given 10mcg dose, twice 21 days apart Inclusion/Exclusion Participant met exclusion criterion #19 (Phase 1 only: any screening hematology and/or blood chemistry laboratory value that meets the definition of a >=grade 1 abnormality) 1 C4591001 1003 10031047 - Subject was included in the trial and given 30mcg dose, twice 21 days apart Inclusion/Exclusion Participant met exclusion criterion #19 (Phase 1 only: any screening hematology and/or blood chemistry laboratory value that meets the definition of a >=grade 1 abnormality) 2 C4591001 1003 10031017 - Subject was included in the trial and given a placebo, twice 21 days apart C4591001 1003 10031070 - Subject was included in the trial and given a placebo, twice 21 days apart ** I would additionally note, that when documents for review are assigned by the first letter of the reviewer to the exclusion of other documents things like the above may be missed, because many of documents may be linked to together to build a bigger picture such as what I have noted above.
4/8/2022 18:27:05	5.3.6. BNT 16262_PF- 07302048(BNT162B2)		38 All paragraphs	Adverse Effects - Other	All of the pages and paragraphs are disturbing there's 42028 cases with 158,288 adverse events how is that you have more AER's then cases
4/8/2022 20:02:43	125742_S1_M5_5351_c4591001-fa-interim-sample-crf.pdf		33 3rd section	Other	I think this section is about being in a test group. One of the exclusions is "Receipt of medications intended to prevent Covid-19". So Pfizer appears to be admitting that there are medications that prevent Covid-19, like possibly Hydroxychloroquine and Ivermectin. Also, if this virus was created in a biolab, then the antidote was probably created as well, which would be the cure for the virus. If there were cures to this virus, then the "vaccine" was irrelevant and unnecessary, especially since it proved to be fatal to many and harmful to many.
4/8/2022 23:53:27	VACCINE BNT 162b1in adults nature2020 10.1038/54.1586-020-2639-4	Page 2	1	Other	The media had to let CDC edit their reports before going on public with them
4/9/2022 1:41:18	STN-125742_0_0		17 2.5.1.2.1.1	Other	Ivermectin is listed as a current therapy in a clinical trial setting for clinical management of Covid-19.
4/9/2022 1:43:47	STN-125742_0_0		18 2.5.1.2.1.2	Study Protocol	The vaccine is based on SARS-CoV-2 spike glycoprotein (S) antigens encoded in RNA formulated in lipid nanopartiles (LPNs) and is referred to as BNT162b. The structural elements of the vector backbones of BNT162 vaccines are optimized for prolonged and strong translation of the antigen-encoding RNA. The potency of RNA vaccines is further optimized by encapsulation of the RNA into LNPs, which protect the RNA from degradation by RNAses and enable transfection of host cells after IM delivery. So one optimization was encapsulating the RNA into LNPs, but it does not describe how the structural elements of the vector backbones of the vaccine are optimized.
4/9/2022 1:45:51	STN-125742_0_0		21 2.5.1.2.3.2.1	Study Protocol	For each vaccine candidate, participants received escalating dose levels (N=12 per dose level) with progression to subsequent dose levels based on recommendation from a Sponsor Safety Review Committee (SRC). Note: the SRC recommended that a second dose of BNT162b1 at 60 µg not be administered due to reactogenicity after the first dose. Note: that at the time of BNT162=01 Interim CSR preparation, data for BNT162b2 dose levels of 50 µg and 60 µg were not available.

4/9/2022 1:48:11	STN-125742_0_0		21 2.5.1.2.3.2.2	Study Protocol	Ongoing, randomized, placebo-controlled study. It was started as a Phase 1/2 study in adults in US, was then amended to expand the study to a global Phase 2/3 study planning to enroll enough participants to accrue sufficient COVID-19 cases to conduct a timely efficacy assessment; ammended to include older adolescents 16-17 years of age, then later amended to include younger adolescents 12-15 years of age.
4/9/2022 1:51:08	STN-125742_0_0		21 2.5.1.2.3.2.2	Study Protocol	In Phase 2/3, participants were enrolled with stratification of younger adults (18-55) and older adults (>55) to achieve approximately 40% enrollment in the older adult group Additional adolescents were added later by a protocol amendment: older adolescents 16-17 were included in the younger adult stratum and younger adolescents 12-15 were analyzed as a separate age stratum. Eligibility in Phase 2/3 included higher risk for acquiring Covid-19 in the investigators judgement, due to medical conditions or exposure. So they changed the eligibility requirements between phase 1 and phase 2/3 as well as, modifying the ages of individuals in the groups.
4/9/2022 1:53:53	STN-125742_0_0		24 2.5.1.2.3.2.3	Study Protocol	Pediatric studies in children < 12 years of age: C4591007 Maternal immunization during pregnancy: C4591015 Immunocompromized adults, children < 18 BNT162-01, C4591024 Booster vaccination(s) with BNT162b2SA. Planned studies of vaccine and booster effects on children, pregnant women were planned.
4/9/2022 1:55:43	STN-125742_0_0		27 2.53	Study Protocol	Pharmacokinetic studies are not usually required for vaccines. Measurement of the plasma concentration of the vaccine over time is not feasible. Pharmacokinetic definition is the process by which a drug is absorbed, distributed, metabolized and eliminated by the body.
4/9/2022 1:58:23	STN-125742_0_0		45 2.5.4.3.2.1.1	Efficacy	There were 311 participants (1.4%) in th BNT162b2 group and 60 participants (0.3%) in the placebo group excluded for having important protocol deviations on or prior to 7 days after Dose 2. A post hoc evaluation was performed to assess the imbalance of these important protocol deviations in the BNT162b2 and placebo groups for the final analysis of efficacy. This showed that the majority of exclusions from the evaluable efficacy (7 days) population in the BNT162b2 group were due to dosing/administration errors or administration of study intervention that was deemed not suitable for use. This is detailed in the C4591001 Final Analysis Interim CSR and in Module 2.73. Most of the exclusions from the efficacy study were a result of dosing/ administration errors or administration of study intervention that was deemed not suitable for use.
4/9/2022 2:02:28	STN-125742_0_0	150-151	2.5.5.3.3	Adverse Effects - Other	In Phase 1 of the Study, the majority of participants who received both BNT 162b1 and BNT 162b2 across age groups and dose levels reported one or more adverse events after vaccine dosing
4/9/2022 2:04:39	STN-125742_0_0	150-151	2.5.5.3.3	Adverse Effects - Other	Adverse event incidences were lower in the older age groups compared to the younger age groups, particularly in those groups receiving the BNT 162b2 vaccine.
4/9/2022 2:07:22	STN-125742_0_0		254 2.5.5.5.3.5.2	Adverse Effects - Other	noted that many times a serious adverse event or life-threatening event would be ruled out by the investigator as not related to the study interventions. Didn't find any criteria as to why that was a rule-out. For instance, a participant with a strong history of blood clots, who received one dose of vaccine and developed a blood clot, was ruled-out as a vaccine related incident. 15 deaths in the vaccinated group mentioned on page 272 were all deemed unrelated to the vaccine. One was an auto accident, one was cholecystitis, one was metastatic cancer but for most of them, I not clear on why they were considered unrelated. All of these cases may be truly unrelated. I just didn't see the reasoning used by the investigator to make the determination. Since they can skew the final data results, I thought I would mention it.
4/9/2022 2:09:38	STN-125742_0_0	270-271	2.5.5.5.3.5.2	Adverse Effects - Other	first 5-6 bullet points.
4/9/2022 2:11:30	STN-125742_0_0		271 2.5.5.5.3.5.2	Adverse Effects - Other	first 3-4 bullets in Life-Threatening Adverse Events section
4/9/2022 2:17:05	STN-125742_0_0	57-112	2.5 (inclusive of the following) 2.5.4.3.2.1.3.3. 2.5.4.3.2.2. 2.5.4.3.3. 2.5.4.3.3.1. 2.5.4.3.3.2. 2.5.4.3.3.3. 2.5.4.3.3.4. 2.5.4.3.3.5. 2.5.4.3.3.6	Study Protocol	period. These tables give Dose 1 and Dose 2 results in subjects either with or with & without evidence of infection 7 and 14 days after Dose 2. Subgrops pertaining to age group, risk status, comorbidity status, severe, CDC definition of "severe," (and some without CDC definition of "severe"), country, ethnicity, race and "at risk". Results indicate most subjects were Caucasian Americans (83%). Analysis sections discuss updated and final analyses of efficacy after Dose 2 for 7 and 14 day periods, and efficacy for "severe" Covid-19 cases, the latter as an updated analysis for greater than or equal to 7 days after Dose 2. Surveillance time is given in 1,000 person-years (indicating a study following 1,000 people for one year would contain 1,000 person years of data). Highest numbers of infection were for Caucasians ages 16 to 55, most cases studied from the US (but Argentina, Brazil, South Africa, Germany, Turkey were also included). Note is made that HIV-positive subjects were included in the summary but not included in the analyses of overall study objectives. The tables included use of the "Charlson Comorbidity Index" categories; however, the Charlson index includes patient age, myocardial infarction, congestive heart failure, peripheral vascular disease, cerebrovascular disease, dementia, chronic obstructive pulmonary disease, connective tissue disease, peptic ulcer disease, diabetes mellitus, moderate to severe chronic kidney disease, hemiplegia, leukemia, malignant lymphoma, solid tumor, liver disease and AIDS. Charlson does not include obesity; however, Pfizer's tables did include obesity and left out most of the Charlson list [Tables 36-37 - risk status and Tables 38-39 comorbidity status]: obese, any malignancy, cardiovascular, chronic pulmonary disease, diabetes and hypertension. Few tables concerned information after Dose 1 (only Tables 22, 23, 32, & 35). Efficacy endpoints were based on positive or unknown NAAT (nasal swab) results. "At Risk" tables included only comorbidity of obesity vs. non-obese subjects. Analysis reported on 2.5.4.3.2.1.3.2 included "posterior probability" for "true vaccine efficacy" greater than 30% was 74.29% which did not meet the prespecified success criterion of >98.6% due to the small number of severe cases observed after Dose 2 therefore statistical testing of subsequent endpoints related to severe disease ended. Note is made on Table 22 that the cutoff date was 11/14/2020 but the snapshot was not taken until 11/16/2020. Posterior probability is the revised or updated probability of an event occurring after taking consideration of new information. It is the probability of event A occurring given that event B has occurred. Additionally noted in 2.5.4.3.2.2. is that observed VE (vaccine efficacy) of 66.3% against severe Covid-19 occurring at least 7 days after Dose 2 did not meet the prespecified success criterion of posterior probability > 98.6% due to the small number of severe cases. One has to question how did they have only 1 severe case when so many patients were on ventilator? It is interesting that Pfizer did not define "severe disease" nor the CDC's definition of "severe disease," at least not in these tables nor in the footnotes. In section 2.5.4.3.3.1, updated analysis, they discuss important protocol deviations including improper administration, errors in dilution of the vaccine, and temperature excursions in shipment or in storage at the distributor. Other reasons for exclusions (Table 28) include did not receive at least 1 vaccination, data considered potentially unreliaable due to lack of PI (principal investigator) oversight, did not receive 2 vaccinations, unblided prior to 7 days after dose 2, subjects without evidence of infection prior to 7 days after dose 2, subjects randomized but did not meet all eligibility criteria [criteria not given], and "other important protocol deviations" (also not given). Per Section 2.5.4.3.3.2, verbiage of "available data" was used. Was there any data that was NOT available? Also, estimated vaccine efficacy by country (on Section 2.5.4.3.3.4), there was "100%" VE in South Africa, Germany and Turkey." Lastly, concerning CI (confidence interval): (example): if an 88% CI is sought, that means we only want a 12% chance that the interval does not
4/9/2022 3:54:03	125742_S1_M5_5351_c4591001-fa-interim-publications.pdf	N/A	N/A	Data Missing	Incomplete Interim Publication - NEJM. Hi, the sections my name has me in basically have no information that I would not be able to make heads or tails of what to do with, so I began going through the section here. When reading the part where the NEJM journal article was, "Safety and Immunogenicity of Two RNA-Based Covid-19 Vaccine Candidates", there were missing charts. I located the article on the Web and and uploading the article and missing charts that were located in a supplemental appendix. I recently provided a submission on my previous section on safety that pointed out the high incidence of headache, chills and other adverse events where the reported percentage of occurrence in the narrative were much higher than the adverse events reported in the tables in that section. E.g. Headaches in 40% of subjects and in the tables only 6%. See Figure S1 in attached supplemental appendix. Am sending just to save y'all time and point out at least that one observation.

4/9/2022 6:35:28	125742_S1_M4_4223_185350.pdf	10	2	Other	This is a radio-labeled mRNA (gene). We know mRNA integrates into the nucleus of certain cells. Red blood cells have no nucleus and no DNA. By finding the mRNA distributed in the liver, spleen, adrenals, ovaries and not RBCs, they know the distribution is in nucleated cells and nucleated cells only.
4/9/2022 6:44:00	125742_S1_M4_4223_185350.pdf	11	section 5.2	Study Protocol	Section 5.2 - rat study to test distribution of mRNA into other tissues was started 17-Jun-2020 and ended 24-Sept-2020. PDF 125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf PAGE 127 shows human trials underway as early as 08-Jun-2020. Why would you start human trials prior to starting animal trials? If this is the case, they did not know the mRNA was distributed throughout tissue for at least 9 days after dosing humans. Standard protocol is to use animal studies to determine ADME prior to expanding into human subjects.
4/9/2022 6:57:32	125742_S1_M4_4223_185350.pdf	20	3	Other	"Low levels of radioactivity were detected in most tissues from the first time point (0.25 h), with the greatest level found circulating in plasma between 1-4 hours post-dose. The plasma and blood mean concentrations and blood:plasma ratios are presented in the table below." Radioactive mRNA was detected in most tissues and concentration was highest in the plasma. This is likely because the mRNA is integrating into the genomes of the WBCs in the plasma / buffy coat. It is less concentrated in the blood (RBCs, which don't have DNA). It is clear, in the rat models, that the mRNA is integrating into the WBCs which are responsible for immune response. A logical conclusion is that the mRNA is distributed to all tissues, cleared by the liver and concentrated in the WBCs.
4/9/2022 7:49:03	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events-sensitive.pdf	2	NA	Data Discrepancy	Page 2 (dated 21-April-2021) reports "no severe and Grade 4 systemic events reported" in all subjects >/= 16 yrs old. FDA document BNT162b2 "Cumulative analysis of post-authorized adverse event reports of PF-07302048 received through 28-Feb-2021" lists thousands of reported severe systemic events almost a month before the 21-April-2021 report.
4/9/2022 9:50:35	125742_S1_M5_5351_c4591001-fa-interim-sample-crf.pdf	Multiple pages	Multiple paras	Adverse Effects - Other	Others will have mentioned this, no doubt - the AEs that participants could list were very limited: temperature, redness, swelling etc. There seems to be nowhere participants could list other AEs such as numbness, tremor etc.
4/9/2022 10:26:18	125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf; 125742_S1_M5_5351_c4591001-fa-interim-invest-signature.pdf; 125742_S1_M5_5351_c4591001-fa-interim-sponsor-signature.pdf - 16.1.5.1 SPONSOR CLINICAL STUDY REPORT APPROVAL FORM	All	All	Other	I found no concerning data.
4/9/2022 11:58:14	FDA Press Release FDA Authorizes Pfizer-BioNTech COVID-19 Vaccine for Emergency Use in Children 5 through 11 Years of Age	1	1	Adverse Effects - mYocarditis	Oct 2021: risk of myocarditis known, BUT determined to be balanced out by reduction in risk of dying from the virus
4/9/2022 13:12:34	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-sponsor-signature.pdf	page 2	n/a	Data Missing	Complete page 2 missing. Note the gap from end of page one to the document approval record which is on page 3. I am submitting screenshots:4 9-22 Second Batch #2 and #4 below to illustrate the missing document.
4/9/2022 13:24:36	125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf	pg. 49	3rd and 4th para from top of page	Adverse Effects - Other	This part of the document is the consent form parents sign for their child to enroll. Together, these two paragraphs are telling parents that the only risks caused by the study vaccine from 350 people plus approx. half of 36,576 people to whom it was administered are: Injection site pain, fatigue (tiredness), increased body temperature (fever), chills, headache and muscle aches. So, Pfizer didn't record any other "risks" in these approx. 18,638 people by the time this consent form was given to parents? (7 Oct 2020 is the date on the side of the page.) Did Pfizer withhold vaccine side effects from parents who were trying to decide whether or not to enroll their children in a medical experiment? When would parents have been reading the consent forms? The FDA presented a slide of possible adverse events that are much more serious in a 22 Oct 20 VRBAC meeting. See slide #16 in https://www.fda.gov/media/143557/download What other, more serious, adverse events did Pfizer know about that they didn't tell parents before parents enrolled their children?
4/9/2022 13:49:14	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-sponsor-signature.pdf	page 1	n/a	Study Protocol	It is vital to attach real names to these studies and the most important ones are these people who felt so assured of their own immortal standing that they put their names to a study knowing what the results and outcomes would be. We have names and faces to prosecute not just theories and ideas. Please find these legal documents illustrated in 4-9-22 BATCH 2 #s 3 and 5. Thank you for your time.
4/9/2022 14:02:32	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-sponsor-signature.pdf	page 1	n/a	Study Protocol	Such a complicated study with thousands of pages and complicated data has ONLY ONE AUTHOR? Dzung Nguyen didn't formally sign anywhere on the document. Do we know if this is a real person? Can they produce this person if called to testify in court? Please find screenshot 4-9-22 Batch 2 #5 uploaded for verification. Thank you for your time.
4/9/2022 14:28:03	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-sponsor-signature.pdf	page 1	N/A	Study Protocol	In addition to Dzung Nguyen, supposed single author of the massive clinical study report, there is no handwritten signature for Kenneth Koury head of statistics and John Perez, clinical lead for all centers. Is a document subject to legal scrutiny without these signatures? Why are they not included as are the signatures of other important witnesses? Please find screen shot for reference; 4-9-22 Second Batch #7. Hopefully, I am not wasting your time with stupid questions. Thanks for your time.
4/9/2022 14:40:03	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-sponsor-signature.pdf	page 3	n/a	Study Protocol	The final approved record for C4591001/16.1.5.1-Sponsor Agent document has no written signatures for either Kenneth Koury or John Perez. Is this to be considered legally binding them to the results and effects of a now-known failure of efficacy? An acceptable electronic signature? Curious minds want to know. Please find screen shot 4-9-22 Second Batch #1 as supporting documentation if needed. Thank you for your time.
4/9/2022 15:01:30	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-sponsor-signature.pdf	pages one and three	throughout-refer to screenshots please	Study Protocol	Two dates: March 16, 2020 and December 3, 2020....3-16-2020...Ugur Sahin, Chief Executive Officer of BioNTech SIGNS OFF on C4591001 Final Analysis Interim Report NINE MONTHS before Stephen Thomas SIGNS OFF December 3, 2020. John Perez and Kenneth Koury are noted to give final approval Dec. 3, but with no signatures. Please find date relative to Sahin's signature on uploaded screen shot 4-9-22 Second Batch #5. Previous screenshots I have provided include dates relative to December 3, 2020. Thanks for your time.
4/9/2022 15:09:58	125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf	multiple	multiple	Other	multiple findings
4/9/2022 15:16:31	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-sponsor-signature.pdf	Page 1	6	Study Protocol	Someone went back with a SHARPIE and wrote in 3-16-2020. Odd but not damning. Except, why not fill it in at the time of signing and why a sharpie and not a pen? Or why not do the whole page again and insert the date properly? It is not initialed by any authority.Suspicious.Why back-date to March if everybody else signed off in December? Please find screen shot 4-9-22 Second Batch #8 for reference.
4/9/2022 15:44:33	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-sponsor-signature.pdf	page 1	n/a	Study Protocol	Ugur Sahin, CEO of BioNTech signed off on the final analysis of the report 3-16-2020, the date in sharpie. Notice the template date [bottom of page] is 01-July-2020 which is 3 1/2 months after the date implied for approval. The template date is not included on Page 3 where Koury and Perez are listed as signing off on the final report, listed as approved December 3, 2020. Is the template date unreconciled to the 3-16-2020 date written in sharpie? Please find screen shot 4-9-22 Second Batch #9 with template verification
4/9/2022 16:05:15	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-sponsor-signature.pdf	page1/2	n/a	Study Protocol	A previous submission may have been in error. I presumed Page 2 was missing, but it appears it was mislabeled by the authors as page 1 information. Please find screen shot 4-9-22 Second Batch #10 as verification that the page in question is either missing or mislabeled as page 1. Sorry. Also note the template date for this page is July 1,2020 which is the same date as the 3-16-2020 sign-off date for BioNTech CEO Ugur Sahin on page 1

4/9/2022 16:13:21	125742_S1_M4_4223_185350.pdf	11	4	Other	100 unit dose - male rats given 100 unit doses had "adverse clinical signs" and dose was lowered to 50 units for the rest of the study. "results are not discussed" for these rats that got 100 unit doses. The dates of this study are July to September 2020 AFTER 12 human subjects were given 100 unit doses in May 2020 (see pages 39 and 51 of 125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf for these 12 subjects). Page 17 paragraph 4 of STN 125742_0_0Section 2.7.3 Summary of Clinical Efficacy.pdf says "The IRC recommended that a second dose of BNT162b1 at 100 units not be administered due to reactogenicity after the first dose" and 10 units were given for the second dose. WHY WAS THE RAT STUDY OF 100 UNITS DONE AFTER 12 SUBJECTS HAD ALREADY BEEN GIVEN 100 UNIT DOSES. THE "REACTOGENICITY" WAS SO SEVERE THAT THE SECOND DOSE WAS LOWERED TO 10 UNITS. WHY ARE THERE NO CRF REPORTS FOR SITES 1001 AND 1002 WHERE THE 12 SUBJECTS RECEIVED THE 100 UNIT DOSES. CRFs are only available for sites 1055, 1081, 1096, and 1128. The 12 subjects given 100 unit doses were at sites 1001 and 1002. What happened to these 12 subjects who were given a dose that was immediately lowered for the rats? 100 unit doses were ONLY given to 12 subjects. Clearly that dose is too high. We need to know the history of these subjects. I will try to upload pdfs of the three Pfizer pdfs I mention above.
4/9/2022 16:16:29	CRFs for site 1055.pdf	general	general	Data Missing	Why are the CRF files only for a few of the many subjects at a given site? Site 1055 has 11 CRFs out of 247 subjects.
4/9/2022 16:52:04	Interim Demographics.pdf Document 125742_S1_M5_5351_c4591001-	7	Tabulated Demographics Table	Other	SAMPLE SIZE: Phase 1: Vaccine candidate BNY162b1. Two age groups. 18 Years of Age (yoa) through 55 yoa and 65 yoa - 85 yoa. No doses given to age group 56 - 64 yoa. No statement as to why not. Sample as stated: 18-55 yoa; 10 mg. , 20 mg., and 30 mg. doses each given to 12 (total) subjects per dose. Placebo doses given to nine (9) subjects. Total sample = 45 subjects. 65-85 yoa group. Same strategy: 10 mg., 20 mg., and 30 mg. doses given to 12 (total) subjects per dose. Placebo administered to nine (9) subjects. Total sample size = 45. Same strategy to the letter for vaccine candidate BNT162b2. Again, total sample size = 45. Twelve additional subjects were given a single 100 mg. dose, with the grand total of three (3) given a placebo. 100 mg. dose total sample size = 15 subjects. Grand total sample size = 105 subjects. I am assuming this Phase 1 trial was for the entire country since no other information is presented about any doses administered to any of the additional thousands of people listed as subjects (3100 + pages of them with 14 per page). THERE IS NO RATIONAL WAY TO EXPLAIN THIS SAMPLE SIZE IN ANY PHASE OF A VACCINE TRIAL IN MY VIEW. IF CLARIFICATION IS TO BE HAD I WOULD LIKE TO HEAR IT. STATISTICALLY THIS IS USELESS AS A PROJECTION OF EITHER EFFICACY OR SAFETY IF EXTRAPOLATED ACROSS THE POPULATION OF THE USA.
4/9/2022 17:02:52	phmpt.org/wp-content/uploads/2022/o4/125742_s1_M5_5351_c4591001_fa-interim-randomization_sensitive.pdf	4407	16.1.7.4 listing of randomization scheme and all subjectsl vaccine received all	Other	two groups one age group 16-55 other group under the age of 55 some received the vaccine and some received a placebo
4/9/2022 17:20:00	125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf	29, 30, 46	P29, paragraph #3	Subdivided Data (to make the numbers smaller)	"If you are part of the selected group of participants, you or your parent(s)/ guardian(s) will be asked to complete an electronic diary about how you are feeling for 7 days after the visits." (These visits refer to when the participant receives their first and second injections) Why would only "select participants" record how they feel for 7 days after their injections? Page 46 - Everyone in the study records covid symptoms into their online diary but only a subset of participants record post-vax side effects. Why? Is efficacy more important than safety? Please also note that these are children.
4/9/2022 17:24:37	phmpt.org/wp-content/uploads/2022/04/125742_s1_m5_5351_c4591001-fa-interim-randomization-sensitive.pdf	page 2000	16.1.7.4 listings of randamizations scheme and actual vaccine received all subjects	Other	oct 29,2020, under 55 group received the vaccine; dose 1.. age 16-55 group received a placebo....dose 1...under 55 group received a placebo dose 1
4/9/2022 17:27:55	125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf	137-140	Screenshots and descriptions from TrialMax app	Study Protocol	This section of the document shows and describes custom reports and dashboards for research teams who are tracking participants. The system tracks the following symptoms: temperature, injection site pain, swelling, redness, fatigue, chills, diarrhea, vomiting, headache, joint pain, and medication. Are these the only symptoms they tracked? Was tracking a list of finite symptoms one of the ways Pfizer tried to "alleviate the large increase of adverse event reports"? Even the "Severe Reactions" dashboard on page 138 seems to only track these basic reactions.
4/9/2022 19:25:18	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf	3105-3139	You only gave me subject line listing for signing informed consent	Other	What location is Site #4444? - See pages 3105-3139 they consented all Whites except for 2 Asians (457 Whites and 2 Asians), during a 4 day period. This is abnormal compared to all of the other sites' enrollment race demographics and amounts of subjects per day.
4/9/2022 19:34:14	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf	page 1-9	n/a	Data Missing	Study participants from page 1 through page 9 are not listed in the compendium of study participants from page 22 to page 3139 where a 'complete list of participants' is alleged to be recorded. There is no further record of these participants. Please find for reference Screen Shot 4-9-22 SECOND BATCH #11; This participant is never listed again anywhere in this information so nothing can be ascertained as to further study. None of the people in this study reoccur.
4/9/2022 19:41:23	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf	pages 20 and 21	n/a	Data Missing	These study participants took 100 mgs; They are not listed in the over-all study participants from page 22 to page 3191
4/9/2022 19:47:41	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf	19	n/a	Data Missing	What data, if any is missing. Odd to leave a page empty. Please find screen shot 4-9-22 Second Batch #13 for reference. Thank you for your time.
4/9/2022 20:10:25	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf	page 10 through18	n/a	Study Protocol	Vaccine Candidate BNT162b2 is suddenly introduced but not with the original participants, Please refer to screen shot 4-9-22 SECOND BATCH #20 and notice the dates of consent screening are exclusively for June and not for March, April or May as for the first group. This is true through page 18.
4/9/2022 20:20:18	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf	pages 20-21	n/a	Data Discrepancy	Pages 20 and 21 are concerned with 13 participants who wee administered 100 mg BNT162b1. They are listed under 16.2.4.1.1. There is no more data about them. Please refer to screen shot 4-9-22 Second Batch #15
4/9/2022 20:54:03	125742-S1-M5-5351-c4591001-fa-interim-demographics.pdf	4-21	16.2.4.1	Data Missing	Table 16.2.4.1 Listing of Demographic Characteristics-Phase 1, @ Doses. 21 days Apart Repeated evidence of nonconsecutive or missing numbers and data. Examples are under subject heading a number would be 10021006 then jump to 10021014, 69 then 71, or71 then 74. Is it data that was excluded during review or something else? Continued throughout Table.
4/9/2022 21:07:45	125742-S1-M5-5351-c4591001-fa-interim-demographics.pdf	1-21	16.2.4.1	Other	BNT162b1 10mcq,20 mcq,30 mcq,and 100 mcq in the (18-55) and (65-85) age groups have 12 human subjects, and 3 to 9 in the placebo groups. BNT162b2 has same numbers in the Phase 1 groups. Under subject heading numbers are not consecutive, for example, number 10011102 then 10011105,or 1001113 the 1011125. this is noted from page 1 to 21.

4/9/2022 23:42:31	16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – Phase 1, 2 Doses, 21 Days Apart and 16.1.7.1.1 Listing of Randomization Scheme and Actual Vaccine Received – Phase 1 – BNT162b1 (100 µg) downloaded from: https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization.pdf	1, 2, 3 to the end	16.1.7.1	Study Protocol	Within the first two pages you can see that the dosing varied by subject from 10 to 20 to 30 micrograms
4/10/2022 13:04:07	125742-S1-M5-5351-c4591001-fa-intermin-audit-certificates.pdf	1-4	pages 1-4	Study Protocol	Are these individuals telling the truth? Is this Regulatory Capture and Big Pharma influence regarding the study information and outcomes? It seems as though we have engineered our own man made demise through science, technology, and greed.
4/10/2022 13:23:05	125742-S1-M5-5351-c4591001-fa-interim-sample-crf.pdf	15	entire page	Fatality	2.1 Cause of Death, 2.3 Comparison Term (hidden), Lowest Term (hidden) are examples on this page to ask what is meant by using the word hidden and why is it used? Where is the hidden information. See the word hidden on pages 30 and 31 again as another exmple
4/10/2022 13:31:19	125742-S1-M5-5351-c4591001-fa-interim-sample-crf.pdf	29,30,31	Illness details (Ill Poten)	Adverse Effects - Other	Illness Details p29-31 numbers 4-14 Term (hidden) written after each detail number . Why is (hidden) included and where is the information if not included? See the word hidden documented in other areas of the document as well. What are they hiding?
4/10/2022 13:42:25	125742-S1-M5-5351-c4591001-fa-interim-sample-crf.pdf	33-35-37	Exclusion Criteria	Study Protocol	Exclusion Criteria: 2b HIV, HepC (HCV or HBV; 2e Immunocompromised individuals, 2f history of autoimmune disease; 2 preganant or breast feeding; 2j immunosuppressive therapy.. The entire list of exclusions could be subject to questions. If these individuals are excluded why has there been such a push to have these people vaccinated with the experimental shot world wide? if they are excluded what information is there to say it is safe and effective for these populations? Where is the evidence?
4/10/2022 13:42:29	16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – Phase 1, 2 Doses, 21 Days Apart	All	NA	Other	Having a grouping of 18-55 year olds is does not give proper risk reward for young adults.
4/10/2022 14:16:32	125742-s1-M5-5351-c4591001-fa-interim-sample-crf.pdf	102,103,145,192	App Subject Facing Screen Report Post 7/12/20	Study Protocol	p 102 App Screen Report info; Use of Trial Max App information. Seems as though it would be very easy for an individual in the trial to find it difficult to enter their information. So how much information was not inputted because of this? Example also include page 145: Their list of reactions included information such as pain at injection site, headache vomiting, diarrhea. chills, fatigue etc. What if the person had other reactions or even death that appear to have no way to be documented in the vaccination diary. Page 192 "went to ER or hospitalized" Where is reason for ER visit, hospitalization, and severity documented?. Only a yes or no response is noted but no to way to document other adverse info in this area. Is some of these adverse reactions documented in the VAERS database and not connected to this study? Page 180 "Note: other messages that could appear on the device include: Error ,unsent answers, something went wrong, etc etc.. people in the study may get frustrated and not enter information because technology is not perfect. " One of society's greatest tools for change is the power of knowledge" Arran Stephens
4/10/2022 14:40:33	125742-S1-M5-5351-c4591001-fa-interim-sample-crf.pdf	81,89,95 and1	p95.81,89 and1	Study Protocol	Page 81-"BNT162b1,BNT162b2, BNT162b3. Where is the BNT162b3 information? Page 1 Study was Blinded. Page 89 Study was Unblinded. Why did this happen. Brook Jackson, a Pfizer whistleblower alleges information on study being unblinded among other Information. So was this information of discrepancies included in the Pfizer final report that allowed for the Biological License Agreement and Emergency Use Authorization? How can one tell if the Alleged Ventavia information was included?
4/10/2022 14:48:09	125742-S1-M5-5351-c4591001-fa-intermin-sample-crf.pdf	122	p 122	Study Protocol	Things that could go wrong when trying to input data into vaccination diary and how it could stop participants from completing information for the study. Page 122
4/10/2022 15:02:48	125742-S1-M5-5351-c4591001-fa-interim-sample-crf.pdf	1	all	Study Protocol	Why are people between the ages of 56 to 64 not studied and how are they included? Ages 18 to 55 and 65 to 85 were studied. Is information from the Ventavia Research group that a Pfizer whistleblower alleges may have committed fraud or discrepancies included in the final Pfizer data? Her allegations are in the public domain.
4/10/2022 15:19:41	125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf	78 is an example but all the pages same	at bottom of pages is a Pfyzer information block	Other	The Clinical Study Informed Consent Template. Pages are all dated (01-Jul-2019) Coincidentally created just before Covid outbreak in China as early as fall of 2019. Hmmm. Interesting, possible created ahead of time knowing that there would be a study forthcoming?
4/10/2022 15:44:18	phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-publications	8	Figure 3	Adverse Effects - Other	Severe fatigue and chills in 60 - 70% of the 30mg group after 2nd dose. Severe = prevents daily activity.
4/10/2022 16:14:40	125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf	1-3139	all	Other	I converted the table data from the pdf into excel and emailed it to Amy. Here is part of the email "I have included a conversion of the 125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf table data into excel (and a csv export of the excel data). It is broken into 3 files. I do a lot of data conversion in my job so this probably took me 3 hours (using regex tools). I included a column "A" data addition to the data for most data entries to add record definitions that were missing due to the formatting of the Pfizer data. Hopefully this data conversion will be helpful. It is pretty easy for me to do and I am willing to work on this as required so please let me know if this is valable."
4/10/2022 18:09:33	125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf	analysis, spreadsheets sent to Amy Kelly	all	Data Missing	The subjects have their sex, age, Weight, height gathered. There are a lot of missing data points which point to sloppy execution in the trial. These participants have a † in their data sets. When you look at the sloppiness in the execution, Blacks are 5.61 times as likely to have a sloppy job done by the trial management team. American Indian/Native Americans are 2.09 times as likely, and Hispanics are 3.85 times as likely to have missing data over the "normal" missing data rate. If the folks administering the trial can't get a height and weight, then I seriously doubt that the informed consent was properly performed.
4/10/2022 18:42:31	125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf -	1-50, 2379-2429	none	Study Protocol	Test group referred to as 'healthy individuals'. Pages 1-50 identified 54 individuals out of 677 that classified as morbidly obese. Pages 2379-2429 identified 155 individuals out of 700 that identified as morbidly obese. Three of those individuals had a body mass index of 60.8 (p. 2396), 87.6 (p.2406), and 61.8 (p. 2426).
4/10/2022 18:45:51	125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf -	1-50	none	Study Protocol	In the first 50 pages 6 individuals were identified in the placebo group. I did not identify any others in over 1000 pages.
4/10/2022 18:57:39	125742-S1-M5-5351-c4591001-fa-sample-crf.pdf	entire article and pdf of Brooke Jackson lawsuit	article and lawsuit	Study Protocol	Important article, lawsuit, and video evidence. "Report of Problems with Pfizer COVID-19 Vaccine trial Being Investigated: Contract Company" article by Zachary Steiber Nov 4,2021 updated Nov8, 2021. This article also includes the PDF of the lawsuit Whistleblower Brooke Jackson filed against Ventavia Research Group,LLC; Pfizer Inc.; and Icon PLC. This information is pertinent to current investigation of released FDA documentation we are working on. A You Tube video "Dr David Martin: Expose' from Nov 20,2021 Describes companies, people, and the govt involved " behind the scenes of Pfizer and vaccine manufacturers that many are not aware of, but. pertinent to current investigation of documents.
4/10/2022 19:41:30	125742-S1-M5-5351-c4591001-fa-sample-crf.pdf	false claims Act lawsuit	entire pdf	Study Protocol	Example from Brooke Jackson's False Claims Act lawsuit, page 32, number 150. ' due to Ventavia's carelessness and rush to enroll and inject as many patients as possible, however, pregnant women appear to have been enrolled in the clinical trial and injected with the vaccine or placebo. See Ex. 12, Email chain with Raney (Sept. 17, 2020), at 3, 5-6 (describing injection of pregnant patient after a positive pregnancy test. Ventavia did not report all clinical trial participants' pregnancies to Pfizer and Icon as required. see Ex. 7 at 67-68, 128 reporting requirements.' "153. for example, Subject 11281302 was enrolled and injected before routine laboratory work and nasal swab COVID-19 test. The subject also did not give informed consent until after the injection. If this Subject was COVID-19 positive, that would have rendered him or her ineligible." This lawsuit pdf is in the public domain on the internet.
4/10/2022 19:50:50	125742- S1-M5-5351-c4591001-fa- interim-sample-crf.pdf	2 articles	entire articles	Other	An Aug.7,2021 by Ehden Biber entitled: "Pfizer Leak-what if the Pfizer Contracts were Declared Illegal?' A 3/07/2021 article by Ehden Biber entitled: "Pfizer Leak: Exposing the Pfizer Manufacturing and Supply Agreement-The Brazilian Job (day5 and 6)" allegedly all the Pfizer contracts are similar.

4/10/2022 22:19:39	125742-S1-M5-5351-c4591001-fa-interim-audit-certificates.pdf	page1, article, and False Claims Act lawsuit pdf	many	Study Protocol	read Nov. 8 2021 article by Zachary Steiber entitled: " Report of Problems with Pfizer COVID-19 Vaccine Trial Being Investigated: Contract Company" In the article is the pdf of a False Claims Act lawsuit filed by Brook Jackson who worked at Ventavia and is a Pfizer whistleblower. Examples of allegations made include: On page 7 of the lawsuit, "25. Relator also reported some clinical trial protocol violations to the Fort Worth Principal Investigator Dr Mark Koch." He acknowledged problems. Page 48, 201,202, and 203of lawsuit It alleges that Dr Mark Koch "signed off on the records but did not personally or adequately examine patients" other clinical trial violations outlined in the lawsuit that applies to BNT162B2.
4/11/2022 11:44:52	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-protocol-deviations.pdf	all	all	Other	Especially in Phase I, and with fewer patients ("n" is small), these patients that met exclusion criteria can greatly affect safety outcomes. They should not have been allowed to enroll at that time, and later labs and reason for abnormal labs during screening need to be analyzed closely.
4/11/2022 13:06:09	125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf	1-21	all	Data Missing	I searched following codes online C4591001 1001, C4591001 1002, C4591001 1003, & C4591001 1007 and they appear to be attached to subjects who were excluded from All-Available and Evaluable Immunogenicity Populations – Further research reveals codes ending in 1002&1003 showed chemistry lab value of blood as "grade 1 abnormality" which when researched defined as an early stage diastolic disfunction. See attached chart. Of listed subjects, most received at least one vaccine.
4/11/2022 15:18:32	125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf	29	3	Other	"If you are part of the selected group of participants, you or your parent(s)/ guardian(s) will be asked to complete an electronic diary about how you are feeling for 7 days after the visit." Why only selected participants, why not all? Do we know who was selected? How do we know that "selected participants" who report issues don't get removed from the "selected participants" grouping? Fauci is known to have allowed/encouraged such maneuverings in the past (See RFK, Jr. "The Real Anthony Fauci", p.166 AZT clinical trials).
4/11/2022 15:25:43	125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf	33 (continuation from page 32)	1 (first full paragraph)	Adverse Effects - Reproductive Issues	(For girls) "If you are sexually active, you must use birth control consistently and correctly during the study and for at least 28 days after your second injection. Your study doctor or nurse will discuss this with you if it is appropriate to do so." This suggests they knew that the vaccine would be dangerous to fetuses. Were there any warnings given to pregnant woman during the EUA rollout? Considering the volume of miscarriages reported in VAERS it would seem they did not.
4/11/2022 15:30:37	125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf	33	2	Adverse Effects - Reproductive Issues	(For boys) "If you are sexually active, you must use birth control (eg a condom) consistently and correctly during the study and for at least 28 days after your second injection. Your study doctor or nurse will discuss this with you if it is appropriate to do so. If you think that you may have gotten a girl pregnant, you must tell your study doctor immediately. The study doctor may ask for information about the pregnancy and the birth of the baby. The study doctor may share this information with others who are working on this study." Are they suggesting the vaccine spike proteins could be transmitted between sexual partners?
4/11/2022 15:34:32	125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf	50	1st paragraph under "Pregnancy-Related Risks; Use of Birth Control"	Adverse Effects - Reproductive Issues	"If your child is currently pregnant, plans to become pregnant, or is breastfeeding a child, they should not join this study." Did they know breastfeeding post vaccine could endanger the baby? Were they any warnings given to those taking the jab that this cohort had been excluded from testing for safety concerns?
4/11/2022 15:42:20	125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf	41	2	Adverse Effects - Other	Paragraph 2 describes the mechanism of the vaccine, i.e., the creation of the spike protein, and says that "These vaccines do not contain the whole virus, or the parts of the virus that can make your child ill". However, I believe it was known by October of 2020 that the spike protein in the virus was causing blood clotting. Thus, to say that the vaccine did not "contain . . . the parts of the virus that can make your child ill" while technically correct (since the vax does not CONTAIN the spike, but teaches your body to manufacture it) is disingenuous at best and certainly very misleading to the average layperson participating in the study.
4/11/2022 20:37:28	FDA-CBER-2021-5683-0002933 to 0002934	37 and 38	Paragraph 7, 8, (on 0002933) Paragraph 1 (on 0002934)	Adverse Effects - Other	Younger age group (18-55) consisted of 88 participants. 1 - participant did not get the second dose because 23 days after first does participant had an SAE of gastric adenocarcinoma!!!! ONE in 88 got cancer!!! (Adenocarcinoma forms in glandular epithelial cells - the cells that MD's are saying the spike protein attaches to???. The other cells are ACE2 Receptor cells???)
4/11/2022 22:41:05	125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf	1-26	N/A	Other	Potential conflict of interest from ethical reviewers. The first 26 pages of this document list the addresses of the "Independent Ethics Committee or Institutional Review Boards." As I looked thru them I noticed almost all of them (& it's a fairly long list) are the Copernicus Group or the Western Institutional Review Board (WIRB), which I looked into and both are under the same parent company, called WCG. So I looked into WCG and found that Dawn Flitcraft, President, Ethical Review Division at WCG was recognized as one of the 100 Most Inspiring Leaders by PharmaVoice 100 in 2020. And Don Deieso, Executive Chairman & CEO was awarded the 2020 Red Jacket Award, which recognizes individuals who have been recognized multiple times as a PharmaVoice 100's inspiring leaders. According to Don's bio he also held "Senior Positions in Federal and State Regulatory Agencies" in the past. I plan to look more into PharmaVoice as I am not familiar with it, but it sounds like a potential conflict of interest. Additionally, on the WCB website in their history timeline, they note that in 2002 WIRB partnered with the WHO/NIH & University of Washington to create a fellowship program. This also sounds like a potential conflict of interest. I plan to try to do some more digging here. And lastly, one of the other addresses was for a German company: Landesaerztekammer Baden-Wuerttemberg – and when I went to their web page, on the first page I see: COVID info, Ukraine info, "Climate Crisis impact on healthcare;" a story about docs there being fined for counseling patients on the covid vaccine if they do not end up giving it to them; Kaiser Permanente is also on the list of ethical reviewers. Again I am not sure if all of this is a conflict of interest but it seems like it has the potential.
4/12/2022 1:07:13	125.742-S1-M5-5351-c45.91001-fa-interim-randomnization.pdf	15	All	COVID Testing	I I'mjust find it disturbing out of 195 trials done they only gave 28 placebos I thought they had to give half of the recipients placebo when they are doing studies on a vaccines
4/12/2022 1:26:52	125742_S1_M2_24_nonclinical-overview.pdf	12	2.4.2.1.4.1	Study Protocol	This paragraph alleges that neutralizing geometric mean titers (GMT) for 30 ug/100 ug dosed rhesus macaques reached 8/18 fold compared to the GMT of a 38 member panel of human convalescent sera. The humans aged between 18 and 83 and were PCR positive and titers sampled when asymptomatic. No where does it say any human had acute covid, so it can't be ascertained that each human would mount an antibody response. As explained in the Dr. Been video "Spike Protein Gets in the Blood of Vaccinated Individuals (Firm Data from a Stanford Study)", spike protein concentration in blood of vaccinated (47 pg/ml mean to as high as 174 pg/ml) is comparable to spike protein concentration in blood of acute COVID patients (70 pg/ml). So, I propose unless each human in the 38 member panel had acute COVID so they could mount an antibody response the comparison of GMTs is meaningless. Moreover, younger humans more than likely didn't have acute COVID.
4/12/2022 8:43:51	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf	3139	last	Study Protocol	possible admission of unblinding
4/12/2022 11:10:32	https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf	76	5	Study Protocol	As part of the protocol an attempt is made to destroy the control group of recipients 16 or older. "Any Phase 2/3 placebo recipient ≥16 years of age who has not already been offered the opportunity to receive BNT162b2 will be given this opportunity no later than 6 months after Vaccination 2 (at the time of the originally planned Visit 4)."

4/12/2022 15:08:20	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-publications.pdf	1-15/30	see above	Other	
4/12/2022 19:32:56	125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf	1, 22	BMI heading throughout	Study Protocol	Weight/BMI figures in the first group (pp 1-21; those given doses of vaccine or placebo) indicate all were fairly fit (BMI<30); there are no obese individuals among these participants. Beginning on p 22, there are many people in the larger list of subjects who are obese (>30 BMI) or morbidly obese (>40 BMI). Is it standard practice in vaccine studies that obese individuals do not receive a vaccine or placebo dose? It seems odd since obesity is a major co-morbidity for COVID-19. I've noted many high BMIs in this section. What impact does exclusion of obese individuals from those who receive a jab have on study results? I.e., is the study biased as a result of exclusion of obese from jab recipients?
4/12/2022 23:02:04	reissue_5.3.6 postmarketing experience.pdf	Page 12, 13	Breast feeding baby cases: 133, of which:	Data Missing	Searching VARES keyword search "Exposure via Breast Milk" I've identified hundreds of cases for Pfizer BioNTech vaccine [BNT162b2]. Most recent search identified 60 serious cases, one death <6month old. It's in searchable pdf or Excel if you like. However, the doc attached is quite unusual. VARES ID: 1505306-1 Breastfeeding Mothers 30-39. The report details how the mother pumped within one hour of receiving Pfizer vaccine at work and gave it to the son the following night. 11 days later the infant was hospitalized and died 2 days later. VARES categorizes the report as non-serious, ID# related to the mother, omits recording the death and delayed entering it the system until late July--167 days later. Coincidently, this serious AE happened during the same reporting period outlined in 5.3.6 doc Missing Information: 01 Dec 2020 and 28 Feb 2021. Shared same file at Team 3 Monday evening meeting.
4/12/2022 23:41:26	125742-S1-M5-5351-c4591001-fa-interim-sample-crf.pdf	video	video	Other	"Dr Ardis,D C: The Lie Has Been Exposed! The Real Origin of COVID! Pure Evil! " The video on 4/12/22 VokelNow.com It is Snake Venom and he exposes all the information and provides evidence and documents. Another video interview is " Dr Ardis...It's In The Water' The 4/11/22 video by Laura Lynn Tyler Thompson on Rumble is another interview with Dr Bryan Ardis. This video also includes the video interview with Dr Bryan Ardis on The Stew Peters Show 4/11/22. Dr Tau Braun also provides evidence about Snake Venom involved with SARS-CoV-2 (COVID-19) medications, the vaccines. he has been interviewed on 4/12/22 Dr Ardis Show Can be viewed on VOKALNOW.com 4/12/22 Dr Bryan Ardis explains during the videos why the CDC is testing wastewater. 4/12/22 Dr Bryan Ardis explains why some people are "MAGNETIC" post COVID jabs. It allegedly is related to Invitrogen's DYNABEADS magnetic beads. Dynabeads is by ThermoFisher Scientific. Dr Bryan Ardis alleges that Genetech and Roche have been mapping out the genome sequence of India King cobra's for the Last 10 years Dr Tau Braun sent a letter to the FBI on 6/21/2021 and received no response. Letter can be viewed on the SYNBIOWARFARE website. The two snakes most discussed and used are: Chinese Krait (Bungarus multicinctus) and Chines cobra (Naja atra) the King cobra A research study looked at gene sequences . "has the most similar codon usage bias with snakes
4/12/2022 23:54:08	125742-S1-M5-5351-c4591001-fa-interim-sample-crf.pdf	video	video	Adverse Effects - Other	"Dr Ardis, D C: The Lie Has Been Exposed! The Real Origin of COVID! Pure Evil!" The 4/12/22 video by Dr Bryan Ardis on VokalNow.com. Snake venom used in COVID-19, the vaccines, medications, diagnostics,etc.. Dr Ardis discusses some antidote therapies and how monoclonal antibodies are antibodies. He alleges that PCR testing is checking for snake venom Reports that Nicotine blocks snake venom.
4/13/2022 0:11:57	125742-S1-M5-5351-c4591001-fa-interim-sample-crf.pdf	videos	videos	Other	4/12/22 video :" Dr Ardis,D C: The Lie has Been Exposed! The Real Origin of COVID! Pure Evil!" on VokalNow.com The Ardis Show. Allegations that snake Venom is the Origin. There are 19 Venom specific toxins(VST's) that showed venom-gland specific expression. 11/16/21 "Pfizer files EUA application for COVID-19 drug Paxlovid' There allegedly is a sequence related to snake toxin in the medication. Phospholipase A2 found in snake venom. 1993 report shows it can be inhibited by the anti-malarials like chloroquine, HCQ, quinine and arteether to cause a 595 inhibition Phospholipase A2 was supposedly found in a massive number of patients who died
4/13/2022 0:52:17	125742-S1-M5-5351-c4591001-fa-interim-sample-crf.pdf	video	video	Adverse Effects - Other	4/12/22 video entitled: ' Dr Ardis,D C: The Lie Has Been Exposed! The Real Origin of COVID! Pure Evil !" on the Dr Ardis Show on VokalNow.com 4/12/22 video "Patents:Proof of Worldwide Envenomation Support Ardis Covid Claims in "Watch the Water" Expose on4/11/22 Remdesivir lipholized powder mixed with saline solution or distilled water in IV bag has snake venom peptides in it allegedly from the cobra snake
4/13/2022 3:17:59	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf	1 through 4 and first half of 5	n/a	Study Protocol	Ethnic breakdown AND participant numbers are grossly inadequate and under-represented for a study purported to be dedicated to safety, efficacy, thorough and in compliance with mandatory international standards. [see screen shot 4-13-22 BNT162b1 Trial Total Numbers=45] Particularly for a life and death emergency use drug study.
4/13/2022 4:06:10	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf	19	n/a	Data Missing	Page has been created with date and time stamp at left margin but information is missing, removed or never generated. See screenshot 4-13-22 missing information page 19
4/13/2022 14:14:19	125742_S1_M5_5351_c4591001-fa-interim-publications.pdf	p. 8, figure 3, and p. 24	N/A	Adverse Effects - Other	Figure 3 shows the percentages of volunteers in the BNT162b1 trial reporting use of antipyretic or pain medication. In the 30 micro gram group this was over 80%, which seems high. In the publication on BNT162b2 corresponding information is lacking, except a statement in the text that this was lower than in BNT162b1
4/13/2022 14:57:26	125742_S1_M5_5351_c4591001-fa-interim-publications.pdf	11, extended data figure 1	N/A	Adverse Effects - Other	The figure shows that in the BNT162b1 trial lymphocyte counts in the 30 micro gram dose group dropped by at least 50%. Even at day 21 they still seem lower. Corresponding data on the BNT162b2 trial are milder, but can only be found in the supplementary material. The authors adduced the drop to a 'transient migration of lymphocytes into tissues'. Note by the way that data on 1 of 12 for lymphocytes are missing (denominator is 11 instead of 112)
4/13/2022 20:45:31	STN 125742_0_0 Section 2.7.4 summary-clin-safety.pdf	13-14	Page 13 last paragraph; page 14 2nd paragraph	Study Protocol	Phase 2 study participants in the placebo group we're given the opportunity to receive the vaccine. There's no mention of how many in the placebo group opted to take the vaccine or, how long they were followed before receiving the vaccine. Doesn't this breakdown in the placebo group cloud true comparison between those vaccinated and those not vaccinated? …..Page 13 - "Phase 2 of the study (for which enrollment has completed) comprised the evaluation of safety and immunogenicity data for the first 360 participants (180 from active vaccine group and 180 from placebo group) that entered the study after completion of Phase 1." …..Page 14 - "C4591001 protocol amendment 10 allowed participants ≥16 years of age who originally received placebo the opportunity to receive BNT162b2 following local or national recommendations, or following completion of the active safety surveillance period. On 14 December 2020, the process of disclosing vaccine assignments for all trial participants ≥16 years of age began."
4/13/2022 21:50:21	STN 125742_0_0 Section 2.7.3 Summary of Clinical Efficacy.pdf	Page 22	Table 3, last row	Study Protocol	One of the Safety Objectives of Phase 1 of the vaccine study (Study C4591001) as listed in Table 3 was "To describe the safety profile of a third dose of prophylactic BNT162b2 administered to healthy adults 6 to 12 months after the second dose of either BNT162b1 or BNT162b2". Makes me curious …… Was this inclusion of 3rd dose testing just standard good research planning / thinking ahead / just in case? Or was it something else, an indication, from the very first phase of the study, that more than the two doses the public was hearing about were being planned?

4/13/2022 22:31:32	125742-S1-M5-5351-c4591001-fa-interim-sample-crf.pdf	6 and 13	Page 6 Nonclinical Data	Study Protocol	Development and Licensure of Vaccines to Prevent COVID-19 Guidance for Industry Final Guidance June 2020(PDF) Docket Number: FDA-2020- d-1137 Issued by CBER A'. General considerations Bullet Point 2 " Data from studies in animal models administered certain vaccine constructs against other coronaviruses (SARS-CoV and MERS-CoV) have raise concerns of a theoretical risk for COVID-19 vaccine-associated enhanced respiratory disease (ERD). In these studies, animal models were administered vaccine constructs against other coronaviruses and subsequently challenged with the respective wild type virus. These studies have shown evidence of immunopathologic lung reactions characteristic of a Th-2 type hypersensitivity similar to ERD described in infants and animals that were administered formalin-inactivated respiratory syncytial virus RSV) vaccine and that were subsequently challenged with RSV Virus due to natural exposure or in the laboratory, respectively (Refs 4-9). Vaccine candidates should be assessed in light of these studies as described in section D, below." Page 13 The Entire Page "D. Efficacy Considerations * Either laboratory-confirmed COVID-19 or laboratory-confirmed SARS-CoV-2 infection is an acceptable primary endpoint for a COVID-19 vaccine efficacy trial. "Acute cases of COVID-19 should be virologically confirmed (eg, by Rt-PCR)." * SARS-CoV-2 infection, including asymptomatic infection, can be monitored for and confirmed either by virologic methods or by serologic methods evaluating antibodies to SARS-CoV-2 antigens not included in the vaccine." * Standardization of efficacy endpoints across clinical trials may facilitate comparative evaluation of vaccines for deployment programs, provided that such comparisons are not confounded by differences in trial design or study populations. To this end, FDA recommends that either the primary endpoint or a secondary endpoint (with or without formal hypothesis testing) be defined as virologically confirmed SARS-CoV-2 infection with one or more of the following symptoms: Fever ot chills, Cough, Shortness of breath or difficulty breathing, Fatigue, Muscle or body aches, Headache, New loss of taste or smell, Sore throat, Congestion or runny nose, Nausea or vomiting, Diarrhea" *"As it is possible that a COVID-19 vaccine might be much more effective in preventing severe versus mild COVID-19, sponsors should consider powering efficacy trials for formal hypothesis testing on severe COVID-19 endpoint. regardless, severe COVID-19 should be evaluated as a secondary endpoint (with or without formal hypothesis testing) if not as a primary endpoint. FDA recommends that severe COVID-19 be defined as virilogically confirmed SARS-CoV-2 infection with any of the following: * Clinical signs at rest indicative of severe systemic illness (respiratory rate>30 per minute, heart rate.125 per minute, SpO2< 93% on room air at sea level or PaO2/FiO2<300mmHg) *" Respiratory failure (defined as needing high-flow oxygen, noninvasive ventilation, mechanical ventilation or ECMO)' *Evidence of shock (SBP<90mmHg, DBP<60mmHg, or requiring vasopressors)" 'Significant acute renal, hepatic, or neurological dysfunction"
4/13/2022 22:49:48	STN 125742_0_0 Section 2.7.4 summary-clin-safety.pdf	25	Last paragraph, last line	Data Missing	Page 25, last paragraph, last line "The booster analyses will be reported at a later time." Raises the question, WHEN will this analysis be reported? I used the abstractor provided on Daily Clout (https://vaccines.shinyapps.io/abstractor/), searched for "booster", and found no booster analysis in the Pfizer documents currently available (4/13/22). (Full paragraph - "Phase 1 participants who originally received BNT162b1 or BNT162b2 at dose levels of 10, 20, or 30 µg at Doses 1 and 2 were offered an additional dose of BNT162b2 at 30 µg approximately 6 to 12 months after their second dose of BNT162. This would provide an early assessment of the safety of a third dose of BNT162, as well as its immunogenicity. The booster analyses will be reported at a later time.")
4/14/2022 16:16:53	125742-S1-M5-5351-c4591001-fa-interim-sample-crf.pdf	1-7	many	Study Protocol	An article entitled ' Why Aren't the FDA and CDC Informing the Public About Documented Adverse Events and mRNA Injections?" written on March 25,2022 by Dr David Gortner, a former professor of pharmacology and biotechnology at Yale University School of Medicine and former Medical Officer at the FDA. Article posted on theFederalist.com He provided access to a 107 page "FDA medical officer review." "BLA Clinical Review Memorandum" Biologics License Application for BioNTech Manufacturing GmbH (in partnership with Pfizer, Inc) August 23.2021 Name: COVID-19 Vaccine, mRNA Comirnaty Page 15: "Efforts reported to eliminate bias for the covered studies consisted of the following: * Randomized, double-blind and multicenter study design as well as pre-specified statistical methods as per statistical analysis plan * Frequent monitoring of investigator trial sites and auditing of trial sites * Validity of data collected was confirmed by standard monitoring procedures *Data processing involved cleaning checks (querying data through electronic edit checks) to ensure that errors were identified and corrected * Study sites performing safety evaluations were determined acceptable based on appropriate certification or historical performance and/or qualifications and credentials"
4/14/2022 16:39:04	125741-S1-M5-5351-c4591001-fa-interim-sample-crf.pdf	page 16	4.3 Nonclinical Pharmacology/Toxicology	Other	Document from the FDA medical officer review: "BLA Clinical Review Memorandum' STN 125742/0 August 23.2021 review complete "The CBER toxicology reviewer identified no issues in preclinical study reports, and based on current hypothesis regarding the etiology of vaccine-associated enhanced disease, the preclinical data provided in the BLA are reassuring due to : as an example, The nonclinical absorption, distribution, metabolism, and excretion studies indicate that the LNP mainly localizes to the site of injection, and to a lesser extent, distributes to the liver."
4/14/2022 16:57:54	125742-S1-M5-5351-c4591001-fa-interim-sample-crf.pdf	17	1 from BLA clinical Review Memorandum Aug 23.2021 review complete	Adverse Effects - mYocarditis	From the FDA medical officer review ,August 23.2021, document :" BLA Clinical Review Memorandum' Paragraph 1, page 17 ' available data from short-term follow-up suggest that most individual affected by vaccine-associated myocarditis/pericarditis have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae and outcomes in affected individuals"
4/14/2022 18:09:15	125742-S1-M5-5351-c4591001-fa-interim-sample-crf.pdf	19,' BLA Clinical Review Memorandum Aug 23" 2021	2	Data Missing	From the ' BLA Clinical Review Memorandum,' FDA medical officer review document of August 23.2021, STN 125742 Paragraph 2 "Because the primary source of pre-licensure study data to support vaccine safety and effectiveness is a single study, c4591001, FDA agreed with the Applicant's proposal not to include integrated summaries of efficacy or safety in the BLA submission. Consequently, the sections of the clinical memo usually reserved for review of these integrated summaries (Sections 7 and 8) are not applicable." Page 19 of the BLA Clinical Review Memorandum. "The most critical issues involving data to support safety and effectiveness of this vaccine were covered in the Oct. 2020, December 2020, and June 2021 VRBPAC meetings.' Third paragraph, page 19 of the BLA Clinical Review Memorandum involving the August 23,2021 FDA medical officer report states; "Post-authorization effectiveness data from observational studies referenced in Section 2 and section 11 are limited to published literature and were not submitted as part of the licensure application. Therefore, FDA has not independently reviewed and confirmed the data or assessed the study designs for potential sources of bias.'

4/14/2022 18:44:54	125741-S1-M5-5351-c4591001-fa-interim-sample-crf.pdf	83 and 84	Bottom of pagen83 to much of 84	Adverse Effects - Reproductive Issues	From the August 23 2021 FDA medical officer review document entitled "BLA Clinical Review Memorandum" STN:125742 Clinical Reviewers: Susan Wollersrheim, MD and Ann Schwartz, MD. Pregnancy "During study C4591001 from Dose 1 through the data cutoff date of March 13,2021, pregnancy was reported by 42 participants who received BNT162b2. For those participants who received BNT162b2 during the open-label period (originally randomized to placebo),8 participants reported maternal exposure during pregnancy prior to the cutoff date. Date on Birth outcomes, Unknown Pregnancy Outcomes and Ongoing Pregnancies is not included in the study report as the Applicant did not collect this information in their standard clinical database." 'Page 84 "Table 35 Disposition of Participants 16 Years of Age and Older Who Experienced Pregnancy, Phase 2/3 Safety Population (Data cutoff date March 13,2021) Total Pregnancies in BNT162b2 group -42 Placebo group 47 Spontaneous abortions in BNT162b2 group-3 Placebo group -7 Miscarriages in BNT162b2 group-3 Placebo group-5 Elective Abortions in BNT162b2 group-0 Placebo group-1" Page 85 9.1.2 "Use During Lactation' "It is not known if BNT162b2 is secreted in human breastmilk. data are not available to assess the effects of BNT162b2 on the breastfed infant or on milk production."
4/14/2022 19:28:31	125741-S1-M5-5351-c4591001-fa-interim-sample-crf.pdf	Page 86 in the FDA medical officer August 23, 2021 document	Page 86	Efficacy	From page 86 of the August 23,2021 medical officer review document " BLA Clinical Review Memorandum" application for biologic license of vaccines. "Due to study exclusion criteria described above, data in the BLA submission are insufficient to inform vaccine safety and effectiveness in immunocompromised populations. Based on published reports of low antibody responses and breakthrough infections among significantly immunocompromised individuals (mainly solid organ transplant recipients) who received the two-dose vaccination series under EUA" "9.1.5 Geriatric Use The effectiveness in geriatric participants was consistent with that seen in younger adult participants, and no safety concerns specific to the geriatric age group were identified. The reported frequencies of adverse reactions, including myocarditis/pericarditis, are lower in the geriatric age group compared with younger adults and adolescents." "9.1.6 Patients with Human Immunodeficiency Virus (HIV) infection As an exploratory objective for study C4591001, the safety, immunogenicity, and efficacy of BNT162b2 vaccine was assessed in individuals with confirmed stable HIV disease (protocol amendment 6 dated September 8,2020) in Phase 2/3 portion of the study. These participants were not included in the overall Phase 3 analysis for safety or efficacy for the general population of study participants>16 years of age. The safety results for individuals with confirmed stable HIV disease were summarized descriptively."
4/14/2022 22:57:57	5.3.6 Cumulative Analysis of Post authorization Adverse Event Reports	12	Table 6	Other	Clarification/confirmation that post market data is Global, not just US (countries for each case is listed)
4/14/2022 23:09:33	5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	25	Footnote to Table 7	Adverse Effects - Other	Previously submitted a finding for this but did not provide a screenshot. This is a screenshot of 7 year old child in the UK that experienced a stroke. The outcome of the stroke was unknown. It was noted that follow-up was not possible for clarification. This information was not documented in the AESI Category of Stroke. Instead the case was burried in the footnote section of Table 7
4/15/2022 6:07:11	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf	38 - 4412	-	Other	Total number of participants in the pfizer study: 43.746 participants. These participants were divide in several researchgroups. For example one group was given a placebo, one group was giving 10 µg of comirnaty, one group was giving 20 µg of comirnaty, one group was giving 30 µg of comirnaty and one group was giving 100 µg of comirnaty.
4/15/2022 6:15:00	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-interim-mth6-audit-certificates.pdf	4	-	Other	Company providing auditing software - Entrust Inc. this is company is of the Quandt family. A Dutch-German industrialist family with a long history in weapons manufacturing and they were involved with the nazi's during the second world war. Website: www.entrust.net second company involved with providing auditing software: MSB docs - www.msbdocs.com
4/15/2022 8:42:19	125742_S_M5_5351_c4591001-fa-interim-publications.pd	4, 12, 26	N/A	Efficacy	The transient decrease lymphocytes within first 7 days after vaccination is well known phenomenon for many vaccines (Ebola, Anthrax [reference#14, #15, page 29]). What was unknown before that "early drop of circulating T -cells negatively correlates with protective immune response". In other words, it was an early sign that the vaccine won't work. The study was published on April 29, 2020 in the peer-reviewed journal, several days before Pfizer had started its phase 1/2 human trials. https://doi.org/10.1080/21645515.2020.1750249 In spite of the fact, that decrease in lymphocytes count was stated in three Pfizer's articles (August, October, and December 2020), this study had never mentioned or referred to the articles.
4/15/2022 10:07:56	125742-S1-M5-5351-c4591001-fa-interim-sample-crf.pdf	7	2	Other	"BLA Clinical Review Memorandum" "Applicant BioNTech Manufacturing GmbH (in partnership with Pfizer, Inc.)" "Established Name COVID-19 Vaccine, mRNA "(Proposed) Trade Name COMIRNATY" "Application Type: Biologics License Application (BLA)" "Review Completion: August 23,2021" Page 7, second paragraph "The clinical data submitted exceed FDA's expectations for data to support licensure of vaccines for prevention of COVID-19, including relevant efficacy success criteria and numbers of vaccinated study participants and follow-up time (ie, at least 3.000 vaccinated study participants in each age group with at least 6 months of total safety follow-up) for an acceptable safety database. The clinical data submitted in this application, together with the quantitative benefit-risk assessment summarized in this review, support approval on BNT162b2 for the indication of active immunization to prevent symptomatic coronavirus disease 2019 (COVID 19) caused by severe acute respiratory syndrome coronavirus (SARS-CoV-2) in individuals 16 years of age and older." From paragraph 3, page 7 " The Applicant also committed to conduct additional post marketing safety studies, including the assessment of pregnancy and infant outcomes following immunization with BNT162b2 during pregnancy."
4/15/2022 10:30:35	125742_S1_M5_5351_c4591001-fa-interim-randomization.pdf	3,6,7	N/A	Data Missing	Pfizer's first article about phase 1/2 BNT162b1 vaccine was submitted to Nature on June 29, 2020 while some of the participants in the phase 1/2 hadn't started yet or hadn't finished their vaccinations.There were 20 people who received their 1st dose on June 29, and July 1, 2020 . They received their 2nd doses on July 20, 21,and 22. The article was accepted by the journal on August 4, 2020, 13 days after the last 2nd dose was administered. Therefore, the safety, tolerability, immunogenicity data that had to be collected on day 14 after 2nd dose (page 4, immunogenicity) weren't included in the results for at least 20 people. It's also unknown if data of other participants who received their 2nd dose on June 29 and after that date were included in the Pfizer's article. It takes average 6-8 weeks or at least 2 weeks to estimate immunogenicity at a standard assay(www.criver.com).Considering that it takes at least 2 weeks to assess immunogenicity, there is also a high probability that data from 19 people who received their 2nd dose on July 8 and 9, weren't included.
4/15/2022 12:04:16	125742_S1_M5_5351_c4591001-fa-interim-randomization.pdf	3,6,7,9,10,12,13	N/A	Data Discrepancy	The second Pfizer's article in NEJM states in the Results (page 21)that "Between May 4,2020, and June 22, 2020, a total of 332 healthy adults ...underwent screening." 195 were randomized. However, there were 40 people who were enrolled after June 22.On June 24, 29, 30, and July 1, 2020 were enrolled 40 people (25 people in group 18-55, and 15 in 65-85).
4/15/2022 12:18:28	125742_S1_M5_5351_c4591001-fa-interim-publications.pdf 125742_S1_M5_5351_c4591001-fa-interim-mth6-demographics.pdf	all	N/A	Data Missing	People from 56 to 64 years old were excluded from the Pfizer's demographic characteristics and the randomization scheme. There are only two groups 18-55 and 65-85.

4/15/2022 20:08:50	125742_S1_M5_5351_c4591001-fa-interim-publications.pdf	4, 12, 26, 28	Pg. 4: 6,10; Pg. 12: chart; Pg. 26: 2,6; Pg. 28: 1	Adverse Effects - Other	In the first study, which did not assess immune response or safety beyond 2 weeks, they found decreases in lymphocytes and also neutropenia. The study claims the lymphocyte count returned to normal after 6-8 days, but it doesn't show any long-term studies were conducted as to the cause, or if further testing was done at a later date, once the lymphocytes returned to normal. The study does mention they were going to follow the 2 participants that had neutropenia, but unknown if this was done. In the discussion portion, they mentioned RNA vaccines are known to induce type 1 interferon which has been associated with transient migration of lymphocytes into tissues. The chart on page 12 doesn't show any data past day 8. In the second study, it noted the transient decreases in lymphocyte counts resolved within 1 week but mentions there was no associated clinical manifestations. The study indicated it probably reflected a temporary redistribution of lymphocytes from the bloodstream to lymphoid tissues as a functional response, but it doesn't appear that they studied this further, or noted anything past the study date which per the chart appears to be 35 days (pg. 27). There is no chart to show specifically what happened with the lymphocytes and how much they decreased, or whether they did further laboratory testing once the lymphocytes returned to normal. There is no mention of neutropenia in this second study that I found.
4/16/2022 13:13:19	PHASE 1/2/3 CLINICAL STUDY ASSENT TEMPLATE FOR OLDER CHILDREN	32	3-4	Adverse Effects - Reproductive Issues	Pfizer specifically did not want teen women who were, or could become pregnant or were nursing in the study. Yes later they claimed the vaccine was perfectly safe for pregnant women. From this section of the study, it's clear they could not have data to back up this claim.
4/16/2022 13:54:19	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf	28	5	Other	The document states "If you decide to be in this study, you will be asked to sign this form. Your parent(s) or your guardian(s) will sign another form. You can talk to your parent(s) or your guardian(s) and ask to read the information the study doctor gives them." In my experience, it is illegal to have a minor sign a medical form that is separate from the parent or guardian. This clearly sates that a parent or guardian will sign a separate form from the child, no other option is offered.
4/16/2022 13:55:00	CT05-GSOP-RF04 7.0 Phase 1/2/3/4 Clinical Study Informed Consent Template (01-Jul-2019)	71	9	Data Missing	Pfizer references animal testing in "other vaccines" ..."but not the COVID 19 vaccine" and they claim that when tested in animals, the other vaccine did cause increased severity of the illness in the animal. 1. No data is provided to instruct the participant as to what percentage of tested animals suffered greater severity (or even to what extent). They could have provided this and it would have been important information. 2. Why did Pfizer not test their vaccines in animals at all before trying it on people? and..."So far this has not been seen with COVID-19 vaccines" is vague and potentially misleading. If the sample size to that point was 1/2 of 350 (half getting placebo); they should have specified this. If non of those people in the sample even caught COVID at all, they should have revealed this.
4/16/2022 14:09:38	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf	31	5-7	Other	The document states "WHAT ARE THE POSSIBLE UNCOMFORTABLE OR HARMFUL THINGS THAT COULD HAPPEN TO ME IF I AGREE TO BE IN THIS STUDY? There is a chance that during the study you could feel pain or feel bad or uncomfortable. Please let the study doctor know if you experience any of these things. The study team will monitor you for risks or discomforts during the study. However, the study team does not know all the effects that the vaccine, or your participation in this study, may have on you. The injection could cause pain, tiredness, increased body temperature (fever), chills, headache, and muscle aches. Other side effects could include redness, swelling and itching; loss of appetite, joint aches and sweating." In this stage of the Trial the more significant side affects have already been established and documented from the adult trials.
4/16/2022 14:22:12	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf	35	entire page	Other	This is a copy of the consent with on Parent or Guardian consent. In my experience, this is illegal.
4/16/2022 14:33:34	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf	40	3	Other	On page 40 the document states "You are being asked to allow your child to be in this research study because your child is healthy and over the age of 16." Perviously, in the document under PHASE 1/2/3 CLINICAL STUDY ASSENT (page 27), the minor patient's age given is "11-year-olds through legal age of adulthood."
4/16/2022 17:34:35	FDA CBER 2021 5683 0029232	1-22	NA	Study Protocol	The vaccine candidate BNT162b1 and BNT162b2 subjects ages ranged 21 to 85 years old. They were all administered different doses of the vaccine ie. 10ug, 20ug and 30ug. Why? How was the effective determined? Were these 2 different vaccines ie. BNT162b1 and BNT162b2? Why? Then table 16.2.4.1 Phase I BNT162b1 vaccine candidates given 100ug. Why this higher dose? I have more questions about this study as well as concerns.
4/16/2022 17:58:58	FDA CBER 2021 5683 0029264	22 to132 out of 3139	NA	Other	I reviewed the findings in "Analysis of table 16.2.4.1 Listing Demographics of all Subjects." This was such a big file so I chose to review pgs 22 to 137. My focus was on the number of subjects that were of teenage years considering the "safe and effective mantra" and cases of myocarditis in teenage males. There was a total of 1,652 subjects of which 105 are teens or 16%. Of this 56 were male or 54%. If this is representative of the total number of teens in this study it's not a big enough part of the sample to justify safe and effective.
4/16/2022 18:52:20	BNT162b2 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	6	most of the page	Adverse Effects - Other	This page refers to the large number of adverse events and describes the plans to hire up to 2400 new employees to handle adverse event cases. Also lists numbers for AEs in various countries.
4/16/2022 18:56:57	BNT162b2 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	7	Table 1	Adverse Effects - Other	Table lists ages & sexes of AE cases, with female cases being approximately three times as much as male cases, and predominant age category 31-50 (nearly twice as much as next highest age category)
4/16/2022 21:33:32	FDA-CBER 2021-5683-00224776. 16.1.7.1. Listing of randomization scheme and actual vaccine recieved	14-15	They are both charts	COVID Testing	My report consist of the dates between05/04/2020-07/22/2020 2 does wetter administered per recipient the usual dosage is 10ug 20ug &30ug which is odd why do many different ug when they're all in same age group 18-35, so on two separate dates 05/18/2020 & 05/20/2020 and only 12 recipient's recieved an astounding high dose of 100ug administrated to the 12 recipient's and no one else thru the 3 month trial, and what happened to these individuals that got 100ug injected into them not once but twice
4/16/2022 22:23:41	L-M Section	N/A	Searched Codex for subject integrity	Data Missing	What deserves attention: there are findings that may be explainable. 1) Subject C4591001 1003 1003 10031017 is listed in exclusions, but not listed in participants. The other 4 of 5 excluded are isted. The codified person above is not on the codex. 2) many subjects across the set do not appear for the 2nd dose. This can be benign (lost to follow-up or no shows). The set does not denote if they didn't show or if they could not show due to sequelae. More info and context needed to determine. This is a codex of participants. It's just a registry, doesn't include results. It is used to link results to individual participants. Researchers maintain their "blindness" in evaluations. They check results, report up, higher ups cross check using this codex. Groupings are 18-55, looks like 55-65, then 65+. Noted different dosages in different areas; that can be part of study design. Audit lists in the L-M last name assigned section do not show specific meaning to me.
4/16/2022 23:26:45	L-M section	N-A	N-A	Study Protocol	In the text chain, I posed that excluded subjects could not be found in the codex. Another person was able to find all five in the codex. Please disregard my previous email.... as it is incorrect. I had a software hangup. The five participants (who are not identified) need to be cross-referenced if there is a list of adverse events. The 5 we found are a mix of placebos and experimental subjects, excluded for reasons not denoted.
4/17/2022 20:21:09	FDA=CBER-2021-5683-0024480	199	entire	Adverse Effects - Other	"In your last vaccination diary entry you have already specified a temperature of 110 degrees F. No further update can be made to this symptom today.' At 110degrees the person is probably dead and there is no way to document further changes in symptoms. Appears as though the questions and answers are all preselected and do not account for symptoms outside this range of information. No way to document for chest pain, seizures, etc.. Appears to have a one month and 6 month condition update with the investigator for documentation..

4/17/2022 20:27:55	FDA-CBER-2021-5683-0024311	30	entire	Adverse Effects - Other	Form for illness details related to renal, hepatic, neurologic only. No documentation for cardiac or integumentary or respiratory systems for example. What is meant by "Comparison term (hidden)? What is meant by Lowest term code (hidden)? What is meant by Highest term code (hidden) ?
4/17/2022 20:37:54	FDA-CBER-2021-5683-0024316	page 44	Exclusion criteria	Study Protocol	"Exclusion criteria example; 2b (HIV): 2e (immunocompromised); 2g (Pregnant or Breastfeeding); 2i (Immunosuppressive therapy or treatment). After the study was completed and the vaccines were rolled out how many individuals in these excluded populations were encouraged to be vaccinated?
4/17/2022 23:30:00	125742-S1-M5-5351-c4591001-fa-interim-sample-crf.pdf	P124 (23 of 57)	many	Adverse Effects - Other	TrialMax App appears to have predetermined questions and narrows down how the participant can respond. "From New FDA factsheet Effective 3/29/22 documents basically the same side effects or that they are "being studied" : as listed in the package insert. No mention of the deaths or 9 pages of side effects noted in the trial. "Package leaflet: Information for the user" "1. Pfizer-BioNTech/Comirnaty concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)" "is a vaccine used for preventing COVID-19 caused by SARS-CoV-2 "As Pfizer-BioNTech's/Comirnaty COVID-19 mRNA vaccine does not contain the virus to produce immunity, it cannot give you COVID-19." "4 "Possible side effects" " Very common side effects: injection site pain ,swelling tiredness headache ,muscle pain, chills ,joint pain, diarrhea, fever" Common and Uncommon side effects described as "rash or itching, insomnia, enlarged lymph nodes' " Rare side effects-Temporary one sided facial drooping, allergic reactions such as hives or swelling of face" "Not known (cannot be estimated from available data): severe allergic reaction, myocarditis/pericarditis, extensive swelling of vaccinated limb, swelling of face" No public documentation of deaths or 9 pages of documentation from the study.
4/18/2022 9:16:23	2.7.4 Summary of Clinical Studies	290	2.7.4.2.4..3.6.2.	Data Missing	In the first batch of documents released I was assigned to review the Post-Authorization Adverse Events documents. Because there were a significant number of AE's reported in pregnant women I decided to pay close attention to future documents as regarding vaccine effects on pregnancy. The "Summary of Clinical Safety" document lists 50 women who were a part of the initial study that reported pregnancies. As I understand it, 16 of them withdrew from the study due to pregnancy. The remaining women "continue to be followed for pregnancy outcomes." (Pg 290) Using the Abstractor tool, I did a search using the terms "pregnant and pregnancy" on many of the current and past documents and as of yet have found no updated information on these women and their pregnancy outcomes. I have been unable to locate "Narratives (Phase 3, Study C4591001)" referenced at the bottom of page 290. I'm sure others have noted this, but I just wanted to basically "flag" this issue as one to watch in future document releases.
4/18/2022 11:11:43	16.1.7.2 Listing of Randomization Scheme and Actual Vaccine Received – Phase 2	multiple: examples on every page of 56-85 YOs receiving placebo. And pgs 39 and 51, age group 18-55 receiving doses of 100mg-- a very high dose.	multiple	Other	They were testing on people who didn't know they were test subjects: Older people who arguably needed protection against infection and then very high doses given, way beyond what is safe, to younger people without their knowledge.
4/18/2022 13:36:07	Listing of Randomization Scheme and Actual Vaccine Received – All Subjects	2781, 2781	1 (first subject)	Study Protocol	Pfizer is using a study group that ranges from 16 years old (pediatric) to 55. Why such a large group? Would it be so that side effects such as myocarditis, as we are now seeing in young men, is easier to hide or minimize in a huge study group? In both these top subjects, only one dose was given. On page 2781 the top subject was given one dose placebo. On page 2782, top subject was given one dose of BNT162b2 (30 µg). No second doses. Why?
4/18/2022 14:22:14	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf	40	5	Other	"There are currently no licensed vaccines" - how about therapeutics? ivermectin, HQ have been around for decades.
4/18/2022 14:26:11	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf	42	5	Other	Why would they release a vaccine in 4-5 months when the study is going on for 26 months?
4/18/2022 16:14:17	16.1.7.2 - 16.1.7.4	1-44	charts	Other	Actual vaccine received several placebo doses documented throughout (this doesn't seem to be formal or measured or systematic not sure what it is based on). Dose in micrograms (mcg a.k.a. ug) consistent (30mcg x 2 doses) until 16.1.7.4 pg 38 where there were 10 mcg (ug) for dose one and dose two. And again dose differences on 16.1.7.4 pps 39-42 a dose as high as 100mcg was given for first dose on page 39 with a second dose of 10 mcg. These doses may have been given by same provider as the subject identifier are consecutive but the next 2 pages the dose reduces to below threshold of 30 mcg to 10 mcg for first and second doses and 20 mcg for 1st and 2nd doses. The randomization vaccine group changed from 16.1.7.1-2 from BNT162b2 p 1-36 to BNT162b1 on 16.1.7.4 p 38-42. If these are finding from Pfizer alone and no other manufacturer then why the dose changes?
4/18/2022 16:46:08	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-interim-mth6-invest-signature.pdf	1	Entire document: signature	Other	Stephen Thomas, M.D. is lead investigator stated on investigator declaration page. https://www.upstate.edu/microb/faculty.php?empID=thomstep Dr. Thomas outlines his various clinical trial experience. Click media link and scroll down for a series of audio interviews. The 2017 Zika interview is Dr. Thomas talking about his involvement with Zika trials while he was in the military. Could it be a conflict of interest for the lead investigator of Covid trials with his history of Zika trials. Additionally, the audio links clearly indicates his strong support of the vaccines even to date. Multiple articles indicate the multiple ethical issues with Zika trials. For example, the article in Science that outlines the trial struggles and how they pushed on because of the enormous investment already made. The same article points out the dangers of passing the live virus to semen. Therefore, only females were used. Weren't male participants in the COVID study told to refrain from sex for a certain number of days? If so, does that mean that the spike proteins produced by mRNA coding is making a live or part of a live virus?? That leads to the question of Human Challenge. The JAMA article proposes the ethical question of conducting Human Challenge clinical trials. But, isn't there a safety issue also? Do the participants know this clinical trial may fall into the definition of Human Challenge? The more important point to ask is if the vaccine program globally is some form of Human Challenge trial in itself. https://www.niaid.nih.gov/diseases-conditions/zika-vaccines https://www.science.org/content/article/massive-zika-vaccine-trial-struggles-researchers-revive-plan-intentionally-infect https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2780744
4/18/2022 18:20:51	125742_S1_M5_5351_c4591001-fa-interim-randomization.pdf	page 14-15		Other	the 100ug group is unbalanced with respect to placebo and intervention (3 vs 12), the age range specified is wide, 18-55, why include this at all given the results would be questionable from a statistical standpoint
4/18/2022 18:36:17	125742_S1_M5_5351_c4591001-interim-mth6-demographics.pdf	whole document	whole document	Other	racial make up of sample seems mostly white, other groups lower N seem underrepresented, don't know why some whites are described ethnically as hispanic/latino and others non-hispanic/non-latino, do they report results by race, ethnicity, age, bmi,sex?

4/18/2022 22:02:03	STN-125742_0_0-Section-2.5-Clinical-Overview.pdf	Pg 23	last paragraph	Other	The last paragraph regarding Booster and Variant Strain Evaluation discusses a third dose of prototype based upon the South African variant BNT162b2sa. At the time this document (report) was written I do not think the South African variant was in existence. I believe this document was written around March 2021. The "South Africa Variant" was reported in the news much later (Nov 25, 2021). Therefore it is possible the SA Variant was planned so a booster dose could be given.
4/18/2022 22:15:54	STN-125742_0_0-Section-2.5-Clinical-Overview.pdf	24	Last paragraph	Other	2.5.1.2.3.2.3. Planned Studies Many types of studies were planned for 2021 among them was a Maternal immunization during pregnancy study (Protocol C4591015). It would be very important to know the results of this planned study. I do not know if the the results are coming in future documents we will receive, or if they have to be specifically requested since they are special population studies. Also note they listed the South Africa Variant booster study (BNT162b2sa) was a planned study (I submitted a separate form regarding this study).
4/18/2022 22:44:11	125742-S1-M5-5351-c4591001-fa-interim-audit-certificates.pdf	entire	entire article and video	Other	Can no longer ignore the contaminants, foreign objects, or nanotechnology being found in the vaccines. Why is the material in the vaccines and has it had adverse effects on human beings? The most recent example of this is an article entitled "Nanotech In the Shots? (mind Blowing)" by Samuel Robinson Kephart, Feb 18, 2022. The "Life of the Blood" website actually has intellectual property rights and requests permission. The "Nanotech In the Shots?" article can be publicly viewed on their website. The video and pictures are stunning. "Life of the Blood" and "NZDSOS.com" from New Zealand is " an international group of concerned citizens, scientists and medical practioners who have observed surprising microscopic phenomena regarding the recently deployed COVID-19 injections." They have many pictures of these objects from the Comirnaty vaccine as well. Stunning . Other international scientists, doctors, and concerned citizens have also discovered this material in the vaccines but not disclosed by the pharmaceutical manufacturers or governments. It can not be ignored.
4/19/2022 10:18:58	BNT162b2 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	9	3.1.2 Table 3, Safety Concerns	Adverse Effects - Other	Important identified risks: Anaphylaxis; Important potential risks: Vaccine-Associated Enhanced Disease, incl. Respiratory; Missing Information: Use in Pregnancy and lactation; Use in Pediatric individuals <12; Vaccine Effectiveness
4/19/2022 10:24:50	BNT162b2 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	10	1 (Table 4, Important Identified Risk)	Adverse Effects - Other	601 cases of Anaphylaxis BC Levels 1 & 2 (highest level of diagnostic certainty of anaphylaxis). Total cases 1833 (levels 1-5)
4/19/2022 10:36:20	BNT162b2 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	12	2	Adverse Effects - Reproductive Issues	Out of 270 cases, 23 spontaneous abortions, with 2 premature birth with neonatal death, 2 spontaneous abortions with intrauterine death, and 1 spontaneous abortion with neonatal death. 75 serious mother cases out of 124 reported incl 25 spontaneous abortions, as well as uterine contraction during pregnancy, premature rupture of membranes, and foetal death. Also common - headache, pain in extremity, fatigue, myalgia, chills, and nausea.
4/19/2022 10:38:12	BNT162b2 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	12	3	Adverse Effects - Reproductive Issues	Of 17 cases, the following clinical events occurred: Pyrexia (5), Rash (4), Infant irritability (3), Infantile vomiting, Diarrhoea, Insomnia, and Illness (2 each), Poor feeding infant, Lethargy, Abdominal discomfort, Vomiting, Allergy to vaccine, Increased appetite, Anxiety, Crying, Poor quality sleep, Eructation, Agitation, Pain and Urticaria (1 each).
4/19/2022 10:41:48	Pyrexia (5), Rash (4), Infant irritability (3), Infantile vomiting, Diarrhoea, Insomnia, and Illness (2 each), Poor feeding infant, Lethargy, Abdominal discomfort, Vomiting, Allergy to vaccine, Increased appetite, Anxiety, Crying, Poor quality sleep, Eructation, Agitation, Pain and Urticaria (1 each).	13	1	Adverse Effects - Reproductive Issues	Suppressed lactation - In 4 cases (3 non-serious; 1 serious) Suppressed lactation occurred in a breast feeding women with the following co-reported events: Pyrexia (2), Paresis, Headache, Chills, Vomiting, Pain in extremity, Arthralgia, Breast pain, Scar pain, Nausea, Migraine, Myalgia, Fatigue and Breast milk discolouration (1 each). Conclusion: There were no safety signals that emerged from the review of these cases of use in pregnancy and while breast feeding.
4/19/2022 10:46:45	In 4 cases (3 non-serious; 1 serious) Suppressed lactation occurred in a breast feeding women with the following co-reported events: Pyrexia (2), Paresis, Headache, Chills, Vomiting, Pain in extremity, Arthralgia, Breast pain, Scar pain, Nausea, Migraine, Myalgia, Fatigue and Breast milk discolouration (1 each). Conclusion: There were no safety signals that emerged from the review of these cases of use in pregnancy and while breast feeding.	13	Vaccine Effectiveness (last paragraph)	Other	Lack of Efficacy - Note: after the immune system as had sufficient time (14 days) to respond to the vaccine, a report of COVID-19 is considered a potential lack of efficacy even if the vaccination course is not complete.
4/19/2022 10:50:35	Note: after the immune system as had sufficient time (14 days) to respond to the vaccine, a report of COVID-19 is considered a potential lack of efficacy even if the vaccination course is not complete.	14	1	Efficacy	Lack of efficacy cases: Number of cases: 1665b (3.9 % of the total PM dataset) of which 1100 were medically confirmed and 565 non medically confirmed; • Number of lack of efficacy events: 1665 [PT: Drug ineffective (1646) and Vaccination failure (19)f]. COVID-19 infection was suspected in 155 cases, confirmed in 228 cases
4/19/2022 10:54:56	COVID-19 infection was suspected in 155 cases, confirmed in 228 cases	14	2	Efficacy	Drug ineffective cases: Drug ineffective event seriousness: serious (1625), non-serious (21)e;
4/19/2022 11:11:50	BNT162b2 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	16	1 (Table 7)	Adverse Effects - mYocarditis	Number of relevant events: 1441, of which 946 serious, 495 non-serious; in the cases reporting relevant serious events; • Reported relevant PTs: Tachycardia (1098), Arrhythmia (102), Myocardial infarction (89), Cardiac failure (80), Acute myocardial infarction (41), Cardiac failure acute (11), Cardiogenic shock and Postural orthostatic tachycardia syndrome (7 each) and Coronary artery disease (6);
4/19/2022 11:16:51	Number of relevant events: 1441, of which 946 serious, 495 non-serious; in the cases reporting relevant serious events; • Reported relevant PTs: Tachycardia (1098), Arrhythmia (102), Myocardial infarction (89), Cardiac failure (80), Acute myocardial infarction (41), Cardiac failure acute (11), Cardiogenic shock and Postural orthostatic tachycardia syndrome (7 each) and Coronary artery disease (6);	17	Table 7	Other	Post-vaccination COVID-19 cases: 3067, 136 fatal (2110 unknown outcome)
4/19/2022 11:21:23	BNT162b2 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	18	2	Adverse Effects - Other	Haematological AESIs: 932 cases; 1080 AEs, 681 serious - Most frequently reported relevant PTs (≥15 occurrences) include: Epistaxis (127), Contusion (112), Vaccination site bruising (96), Vaccination site haemorrhage (51), Petechiae (50), Haemorrhage (42), Haematochezia (34), Thrombocytopenia (33), Vaccination site haematoma (32), Conjunctival haemorrhage and Vaginal haemorrhage (29 each), Haematoma, Haemoptysis and Menorrhagia (27 each), Haematemesis (25), Eye haemorrhage (23), Rectal haemorrhage (22), Immune thrombocytopenia (20), Blood urine present (19), Haematuria, Neutropenia and Purpura (16 each) Diarrhoea haemorrhagic (15); • Relevant event onset latency (n = 787): Range from <24 hours to 33 days, median = 1 day; • Relevant event outcome: fatal (34), resolved/resolving (393), resolved with sequelae (17), not resolved (267) and unknown (371).
4/19/2022 11:23:49	BNT162b2 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	18-19	last, first	Adverse Effects - Other	Hepatic AESIs - Number of relevant events: 94, of which 53 serious, 41 non-serious; • Most frequently reported relevant PTs (≥3 occurrences) include: Alanine aminotransferase increased (16), Transaminases increased and Hepatic pain (9 each), Liver function test increased (8), Aspartate aminotransferase increased and Liver function test abnormal (7 each), Gamma-glutamyltransferase increased and Hepatic enzyme increased (6 each), Blood alkaline phosphatase increased and Liver injury (5 each), Ascites, Blood bilirubin increased and Hypertransaminasaemia (3 each);
4/19/2022 11:27:05	BNT162b2 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	19	2	Adverse Effects - Other	Facial Paralysis - 449 cases - Overall Conclusion: Causality assessment will be further evaluated following availability of additional unblinded data from the clinical study C4591001, which will be unblinded for final analysis approximately mid-April 2021. Additionally, non- interventional post-authorisation safety studies, C4591011 and C4591012 are expected to capture data on a sufficiently large vaccinated population to detect an increased risk of Bell's palsy in vaccinated individuals
4/19/2022 11:30:09	BNT162b2 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	20	1	Adverse Effects - Other	Immune-Mediated/Autoimmune AESIs - 1077 events; 780 serious; Most frequently reported relevant PTs (>10 occurrences): Hypersensitivity (596), Neuropathy peripheral (49), Pericarditis (32), Myocarditis (25), Dermatitis (24), Diabetes mellitus and Encephalitis (16 each), Psoriasis (14), Dermatitis Bullous (13), Autoimmune disorder and Raynaud's phenomenon (11 each). Outcome 12 fatal
4/19/2022 11:32:18	BNT162b2 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	20	2	Adverse Effects - Other	Musculoskeletal AESIs - 3640 events - Reported relevant PTs: Arthralgia (3525), Arthritis (70), Rheumatoid arthritis (26), Polyarthritis (5), Polyneuropathy, Post viral fatigue syndrome, Chronic fatigue syndrome (4 each), Arthritis bacterial (1)

4/19/2022 11:34:53	BNT162b2 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	21	1	Adverse Effects - Other	Neurological AESIs (including demyelination) - 542 events, 515 serious: Most frequently reported relevant PTs (>2 occurrences) included: Seizure (204), Epilepsy (83), Generalised tonic-clonic seizure (33), Guillain-Barre syndrome (24), Fibromyalgia and Trigeminal neuralgia (17 each), Febrile convulsion, (15), Status epilepticus (12), Aura and Myelitis transverse (11 each), Multiple sclerosis relapse and Optic neuritis (10 each), Petit mal epilepsy and Tonic convulsion (9 each), Ataxia (8), Encephalopathy and Tonic clonic movements (7 each), Foaming at mouth (5), Multiple sclerosis, Narcolepsy and Partial seizures (4 each), Bad sensation, Demyelination, Meningitis, Postictal state, Seizure like phenomena and Tongue biting (3 each)
4/19/2022 11:37:55	BNT162b2 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	21-22	last; first	Adverse Effects - Other	Other AESIs - 8241 relevant events; 3674 serious. Most frequently reported relevant PTs (≥6 occurrences) included: Pyrexia (7666), Herpes zoster (259), Inflammation (132), Oral herpes (80), Multiple organ dysfunction syndrome (18), Herpes virus infection (17), Herpes simplex (13), Ophthalmic herpes zoster (10), Herpes ophthalmic and Herpes zoster reactivation (6 each), Outcome: 96 fatal
4/19/2022 11:41:20	BNT162b2 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	22	3	Adverse Effects - Other	Renal AESIs - 69 relevant events; all serious: Acute kidney injury (40); Renal failure (30). Outcome: 23 fatal, 15 not resolved.
4/19/2022 11:43:37	BNT162b2 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	22-23	last; first	Adverse Effects - Other	Respiratory AESIs - 137 relevant events; 126 serious. Reported relevant PTs: Respiratory failure (44), Hypoxia (42), Respiratory disorder (36), Acute respiratory distress syndrome (10), Chronic respiratory syndrome (3), Severe acute respiratory syndrome (2). Outcome: 41 fatal, 18 not recovered.
4/19/2022 11:46:06	BNT162b2 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	23	2	Adverse Effects - Other	Thromboembolic Events - 168 relevant events, 165 serious: Most frequently reported relevant PTs (>1 occurrence) included: Pulmonary embolism (60), Thrombosis (39), Deep vein thrombosis (35), Thrombophlebitis superficial (6), Venous thrombosis limb (4), Embolism, Microembolism, Thrombophlebitis and Venous thrombosis (3 each) Blue toe syndrome (2). Outcome: 18 fatal, 49 not resolved
4/19/2022 11:47:56	BNT162b2 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	23-24	last; first	Adverse Effects - Other	Stroke: 300 relevant events, all serious: Most frequently reported relevant PTs (>1 occurrence) included: o PTs indicative of Ischaemic stroke: Cerebrovascular accident (160), Ischaemic stroke (41), Cerebral infarction (15), Cerebral ischaemia, Cerebral thrombosis, Cerebral venous sinus thrombosis, Ischaemic cerebral infarction and Lacunal infarction (3 each) Basal ganglia stroke, Cerebellar infarction and Thrombotic stroke (2 each); o PTs indicative of Haemorrhagic stroke: Cerebral haemorrhage (26), Haemorrhagic stroke (11), Haemorrhage intracranical and Subarachnoid haemorrhage (5 each), Cerebral haematoma (4), Basal ganglia haemorrhage and Cerebellar haemorrhage (2 each). Outcome: 61 fatal, 85 not resolved
4/19/2022 11:50:20	BNT162b2 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	24	2	Adverse Effects - Other	Vasculitic Events: 34 relevant events, 25 serious. Reported relevant PTs: Vasculitis (14), Cutaneous vasculitis and Vasculitic rash (4 each), (3), Giant cell arteritis and Peripheral ischaemia (3 each), Behcet's syndrome and Hypersensitivity vasculitis (2 each) Palpable purpura, and Takayasu's arteritis (1 each). Outcome: 1 fatal, 12 not resolved
4/19/2022 11:54:09	BNT162b2 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	26	1	Other	Medication error: 2792 relevant events: 7 fatal. Can include the following: Accidental exposures to product; Product administration errors and issues; Product confusion errors and issues; Product dispensing errors and issues; Product label issues; Product monitoring errors and issues; Product preparation errors and issues; Product selection errors and issues; Product storage errors and issues in the product use system; Product transcribing errors and communication issues, OR Preferred Terms: Accidental poisoning; Circumstance or information capable of leading to device use error; Circumstance or information capable of leading to medication error; Contraindicated device used; Deprescribing error; Device use error; Dose calculation error; Drug titration error; Expired device used; Exposure via direct contact; Exposure via eye contact; Exposure via mucosa; Exposure via skin contact; Failure of child resistant product closure; Inadequate aseptic technique in use of product; Incorrect disposal of product; Intercepted medication error; Intercepted product prescribing error; Medication error; Multiple use of single-use product; Product advertising issue; Product distribution issue; Product prescribing error; Product prescribing issue; Product substitution error; Product temperature excursion issue; Product use in unapproved therapeutic environment; Radiation underdose; Underdose; Unintentional medical device removal; Unintentional use for unapproved indication; Vaccination error; Wrong device used; Wrong dosage form; Wrong dosage formulation; Wrong dose; Wrong drug; Wrong patient; Wrong product procured; Wrong product stored; Wrong rate; Wrong route; Wrong schedule; Wrong strength; Wrong technique in device usage process; Wrong technique in product usage process.
4/19/2022 12:00:02	BNT162b2 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	1-9	All pages	Adverse Effects - Other	Appendix 1 - this is a listing of 9 full pages of adverse events of special interest. Hard to believe.
4/19/2022 15:21:49	5.3.6 Cumulative Analysis of Post- Authorization Adverse Event Reports of PE-07302048 (BNT162B2) Received through 28 – February – 2021	5	2	Other	They are mostly interested in a cumulative analysis of post – authorization safety data to support their future BLA submissions
4/19/2022 15:25:51	5.3.6 Cumulative Analysis of Post- Authorization Adverse Event Reports of PE-07302048 (BNT162B2) Received through 28 – February – 2021	5	7	Other	They acknowledge that adverse events are submitted voluntarily and the MAGNITUDE of under reporting is unknown.
4/19/2022 15:35:30	5.3.6 Cumulative Analysis of Post- Authorization Adverse Event Reports of PE-07302048 (BNT162B2) Received through 28 – February – 2021	6	4	Other	They were overwhelmed, in the roll out from Dec. 1, 2019- February 28, 2021!!! They admit that due to the large number of spontaneous adverse event reports received for the product the MAH has prioritize the processing of serious cases… Pfizer has also taken multiple actions to help alleviate the large increase of adverse event reports… As well as increasing the number of data entry and case processing colleagues.
4/19/2022 15:49:25	16.2.4.1, 16.2.4.1.1,16.2.4.4 excel files	summary	summary	Study Protocol	I compared averages of the overall demographic samples & compared them with those in the trials (in the file "AG Summary of Table 16.2.4.1.xlsx"). I have noted my summary in the yellow box in this file. Those who participated in the trial were generally healthy, white females with lower weight and a healthy BMI, which would skew the results of the trial. The 100 µg trial did not have a statistically significant sample size (only 15).
4/19/2022 15:54:11	125742_S1_M5_5351_c4591001-fa-interim-audit-certificates.pdf	1	1	Other	27 Jul 2020 thru 02 Oct 2020 were routine audits. 05 Oct 2020 thru 06 Nov 2020 were non-routine audits. This needs to be crossed referenced to something else to figure out why. Nothing in this documents specifies why.
4/19/2022 15:56:02	Phase 1/2 study of COVID-19 RNA vaccine BNT162b1 in adults	pg 4 exclusion criteria include pregnant women, those immunocompromised	paragraph 1 - Study design	Study Protocol	How could exclusion criteria include pregnant women and anyone who was immunocompromised when Pfizer is recommending the vaccine for everyone? Shouldn't they have been included in the trial to determine if it was safe for that population?
4/19/2022 16:04:35	Phase 1/2 study of COVID-19 RNA vaccine BNT162b1 in adults	12	Lymphocyte loads	Study Protocol	Pfizer only tested 8 days post vaccination for lymph levels to determine if there was a response based on the baselines. But shouldn't they have tested lymph levels longer than 8 days to determine when those levels returned to baseline? Wouldn't that have also identified the issues now being seen with regards to immunity?
4/19/2022 16:10:02	Phase 1/2 study of COVID-19 RNA vaccine BNT162b1 in adults	13	Demographic Table	Study Protocol	How can they only have 1 Latino and 1 Black in a study of 45 and conclude the vaccine is safe on that population? And even if Pfizer is using Phase II data as the foundation for moving to a Phase III trial, how can they know if the vaccine was safe in the Phase II trials on that population if they only had 1 from each group to test?
4/19/2022 16:15:29	Phase 1/2 study of COVID-19 RNA vaccine BNT162b1 in adults	16, 17	Clinical data	Data Discrepancy	Pfizer says on pg 16 that antibodies were n/a but then report on pg 17 that they measured IgG levels, which are antibodies. It may be a nothingburger but if it is a discrepancy, doesn't it indicate they might not be reporting things accurately?
4/19/2022 16:19:16	5.3.6 Cumulative Analysis of Post- Authorization Adverse Event Reports of PE-07302048 (BNT162B2) Received through 28 – February – 2021	9	1	Adverse Effects - Other	injury, poisoning and procedural complications Off label use, 880 (2.1%) Product use issue 828 (2.0%)
4/19/2022 16:23:18	5.3.6 Cumulative Analysis of Post- Authorization Adverse Event Reports of PE-07302048 (BNT162B2) Received through 28 – February – 2021	8	Table 2	Adverse Effects - Other	Blood and lymphatic system disorders Lymphadenopathy 1972 (4.7%) Cardiac disorders Tachycardia 1098 (2.6%)
4/19/2022 16:27:03	5.3.6 Cumulative Analysis of Post- Authorization Adverse Event Reports of PE-07302048 (BNT162B2) Received through 28 – February – 2021	10	Table 4 Important Identified Risk -b	Adverse Effects - Other	There were four individuals in the anaphylaxis evaluation who died on the same day.

4/19/2022 16:55:46	5.3.6 Cumulative Analysis of Post- Authorization Adverse Event Reports of PE-07302048 (BNT162B2) Received through 28 – February – 2021	7	Table 1.	Adverse Effects - Other	Table 1 General overview: selected characteristics of all cases received during the reporting interval December 1, 2020 – February 28, 2021 Cases reported 42,086 158,893 events 34,762 cases from US Table one general overview selected characteristics of all cases received during the reporting interval Female cases 29,914 Mail cases 9182 No data 2990 Of all cases largest was in age group 31–50 13,886 Case outcome: Recovered/recovering 19,582 Recovered with séqueles 520 Not recovered at the time of report 11,361 FATAL 1223 UNKNOWN 9400 How many deaths were there for swine flu vaccination trial before it was shut down?
4/19/2022 17:33:02	125742_S1_M5_5351_c4591001-fa-interim-publications.pdf	3, 4, 5, 7, 8, 14, 18, 20, 21, 24, 25	Pg. 3: summary; Pg. 4: 4-5, 10-11; Pg. 5: 3; Pg. 7-8: charts; Pg.14: chart; Pg. 18: 2; Pg. 20: 1; Pg. 21: chart; Pg. 23: chart; Pg. 24: 1; Pg. 25: chart	Adverse Effects - Other	In the first study from Nature, it mentions the 100ug dose and that a second vaccination with 100ug was not administered due to increased reactogenicity and a lack of meaningfully increased immunogenicity after a single dose compared to the 30ug dose. It doesn't mention what the specific reactogenicity from the 100ug dose is. On page 4, the study discusses 50% reported fever in the 100ug group, and it is unknown if this is the reactogenicity they referred to earlier. Pg. 4 continues with adverse events reported by the 100ug group were 58.3% (7/12) recipients and 1 noted sleep disturbance as a severe AE. Related AE's were reported by 50% in the 100ug group. Page 5 notes since 100ug was not boosted, there is no data for immunogenicity after a second dose. Pg. 7-8 are charts of the reactions showing severe reactions from some participants with the 100ug after 7 days, which included fatigue, headache, chills, muscle pain and joint pain. There were some severe events noted with 10 ug and 30 ug after the second dose. The second study in NEJM, mentions one dose of 100ug of BNT162b1 in one of the groups in the 18–55-year range. The chart on pg. 21 shows the groups (Note: the BNT162b2 didn't receive 100ug). The charts on pgs. 23 and 25 shows data for Dose 1 and Dose 2 for both BNT162b1 and BNT162b2, but there is no data at all for the 100ug that I could find even though it was noted this group was part of the study. It mentions on pg. 24 the second dose of 100ug was not administered because of reactogenicity in the participants, but unknown what specifically for this study.
4/19/2022 18:19:24	125742_S1_M5_5351_c4591001-fa-interim-audit-certificates.pdg	4	all	Other	Two auditors viewed and signed documents on Nov 19, 2020, well after the close of the audit on 11/6/20
4/19/2022 18:24:05	12572_S1_M5_5351_C4591001 Table 16.2.4.11 Listing of Demographic Characteristics	1-21	see copy	Other	I wasn't sure what to look for in this data, but did notice a few things that may be of interest. Pgs 1-21 had the dosages and people (subjects) information. Each age group: 18-55 & 65-85 had 12 subjects for each dosage (10, 20, 30 ug) and 9 subjects in each of the placebo groups for each of the dosages (10, 20, 30 ug). In the 100 ug group there were 12 subjects who got 100 ug but only 3 in the placebo group for 100 ug. The total number of subjects for all was 195. I wasn't sure if this document is related to the 5.3.6 document but noticed "All Subjects Demographics" totaled 43646 subjects/people. The 5.3.6 document had 42086 subjects/people. That is a difference of 1560 people.
4/19/2022 21:25:07	125742_S1_M5_5351_c4591001-interim-mth6-audit-certificates.pdf	1 and 2	Audit Certificate Table	Other	Types of Audits listed as "Routine" and "Non-Routine" for Pfizer Regulatory Quality Assurance Audits, what would trigger a Routine verses Non-Routine Audit for Study C4591001 Phase 2/3 ??
4/20/2022 10:27:34	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-publications.pdf	3	2	Other	I believe that this statement contains incorrect facts regarding RNA vaccines: "RNA is required for protein synthesis, does not integrate into the genome, is transiently expressed, and is metabolized and eliminated by the body's natural mechanisms and, therefore, is considered safe. RNA-based prophylactic infectious disease vaccines and RNA therapeutics have been shown to be safe and well-tolerated in clinical trials. In general, vaccination with RNA elicits a robust innate immune response. RNA directs expression of the vaccine antigen in host cells and has intrinsic adjuvant effects. A strength of the RNA vaccine manufacturing platform, irrespective of the encoded pathogen antigen, is the ability to rapidly produce large quantities of vaccine doses against a new pathogen."
4/20/2022 10:30:55	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-publications.pdf	11	Column 2, paragraph 3	Study Protocol	Competing interests: Competing interests NK, JA, AG, SL, RB, KAS, PL, KK, WK, DC, KRT, PRD, WCG, and KUJ are employee of Pfizer and may hold stock options. US and OT are stock owners, management board members, and employees at BioNTech SE (Mainz, Germany) and are inv tors on patents and patent applications related to RNA technology. MJM, KEL, KN,EEW, ARF, RF, and VR received compensation from Pfizer for their role as study investigators. CFG and PYS received compensation from Pfizer to perform the neutralization assay.
4/20/2022 13:10:15	org/wp-content/uploads/2022/04/125742_s1_m5 ..... interim irb consent form	36	1	Other	date on final page of form is July 2019, instead of the April 2020 on the others
4/20/2022 13:37:36	wp-content/uploads/2022/04/125742_S1_M5 .....irb consent form	44	1	Study Protocol	Why so little data collected in further months? Not collecting height and weight of growing children months after vaccine. CD4 viral count for HIV positive only ?
4/20/2022 14:18:58	125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf	1-3139	Table 1:16.2.4.1, Table 2:16.2.4.1.1, Table 3: 16.2.4.4	Data Discrepancy	I. These 3 tables are not the tables referenced in the other 2 documents associated with Group 2 (125742_S1_M5_5351_c4591001-fa-interim-invest-signature.pdf and 125742_S1_m5_c4591001-fa-interun-sponsor-signature.pdf) . The protocol number is the same, however. II. Table 2 appears to be a carve out from Table 1 However no mention is made in Table 2 of the number of doses, nor the interval, if any, between them. Table 1 specifies 2 doses, 21 days apart; Table 2 lacks this specification. III. Table 3 is titled "All Subjects" However what the "All" in the table title refers to is not defined. The other Tables specify Phase 1 but Table 3 has no specification. Does it refer to all phases or something else?
4/20/2022 14:34:53	125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf	22-3139	Table 16.2.4.4	Study Protocol	I. A cursory examination of the vast list of 43,649 Subjects reveals plenty of Subjects with a BMI greater than 30k/m, which according to the protocols, is a criterium for exclusion from Phase 1. Were all these Subjects excluded per protocol? If they were excluded, why have they all signed informed consents? Why is having a BMI greater than 30k/m only an exclusion for Phase 1; why not for the other phases as well? II. Regarding high numbers of consent forms signed in one day at one site (e.g. site 1231): this begs questions related to the issue of medical experimentation apartheid.
4/20/2022 17:22:34	125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf	137	3	Adverse Effects - Other	38.8 % Subjects with Severe Symptoms listed in TrialManager tutorial, 19 hospitalized next page

4/20/2022 20:17:01	125741-S--M5-5351-c4591001-fa-interim-sample-crf.pdf	many	many excerpts from article	Other	From the "informedChoiceWA.org website, March 13,2021 is an article entitled: "German Corona Extra-Parliamentary Inquiry Committee" "Corona Investigative Committee Hearing #37: Pfizer/BioNTech Safety Issues" by ICWA/March13, 2021" The "Committee was launched by Dr Reiner Fuellmich on July 10.2020". The Committee has obtained expert testimony from various fields of medicine, science, and law. On January 30,2021, expert testimony was provided by Cell Biologist, Dr Vanessa Schmidt-Kruger. The following are some excerpts from her testimony: Using "radioactivity as a marker. They injected the whole muscle and watched how the lipids spread throughout the body, and found that these lipids were in many organs after just 15 minutes." " 50% of the PEG is degraded via excretion, ie, it is excreted from the body" and ends up in the sewer system. "The cationic lipids are exclusively degraded in the cells, only 1% found in the stool. This means the cells take the full hit of toxicity. They analyzed the half life of this cationic lipid in the liver, they say it is 3 weeks. With half life at the beginning the substance always degrades faster, and then it gets less, the curve gets fatter. One can still find 5% of the lipid in the liver after 4-6 weeks." 'when they calculate the conversion from this mouse or rat study to human beings that cationic lipids have a half life of 20 to 30 days in human beings to 5%, so not really eliminated takes 4-5 months. The EMA Committee just said "That's a long Time." (2010 study by Mamoth et al). "What happens to the sewage if so much (lipids) is being eliminated?" Is it degraded in the system? In January 2021 "the BioNTech vaccine that was being used was not "highly purified, it contains contaminants of certain components.' It was documented in the European Medicines Agency report. They asked for improvements and information about BioNTech's Good Manufacturing Processes.. "Product optimization was too fast. It usually takes a year. " During the clinical phase small volumes of vaccine, they were able to use very expensive techniques that delivered highly purified end products.' With mass production meant switching to lower cost production. Now finding problems with batch production variability and contaminants.
4/21/2022 0:19:53	125742-S1-M5- 5351-c4591001-fa-interim-sample-crf.pdf	many	many	Other	Article entitled "Hearing #37 of German Corona Extra-Parliamentary Committee" part 1 of 4 by Yogaesoteric.net July 29.2021. Expert testimony by Cell Biologist, Dr Vanessa Schmidt-Bruger on January 30 2021. Committee members also asked questions and gave responses such as: "WW: In the case of pregnant women one also has the problem that the immune system reacts differently than those who are not pregnant> Because in pregnancy the immune system is switched so that the foetus is tolerated and not rejected. it reacts differently as a result. This may also have a bearing with this vaccination, it can lead to complications in pregnancy, and also in older people, where certain processes no longer take place- the immune system tolerates more than normal, and immunological complications arise as a result. This could occur in elderly people and in pregnancy."
4/21/2022 0:48:27	125742-S1-M5-5351-c4591001-fa-interim-sample-crf.pdf	video	video	Study Protocol	April 7,2022 video on Bitchute entitled: "Self Amplifying RNA Injections- What Does it Mean?' Alexandra Latypova, from Team Enigma, discusses Pfizer testing multiple versions of the product at the same time. The information comes from the "Investigators Brochure" BNT162/PF-07302048 (pdf) August 12, 2020. Much redacted info.. From BioNTech RNA Pharmaceuticals GmbH "BioNTech has three different platforms for the development of BNT162 vaccine candidates that have been ongoing for some time. They are " testing at least 7 versions of mRNA injections throughout different countries. People have been led to believe it is a single product. Informed Consent???? Allegedly, "at the commercial scale Pfizer was not GMP compliant." There are"multiple versions, undisclosed ingredients, and secret technical properties" Regarding the Self Amplifying RNA there is no explanation of course or elimination time from the body. Will continue to replicate in the body...but for how long? "Other ongoing trials...But waving safety pharmacology, pharmokinetics, genotoxic, carcinogenic and other studies as " unnecessary for vaccines" "How Bad is My batch website provides a wealth of information.
4/21/2022 1:05:42	125742-S1-M5-5351-c459101-fa-interim-sample-crf.pdf	Bitchute video	Bitchute video	Study Protocol	Bitchute video on March 21,2022 entitled "Discussion About Regulatory and Scientific Fraud in Pfizer Preclinical Studies". Video discussion with Sasha Latypova from Team Enigma.
4/21/2022 1:42:49	125741-S1-M5-5351-c4591001-fa-interim-sample-crf.pdf	video	video	Other	"The Bluetooth Challenge Explained Why COVID Vaxxed People Are Emitting Bluetooth Codes and How You Can See It For Yourself' by HopeGirl March 27. 2022 HowBadIsMyBatch.com provides a wealth of articles, adverse events related to batches, and videos related to vaccines
4/21/2022 11:37:10	125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf	all	all	Other	I'm having a real hard time reconciling some numbers. This document implies that all subjects from page 18 forward received the placebo, and that only 195 people participated in the 10, 20, 30, & 100 µg trials (pulled out into the excel files provided). But earlier, I reviewed "5.3.6 postmarketing experience.pdf" in which >42,000 subjects are referenced & tracked. It's not clear to me how these very different populations reconcile.
4/21/2022 12:19:53	125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf	6 through 14	Thisis a list of IRB's	Study Protocol	Copernicus Group and Western were used for almost all US studies. Copernicus and Western merged recently. Copernicus Group s owned by Novo Nordisk Foundation. This is said to be the richest foundation. According to their current CEO thay are pro rNa vaxes and like the Covid 19 shot.
4/21/2022 13:04:53	125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf	21-22	All	Data Missing	Noticed that "Vaccine Group (as Randomized) was dropped from the header.
4/21/2022 13:23:56	125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf	1248-1325(16-55yo), 2897-2916(>55yo)	All subjects for test site "1226"	Other	Very high enrollment rates at this site for 16-55yo and >55 yo subjects(1350 total from 8/5-10/20). Mostly Hispanic/Latino population. May be interesting to check out how adverse events play out for this site. For comparison, other sites over a similar time period may only have about 175-250 subjects enrolled total on average; this appears to be a more typical scenario. (See site "1168" on pp. 1066-1077 and pp. 2791-2796, with 238 total subjects enrolled from 8/11-10/28/20 and site "1179" on pp. 1159-1164 and pp. 2845-2852, with 173 total subjects enrolled from 8/14-10/30/20 as more typical enrollment examples.)
4/21/2022 13:39:27	125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf	1350-1574(16-55yo), 2922-3018(>55yo)	All subjects enrolled for test site "1231"	Other	Very high enrollment numbers for test subjects. From 8/6-8/31/20, **4,490** total subjects were enrolled. This 26 day period is the only documented time that patients were enrolled. (For instance, on 8/28/20 alone, there were 357 subjects enrolled total for both age groups.) This was a predominantly Hispanic/Latino population. It may be interesting to see how adverse events play out for this site as that information is available. It also would be interesting to understand just how this many people that conformed to all of the inclusion criteria could be found in such great numbers in one test area and that all agreed to participate in this study, as well as how study administrators were able to assess the subjects adequately for inclusion and give appropriate informed consent to each subject in such a short time period with the sheer volume of subjects. For comparison, more typical enrollment rates for a much longer time period (2-3 months, for example) tended to yield 175-250 total subjects for that much longer time period.
4/21/2022 13:45:45	125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf	1604-1696(16-55yo), 3035-3052(>55yo)	All subjects for test site "1241"	Other	Very high subject enrollment rates for this test site. From 8/7-11/4/20, **1,479** total subjects were enrolled. There were a high number of Black and Multiracial subjects for this site. It may be of interest to see how adverse events play out for the subjects enrolled at this site. For comparison, more typical enrollment numbers over a similar time period for other sites average at 175-250 total subjects enrolled.
4/21/2022 13:53:28	125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf	1793-1850(16-55yo), 3105-3139(>55yo)	All subjects enrolled for test site "4444"	Other	Very high subject enrollment rates at this test site. From 9/21-9/27/20, there were **1,274** total subjects enrolled. This was the only time period that had subjects enrolled. This site had a high Hispanic/Latino population. This may be interesting to see how adverse events play out for this site when that information is available. For comparison, more typical enrollments for other test sites over a much longer time period (2-3 months generally) yielded on average 175-250 subjects total over that longer time period.
4/21/2022 14:26:42	125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf	140	1	Adverse Effects - Other	Very high numbers of adverse reactions at site 6000 and also 1001

4/21/2022 14:55:40	125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf	213	2	Other	Many duplicated subjects (35) in Russia and 31 (undefined), why duplicated?
4/21/2022 15:03:17	125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf	218	3	Adverse Effects - Other	Interim data? 16.4 % Subjects with Severe side effects, (only 9 at the time)
4/21/2022 15:09:42	125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf	220	2	Data Missing	Interim Diary Compliance 17.4 %, 27 completed, 128 missing
4/21/2022 17:03:32	125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf	51	1	Other	Randomization, but 7 consecutive 100 mcg shots in 18 to 55 age group at site 1001
4/21/2022 17:29:12	5.3.6 Cumulative Analysis of Post-Authorization Adverse Event Reports of PF-07302048 (BNT162B2) Received Through 28-Feb-2021	Page 10	Table 4 including a., b.	Fatality	Important Identified Risk Table 4 (just below the table) b. "There were 4 individuals in the anaphylaxis evaluation who died on the same day they were vaccinated. Although these patients experienced adverse events (9) that are potential symptoms of anaphylaxis, they all had serious underlying medical conditions, and one individual appeared to also have COVID-19 pneumonia, that likely contributed to their deaths"
4/21/2022 17:36:52	125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf	92	1	Other	Subject received 1st dose of 30 mcg but did not receive 2nd injection
4/21/2022 17:46:01	125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf	107-110	1	Data Discrepancy	About 30 consecutive participants did not receive 2nd dose, site 1005
4/21/2022 18:00:48	125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf	127	1	Data Discrepancy	4 subjects in a row that received 1st shot, but not 2nd. End of Oct, Nov, Site 1006
4/21/2022 18:26:19	125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf	165 - 167	1	Other	Last 24 people at site 1007 received 1st dose, but not 2nd dose.
4/21/2022 18:42:07	125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf	236 - 242	1	Other	Last 60 people at Site 1008 had 1st shot, but not 2nd.
4/21/2022 19:12:49	5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	Page 12, 13. Table 6 Description of Missing Information /Use in pregnancy and lactation	Two (first two bullet points under Pregnancy cases:274 cases including:	Fatality	"Pregnancy cases:274 including: 270 mother cases and 4 foetus/baby cases" They state the four foetus cases are linked to the mother cases, so the number of pregnancy cases is 270. Out of these 270 cases, 238 no information was given plus 5 unknown outcomes. That is 90% unknown. 23 spontaneous abortions +2 premature birth with neonatal death +2 spontaneous abortions with intrauterine death + 1 spontaneous abortion with neonatal death= 28 deaths.....that is 10.3%. Then 1 normal outcome is noted.....that is .0037% normal outcomes known. (This info does not include lactation numbers from the same table. I have not reviewed that yet.) Please check my math. 270 pregnancies listed in these two bullet points, 243 unknown outcomes, 1 normal outcome, 28 deaths. Page 13, fist paragrph in the same table, "CONCLUSION: There were no safety signals that emerged from the review of these cases of use in pregnancy and while breast feeding."
4/21/2022 19:39:51	5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	Page 12,13 Table 6 Description of Missing Information	Under the heading: Pregnancy cases: 274 cases including: Fourth bullet point, second paragraph	Fatality	"124 mother cases, 49 non-serious and 75 serious reported clinical events." 75 of these 124 are 60%, so 60% are serious! Spontaneous abortions in 25 of the cases. That is 20% of this group. Other adverse events listed in this group but apparently not included in the 25 are uterine contraction during pregnancy, premature rupture of membranes, abortion, abortion missed(?), and foetal death at 1 each. Next bullet point: 4 serious foetus/baby cases reported...foetal growth restriction 2 cases, premature baby 2 cases, and neonate death in 1.
4/21/2022 19:50:30	125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf	1-26 listing of IRBs	N/A	Study Protocol	There were no ethics committees listed for the United States. Yale University Human Research Protection Program was listed, perhaps this served to protect human subjects. Concern if there was enough protection for young and adult subjects. The Copernicus Group Institutional Review Boards were the dominant IRBS used for the study, concern of possible bias. https://www.wcgirb.com/wp-content/uploads/sites/2/2020/08/Guide_for_Researchers.pdf Special Considerations for Drug Research: Do You Need an IND WCG IRB's "Initial Review Submission Form asks for information about an IND. As a general rule, WCG IRB requires that a sponsor or investigator obtain an IND from FDA for clinical investigations involving drugs or dietary supplements. However, if the investigation uses a marketed drug, the sponsor or investigator may propose that the investigation is exempt from an IND under 21 CFR § 312.2. COVID-19 Related Changes to Research WCG IRB has received questions from several research sponsors about the appropriate process for making changes to clinical studies in response to the COVID-19 epidemic."
4/21/2022 23:29:02	Table 16.2.4.4 Demographic Characteristics, All Subjectss	All	Single table	Other	On or about line 61113 there was a VERY quick flash of print in lower case beginning at column F or G and extending to the right of column "K", off the right hand side of the screen. After it disappeared I could not get it back. Has anyone screened these tables for 'hidden' information many lines below the bottom and/or many columns to the right of the apparent end? I'm not able to scroll to the right in this table, and I don't know why, but I've known of some in the fed and commercial realms to stash data in sundry locations to prevent ready availability and this is the trick they use to hide information and still comply with the Federal Records Protection Act.
4/21/2022 23:51:41	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf	1-4412	tables	Study Protocol	This document was 4,412 pages of tables listing ALL vaccines received by ALL subjects. There were 10 subjects per page. The tables I'm referring to start on page 38. Some general observations: ---When the vaccines started the age groups are 18-55 & 65-85 (where are the 55-65-yr-olds put?) until July 1, 2020. The groups that are vaccinated starting July 28, 2020 are now listed as >55 & 16-55. ---In May 2020 there are 12 subjects in the 18-55 group who received 100(!)mg & then a 2nd dose of 10mg in Aug. Where there AE in this group? (The last set of docs I read said that anyone who received 60mg shouldn't get a 2nd shot due to reactogenicity.) ---There was no one listed who received 60mg (but there were a few who received 10 or 20mg). If the last set of docs mentioned there had been some who received such a dose, where are they in these tables of ALL subjects? ---In the placebo group 752 didn't receive Dose 2 vs 676 in BNT group. ---Some locations had the exact same number in the placebo & BNT groups who didn't receive Dose 2...kind of interesting if the subjects were truly randomized. ---Was there a pre-determined end date for subjects to be vaccinated. I found that those who received Dose 1 later than Oct 22 didn't get Dose 2. If it was known that these people wouldn't be able to get their Dose 2 3 weeks later, why were they given Dose 1? Were they followed up by the study? ---How were those who didn't get Dose 2 evaluated for the safety & efficacy of the Dose 2 regimen?
4/21/2022 23:58:44	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf	3046-3053	Site location code 1185	Study Protocol	At location 1185 NO ONE received Dose 2. There were 75 enrolled.
4/21/2022 23:59:56	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf	3089-3090	Location site 1202	Study Protocol	Site 1202 had only 12 in the study. None of them received Dose 2.
4/22/2022 0:01:47	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf	3133-3139	Location site 1207	Study Protocol	69 enrolled at site 1207. 4 received Doses 1 & 2 of BNT; only 1 received 2 doses of placebo.

4/22/2022 0:04:15	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf	3139-3144	Site location 1208	Study Protocol	55 enrolled. 2 received both doses of BNT & 2 received both doses of placebo.
4/22/2022 0:07:26	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf	3145-3146	Location site 1209	Study Protocol	11 enrolled; 1 each received 2 doses of BNT or placebo.
4/22/2022 0:09:18	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf	3147-3153	Location site 1210	Study Protocol	60 enrolled; 4 received both BNT & 3 received both placebo.
4/22/2022 0:10:52	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf	3153-3156	Location 1212	Study Protocol	35 enrolled; 3 each received both doses of BNT or placebo.
4/22/2022 0:12:34	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf	3157-3162	Location 1213	Study Protocol	60 enrolled; 4 each received both doses BNT or placebo.
4/22/2022 0:14:13	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf	3163-3168	Location 1214	Study Protocol	56 enrolled; 3 received 2 doses BNT & 2 received placebo.
4/22/2022 0:15:37	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf	3169-3174	Location site 1217	Study Protocol	62 enrolled; 6 each received both doses of BNT or placebo.
4/22/2022 0:17:00	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf	3175-3176	Location site 1218	Study Protocol	19 enrolled; 3 each received 2 doses BNT or placebo.
4/22/2022 0:19:22	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf	3180-3183	Location 1220	Study Protocol	30 enrolled; 5 each received both doses BNT or placebo.
4/22/2022 0:21:39	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf	3183-3186	Location site 1221	Study Protocol	29 enrolled; 9 received both doses of BNT & 5 received both doses of placebo.
4/22/2022 0:33:57	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf	various	Location site 1231 (Argentina)	Study Protocol	There were 148 people who didn't receive Dose 2 of either the BNT or placebo. 118 were in the 16-55 age group.
4/22/2022 0:37:55	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf	various	Location site 1235	Study Protocol	Of the 13 who didn't receive Dose 2 of the vax, only 2 were >55.
4/22/2022 0:39:16	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf	various	Location site 1241 (Brazil)	Study Protocol	All 6 who didn't receive the 2nd dose were in the 16-55 group.
4/22/2022 0:44:02	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf	3144-3146	Location site 1209	Study Protocol	Of the 19 enrolled, only 5 were in >55 group.
4/22/2022 0:47:00	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf	3174-3176	Site location 1218	Study Protocol	Of the 20 enrolled, only 2 were in the >55 group.
4/22/2022 0:50:44	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf	3180-3185	Location site 1220	Study Protocol	Of 35 enrolled, only 6 were >55.
4/22/2022 1:15:53	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf	1 & 2	Tables	Other	This is an audit certificate that groups audits as routine or non-routine. Is a non-routine audit done when there might be a suspected problem? There were 17 routine audits & 7 non-routine. The sites audited were in the US, Brazil, Argentina, South Africa, Germany & Turkey. Sites 1109 (US) & 1231 (Argentina) had routine & non-routine audits. Both non-routine audits were done 2 months after the routine. The title of this is Pfizer Regulatory Quality Assurance. Somebody didn't assure the quality of the study. "...site audits were performed 29-Apr-2020 and 12-Mar-2021..." The 1st audit wasn't done until July 27, 2020. Why was Pfizer doing audits into Mar 2021 if the vax was rolled out in Dec 2020?
4/22/2022 14:15:06	reissue_5.3.6 postmarketing experience.pdf	16	Table 7	Adverse Effects - Other	Sex distribution skewed. The sex distribution of frequency of AEs is often very skewed, for instance cardiovascular, F/M 1076/291, whereas generally CVD more common in males. Is there a relation with unequal biodistribution as described here?: https://viralimmunologist.substack.com/p/a-moratorium-on-mrna-vaccines-is?utm_source=%2Fprofile%2F60901543-dr-byram-w-bridle&utm_medium=reader2&s=r
4/22/2022 14:18:37	reissue_5.3.6 postmarketing experience.pdf	13	Table 6 row 3	Efficacy	Note the change of definition of vaccine failure as per 15 Februari 2021
4/22/2022 18:15:32	125742-S1-M5-5351-c4591001-fa-interim-sample-crf.pdf	many	many	Other	An April 20, 2022 article by Sasha Latypova of Team Enigma entitled; " Did Pfizer Perform Adequate Safety Testing for its Covid-19 mRNA Vaccine in preclinical Studies? Evidence of Scientific and Regulatory Fraud" Found under "Leaked emails and FOI documents", number 13 as a PDF, on the How Bad Is My Batch website.
4/23/2022 11:36:53	16.2.7.2.3 Listing of Severe and Grade 4 Local Reactions – Subjects With Indeterminate Vaccine – All Subjects ≥16 Years of Age	1	d. Duration	Other	d. Duration (days) was calculated as the difference from the start of the first reported reaction to resolution of the last reported reaction, inclusive. If the reaction continued beyond Day 7, the calculation includes all days from the last e-diary day until the date of resolution collected on the case report form. If the reaction was ongoing at the time of the subsequent vaccination, the end date/day for the reaction is the date/day that the next vaccine was administered, which was used for the duration calculation. Question: Does this mean that if you still had side effects from the first dose, that they considered them to be "resolved" because you took the second dose, therefore didn't follow up on the original date of the first side effect/adverse event reported?
4/23/2022 13:40:10	5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	7	table 1	Fatality	This is about the fatality % and how grossly understated it truly is and exactly why so. In table 1 there is an indicator stating unknown at the bottom. Because 34,952 is the "actual" number of participants inlcuded in the data the fatality rate is 3.4% or 1223/34,952. However, as indicated in table 1 a total 11,361 are labled "not recovered." It is my opinion this 11,361 needs to be subtracted from the 34,952 PRIOR to calculating the fatality %. So truyly, 34,952 minus 11,361 = 23,591 as the known outcomes. So 1223 divded 23,591 = 5.1%. Conclusion becomes the new and true fatality rate should henceforth be referred to as 5.1%. HOLY SMOKES! Thank you for allowing people to be are part of exposing one of the greatest harms of mankind's history!

4/23/2022 14:37:25	16.2.4 Listing of Demographic Characteristics – All Subjects ≥16 Years of Age	Filtered "Age _Years" column of the Xcel version of this document	"Age _Years" column of document	Study Protocol	I recalled that I had seen criticism of vaccine trials not including enough older age subjects. I filtered the Xcel version of the Pfizer trial document for the percentages of subjects for 65 and above, 70 and above, and 75 and above. My results showed approx. 21% for 65 and above; 11% for 70 and above; and 4% for 75 and above. I believe the Pfizer trial protocol should be further evaluated to determine whether the percentages of older participants were appropriate or an attempt to get better results by biasing the trial toward younger age groups. The document "The Exclusion of Older Persons From Vaccine and Treatment Trials for Coronavirus Disease 2019—Missing the Target" Benjamin K. I. Helfand, MSc1,2; Margaret Webb, BA3; Sarah L. Gartaganis, MSW, MPH3; et alLily Fuller, BA3; Churl-Su Kwon, MD, MPH4; Sharon K. Inouye, MD, MPH3 Author Affiliations Article Information JAMA Intern Med. 2020;180(11):1546-1549. doi:10.1001/jamainternmed.2020.5084 (https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2771091) notes: "Older adults are at greatest risk of severe disease and death due to coronavirus disease 2019 (COVID-19). Globally, persons older than 65 years comprise 9% of the population,1 yet account for 30% to 40% of cases and more than 80% of deaths.2 Unfortunately, there is a long history of exclusion of older adults from clinical trials. In response, the National Institutes of Health instituted the Inclusion Across the Lifespan policy, requiring the inclusion of older adults in clinical trials.3 Thus, we reviewed all COVID-19 treatment and vaccine trials on http://www.clinicaltrials.gov to evaluate their risk for exclusion of older adults (≥65 years)..." The conclusion of the paper states: "Our findings indicate that older adults are likely to be excluded from more than 50% of COVID-19 clinical trials and 100% of vaccine trials. Such exclusion will limit the ability to evaluate the efficacy, dosage, and adverse effects of the intended treatments. We acknowledge that some exclusions for severe or uncontrolled comorbidities will be essential to protect the health and safety of older adults. However, caution must be taken to avoid excluding otherwise eligible participants for reasons that are not well-justified..." An article commenting on this paper is also available at: https://www.healthline.com/health-news/older-adults-are-more-at-risk-for-covid-19-so-why-dont-vaccine-trials-include-them Please check further on whether the Pfizer trial protocol represents improper age-biasing. Thanks!
4/23/2022 15:36:01	125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf	Pages 31	Paragraph 3	Adverse Effects - Reproductive Issues	"https://www.federalregister.gov/citation/46-FR-8951" 46 FR 8951, Jan. 27, 1981, as amended at HYPERLINK "https://www.federalregister.gov/citation/64-FR-10942" 64 FR 10942, Mar. 8, 1999] A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.
4/23/2022 20:37:12	125742-S1-M5-5351-c459101-fa-interim-sample-crf.pdf	1	1	Other	Alleged included LNP ingredient 1. CN112220919- Nano Coronavirus Recombinant Vaccine Taking Graphene Oxide As Carrier Office-China Applicant: Shanghai National Engineering Research Center for Nanotechnology Co., Ltd. Abstract " The invention belongs to the field of nano materials and biological medicines, and relates to a vaccine, in particular to development of a 2019-nCoV coronavirus nuclear recombinant nano vaccine. The invention also comprises a preparation method of vaccine and application of the vaccine in animal experiments. The novel coronavirus vaccine contains graphene oxide, carnosine, CpG, and novel coronavirus RBD; The carnosine, the CpG and novel coronavirus RBD are combined in a framework of the graphene oxide; the coding sequence of the CpG is as shown in SEQ ID NO 1 and the novel coronavirus RBD refers to that a novel coronavirus protein receptor binding region can generate a high-titer specific antibody aiming at the RBD in a mouse body, and strong support is provided for prevention and treatment of the novel coronavirus.'
4/23/2022 20:57:09	reissue_5.3.6-postmarketing-experience.pdf	25	j. and m.	Other	Young age of trial recipient: were they not supposed to experiment on adults only? Why no follow up on these young "experiment victims"? j. This UK case report received from the UK MHRA described a 1-year-old subject who received the vaccine, and had left postauricular ear pain that progressed to left-sided Bell's palsy 1 day following vaccination that had not resolved at the time of the report m. This UK case report received from the UK MHRA described a 7-year-old female subject who received the vaccine and had stroke (unknown outcome); no follow-up is possible for clarification
4/23/2022 21:09:45	reissue_5.3.6-postmarketing-experience.pdf	26	3	Other	Is this paragraph not concerning? Unknown Outcome - why is that considered non serious - how do they know that? Causes of death - weak? How is that not a concern when the outcome was the most serious of side effects?? 3 All the medication errors reported in these cases were assessed as non-serious occurrences with an unknown outcome; based on the available information including the causes of death, the relationship between the medication error and the death is weak.
4/23/2022 23:00:35	other	other	other	Other	see link - https://www.youtube.com/watch?v=BzEigubrO5A
4/24/2022 2:44:51	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events-sensitive	1-3	Page 1, Paragraph d & Page 2, Paragraph c.	Adverse Effects - Other	Note states that ongoing negative reactions would be reported as ended on the date of the subsequent vaccination even if the reaction was ongoing. This would create artificial data listing negative reactions shorter than they were in reality.
4/24/2022 2:46:44	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events-sensitive	3	chart	Other	Shows "anxiety" result with no context and not accompanied by any other events. Doesn't sound likely. People are usually "anxious" about something...
4/24/2022 7:51:40	I have a separate document	1-143	not applicable	Other	Relative to the issue of lost records, FDA Record Retention Guide re Drug Development was left behind from a firm that consulted on clinical trials (a former tenant). This is related to 21 CFR Part 11 as it pertains to clinical trials and to regulatory submissions that the industry will submit to FDA. Does anyone want this?
4/24/2022 8:08:31	125742_S1_M5_5351_c4591001-fa-interim-sample-crf	overall	overall	Other	There is nothing in particular in this document other than it describes an app each trial participant was to use to record and track their symptoms after their Pfizer dose. It was a "Vaccination Diary". It would be good to find out if Pfizer compiled their AEs from these entries.
4/24/2022 8:45:35	125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf	Throuth page 21-dosage levels	through 21	Other	Through page 21 there were varying dosages and some placebos. 10 people received 100 ug. By their CASE# we should see what kind of AEs they experienced/AND did people know they were receiving more toxic levels? Also, I don't recall if we actually know the study size, but a rough extrapolation from this document would indicate DEMOGRAPHICS / ALL SUBJECTS would be approximately = 43652 in the trial (3118 pages with 14 entries per page.) Please verify as I am curious how many were in the Pfizer trial with 158K AE's, and over 1200 deaths.

4/24/2022 12:13:27	125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf	See the attached-	See attached	Study Protocol	numbers were noted, Phase 1 was only 350? Really? Everybody in Phase 2 got the same dose level-and according to this document 1/2 got the shots, 1/2 did not; the person giving the knew if it was a placebo or not. Reading the Consent form 125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf Page 31-the list of potential side effects for children does not list blood clots or myocarditis Page 32-pregnant girls could not participate, warnings about using birth control, and they would be tested to ensure they were not pregnant Page 35 person conducting the assent assessment says they have explained EVERYTHING Page 39- where do they go for recourse for patient study rights if harmed Page 40-A minor could have confidential consults with the doctor and according to state laws these consults could be withheld from the parent Page 40-BioNTech and Pfizer FUNDED the study…..such a conflict of interest Page 40- They called it a NEW Coronavirus disease Page 41 - Consent form acknowledges they will test different dose levels and that how the shots would work-they are made from genetic code and the child's body will produce the spike to produce antibodies Page 42- Children took part in Phase 2/3 of the study and EVERYONE (children and adults) would receive the SAME Dose level based upon their results from Phase 1 Page 42-approximately 44,193 total people could take part in Phase 2/3 of the study-approximately 2000 of them would be 12-15 yrs old. Page 43-only the person giving the shot would know if it was placebo or Pfizer-ratio of 1 to 1- Page 44- did they only report vaccine side effects for 7 days in their e-diary? Page 46-Wondering how they chose this subset to report side effects for 7days after each injection Page 48 - they don't know all the effects the shot may have on your child Page 49- they publish the 'known' risks caused by the shot from the original study of 350 people. They only list minor reactions an leave the possibility of 'unknown'. Page 50- again warnings about becoming pregnant and preventing pregnancy during study participation Page 51- they were to report if they became pregnant up to 6 months after their last injection Page 51-Pfizer owns their samples and test results, swabs for up to 15 years and can do further research without them knowing what it is Page 52- there is a 'click here' link for 'mandatory research injury language'. Unable to access from this document Page 53- Pfizer may use information from this study to make more products for profit! Page 53- where the results from this study are to be posted here: summary at most: http://www.ClinicalTrials.gov www.pfizer.com and https://www.clinicaltrialsregister.eu/ Page 58 - some records will be kept for XX years Page 62- C4591001 Sponsor Study # Consent Form for Phase 1/2/3 Page 63- Again, statement they are testing dose levels-the vaccine has been crated from part of the virus's genetic code and your body may produce part or all of the spike protein.
4/24/2022 22:34:12	125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf	Pages 1-20	It's a chart	Study Protocol	Table 16.2.4.1 Listing of Demographic Characteristics – Phase 1, 2 Doses, 21 Days Apart. Page 1 - 19; Groups of 10 subjects were given 10mg, 20mg, 30mg and Placebo dosages respectively, 21 days apart. Cut off date 28 AUG 2020. Then on page 20 —a test group of 10 was given a dosage that jumped all the way to 100mg -and a placebo group of 5 not 10. Cut off date 24 AUG 2020; Why would dosage jump from 30mg to 100mg? Dr. Wolf relayed that Team 5 found documentation Pfizer knew 100mg of contents in vaccine kill leukocytes.
4/25/2022 7:28:23	125742_S1_M5_5351_c4591001-fa-interim-publications.pdf	3	Last para, left column	Other	Document claims "RNA-based prophylactic infectious disease vaccines and RNA therapeutics have been shown to be safe and well-tolerated in clinical trials." Is this true? It has no reference and I seem to recall (possibly incorrectly!) that I either read in RFK's book, or heard Dr Malone on warroom that no mRNA vaccine had been produced prior to this.
4/25/2022 7:34:50	125742_S1_M5_5351_c4591001-fa-interim-publications.pdf	5	4. left hand column	Study Protocol	It appears they don't know what kind or level of immunity is needed! "Our study had several limitations. While we used convalescent sera as a comparator, the kind of immunity (T cells versus B cells or both) and level of immunity needed to protect from COVID-19 are unknown. Further, this analysis of available data did not assess immune responses or safety beyond 2 weeks after the second dose of vaccine. Both are important to inform the public health use of this vaccine." Did they ever fulfil the statement in the last sentence?
4/25/2022 9:48:57	16.1.7.2 Listing of Randomization Scheme and Actual Vaccine Received – Phase 2 and 16.1.7.4 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects	idk	idk	Other	This question/comment is on the Volunteer page and I wanted to answer it: In relation to the second document listed above (125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf), the volunteer who created the Excel file also created these charts. He writes, "The Phase2 charts show that the 65-85 age group was 'tacked on' over a month after the 18-55 group randomisation started. This seems odd to me but may be perfectly normal to someone who runs these trials for a living. The All Subjects (excluding the Phase 2 people) charts seem to show the proportion of 55-plus to 16-55 people fluctuates." This is completely normal and reflects that the testing was completed first in the younger volunteers before initiating study in an elderly cohort. This is typical trial design to test for safety in the young and healthy first before testing in special populations, eg, elderly, and this was done in the Pfizer study.
4/25/2022 11:35:54	Pfizer test subject data 125742-S1-M5-5351-C4591001-F9-interimrandomization-srnsitivity.pdf	All of them	That's no paragraphs	Other	Why is there minimal reports on none white ethnicity
4/25/2022 14:21:40	https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	6	1	Fatality	1,243 people died out of 42k in the first 3 months of the vaccine roll out. I found this document and posted it online. Pfizer never meant for this to be released. It was not part of the dump everyone assumes it was from. I dumped it on Twitter because the truth needed to get out.
4/25/2022 14:41:59	5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021	20	AESIs Evaluation for BNT162b2	Adverse Effects - Other	Not so much a "finding" as a general comment. Many AE's identified but yet "case reviews" for the most part indicate no concern. What threshold was used to justify the no concern answer. In the category of Cardiovascular events it was identified there were 136 fatal events, but yet the conclusion is reached that "This cumulative case review does not raise new safety issues. Surveillance will continue " How this determination can be reached is incomprehensible to me.
4/25/2022 14:43:58	FDA-CBER-2021-5683-0000057,5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021	4	1	Other	Definition of Brighton Collaboration
4/25/2022 15:22:22	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf	27 and 40	uploaded screenshots	Study Protocol	discrepency in age between child assent and parent consent
4/25/2022 15:28:02	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf	31	screenshot uploaded	Study Protocol	child assent form lists possible adverse events which do not include any true risks

4/25/2022 15:34:53	BNT162b2 5.3.6 Cumulative Analysis of Po, FDA-CBER-2021-5683-0000058 st-authorization Adverse Event Reports,	5	1-4 and 6-7	Other	Par 1*** noted wording: BLA for "investigational" COVID-19 Vaccine Par 2-3***Request for comments and advice submitted was made 2/4/21. US and foreign post authorization data was not finished until and through 2/28/21. No response to 2/4/21 request until 3/9/21 "Reference is made to the Request for Comments and Advice submitted 04 February 2021 regarding Pfizer/BioNTech's proposal for the clinical and post-authorization safety data package for the Biologics License Application (BLA) for our investigational COVID-19 Vaccine (BNT162b2). Further reference is made to the Agency's 09 March 2021 response to this request, and specifically, the following request from the Agency." Par 6-7***many HC Professionals and consumers are not aware of VAERS reporting. Per whistleblower information we know HC Professionals failed to report many adverse reactions or possible adverse reactions "The limitations of post-marketing adverse drug event reporting should be considered when interpreting these data: • Reports are submitted voluntarily, and the magnitude of underreporting is unknown. * awareness by health professionals and consumers of adverse drug event reporting, and litigation"
4/25/2022 15:50:01	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf	49	screenshot sent	Adverse Effects - Other	Parent consent states risks based on "similar vaccines." There has never been a similar vaccine and it misrepresents the true risk to parents who may not have researched themselves before signing.
4/25/2022 16:05:04	FDA-CBER-2021-5683-0000059	6	1,4,5,6	Other	Par 1***What determines or defines a signal especially in regard to the FDA CDC et al in the US, regarding this particular inoculation (what exactly is the "signal" parameter)? We know previous vaccines were pulled from the market after even a small number of incidents. Why would the signals of this inoculation not support pulling from the market? " the spontaneous reporting system should be used for signal detection" Par 4***Did not fully process data "Among adverse event reports received into the Pfizer safety database during the cumulative period, only those having a complete workflow cycle in the safety database (meaning they progressed to Distribution or Closed workflow status) are included in the monthly SMSR. This approach prevents the inclusion of cases that are not fully processed hence not accurately reflecting final information. Due to the large numbers of spontaneous adverse event reports received for the product, the MAH has prioritized the processing of serious cases, in order to meet expedited regulatory reporting timelines and ensure these reports are available for signal detection and evaluation activity." Par 5 &6***After only 21/2-3 months if data? Seems this should have been a "signal" " first temporary authorization for emergency supply on 01 December 2020 through 28 February 2021. " "Cumulatively, through 28 February 2021, there was a total of 42,086 case reports"
4/25/2022 16:22:26	FDA-CBER-2021-5683-0000060	7	Table and Paragraph	Adverse Effects - Other	***1). Relying on Pfizer to determine "Relevant cases" 2.) Largest cases working age adults. May coincide with insurance company all- cause mortality data and/or disability claim data. 3.) Unknown???? What is unknown!? 4.) Recovered/Recovering? Patients are either recovered or they are not 5.) Sequelae? Specifically what secondary issues/illness are the recovered experiencing? i would not consider this a recovery. (Sequelae = an aftereffect of a disease, condition, or injury. A secondary result) 6.) 1,223 fatal outcomes in 21/2-3 months? Red flag! , and the specific reasons for these fatalities? 7.) We should know more specifics in the cases reported for the <16yrs and <12 cohorts, what and why. This afterthought notation is too vague. 8.) Investigations 3,693= ongoing at the time of report? 9.) Mediastinal disorders? Should be more specific to secondary AE (The mediastinum is the central compartment of the thoracic cavity. Surrounded by loose connective tissue, it is an undelineated region that contains a group of structures within the thorax, namely the heart and its vessels, the esophagus, the trachea, the phrenic and cardiac nerves, the thoracic duct, the thymus and the lymph nodes of the central chest.)
4/26/2022 0:15:05	125742_S1_M5125742 S1 M5 5351_c4591001-fa-interim-demographics.pdf	pg 2	Table 16.2.4.1	Study Protocol	Age group 18 -55. Youngest subject is 24.
4/26/2022 0:31:27	12742 S1 M5 5351 c4591001-fa-interim-demographics.pdf	pg 2	Table 16.2.4.1 20µg	Study Protocol	9/10 subjects, BMI 25 - 29 overweight
4/26/2022 0:36:42	125742 S1 M5 5351 c4591001-fa-interim-demographics.pdf	pg 4	Table 16.2.4.1 30µg	Other	30µg doses subjects, 8/10 have normal BMIs (18.5 - 24.9)
4/26/2022 1:09:04	125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf	pg 13	Table 16.2.4.1 Listing of demographic characteristics	Other	Subject C4591001 1003 10031016 is 19 y.o. male, received placebo, BMI 29.8 (overwt.) Youngest subject noted and odd he received placebo.
4/26/2022 1:32:38	125742_S1_M5_5351_c4591001-fa-demographics.pdf	p 21	Table 16.2.4.1.1	Other	Subject C4591001100110011013 is 19 y.o. female, BMI 21.9, given placebo. This is the second subject in their teens in the study who was given placebo and not a dosage.
4/26/2022 10:19:47	125742_S1_M5_c4591001-A-201114-hiv-preferred-terms.pdf	1,2	Entire page	Other	Why is there a page on HIV descriptions and differences. Why would HIV even be in this? Does the the jab give one VHIV, "vaccine" induced HIV?

					of concern to me: Drug ineffective, Paraesthesia, Dyspnoea, off label use, product use issue Table 4 in its entirety ?****The potential safety concerns were known in Feb of 2021! We know according to Table 1 Page 7 there were 34 adverse cases in those <12 yrs old however we do not get information nor specific adverse event data associated with them. Page 10 Table 4 Anaphylaxis-There were 1002 cases (54.0% of the potentially relevant cases retrieved), 2958 potentially relevant events Table 4 b "Although these patients experienced adverse events (9) that are potential symptoms of anaphylaxis, they all had serious underlying medical conditions, and one individual appeared to also have COVID-19 pneumonia, that likely contributed to their deaths" ?***Is there not a protocol for temp check or rapid test before inoculation? The trials did not include participants that had serious underlying conditions but these vaccines were administered without any consideration of those who did? This tells me that not procuring a truly informed consent killed these people who were unaware. This one sentence blows the thesis that those who are elderly with underlying medical issues and those compromised should get 2-4 jabs with this soup ("underlying medical conditions likely contributed to their deaths") Page 11 Table 5 Last Para within the table ?***Conclusion: VAED may present as severe or unusual clinical manifestations of COVID-19 75 of the 101 subjects had what was considered severe COVID-19 symptoms yet none of the 75 were considered as VAED/VAERD and VAED/VAERD and was considered a theoretical risk. (I am looking at the numbers 75 of 101 and theoretical risk?) Page 12 Table 6 "Pregnancy outcomes for the 270 pregnancies were reported as spontaneous abortion (23), No outcome was provided for 238 pregnancies" 124 mother cases, 49 non-serious and 75 serious, reported clinical events, which occurred in the vaccinated mothers. ?***The short duration of data accumulation makes these statistics devastating. 23 out of 270 and 75 serious events of 124 . No outcome was provided for 238 pregnancies.
4/26/2022 13:41:25	FDA-CBER-2021-5683-0000062 BNT162b2 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	9-14	numerous, Tables	Adverse Effects - Other	
4/26/2022 14:15:37	https://investors.biontech.de/node/11931/html#ic5e06a05a31d4c4491031d3208cef8c2_2806	page 6, Item 3	"Risk Factors"	Efficacy	Appears to be a legal statement acknowledging ahead of time of the possibility of lack of efficacy and avoiding future lawsuits. Is this standard practice?
4/26/2022 14:15:49	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events-sensitive.pdf	3	Entry in table for 16.2.7.4.3 Listing of Adverse Events – Subjects With Indeterminate Vaccine – All Subjects ≥16 Years of Age	Other	It is notable that the sole subject in the table (subject identifier C4591001 1163 11631008) who suffered anxiety is in the randomisation data as assigned to the Placebo Group. There is a Randomisation Date and a Dose 1 date (both 2020-07-31) but the nature of Dose 1 is absent, suggesting that anxiety led to a last-minute decision to not have a jab. Dose 2 date and Dose 2 details are also absent.)
4/26/2022 14:42:13	FDA-CBER-2021-5683-0000069 BNT162b2 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	16-26 and 29	numerous, Tables	Adverse Effects - Other	Cardiovascular AESI- • Number of relevant events: 1441, of which 946 serious, COVID-19 AESIs Ageusia; Anosmia- • Number of relevant events: 3359, of which 2585 serious, Hematological AESIs- • Number of relevant events: 1080, of which 681 serious, Hepatic AESIs-• Number of relevant events: 94, of which 53 serious Facial Paralysis- • Number of relevant events 453, of which 399 serious "Overall Conclusion: This cumulative case review does not raise new safety issues." Immune-Mediated/Autoimmune AESIs-including Cytokine storm- • Number of relevant events: 1077, of which 780 serious Musculoskeletal AESIs- Number of relevant events: 3640, of which 1614 serious Neurological AESIs (including demyelination)-• Number of relevant events: 542, of which 515 serious Other AESIs- • Number of relevant events: 8241, of which 3674 serious Renal AESIs- • Number of cases: 69 cases, • Number of relevant events: 70, all serious; (from the same box/table) Respiratory AESIs- • Number of relevant events: 137, of which 126 serious Thromboembolic Events- • Number of relevant events: 168, of which 165 serious Stroke- Cerebrovascular venous and sinus thrombosis (Primary Path)-• Number of relevant events: 300, all serious Vasculitic Events- • Number of relevant events: 34, of which 25 serious Page 25 c. Subjects with age ranged between 18 and 64 years; d. Subjects with age equal to or above 65 years; e. Subjects with age ranged between 2 and 11 years; f. Subjects with age ranged between 12 and less than 18 years; ?***Some subject ages don't correspond to above table 6 particularly e. This is either an oversight or deception m. "This UK case report received from the UK MHRA described a 7-year-old female subject who received the vaccine and had stroke (unknown outcome); no follow-up is possible for clarification." ?***unknown outcome? no follow-up possible? or they just didn't follow-up Page 26 Medication error, • Number of relevant medication error cases: 20562 (4.9%) , • Number of relevant events: 2792, − US (1201) Page 29
4/26/2022 16:47:19	125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf	32	Paragraph 1 and bullet poins	Adverse Effects - Other	It seems the form lists the minimum stand for possible side effects. Did the study team list all the known adverse effects known including from phase 1 of the study?
4/26/2022 17:07:25	125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf	49 and refer to pg 32	3 through 8	Adverse Effects - Other	The side effects pages do not match. A severe allergic reaction should be included in verbiage the youth can understand on the assent form.
4/26/2022 17:16:30	125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf	51	Paragraph 3 Pregnancy Related Risks	Adverse Effects - Reproductive Issues	"https://www.federalregister.gov/citation/64-FR-10942" 64 FR 10942, Mar. 8, 1999] A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable. This statement is missing from the explanation to adult guardian/parent consent form.

4/26/2022 17:39:54	For Groups 3, 4, 5, & 6Excel file, which is a combination of data from these two Pfizer documents: 125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf (only pp. 38-4412) 125742_S1_M5_5351_c4591001-interim-mth6-demographics.pdf	See "Race" column of the filtered spreadsheet Pfizer_test _subject_data_19APR2 2 (2)_RACE_SORTED placed in dropbox.	See "Race" column of the filtered spreadsheet Pfizer_test _subject_data_19APR2 2 (2)_RACE_SORTED placed in dropbox.	Study Protocol	Concerns have been expressed that people of color need to be better represented in covid vaccination trials due to disproportionate COVID-19 impacts on non-whites and underrepresentation in past clinical trials. These issues are discussed in the following articles: 1) "Racial Diversity within COVID-19 Vaccine Clinical Trials: Key Questions and Answers", https://www.kff.org/racial-equity-and-health-policy/issue brief/racial-diversity-within-covid-19-vaccine-clinical-trials-key-questions-and-answers/ 2) "Here's What We Know about the Demographic Makeup of the COVID-19 Vaccine Trials", https://www.healthline.com/health-news/heres-what-we-know-about-the-demographic-makeup-of-the-covid-19-vaccine-trials I have analyzed the Pfizer trial data in the spreadsheet included in the drop box to determine the racial breakdown of the trial participants. The approximate breakdown is as follows: White 82.0%; Black or African American 9.6%; Asian 4.3%; Multiracial 2.5%; American Indian or Alaska Native 1.0%; Native Hawaiian or other Pacific Islander 0.2%; Not Reported/Blank 0.5%. I submitted a similar spreadsheet filtering analysis for trial participant age last week and will also run breakdowns of participant BMI and sex.
4/26/2022 19:45:54	16.1.7.2 Listing of Randomization Scheme and 16.1.7.4 Listing of Randomization Scheme and Actual Vaccine Received – All SubjectsActual Vaccine Received – Phase 2 and	1-4412 in Pdf; Data converted to excel file	Subject Study Identifier Column in Pdf; Subject ID column in excel worksheet	Data Missing	The first four digits of the Subject Study Identifier code is the site location of the administered dose. The last four digits is the subject number for that site. There are 43,736 Subject Study Identifier codes; however, there are 1,759 missing numbers in sequence of the Subject Study Identifier codes. My concern is if the data was scrubbed due to bad results.
4/26/2022 21:00:18	125742-S1-M5-5351-c4591001-fa-interim-sample-crf.pdf	entire article	many	Study Protocol	An April 20, 2022 article by Sasha Latypova,from Team Enigma, entitled; "Did Pfizer perform Adequate Safety Testing for its Covid-19 mRNA vaccine in Preclinical Studies? Evidence of Scientific and regulatory Fraud" She states" In Summary, I have identified the following: Finding 1: Pfizer relied on studies for different versions of its product and different formulations of the lipid nanoparticle(LNP) delivery platform. The program did not include a comprehensive test of all components of the final product." "Finding 2: The safety of the vaccine's mRNA active ingredient was never studied!" Finding 3: Pfizer claimed absence of potential for enhanced covid illness in a study where no covid illness was observed. Finding 4: CDC, FDA, and Pfizer lied about "vaccine staying in the injection site." Finding 5; Pfizer skipped major categories of safety testing altogether. Finding 6: Pfizer used dishonest and self=serving interpretation of regulatory guidelines to avoid routine safety testing.' Review of the entire article provides information from one document entitled "BNT162b2 Module 2.4. Nonclinical Overview" (466 pages)"
4/26/2022 22:00:25	125742-S1_M5-5351-c4591001-fa-interim-sample-crf.pdf	15,16,20,29.31	many	Study Protocol	Excerpts from " BNT162b2 Module 2.4 nonclinical Overview" FDA-CBER- 2021-5683-0013880- 91 " Assessment of the ADME profile of BNT162b2 Included evaluating the Pk and metabolism of two lipid excipients (ALC-0315 and ALC-0159) in the LNP and potential biodistribution of BNT162b2 using luciferase expression as a surrogate reporter. The luciferases reporter was used as it was readily available reporter that has been widely used to develop an understanding of protein/organ expression" on page 15, paragraph 1. "2.4.3.7 Pharmokinetic Drug Interactions (page 20) No Pk interaction studies have been conducted with BNT162b2" Page 16-"2.4.3.3.2 Single Dose Pharmokinetics ; An intravenous rat Pk study was performed using LNPs containing surrogate luciferase RNA with the identical composition as BNT162b2." Page 29-" 2.4.4.4 Genotoxicity No genotoxicity studies are planned for BNT162b2 as the components of the vaccine construct are lipids and RNA and are not expected to have genotoxic potential (WHO 2005)." "2.4.4.5 Cardiotoxicity testing is generally not considered necessary to support the development and licensure of vaccine products for infectious diseases (WHO 2005)"on page 29. "2.4.4.8.7 Studies of Impurities stand alone studies with administration of impurities of BNT162b2 have not been conducted" on middle of page 31.
4/27/2022 14:05:42	125742 S1 M5 5351 C4591001-fa-interim-lec-irb-consent-form.pdf	p.49, p.71, p. 92	"Section 8. What are the possible risks and discomforts in this study?"omforts in	Other	Section 8 of the "Consent To Take Part in Study" Form (which is included in the 3 different consent forms within this Pfizer document pdf) includes the following question: "What are the possible risks and discomforts of this study?" This is followed by a list of risks identified based on the early studies of the vaccine administered to 350 people up until 8/6/2020. At the end of this list of vaccine study risks (which was presented in paragraph form) a question is posed in bold face type and underlined: "If I catch COVID-19 disease, will the vaccine make it worse?" (see pages 49, 71 and 92) The Consent Form then goes on to answers this question as follows: "For some other vaccines tested in animals {"in animals" is underlined} against similar viruses (but not the coronavirus that causes COVID -19), there have been reports of the illness being more severe in the animals that received the vaccine than in those that did not. So far this has not been seen with COVID-19 vaccines, but at the moment we do not know whether the study vaccines could make a later COVID -19 illness more severe. That is one of the reasons why you {you/your child} are asked to contact your study doctor if you {your child} develop symptoms that might be caused by COVID-19 (for example, fever, cough, shortness of breath)." This question is obviously addressing the concerns related to the possible risk of ADE (Antibody Dependent Enhancement) in the new COVID-19 mRNA vaccine. Interestingly, they highlight that the vaccines studies were "in animals" (underlined). There is no mention that in many of the vaccine studies for these "other viruses" not only did the animals get sick, most of them died when exposed to the virus in the wild. No mention of the type of animals studied which included mice, ferrets and nonhuman primates (macaque monkeys).There is no mention of the 2 children who died from ADE in the 1960's from the RSV vaccine. There is no mention of any of the details of the failed vaccine trials for SARS Co V, MERS and other respiratory viruses in which ADE played a role. As scientists and researchers working in the field of vaccine development it seems very unlikely that Pfizer was not aware of the failed vaccine trials in animals and non-human primates due to ADE and the death of the animals. My question/concern is this:
4/27/2022 15:09:55	Excel file, which is a combination of data from these two Pfizer documents: 125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf (only pp. 38-4412) 125742_S1_M5_5351_c4591001-interim-mth6-demographics.pdf	"BMI Column" of the BMI SORTED version of the Excel version of the Pfizer trial data.	"BMI Column" of the BMI SORTED version of the Excel version of the Pfizer trial data.	Study Protocol	Obesity is recognized as one of the medical conditions resulting in higher risk for severe COVID-19. I found two articles that reference BMI in relation to COVID-19: 1) "Phase 1 allocation COVID-19 vaccine: Work Group considerations", Kathleen Dooling, MD MPH September 22, 2020 (https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-09/COVID-07-Dooling.pdf). 2) "How frequent are acute reactions to COVID-19 vaccination and who is at risk?", Nancy Dreyer,a,, Matthew W. Reynolds,a Lisa Albert,a Emma Brinkley,a Tom Kwon,a Christina Mack,a and Stephen Tooveyb, Vaccine. 2022 Mar 15; 40(12): 1904–1912.; (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8825448/) I have analyzed the Pfizer trial data in the spreadsheet that I included in the drop box to determine the BMI breakdown of the trial participants. The approximate breakdown is as follows: Severe Obesity 5.5%; Obesity 28.8%; Overweight 55%; and Underweight and Normal Weight 10.7%. I also submitted similar spreadsheet filtering analyses within the last week for trial participant age and race. Hopefully, this information will be useful to our War Room teams in evaluating whether the Pfizer trials were properly run.

4/27/2022 19:13:41	Pfizer Annual Report Form 10-K Period ending December 2020 filed with the SEC	Page 26-27 in the PFE 10K or 65-66 in search feature	Last paragraph pp. 26 and first paragraph pp. 27	Other	In the Pfizer Annual Report (Form 10-K) for period ending December 2020 filed with the SEC, the Report disclosed, "Analysis of the data indicated a vaccine efficacy rate against COVID-19 of 95% in participants without prior SARS-CoV-2 infection (first primary objective) and also in participants with and without prior SARS-CoV-2 infection (second primary objective), in each case measured from seven days after the second dose."
4/27/2022 21:02:17	125742_S1_M5_5351_c4591001-fa-interim-randomization.pdf	All	All	Other	This particular study included 195 individuals, of which 39, (or 20%) who received placebo. The important point is that when calculating the rate of adverse effects for this particular study the total number of 195 would have to be reduced by 20% to calculate the actual rate because of the 20% who did not receive any 'vaccine'. If this holds true across all of the studies the rate of adverse effects would essentially be about 20% higher. The formula to accurately calculate the rate of adverse effects would be: rate {%} = (# of those with adverse effects) divided by (total # of participants minus # who received placebo)
4/27/2022 21:14:35	125742_S1_M5_5351_c4591001-fa-interim-sample-crf.pdf	103-105	Top of each pg	Study Protocol	Signant Health used along with "... using the TrialMax App. On the phone provided ..." to study subjects, I just wanted to know if/when phones used can be accessed for accuracy in what was indicated on these reports vs. what was reported on phones or to Signant. (Phone app for BYOD subjects.)
4/28/2022 12:04:49	Excel file, which is a combination of data from these two Pfizer documents: 125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf (only pp. 38-4412) 125742_S1_M5_5351_c4591001-interim-mth6-demographics.pdf	"Sex" column of the Pfizer Excel spreadsheet filtered by sex of participants.	"Sex" column of the Pfizer Excel spreadsheet filtered by sex of participants.	Study Protocol	Studies have indicated differences in morbidity and mortality for COVID-19 related to sex/gender. See the paper referenced below that reviews this issue: "Sex-Based Differences in COVID-19 Outcomes", Astha Tejpal, MD,1,* Eugenia Gianos, MD,1,2,* Jane Cerise, PhD,3 Jamie S. Hirsch, MD,2,3,4,5 Stacey Rosen, MD,2,6 Nina Kohn, MBA, MA,3 Martin Lesser, PhD,2,3 Catherine Weinberg, MD,1,2 David Majure, MD,2,6 Sanjaya K. Satapathy, MD,2,7 David Bernstein, MD,2,7 Matthew A. Barish, MD,2,8 Alex C. Spyropoulos, MD,2,3,9 and Rachel-Maria Brown, MD1,2,* J Womens Health (Larchmt). April 2021; 30(4): 492–501; Published online 2021 Apr 19. doi: 10.1089/jwh.2020.8974 (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8182657/) This paper concludes as follows: "Conclusions: Female sex is associated with lower odds of in-hospital outcomes, major adverse events, and all-cause mortality. There may be protective mechanisms inherent to female sex, which explain differences in COVID-19 outcomes." I have analyzed the Pfizer trial data in the spreadsheet (Pfizer_test _subject_data_19APR22 (2)_SEX_SORTED) that I included in the drop box to determine the breakdown of trial participants by sex. The approximate breakdown is as follows: Female 49.1%; Male 50.9%. I have also submitted similar spreadsheet filtering analyses within the last week for trial participants relative to age, race, and BMI. Hopefully, this information will be useful to our WarRoom teams as we evaluate whether the Pfizer trials were properly run.
4/28/2022 19:51:27	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-publications.pdf	all	all	Adverse Effects - Other	• About half of the mid and highest dosing groups had decreases in lymphocyte count (of any grade)! • "One participant each in the 10-µg group (8.3% [1/12]) and 30-µg group (9.1% [1/11]) dose levels and 4 participants in the 100-µg group (33.3% [4/12]) had Grade 3 decreases in lymphocytes." Grade 3 lymphocyte decrease is very significant. • "Grade 2 neutropenia was noted 6 to 8 days after the second dose in 1 participant each in the 10-µg and 30-µg BNT162b1 groups." ANY grade of neutropenia is clinically significant and concerning in early drug development. When did the neutrophil count normalize, if in fact, it did? • Breakthrough infections occurring up to Day 14 are considered to be in the 'unvaccinated,' per CDC. How many of these infections are associated with a lowered lymphocyte and/or neutrophil count? • Lymphopenia (low lymphocyte count) is an independent predictor of MIS-C. • Grade 3 skin reactions are very concerning, especially in early drug development. NO safety signal of Grade 3 skin reaction from a Phase 1 study in a healthy subject gets ignored in drug development. Where is the potential risk language in Investigator's Brochure and subsequent labeling? • The subjects were followed for two years. Where is the follow-up data?
4/28/2022 19:57:22	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf	all	all	Other	available safety data. For example, when did FDA/Pfizer first learn of a specific potential risk, such as myocarditis or pericarditis, and was this translated into the Investigator's Brochure (IB)s and ICs? Regarding ICs, the FDA states: "The explanation of risks of the test article should be based upon information presented in documents such as the protocol and/or investigator's brochure, package labeling, and previous research study reports." I found an Australian Investigator's Brochure (IB) (August 12, 2020), but could not find a US IB. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guide-informed-consent - children In these current documents, Pfizer did not include risks of antibody-dependent enhancement (ADE) in the pediatric IC, lymphocyte decrease in either the pediatric or adult ICs, or unknown risks of adverse pregnancy/fetal outcomes in either pediatric or adult IC. In general, the ICs downplayed possible risks. 1) ADE is a potential risk. "Potential for COVID-19 enhancement." https://cdn.pfizer.com/pfizercom/2020-11/C4591001_Clinical_Protocol_Nov2020.pdf "The Sponsor identified vaccine-associated enhanced disease including vaccine-associated enhanced respiratory disease as an important potential risk." https://www.fda.gov/media/144245/download 2) Lymphocyte decrease noted in August 12, 2020 Australian IB. "pattern of changes to lymphocytes and CRP, in a dose dependent manner, to candidate BNT 162b1 have been noted,"…"Most laboratory changes in younger and elderly adults were decreases in lymphocyte count post-dose 1." https://www.tga.gov.au/sites/default/files/foi-2183-09.pdf 3) No mention of risks of adverse pregnancy/fetal outcomes. 4) General downplaying of risks for near first in human (FIH) studies of novel biologic (initial study BNT162-01 was "ongoing" as of December 2020 FDA authorization meeting). "Study Vaccine Risks In early studies, these vaccines were administered to approximately 350 people (up until

4/28/2022 20:17:45	https://phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf	all	all	Adverse Effects - Other	All median "relevant" event onset latencies above are 4 days or less. This should be considered as a strong temporal association, suggesting reasonable evidence of a causal relationship, i.e., a "new safety issue." This is especially true when an event is "strongly associated with drug exposure" or when "uncommon in the study population," such as in pediatric or young adult subgroups. From https://www.fda.gov/media/79394/download "To assist sponsors with determining whether an adverse event meets the definition of suspected adverse reaction, the requirement under 21 CFR 312.32(c)(1)(i) specifies that sponsors are to report to FDA only if there is evidence to suggest a causal relationship between the drug and the adverse event and it provides examples of such evidence, described below. 1. Individual Occurrences (21 CFR 312.32(c)(1)(i)(A)) Certain serious adverse events are informative as single cases because they are uncommon and are known to be strongly associated with drug exposure. Some examples include angioedema, blood dyscrasias, rhabdomyolysis, hepatic injury, anaphylaxis, and Stevens-Johnson Syndrome. The occurrence of even one case of such adverse events would meet the definition of suspected adverse reaction (i.e., there is a reasonable possibility that the drug caused the event). 2. One or More Occurrences (21 CFR 312.32(c)(1)(i)(B)) A single occurrence, or a small number of occurrences, of a serious adverse event that is uncommon in the study population, but not commonly associated with drug exposure may also be informative. If the event occurs in association with other factors strongly suggesting causation (e.g., strong temporal association, event recurs on rechallenge), a single case may be sufficiently persuasive to report in an IND safety report. Often, more than one occurrence from one or multiple studies would be needed before the sponsor could determine that there is a reasonable possibility that the drug caused the event. Examples include tendon rupture or heart valve lesions in young adults, or intussusception in healthy infants. 3. Aggregate Analysis of Specific Events (21 CFR 312.32(c)(1)(i)(C))...
4/28/2022 20:34:03	https://phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf	all	all	Other	"Relevant events," "relevant cases," "relevant PTs": Nowhere is "relevant" defined. • Pg.5: "Pfizer's safety database contains cases of AEs reported spontaneously to Pfizer, cases reported by the health authorities, cases published in the medical literature…": I see no literature mentioned anywhere in 5.3.6. • Pg. 9-11: "Anaphylaxis is appropriately described in the product labeling" and "There were 4 individuals in the anaphylaxis evaluation who died on the same day they were vaccinated.": Anaphylaxis is not "appropriately described" in the Comirnaty package insert (PI). Under CONTRAINDICATIONS: "Known history of a severe allergic reaction (e.g., anaphylaxis) to any component of COMIRNATY" and under WARNING AND PRECAUTIONS, "in the event an acute anaphylactic reaction occurs." Neither inform of risk of fatality. An "important identified risk" should be clearly discussed, including possibility of death, in either CONTRAINDICATIONS or WARNINGS AND PRECAUTIONS. Also, myocarditis and pericarditis are not even noted as Important Potential Risks in 5.3.6, much less identified risks, despite their presence in the PI's WARNINGS AND PRECAUTIONS: "Postmarketing data demonstrate increased risks of myocarditis and pericarditis." C3isolutions states "Normally, any risk that is likely to be included in the contraindications or warnings and precautions section of the product information should be considered important." • https://labeling.pfizer.com/ShowLabeling.aspx?id=15623 • https://www.c3isolutions.com/blog/terminology-signals-potential-signals-risks-identified-risks-and-potential-risks/ • Pg. 11: The search criteria for VAED/VAERD in 5.3.6 does not include the COVID-19 Standardised MedDRA Queries (SMQ) or even the Preferred Term (PT) "COVID-19." As VAED/VAERD may also present as an increased incidence of disease in vaccinees compared with controls or known background rates, ALL Covid PTs should have been searched—I only see "COVID 19 pneumonia" here. • https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7901381/ • https://www.meddra.org/standardised-meddra-queries • Pg. 16, 20: Table 7: I'm not sure why myocarditis was not classified under Cardiovascular AESIs, and was instead classified under Immune-Mediated/Autoimmune AESIs. As shown below in the screenshot, the primary path in MedDRA for myocarditis is under the SOC Cardiac Disorders. Although myocarditis can be immune-mediated, it can also have infectious and drug-associated etiologies. • Only "relevant" PTs with > 10 occurrences were listed under Immune-Mediated/Autoimmune AESIs, whereas Cardiovascular AESIs did not have this caveat. As myocarditis and pericarditis are considered "increased risks," any other myocarditis or pericarditis-type PTs would have been critical to include, even those totaling <10. • http://farmakovijilansdernegi.org/files/2016.12.20_Guideline_on_Good_Pharmacovigilance_Practices_Module_VII-Signal_management.pdf • Pg. 25, app. 1: "For the complete list of the AESIs, please refer to Appendix 5; ":Do they mean Appendix 1 (instead of App. 5)? There is no App. 5 in 5.3.6. Appendix 1 has only five (5) search terms for myocarditis. There are more PT terms with "myocarditis" than this list of five (5) that should have been searched, such as "hypersensitivity myocarditis."
4/28/2022 23:28:17	Pfizer Press Releases filed with the Securities and Exchange Commission (SEC)	See Press Releases	See Press Releases	Other	The Pfizer and BioNTech Press Releases filed with the SEC state that, "Efficacy was consistent across age, gender, race and ethnicity demographics; observed efficacy in adults over 65 years of age was over 94%." and "The Phase 3 data demonstrated a vaccine efficacy rate of 95% in participants without prior SARS-CoV-2 infection (first primary objective) and also in participants with and without prior SARS-CoV-2 infection (second primary objective), in each case measured from 7 days after the second dose." Section 18 of the Exchange Act imposes liability for false and misleading statements in documents filed with the SEC to any person who makes such false or misleading statements, subject to applicable defenses (I. General Anti-Fraud Provisions).
4/29/2022 10:55:59	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-publications.pdf	Page 2 List of Authors	List of authors	Study Protocol	Seems absurd that half of the authors evaluating the "Phase 1/2 Study of the vaccine BNT162b1" were from PFIZER & BIONTECH. The 25 authors are from: New York University Langone Vaccine Center, New York, NY; New York University Grossman School of Medicine, New York, NY; University of Maryland School of Medicine, Center for Vaccine Development & Global Health, Baltimore, MD; Vaccine Research & Development, PFIZER INC, Hurley, UK; Vaccine Research & Development, PFIZER INC, Pearl River, NY; Vaccine Research & Development, PFIZER INC, Collegeville, PA; University of Texas Medical Branch, Galveston, TX; BIONTECH, Mainz, Germany; University of Rochester, Rochester, NY; Rochester General Hospital, Rochester, NY; Cincinnati Children's Hospital, Cincinnati, OH. And the person named as contact for the ✉e-mail: judith.absalon@pfizer.com (By the way, Mark Mulligan, Lead Author & also Principal Investigator on the Study, told an outright lie in this interview https://www.everydayhealth.com/coronavirus/how-to-stop-the-covid-19-pandemic-inside-the-vaccine-clinical-trials/ when he said: "Vaccines for the COVID pandemic have moved quickly but no corners were cut on the safety evaluations. We did everything we normally do, everything we've done for all of the safe and effective vaccines that are out there.") Total lie!
4/29/2022 15:08:32	FDA-CBER-2021-5683-0023500-to-0023507_125742_S1_M5_c4591001-A-c4591001-phase-1-subjects-from-dmw	ALL	ALL	Study Protocol	according to this document-there were only 332 volunteers (and it says they obtained informed consent) in Phase 1 (the dose finding Phase) -of which according to another document I read 1/2 received a placebo. Study size and informed consent would be the two red flags in this document.

4/29/2022 15:34:21	PF-07302048 (BNT162 RNA-Based COVID-19 Vaccines) Protocol C4591001	67-69	8.3.5	Study Protocol	through the documents using the search terms, pregnancy and pregnant, I came upon the information below in the Pfizer Protocol Documents. There are two points that I would like to bring out. 1. This section of the document reinforces the protocol I pointed out in my earlier report of following up on the women who became pregnant during the clinical trials through the end of their pregnancies. At some point in the release of the documents we should be able to find the reports of this follow up. 2. In the sub-section 8.3.5.1, the descriptions of what constitutes an EDP make me ask “What the heck did they know?!” I am not medically trained and don’t know what is standard protocol in clinical testing of a new vaccine, perhaps this is normal. But some of these EDP definitions are alarming to me. How does the vaccine jump from a “male participant who is receiving or has discontinued study intervention” to his female partner? Pfizer Clinical Protocol Doc: https://cdn.pfizer.com/pfizercom/2020-11/C4591001_Clinical_Protocol_Nov2020.pdf Amended Document: https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf *Pg 67-69 (Pg 111-113 in Amended document.)* *8.3.5. Exposure During Pregnancy or Breastfeeding, and Occupational Exposure* Exposure to the study intervention under study during pregnancy or breastfeeding and occupational exposure are reportable to Pfizer Safety within 24 hours of investigator awareness. 8.3.5.1. Exposure During Pregnancy _An EDP occurs if:_ _• A female participant is found to be pregnant while receiving or after discontinuing study intervention._ _• A male participant who is receiving or has discontinued study intervention exposes a female partner prior to or around the time of conception._ _• A female is found to be pregnant while being exposed or having been exposed to study intervention due to environmental exposure. Below are examples of environmental exposure during pregnancy:_ _• A female family member or healthcare provider reports that she is pregnant after having been exposed to the study intervention by inhalation or skin contact._ _•_ _• A male family member or healthcare provider who has been exposed to the study intervention by inhalation or skin contact then exposes his female partner prior to or around the time of conception._
4/30/2022 1:52:40	125742-S1-M5-5351-c4591001-fa-interim-sample-crf.pdf	article and letter	many	Other	From a 5/21/2021 article written by Kevin Breuninger entitled: " Pfizer CEO opposes U. S. call to waive Covid vaccine patents, cites manufacturing and safety issues" "Pfizer CEO Albert Bourla warned Friday that waiving patent protections for Covid vaccines would set off a worldwide race for raw materials that threatens the safe and efficient manufacturing of Covid shots" Currently infrastructure is not the bottleneck For us manufacturing faster Bourla wrote in a dear colleague letter posted on LinkedIn" The title of Albert Bourla's May 7,2021 letter is: "Today I sent This Letter to have a candid Conversation With Our Colleagues About the Drivers of Covid-19 Access and Availability" " In the letter he wrote, "Pfizer's vaccine requires 280 different materials and components that are sourced from 19 countries around the world. Without patent protections, entities with much less experienced than Pfizer at manufacturing vaccines will start competing for the same ingredients." When was he made aware of the BNT162b2 study results and what was the real reason for vaccine patent protection? Where was the materials and countries sourced from? March 13.2021 was the BNT162b2 study data cutoff.
4/30/2022 2:36:53	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-publications.pdf	PP 3 & following (listed below)	Details below	Study Protocol	Document title: Phase 1/2 study of COVID-19 RNA vaccine BNT162b1 in adults. Page 3: Half the authors were from Pfizer & BioNTech. P3: They KNEW the injections dampen the immune system: "Vaccine RNA can be modified by incorporating 1-methyl-pseudouridine which DAMPENS innate immune sensing". (This study tracked 45 adults aged 18-55 for 14 days after a second dose. Some received 10mcg, others 30mcg or 100mcg. 9 had placebos.) P4: 50% on the lower doses reported AEs versus 11% on the placebo. 1 reported "severe fever". Lab values showed "DECREASES IN LYMPHOCYTE COUNT" after Dose 1" of up to FIFTY PERCENT. P4: They suggest neutralizing titers are created by the product & claim "robust immunogenicity was observed" - which illustrates why LONG-TERM studies were protocol for vaccines before 2020. P5. They admit the study was "limited" and "the kind of immunity (T cells versus B cells or both) and level of immunity needed to protect from COVID-19 are unknown. Further, this analysis did not assess immune responses or safety beyond 2 weeks after the second dose of vaccine." P5. They suggest a vaccine presenting additional epitopes might be better than their product at producing "neutralizing titers robust to potential antigenic drift of SARS-CoV-2". Which means they were aware their injections could result in creation of new variants. P10. "The authors would like to thank Carol Monahan & Deb Gantt (PFIZER Inc) for writing and editorial support and Hua Ma, James Trammel, and Kiran Challagali (PFIZER Inc) for statistical analysis support." P10. Authors "NK, JA, AG, SL, RB, KAS, PL, KK, WK, DC, KRT, PRD, WCG, & KUJ are employees of PFIZER and may hold stock options. US and ÖT are stock owners, management board members, and employees at BioNTech SE (Mainz, Germany) and are inventors on patents and patent applications related to RNA technology. MJM, KEL, KN, EEW, ARF, RF, and VR received compensation from PFIZER for their role as study investigators. CFG and PYS received compensation from PFIZER to perform the neutralization assay".
4/30/2022 13:58:12	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-audit-certificates.pdf	1	one page chart	Other	Non-routine audits. Out of 16 audits conducted from July through November 2020, 6 were non-routine. What does "non-routine" mean? Was a problem reported that set off non-routine audits?
4/30/2022 14:12:35	125742_S1_M5_5351_c4591001-fa-interim-audit-certificates.pdf	4	1 page chart	Other	Out of the six non-routine inspections, Robert N. Cutler conducted 4/6. He is the only one who conducted non-routine inspections mentioned in this chart, "The Audit Trail Report."

4/30/2022 16:40:58	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf	1 - 10	n/a	Other	In the first ten demographics pages, so far the participants are overwhelmingly white, non-hispanic, and only 2 are from the placebo group. With thousands more pages left, I don't know how significant this is. White, non-hispanic: 85/100. White, hispanic: 2/100 White, unknown: 1/100 Black, non-hispanic: 3/100 Asian, non-hispanic: 9/100 Placebo group: 2/100 Overweight: 44/100 Obese: 1/100 Underweight: 2/100 Ages: 23 - 82
4/30/2022 21:56:19	reissue_5.3.6 post marketing experience.pdf	11	1 and 5 (conclusion)	Study Protocol	Paragraph 1 says they don't have "identified" VAED/VAERD data and it would be "difficult" to analyze- so they won't until they get more data (if people are injured). Then, in paragraph 5 (conclusion) - they admit extreme cases of COVID-19 DO OCCUR AFTER vax and might be VAED/VAERD. -so they call it "theoretical" They are admitting that public statements like - "Getting the vax will lesson your symptoms if you get covid-19" are false statements. They CONCLUDE that their own statements are a LIE and it also might make you worse.
4/30/2022 22:37:13	Reissue 5.3.6 postmarketing experience.pdf	19	Last - (conclusions)	Adverse Effects - Other	In the conclusions of most sections - they say "no NEW significant safety information was identified" - AFTER showing known hazards, damage, and missing data. No "NEW" - safety concerns Nothing new = the same as before. Their conclusions are a CONFIRMATION of known hazard. No surprises does NOT equal no risk.
5/1/2022 2:12:22	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form.pdf	63 and 64	screenshots sent	Study Protocol	Phase 2/3 adult consent on page 63 states two different kinds of vaccines and different doses are being given and next page states is phase 2/3 and that this phase looking at one dose level
5/1/2022 7:01:02	5.2 tabular listing.pdf November 17, 2021	FDA-CBER-2021-5683-0000001/0024760 3-0000001/16.1.5.1 SPONSOR AGENT PAGE 2	N/A	Data Discrepancy	FDA-CBER-2021-5683 NUMERIC SERIES IS OUT OF CHRONOLOGY: LEFT MARGIN TIME-STAMPED APPROVAL FOR 0000001 IS APRIL 29, 2021 WHILE APPROVAL FOR 0024760 IS DEC 3, 2020. TWO SCREENSHOTS: #1 AND #13 FDA-CBER SERIES CROSS-REFERENCE
5/1/2022 7:48:33	PF-07302048 (BNT162 RNA-Based COVID-19 Vaccines) Protocol C4591001)	42, 55, 58, 59, 60, 65, 66, 67, 68, 70. 92, 95, 99, 116, 117, 118	See attached, my apologies, I did not capture the Sec. or para. I will going forward.	Study Protocol	Generally the protocol appears to be derived from a template and does not consider the nuance of mRNA. For example, the timing elements (pregnancy) and non-considered (cardiovascular) don't make sense.
5/1/2022 8:07:07	125742_S1_M5_5351_c4591001-fa-interim-sample-crf.pdf	1-15	n/a	Data Discrepancy	1. No samples for ages between 56-65 2. Same dosage for both injections 3. Doses ranged from 10ug to 100ug 4. 12 tests at 100 ug, all at 18-55 years old, none at 56-85.
5/1/2022 8:27:23	125742_S1_M5_5351_c4591001-interim-mth6-audit-certificates.pdf	1-5	N/A	Data Discrepancy	1. The audits were all conducted between 07/27/2020 and 12/10/2020 2. For some reason “non-routine audits” were only conducted between 10/05/2020 and 12/03/20. 3. The second audit for site 1231 in Argentina from 10/13/2020 to 10/20/2020 was a “non-routine audit” and lasted a week. The original 1231 “routine” audit was 08/27/2020-09/03/2020 was also a week. 4. All of the other audits were only 2-3 days. 5. It appears the auditor Andrea Mohr was having issues with the investigator’s, Fernando Pedro Pollack, work. 6. Of note, the Pfizer Senior Director for Regulatory Quality Assurance, Cecilia Gabarain is from Argentina
5/1/2022 9:59:18	5.2 listing of clinical sites and cvs pages 1-41.pdf November 17, 2021	FDA-CBER-2021-5683-0000013/0000014(PAGE 1 OF 40)	N/A	Data Discrepancy	The Table of Contents at FDA-CBER-2021-5683- 0000013 is incongruent with 0000014 and the 39 pages that follow. Screen Shots #3 FDA-CBER SERIES AND #4 FDA-CBER SERIES cross-reference with detailed information.
5/2/2022 11:39:36	FDA-CBER-2021-5683-0024522	p.3	4	Study Protocol	Only a select group of participants were chosen to complete an ediary about how they were feeling 7 days after visit. Why not everyone?
5/2/2022 11:45:48	FDA-CBER-2021-5683-0024533	5	5	Other	They say companies have started looking for treatments and ways to prevent Covid-19. I think this is based on fraud because I believe they knew of the treatments available that would work, such as HCQ and Ivermectin, and chose to suppress it in order to push the vaccines.
5/2/2022 11:50:12	FDA-CBER-2021-5683-0024543	15	3	Adverse Effects - Reproductive Issues	They didn't want to test on pregnant women. It was absolutely not allowed. They had to have known about serious affects. How they can say it's safe and effective for pregnancy is beyond me.
5/2/2022 11:56:21	FDA-CBER-2021-5683-0024544	16	1	Adverse Effects - Reproductive Issues	They wanted to know immediately if a participant became pregnant up to 6 months after their last injection. That shows major concern to mother and/or fetus.
5/2/2022 11:59:48	FDA-CBER-2021-5683-0024526	7	2	Adverse Effects - Reproductive Issues	There was concern for boys impregnating someone. It shows concern for the vaccine adversely affecting sperm and therefore afftecting the fetus.
5/2/2022 12:09:24	FDA-CBER-2021-5683-0024542	49	11	Adverse Effects - Other	It is acckowledged that other vaccines tested in animals against similar viruses have reported that the illness was more severe in the animals that received the vaccine than in those that did not. They did not know if this was the case with this vaccine. Did they not test this in animals?
5/3/2022 8:30:25	125742_S1_M1_priority-review-request-1.pd	10	4	Efficacy	It is stated their success was based on prespecified success. If your bar is low, then the success would be greater.
5/3/2022 9:43:22	125742_S1_M5_5351_bnt162-01-interim3-compliance.pdf	16	chart	Adverse Effects - Reproductive Issues	They were doing studies on children in 2010-2011 and having ill effects in the groin at that time.
5/3/2022 9:54:17	125742_S1_M5_5351_bnt162-01-interim3-compliance.pdf	26	chart	Adverse Effects - Other	Glaucoma
5/3/2022 13:52:51	125742_S1_M5_c4591001-A-report-cci-lymphoma.pdf	the whole document	document	Adverse Effects - Other	150 people developed lymphoma
5/3/2022 13:56:28	125742_S1_M5_c4591001-A-report-cci-hemiplegia.pdf	whole document	whole document	Adverse Effects - Other	all test subjects that developed some sort of Hemiplegia
5/3/2022 13:59:51	125742_S1_M5_c4591001-A-report-cci-leukemia.pdf	whole document	whole document	Adverse Effects - Other	98 People who developed leukaemia
5/3/2022 14:05:11	125742_S1_M5_c4591001-A-report-cci-periph-vasc.pdf	whole document	whole document	Adverse Effects - Other	90 people developed vascular disease
5/3/2022 14:07:52	125742_S1_M5_c4591001-A-report-cci-pulmonary.pdf	whole document	whole document	Adverse Effects - Other	78 people developed heart and lung problems
5/3/2022 14:09:58	125742_S1_M5_c4591001-A-report-cci-peptic-ulcer.pdf	whole document	whole document	Adverse Effects - Other	16 people developed peptic ulcers
5/3/2022 14:12:20	125742_S1_M5_c4591001-A-report-cci-mild-liver.pdf	whole document	whole document	Adverse Effects - Other	50 people who developed mild liver conditions
5/3/2022 14:14:10	125742_S1_M5_c4591001-A-report-cci-mod-sev-liver.pdf	whole document	whole document	Adverse Effects - Other	15 people developed sever liver problems
5/3/2022 14:19:35	125742_S1_M5_c4591001-A-report-cci-metastatic-tumour.pdf	whole document	whole document	Adverse Effects - Other	171 people developed a spreadable cancer
5/3/2022 14:24:39	125742_S1_M5_c4591001-A-newlist-c4591001-6k-participants-enrolled-v3-17sep2020.pdf	whole document	whole document	Other	there were 6440 people who participated in the study according to this document
5/3/2022 14:27:01	125742_S1_M5_c4591001-A-report-cci-mi.pdf	Whole document	whole document	Adverse Effects - mYocarditis	7 people in this study developed myocarditis
5/3/2022 14:30:57	125742_S1_M5_c4591001-A-report-cci-any-malignancy.pdf	whole document	whole document	Adverse Effects - Other	850 people developed some sort of cancer

5/3/2022 14:32:49	125742_S1_M5_c4591001-A-report-cci-aids-hiv.pdf	whole document	whole document	Adverse Effects - Other	47 people developed HIV
5/3/2022 14:59:50	16.2.4 Listing of Demographic Characteristics – All Subjects ≥16 Years of Age	Filtered "Vaccine Received All Subjects::Vaccine_Dose_1" and "Vaccine Received All Subjects::Vaccine_Dose_2" columns of the EXcel version of this document	Filtered "Vaccine Received All Subjects::Vaccine_Dose_1" and "Vaccine Received All Subjects::Vaccine_Dose_2" columns of the EXcel version of this document	Study Protocol	I checked the Pfizer trials data in the spreadsheet that I have included in the drop box to compare numbers and percentages of participants receiving Dose 1 vs. Dose 2 vs. Placebo. Comparing Dose 1 to Dose 2: The 30 ug dosage apparently was the optimal dosage Pfizer selected for the trials. There were 1249 less 30 ug Dose 2 jabs compared to 30 ug Dose 1 jabs. Likewise Dose 2 Placebo injections were reduced by 1238 compared to Dose 1 Placebo injections. This kept the 30 ug doses for Dose 1 and Dose 2 at 49.9% of the total injections given for each dose and the Placebo doses at 49.8% of injections for both Dose 1 and Dose 2. The percentages of the 10 ug, 20 ug, and 100 ug doses listed were given at very low percentages of total doses given at 0.1%, 0.1%, and 0.03%, respectively, for both Dose 1 and Dose 2. The dates the Dose 1 and Dose 2 injections were given were approximately three weeks apart based on a rough sampling of the dates listed for several participants. The reduction of 30 ug Dose 2 injections given vs. Dose 1 jabs by 1249 injections should be evaluated further to determine whether this reduction of Dose 2 injections resulted from deaths and other adverse effects from Dose 1 based on other data that Pfizer may have submitted so far. This reduction of 30 ug injections from Dose 1 to Dose 2 represents a 5.7% decrease. I have also submitted similar spreadsheets filtering analyses within the last two weeks for trial participants relative to age, race, BMI, and sex. Hopefully, this information will be useful to our WarRoom teams as we evaluate whether the Pfizer trials were properly run.
5/4/2022 4:50:13	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf	21	Table 16.2.4.1.1	Data Discrepancy	There is a difference in the number of people tested for the 100 microgram dose and the other doses, as follows: BNT162b1 18-55 year olds: 12 people got 10 microgram, 12 got 20 microgram, 12 got 30 microgram, 9 got placebo. BNT 162b1 65-85 year olds: 12 people got 10 microgram, 12 got 20 microgram, 12 got 30 microgram, 9 got placebo. The same numbers apply to the BNT162b2 product. For the BNT 162b1 100 microgram dose, 12 people aged 18-55 years old got the dose and only THREE got the placebo. Why weren't 9 people given the placebo? There is no record of the product being given to the 65-85 year old group. Why?
5/4/2022 4:54:07	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf	1-21	Table 16.2.4.1	Data Missing	The groups are 18-55 year olds and 65-85 year olds. Why are 56-64 year olds excluded?
5/4/2022 5:03:34	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf	1858-1864	Table 16.2.4.4	Data Discrepancy	From page 22-1858 subjects are listed under the heading "age 18-55". From page 1858-1864 they are listed under the heading "age 65-85". On page 1864, this changes to ">55". Why the change?
5/4/2022 5:07:29	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf	22-3139	Table 16.2.4.4	Study Protocol	Very rough calculation - 1836 of 3117 pages list subjects aged 16-55. 1281 pages list subjects aged >55. So a 60-40 split. Is this the right proportion for a disease primarily affecting the elderly? And no one aged over 85 was enlisted in the study - this is the most vulnerable group and was the first to be injected.
5/5/2022 11:24:16	Excel version of 125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf	Sheet 1 of excel file	N/A	Other	Using the excel file, I calculated the number of days between the 2 doses that were received by each subject to determine if the time span fell within the 19-23 day time frame required by the protocol. Using a basic frequency calculation (# of subjects that fell within any time frame), I found that the days between doses ranged from 6 days to 105 days. Out of the 41,196 subjects that received both doses (regardless of type of dose, age, sex, time of year, etc), 39,148 (95%) received the second dose within the 19-23 day time frame (95%), which means 5% of the subjects (2,048) were out of compliance with the protocol. This is a deviation that has to be reported and these subjects would need to be eliminated from analysis. If this is further broken down by type of injection, age, ethnicity, sex, etc (which I have not yet done), the statistical power of the data would decrease thus making conclusions less certain. Were these 2,048 deviations reported and were these data eliminated from the final analysis of the data? Why were subjects injected outside of the 19-23 day time frame when this was not approved?
5/5/2022 14:11:02	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_bnt162-01-interim3-report-body.pdf	17	2	Study Protocol	This technology platform is especially attractive because it has the ability to deliver high numbers of vaccine doses rapidly in a single production campaign.
5/5/2022 14:20:40	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_bnt162-01-interim3-report-body.pdf	20	Items 6 through 13	Study Protocol	Explains study protocol for women of childbearing potential and their partners
5/5/2022 14:22:36	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_bnt162-01-interim3-report-body.pdf	20	9.5 Exclusion Criteria #2	Study Protocol	Women cannot be breastfeeding or planning to breastfeed during study or until 90 d after receiving last dose.
5/5/2022 14:26:22	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_bnt162-01-interim3-report-body.pdf	22	1 (#19)	Study Protocol	History of Guillain-Barré syndrome following previous vaccination precludes participation in study
5/5/2022 14:40:37	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_bnt162-01-interim3-report-body.pdf	35	9.12.1.3	Study Protocol	Dosing of participants with the second 60 µg BNT162b1 dose was not performed. After 12 participants had received Dose 1, the SRC decided not to administer Dose 2 to these participants.
5/5/2022 14:56:59	Dosing of participants with the second 60 µg BNT162b1 dose was not performed. After 12 participants had received Dose 1, the SRC decided not to administer Dose 2 to these participants.	55	entire page	Study Protocol	Discussion of strong dose-dependent antibody response, indicating need for more doses & boosters
5/5/2022 15:03:15	Dosing of participants with the second 60 µg BNT162b1 dose was not performed. After 12 participants had received Dose 1, the SRC decided not to administer Dose 2 to these participants.	64	entire page	Efficacy	Discussion of pro-inflammatory T-cell responses in almost all participants & accumulation of cytokines
5/5/2022 15:10:14	Dosing of participants with the second 60 µg BNT162b1 dose was not performed. After 12 participants had received Dose 1, the SRC decided not to administer Dose 2 to these participants.	70-71	12.1.1	Adverse Effects - Other	72 participants (86% of younger participants) reported solicited local reactions, 18% grade >3 solicited local reactions, 77 participants (92%(reported solicited systemic reactions, of which 37 participants (44%) reported >3 solicited systemic reactions. 38 participants (45%) reported 83 TEAEs of which 51 were related TEAEs.
5/5/2022 15:26:32	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf	all	N/A	Study Protocol	The age ranges that were analyzed are the following: 18-55, >55, 65-85. This is a very strange breakdown since body size, metabolism (pharmacokinetics), BMI and many other factors will differ from 18 to 55 years of age (i.e., young adult to middle age adult). The probably reason for this grouping was to increase the # of subjects and the statistical power within the grouping since if they separated out by 10 or 20 year increments, they likely would not have enough numbers to make meaningful statistical comparisons. Also, >55 includes 65-85 so likely this latter group was added at a later date, which fits with another volunteer's observation that randomization among the older ages occurred only later in the trial.
5/5/2022 15:30:07	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf	page 20	N/A	Study Protocol	I just submitted a response that the age group breakdown did not make sense and was likely an attempt to increase numbers, but ignores age differences in pharmacokinetics. Starting on page 20, a 16-55 age group appears. So they started with 18-55 and then expanded to 16-55 - how were the data analyzed? Were these groups combined? This is very poor experimental design and would cover up age-related differences in responses plus fails to take into account dose differences - it should not be 30 mg per person - it should likely be dosed per kg.
5/5/2022 16:40:29	125742_S1_M5_5351_bnt162-01-interim3-report-body.pdf	Title page	N/A	Study Protocol	Title includes immunocompromised individuals, but the protocol was only approved for healthy individuals.
5/5/2022 16:42:45	125742_S1_M5_5351_bnt162-01-interim3-report-body.pdf	19	2 and 4	Study Protocol	Inclusion criteria indicate that younger and older adults must fall with specific BMI ranges, but both groups had BMIs above and below these respective ranges. Also the age listed for young adults was 18-55, but dataset contains BMI from individuals as young as 15 years of age.
5/5/2022 20:40:59	125742_S1_M5_CRF_c4591001-1005-10051047.pdf	48-50	n/a	Adverse Effects - Other	AORTIC ANEURYSM
5/5/2022 20:56:14	125742_S1_M5_5351_bnt162-01_20242.pdf	90	n/a	Adverse Effects - Other	syncope

5/5/2022 21:20:19	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_bnt162-01-interim3-adverse-events.pdf	174-175	Line items in table associated with subject 10197	Adverse Effects - Other	Subject 10197 experienced SEVERE adverse events, which according to the criteria in the table as related or not related , were marked as injection related: hallucinations, photophobia, and musculoskeletal chest pain.
5/5/2022 21:59:01	L-M Group Overview	Noneapecific	Nonspecific	Data Discrepancy	The 2000 page report at the top allegedly lists adverse events. It focuses solely on minor reactions, malaise, fevers, etc. No mention of anything serious. The bottom four documents are for 4 subjects with adverse events: including cardiac arrest, respiratory failure, neuritis.... oddly these items do not appear within the report above. Our section includes a codex with subjects by number. It appears updated from the previous codex, adding in what gene therapy dosage the placebo subjects received when they disbanded the placebo group. Notably, I was unable to locate 2 of the 4 adverse reaction participants within this codex. Along with numbering discrepancies from April's dump, it is possible these significant points were scrubbed from data analysis at Pfizer. I'm doubting myself because this next point is so crazy and I covered a lot of pages tonight: Pfizer reports their cardiac arrest person as "lost to follow up." Someone needs to corroborate that one. Funny way to say he died, but his report insists death did not occur. Hope that helps.
5/5/2022 23:17:41	125742_S1_M5_5351_bnt162 01	3809-7040	No smoking gun findings. No clinically significant vital signs, blood, urine, EKG findings in older and younger age group receiving a variety of injection doses during relatively short F/U period.	Other	No clinically significant vital signs, blood, urine, EKG findings in older and younger age group receiving a variety of injection doses during relatively short F/U period.
5/6/2022 6:10:38	125742_S1_M5_5351_bnt162-01-interim3-demographics.pdf	34	4	Adverse Effects - Other	Terminated after 1 month due to non disclosed adverse event
5/6/2022 6:42:04	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_bnt162-01-interim3-synopsis.pdf	13 & 14	Para 1 bullet #2 & Para 1 bullet#2	Other	High reporting of headaches @ 53% & 47%
5/6/2022 7:55:29	125742_S1_M5_CRF_c4591001-1006-10061020.pdf	167	section 3 adverse event section	Adverse Effects - mYocarditis	under adverse event - DYSPNEA UPON EXERTION
5/6/2022 8:02:22	125742_S1_M5_CRF_c4591001-1006-10061020.pdf	171	3 adverse event	Adverse Effects - Other	angina - most say not related to study - how do they know that?
5/6/2022 8:12:03	125742_S1_M5_CRF_c4591001-1006-10061020.pdf	182	first block top of page	Adverse Effects - Other	PROGRESSION OF MYXOMATOUS MITRAL VALVE - again this is heart related but says "not related" due to OTHER
5/6/2022 8:19:04	125742_S1_M5_CRF_c4591001-1006-10061020.pdf	175	3? under DATA ENTRY	Adverse Effects - mYocarditis	NON ST ELEVATED MYOCARDIAL INFARCTION
5/6/2022 8:25:02	125742_S1_M5_CRF_c4591001-1006-10061020.pdf	174	3 under adverse events	Adverse Effects - Other	CAD another heart issue coronary artery occlusion? Not sure but there are so many subjects with heart issues, they say that aren't related to study?
5/6/2022 8:48:05	125742_S1_M5_CRF_c4591001-1006-10061020.pdf	148	? section NOV 13/2020 JOSEE ROBILLARD	Other	SAE (serious adverse event?) I wonder what happened to this participant that required them to withdraw from study????? Closing as confirmed with stats/spa that the dates are correct as entered given the scenario. SAE with a resolution date of 27AUG2020 however subject withdrawn due to SAE and same time withdrew consent on 16SEP2020 following discussion with PI.
5/6/2022 9:08:26	125742_S1_M5_CRF_c4591001-1006-10061020.pdf	150-170	seems to be confused	Data Discrepancy	over those 20 pages, give or take, there seems to be confusion among the people recording and the updating or changing of data to reflect desired outcomes? (I may be totally incorrect as I am confused with this info myself) but thought I'd inquire regardless.
5/6/2022 9:21:30	125742_S1_M5_5351_bnt162-01-interim3-demographics.pdf	19 - 25 and 48 - 53	not applicable	Study Protocol	BNT162b1 - All participants were white except 3. BNT162b2 - all participants were white. There were no participants with BMI under 18.5 or over 30 in either study.
5/6/2022 10:56:39	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_bnt162-01-interim3-report-body.pdf	72	12.2.1.2, 12.2.2.1, 12.2.2.2	Adverse Effects - Other	>80% local and systemic reactions with both BNT162b1 and BNT162b2 in both older and younger participants
5/6/2022 10:59:36	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_bnt162-01-interim3-protocol.pdf	206	2.2.1	Study Protocol	Based on this paragraph from the first early trials to determine dosage and vax candidate to use in the larger trial they used a Covd infection without a vaccine as the "benchmark" to improve upon a natural infection. 1. What T cell counts did they use for a natural infection? 2. Did BNT162b2 surpass the counts from a natural infection? 3. Why did they recommend 2 doses if at 21 days it was robust? "BNT162b2 suggest a robust induction by day 21 post first dose, of the production of antibodies conformational to complete CoV-2 spike protein"
5/6/2022 13:27:55	125742_S1_M5_bnt162-01-A-adrg.pdf	11	14	Data Missing	Under item 3.4: Were unscheduled visits used in any analyses? No. Data collected at unscheduled visits will not be included and analyzed for safety and efficacy analysis. Shouldn't a proper study include data from all visits subsequent to beginning of study?
5/6/2022 13:43:00	125742_S1_M5_bnt162-01-A-adrg.pdf	5	6	Other	number and type of amendments; I thought the number and type of amendments to the protocol seemed odd, especially the second one listed. Are 8 amendments typical in this type of study? Also, amending the protocol to allow vaccine in elderly subjects, given its favorable safety, tolerability, and immunogenicity profile in younger adults to date and recently available in non-human primate data ?? How can they say in such a short period of time (doc dated 09-Mar-2021) and the known adverse reactions that there was tolerability in younger adults? I know this document is the protocol description but I know for a fact the shot was being promoted especially for older people from the start.
5/6/2022 15:31:48	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1003-10031207.pdf	pg 151-154	as shown	Other	DVT, pulmonary embolism and S Protein Deficiency - there is a lot of back and forth regarding the S Protein Deficiency, which is why I sent the SS from Cancer Therapy Advisor - it can be hereditary or acquired. No prior history, so did the injection cause it?
5/6/2022 17:18:48	125742_S1_M5_5351_bnt162-01-interim3-report-body.pdf	25 table	table 2	Study Protocol	this report appears to be a study of dose escalation (phase 1/2), that includes safety assessments. ECG's assessed only at start of study not at later data points.

5/6/2022 21:19:47	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_bnt162-01-interim3-sponsor-signature.pdf	1	1: Trial title	Study Protocol	This Trial Title says that this trial is "A mulit-site....investigating the...safety &...of FOUR ...vaccines...using different dosing regimens in healthy & immunocompromised adults. #1: When were immunocompromised ok'd for trials? #2: If Dose 2 follows Dose 1 after 3 weeks & Dose 3 follows 8 months & Dose 4 follows 6 months, how could there be enough time for evaluation for boosters by Aug '21 when FDA & CDC authorize additional dose (Dose 3) for > 12 & immunocompromised. #3: Why are there different dosings when by Aug '20 the trials I've seen are using 30micrograms only? #4: Why are they testing for FOUR vaccines?
5/6/2022 21:27:08	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_bnt162-01-interim3-report-body.pdf	21	#22	Study Protocol	A reason to be EXCLUDED from the testing was a history of or suspected immunosuppressive condition. The Trial Title explicitly says that the trials are to be run on immunocompromised adults.
5/6/2022 21:31:41	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_bnt162-01-interim3-report-body.pdf	34	chart	Study Protocol	Why don't those in the 56-85-year-old cohort receive more than 30 micrograms while 18-55-year-olds are dosed with 50 or 60 micrograms? Earlier docs I read said that anyone who receives 60 micrograms should NOT receive a Dose 2 because of reactogenicity yet those who received 60 micrograms were to receive Dose 2.
5/6/2022 21:34:37	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_bnt162-01-interim3-report-body.pdf	37 & 38	Charts	Study Protocol	Why are there 84 in the younger (18-55) cohort & only 36 in the older (56-85) cohort?
5/6/2022 23:36:58	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_bnt162-01-interim3-report-body.pdf	84	12.4.1.1,12.4.1.2	Adverse Effects - Other	Systemic reactions of >80% of all participants
5/6/2022 23:41:41	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_bnt162-01-interim3-report-body.pdf	84	12.4.2.1, 12.4.2.2	Adverse Effects - Other	44% of younger participants & 28% of older participants experienced severe systemic reactions. Most frequently reported were headache, fatigue, myalgia and malaise.
5/7/2022 7:39:25	c4591001 COHORT SELECTION	205	3	Adverse Effects - Other	Subject received first shot in April 2020, in Oct 2020 adverse event recorded forATRIAL FIBRILLATION INTERMITTENT
5/7/2022 9:38:46	135742_S1_M5_c4591001-S-csdrg	7	Amendment 5	Study Protocol	The amendment stated that 30 mcg dose of BNT162b2 was selected for phase 2/3.Further,the statement, "Moved to immunogenicity objectives in phase 2/3 to become exploratory" raises the question whether Pfizer had the immunogenicity data by July 24, 2020 to select 30 mcg dose. The same document on page 10: "On the basis of safety and/or immunogenicity data generated during the course of this study, and/or the BioNTech study conducted in Germany(BNT162-01), 1 vaccine candidate was selected to proceed into Phase 2/3". The current study at the 16.17.1 List of Randomization Scheme and Actual Vaccine Received-Phase 1, 2 Doses, 21 Days Apart (125742_S1_M5_5351_c4591001-fa-interim-randomization.pdf-16.17.1) administered a 30 mcg dose in the 65-85 group between June 15 and July 15,2020 and in the 18-55 group between June 16 and July 9,2020 (pages 12,13).According to the Clinical Study Data Reviewer's Guide (page 10),the IRC (internal review commmittee) will select 1 vaccine candidate that, in Phase 1, has an established dose level per age group based on induction of post-Dose 2 immune response...for progression into Phase 2/3". Pfizer has to collect safety and immunogenicity data on the 7th day after the 2nd dose(29 day).In addition, to assess immunogenicity Pfizer needs at least 2 weeks. Therefore, by July 24,2020 Pfizer didn't have immunogenicity data post Dose2 in the study c4591001. Another study, (BNT 162-01) conducted in Germany, didn't have the immunogenicity data either. The younger group had been receiving 30 mcg dose from June 22 to July 23,2020 (29 day) (125742_S1_M5_5351_bnt162-01-interim3-lab-measurements.pdf, pages 5479-5761). The group of older participants was enrolled in the study at the end of August,2020 (the same document, page 6321). In spite of that ,Pfizer proceeded on July 28,2020 to Phase 2/3 (125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive).
5/7/2022 11:50:33	Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1	starts on page 35	N/A	Other	A booster was not given to the 60 µg dose group. All other groups received a booster Dosage group youger included 1 µg, 3 µg, 10 µg, 20 µg, 30 µg, 50 µg and 60 µg Dosage group older included 10 µg, 20 µg, and 30 µg
5/7/2022 11:52:04	125742_S1_M5_CRF_c4591001 1003 10031065.pdf	108, 111, 390, 397	n/a	Adverse Effects - Other	neuritis right arm - persistent or significant disability/incapacity
5/7/2022 11:56:20	Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1	starting on 118	N/A	Other	A booster was not given to the 60 µg dose group. All other groups received a booster Dosage group youger included 1 µg, 3 µg, 10 µg, 20 µg, 30 µg, 50 µg and 60 µg Dosage group older included 10 µg, 20 µg, and 30 µg
5/7/2022 12:09:27	Listing 16.2.3-1.3-3: Listing of solicited systemic reactions - BNT162b2	The missing data should have started on page 284, which was uploaded.	N/A	Data Missing	Solicited systemic reactions were not reported for dosage groups 50 µg younger and 60 µg younger (top dose groups).
5/7/2022 13:16:07	125742_S1_M5_CRF_c4591001 1005 10051047.pdf	49-50, 155, 157	n/a	Adverse Effects - Other	aortic aneurysm after one jab - serious event - didn't result in persistent or significant disability
5/7/2022 13:37:08	file:///C:/Users/14012/Downloads/STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy.pdf	Page 13- 2.7.3.1. Background and Overview of Clinical Efficacy/Immunogenicity	Paragraph 1	Other	Immunosuppression- possible susceptibility to Covid and other infectious diseases. According to the document, the technology works as such: "BioNTech has developed multiple RNA-LNP platforms, including nucleoside-modified RNA (modRNA), which has blunted innate immune sensor activating capacity and thus augmented antigen expression" Fundamentally, this would suggest that there is a period of time between the "blunting" and antibody production where the vaccine recipient is more vulnerable to infection. So, if I'm looking at this logically, using this technology in the midst of a pandemic would open up the vaccine recipient to become infected with Covid or some other infectious agent at a much higher probability than otherwise.

5/7/2022 14:26:42	125742_S1_M5_CRF_c4591001-1005-10051054.pdf	210	1 Subject Status	Adverse Effects - Other	CHEST PAIN ISSUE - Note written in narrative section of SAE form dated 9.21.2020 states "Telephone call from subject on 21SEP2020 - per subject she was hospitalized for intermittent non-cardiac chest pain from 16SEP2020 to 17 SEP2020." Please clarify quer NEXT BOX BELOW: CLINICAL - please submit a SAE F/u to clarify "On 21Sep2020, subject was hospitalized for intermittent non-cardiac chest pain from 16Sep2020 to 17Sep2020." Is this "Subject was hospitalized from 16Sep20 to 17Sep20 for intermittent non-cardiac chest pain"?
5/7/2022 15:05:01	file:///C:/Users/14012/Downloads/STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy.pdf	16, 17, 18	page 16- paragraph 8, page 17- paragraph 1, page 18- paragraph 2	Efficacy	Efficacy groups in Phase 2/3 different from dose determination group in Phase 1. In determining dose in Phase 1, the study used on healthy individuals. Then in Phase 2/3, the group was expanded to include at risk, immunocompromised, HIV, HBV, HCV positive, etc. participants. This strikes me as irresponsible in that a safe does was determined with a largely healthy population but then administered to a largely unhealthy population. Also, one would expect to find a larger discrepancy between cases and controls in a study using healthy populations vs. unhealthy populations (i.e. healthy controls would be much less likely to contract a Covid infection requiring medical intervention).
5/8/2022 11:32:57	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_bnt162-01-interim3-report-body.pdf	20	Inclusion criteria #12	Study Protocol	"They must have confirmation of their health insurance coverage prior to Visit 0." This study took place in Germany. Germany has socialized medicine. The German government wouldn't cover the costs of any AE for those who volunteered for the trial? More shockingly is that Pfizer wouldn't have insurance to cover the AE's of the trial participants. (Maybe no insurance company would touch this with a 10-foot pole?) Of course, by the time these trials were being conducted (March 2021), Pfizer would have known of the AE's because the vaccine had been rolled out in Dec 2020.
5/8/2022 14:49:04	FDA-CBER-2021-5683-0041709	All see summary	see summary	Study Protocol	Unbinding of Study after 2 placebos received,
5/8/2022 17:13:42	125742_S1_M5_5351_bnt162 01 interim3 report body.pdf	162	Table 14.1-4.2-1: Demographic characteristics, categorical - BNT162b1	Study Protocol	Of the 120 participants in this study of adverse events based on the dosing and the time from the primary and/or second dose (in a younger and older cohort groups) all but three were white.
5/8/2022 17:21:02	125742_S1_M5_5351_bnt162 01 interim3 report body.pdf	159	Table 14.1-4.1-1: Demographic characteristics, continuous - BNT162b1	Study Protocol	In this study of adverse events based on dosing, in older and younger cohorts, the mean age in the older cohort (depending on dose) ranged from 64.31 to 67.16. Considering the age stratification regarding the morbidity and mortality of covid (which should have been known when the trials started) I would have thought the means should have been in the mid 70s.
5/8/2022 17:55:09	125742_S1_M5_5351_bnt162 01 interim3 lab measurements.pdf	5566	N/A	Data Missing	Missing grade data for assessment day
5/8/2022 18:33:21	125742_S1_M5_5351_bnt162 01 interim3 report body.pdf	158,160	Table 14.1-4.1-1: Demographic characteristics, continuous - BNT162b1	Study Protocol	In this study regarding adverse events based on dosing and a younger and older cohort the mean BMI for both cohorts ranged between 24.20 to 25.63. Since obesity was also a critical factor in covid morbidity and mortality this BMI range does not include obese people.
5/8/2022 20:28:19	125742-S1-M5-bnt162 01 interim3compliance.pdf	article	article	Other	A May 6, 2022 article by Patrick Howley from National File entitled: " UPenn, Sponsor of Biden's Think Tank, Profits From Vaccines and Had Staff Shakeup Over Foreign Money Including 'CHINA' Money" Info on mRNA vaccine and money
5/8/2022 21:15:59	125742-S1-M5-CRF-c4591001 1006 10061020.pdf	48-59/187 pages	many	Adverse Effects - Other	c4591001 COHORT SELECTION DOC Adverse Event Report Coronary Artery Occlusion Aug 25,2020 Tox Grade 4 Required hospitalization, life threatening event. Withdrawn from study. Event was NOT related to study treatment. Was the only adverse event rported to Pfizer in this group. Other adverse events documented such as dyspnea, angina, non ST elevated myocardial infarction were not related to study treatment.
5/8/2022 21:31:58	125742-S1-M5-CRF-c4591001-1005 10051054.pdf	17-18/212 pages	all	Data Missing	From c459-1001 COHORT SELECTION Vaccination symptoms Doc. Only able to record for fever, fatigue, headache, chills, vomiting. diarrhea, muscle pain, joint pain, redness, swelling, pain at injection site. No way to record other body systems symptoms related to respiratory, cardiac, neurologic as examples.
5/9/2022 6:17:48	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_bnt162-01-interim3-lab-measurements.pdf	Across the whole document	Across the whole document	Adverse Effects - Other	This document lists lab tests & vital signs for over 230 trial participants. There were 2024 Abnormal results; 1535 results too High for the Normal range; 1358 too Low for the Normal range & 752 Missing results. Pfizer list NONE of these abnormalities as clinically significant. It could be useful to have a doctor review that claim.
5/9/2022 10:45:22	11.33	63	11.3	Other	The impact of SARS-CoV-2 infection on the persistence of vaccine induced immune response can't be evaluated since the participants were not monitored for an infection on a regular basis during the course of the study 12.6 All the described participants with AEs one withdrawal were female. page 117
5/9/2022 11:39:13	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1005-10051293.pdf	35, 38, 40, 67, 69, 74, 76	n/a	Adverse Effects - Other	ER, intensive care, ventilation, abnormal chest X-ray, cardiac arrest, life threatening, recovery
5/9/2022 13:22:04	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1006-10061094.pdf	70, 206	n/a	Adverse Effects - Other	injection site pain resolved next day, upper respiratory infection - no major issues

5/9/2022 14:17:48	125742-S1-M5-5351-bnt162 01 interim3labmeasurements.pdf	571,257,405,759	multiple	Data Discrepancy	Doc title: Listing 16.23-2.10-3 :Listing of comments-BNT162b2 Page 5712 day 50, 30 mcgs younger, normal range for Ferritin (15-150), creatinine (44.2-79.6) bili (<20.4) Page 5740 Day -11 30mcgs younger, normal range for Ferritin (30-400), creatinine (61.9-106.1), bili (<20.4) Why the change in normal lab values? Have observed occasional HIGH lab results for Ferritin and Creatinine.
5/9/2022 18:15:57	125742_S1_M5_CRF_c4591001-1003-10031111	6 ,9	2e(p.6), 1b(p.9)	Other	The participant on the site 1003 wasn't screened properly for autoimmune conditions. His medical history states that he has had "seasonal allergies" since 2010 and still ongoing. He was diagnosed with psoriatic arthritis on 3rd day after his 2nd placebo shot (September 26,2020). There is no psoriatic arthritis without psoriasis. Psoriasis, probably, was hidden under "seasonal allergies" diagnosis, because it has seasonality too. His "allergies" have started in 2010, when the participant was 16 years old . It is a common age for beginning of psoriasis. The man was enrolled in the study on June 30,2020 (page 99) and completed screening on July 30,2020. Usually summer is a remission period of psoriasis. It became to aggravate when the weather became cold and more humid in the fall .(The site 1003 is located in New York).The participant was prescribed leflunomide (page 173) which is given to the people with moderate and severe arthritis. There are also notes on pages 174-175 that mention the absence of the iron study. Currently it isn't possible to have a full picture of screening failure without laboratory measurements which haven't been released yet. I will resubmit the findings as soon as the laboratory measurements will be available.
5/10/2022 13:09:17	FDA-CBER-2021-5683-0044710	see notes	see notes	Study Protocol	
5/10/2022 15:26:12	FDA-CBER-2021-5683-0042315	see attached doc	see attached doc	Study Protocol	
5/10/2022 16:26:56	FDA-CBER-2021-5683-0042997	see attached document	see attached document	Study Protocol	
5/10/2022 16:41:13	125742_S1_M5_5351_bnt162 01 interim3 report body.pdf	25	Table 2	Study Protocol	According to the Schedule of Study Procedures and assessments an ECG was only performed prior to the day of the first dose and again the day of the first dose. No post dosing ECGs were performed. However, there were clinical blood draws on days 1, 2, 8, 29, and 50.
5/10/2022 17:16:04	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf	pages 1 through 61	n/a	Study Protocol	I am submitting a completed article on the subject of placebo participants who were knowingly given active doses of the vaccine candidate(s) during the 2020-21 Pfizer trials, rendering the entire study invalid and possibly illegal. In addition, I am including 4 screen shots to illustrate findings and the names of relevant trial officials who are pertinent to this submission. The list of screen shots is listed here for convenience and below where the list may not appear. Screen Shot:(article titled:) Pfizer Trial Rendered Invalid; {1} 16.1.7.1 #1 Dose 3/4; {2} Stephen Thomas UMU; {3} Ugur Sahin BioNTech; {4} Koury, Perez Pfizer Thank you for your time. Sincerely, Denise Mason
5/10/2022 17:29:27	FDA-CBER-2021-5683-0044793	see attached	see attached	Study Protocol	
5/10/2022 22:29:21	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_bnt162-01-interim3-lab-measurements.pdf	7037	last row, test subject #20138	Adverse Effects - Other	young test subject #20138 experienced "stabbing pains in the heart region" on day 2 of vaccine injection, "probably due to stress"
5/11/2022 1:00:38	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_bnt162-01-interim3-lab-measurements.pdf	7011-7032	n/a	Study Protocol	It appears three young test subjects #20154, #20102, and #20127 had high covid antibodies (see p 7023 for example) pre vaccine trial. The argument I hear for vaccinating children for a disease that effects them mildly is to keep them from catching covid and spreading it to the vulnerable. How could the efficacy of the vaccine be measured if the young vaccine test subjects already had covid? The older test group did not have covid-19 antibodies tested at all, or those records are missing. See p. 7031
5/11/2022 11:35:32	Listing 16.2.3-1.5-1: Listing of adverse events - BNT162b1	16 of 66	N/A	Adverse Effects - mYocarditis	The attached spread sheet shows chest pain complaints from participants. All but one was reported as non-cardiac. As an ER nurse I would have initiated a cardiac workup with these complaints unless there was a clear mechanism of injury. Chest pain due to "muscular tension" is a new one on me.
5/11/2022 19:39:35	file:///Users/kathryn/Downloads/125742_S1_M5_5351_c4591001-fa-interim-audit-certificates.pdf	1	n/a	Other	I swear I am going crazy. 4444 didn't start enrolling patients until late October. 1231 official site was up and running late July. Nevertheless, only site to have 2 x 8 day audits.
5/12/2022 11:51:13	PF-07302048 (BNT162 RNA-Based COVID-19 Vaccines) Protocol C4591001 Final Protocol, 15 April 2020	1402	Last para	Study Protocol	Pfizer appear to have broken their protocol with respect to the follow-up of Maddie de Garay when she suffered severe injury: "The investigator is *obligated to perform or arrange for the conduct of supplemental measurements and/or evaluations as medically indicated or as requested by the sponsor* to elucidate the nature and/or causality of the AE or SAE as fully as possible. This may include additional laboratory tests or investigations, histopathological examinations, or consultation with other healthcare providers". (My asterisks.)
5/12/2022 14:01:42	Clinical Trial Protocol	page 9	Table 1	Study Protocol	In reviewing the protocol for dosage of prime injection, the recommended dosage was 10, 20 or 30 units. This was for BNT162b1 I reviewed 2 subjects who were given this Vaccine. The first, identified as 276-01-0010 was given 10units (0.5ml) The second, identified as 276-01-0075 was given 60 units (0.3 ml) Both received BNT162b1. If the Vaccine was the same, how does the math work out? If there are 10 units in 0.5 ml how can there be 60 units in 0.3ml ? Also, the maximum dose for this vaccine was 30 units per protocol. The subject 276-01-0075 did not receive the second dose. There was no documentation as to why she did not receive it. There were no serious adverse reactions reported. I did see on the same chart that the planned dose of two 30 unit doses were listed for a different Vaccine: BNT162b2
5/12/2022 14:25:38	125742-S1-M5-5351-bnt162 01interim3compliance.pdf	article	fda pdf doc	Other	"IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving no More than Minimal Risk to Human Subjects Guidance for Sponsors, Investigators, and IRBs" (Contains Nonbinding Recommendations) From the FDA "On December 13,2016, the 21st century Cures Act (Cures Act) (P.L. 114-255) was signed into law. Title III, section 3024 of the Cures Act amended sections 520 (g) (3) and 505 (i) (4) of the FD&C Act to provide FDA with the authority to permit an exemption from informed consent requirements when the proposed clinical testing poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of the human subject. This statutory amendment became effective on December 13,2016. FDA intends to promulgate regulations to reflect this statutory change, including appropriate human subject protection safeguards." " The requirement in section 505 (i) of the FD&C Act for informed consent for investigational use of drugs (Including biologics) provided that FDA regulations must ensure informed consent is obtained " except where it is not feasible or it is contrary to the best interest of such human beings." In orde4r to promote consistency across medical products, FDA adopted regulations reflecting the device standard for all medical product research." " In light of the Cures Act amendment to the FD&C Act described above, FDA intends to revise its informed consent regulations to add this waiver or alteration under appropriate human subject protection safeguards to the two existing exceptions from informed consent (i.e., in life-threatening situations and for emergency research)."
5/12/2022 16:54:00	125742-S1-M5-5351-bnt16201 interim3compliance.pdf	FDA-CBER-2021-5683-0019455	graph	COVID Testing	from 16.2.6.1.1 Listing of Assay Data-Phase 1, 2 Doses, 21 Days Apart 10 mcgs for age group 65-85; c4591001 1003 10031077 Dose 1/Prevax July 1, RBD-Binding IgG Level -BLQ; Dose 1/Day 21- July 22,IgG Level 163.788; Dose 2/Day 7 July 29 IgG Level-4376.381; Dose 2/Day 14, Aug 5, IgG Level-3687.991; Dose 2/1Month, Aug 19 IgG Level- 3687.991 Example among many where there is an upslope in the level, then a drop off at 1 month. Going through the data one can see similar rise and drop in IgG levels which helps describes efficacy of the injections. No data available after one month though. Credit to Chris Martinson from Peak Prosperity website for video explanation.

5/13/2022 8:54:55	S1 M5 5351 c4591001-interim-mth6-sample-crf.pdf	159	1	Study Protocol	Study design flaw: Trial participants were given a predetermined list of possible reactions and did not have the opportunity to note if they had a reaction outside of that list. Starting on pg 137 ending on pg 159 it confirms Maddie de Garay's mother's claim there was no Other (please specify) option to record her daughter's hospitalizations and being confined to wheelchair after getting the vaccine. To use an example, if the vaccine caused a participant's hair to fall out there would be no place to note this, and if that happened to 10% of the participants we would never know. In market research terms they provided a closed-ended list of reactions and did not allow for an open-end response. If this were a market research study, an other specify or a follow up open-end question would have followed the precoded list of reactions. Did you have any reactions other than the ones previously mentioned? Yes/No -- If yes, please describe your reaction in a much detail as possible. Was it mild, moderate or severe? The response would be coded to group same mentions (i.e., loss of hair) and report a % on the total participants (example, 10% hair loss, of them 60% mild, 20% moderate, 20% severe)
5/13/2022 10:34:05	S1 M5 5351 bnt162-01-interim3-synopsis.pdf	9, 10	1	Study Protocol	Study protocol: Pg 9, 10 In this early trial they used extremely small base sizes to determine which vaccine candidate and which dose of that candidate to select for the next phase of testing. Each was tested in 12 younger participants and 12 older participants, only 24 in total. BNT162b1 (1 ug, 3 ug, 10 ug, 20 ug, 30 ug) BNT162b2 (1 ug, 3 ug, 10 ug, 20 ug, 30 ug) In market research terms this is qualitative data not quantitative. In a quantitative analysis a base size of n=24 would be *cautious small base size, noting to the reader to use cautious when viewing the results.
5/13/2022 13:34:06	c4591001 COHORT SELECTION	23	lines 8 & 9	Data Missing	Line 8 (dose) is blank. Line 9 (unit) is blank.
5/13/2022 15:05:04	125741-S1-M5-5351-bnt162 01 interim3 compliance.pdf	FDA-CBER-2021-5683-0019498	graph	Other	Examples from 16.2.6.1.1 Listing of Assay Data- Phase 1, 2 Doses, 21 Days Apart Age group:65-85; Dose-30mcgs; RBD-Binding IgG Level results on c4591001 1007 10071052; 1/prevax-BLQ(below detectable limits); Dose 1/Day 21-IgG is94.91; Dose 2/Day 7 IgG is 4847.691; Dose 2/ Day 14 IgG is 2785.921; Dose 2/1 month IgG is 2700.905 No more info beyond this date. Age group 65-85; Dose 30mcgs; RBD-Binding IgG Level results on c4591001 1003 10031037; 1/prevax-1.513; Dose1/Day21 IgG is 2004.880; Dose 2/Day7 IgG is 30209.881; Dose 2/Day 14 IgG is 29549.649; Dose 2/1 month IgG is 22144.452. No further data beyond this date. Note rise and fall of RBD-Binding IgG level which also varies from person to person during bnt162b1 and bnt162b2 studies. Similar rise and fall in 18-55 yr age group.
5/13/2022 15:59:25	125742-S1-M5-5351-bnt162 01 interim3compliance.pdf	1	bottom of page 1	Other	"IRB Waiver or Alteration of Informed Consent for Clinical Investigation Involving No More than Minimal Risk to human Subjects Guidance for Sponsors, Investigators, and IRBs'" July 2017 The document defines: "Minimal risk is defined in applicable FDA regulations as "the probability and magnitude of harm or discomfort anticipate in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.'" (21 CFR 50.3(k), 56.102(i)). Could this be open to interpretation?
5/13/2022 16:05:09	c4591001 COHORT SELECTION	23	Line 10	Data Missing	No parameters for protocol given. Can the public see this protocol?
5/13/2022 16:06:45	c4591001 COHORT SELECTION	29-33	all	Data Missing	If the visit took place, there is no information filled out on these pages.
5/13/2022 16:08:13	c4591001 COHORT SELECTION	35	all	Adverse Effects - Other	first appearance of on-going symptoms
5/13/2022 16:11:06	c4591001 COHORT SELECTION	38	Line 9	Data Missing	Trade name of nasal swab not known
5/13/2022 16:14:04	c4591001 COHORT SELECTION	40	Line 4	Study Protocol	Why swab the subject if, according to protocol, no sample will be needed or collected? Can the public see this protocol?
5/14/2022 15:55:13	125742_S1_M5_5351_bnt162-01-interim3-lab-measurements - Part 8 Listing 16.2.3-2.10-3 Listing of comments - BNT162b2-verified - formatted	Part 8 Listing of comments	Line 60	Adverse Effects - mYocarditis	Subject #20138 - ECG induced stabbing pains in heart region - in younger participants group
5/14/2022 17:26:08	125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form	1 - 26	All	Study Protocol	Institutional Review Boards (IRBs) serve as required and objective third parties to protect and manage risk to human research participants. According to Brook Jackson, Advarra was the IRB that oversaw the Ventavia research sites. On Advarra's website, they state that they supported "100% of Operation Warp Speed vaccine trials" and that they oversaw 2500+ COVID-19 research sites. However, Advarra is NOT listed as an IRB in the Pfizer/FDA documents. Of the U.S. IRBs listed in the "interim IEC IRB consent form" document, are instead associated with Western Copernicus IRB, including the NYU Langone IRB. https://www.advarra.com/resource-library/by-the-numbers-advarras-response-to-covid-19/
5/14/2022 18:26:46	c4591001-100610061052	21,42,70,99,100,109	one	Study Protocol	Three positive covid tests in first two months (pg 21,42 and 70) Treatment unblinded to "assess eligibility for additional vaccine" (pg 100) Note generated "patient is willing to return for vaccination 3. Patient is is eligible per other protocol allowances and confirmed to have received placebo at vaccination 1/2." (pg 99) Note date 3/29/21. Patient had first BNT dose on 2/5/21 (pg 109)

5/15/2022 8:01:35	Cumulative 5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021	31, 32, 34	Lists are not in paragraph form but I'm including screenshots	Adverse Effects - Other	Infant AESIs in 5.3.6 Post Authorization Adverse Events Report I did a previous search on pregnancy related terms and put in a report on my findings concerning pregnant women in the Clinical Trials. It was suggested that I run the search using other related terms. Using the term "infant", I found that there are three serious "infantile" conditions listed in the APPENDIX 1. LIST OF ADVERSE EVENTS OF SPECIAL INTEREST Page 30-38 of the report. The three events were: Page 31 - Autoinflammation with infantile enterocolitis Page 32 - Early infantile epileptic encephalopathy with burst-suppression Page 34 - Infantile spasms While these instances may have been included in another area of the document such as Page 21 "Other AESIs" which includes 6 infants in the age breakdown, we have no idea how, or at what point they were exposed to the vaccine. This document was post-authorization for ADULTS dated February 28, 2021. Children under 12 years of age were not approved to be vaccinated until Oct 29, 2021. There were obviously many children given the vaccine, probably by mistake, and this could have included some infants. Or, the exposures could have been in the womb, or through breast milk. This is invaluable information to assess the safety of administering the vaccine in children and pregnant women. I hope to also find time to do a breakdown of the paediatric exposures and adverse events listed on Page 13. I noticed while scanning the above appendix that there were quite a number of "juvenile" AESIs listed. Pfizer had this information before the FDA approved the vaccine for children under 12. It would be interesting to know if and how carefully they followed these children in the lead-up to the FDA approval. I look forward to searching future documents, particularly the AE reports that are in this latest batch.
5/15/2022 8:15:41	demographic data, see my comment below for Site 4444	see comment below about site 4444	see my comment below about site 4444	Data Discrepancy	I asked about site 4444 on April 9 at 19:25 (see time stamp on your documents received) and I never received an answer. I provided a link and page numbers. I know you are swamped so it is hard for you to answer all questions. Professionally I have been trained to audit for data integrity issues and have been doing it for 30 years along with being trained in violations of federal regulations.
5/15/2022 15:18:58	16.2.5.1.2 Listing fo subjects who received vaccine not as randomized - Phase 2	pg 1-3	n/a	Data Discrepancy	re previous submission re exclusion doc - there is also this doc, but only 13 BNTb2 patients are listed, and 10 placebo patients are listed as receiving jab as not randomized. In Phase 2 (page 1) it says no one meets this criteria. Page 2-3 is cutoff date of Nov 14 I believe. Just an FYI. Not sure where/when I found this doc - can't find to copy and paste, but above is the title. No children 12-15 listed.
5/15/2022 17:20:42	125742-S1-M5-5351-bnt 01 interim3compliance.pdf	article	article	Other	"A Health Public Policy Nightmare" article by Dr Robert Malone, on Feb 8 2022. He discusses information found in a research paper entitled : " Immune Imprinting, Breadth of Variant recognition and Germinal Center Response in Human SARS-CoV-2 Infection and Vaccination" by Katharina Roltgen et al, March 17, 2022 in Cell Press From the Roltgen paper: "needle core biopsies of ipsilateral axillary lymph nodes 6-70 days after second dose of mRNA-1273 or BNT162b2 vaccination and detected vaccine mRNA collected in the GCs of LNs on day 7, 16,, and 37 post vaccination, with lower but still appreciable specific signal at day 60." In Dr Robert Malone's article he describes that " The paper also notes that the antibody response is IgG, not IgA or IgM. IgA and IgM antibodies produce a strong mucosal immune response needed for respiratory diseases, unlike IgG." Roltgren reports: : We find the BNT162b2 vaccination produces IgG responses to spike and RBD at concentrations as high as those of severely ill COVID-19 patients and follows a similar course."
5/15/2022 17:55:08	125742_S1_M5_5351_bnt162-01-interim3-lab-measurements - Part 4 Listing .... of comments	4311 or 4312	1	Study Protocol	6 subjects who did not receive booster dose (2nd?) due to SRC decision (60 ~g group)
5/16/2022 11:58:30	125742_S1_M5_5351_bnt162 01 interim3 report body.pdf	52, 54, 62, 63, 64, 66	see narrative	Study Protocol	In section 11, "IMMUNOGENICITY, CELL-MEDIATED IMMUNE RESPONSE, AND GENETICS RESULTS" of the "Interim Clinical Study Report", page 52, there was what I thought was curious data with respect to the use of human convalescent serum (HCS) as benchmarks. For both BNT162b1 and BNT162b2 the benchmark was based on HCS from 38 patients aged 18-85, 14 days post a confirmed diagnosis "and at a time when the individuals were asymptomatic", pg 55. The study would then compare the fold increase of the antibody titers at day 43 (21 days after dose 2) to the antibody titers of the HCS that was all collected at 2 weeks post diagnosis in asymptomatic people. The study then states that seroconversion occurred at a minimum 4 fold increase in the titer from the baseline and based on the charts, figures 8 and 9 pg 54, that occurred at day 29 (7 days post dose 2). There is a similar situation with respect to CD4+ and CD8+ T cell responses. For BNT162b1 benchmarking was provided by "PBMCs [peripheral blood monoclonal cells] from 15 COVID-19 convalescent virologically confirmed patients were used", pg 63. There is no data as to how long after infection was the blood drawn from these fifteen people. The authors state, "The mean fraction of both CD4+ and CD8+ cytokine producing T cells in the BNT162b1-dosed participants (1 to 50 µg) was substantially higher (e.g., for participants dosed at 30 µg, 11-fold higher) than that observed in 15 patients who recovered from COVID-19." This in the last paragraph on pg 63. In the first paragraph oh section 11.3.2.1 it states that baseline data at Day 1, before dosing, and at day 29 (28 d past does 1) of CD4+ and CD8+ t cells were available. Though it is not clear if the comparison between participants and convalescent patients was based on the 29 day data or some other later date. Fig 16 on page 62 clearly shows that T cell response is time dependent. For BNT162b2, section 11.3.2.2 page 64, the benchmark of PBMC was from 18 convalescent patients. Data for the T cell responses from the participants was available at days 29, 43, 85, and 184. The only statement comparing the test subjects and the benchmark data is found on page 66, second paragraph, is "Overall, the mean fractions of S-specific CD4+ and CD8+ T cells were substantially higher at Day 29 (e.g., the S protein pool 1 IFNy CD8· response of 30 ~g dosed participants was 12.5-fold higher) than that observed in 18 patients who recovered from COVID-19." Again, there is no data as to when, post infection, the benchmark blood was drawn, and there were comparisons for the later dates of test subjects blood levels. Is this an honest way to use the benchmarks or was the comparison made between the vaccines and benchmark done in such a way to inflate the vaccines efficacy?
5/16/2022 14:14:33	125742_S1_M5_5351_bnt162 01 interim3 demographics.pdf	37	Listing 16.2.1-1-3: Listing of subjects disposition - BNT162b2	Data Discrepancy	Subject 20183 - the listing indicates that this subject completed the trial on 03SEP2020, but also prematurely withdrew on 05OCT2020. The reason for the withdrawal states "Withdrawal By Subject". I search the "Interim Clinical Study Report", 125742_S1_M5_5351_bnt162 01 interim3 report body.pdf, but found no evidence as to the withdrawal of this subject. Could be a mistake but it seems odd.

5/16/2022 19:37:30	125742-S1-M5-5351-bnt162 01interim3compliance.pdf	8 pages	8 pages	Other	Information on vaccine shedding A pre print study published on May 1, 2022 in MedRxIv entitled " Evidence for Aerosol Transfer of SARS-CoV2- specific Humoral Immunity" by Ross M Kendl et al from the University of Colorado Anschultz Medical campus School of Medicine. Less appreciated than the systemic immunity generated by the vaccines are the high levels of antibody (IgG and IgA) found within the nasal cavity and saliva of vacinees. This outcome is found in both humans and primates, and in response to both MRNA and protein based vaccines." " Respiratory transmission of viral infection is proof that oral/nasal cavity constituents can be communicated through aerosols and/or respiratory droplets." "we obtained nasal swabs from children living in households in which parents or family members had varying degrees of SARS-CoV2-specific immunity, including those unvaccinated, vaccinated and COVID 19+." Used data from 34 different pairs "adult-child pairs". "Evaluation of samples in this fashion revealed that high intranasal IgG in vaccinated parents was significantly associated (p-value=0.01) with a 0.38 increase in the log transformed intranasal IgG gMFIs within a child from the same household." They tested the surgical masks of vaccinated lab staff at the end of the day and found "anti-SARS-CoV2 specific antibodies in them. IgG and IgA was also found in the saliva of these vaccinated staff. "our results suggest that aerosol transmission of antibodies may also contribute to host protection and represent an entirely unrecognized mechanism by which passive immune protection may be communicated."
5/16/2022 20:01:18	125742-S1-M5-5351-bnt162 01interim3compliance	12 FDA-CBER-2021-5683-0000065	breast feeding baby cases	Adverse Effects - Other	Breast feeding sheds vaccine. "116 cases reported exposure to vaccine during breastfeeding (PT Exposure via breast milk) " 17 cases, 3 serious and 14 non-serious, reported the following clinical events that occurred in the infant exposed to vaccine via breastfeeding: Pyrexia(5), Rash(4), Infant irritability (3), Infant vomiting, Diarrhea, Insomnia, and Illness (2 each), Poor feeding infant, Lethargy, Abdominal discomfort vomiting, allergy to vaccine, increased appetite, anxiety, crying .etc etc... Is it vaccine shedding or transmission
5/16/2022 20:40:57	125742-S1-M5-5351-bnt162 01interim3compliance.pdf	62, 63	8.3.5. and 8.3.5.1	Adverse Effects - Reproductive Issues	From Pfizer protocol PF-07302048 (BNT 162 RNA-Based COVID-19 Vaccines) 8.3.5. Exposure During Pregnancy or Breastfeeding, and Occupational Exposure "reportable to Pfizer Safety within 24 hours of investigator awareness" 8.3.5.1. Exposure during pregnancy " examples of environmental exposure during pregnancy": "A female family member or healthcare provider reports that she is pregnant after having been exposed to the study intervention by inhalation or skin contact. A male family member or healthcare provider who has been exposed to the study intervention by inhalation or skin contact then exposes his female partner prior to or around time of conception.' The FDA's Center for Biologics Evaluation and Research (CBER), wrote about shedding in the document entitled : " Design and Analysis of Shedding Studies for Virus or Bacteria-Based gene Therapy and Oncolytic Products Guidance for industry" in August 2015
5/16/2022 21:20:43	125742-S1-M5-5351-bnt162 01interim3compliance.pdf	6 and 53	entire page	Other	A October 9, 2018 document by John Hopkins Bloomber School of Public Health entitled: "Technologies to Address global Catastrophic Biological Risks" described medical countermeasures that included self spreading vaccines, self-amplifying mRNA vaccines, ingestible bacteria for vaccination, drone delivery, robotics and telehealth and portable ventilators. Page 6 and 53 describe self amplifying mRNA vaccines. Could this be a coincidence of things to come?
5/16/2022 22:57:26	125742_S1_M5_5351_c4591001 interim mth6 randomization sensitive.pdf	whole document	all	Data Discrepancy	All placebo for shots 3 and 4 were eliminated and given 30ui of vaccine
5/17/2022 11:23:13	BioN Tech Interim Clinical Study Report BNT 162-01(125742_S1_M5_5351_bnt162-01-interim3-report-body.pdf)	Page 20	Paragraphs 7-11	Adverse Effects - Reproductive Issues	In paragraph 7: the requirement that male partners of female participants wear condoms suggests an extraordinary level of concern over reproductive risks and given that it applies to men who are not participating in the trial(s) seems unethical at a minimum. In paragraph 11: the requirement that male participants not donate sperm from day 0 until 60 days after the last IMP dose is evidence of a serious concern with the vaccine's possible effect on reproduction. Was this adequately disclosed to all relevant parties?
5/17/2022 21:54:35	125742_S1_M5_5351_c4591001 interim mth6 randomization sensitive.pdf	document	Lines 3718, 3721, 3724, 3726, 3729	Data Missing	Those lines they never got shots 1 or 2, but some how got shots 3 and 4
5/18/2022 13:19:05	125742_S1_M5_5351_c4591001 interim mth6 randomization sensitive.pdf	document	many lines through out	Data Discrepancy	There are a great number of people whom never received shots 1 and or two but received shots 3 and or 4
5/18/2022 22:06:30	125742_S1_M5_CRF_c4591001-1003-10031113.pdf	Various	Various	Other	- High number of transcription/barcode/handling errors and other irregularities that needed answering Detail pp. 203, 219, 232, 251: 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. p. 234, Mar-04-2021: 'PDQ: Date of visit at V4_MONTH6_L is out of window for 1 days from V2_VAX2_L DOV or V2 Vaccination date. Please verify and update. Else, confirm in query response appropriately.' p. 236, Oct-22-2020: Illness onset triggered visit. 'severe sepsis, possible pneumonia(onset date:14Oct2020) was reported as serious in Safety database but missing in AE CRF/ Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing/ Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing.' p.238, 239, Feb-02-2021: 'Date of Last Symptom Resolve d: Dec/4/2020/ Last Symptom Resolved date is a future date compared to when it was entered. Please correct./Date of Last Symptom Resolved: Dec/4/2021' p. 249, Oct-15-2020: ''Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate. Reason: swab obtained on site' p. 287, Mar-10-2021: error. The Erythrocytes Unit should be "10^12/L" instead of "/uL". p. 292, Oct-15-2020: Neutrophils_ PX608 out of normal range p. 294, 296, 297, 299, 300, 302 Oct-16-2020: Transcription error. (also, DMW4988798;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.) p. 308, 309, Oct-16-2020: Systolic BP 80 and Diastolic BP 53 recorded as clinically significant p. 313, Dec-01-2020: The response for "FiO2 (Fraction of Inhaled Oxygen)" is missing p. 315, Oct-15-2020: 'increased retrocardiac airspace opacity of left lower zone, concerning for pneumonia'. p. 317 Jan-21-2021: Date of Visit is completed but Self Swab CRF is not initiated. p. 316-7, Feb-18-2021: PDQ: Convalescent visit is missing and 35 days (36) have passed since COVID Illness Visit. If visit occurred record data as a matching CONVA visit; if visit did not occur attempt to schedule visit even if OOW and obtain the CONVA sample else clarify. Mar-02-2021 said to have 'happened on 26Feb'. p. 318, Jan-15-2021: Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing/Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. p. 319, Jan/13/2021: Unscheduled Visit with signs and symptoms of potential Covid-19. Jan-15-2021: Date of assessment is not same as Date Visit. p. 326-7. Jan-15-2021: transcription errors. p. 331, Jan-15-2021: Date of Collection 11/Jan/2021 is different from Date of Visit 13/Jan /2021. This is correct - subject hospitalized and swab was taken from hospital sample on date of admittance.? p. 332, Jan-15-2021: 'Sample Collected?' is Yes, however no barcodes are entered. p.340, Nov-18-2020: Unscheduled Visit. [Reason and outcome of examination not clear.] p. 341, Nov-18-2020: 'Sample Collected?' is Yes, however no barcodes are entered. p. 343, Feb/26/2021: Unscheduled Visit. [Reason and outcome of examination not clear.]

5/18/2022 22:09:26	125742_S1_M5_CRF_c4591001-1003-10031113.pdf	Various	Various	Adverse Effects - Other	p. 209, Aug-20-2020 (also p.224): fever symptoms reported p. 210, Aug-20-2020: Fatigue/headache symptoms reported p. 212, Aug-20-2020: Vomiting/diarrhea symptoms reported p. 213, Aug-20-2020: Diarrhea/muscle pains symptoms reported p. 214, Aug-20-2020: Joint pain symptoms reported? p. 215, Aug-20-2020: Redness at injection site reported? pp. 216, Aug-20-2020: Pain/swelling at injection site reported p. 225, Sep-21-2020: Fatigue symptoms reported p. 226, Sep-21-2020: Headache/chills symptoms reported p. 227, Sep-21-2020: Vomiting symptoms reported p. 228, Sep-21-2020: Diarrhea/muscle pains symptoms reported p. 229, Sep-21-2020: Joint pain symptoms reported p. 230, Sep-21-2020: Redness at injection site reported p. 231, Sep-21-2020: Pain/swelling at injection site reported p. 236, Oct-22-2020: Illness onset triggered visit. 'severe sepsis, possible pneumonia(onset date:14Oct2020) was reported as serious in Safety database but missing in AE CRF/ Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing/ Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing.' p. 239, Oct-15-2020: Fever still present p. 240, 241, Oct-15-2020: New or increased shortness of breath, chills, and new or increased muscle pain. p. 242, Oct-15-2020: New or increased muscle pain. p. 245, Oct-15-2020: weakness. p. 254, Oct-15-2020: unscheduled emergency room visit p. 255, Oct-15-2020: urgent care p. 260, Nov-29-2020: hospitalisation ongoing; discharged Nov-30-2020 (inconsistent with discharge date of Oct-16-2020 on the same page) p. 263, Oct-15-2020: potential Covid 19 illness; Jan-21-2021 severe sepsis (in spite of suggestion to change term to 'interstitial lung disease possible scleroderma') p. 319, Jan/13/2021: Unscheduled Visit with signs and symptoms of potential Covid-19. Jan-15-2021: Date of assessment is not same as Date Visit. p.321, Jan-15-2021: new or increased shortness of breath. p. 354, Oct-23-2020: Clinical - Per SAE report, subject has a second event of diffuse pneumonia vs pulmonary edema. p. 356, Oct-22-2020: For AE severe sepsis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank p. 366, Nov-04-2020: Is this serious event life threatening? YES p. 378, Jan-13-2021: respiratory failure
5/18/2022 23:46:24	Didnt write it down but will try to include if I can toggle back and forth	Page 10 of 86	Not sure	Study Protocol	If I'm reading this correctly, in the clinical trials the placebo group are also offered the real Pfizer shot after receiving the placebo - if that's the case it's a flawed study
5/19/2022 0:00:03	Study C4591001 (3.4.5 Death Detsils) Clinical Study Data Reviewer's Guide - BLA Analysis for Participants ≥16 Years of Age - BioNTech SE and PFIZER INC. - Study C4591001	31-86	Several pages	Data Missing	Several pages of charts titled "Death Details" - under "Explanation" for death, about 90% of the explanations are as follows: Duplicate records Missing documents Study still ongoing (from April 2021) Complete data not obtained
5/19/2022 10:59:03	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1001-10011093.pdf	p. 42	line 1	Other	respiratory treatment N/A
5/19/2022 11:01:35	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1001-10011093.pdf	47-51	entire pages	Other	repeating chemistry- all N/A
5/19/2022 11:02:59	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1001-10011093.pdf	52-58	entire pages	Other	Hematology all N/A
5/19/2022 11:04:14	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1001-10011093.pdf	59-60	entire pages	Other	vital signs- Covid- all N/A
5/19/2022 11:05:32	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1001-10011093.pdf	61-62	entire pages	Other	Vital signs- Pulse Ox Room Air- all N/A
5/19/2022 11:07:10	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1001-10011093.pdf	63-64	entire pages	Other	oxygenation parameters- all N/A
5/19/2022 11:08:45	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1001-10011093.pdf	67-68	entire pages	Other	imaging not done
5/19/2022 11:11:17	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1001-10011093.pdf	73-75	entire pages	Other	Subject makes unscheduled phone call. No information in noted.
5/19/2022 11:15:21	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1001-10011093.pdf	78-80	entire pages	Adverse Effects - Other	Subject is hospitalized for chest pain. It is called a "serious adverse event" (#15, p. 80) The whole incident is written in code. The code favors non-disclosure in Pfizer's favor.
5/19/2022 11:18:24	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1001-10011093.pdf	81-82	entire pages	Data Missing	
5/19/2022 11:20:21	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1001-10011093.pdf	95	entire page	Other	Did Pfizer not do a six month review of this subject?
5/19/2022 11:24:20	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1001-10011093.pdf	97	entire page	Other	Subject never gives informed consent for "asymptomatic surveillance."
5/19/2022 11:27:29	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1001-10011093.pdf	101	line 1	Other	Previous to this confirmation, the subject refused the booster.
5/19/2022 11:29:48	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1001-10011093.pdf	107-229	entire pages	Study Protocol	The only Pfizer employee who has signed paperwork for this subject that has an affidavit is Mark Mulligan. All other employees have invalidated signatures.

5/20/2022 11:12:12	125742_S1_M5_5351_bnt162-01-interim3-protocol.pdf	206	2	Study Protocol	Why would they have excluded a One dose study group in the follow-up trials when they knew based on their preliminary data One dose was working as they desired? The file above notes preliminary data showed ONE dose by day 21 of BNT162b2 produced robust production of antibodies YET in the FDA Briefing Document they noted in the follow-up phase of testing "The trial did not have a single-dose arm to make an adequate comparison". Pg 206 from above file "Preliminary data (at the time of preparation of this summary) from subjects with BNT162b2 suggest a robust induction by day 21 post first dose, of the production of antibodies conformational to complete CoV-2 spike protein, the antigen encoded by the RNA in this vaccine construct. The order of magnitude of response seems at least equivalent to that seen for anti-RBD antibodies with the b1 vaccine constructs." Pg 32- 33 Official FDA Briefing Document: https://www.fda.gov/media/144245/download "Among all participants (regardless of evidence of infection before or during the vaccination regimen), 50 cases of COVID-19 occurred after Dose 1 in the BNT162b2 group compared with 275 cases in the placebo group, indicating an estimated VE of 82% (95% CI: 75.6%, 86.9%) against confirmed COVID-19 occurring after Dose 1, with VE of 52.4% (95% CI: 29.5%, 68.4%) between Dose 1 and Dose 2. The efficacy observed after Dose 1 and before Dose 2, from a post-hoc analysis, cannot support a conclusion on the efficacy of a single dose of the vaccine, because the time of observation is limited by the fact that most of the participants received a 33 Pfizer-BioNTech COVID-19 Vaccine VRBPAC Briefing Document second dose after three weeks. The trial did not have a single-dose arm to make an adequate comparison."
5/20/2022 13:50:45	125742_S1_M5_5351_c4591001 interim mth6 randomization sensitive - Pfizer_subjects_four_shots.xlsx	1	spreadsheet numbers. BMI Index.	Data Missing	Typically when shots are given they are adjusted for the BMI index and the grams or cc's are listed next to the patients name so the dose is recorded in the amount. I'm not seeing this anywhere in this excel spreadsheet where the dosage given is adjusted for the BMI index. Concentrations in a dose always has an affect if not adjusted for the BMI index. This was taught early on in all first responders courses. Maybe I'm missing where the doses are listed in cc's but all I'm seeing are placebo's and the number 30 for dose. But nothing for the adjustment for a person's weight of 85 for example when others are 125 or 67 or 68 in weight and the BMI's are different as well. The adult body has a mass index much higher than a child or teen. So why are they providing 30 as the blanket dose to everyone?
5/21/2022 6:12:15	125742_S1_M5_CRF_c4591001 1006 10061020.pdf	3, 7-13, 48-50, 57, 158	Hghlighted most important information	Adverse Effects - Other	This is a trial subject report. His medical history reads like an example of who should have been Excluded from the trial. He has a history of heart and blood clot issues. Day 13 after injection he had a heart attack and was withdrawn.
5/21/2022 22:54:29	Listing 16.2.1-1-1: Listing of subjects disposition - BNT162b1	1-59	ALL	Data Missing	According to the Tables Informed consent was collected at least 4 times (screening, prime immunization, boost immunization, and trial completion). The tables reveal that sometimes consent was not obtained, or was obtained after the date of immunization or trial completion. It would be helpful to view the protocols for both of these trials to follow when informed consent was obtained. If study protocols require informed consent at each of these visits (this is my assumption looking at these tables) this raises a few questions regarding these subjects. • Were the subjects made aware of new information (adverse events, dose changes, their right to opt out etc, via the consent form each time they came back for an immunization, or other study procedures if this was a part of the study protocol? • Was the same informed consent signed each time? Therefore no new info was shared? • Were subjects signing the consent post visit and therefore, not made aware of updates before they had an immunization or procedure? • Was omission of signed consent forms considered protocol violations? Were these violations recorded? Is there a summary of study drop outs due to adverse events somewhere in the report, as usually required by FDA? The Demographics reveal that the race of the overwhelming majority appear to be white, therefore there is very little racial diversity in the study. Medical history is not reported for a large majority of subjects. In a well controlled study this information should be collected for patient safety for both inclusion/exclusion criteria of the protocol, as well as for evaluation of adverse events. For study BNT162b1, of the 120 subjects enrolled in the Younger and Older dose groups, the medical history of only 18 subjects was reported. For study BNT162b2, of 96 subjects total in the Younger and Older dose groups, medical history was provided for only 37 subjects.
5/23/2022 19:24:40	Listing 16.2.1-7-1Listing of Medical History BNT162b1	19-59	chart review	Study Protocol	Listing 16.2.1-5-1: Listing of subjects demographics - BNT162b1 1. Trial period only appears to total sixty days from mid-June to mid-August 2020. 2. Page 19 – 25 .pdf. This appears to be a very flawed study from a demographic standpoint. There are few minorities, only three. Most appear to relatively fit, there are no obese people. For some reason there are very few overweight females, until you get to the larger doses. a. One black, two Asians, no pacific islanders, Hispanics, etc. b. The black male is under 30 years old c. Only seven over 70 years old d. The black has a “normal” BMI e. There were no “obese” (>30 BMI in the study) f. Fifty were “overweight” (BMI between 25-29.9) g. The majority of those with a BMI > that 27.5 are male, until the dosage goes over 20µg, then it’s about 50/50. 3. Medical history (page 26-27) a. Mostly females with hysterectomies or menopause b. No heart conditions c. No pregnancies d. No arthritis/joint pain Listing 16.2.1-7-3: Listing of medical history - BNT162b2 4. 100% are white 5. Zero “obese” patients. Most with BMI greater than 27.5 are males. 6. Medical history (page 54-59 .pdf) a. Much longer list b. Much broader list of medical issues including immune system disorders c. The largest number (modestly) is for those receiving above 30µg
5/25/2022 18:46:17	125742_S1_M5_5351_bnt162-01 part 8 comments	7037?	Row (line) 60. Subject# 20138.	Adverse Effects - Other	Possible myocarditis/pericarditis or other heart AE. Patient had a 12 lead ECG due to stabbing pains in the heart region, comment said probably stress induced.
5/26/2022 10:32:09	125742-S1-M5-5351-bnt162 01interim3compliance	article	article	Other	A May 21,2002 article by Zachary Steiber on EPOCH TIMES website entitled: " Pfizer Moves to Dismiss lawsuit From COVID-19 Vaccine Trial, Citing 'Prototype' Agreement' ' This is about the Brook Jackson lawsuit. The Feds and Pfizer define the vaccine as a prototype.
5/26/2022 13:02:35	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1001-10011093.pdf	265	1	Other	No end date for bilateral cataracts
5/26/2022 13:04:32	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1001-10011093.pdf	267	2 & 3	Other	osteoarthritis start date unknown
5/26/2022 13:06:37	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1001-10011093.pdf	269	2	Other	pectus exavatum start unkown

5/26/2022 13:08:57	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1001-10011093.pdf	273	3	Other	start date unknown
5/26/2022 13:12:33	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1001-10011093.pdf	275	whole page	Other	start date unknown and end date unknown
5/26/2022 13:16:05	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1001-10011093.pdf	285	10	Other	What is the exact time frame for the "protocol specified observation period?"
5/26/2022 13:19:25	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1001-10011093.pdf	301-302	#4	Adverse Effects - Other	Subject had severe local reaction after injection
5/26/2022 13:22:25	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1001-10011093.pdf	317-319	whole pages	Data Missing	sample collection error? was it resolved?
5/26/2022 13:24:54	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1001-10011093.pdf	320-321	several lines	Other	data corrected per protocol- where is the protocol defined?
5/26/2022 13:26:21	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1001-10011093.pdf	322	3 & 4	Data Missing	
5/26/2022 17:41:37	BNT162b2 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports	1	1- last 4 lines of paragraph	Other	Date at side of page: April 30, 2021; concerning is that this states: Pfizer The information contained in this document is proprietary and confidential. Any disclosure, reproduction, distribution, or other dissemination of this information outside of Pfizer, its Affiliates, its Licensees, or Regulatory Agencies is strictly prohibited. Except as may be otherwise agreed to in writing, by accepting or reviewing these materials, you agree to hold such information in confidence and not to disclose it to others (except where required by applicable law), nor to use it for unauthorized purposes.
5/26/2022 19:47:19	BioNTech RNA Pharmaceuticals Listing 16.2.3-2.10-3 Listing of comments	7033-7040	no paragraph numbers	Adverse Effects - Reproductive Issues	for 46 respondents, 4 had menstrual issues. That is 8.7%
5/26/2022 19:56:51	125742_S1_M5_5351_bnt162-01-interim3-adverse-events.pdf	171, 220, 189, 224, 305, 224, 188	N/A	Adverse Effects - Other	On the pages listed above I found noted AE's of: genital herpes x2, herpes of lips/nose x 3 & pityriasis rosea x 2 which is a condition that is related to herpes. They were all noted as "related" to the vaccine.
5/26/2022 19:59:06	125742_S1_M5_5351_bnt162-01-interim3-adverse-events.pdf	195	N/A	Adverse Effects - Other	I found an AE noted for "dysphagia" or problems swallowing in the "younger" age group. It was noted as not-related without any additional info noted. I will look in the other AE's that are assigned in my group and note if it comes up again. But I've worked in hospitals in a clinical role for 13 years and dysphagia is very uncommon in younger people without other health issues. Generally we see it after strokes in older adults or in people with neurological degenerative conditions.
5/26/2022 20:00:29	125742_S1_M5_5351_bnt162-01-interim3-adverse-events.pdf	201 & 224	N/A	Adverse Effects - Reproductive Issues	Noted AE's for "dysmenorrhoea" - both noted as "not related." I will look for more instances of this in the other documents I will be reviewing next.
5/26/2022 20:01:22	125742_S1_M5_5351_bnt162-01-interim3-adverse-events.pdf	208	N/A	Adverse Effects - Other	I found a noted AE of elevated GGT levels, which are related to or a marker for liver damage.
5/26/2022 20:09:19	125742_S1_M5_5351_bnt162-01-interim3-adverse-events.pdf	N/A	N/A	Adverse Effects - Other	In this document, all of the AE's that were noted as related to the vaccine, were all noted as "resolved/recovered." I can't believe that all of these conditions resolved without issue. And there is no long-term follow-up to notd if any of them came back or caused other issues down the line. It does not ring true that they all magically resolved.
5/27/2022 11:13:34	125742_S1_M5_5351_btn162 01 interim3demographics.pdf	1-18 and 27-47	16.2.1.1-1 and 16.2.1.1-3 (Listing of subjects disposition for BNT162b1 and BNT162b2)	Data Missing	Why are there no dates of followup completion for these subjects?
5/27/2022 11:41:55	15742_S1_M5_5351_bnt162 01 interim3protocol.pdf	p. 10, p. 12, pp. 13-15	Table 2, Trial Duration, Key Exclusion Criteria	Study Protocol	Regarding Table 2 "Based on the tolerability profile after the prime dose at 60ug (BNT162-01 trial) and 100ug (BNT162-02 trial), the respective boost doses were not administered." Questions: What happened to the subjects who received these higher doses? Was there any followup? If so, for how long afterwards? Regarding Trial Duration "In total, the planned trial duration (i.e. the sum of the screening, treatment, and followup phases) for subjects is expected to be approximately 214d for Cohorts 1-10 and 738d for Cohorts 11 to 13." Questions: If the trial duration for Cohorts 11 to 13 is 2+ years how can there be an adequate assessment for both safety and efficacy before that period has concluded? Why is there such a big difference in the duration of the trial for Cohorts 1-10 vs. Cohorts 11-13? Regarding Key Exclusion Criteria Question: If subjects were excluded from the trial because of these criteria, why would the vaccine be deemed OK for people who have any of these exclusion criteria AFTER THE TRIAL?
5/29/2022 7:22:45	125742_S1_M5_5351_bnt162-01-interim3-lab-measurements - Part 1 Listing 16.2.3-2.2-1 Listing lab meas-BNT162b1	Whole document	N/A	Adverse Effects - Other	Toxicity in dose escalation study of BNT162.1 on basis of chemistry and hematology visualized in graphs (especially Neutrophil/Lymphocyte ratio). Furthermore many values seem to be missing (but needs to be checked as maybe result of irregular document structure)
5/29/2022 11:44:14	125742_S1_M5_5351_bnt162 01 interim3 adverse events.pdff	53	10073	Adverse Effects - Other	circulatory problems/cardiovascular disorder 1 day post injection
5/29/2022 11:48:08	125742_S1_M5_5351_bnt162 01 interim3 adverse events.pdf	23, 41	10011, 10049	Adverse Effects - Other	adverse event of herpes related to injection both three days post injection
5/30/2022 9:16:08	125742_S1_M5_5351_bnt162 01 interim3 adverse events.pdf	12	20105	Adverse Effects - Other	Herpes reported 1 day post injection
5/30/2022 17:06:23	125742_S1_M5_5351_bnt162 01 interim3 adverse events.pdf	4	20201	Adverse Effects - Reproductive Issues	dysmennorrhea reported but determined to be "not related" to the injection.
5/30/2022 17:56:57	125742_S1_M5_5351_bnt162-01-interim3-lab-measurements.pdf	multiple pages included on a table that will be downloaded	Intermin3 Lab Tables	Other	C Reactive Protein is a nonspecific sign of inflammation that can be detected on a blood chemistry test. This test was performed and show that as the dosage increased, so did the number of patients with elevated CRP on day 2. The degree of elevation also increased as dosage increased. In each case this finding was dismissed as not relevant.
5/30/2022 18:40:25	1257_S1_M5_5351_bnt162-01-interim3-lab	250-274	table Listing 16.2.3-2.1-1: Listing of drug exposure - BNT162b1	Other	These pages list the dosage for each patient and the date on which each dose was given. "Young" subjects were given doses of 1, 3, 10, 20, 30, 50, and 60 ug. The 60 ug group was not given a second dose. "Older" subjects were only given doses of 10, 20, and 30 ug. I have not come upon an explanation for these discrepancies.
5/30/2022 19:11:53	1257_S1_M5_5351_btn162-01-interim3-lab-	addendum to previous submission	Listing 16.23-2.2-1 Listing of lab measurements	Other	Addendum to previous submission on elevated C Reactive Protein in high doses: all elevations in CRP occurred on day 2. This most likely represents the time of spike protein production.
5/30/2022 22:23:09	125742_S1_M5_5351_c4591001 interim mth6 randomization sensitive.pdf	document	all	Other	There were 44,373 subjects to start this trial. 696 did not get shot 1 2663 did not get shot 2 24502 did not get shot 3 28153 did not get shot 4 1098 did not get shot 1 and or 2 but got shot 3 772 did not get shot 1 and or 2 but got shot 4 8 did not get shot 1 but got shot 2

5/31/2022 2:58:46	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_bnt162-01-interim3-report-body.pdf	52 thru 68	All of Section 11	Efficacy	Dosage of Pfizer/Bio-N-Tech mRNA Treatment Please refer to pages 52 thru 68: https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_bnt162-01-interim3-report-body.pdf BEFORE I BEGIN, LET ME SAY THAT IN MY OPINION, THERE IS NO SUCH THING AS A "SAFE" DOSAGE OF THIS "STUFF" (TECHNICAL TERM THERE)... IN ADDITION, I HAVE NOT SEEN ANYTHING IN THE AVAILABLE PFIZER DOCUMENTS THAT EXPLAINS THE WHY OF THE 30 µg DOSE OVER A LOWER DOSE. THE HIGHER DOSES WERE GIVEN UP ON QUICKLY AS THE REACTOGENICITY CONCERNED THE SAFETY COMMITTEE. This has more to do with choosing the 30 µg dose over the 10 µg dose than efficacy, but IMO is related. I am an engineer and not an immunologist; however, I did review a number of papers on the various tests, substances being tested for and meaning of the results. There was no mention of any particular test holding the key to efficacy - more of a balance. As an engineer, I CAN READ CHARTS AND GRAPHS. I do know there should have been an ongoing analysis to check the risk/benefit and a situational awareness that millions and potentially billions of people were going to get this treatment under EUA and still within an ongoing clinical trial. When looking at this data, it is also known that reactogenicity (risk) went up as dosage increased which is logical. It is difficult to tell if increase in reactogenicty is a linear or exponential function of the dosage. With all that in mind, it would seem that the lowest dose possible would be desirable while maintaining a beneficial efficacy THAT OUTWEIGHED THE RISK! On the other hand, if efficacy is only increased by a minor amount but reactogenicity (risk) is increased disproportionately, that would seem to be a poor trade-off. The detailed data and reports that supported the charts, graphs and discussions are listed in the Appendices, but I could not locate in the documents provided. (See Section 16.1.14 in List of Appendices on page 9 of this Bio-N-Tech document) From page 9, "List of Appendices": ("16.1.14 R&D Study reports R-20-0253 - Neutralizing antibody titer and SARS-COV-2 S1- and RBD-specific antibody concentration in serum from participants in the BNT162-01 trial GA-RB-022-01A - T cell immune monitoring (TCIM) of study participants in the BNT162-01 clinical trial - GC(L)P analytical study interim report R-20-0235 - Analysis of the Th1/2 cytokine profile of BNT162b1-specific CD4 and CD8 T cells (interim report for 95 subjects) R-20-0241 - Analysis of the Th1/2 cytokine profile of BNT162b2-specific CD4 and CD8 T cells (interim report for 74 subjects) R-20-0244 - Ex vivo ELISpot data processing and analysis within BNT162-01 clinical trial") This section addressed both BNT162b1 and BNT162b2; however, I only looked at the data for BNT162b2 since it was ultimately chosen. You will also note that there was little data for the "older" age group, so the discussion is basically limited to the "younger" group, but in most cases the older group is not ignored altogether. This Bio-N-Tech report looked at 4 aspects of immunogenicity 11.1 Immunogenicity – functional antibody responses (secondary objective) Page 52
6/1/2022 17:15:43	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1001-10011093.pdf	324	line 4c	Adverse Effects - Other	new or increased shortness of breath
6/1/2022 17:19:02	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1001-10011093.pdf	325-326	line 4e	Adverse Effects - Other	new or increased chills and muscle pain
6/1/2022 17:22:05	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1001-10011093.pdf	331	line 1	Data Missing	trade name of swab that was used was asked for, but was the trade name ever delivered?
6/1/2022 17:23:18	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1001-10011093.pdf	41-336	all	Adverse Effects - Other	Subject ended up in the ER once.
6/1/2022 17:25:55	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1001-10011093.pdf	44	line 3	Other	Subject had toxicity grade 2. What does that mean?
6/1/2022 17:27:48	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1001-10011093.pdf	385	whole page	Other	Imaging Not Done, as opposed to N/A
6/1/2022 17:29:40	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1001-10011093.pdf	422	section 2	Other	Question asked on this page was never answered.
6/2/2022 0:01:15	125742_S1_M5_CRF_c4591001 1081 10811194 reissue.pdf	Page 68	Paragraph 2	Fatality	355 pages for one patient, 2nd dose Pfizer vaccine on 29 Sept.2020, Cough and sore throat on 9 Oct 2020 and death from myocardial infarction on 4 Nov 2020. Ruled 'Not related' due to preexisting conditions and medications for heart issues.
6/2/2022 13:08:51	125742_S1_M5_5351_bnt162 01 interim3 compliance.pdf	43	BNT162b1	Other	This specific medication was given to the subject for flu like symptoms in the space of 2 hours when recommended use is every 4 hours.
6/2/2022 13:50:31	Part_10_2250001to2258681_FDA-CBER-2021-5683-0066701-to-0123167_125742_S1_M5_c4591001-A-D-adfacevd.xlsx	All	All	Data Discrepancy	Hundreds of subjects were vaccinated all at the same times. This appears over and over throughout the document for each administration of the placebo and/or vaccine.
6/2/2022 17:58:42	125742_S1125742_S1_M5_5351_btn162-01-interim3-report-body.pdf	123	12.7.2.2 Clinical Chemistry	Data Discrepancy	Missed/Buried Safety Signal? ' In the Interim 3 Report (page 123, paragraph 12.7.2.2 of document 125742_S1_M5_5351_btn162-01-interim3-report-body.pdf), the report states that there were 3 subjects with elevated CRP levels at 48 hours. The cases where deemed insignificant because the levels returned to normal at the next test (Day 8). I was suspicious of this finding and closely examined the Interim 3 lab reports (multiple pages of document 125742_S1_M5_5351_btn162-01) and discovered that there 28 subjects in BNT162b1and 5 subjects in BNT162b2 with elevated CRP levels. I believe that this is a significant finding. Both groups show a clear, direct relationship between dose and incidence of elevated CRP. Many of the elevations were mild, but with the tests performed 24 hours after vaccination, this may reflect rising CRP levels and not peak levels. C Reactive Protein (CRP) is a nonspecific indicator of inflammation. It can be detected in the blood within hours of an acute tissue injury. It reaches a peak value in 36 to 48 hours, then declines rapidly An additional point that is significant is that the second dose for the 60 ug cohorts was cancelled. No reason is given for this cancellation but as you will see, 66.6% had elevated CRP and 3 had a fever (measured and registered in Vital signs) on Day 2. There were no serious adverse events recorded for this group other than "malaise". Something caused the Site Operator to cancel the second dose. The Interim 3 Report also states that no older patients had elevated CRP levels. As you will see in the documents that I am submitting, this is a false statement. Uploaded documents to Craig: Interim 3 Report. Table and Graph of all CRP Reactions. Patient Data.

6/2/2022 19:14:13	125742_S1_M5_5351_bnt162-01-interim3-report-body.pdf	page 33	Heading: Sample size	Study Protocol	Quote: "No formal sample size calculation was performed. For part A, the inclusion of 12 participants per group was considered to be adequate to observe a particular TEAE with incidence of 15% at least once in 12 participants per dose is 85.8%." I may be reading this incorrectly, but it looks to me that if death occurred in 15% of subjects at a particular dose, they thought that an 85.8% chance of detecting it was good enough. And if it occurred in only 10% of participants, the likelihood is that they would not catch it at all!
6/2/2022 20:18:00	125742_S1_M5_5351_c4591001-fa-interim-protocol-deviations-sensitive and 125742_S1_M5_5351_c4591001-fa-interim-discontinued-patients	protocol deviations p40-44; discontinued patients p48	see page numbers	Data Discrepancy	43 subjects from site #1161 were removed from the study. The reason given: All data considered unreliable due to lack of PI oversight identified as significant quality event. Site 1161 is Benchmark Research in San Angelo Texas. The IRB is Copernicus Group in Cary North Carolina. The subjects listed are numbered sequentially. 1001-1044. The only one not listed is subject #1039. Oddly enough, a few of these patients are listed in 125742_S1_M5_5351_c4591001-fa-interim-discontinued-patients with different reason codes including "exclusion criteria 5" (this is covid+) and "lost to follow-up". Also, what happened at this research facility that invalidated the research? "Significant quality event"
6/2/2022 20:20:55	125742_S1_M5_CRF_c4591001-1003-10031207.pdf	48	N/A	Adverse Effects - Other	The participant had an adverse event noted as a "pulmonary embolism" which is a blood clot in the lungs. They noted it was NOT due to the vaccine, and that it was due to "other - DVT" - which is a deep vein thrombosis which is a blood clot in the leg. They noted the DVT as an adverse event as well, and also noted that was NOT related to the vaccine and that is was due to "other - unknown." I do not see how they could rule this out as related when they note that they do not know the cause. They are both blood clots so I could see it being related.
6/2/2022 20:34:22	125742_S1_M5_5351_c4591001-fa-interim-protocol-deviations-sensitive	26-33	NA	Study Protocol	144 subjects were affected by important protocol deviations across multiple research sites. Reason given: IP administered that was deemed not suitable for use by Almac Almac provides secondary labelling, storage, distribution, provision of depots, temperature management, etc. for BioNTech.
6/2/2022 21:08:50	125742_S1_M5_5351_c4591001-fa-interim-discontinued-patients	55-72; 103-108	NA	Study Protocol	More than 150 subjects from site #1231 left the study for various reasons. This is suspicious because this is the site associated with the now infamous site #4444. Did they release subjects because they didn't support the desired outcome?
6/2/2022 21:35:54	125742_S1_M5_CRF_c4591001-1005-10051214.pdf	46, 48	N/A	Adverse Effects - Other	Subject had an adverse event of facial swelling & facial tenderness both noted as NOT related to the vaccine; it was noted as an "allergic reaction to unknown agent." I do not see how they ruled this out as not related. It would seem that it could potentially be an allergic reaction to the shot.
6/3/2022 17:03:14	125742_S1_M5_CRF_c4591001-1081-10811194-reissue.pdf	72	full page	Fatality	The lady to start with had heart problems, the jab just pushed it along.
6/3/2022 17:19:29	125742_S1_M5_CRF_c4591001-1015-10151238.pdf	107	full page	Data Discrepancy	The guy had Pneumonia, but they kept retaking his vitals till they got numbers they liked. He was admitted after 3 visits and 4 calls to doctors.
6/4/2022 4:19:47	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_bnt162-01-interim3-report-body.pdf	8-11	N/A - Section 16 Appendices	Data Missing	All the Appendices (Section 16) listed on pages 8-11 are missing.
6/4/2022 12:26:06	125742_S1_M5_CRF_c4591001-1007-10071443.pdf	33	1	Adverse Effects - Other	The 17 yr old female had a grand mal after getting the jab
6/4/2022 14:10:06	125742_S1_M5_CRF_c4591001-1008-10081056.pdf	40	9	Adverse Effects - Other	The 60 yr old male became SOB after shot, The clinic said it was not due to vaccine, but they could not say what caused it.
6/4/2022 14:37:15	125742_S1_M5_CRF_c4591001-1008-10081184.pdf	115- 116	document	Adverse Effects - Other	The male was found to have prostate cancer after he got his second shot. prostate cancer is one of the fastest spreading cancers and the study listed it as non serious.
6/4/2022 15:02:17	125742_S1_M5_CRF_c4591001-1008-10081337.pdf	several	several	Adverse Effects - Reproductive Issues	The 41 yr old lady became pregnant two months after shot and was on contraception. She reported being pregnant on Dec 23 2020, the study didn't record the effect till Jan. 2021 and saying the shot had nothing to do with her getting pregnant.
6/4/2022 16:39:02	file:///C:/Users/yllon/Downloads/125742_S1_M5_5351_c4591001-fa-interim-patient-batches.pdf	1-139	1-139 with specific references in the explanation	Study Protocol	This 139 pg. document lists "Study Drug Information" and a line beneath that in italics states "data is presented by site and country". Argentina (pg.1), Brazil (pg. 2-3), Germany (pg.3-5), South Africa (pg.5-7), Turkey (pg.7-10)and the United States (pg. 10-139). To the left of the country designations there are numbers which probably indicate specific sites, e.g. 1231 Argentia. The whole doc is 5 colums spreadsheet of data (investigational product description/Vendor Lot No./Pfizer Lot no./Strength-Potency/Dosage Form). The Vendor Lots are listed with different preface letter codes, BCV and ED, and EE and DK. Do the different Vendor Lot numbers and separate Pfizer Lot numbers indicate that there were multiple subcontractor manufacturers for Pfizer which actually made the products? The products are listed as BNT162b2 0.5 mg/ml 0.2 (or 0.3ml) Vial. Another product is listed on pgs. 11-13 as "Labelled Carton containin 1xLabelled Vial of BNT162b2al (or not al) 0.15mg/0.3ml in Mylar bag containing 4 kits for Protocol C4591001 (Stage 1)." This 2nd product was only listed in the United States products. A third product is listed as "Sodium Chloride Injection ISP, 0.9% vial". The bottom of each page has a date of 19 Nov 2020 (same as approved date written vertically on left side margin).

6/4/2022 18:25:11	125742_S1_M5_5351_bnt162-01-interim3-report-body.pdf	##################	Multiple Tables	Data Missing	Reference is made to a previous submission entitled: “Important safety signal missed and/or misrepresented”. In this submission, I documented a clear pattern of rising levels of C Reactive Protein (CRP) in both BNT162b1 and BNT162b2 based on dosage. I also indicated that 4 participants with elevated CRP had an elevated body temperature as measured and recorded by Pfizer on Day 2. BNT162b1 Pfizer performed an investigation on the older group for correlation between body temperature increase and CRP increase. They did not find any correlation (see page 826). However, participant 20238, 20 ug dose, had both elevated CRP and body temperature on Day 2 (see previous submission). Pfizer also performed an investigation on the younger group (which also including muscle strength abnormality and elevated lymphocytes). Again, they found no correlation. I found 3 participants with both elevated CRP and body temperature, all in the 60 ug dosage group. This entire group has been eliminated from the data (see page 815). I found additional data produced by Pfizer listing mean CRP levels and mean body temperature levels on Days 1 (injection day) and Day 2. Mean CRP level for the younger group show CRP levels increasing (in comparison to Day 1) starting at the 3 ug dose and continuing through the 60 ug dose (see page 945). The older group shows the same pattern in all three dose groups (see page 978). Pfizer did prepare Mean Body Temperature Data for the Younger group, but the 50 ug and 60 ug dose groups were both eliminated. In its place, I am sending fever and it’s severity, as reported by the participants during week 1. Again, there is a clear pattern of increasing incidence and severity of fever with increased dosage (see pages 271 and 272). Fever, as reported by the older group, also shows increasing incidence and severity as dosage increases (see page 279). BNT162b2: I could not find a similar investigation into this group performed by Pfizer. However, I did find mean CRP levels showing the same pattern as BNT162b1.
6/4/2022 21:47:04	https://docs.google.com/forms/d/e/1FAIpQLSefx2Lh1cMQHbp-rIXG_Yr5mM1c9akRdXt9nRVANoFFXle1Sw/viewform	1-112	noted in explanation section	Other	This doc. of 112 pages is titled: Listing of Subjects Withdrawn from Study; Doc created 28 Aug 2020. Gives reasons people left study (mostly after first shot but some after 2nd) Includes 5 Deaths, Adverse Effects. Approx. 500+ People left study by choice, nonresponse to calls & letters; moved away; work conflict, incarceration; pregnancy. Read as a whole, it's clear that participants became unwilling to continue, purposely avoided calls and letters, provided excuses about work, moving etc. Many comments states particpants personal desire to discontinue. 125 people left the study due to Covid + results or symptoms 5 DEATHS: after 34 days (pg. 18); after 8 days (pg. 47); after 63 days (pg. 80); after 16 days (pg. 86 and another pg. 106) Serious Adverse Effects include these and more: gastric adenocarcinoma, Dysphgia, atrial fabrication, diverticular perforation, diabetic foot, presyncope, hypertension, amnesia and paraparesis, cerebral infarction, pulmonary embolism
6/5/2022 5:39:51	https://www.google.com/url?q=https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1128-11281009-reissue.pdf&sa=D&source=editors&ust=1654427808466594&usg=AOvVaw07sr76YsKj546UEDQMVHb-	9-12, 35, 70-74	Highlighted on page	Fatality	I have highlighted pages of interest. I'm beginning to see a potential pattern between medical history and subject outcomes. This subject had a heart attack 1 month after shot 2. He also had a suspected case of Covid. Looks like he was never tested. He died "from" pneumonia after 1 month of hospitalization, 2 months after shot 2. This subject report has lots of missing information some of which was removed but can be seen in the trial audit.
6/5/2022 10:43:20	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1007-10071276.pdf	1-187, specific pg. nos. noted in explanation	1-187	Fatality	My overall impression is that this individual died and there were many entries in the database about following his history, illnesses and serious AE’s and then recording him as a removal from the study due to protocol deviation and going back into the system to minimize the seriousness of the AE’s. Concede that I do not know the Pfizer computer system utilized and may be misinterpreting some of the entries but my comprehensive impression remains the same. In the final entries there was an effort to blame his death as unrelated to the Pfizer study due to his own illnesses, which were earlier recorded as adverse actions. (Pg. 6) 29 March 21/ Date of Completion/Discontinuation /Death Aug/26/2020 on day 1 of Vax 1 ? (“Visit: V1_DAY1_VAX1_L”) (pg. 26-28) Illness onset/ COVID-19 Illness Visit: COVID A/ visit & Oct 2020/ symptoms: fever, cough, increased shortness of breath, sore throat (pg. 29) assay of this patient: SEVERE ACUTE RESP SYND ROME CORONAVIRUS 2/ (pg.37) noted as SEVERE ILLNESS/ (pg. 58), Date of Completion/Discontinuation /Death : Oct/15/2020 2. Phase of Disposition: VACCINATION/ (pg. 59) Date of Completion/Discontinuation /Death : Dec/30/2020 2. Phase of Disposition: FOLLOW-UP 3. Status: PROTOCOL DEVIATION 4. Specify Status: [Receipt of non-study COVID vaccine prior to study end Does this indicate individual who died after vaccine was removed from the study for a protocol deviation]; unclear whether this is legitimate or suggests cover-up. (pg. 62) Adverse Events [leukocytosis, thrombocytosis, chronic myelogenous leukemia – all began on Sept 24,2020 (pg. 63) leukocytosis ended Oct/19/2020 (pg.65) thrombocytosis ended Oct/26/2020 (pg. 105) Medical history of asthma from 1990 and ongoing (pg. 119) reason for visit Oct 13, 2020 note says subject e-diary replied yes to Q have you experienced Covid-10 symptoms or diagnosis but there is no Covid note in the database (pg. 124) Vax 2 given (Pg. 144-145) Emergency room visit – Urgent Care and Telephone Consult, Oct. 14, 2020 (pg. 148) diagnosis – seasonal allergies Mar 11, 2021 (pg. 151) telephone visit Sept 25, 2020 (pg. 153) Feb. 21, 2021 protocol deviation (pg. 154) Jan 30, 2021 no longer meets eligibility criteria (pg.160) records of changed data entry -leukocytosis is not serious; Oct 15, 2020; on Sept 25. 2020 the AE is serious but serious AE event number left blank (pg. 161) the serious AE is life threatening. And the event is not related to the study due to Chronic myelogenous leukemia (pg. 162) AE not related to study due to Probable lymphoproliferative disorder (pg. 164) AE Thrombocytosis on Sept 25, 2020 (pg. 165-166) thrombocytosis listed as grade 4 AE but not serious; notes about how to qualify the AE (pg. 167-168) not related to the study due to other: Probable lymphoproliferative disorder (pg. 169) downgrade thrombocytosis to non-serious Oct. 16, 2020 (pg. 172-3) AE of chronic myelogenous leukemia is serious but AE event number is blank (pg. 174) AE (of chronic myelogenous leukemia?) Not Related to study due to: Genetic change in stem cells, Oct. 15, 2020 (pg. 182) patient in unwilling to return for Vax3 or is otherwise not eligible, dated Jan 30, 2021, months after death in Aug 2020 in first entries

6/5/2022 12:52:43	125742_S1_M5_CRF_c4591001 1009 10091123.pdf CRF documents from Site 1009 (J. Lewis Research, Inc. Foothill Family Clinic South	multiple, as noted	Multiple, as noted	Study Protocol	2. There appears to be little concern about the unplanned visits. 3. Site 1009, subject 10091123, March 29, 2001 – a. Overweight, BMI 29.4, page 11 b. Multiple pre-existing conditions, (hypercholesterolemia, “abnormal cervix discharge”, partial Thyroidectomy, ascending colon polyp, etc.), pages 8-10 4. LAB URINALYSIS - PREGNANCY TEST, comment links to page 79-82. Why? The patient had a known hysterectomy, page 8 5. VACINATION: Blinded therapy, August 27, 2020 6. REACTOGENICITY DIARY – eDiary not collected. Why? What % were collected? 7. Visit 2, LAB URINALYSIS - PREGNANCY TEST, collected September 15, 2020. Why? See #7 above 8. Visit 3, October 13, 2020 9. Visit 4, March 11, 2021, “Erroneous visit”. Why did she visit? Honest mistake or was she having issues. It appears the took blood anyway, page 26 10. Visit 5 is blank 11. Visit 6 is blank 12. “POT-COVID ILL, New unscheduled without a date, “DATE OF VISIT – ILLNESS ONSET” 13. ‘HEALTH CARE UTILIZATION, ILLNESS DETAILS, ILLNESS CONVALESCENT, UPLANNED VISIT” are all blank, including the date of the visits page 35-40 14. “DISPOSITION OF TREATMENT”, status – completed, page 41, Backdated to October 13, 2020? There appears to have been four, or more patient visits after this form, and this form very clearly is located after the records indicating the other visits. 15. “ADVERSE EVENT REPORT”, “TUBULAR ADENOMA OF ASCENDING COLON, June 20, 2020 start date, ongoing December 17, 2020. This is the first form indicating an adverse reaction showing up well after multiple visits 3, 4, etc. Why? 16. The event did require hospitalization, page 46 17. Is this a result of a study medication error? “NO”, page 47 18. MEDICATION ERROR form is included, page 48, but is blank. “Concomitant Medication” was acknowledged to have been given. Page 47. 19. October 17, 2020 and January 12, 2021 Shingrix (shingles and herpes Zostra) vaccinations, page 51-52 20. Multiple blank unscheduled visits with no comments regarding transfusions, radiation, etc. I’m not sure if these are normal forms that are not applicable or actual visits where no comments are included, page 54-56 21. Page 63-64, contact outcome forms are blank. 22. INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE, page 66 is blank, but the MAIN INFORMED CONSENT is dated 8/27/2020 acknowledged by the auditor? Mikaela Jones. This appears to be an after-the-fact consent. 23. January 12, 2021, FURTHER VACCINATION CONFIRMATION (#3), “Participant is: eligible and NOT confirmed to have received only placebo at Vaccination ½ (sic)… (1 and 2). Apparently she was vaccinated even though she was in the placebo group. 24. TREATMENT UNBLINDED, reason? “ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION” 25. WITHDRAWL OF CONSENT, blank page 72
6/5/2022 12:55:39	125742_S1_M5_CRF_c4591001 1009 10091123.pdf CRF documents from Site 1009 (J. Lewis Research, Inc. Foothill Family Clinic South)	Multiple	Multiple	Other	Who do the file auditors work for? There are multiple folks who have signed-off, reviewed/audited the file, and recommended changes. Some significant regarding changed or omitted dates and further detail or clarification of an AE.
6/5/2022 14:04:30	STN-125742_S1__M5_5351_bnt162-01-interim3-report-body.pdf	page 880	Table 14.3.2.2.1.1-1 Laboratory Descriptive Statistics	Other	I don't know what this means. If you look carefully at the line for Lymphocytes/Leukocytes Median, the numbers don't quite line up.
6/5/2022 15:04:57	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1013-10131084.pdf	Multiple; please see below	Multiple; please see below	Adverse Effects - Other	Trial subject 10131084 (female in her 50s) had headache, redness, swelling, chills, diarrhea, severe vomiting, joint pain, muscle pain & fever & was hospitalized. (P126: "Subject has reported severe Vomiting".) In hospital the woman, who had previously had a renal stent fitted, was diagnosed as have an obstructed renal stent. One of the 3 causes of blocked renal stent is a blood clot. The documentation of this case is chaotic & repetitive, across numerous pages. Multiple staff report on the woman; there are instructions (eg. P151) to edit/review data: "Contact Outcome is ticked however CONTACT OUTCOME form is not entered. Please review..." P152: "Subject went to ER for vomiting and abdominal pain." This was a 2nd visit to ER, in September 2020. P156: "PER AE TERM STENT WAS LOCATED IN ARTERY." "Please confirm if this renal stent (which became 'clogged') was located in the renal artery, in the ureter, or in other location." P157: "SAE RECON 3:The event term was updated in Safety database to 'obstructed renal artery stent' as SERIOUS adverse event. However, in AE CRF seriousness was answered NO. please confirm if it should be updated to YES. Otherwise submit a follow up AEM form". P158: "AE OF OBSTRUCTION RENAL STENT IS NOT AN SAE." P165: "For AE OBSTRUCTED RENAL STENT (ARTERY): Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank". On P167: the AE/SAE is said to have been "Recovering/Resolving" on September 2nd. But on P173: the AE/SAE is said to be "NOT RECOVERED/NOT RESOLVED" on September 8th. P173: "SAE RECON:AER#2020345173 outcome was reported as Not recovered/Not resolved in SAE form however, recorded as RECOVERING/RESOLVING on AE CRF. Please confirm correct outcome." P176: "The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit."
6/5/2022 15:39:08	125742_SIMS_5351 c45591001 fa interim protocol deviation sensitive pages 1-112	112	All pages	Efficacy	Abnormal repetition in documentation indicating possible fraud
6/5/2022 16:07:28	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1009-10091128.pdf	Pp 2; 26; 29; 32	Multiple	COVID Testing	Trial subject 10091128 was diagnosed with covid. A 53-year-old Hispanic male, he joined the trial on 28th August 2020 (this is the date he signed the consent form; noted on Page 2.) It is not clear when he was vaccinated. On 16th October 2020 he tested positive for Covid. (Page 26, page 32.) He had many symptoms (Pp 157-160) and went to ER for urgent treatment. (Page 29.) He was still ill on 16th November. (Page 52.) He was recorded as having his last covid symptoms on 24th February 2021. He continued the trial, was unblinded and was vaccinated again on 10th March 2021. (Page 89.) This file does not report any further follow-up of trial subject 10091128. ~ So they injected a person, ostensibly against covid; he caught covid; they injected him again, against covid for which he now had immunity. ~
6/5/2022 18:41:54	125742_S1_M5_5351_c4591001 fa interim adverse events.pdf	Page 492	Footnote below graph	Efficacy	It appears the stop dates fell within the 7 day monitoring period following the vaccine. If the AE hadn’t resolved by the 7 days, they gave a resolve (stop date) calculating when the last vaccine was administered +7 days!! If I’m reading it correctly there was no follow up preceding these reactions and the person was on their own.

6/5/2022 19:32:38	125742_S1_M5_CRF_c4591001 1009 10091123.pdf CRF documents from Site 1009 (J. Lewis Research, Inc. Foothill Family Clinic South)	multiple	multiple	Study Protocol	protocol. 2. J. Lewis Research Inc., Family Foothills Clinic South, 6360 South 3000 East Suite 100 Salt Lake City, Utah 84121, Phone: (801) 365-1032 ext. 5802, Cell: (801) 554-0158, Location for both - ACV0PFEINFP600 3. Visit 1, vaccination #1 and written consent obtained 08/31/2020 – PLACEBO 4. Medical history – hysterectomy, mild asthma, environmental allergies, hyperthyroidism, etc., (depression, I think 10091123 suffered from depression), page 7-9 5. Obese with BMI of 41.8 and 243#s, page 10 6. Blinded therapy, page 15 7. Visit #2, vaccination #2, 09/22/2020 - PLACEBO 8. No urinalysis taken in either of the first two visits 9. Visit #3, vaccination #3, 10/21/20 – PLACEBO 10. It appears visits #4 and 5 were skipped 11. Visit UNSCHEDULED, COVID appointment 10/28/20, SHOWN AS ERRONEOUS VISIT. Page 30 12. Has pretty much all the typical symptoms, fever, chills, loss of taste, pains, difficulty breathing, etc. Page 31-34 13. No comments on health care, emergency room, primary care, urgent care, etc. utilization 14. Was a diagnosis obtained for Potential COVID 19 illness? Blank no comment. Page 41 15. For some reason the Form was upgraded on page 42 from "Illness Details" to "Illness Details – Severe" 16. However, illness details on page 43-55 are blank. As are the Laboratory Data (chemistry, hematology, etc.), vital, pulse, oxygen room air, concomitant medications – vasopressors, imaging are all blank. 17. End of treatment 10/21/2020 ONE WEEK BEFORE SHE CAME BACK FOR AN UNSCHEDULED VISIT WITH COVID 19! Page 66 18. On 9/02/20 she was diagnosed with a lump in her right breast. It was toxicity level no and deemed not serious, therefor Pfizer was not notified. Page 67 19. Deemed not related to treatments. Why was none of this reported during visits #2 and #3? Page 67 20. The cancer did not cause the subject to discontinue the study. Page 68 21. This Adverse Event was deemed "serious" Page 69 22. The AE is not due to "a study medication error" and instead, "spontaneous onset". 23. The serious AE number for Pfizer is 2020411592 24. No comments on radiation, transfusions, etc. 25. Page 83, "Lab Urinalysis – Pregnancy Test" introduced without a date. It did not appear in any of the earlier visits. 26. 02/21/2021, potential re-vax. Only placebo at 2 and 3. 27. 02/25/2021, the patient is unblinded 28. Consent is blank, page 97. 29. 10/21/20, page 100, follow-up to "assess eligibility for additional vaccinations" 30. Shane Christensen approved on 3/08/2021 all case report forms.
6/6/2022 13:36:11	125742_S1_M5_CRF_c4591001-1008-10081667.pdf	36	1	Adverse Effects - Other	The subject developed liver cancer
6/6/2022 13:44:30	125742_S1_M5_CRF_c4591001-1009-10091123.pdf	14	page	Other	The elderly lady received 5 shots
6/6/2022 13:58:55	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1009-10091128.pdf	32	1	Adverse Effects - Other	The subject tested negative to start and after 5 shots he got covid
6/6/2022 14:21:33	125742_S1_M5_CRF_c4591001-1009-10091135.pdf	67	1	Adverse Effects - Other	The subject developed breast cancer after receiving 5 shots
6/6/2022 14:40:58	125742_S1_M5_CRF_c4591001-1009-10091149.pdf	40	1	Adverse Effects - Other	Subject developed diverticulitis after 5 shots
6/6/2022 14:52:55	125742_S1_M5_CRF_c4591001-1013-10131084.pdf	43	2	Adverse Effects - Other	The lady received 5 shots and developed a UTI so bad she had to go to ER for it twice
6/6/2022 15:01:42	125742_S1_M5_CRF_c4591001-1013-10131165.pdf	47	1	Adverse Effects - Other	The subject was a 5 shooter and developed a pulmonary embolism bilateral. The tester claim it is non life threatening.
6/6/2022 15:11:48	125742_S1_M5_CRF_c4591001-1013-10131229.pdf	43	1	Adverse Effects - Reproductive Issues	Had tested negative but got pregnant
6/6/2022 21:21:25	125742_S1_M5_5351_c4591001 fa interim protocol deviations sensitive.pdf	2566	1626	Adverse Effects - Other	The volunteer numbers starting 1001-1264 continually repeat with alarming increase in the AE each time they repeat in the pages. As you get to the last set starting with 1001 -1264 if I'm reading the info accurately, it's very alarming!! I'm not certain if anyone has noted this. I haven't been able to get much feedback.. thanks
6/7/2022 11:01:33	www.phmpt.org and search for 125742_S1_M5_5351_c4591001 interim mth6 publications.pdf	71	1	Adverse Effects - mYocarditis	In page 71 adverse effect myocardial infarction. Subject No: 10811194 Nov/4/2020 UNK:UNK result in death INJECTION Sep/29/2020 13:39 page 20 Is this event related to study treatment: NOT RELATED. page 72 Did the adverse event cause the subject to be discontinued from the study? YES Data Entry: 2020447660
6/7/2022 12:07:30	All the patient that they were vaccinating	Alot	Na	Study Protocol	Why are they testing for aids in every patient that did their study after they get the vaccination but before but after the vaccination they are getting tested for aids why
6/7/2022 18:57:33	125742_S1_M5_5351_c4591001-fa-interim-discontinued-patients.pdf	122	Multiple page pdf	Fatality	Multiple adverse events including pregnant women
6/7/2022 20:26:47	125742_S1_M5_5351_c4591001 fa interim protocol deviations sensitive.pdf	2566	1626	Adverse Effects - Other	The volunteer numbers starting 1001-1264 continually repeat with alarming increase in the AE each time they repeat in the pages. As you get to the last set starting with 1001 -1264 if I'm reading the info accurately, it's very alarming!! I'm not certain if anyone has noted this. I haven't been able to get much feedback.. thanks
6/7/2022 21:33:21	16.2.1.1.1 Listing of subjects withdrawn from the study before dose 2-phase1-BNT162b1 (100mcg)	18	Page 18 middle of center column	Fatality	This death is listed with adverse events. Subject is listed, we need details, lot and batch #s, etc.
6/7/2022 21:49:57	16.2.1.1.1 Listing of Subjects Withdrawn From the Study Before Dose 2 – Phase 1 – BNT162b1 (100 µg)	21	Page 21	Other	Lost to follow up but PREGNANCY. What happened to this woman and her baby?
6/8/2022 1:42:28	125742_S1_M5_CRF_c4591001-1007-10071101.pdf	Whole document, in particular p. 46	N/A	Fatality	Woman in phase 3 trial, born 1963 (aged 56/57, i.e. not eligible), with sever obesity (BMI 46.2, gastric sleeve), supraventricular tachycardia, hypothyroidism, asthma. Died 2 months after receiving second shot (cause of death indicated as cardiac arrest, not related to injections)
6/8/2022 12:49:08	125742_S1_M5_CRF_c4591001 1008 10081152.pdf	Page 7	Line 4	Study Protocol	Protocol deviation report: Dosing error in 151 subjects
6/8/2022 13:13:19	125742_S1_M5_CRF_c4591001 1008 10081152.pdf	22	the only line on the page	Study Protocol	Protocol Deviation - temperature out of range for injection solution - 144 subjects
6/8/2022 13:19:29	125742_S1_M5_CRF_c4591001 1008 10081152.pdf	40	4th line	Other	43 subjects removed due to lack of PI oversight
6/9/2022 6:14:02	125742_S1_M5_CRF_c4591001 1007 10071101.pdf	Pages 45, 46 (document has 201 pages)	Chart	Fatality	One month post vax this patient is listed as "death" status on completion paperwork.
6/9/2022 6:39:38	125742_S1_M5_CRF_c4591001 1007 10071101.pdf	Pages 50, 51	Chart	Fatality	This is the same patient Death I submitted from this document. In continuing to read through, I noticed the cardiac arrest and subsequent death is charted as notcrelated to study! Chart states reason is the fatality is two months out from last vax.
6/9/2022 7:07:56	125742_S1_M5_CRF_c4591001-1007-10071280.pdf	57	2	Adverse Effects - Reproductive Issues	documentation of swollen cervical lymph nodes that allegedly resolved without treatment
6/9/2022 7:25:19	125742_S1_M5_CRF_c4591001-1007-10071276.pdf	62	1	Adverse Effects - Other	chronic myelogenous leukemia, attributed to "genetic change in stem cells" not the "study treatment"
6/9/2022 8:54:15	125742_S1_M5_CRF_c4591001-1012-10121163.pdf	63	1	Adverse Effects - Other	dermatitis at injection site that was ongoing after the subject withdrew consent on 9/24/20 (date of consent 9/9/20 and date of onset 9/11/20)
6/9/2022 8:56:17	125742_S1_M5_CRF_c4591001-1012-10121163.pdf	65	1	Adverse Effects - Other	SOB listed as AE and then struck through, also later listed as reason for subject to be removed from study but also documented that subjects withdrew consent to continue on 9/24/20; date of last contact listed at 10/17/20 with ongoing AE.
6/9/2022 8:58:40	125742_S1_M5_CRF_c4591001-1012-10121163.pdf	66	1	Adverse Effects - Other	Insomnia listed as AE, also listed as ongoing after subject withdrew consent. This subject's status as being given placebo/shot was not unblinded as the subject withdrew from trial or was removed d/t SOB AE.

6/9/2022 8:59:54	https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-protocol.pdf#page=77	77 and more	8.3.5.2	Other	The possibility of exposure to the vaccine through skin or inhaling
6/9/2022 9:01:21	125742_S1_M5_CRF_c4591001-1012-10121163.pdf	69	1	Adverse Effects - Other	Weight loss listed as AE; subject was 5'9" and 139 at the onset of her trial, amount of weight loss not listed.
6/9/2022 9:25:01	125742_S1_M5_CRF_c4591001-1128-11281009-reissue.pdf	67	1	Fatality	On pgs 73/74 listed AE as pneumonia and not related to study treatment, but in response to question 13 "what was the coutcome of the adverse event?" the response was "fatal". Subject first shot 8/19/20, DOD 11/28/20.
6/9/2022 9:31:01	125742_S1_M5_CRF_c4591001-1128-11281009-reissue.pdf	n/a	n/a	Other	In the grouping of paperwork for the A-C group, there are 12 subjects "profiles." I just found it interesting that 6 were in the study completed by Cincy children's: 2 were given the shots and 4 were given placebo; 2 were in the study completed by Clinical Research Consulting and both were given placebo; 3 were in the study completed by HOPE Research Institute and 2 were given placebo while the 3rd is unknown as she withdrew/was removed; and the last was from Ventavia and was unknown as he was removed d/t death that was documented as pneumonia unrelated to the shots even though the pneumonia was listed as an AE. I think it's hard to state "safe and effective" when only 2/10 from this grouping received the actual shot.
6/9/2022 9:53:48	https://docs.google.com/spreadsheets/d/1wfIfR8c6q0-_P1qMvwvWWn118zmgykyy4wyif0NDkSA/edit?usp=drivesdk 125742_S1_M5_CRF_c4591001-1128-11281009-reissue	14	Line 3	Data Discrepancy	Site No: 1128 Site Name: (1128) Ventavia Research Group Subject No: 11281009 Page 14, Line 3, Randomization Group, answer left blank. Is there no randomization group for this subject?
6/9/2022 10:54:00	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1007-10071315.pdf	1-172	noted in explanation section	Adverse Effects - Other	Subject No. 10071315 (pg. 3, 7-9) Patient was born in 1946; has hypertension since 1978; diabetes mellitus 2 since 1991; high cholesteral since 1986; gastroesophageal reflux disease since 1978; deviated septum repair 1986; ethmoid sinus surgery 1988 and 1991; lumbar discectomy 1996; herniated disc 1998 (pg. 15) vaccination "Vax1_L" given Oct. 13, 2020 (pg.20) delay of Vax 2 noted due to recent corticosteroid treatment (pg. 33-35) AE-hearing loss 1 Nov 2020-20 Jan 2021; recovered (pg. 42-43) Deleted/ Corticosteroid/ Prednisone/ dose description 60; next pg. lined-through info of Corticosteroid/ Prednisone/ 60 mg/ oral/ QD (daily)/ start date 2 Nov 2020/ end date 12 Nov 2020 (pg. 55) visit – unscheduled end of treatment; "Date of Completion/Discontinuation /Death" : Jan/14/2021 Phase of Disposition: VACCINATION (pg. 56-57) potential revax visit Dec 25, 2020; patient willing to return for vax 3, confirmed to have received only placebo at vaccination ½ (pg. 59) Unblinded Jan 14, 2021 to assesss eligibility for addtl vax (pg. 68) vax 3 given Jan 19, 2021 (pg. 71) Vax 4 given Feb 9, 2021 (pg. 129) Adverse Event entry but not specified Nov. 2, 2020; initial entry (pg. 131) notes that adverse event of hearing loss is not related to study but to recreational firearm noise; from this is it derived that "ACV0PFEINFP6000" may refer to an adverse event and other types of entries but it is not discernable what each means. (pg. 132) an unspecified AE is noted to be due to an injury
6/9/2022 11:26:56	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1007-10071280.pdf	1-212, specific pg. nos. noted in explanation	1-212	Other	subject 10071280 (pg. 3-6) born 1982 white female; screened Aug. 27, 2020' (pg. 7- 8) med history-kidney stones 2019; lithotripsy 2020, pyeloplasty Aug 2020, asthma 1997, seasonal allergy, 1990: allergy to cats, dust allergy; sleeve gastrectomy 2019, overweight 1996'; (pg. 10) pregnancy test – neg. Aug. 2020 (pg. 14) Vax 1 given Aug. 27, 2020 (pg. 20) delayed 2nd vax, given sept 23, 2020 due to fever or acute illness (pg. 23) Covid A Sept. 17, 2020 (pg. 49) Oct. 21, 2020 illness visit, Covid A1 (pg. 57) AE: bilateral deep cervical swollen lymph nodes Feb. 18, 2021 (pg. 60) bilateral lymph swelling ended Feb. 25, 2021; nonserious but it is related to the study, recovered (pg. 79) pt willing to return for vax 3; had placebo for vax ½ (pg. 90) Vax 3 given Jan. 28, 2021 (pg. 94) Vax 4 given Feb. 17, 2021 (pg. 163) pt. had new or increased sore throat sept 17, 2020
6/9/2022 12:35:44	125742_S1_M5_CRF_c4591001 1007 10071097.pdf	74	2.n	Adverse Effects - Other	Lymph nodes examined and found ABNORMAL. SUBJECT 1007 1050
6/9/2022 12:43:19	125742_S1_M5_5351_c4591001 fa interim patient batches.pdf	1-139	Sample Site = 1231, ARGENTINA, Page 1	Study Protocol	Throughout this document, dosages for site and country are given. Although some sites show that BNT162b2 0.5 mg/ml 0.2 ml Vial and Sodium Chloride Injection USP, 0.9% vial are used 50/50 at the site, the majority of sites show that the majority of dosages were for BNT162b2 0.5 mg/ml 0.2 ml Vial or similar type of dose. The skewing or making the number of Sodium Chloride Injection USP, 0.9% vial dosages less than 50%, most likely would result in the study showing a higher percentage of that Sodium Chloride Injection group getting COVID. For example, at the site, if 10 individuals receive BNT162b2 0.5 mg/ml 0.2 ml Vial and 5 receive Sodium Chloride Injection USP, 0.9% vial, and two individuals from each group get COVID, the results would show that 20% of the vaccinated got Covid while 40% of the unvaccinated did. Hence, it could be reported that at that site, by percentage, vaccinated individuals were less likely to get Covid.
6/9/2022 13:09:28	FDA-CBER-2021-5683-0010346	70, 71/364	graph	Adverse Effects - Other	Myocardial Infarction Oct 28, 2020 not related to study treatment. Tox grade 4 Numerous adverse events ongoing 194/225 as an example
6/9/2022 13:15:24	125742-S1-M5-CRF-c4591001-1128-11281009-reissue.pdf	6/364	graph	Study Protocol	2b Exclusion number: 2b Known HIV,HCV,or HBV; 2e Immunocompromised individuals; 2g Women who are pregnant or breast feeding. All these populations eventually end up being injected during and after the study.
6/9/2022 13:26:26	sion: Sponsor: Trial title: Brief title: Trial phase: Indication: Product: CLINICAL TRIAL PROTOCOL INCLUDING AMENDMENTS NOS. 01 TO 06 BNT162-01 9.0	Pg 14	Dot point 9	Study Protocol	I have uploaded screenshots of my questions regarding: *why exclusion for someone who had already been in an LNP trial Here is a link to the site: https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_bnt162-01-interim3-protocol.pdf
6/9/2022 13:34:54	sion: Sponsor: Trial title: Brief title: Trial phase: Indication: Product: CLINICAL TRIAL PROTOCOL INCLUDING AMENDMENTS NOS. 01 TO 06 BNT162-01 9.0	Pg. 12	Chart at bottom of page	Study Protocol	I noticed that the mRNA was labelled in different ways, as in subcategories. I wanted to know what these (sub?) labels of mRNA were. They are listed as different types of MRNA https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_bnt162-01-interim3-protocol.pdf
6/9/2022 13:36:04	125742 S1 M5 CRE c4591001 1007 10071097.pdf	135, 517, 609	1.2	Other	Subject 10071050 unblinded; additional vaccination requested; p517 - 523 Abnormal lymph node discussion with medical "monitor" presumably Pfizer rep; p609 unblinded, not confirmed if subject only received placebo at vax 1 and vax 2, unresolved at end of record.
6/9/2022 14:03:17	16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart	20	You will see red arrows with my screenshot	Data Discrepancy	I was utterly perplexed that a vaccine could be ready for testing by mid May 2020 I had questions as to how could the production of a 'trial' vaccine (including Lipid nanoparticles), be ready to GO WHEN the virus was first known about in mid Jan 2020. There were arguments about the origins of the virus for quite awhile and YET by May 2020, a Pfizer vaccine was ready to to be used. 😬 The timeline doesn't add up to me at all. So I went and ask Dr Yeadon and I include my message to him (via Michael P Senger's substack from I think the 6th June 2022) and Dr Yeadon's response. All screenshots

6/10/2022 11:16:19	CRF documents from Site 1007 (Cincinnati Children's Hospital Medical Center)	page 33 of 157	n/a	Adverse Effects - Other	1. ADVERSE EVENT - 1 Grand Mal Seizure Nov/29/2020 UNK:UNK NO End Date Time: Nov/29/2020 UNK:UNK (following page - page 34, Items 7 - 9: 7. Is the adverse event serious? NO 8. Is this adverse event the result of a study Medication Error? NO 9. Is this event related to study treatment: NOT RELATED 13. What was the outcome of this adverse event?: RECOVERED/RESOLVED 14. Did the adverse event cause the subject to be discontinued from the study? NO
6/10/2022 13:13:07	125742_S1_M5_5351_c4591001-fa-interim-protocol-deviations-sensitive.pdf	9, 22, 36	All rows	Study Protocol	Protocol Deviations appear to show vaccines administered carelessly. Page 9: 151 Patients were removed because subjects did not receive correct doses of vaccine. Page 22: 144 patients were administered IP that was not suitable for use by Almac. Page 36: 10 Incorrect vaccine/allocation/assigned to 10 subjects
6/10/2022 15:28:01	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1013-10131699.pdf	90	5	Adverse Effects - Other	The subject received two placebo shots, contracted COVID and then signed up to be vaccinated. Approximately 15 days after the second real injection (2/4/21), subject was hospitalized with kidney stones on 2/19/21.
6/10/2022 15:58:12	125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf	798	case #10831142	Study Protocol	The subject had to be excluded from the study after 1st shot due to an adverse event. However, he/she continued to participate in the study and received 2nd shot. The adverse event was a Worsening Panic Attack on August 31,2020. That diagnosis meets Pfizer's exclusion criteria 2a-Other medical or psychiatric condition including recent (within past year)or active suicidal ideation/behavior/lab abnormality. Unfortunately , the protocol of the case isn't available to fully assess the case.
6/10/2022 16:36:51	125742_S1_M5_5351_c4591001 fa interim adverse events.pdf	495-2321	Tables	Adverse Effects - Other	AEs determined "unrelated" to vaccine by investigators. Except for pain at site, swelling, and high temperature, the majority of other reported AEs appear to have been determined not vaccine related by the investigator. This raises a number of questions: - What % of each type of AE was determined to be vaccine related? - Does this vary by site and/or investigator? - What caused these other AEs (only a small number of other causes are documented)? - Was there a (deliberate or unconscious) bias operating causing investigators to dismiss other AEs? - How do the incidence of these "unrelated" AEs compare to the incidence in VAERS? Did investigators miss the outcomes we now see in real world reporting?
6/10/2022 17:23:30	125742_S1_M5_5351_c4591001 fa interim adverse events.pdf	553 - 2349	Tables	Adverse Effects - Reproductive Issues	Changes to menstruation noted but dismissed as unrelated. 21 out of 22 reports of changes in menstruation were classified as not related to the vaccine by the investigator. Including one case of post-menopausal bleeding that lasted 12 days.
6/10/2022 19:05:04	FDA-CBER-2021-5683-0128988 at https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_5351_c4591001-interim-mth6-randomization.pdf	Pages 1 and 2	16.1.7.2 Listing of Subjects Who Transferred to a Different Site – All Subjects ≥16 Years of Age	Data Missing	List of 44 subjects transferred to another testing site showed 33 subjects transferred at own request and 11 at training center request. Receiving testing sites noted but only 2 records note sites transferred from; otherwise no data given on (1) what sites subjects transferred from or (2) what reasons testing centers initiated transfers.
6/10/2022 23:38:59	125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf CRFs-for-site-1055	750-751,	case#10551145	Adverse Effects - Other	The severity of adverse events in the subject was downgraded. The subject was screened on August28,2020.There was no medical history(p.7, case#10551145).The woman wasn't screened properly because her BMI was 32.3 which indicated that she was obese(p.8).After the 1st shot she developed 3 adverse events :Dysphagia (August 2020),Cerebral Capillary Telangiectasia (September 26,2020),and Right Upper Extremity Pain (October 10,2020).According to the site investigator, all events weren't related to the shot and had toxicity grade 1 (p.750-751,Listing of Adverse Events-All Subjects 16.2.7.4.4). The subject didn't visit the site again and the protocol stated that she had withdrawn from the study on October 14,2020. However, on February 18,2021 the protocol had a note that "the subject is not eligible due to medical issues. Wants to be unblinded to get vaccine elsewhere."(p.70-71).She still had ongoing medical issues in February 2021 which made her ineligible for vaccination. Nevertheless, the subject wanted to get a vaccine .It is unclear from the protocol what she received in the trial. Her medical issues hadn't been updated. From all available information I can conclude that the subject had a persistent disability or incapacity for 6 months after the 1st shot. That qualified her case as severe adverse event, grade 4, according to Pfizer's protocol. There weren't any attempts from the site or Pfizer to update her diagnosis or upgrade her adverse reactions' toxicity before they had removed her from the study.
6/11/2022 13:27:23	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1005-10051054.pdf	5-99	whole pages	Data Missing	Why is data which is needed to be included in the study "Not Applicable?"
6/11/2022 13:29:36	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1005-10051054.pdf	7	whole page	Other	pre-existing conditions- high blood pressure, anxiety, depression, menopause
6/11/2022 13:30:46	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1005-10051054.pdf	8	whole page	Other	More pre-existing conditions- morphine allergy, hysterectomy, uterine fibroids
6/11/2022 13:32:59	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1005-10051054.pdf	9	line 2	Other	This subject is outside normal range for weight- 302 lbs- should she even be subjected to this gene therapy?

6/11/2022 13:34:12	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1005-10051054.pdf	14	line 8	Data Missing	actual dose is blank
6/11/2022 13:35:25	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1005-10051054.pdf	22	line 10	Data Missing	We are never told the amount of time that is "the protocol specified observation period."
6/11/2022 13:37:16	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1005-10051054.pdf	50	whole page	Data Missing	No data
6/11/2022 13:38:17	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1005-10051054.pdf	52	whole page	Data Missing	No Data
6/11/2022 13:38:54	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1005-10051054.pdf	54	whole page	Data Missing	No data
6/11/2022 13:39:40	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1005-10051054.pdf	56	whole page	Data Missing	No data
6/11/2022 13:40:20	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1005-10051054.pdf	58	whole page	Data Missing	No data
6/11/2022 13:42:14	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1005-10051054.pdf	60	line 3	Other	Covid illness
6/11/2022 13:43:32	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1005-10051054.pdf	65	whole page	Other	No follow up visit after having Covid.
6/11/2022 13:44:37	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1005-10051054.pdf	66	line 3	Data Missing	repeat swab- no data
6/11/2022 13:46:01	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1005-10051054.pdf	68	line 1	Adverse Effects - Other	intermittent non-cardiac chest pain
6/11/2022 15:23:34	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1005-10051054.pdf	85	whole page	Data Missing	No data
6/11/2022 15:25:03	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1005-10051054.pdf	89	whole page	Data Missing	No Data
6/11/2022 15:26:00	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1005-10051054.pdf	90	whole page	Data Missing	No data
6/11/2022 15:29:02	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1005-10051054.pdf	29-32	whole pages	Other	Was a mandated visit missed?
6/11/2022 15:30:08	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1005-10051054.pdf	33-174	whole pages	Data Missing	Incomplete information?
6/11/2022 15:31:36	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1005-10051054.pdf	36-67	whole pages	Other	Not done
6/11/2022 15:33:03	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1005-10051054.pdf	39-187	whole pages	Other	Nasal swab was employed, but by protocol no sample was needed?
6/11/2022 15:34:13	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1005-10051054.pdf	41-42	whole pages	Other	No respiratory treatment was given.
6/11/2022 15:35:31	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1005-10051054.pdf	43	line 3	Other	Toxicity Grade- 2, Does this refer to the vaxx's potency?
6/11/2022 15:36:35	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1005-10051054.pdf	46-47	whole pages	Data Missing	No data
6/11/2022 15:37:29	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1005-10051054.pdf	48-49	whole pages	Other	No data
6/11/2022 15:39:56	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1005-10051054.pdf	96-210	whole pages	Other	more paperwork concerning the subject's hospitalization for chest pain
6/11/2022 15:43:18	https://www.phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1005-10051054.pdf	110	next to last line	Other	Chelsey LoMonaco's signatures are invalid
6/11/2022 17:37:10	125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf CRFs-for-site-1081.pdf	793	case #10811135	Adverse Effects - Other	In the Listing of Adverse Events-All Subjects 16.2.7.4.4 several adverse events were missing because the site failed the properly screen the subject.(p.793, case #10811135).The subject was screened on August 31,2020.There was no medical history(p.7, CRF for site 1081, case # 10811135)which meant that he was healthy. However, on page 12 there is a New Onset Essential Hypertension that was diagnosed on August 31,2020 at 12:11p.m. (p.57), 4 minutes before he had received his first shot(p.12).The trial site can't diagnose anything. The protocol, phase 3 doesn't require the measurement of the blood pressure before the shot. If the site really measured the blood pressure and it was high (hypertension) at 12:11 pm why they did administer the shot at 12:15 pm? Obviously that the Hypertension diagnosis was added later, after the subject returned from the hospital. It also absent in the Listing of Adverse Events-All Subjects because it was "diagnosed" before the treatment. Another flaw was the subject's BMI which is 35 and already indicated that he was obese. The obesity diagnosis couldn't be found either in the protocol nor in the adverse events listing. In addition, two more diagnosis that are in the protocol are absent in the list of the adverse events, in spite of cut off date being November 14,2020: New Onset Unspecified Hyperlipidemia (October 29,2020) and Coronary Artery Disease (November 4,2020)(pp.66,68).

6/11/2022 18:50:24	125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf 125742_S1_M5_CRF_c4591001 1007 10071276.pdf	557	case#100071276	Adverse Effects - Other	The subject failed to disclose his full medical history in order to receive the vaccine earlier. However, Pfizer was interested in keeping him in the trial, in spite of his medical condition. The subject probably was a medical worker at the trial site, Cincinnati Children's Hospital Medical Center. When he found out that he had received the placebo, he withdrew from the study and received the vaccine on December30,2020 out of the study.(p.59, CFR case#10071276). December 30, 2020 was the date when the subject was officially unblinded and removed from the study. Before that his medical history stated that he had asthma, seasonal allergies, and a vasectomy.(p.7, CFR case #10071276). He received 2 placebo shots. Within 7 days after 2nd shot, he developed leukocytosis and thrombocytosis both of which were initially graded 4 for toxicity on September 25,2020 but then were downgraded to 3 by Pfizer on October 16,2020. The subject didn't seek medical assistance for his condition (p.33,CFR case #10071276). However, the diagnosis- Chronic Myelogenous Leukemia (CML), grade 4 toxicity , appeared on the same day as leukocytosis and thrombocytosis. The site can't diagnose or treat diseases, so the subject probably disclosed his condition and was unblinded due to the severity of his condition. However, his protocol didn't state that and the Severe Adverse Event was removed from the report to Pfizer on October 9,2020 (p.166, CFR case#10071276).On the same page the query about the severity of the event was deleted because the query could be "addressed internally". The subject started taking medication, Dasatinib, on October 6,2020 without any indication that he was examined by a specialist(pp.73-74, CFR case#10071276).Based on the above information, the subject had to be excluded from the study due to taking the immunosuppressive drug (exclusion criteria 2i). In addition, the protocol doesn't state that the condition is a newly diagnosed. Probably because it wasn't new. Eventually the site reported the SAE to Pfizer and it appeared at The Listing of Adverse Events Phase 2, 16.2.7.4.2 (p.557) as grade 4 toxicity and was included in the Pfizer's report to FDA. The subject had to be excluded from the study right after his CML diagnosis was revealed on September 24,2020. However, Pfizer was interested in keeping him in the trial and withdrew him two months later after his out of the study shot. I suggest that Pfizer was interested in making the placebo group sicker in order to soften the side effects in the treatment group. I reported before two cases-10811135, and 10031101 that exhibit the same behavior- failing the proper screening the subjects in the placebo group.
6/11/2022 20:01:45	https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	8	Figure 1and Table 2	Data Discrepancy	Electronic copy shows blacked out figure and table but print copy shows data.
6/11/2022 22:17:27	https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf	8	Figure 1	Other	Need to correct previous Finding submitted for this document and page. There are 2 black boxes on pg 8 on the electronic copy, but the 2nd black box does not correlate with Table 2 as previously stated in the original Finding. It appears the 2nd black box is either covering Figure 1's system organ classes or another item entirely. Table 2 is visible in both electronic and print copies.
6/12/2022 2:52:27	09017e196ae402e/final/final On:01Apr.2021 c4591001	6 15	2.b. 5. abcde	Study Protocol	Why they test for aids. Why have to enter nat codes to see the Aliquot. These pages have no info pages 32-35. 39-40. 42-62. 69-71 and pages 105-114 all duplicates
6/12/2022 14:59:22	125742_S1_M5_CRF_c4591001-1013-10131089.pdf	44	1	Adverse Effects - Other	30 yo female. AE LEFT ARM DEEP VEIN THROMBOSIS 12/20/2020, SAE # 2020506317. Was later unblinded and confirmed had received 2 placebos in left arm (8/6/2020, 8/27/2020). AE required hospitalization. No hospital COVID test. (p. 183, odd?). Received actual vaccinations in right arm 2/2/2021, 2/25/2021 with no follow-up.
6/12/2022 16:35:27	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1013-10131089.pdf	all of them	no paragraphs	Study Protocol	I have general observations to be made about the 11 docs assigned to Team 4. These docs were from 2 testing sites (Clinical Neuroscience Solutions Inc, Jacksonville, FL & Boston Med Center) & reported subjects' general medical history & AE's from consent to test completion. There is an amazing amount of wasted paper in each of these files; pages & pages are empty of any info. Were they blank or were they scrubbed? 10 of the 11 were definitely given the placebo & unblinded within a 4-6 month window of receiving Dose 1 of placebo. The time for which they were observed after Doses 1 & 2 is not mentioned, but all were observed for 30 min after their first & second BNT162b2. Was that a hint that there was no blinded study happening? The mgs of the placebo weren't noted, but the Pfizer doses were. ALL subjects received 30mg of the shot---from a 95 lb female to a 208 lb male & 211 lb female. NONE of the subjects were assessed after the Pfizer shot. The visit for "vax 4" (their term) was for Pfizer shot & considered to be conclusion of study, as well. According to doc headings, there were supposed to be 6 visits throughout a 24-month time. NONE of the subjects were seen more than 5 times (2 for placebo injections, 1 month post Dose 2 & then 2 more visits for Pfizer shot).
6/13/2022 14:31:25	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1007-10071443.pdf	143 of 157	n/a	Other	Grand Mal seizure said to be unrelated since participant had been given placebos for the first 2 injections. Was cleared for 3rd injection and no further notes indicating problems.
6/13/2022 14:37:43	125742_S1_M5_CRF_c4591001 1008 10081056.pdf	page 31	n/a	Other	underlying conditions - Hypertension (2013); Epilepsy (2007); Vitam B12 Deficiency (2019)
6/13/2022 14:41:28	125742_S1_M5_CRF_c4591001 1008 10081056.pdf	35	n/a	Adverse Effects - Other	1. Injection site pain (1/20/2021) and 2. Shortness of breath (Toxicity Grade 3). and 3. SAE 2021264468 (Medication Error)
6/13/2022 14:42:57	125742_S1_M5_CRF_c4591001 1008 10081056.pdf	58	n/a	Other	Confirmed for Vax 3, but rec'd placebo for V1 and V2. (Does this mean V3 is also a placebo? Doesn't say.)
6/13/2022 15:17:11	https://phmpt.org/wp-content/uploads/2022/06/STN-125742-0-0-Section-2.5-Clinical-Overview-reissue.pdf	P27.	2.5.2.2; & 2.5.3	Study Protocol	"Vaccine induced activation of antigen-presenting cells takes place at the site of injection (ie, muscle)". Not true. "Pharmacokinetic studies are not usually required for vaccines. Measurement of the plasma concentration of the vaccine over time is not feasible." The second sentence is not true.
6/13/2022 17:44:32	125742_S1_M5_CRF_c4591001 1013 10131255.pdf	40	9	Adverse Effects - Reproductive Issues	The test subject became pregnant and had a miscarriage. The adverse event of "miscarriage" was labeled unrelated to the test medication. As far as I can tell, no reason for this determination is given. I have noticed all adverse events reported with all subjects I've reviewed so far are determined to be unrelated to the vaccination. No additional reasoning is given for the determination.
6/14/2022 4:46:25	125742_S1_M5_CRF_c4591001 1128 11281009 reissue.pdf	5-7 and 66-74	All pages	Fatality	myocarditis for 24 hours then Pnemonia for a month then resultant death.

6/14/2022 12:18:09	1.125742 S1 M5 5351 bnt162-01-interim3-protocol.pdf page 53; 2.125742 S1 M5 5351 c4591001-interim-mth6-randomization-sensitive.pdf; 16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received –All Subjects >/= 16 Years of Age, pages 1-20; 3.125742 S1 M5 5351 bnt162-01-interim3-demographics.pdf, pages 1-18 and 28-47; 4.125742 S1 M5 5351 bnt162-01-interim3-report-body; Interim Clinical Study Report BNT162-01; Study Objectives and Endpoints, page 18	Document #1, page 53, paragraph 4 Document #2, pages 1-20 (Tables) Document #3, pages 1-18 and 28-47 (Tables) Document #4, page 18 (Tabular Summary)	see above in "Paragraph number(s)"	Other	in the German BioNTech162-01 Phase 1 Study and the Pfizer US (C4591001) Phase 1 Study. (125742S1M5 5351 c451991-interim-mth6-randomization-sensitive.pdf, pages 1-20 and 125742S1M5 5351bnt162-01-interim3-demographis pdf, pages 1-18 and 28-47 These were dose escalation studies evaluating safety (reactogenicity) and immune function (immunogenicity) in order to identify the preferred vaccine candidate and dose level. BNTb2 would be chosen for the large -scale Phase 2/3 trial, receive the EUA and become "the safe and effective vaccine." I created a "flow summary" coordinating all the vaccination dates of BNTb1 and BNTb2 in both age groups (Younger, Older) at all the dose levels from the two studies (BioNTech162-01 Germany and Pfizer US (C4591001). The date ranges (X/X-X/X) indicate the first and last date subjects were vaccinated with Dose 1 in each dosage group (cohort). Dose 2 would be given 21 days later. I will refer to this summary as I present my findings/concerns for the daily clout team. Germany - Younger (18-55), study later extended to Older (56-85) US -Younger (18-55, Older (65-85) BioNTech German (Ger) Trial Begins 4/23 Ger 10 ug b1 Younger Dose 1, 4/23-4/28 Ger 30 ug b1 Younger Dose 1, 4/29-5/7 Ger 1 ug b1 Younger Dose 1, 4/29-5/8 Pfizer US Trial Begins 5/4 US 10 ug b1 Younger Dose 1, 5/4-5/6 US 30 ug b1 Younger Dose 1, 5/11-5/13 Ger 50 ug b1 Younger Dose 1, 5/12-6/5 US 100 ug b1 Younger Dose 1, 5/18-5/21 Ger 60 ug b1 Younger Dose 1, 5/19-5/22 US 10 ug b2 Younger Dose 1, 6/8-6/11 (first BNTb2 cohort) US 10 ug b1 Older Dose 1, 6/9-6/11 (first Older cohort) Ger 10 ug b2 Younger Dose 1, 6/15-6/18 US 20ug b1 Older Dose 1, 6/15-5/17 US 20 ug b2 Younger Dose 1, 6/15-6/17 US 20 ug b2 Older Dose 1, 6/15-6/17 US 30 ug b1 Older Dose 1, 6/15-6/18 US 30 ug b2 Older Dose 1, 6/15-6/18 Ger 30 ug b2 Younger Dose 1, 6/22-6/25
6/14/2022 17:27:07	125742_S1_M5_5351_c4591001 fa interim discontinued patients.pdf (16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects}	18, 47, 80, 86, 87, 106, 107	Not applicable	Fatality	I reviewed the document and noted that "death" was listed as the "Withdrawal Reason" for five (5) of the participants. Two of the deaths followed Dose 1 and three deaths after Dose 2. The "Relative Day" listed for each death ranged from Day 8 to Day 63. One death listed Day 8 after Dose 1; and two of the deaths listed Day 16 - one after Dose 1 and the other after Dose 2. This information may correlate with the large number of deaths related to the Pfizer jabs documented in VAERS.
6/15/2022 14:13:45	https://phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-demographics.pdf#page=47 , https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_c4591001-A-report-cci-any-malignancy.pdf#page=10	page 47, page 10	Line 10, Line 41	Data Discrepancy	This is a huge issue as a biological Female health issue is diagnosed to a subject who is denoted as a biological Male. Ist document page 47 shows the demographics listing subject as a male, on the 2nd document the CO AE TeList, page 10 lists a Female reproductive health issue to this Male subject.
6/15/2022 17:40:08	CRF docs	all of them	all of them	Study Protocol	More general questions pertaining to the 11 test subjects I reviewed: -The Inclusion & Exclusion Criteria Met blocks are listed as NOT APPLICABLE. A doc from Germany lists inclusion & exclusion criteria. Was there no such criteria for US trials? --Sample Collected? blocks all had "Yes, however no barcodes are entered. Please review & correct as appropriate." when audited. There were no updates in any of the test subjects record. Were these unanswered on purpose (evidencing shoddy follow-up)? Or was info deleted on all these docs? --Were test subjects paid? If so, at what point did they receive compensation? Did they have to consent to vax 3 after being unblinded to receive pay or was it after they received vax 3 & 4?
6/15/2022 18:10:54	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1013-10131089.pdf	summary of 225 pages	no paragraphs	Study Protocol	This subject received the placebo in Aug 2020. There was only 1 follow-up in Sept. In Dec subject had an SAE which required hospitalization. The SAE was DVT & considered at toxicity level 3. It was so serious that her her oral contraception, Yaz, was discontinued. There was concern that no COVID tests had been done while she was in the hospital for the DVT. The investigator determined it wasn't related to study. Despite the SAE, she was unblinded & determined eligible for the BNT162b injection. Feb 2 & 25, 2021 she received vax 3 & vax 4 even though her SAE & AE were reported on Feb 11 as ongoing. No vitals are listed at either visit only that her pregnancy tests are negative. (AE & SAE mentioned but can't find what the AE is.)
6/15/2022 20:48:23	125742_S1_M5_CRF_c4591001-1013-10131176.pdf	43, 447 & 419	N/A	Other	On page 43, they note that this subject has "potential Covid-19" because he was noted to have aspiration pneumonia in the hospital - it appears from their documentation that no one ever tested this patient actually for COVID but it's just assigned as such secondary to the asiration pneumonia diagnosis. They ask throughout the documentation if he was tested and it seems from the responses that he was not. Additionally, on page 447 they document that they are downgrading all of his issues to non-serious: "CLINICAL - thank you for your reply. Please submit the CHANGE (to non-serious) for all 5 [CHF, Sepsis, Anemia, hypokalemia, acute renal failure] as a safety update, so SAE report will also have non-serious." This patient had a bowel obstruction which they note is secondary to prior medical history of the same issue w/surgical intervention in the past, which makes sense on its face, but I don't see sepsis or renal failure or CHF for that reason being considered non-serious - that does not sound right to me. The patient was noted to have been intubated and in the ICU. Lastly, in this subject's Adverse Event (AE) documentation, someone notes this: "CLINICAL - to avoid use of a surgical treatment (lysis) consider SAE event term as high grade small bowel obstruction (treated by lysis of adhesions) as reported in SAE followup." It sounds to me like they do not want to note a surgical treatment or surgical AE perhaps, so they are categorizing it differently to avoid doing so.
6/16/2022 10:50:20	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_CRF_c4591001-1006-10061176.pdf#page=14%20%20(Vax%20delayed%20from%20original%20date)	14 & 194	Section 1	Study Protocol	Subject 10061176 16yr old white, female had her 1st study injection delayed by what is stated is a "Recent Non-Study Vaccination". According to the protocol listed under (6.5 Concomitant therapy(https://phmpt.org/wp content/uploads/2022/05/125742_S1_M5_5351_bnt162-01-interim3-protocol.pdf#page=63) "Trial subjects are required to agree to not be vaccinated during the trial, starting after Visit 0 and continuously until 28 d after receiving the last immunization (see the inclusion criterion 13)." The date of when the Non-study vaccination was given is missing, therefore it can not be determined if this is a violation of the protocol's 28 day requirement.

6/16/2022 12:34:33	https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization.pdf	Pages 14-15	Please read the entire page for 14 & 15.	Study Protocol	Test subjects who received the 100ug dose apparently only received one dose, not two, unlike test subjects who received the 10ug, 20ug and 30ug doses. This appears to be intentional as the placebo group associated with 100ug subjects also only received one dose. Do we have information about outcomes for subjects who received the 100ug dose?
6/16/2022 12:56:07	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1013-10131718.pdf	summary 428 pages	none	Study Protocol	This female test subject should have been excluded from the trial because of her BMI (max is 30; hers was 31.5). Additionally she was allergic to sulfa & had anxiety disorder. According to Pfizer the vax contains nothing that present a risk to those allergic to sulfa. (Can we trust that statement?) An exclusion criteria is "...a history...of...psychological, or social conditions which, IN THE OPINION OF THE INVESTIGATOR, could compromise their wellbeing..." Were the investigators qualified to assess psychological or social conditions? She received the placebo in Oct & Nov 2020 & tested c19 positive in Nov. In spite of having c19, she was offered & received the vax in Feb. She didn't return for vax 4. What happened to her?
6/16/2022 14:02:46	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1013-10131786.pdf	summary of 629 pages	summary	Study Protocol	This female subject is older (dob 1955). She had 14 medical conditions listed. One condition should have disqualified her immediately---she was obese; her BMI was 34.1 (max was 30). These are criteria she had that should have excluded older volunteers from the study: hypertension, diabetes, & serious heart conditions (angioplasty 2018 & myocardial infraction 2019). The general exclusion criteria she had were psychological conditions (depressive disorder & anxiety) & possibly some of her allergies. This subject was unblinded Jan 18 & received Pfizer vax on Jan 25. On Jan 30 she reported potential covid illness (cough, shortness of breath, diarrhea, fatigue) toxicity 2 & syncopal episode. On Feb 8 she presented at ER with diarrhea (started Feb 2) toxicity 3. She also reported a syncopal episode (Jan 30-Feb 1) & covid pneumonia (Feb 2-26) & went to ER 2 times. Both events were considered SAEs but there was NO event number recorded. The subject was considered to have experienced 2 covid illnesses. But it's all very confusing. At 1 point the auditor is asking if the symptoms were concurrent & if not, they should be considered 2 separate illnesses. The auditor continues asking for more info & clarification but receives neither, but the 2nd illness is classified as covid illness 2. On p 607 the influenza vaccine is mentioned, but it's also the date that subject received the vax 2 placebo. She was overdue for that vax by 2 weeks. The record-keeping is so sloppy & confusing. There is NO follow-up recorded after the covid illnesses---NOT EVEN A PHONE CONSULT. The auditor asked if she was on any meds for the depression & anxiety; no answer.
6/16/2022 17:25:48	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1015-10151011.pdf	summary of 205 pages	summary	Study Protocol	This subject was male & received the placebo Aug & Sept 2020. An AE was filed: exposure during partner pregnancy. His partner's LMP was 11/25. There was a concern about the birth control method used before conception; reported that it was oral contraception AND. condoms. Subject was unblinded Jan 2021 & despite the pregnancy, received vax 3/4 in Jan & Feb. He was told to use condom barrier method during vax 3/4. WHY would he be told to use a condom AFTER conception had occurred? This stuff must be really BAD!! There was NO follow-up report after vax 4. How is the baby?
6/16/2022 17:51:10	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1015-10151047.pdf	summary of 156 pages	summary	Study Protocol	This female test subject received injections in Aug & Sept. I can't be sure what she received because when she was unblinded in Dec the note was "Participant is: eligible and NOT CONFIRMED TO HAVE RECEIVED ONLY PLACEBO AT VACCINATIONS 1/2". This subject suffered an AE (corneal irritation) after vax 1, Aug 17, which resolved on Aug 20. She suffered 2 SAEs considered toxicity 3 (SIRVA & immune-mediated bronchial plexis neuropathy) after vax 2, Sept 9. Even though the SAEs were ongoing in a Feb 2021 report they were assumed to be temporary. She didn't return for vax 3 even though she'd agreed to vax 3/4 on Dec 15, 2020.
6/16/2022 17:51:44	125742_S1_M5_5351_c45910001-fa-interim-adverse-events.pdf	888	case #11111130	Adverse Effects - Other	The subject (16-55) had the SAE after the 1st shot that qualified him/her to be excluded from the study (exclusion#10, prolong bleeding). However, the participant wasn't excluded and received the 2nd shot (p.1847, 125742_S1_M5_5351-c4591001-fa-interim-randomization-sensitive(1)). The participant received the 1st shot on August 18,2020. On August 26,2020 he/she developed "Subarachnoid hemorrhage", brain bleeding, that was assessed by the investigator as grade 2 toxicity and not related to the treatment. The subject probably was hospitalized (that's why the event was marked as SAE on page 888).The SAE was resolved on September 3,2020. On September 24,2020 the subject received the 2nd shot. The CRF for this case isn't available to fully assess the adverse event.
6/16/2022 18:04:57	125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf	898	case #11171036	Adverse Effects - Other	The subject must be excluded from the trial after the 1st shot (exclusion #1, active suicidal ideation). However, he/she was not excluded and received the 2nd shot. He/she received the placebo on August 20 and September 10,2020 (p. 1937, 125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive(1)).On August 27,2020, the subject developed "Suicidal ideation" with toxicity grade 4 that qualified his/her condition for SAE and exclusion. The SAE resolved on August 30,2020 (p.898).The CRF for this case isn't available to fully assess the adverse event.
6/16/2022 18:17:20	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1015-10151071.pdf	summary of 155 pages	summary	Study Protocol	This female test subject was not observed after vax 1 or 2; she hurried out after injection per notes. Dec she was unblinded & received vax 3. When she returned for vax 4 Jan 11, her pregnancy test was negative. Another report said that she had a positive pregnancy test Jan 7 but another report said LMP was Jan 7. She was 117 lbs & received a full 30 mg dose. The only follow-up was a phone call Feb 16. A note from the report says," ...an "Exposure During Pregnancy" is not an SAE...only abnormal outcomes or pregnancy are evaluated for serious criteria." Unfortunately there seems to be NO follow-up after the Feb phone call to see if there was an abnormal outcome.
6/16/2022 18:33:00	125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf	537	case #10051054	Adverse Effects - myocarditis	Cardiac-related adverse events are hiding under general diagnosis. The subject was hospitalized for 2 days with "intermittent non-cardiac pain" after the 2nd shot. According to the site investigator, the adverse event wasn't related to the treatment, and the cause of the pain is idiopathic. The subject had high blood pressure, severe obesity (BMI 48.8), anxiety, and depression in her medical history (p.7, 125742_S1_M5_CRF_c4591001-1005-10051054).She received the treatment on August 13 and September 4, 2020 (p.77, 125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive(1)). On September 9,2020 she developed chest pain and was hospitalized on September 16-17,2020 (p.69-70, CRF case#10051054). She wouldn't have been hospitalized if her tests were normal. The diagnosis "Idiopathic Chest Pain" after hospitalization is unacceptable. The fact the protocol didn't mention the hospital diagnosis or any tests performed in the hospital and recommended treatment, makes this case suspicious that the serious adverse event was cardiac-related. The SAE resolved on September 17,2020 (p.537). The beginning and development of the disease and close proximity to the 2nd shot, may suggest that SAE was myocarditis.
6/16/2022 19:00:46	125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf	528	case #10791004	Adverse Effects - Other	The subject (16-55) was diagnosed with invasive cancer after the 1st shot. It was assessed by the investigator as toxicity grade 3 and not related to the shot. The subject received the shot on July 29,2020 (p.1120, 125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive(1)) .He/she was diagnosed with "Infiltrate Poorly Differentiated Adenocarcinoma Stomach" on August 20,2020, 23 days later (p.528). The diagnosis on August 20,2020 contained the pathology report that took several days to finish (depend on the diagnosis from 5 to 14 days). So the disease started probably earlier than August 20,2020. The SAE wasn't resolved and outcome of the case is unknown. He/she was withdrawn from the study on August 20,2020 (p.18, 125742_S1_M5_5351_c4591001-fa-interim-discntinued-patients(1).pdf). The CRF isn't available to fully assess the event.
6/16/2022 19:17:18	125742_S1_M5_5351_c4591001-fa-interim-adverse- events- pdf	556	case #10071208	Adverse Effects - myocarditis	The subject (16-55) probably had myocarditis .He/she received the vaccine on August 17 and September 8,2020 (p.144, 125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive(1)). Within 1 day after the 2nd shot , the subject developed palpitations that were graded 1 for toxicity and assessed as not related to the treatment. On September 23,2020 the subject developed chest pains that were assessed in the same way as the palpitations. It was stated that the subject had been recovering (p.556). CRF for this case isn't available to fully assess the event.
6/16/2022 19:29:25	125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf	901	case #11221005	Adverse Effects - myocarditis	The participant developed long-lasting chest pain that could be missing myocarditis. The subject(16-55) received the 1st shot on September 3,2020(p.2013, 125742_S1_M5_5351_c4591001-fa- interim-randomization-sensitive(1)). Within 4 days he/she developed chest pain that was graded by the investigator as toxicity 1 and related to the treatment. The pain resolved on October 1,2020 (p.901). However, on September 24,2020 the subject received the 2nd shot. The CRF isn't available for this case to fully assess the adverse event.
6/16/2022 19:52:35	125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf	849	case #10951173	Adverse Effects - Other	The subject (16-55) had SAE within close proximity to the treatment but his condition was assessed by the investigator as not related to the treatment. Unfortunately, the CRF of the case isn't available to fully asses the event. The subject received the 1st shot on August 29,2020(p.1623, 125742_S1_M5_5351_c4591001-fa-inrterim-randomizatin-sensitive(1)). On September 5,2020 he/she was hospitalized with STEMI, the most severe myocardial infarction, that is result of the occlusion of the major coronary artery. However, The Listing of Adverse Events has only one diagnosis(p.849).If the subject's condition was not related to the treatment, the Listing should have additional diagnosis considering that he/she had a preexisting conditions. The SAE was resolved on September 9,2020. The participant was withdrawn from the study on September 5,2020 due to SAE (p.25, 125742_S1_M5_5351_c4591001-fa-interim-discontinued-patients(1).pdf).

6/16/2022 20:12:50	125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf	848	case #10951168	Adverse Effects - Other	The subject (16-55) had adverse event the severity of which was downgraded. She received the treatment on August 29,2020 (p.1622, 125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive(1)). On the same day she developed arthralgia that according to the investigator was related to the shot with toxicity grade 2. It was marked that the event resolved on August 31,2020 (p.848). However, the subject refused to receive the 2nd shot probably due to continuation of the adverse event. She withdrew from the trial on October 15,2020 (48 days later) by herself (p.25, 125742_S1_M5_5351_c4591001-fa-interim-discontinued-patients(1).pdf). The CRF for this case isn't available to fully asses the event.
6/16/2022 20:30:41	125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf	529	case #10951005	Adverse Effects - Other	The severity of the adverse event was downgraded and causality was not established. The subject (16-55) received the 1st treatment on July 30,2020 (p.1607, 125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive(1)). On August 6,2020 the subject developed polyarthralgia that was graded as toxicity1 "undetermined etiology", and was not related to the shot. The adverse event didn't resolve. However, the subject received the 2nd shot on August 18,2020. The CRF for the case isn't available to fully assess the event.
6/17/2022 16:29:48	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1015-10151089.pdf	summary of 145 pages	Summary	Study Protocol	This female subject should have been excluded based on her BMI of 30.8 (BMI under 30 criteria). She's had migraines & allergies but was cleared for vax 1 in Aug. & received vax 2 Sept 11. She received the flu vax in Oct. On Sept 12 she called to report 3 AEs (all toxicity 1): whole arm pain, swollen lymph node, & fever. There is no follow-up call but there are dates for these AE's being resolved after taking tylenol. On Sept 15 there is a note, " This was regarding COVID illness diary. Participant had been filling it out every day, we have since instructed HIM not to do so." Questions: This is a female subject, why does the investigator mention HIM? Why would she be instructed to stop filling out the diary? This is the only subject I reviewed who had a visit 4 at 6 mon with a date. There is no info with this visit of March 8, 2021. In Dec 15, 2020, note says, "Participant is: eligible & NOT confirmed to have received only placebo." Subject agreed to vax 3 but there are no notes about vax 3/4.
6/17/2022 16:42:05	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1015-10151101.pdf	summary of 133 pages	summary	Study Protocol	The male test subject had asthma. He was vaxxed in Aug & Sept; he left immediately after both injections. He reported an AE of gout that lasted from Oct 1-12. Dec 15 it's noted, "Participant is: eligible & NOT confirmed to have received only placebo." No vax 3/4 noted.
6/17/2022 17:22:10	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1015-10151134.pdf	Summary of 207 pages	summary	Study Protocol	This male test subject is considered to be older. He should have been excluded from the trials due to his asthma. He also reported acid reflux & vertigo. There was a report of appendicitis Aug 17. No mention of appendectomy, but if he did he should have been excluded because any surgery requiring general anesthesia in the past 5 years was an excluding criteria. After vax 1 he reported 4 AEs: worsening vertigo, headache, nausea & diarrhea. Due to his worsening vertigo, the PI decided the 2nd dose should be skipped for safety. He received the flu vax Sep 28. Dec 21 he was received vax 3 & suffered a site pain AE. Following vax 4 Jan 13 he experienced 3 AEs: chills, site pain, & headache. There was a telephone consult Feb 10, 2021 & no other follow-up was noted.
6/17/2022 17:32:09	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1015-10151225.pdf	summary of 206 pages	summary	Study Protocol	The female test subject should have been excluded due to her low weight (95 lbs vs required 110 lbs). She also suffered anxiety. She was injected Sept 15 & Oct 8. An AE of dizziness is listed for Oct 8. She received the flu vax Oct 23. Subject was unblinded & received vax 3 Dec 22---30mg same amount as a 200 lb person. Following that vax she experienced 4 AEs (site pain, general muscle aches, swollen neck lymph on both sides, & fever) with no toxicity listed. In spite of AEs, she received vax 4 Jan 14 & immediately experienced 5 AEs which lasted 2 days: fatigue, headache, myalgia, chills & fever. No toxicity specified. There was a telephone consult on Feb 17 & no further check ups.
6/17/2022 18:47:47	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1015-10151238.pdf	summary of 435 pages	summary	Study Protocol	This Spanish-speaking older male subject should have been excluded due to BMI (34.6) in excess of 30, as well as, diabetes, alcoholic cirrhosis, asthma, congestive heart failure, hypertension, & known psychological/social conditions (anxiety disorder & depression). He was HIV positive & had 6 other medical conditions. He received vax1/2 Oct 2 & 27. Vax 2 was delayed because they needed to get a Spanish consent. This subject had 3 ER visits: Jan 20 he experienced fatigue, shortness of breath, chills, & chest tightness. He was admitted to the hospital & discharged Jan 23 after receiving high oxygen treatments. Jan 27 pneumonia Feb 3 peripheral edema His PCR test was neg for COVID even though the report originally said it was a COVID illness. Because of the negative PCR none of the symptoms were considered trial related. He refused to be swabbed by a visiting nurse Feb 11. This subject was not unblinded like all the other subjects I reviewed. Did he receive the placebo at vax 1/2 or the Pfizer vax? "Conversation" between reporter(R) & auditor(A): R: "I'm confused & do not understand what you are asking for in these queries. Would you be able to rephrase it? Or potentially give an example so I can give a better answer. Thank you!" A: "My calculations are: Result=0.666...." R: "Ohh so it just needed the 0 in front of it, that why the.666 I put got queried before. Thanks so much for your help!!!"
6/18/2022 22:09:43	125742_S1_M5_CRF_c4591001-1013-10131190.pdf	326	N/A	Other	This participant is noted to have a "potential covid 19 illness" secondary to c-diff infection. It does not appear that any test was ever done to confirm diagnosis.
6/18/2022 23:42:24	https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=660 & https://phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf#page=100, https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=684	First doc. pg 660 & second doc. pg 100 & third doc. pg 684 doc. pg	Subject # 10051295	Data Discrepancy	This 16-year-old subject was excluded as stated on form: "Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1" "Dose 2 all available efficacy Did not complete 2 vaccination doses. Evaluable efficacy (7 Days) Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1)" However, both the form dated Nov. 2020 "16.1.7.4 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects Vaccine Received ", and form dated April 2021 "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age", both clearly state the subject did in fact receive the study doses 1 & 2. I have found many like this and I will be filing additional reports for each subject. The incorrect exclusion of these subjects could have skewed the data and hide the real harm from these mRNA gene therapy treatments.

6/19/2022 11:38:04	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=688, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=340,	First doc. page 688, second doc. page 340	Subject #10051394	Data Discrepancy	This 17-year-old subject was excluded as stated on form: "Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1" "Dose 2 all available efficacy Did not complete 2 vaccination doses. Evaluable efficacy (7 Days) Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1)" However, both the form dated Nov. 2020: "16.1.7.4 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects Vaccine Received ", and form dated April 2021 "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age", both clearly state the subject did in fact receive the study doses 1 & 2. I have found many like this and I will be filing additional reports for each subject. The incorrect exclusion of these subjects could have skewed the data and hide the real harm from these mRNA gene therapy treatments.
6/19/2022 11:42:38	21 : https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=689, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=666, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=340	First doc. page 689, second doc. page 666, third doc. page 340	Subject # 1051398	Data Discrepancy	This 16-year-old subject was excluded as stated on form: "Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1" "Dose 2 all available efficacy Did not complete 2 vaccination doses. Evaluable efficacy (7 Days) Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1)" However, both the form dated Nov. 2020: "16.1.7.4 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects Vaccine Received ", and form dated April 2021 "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age", both clearly state the subject did in fact receive the study doses 1 & 2. I have found many like this and I will be filing additional reports for each subject. The incorrect exclusion of these subjects could have skewed the data and hide the real harm from these mRNA gene therapy treatments.
6/19/2022 12:05:01	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=689, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=666, https://phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf#page=110, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=3, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_c4591001-A-c4591001-subject-list-for-12-25-immuno-analysis-27jan2021.pdf#page=1	First doc. page 689, second doc. page 666, third doc page 110, fourth doc. page 3, fifth doc. page 1	10051400	Data Discrepancy	This 17-year-old subject was excluded as stated on form: "Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1" "Dose 2 all available efficacy Did not complete 2 vaccination doses. Evaluable efficacy (7 Days) Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1)" However, both the form dated Nov. 2020: "16.1.7.4 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects Vaccine Received ", and form dated April 2021 "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age", both clearly state the subject did in fact receive the study doses 1 & 2. I have found many like this and I will be filing additional reports for each subject. The incorrect exclusion of these subjects could have skewed the data and hide the real harm from these mRNA gene therapy treatments.
6/19/2022 12:34:55	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=689, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=3, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=666	First doc. pg 689, second doc pg 3, third doc pg 666	Subject 10051408	Data Discrepancy	This 16-year-old subject was excluded as stated on form: "Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1" "Dose 2 all available efficacy Did not complete 2 vaccination doses. Evaluable efficacy (7 Days) Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1)" However, either or both forms dated Nov. 2020: "16.1.7.4 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects Vaccine Received ", and form dated April 2021 "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age", both clearly state the subject did in fact receive the study doses 1 & 2. Also, the Nov 2020 Exclusion form lists this subject but is missing from on the Dec 2020 Exclusion form. I have found many like this and I will be filing additional reports for each subject. I have also been documenting all the information on a spreadsheet which when I am finished, I will be sharing with Dr. Flowers. The incorrect exclusion of these subjects could have skewed the data and hide the real harm from these mRNA gene therapy treatments.
6/19/2022 13:01:49	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=688, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=1, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=664	First doc. pg 688, second doc. pg 1, third doc pg 664	10051371	Data Discrepancy	This 17-year-old subject was excluded as stated on 24 Nov 2020 & 02-Dec-2020 forms: ("Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1"), "Dose 2 all available efficacy Did not complete 2 vaccination doses. Evaluable efficacy (7 Days) Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1)" However the subject did indeed receive the 2nd dose on 16-Nov-20, documented on form dated 01- April 2021 "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age", which clearly states the subject did in fact receive the study doses 1 & 2. I have found many like this and I will be filing additional reports for each subject. I have also been documenting all the information on a spreadsheet which when I am finished, I will be sharing with Dr. Flowers. The incorrect exclusion of these subjects could have skewed the data and hide the real harm from these mRNA gene therapy treatments.

6/19/2022 13:21:19	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=699, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=3, https://phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf#page=127	First doc pg 699, second doc pg 3, third doc pg 127	Subject # 10061180	Data Discrepancy	This 17-year-old subject was excluded as stated on 24 Nov 2020: ("Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1"), "Dose 2 all available efficacy Did not complete 2 vaccination doses. Evaluable efficacy (7 Days) Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1)" However the subject did indeed receive the 2nd dose on 25-Nov-20, documented on form dated 01- April 2021 "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age", which clearly states the subject did in fact receive the study doses 1 & 2. This subject is not found on the 02-Dec exclusion form, so it is not known if this subject was excluded or not from the study.
6/19/2022 15:42:11	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=707, https://phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf#page=157, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=667	First doc pg 707, second doc pg 157, third doc pg 667 pg	Subject# 10071341	Data Discrepancy	This 16-year-old subject was excluded as stated on 02 Dec 2020: ("Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1"), "Dose 2 all available efficacy Did not complete 2 vaccination doses. Evaluable efficacy (7 Days) Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1)" However the subject did indeed receive the 2nd dose on 04-Nov-20, documented on form dated 01- April 2021 "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age", which clearly states the subject did in fact receive the study doses 1 & 2.
6/19/2022 15:55:08	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=707, https://phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf#page=158, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=668	First doc pg 707, second doc pg 158 , third doc pg 668	Subject #10071353	Data Discrepancy	This 16-year-old subject was excluded as stated on 02 Dec 2020: ("Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1"), "Dose 2 all available efficacy Did not complete 2 vaccination doses. Evaluable efficacy (7 Days) Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1)" However the subject did indeed receive the 2nd dose on 05-Nov-20, documented on form dated 24-Nov-2020 & again on 01- April 2021 form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age", which clearly states the subject did in fact receive the study doses 1 & 2. So were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad?
6/19/2022 16:14:32	https://phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf#page=161, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=670, https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=709	subject # 10071385	First doc pg 161, second doc pg 670 , third doc pg 709,	Data Discrepancy	This 16-year-old subject was excluded as stated on 02 Dec 2020: ("Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1"), "Dose 2 all available efficacy Did not complete 2 vaccination doses. Evaluable efficacy (7 Days) Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1)" However, the subject did indeed receive the 2nd dose on 10-Nov-20, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated 24-Nov-2020 & again on the 01- April 2021 form, both clearly state the subject did in fact receive the study doses 1 & 2. So, were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad?
6/19/2022 16:37:04	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/060122/125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf#page=2280, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=671, https://phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf#page=163	First doc pg 2280, second doc pg 671 , third doc pg 163, fourth doc pg 710	Subject #10071400	Data Discrepancy	This 17-year-old subject was excluded as stated on 02 Dec 2020: ("Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1"), "Dose 2 all available efficacy Did not complete 2 vaccination doses. Evaluable efficacy (7 Days) Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1)" However, the subject did indeed receive the 2nd dose on 11-Nov-20, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated 24-Nov-2020 & again on the 01- April 2021 form, both clearly state the subject did in fact receive the study doses 1 & 2. So, were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad?
6/19/2022 16:45:47	https://phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf#page=163, https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=710, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=672	Subject#10071403	First doc pg 163, second doc pg 710 , third doc pg 672	Data Discrepancy	This 16-year-old subject was excluded as stated on 02 Dec 2020: ("Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1"), "Dose 2 all available efficacy Did not complete 2 vaccination doses. Evaluable efficacy (7 Days) Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1)" However, the subject did indeed receive the 2nd dose on 11-Nov-20, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated 24-Nov-2020 & again on the 01- April 2021 form, both clearly state the subject did in fact receive the study doses 1 & 2. So, were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad?

6/19/2022 16:51:50	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/060122/125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf#page=2280, https://phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf#page=163, https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=710, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=672	First doc pg 2280, second doc pg 163 , third doc pg 710, fourth doc pg 672	Subject #10071404	Data Discrepancy	
6/19/2022 16:57:25	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/060122/125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf#page=2280, https://phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf#page=163, https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=710, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=672	First doc pg 2280, second doc pg 163 , third doc pg 710, fourth doc pg 672	Subject #10071404	Data Discrepancy	My apologies, I forgot the explanation on this same subject # previously reported ! This 16-year-old subject was excluded as stated on 02 Dec 2020: ("Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1"), "Dose 2 all available efficacy Did not complete 2 vaccination doses. Evaluable efficacy (7 Days) Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1)" However, the subject did indeed receive the 2nd dose on 11-Nov-20, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated 24-Nov-2020 & again on the 01- April 2021 form, both clearly state the subject did in fact receive the study doses 1 & 2. So, were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad?
6/19/2022 18:03:36	https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-lab-measurements-sensitive.pdf#page=2, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-lab-measurements-sensitive.pdf#page=139, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-lab-measurements.pdf#page=1, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=1, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=645	First doc pg 2, second doc pg 139, third doc pg 1, fourth doc pg 1, fifth doc pg 645	Subject# 10071409	Study Protocol	This 13-year-old is on the exclusion form list of 24-Nov 2020 & 02-Dec-2020 because he did not receive the second dose and it seems the reason is due to adverse events from the first dose. It would seem subjects that experience adverse events and/or “test positive” for Sars Cov-2 after getting the shot and are then excluded would skew the results. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.
6/19/2022 21:51:58	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/060122/125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf#page=2281, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=674, https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=712, https://phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf#page=164	First doc pg 2281, second doc pg 674, third doc pg 712, fourth doc pg 164	Subject # 10071423	Data Discrepancy	Excluded: Claimed to not get 2 doses or within the prescribed time. But data shows subject did get 2 within time-frame. This 16-year-old subject was excluded as stated on 02 Dec 2020 because he did not receive the second dose and it seems it is due to adverse events from the first dose. However, the subject did indeed receive the 2nd dose on 12-Nov-20, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated 24-Nov-2020 & again on the 01- April 2021 form, both clearly state the subject did in fact receive the study doses 1 & 2. It would seem subjects that experience adverse events and then are excluded would skew the results.It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.
6/19/2022 22:10:14	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/060122/125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf#page=2282, https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=712, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=674,https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=342	First doc pg 2282, second doc pg 712, third doc pg 674, fourth doc pg 342	Subject # 10071433	Data Discrepancy	Excluded: Claimed to not get 2 doses or with the prescribed time. But data shows subject did get 2 within time-frame. This 17-year-old is on the exclusion form list of 24-Nov 2020 & 02-Dec-2020 stating he did not receive the second dose and it seems it's because he due to adverse events from the first dose. However, the subject did indeed receive the 2nd dose on 17-Nov-20, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated 01- April 2021 form, clearly states the subject did in fact receive the study doses 1 & 2. So, were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or “test positive” for Sars Cov-2 after getting the shot and then are excluded would skew the results. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.
6/19/2022 22:23:42	https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=4, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=675, https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=712, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_c4591001-A-c4591001-subject-list-for-12-25-immuno-analysis-27jan2021.pdf#page=1	First doc pg 4, second doc pg 675, third doc pg 712, fourth doc pg 1,	Subject # 10071434	Data Discrepancy	Excluded: Claimed to not get 2 doses or with the prescribed time. But data shows subject did get 2 within time-frame. This 16-year-old is on the exclusion form list of 24-Nov 2020 & 02-Dec-2020 stating he did not receive the second dose and it seems it's because he due to adverse events from the first dose. However, the subject did indeed receive the 2nd dose on 17-Nov-20, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated 01- April 2021 form, clearly states the subject did in fact receive the study doses 1 & 2. So, were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or “test positive” for Sars Cov-2 after getting the shot and then are excluded would skew the results. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.

6/19/2022 22:33:56	https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=342, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=675, https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=712	First doc pg 342, second doc pg 675 , third doc pg 712 ,	Subject # 10071435	Data Discrepancy	Excluded: Claimed did not get 2 doses or with the prescribed time. But data shows subject did get 2 within time-frame. This 16-year-old is on the exclusion form list of 24-Nov 2020 & 02-Dec-2020 stating he did not receive the second dose and it seems it's because he due to adverse events from the first dose. However, the subject did indeed receive the 2nd dose on 18-Nov-20, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated 01- April 2021 form, clearly states the subject did in fact receive the study doses 1 & 2. So, were subjects wrongly excluded from the study due to adverse events which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or "test positive" for Sars Cov-2 after getting the shot and then are excluded would skew the results. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.
6/19/2022 22:40:37	https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=342, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=675, https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=712	First doc pg 342, second doc pg 675, third doc pg 712,	Subject # 10071436	Data Discrepancy	Excluded: Claimed did not get 2 doses or with the prescribed time. But data shows subject did get 2 within time frame. This 17-year-old is on the exclusion form list of 24-Nov 2020 & 02-Dec-2020 stating she did not receive the second dose and it seems it's because he due to adverse events from the first dose. However, the subject did indeed receive the 2nd dose on 18-Nov-20, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated 24-Nov-2020 & again on the 01- April 2021 form, both clearly state the subject did in fact receive the study doses 1 & 2. So, were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or "test positive" for Sars Cov-2 after getting the shot and then are excluded would skew the results. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.
6/19/2022 22:54:24	https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=4, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=675, https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=713, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_c4591001-A-c4591001-subject-list-for-12-25-immuno-analysis-27jan2021.pdf#page=1	First doc pg 4 , second doc pg 675 , third doc pg 713 , fourth doc pg 1,	Subject # 10071439	Data Discrepancy	Excluded: Claimed did not get 2 doses or with the prescribed time. But data shows subject did get 2 within time frame. This 17-year-old is on the exclusion form list of 24-Nov 2020 & 02-Dec-2020 stating she did not receive the second dose. However, the subject did indeed receive the 2nd dose on 19-Nov-20, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated 24-Nov-2020 & again on the 01- April 2021 form, both clearly state the subject did in fact receive the study doses 1 & 2. So, were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or "test positive" for Sars Cov-2 after getting the shot(s) are then excluded. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.
6/19/2022 23:02:16	https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=343, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=675, https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=713	First doc pg 343, second doc pg 675, third doc pg 713	Subject # 10071442	Data Discrepancy	Excluded: Claimed did not get 2 doses or within the prescribed time. However, the data shows subject did get 2 within time frame. This 16-year-old is on the exclusion form list of 24-Nov 2020 & 02-Dec-2020 stating she did not receive the second dose. The subject did indeed receive the 2nd dose on 23-Nov-20, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated 24-Nov-2020 & again on the 01- April 2021 form, both clearly state the subject did in fact receive the study doses 1 & 2. So, were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or "test positive" for Sars Cov-2 after getting the shot(s) are then excluded. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.
6/19/2022 23:15:11	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=713, https://phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1007-10071443.pdf#page=117, https://phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1007-10071443.pdf#page=127, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=343, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=676	First doc pg 713 , second doc pg 117, third doc pg 127, fourth doc pg 343, fifth doc pg 676	Subject # 10071443	Data Discrepancy	Excluded: Claimed did not get 2 doses or within the prescribed time. But data shows subject did get 2 within time frame. This 17-year-old is on the exclusion form list of 24-Nov 2020 & 02-Dec-2020 stating she did not receive the second dose. However, the subject did indeed receive the 2nd dose on 25-Nov-20, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated 24-Nov-2020 & again on the 01- April 2021 form, both clearly state the subject did in fact receive the study doses 1 & 2. So, were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or "test positive" for Sars Cov-2 after getting the shot(s) are then excluded. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.
6/19/2022 23:38:33	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=713, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=5, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_c4591001-A-c4591001-subject-list-for-12-25-immuno-analysis-27jan2021.pdf#page=1	First doc pg 713 , second doc pg 5 , third doc pg 1	Subject # 10071447	Data Discrepancy	Excluded: Claimed did not get 2 doses or within the prescribed time. But data shows subject did get 2 within time frame. This 16-year-old is on the exclusion form list of 24-Nov 2020 stating he did not receive the second dose. However, the subject did indeed receive the 2nd dose on 2-Dec-2020, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated 24-Nov-2020 & again on the 01- April 2021 form, both clearly state the subject did in fact receive the study doses 1 & 2. So, were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or "test positive" for Sars Cov-2 after getting the shot(s) are then excluded. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.
6/20/2022 11:11:04	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=714, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=343	first doc pg 714, second doc pg 343	Subject # 10071448	Data Discrepancy	Excluded: Claimed did not get 2 doses or within the prescribed time. But data shows subject did get 2 within time frame. This 16-year-old is on the exclusion form list of 24-Nov 2020 stating he did not receive the second dose. However, the subject did indeed receive the 2nd dose on 2-Dec-2020, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated 24-Nov-2020 & again on the 01- April 2021 form, both clearly state the subject did in fact receive the study doses 1 & 2. So, were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or "test positive" for Sars Cov-2 after getting the shot(s) are then excluded. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.

6/20/2022 11:17:18	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=714, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=344	First doc pg 714, second doc pg 344	Subject # 10071449	Data Discrepancy	Excluded: Claimed did not get 2 doses or within the prescribed time. But data shows subject did get 2 within time frame. This 17-year-old is on the exclusion form list of 24-Nov 2020 stating she did not receive the second dose. However, the subject did indeed receive the 2nd dose on 2-Dec-2020, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated 24-Nov-2020 & again on the 01- April 2021 form, both clearly state the subject did in fact receive the study doses 1 & 2. So, were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or "test positive" for Sars Cov-2 after getting the shot(s) are then excluded. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.
6/20/2022 11:25:17	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=714, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=5	First doc pg 714, second doc pg 5	Subject # 10071450	Data Discrepancy	Excluded: Claimed did not get 2 doses or within the prescribed time. But data shows subject did get 2 within time frame. This 16-year-old is on the exclusion form list of 24-Nov 2020 stating the subject did not receive the second dose. However, the subject did indeed receive the 2nd dose on 2-Dec-2020, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated 24-Nov-2020 & again on the 01- April 2021 form, both clearly state the subject did in fact receive the study doses 1 & 2. So, were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or "test positive" for Sars Cov-2 after getting the shot(s) are then excluded. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.
6/20/2022 11:30:49	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=714, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=5	First doc pg 714, second doc pg 5	Subject # 10071451	Data Discrepancy	Excluded: Claimed did not get 2 doses or within the prescribed time. But data shows subject did get 2 within time frame. This 17-year-old is on the exclusion form list of 24-Nov 2020 stating the subject did not receive the second dose. However, the subject did indeed receive the 2nd dose on 3-Dec-2020, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated 24-Nov-2020 & again on the 01- April 2021 form, both clearly state the subject did in fact receive the study doses 1 & 2. So, were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or "test positive" for Sars Cov-2 after getting the shot(s) are then excluded. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.
6/20/2022 11:35:10	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=714, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=5	First doc pg 714, second doc pg 5	Subject # 10071452	Data Discrepancy	Excluded: Claimed did not get 2 doses or within the prescribed time. But data shows subject did get 2 within time frame. This 16-year-old is on the exclusion form list of 24-Nov 2020 stating the subject did not receive the second dose. However, the subject did indeed receive the 2nd dose on 3-Dec-2020, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated 24-Nov-2020 & again on the 01- April 2021 form, both clearly state the subject did in fact receive the study doses 1 & 2. So, were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or "test positive" for Sars Cov-2 after getting the shot(s) are then excluded. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.
6/20/2022 11:37:51	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=714, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=5	First doc pg 714, second doc pg 5	Subject # 10071454	Data Discrepancy	Excluded: Claimed did not get 2 doses or within the prescribed time. But data shows subject did get 2 within time frame. This 17-year-old is on the exclusion form list of 24-Nov 2020 stating the subject did not receive the second dose. However, the subject did indeed receive the 2nd dose on 3-Dec-2020, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated 24-Nov-2020 & again on the 01- April 2021 form, both clearly state the subject did in fact receive the study doses 1 & 2. So, were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or "test positive" for Sars Cov-2 after getting the shot(s) are then excluded. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.
6/20/2022 11:41:27	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=714, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=344	First doc pg 714, second doc pg 344	Subject # 10071455	Data Discrepancy	Excluded: Claimed did not get 2 doses or within the prescribed time. But data shows subject did get 2 within time frame. This 17-year-old is on the exclusion form list of 24-Nov 2020 stating the subject did not receive the second dose. However, the subject did indeed receive the 2nd dose on 9-Dec-2020, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated 24-Nov-2020 & again on the 01- April 2021 form, both clearly state the subject did in fact receive the study doses 1 & 2. So, were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or "test positive" for Sars Cov-2 after getting the shot(s) are then excluded. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.
6/20/2022 12:11:32	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=745, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=676	First doc pg 745, second doc pg 676	Subject # 10081598	Data Discrepancy	Excluded: Claimed did not get 2 doses or within the prescribed time. But data shows subject did get 2 within time frame. This 17-year-old is on the exclusion form list of 02-Dec 2020 stating the subject did not receive the second dose. However, the subject did indeed receive the 2nd dose on 4-Nov-2020, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated 24-Nov-2020 & again on the 01- April 2021 form, both clearly state the subject did in fact receive the study doses 1 & 2. So, were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or "test positive" for Sars Cov-2 after getting the shot(s) are then excluded. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.
6/20/2022 12:15:57	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=746, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=676	First doc pg 746, second doc pg 676	Subject # 10081611	Data Discrepancy	Excluded: Claimed did not get 2 doses or within the prescribed time. But data shows subject did get 2 within time frame. This 17-year-old is on the exclusion form list of 02-Dec 2020 stating the subject did not receive the second dose. However, the subject did indeed receive the 2nd dose on 4-Nov-2020, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated 24-Nov-2020 & again on the 01- April 2021 form, both clearly state the subject did in fact receive the study doses 1 & 2. So, were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or "test positive" for Sars Cov-2 after getting the shot(s) are then excluded. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.
6/20/2022 12:51:10	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=747, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=678	First doc pg 747, second doc pg 678	Subject # 10081630	Data Discrepancy	Excluded: Claimed did not get 2 doses or within the prescribed time. But data shows subject did get 2 within time frame. This 17-year-old is on the exclusion form list of 02-Dec 2020 stating the subject did not receive the second dose. However, the subject did indeed receive the 2nd dose on 6-Nov-2020, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated 24-Nov-2020 & again on the 01- April 2021 form, both clearly state the subject did in fact receive the study doses 1 & 2. So, were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or "test positive" for Sars Cov-2 after getting the shot(s) are then excluded. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.

6/20/2022 12:54:40	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=747, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=678	First doc pg 747, second doc pg 678	Subject #10081632	Data Discrepancy	Excluded: Claimed did not get 2 doses or within the prescribed time. But data shows subject did get 2 within time frame. This 17-year-old is on the exclusion form list of 02-Dec 2020 stating the subject did not receive the second dose. However, the subject did indeed receive the 2nd dose on 9-Nov-2020, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated 24-Nov-2020 & again on the 01- April 2021 form, both clearly state the subject did in fact receive the study doses 1 & 2. So, were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or "test positive" for Sars Cov-2 after getting the shot(s) are then excluded. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.
6/20/2022 13:02:22	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=747, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=678	First doc pg 747, second doc pg 678	Subject # 10081633	Data Discrepancy	Excluded: Claimed did not get 2 doses or within the prescribed time. But data shows subject did get 2 within time frame. This 17-year-old is on the exclusion form list of 02-Dec 2020 stating the subject did not receive the second dose. However, the subject did indeed receive the 2nd dose on 9-Nov-2020, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated 24-Nov-2020 & again on the 01- April 2021 form, both clearly state the subject did in fact receive the study doses 1 & 2. So, were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or "test positive" for Sars Cov-2 after getting the shot(s) are then excluded. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.
6/20/2022 13:06:21	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=748, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=679	First doc pg 748, second doc pg 679	Subject # 10081659	Data Discrepancy	Excluded: Claimed did not get 2 doses or within the prescribed time. But data shows subject did get 2 within time frame. This 17-year-old is on the exclusion form list of 02-Dec 2020 stating the subject did not receive the second dose. However, the subject did indeed receive the 2nd dose on 11-Nov-2020, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated 24-Nov-2020 & again on the 01- April 2021 form, both clearly state the subject did in fact receive the study doses 1 & 2. So, were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or "test positive" for Sars Cov-2 after getting the shot(s) are then excluded. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs
6/20/2022 13:10:09	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=750, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=681	First doc pg 750, second doc pg 681	Subject # 10081678	Data Discrepancy	Excluded: Claimed did not get 2 doses or within the prescribed time. But data shows subject did get 2 within time frame. This 17-year-old is on the exclusion form list of 02-Dec 2020 stating the subject did not receive the second dose. However, the subject did indeed receive the 2nd dose on 13-Nov-2020, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated 24-Nov-2020 & again on the 01- April 2021 form, both clearly state the subject did in fact receive the study doses 1 & 2. So, were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or "test positive" for Sars Cov-2 after getting the shot(s) are then excluded. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.
6/20/2022 13:18:47	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=753, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=9, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=685	First doc pg 753, second doc pg 9, third doc pg 685	Subject # 10081741	Data Discrepancy	Excluded: Claimed did not get 2 doses or within the prescribed time. But data shows subject did get 2 within time frame. This 16-year-old is on the exclusion form list of 24-Nov-20 & 02-Dec 2020 stating the subject did not receive the second dose. However, the subject did indeed receive the 2nd dose on 25-Nov-2020, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated 24-Nov-2020 & again on the 01- April 2021 form, both clearly state the subject did in fact receive the study doses 1 & 2. So, were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or "test positive" for Sars Cov-2 after getting the shot(s) are then excluded. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.
6/20/2022 13:25:32	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=753, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=347, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=686	First doc pg 753, second doc pg 347, third doc pg 686	Subject #10081742	Data Discrepancy	Excluded: Claimed did not get 2 doses or within the prescribed time. But data shows subject did get 2 within time frame. This 17-year-old is on the exclusion form list of 24-Nov-20 & 02-Dec 2020 stating the subject did not receive the second dose. However, the subject did indeed receive the 2nd dose on 25-Nov-2020, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated 24-Nov-2020 & again on the 01- April 2021 form, both clearly state the subject did in fact receive the study doses 1 & 2. So, were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or "test positive" for Sars Cov-2 after getting the shot(s) are then excluded. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.
6/20/2022 13:31:50	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=753, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=9, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=686	First doc pg 753, second doc pg 9, third doc pg 686	Subject # 10081743	Data Discrepancy	Excluded: Claimed did not get 2 doses or within the prescribed time. But data shows subject did get 2 within time frame. This 16-year-old is on the exclusion form list of 24-Nov-20 & 02-Dec 2020 stating the subject did not receive the second dose. However, the subject did indeed receive the 2nd dose on 24-Nov-2020, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated 24-Nov-2020 & again on the 01- April 2021 form, both clearly state the subject did in fact receive the study doses 1 & 2. So, were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or "test positive" for Sars Cov-2 after getting the shot(s) are then excluded. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.
6/20/2022 13:36:19	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=753, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=9	First doc pg 753, second doc pg 9	Subject # 10081745	Data Discrepancy	Excluded: Claimed did not get 2 doses or within the prescribed time. But data shows subject did get 2 within time frame. This 16-year-old is on the exclusion form list of 24-Nov-20 stating the subject did not receive the second dose. However, the subject did indeed receive the 2nd dose on 03-Dec-2020, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated 24-Nov-2020 & again on the 01- April 2021 form, both clearly state the subject did in fact receive the study doses 1 & 2. So, were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or "test positive" for Sars Cov-2 after getting the shot(s) are then excluded. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.
6/20/2022 13:49:53	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=753, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=347, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=686	First doc pg 753, second doc pg 347, third doc pg 686	Subject # 10081744	Data Discrepancy	Excluded: Claimed did not get 2 doses or within the prescribed time. But data shows subject did get 2 within time frame. This 17-year-old is on the exclusion form list of 24-Nov-20 & 2-Dec-20 stating the subject did not receive the second dose. However, the subject did indeed receive the 2nd dose on 25-Nov-2020, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated 24-Nov-2020 & again on the 01- April 2021 form, both clearly state the subject did in fact receive the study doses 1 & 2. So, were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or "test positive" for Sars Cov-2 after getting the shot(s) are then excluded. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.

6/20/2022 13:54:46	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=753, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=347	First doc pg 753, second doc g 347	Subject # 10081746	Data Discrepancy	Excluded: Claimed did not get 2 doses or within the prescribed time. But data shows subject did get 2 within time frame. This 17-year-old is on the exclusion form list of 24-Nov-20 stating the subject did not receive the second dose. However, the subject did indeed receive the 2nd dose on 4-Dec-2020, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated 24-Nov-2020 & again on the 01- April 2021 form, both clearly state the subject did in fact receive the study doses 1 & 2. So, were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or "test positive" for Sars Cov-2 after getting the shot(s) are then excluded. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.
6/20/2022 14:04:47	https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=646, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_c4591001-A-c4591001-subject-list-for-12-25-immuno-analysis-27jan2021.pdf#page=3	First doc pg 646, second doc pg 3	Subject #10091205	Data Discrepancy	Excluded: Claimed did not get 2 doses or within the prescribed time. But data shows subject did get 2 within time frame. This 15-year-old is on the exclusion form list of 24-Nov-20 stating the subject did not receive the second dose. However, I found the subject did indeed receive the 2nd dose on 6-Nov-2020 but I lost track of the doc for it. But why would they do the immuno analysis on this subject if excluded for not getting 2 doses? 125742_S1_M5_c4591001-A-c4591001-subject-list-for-12-25-immuno-analysis-27jan2021.pdf#page=3
6/20/2022 14:20:52	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=762, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=9, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=686, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_c4591001-A-c4591001-subject-list-for-12-25-immuno-analysis-27jan2021.pdf#page=3	First doc pg 762, second doc pg 9, third doc pg 686, fourth doc pg 3	Subject # 10091210	Data Discrepancy	Excluded: Claimed did not get 2 doses or within the prescribed time. But data shows subject did get 2 within time frame. This 16-year-old is on the exclusion form list of 24-Nov-20 & 2-Dec-20 stating the subject did not receive the second dose. However, the subject did indeed receive the 2nd dose on 16-Nov-2020, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated 24-Nov-2020 & again on the 01- April 2021 form, both clearly state the subject did in fact receive the study doses 1 & 2. Also if excluded why do the immuno analysis? So, were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or "test positive" for Sars Cov-2 after getting the shot(s) are then excluded. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.
6/20/2022 14:30:56	https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=337, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=646	First doc pg 646, second doc pg 337	Subject # 10091212	Efficacy	Why is this 13 yr old subject excluded from the study after getting 1 dose on 16-Oct-20. Can not find data as yet if this subject had AE's. It seems most serious AE's seem to be documented as being "Not Related" to the vax. Was this subjects data included in the results?
6/20/2022 16:46:48	Video analyzing Pfizer vaccine trials for 6 mo to 4 yr old children (see https://gettr.com/post/p1eu2rr8b3a or https://rumble.com/v18s66i-bombshell-dr.-clare-craig-exposes-how-pfizer-twisted-their-clinical-trial-d.html)	not applicable	not applicable	Other	Found this short video analysis of the Pfizer C19 vaccine trials applicable to infants to 4 yr olds (see: https://connect.xfinity.com/appsuite/#!!&app=io.ox/mail&folder=default0/INBOX&waitSeconds=30) on the Steve Kirsch substack site from 6/19/22 by Dr. Clare Craig (co-chair and diagnostic pathologist for the HART Group; https://www.hartgroup.org/). She points out what appear to be glaring problems with the Pfizer analyses of vaccine adverse effects and efficacy. This appears to be another instance of fraud by Pfizer by leaving out data that would have shown the vaccine to be both unsafe and ineffective. I recommend that Dr. Craig be contacted for further details on what she has found about these recent vaccine trials (https://www.hartgroup.org/contact-us/). Not sure if these trials are covered by the FOIA court order from which we have been receiving data for our review efforts. Also, see the HART Group open letter sent to the FDA vaccines committee 6/13/22 https://www.hartgroup.org/open-letter-2-fda-vaccines-committee/ and an earlier open letter HART Group sent: "Open Letter from the Children's Covid Vaccines Advisory Group (CCVAG) to the JCVI: Pause vaccines for children pending urgent review" https://www.hartgroup.org/open-letter-to-the-jcvi-pause-vaccines-for-children-pending-urgent-review/
6/20/2022 17:16:18	HART Group editorial pointing out flaws in Pfizer trials on vaccine for 0 to 4 yr olds, see: https://www.hartgroup.org/fda-approve-covid-vaccine-for-0-4-years/	Not applicable	Not appicable	Other	Possible fraud on the part of Pfizer in their vaccine trials for 0-4 yr olds is described in this editorial by the HART Group from the UK. Info from HART Group suggests Pfizer trial showed the vaccine to be both unsafe and ineffective. I also sent a video from Dr Clare Craig of HART Group describing this earlier today. I recommend our team experts contact and coordinate with HART Group to get further details on this. Contact link for HART Group: https://www.hartgroup.org/contact-us/
6/20/2022 17:34:57	4591001-i terim-mth6-randomization. 125742	2	1	Other	12574251 s1 m5 5351 4591001-interim-mth6-randomization pages 1&2
6/21/2022 10:55:49	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1015-10151134.pdf	many	n/a	Adverse Effects - Other	55y.o. male. AE - worsening and continuing episodes of vertigo starting 1 day after Dose 1 (8/27/20), discontinued treatment and did not receive Dose 2 due to safety concerns. Returned on 11/6/20 for V3_MONTH1_POSTVAX2_L and serum was taken but no other vitals. Later unblinded as placebo and consented to Dose 3 and 4 (both Pfizer 12/21/20 and 1/13/21). Date AE was recovered/resolved was 12/21/20, same date as Dose 3. Initial consent was same day as Dose 1. Swabs at Dose 1, 3, 4. Serum at Dose 1, 3. No results provided in this document. Only follow-up after Dose 4 was a phone call on 2/10/21 with no additional information.
6/21/2022 11:32:47	125742_S1_5_CRF_c4591001-1007-10071101	46, 49, 50, 51, 195	forms	Adverse Effects - Other	Patient 10071101 received the 1st dose 7/30/20; the second dose 8/20/20; the third dose 9/17/20. HER DEATH from heart attack is reported on 10/21/20. She was approx 37 years old with underlying conditions e.g. obesity, asthma, sleep apnea.
6/21/2022 12:49:51	STN 125742-0-0-Sect 2.5-Clinical overview-reissue.pdf.pdf	p 17	#2. - 2.5.1.2.1.1. Current Therapies	Other	Current therapies are listed for severe disease or critical care hospital setting; ambulatory care setting; and clinical trial setting. Ivermectin and famatodine are listed as therapies.
6/21/2022 13:04:20	STN 125742-0-0-Sect 2.5-Clinical overview-reissue.pdf.pd	#20	#4	Adverse Effects - Reproductive Issues	There is denial of vaccine-related adverse effects on female fertility, fetal development or postnatal development reported in the study.
6/21/2022 14:22:18	125742_S1_M5_CRF_c4591001-1007-10071117	49,56, 57, 58, 87, 91, 306	forms	Adverse Effects - Other	Subject received dose 1 on 8/3/20; dose 2 on 8/24/20; dose 3 on 9/21/20. On 3/9/21 she was examined for swollen lymph node p.49 and p, 56 - 58. She was re-vaccinated: dose 3 on 2/15/21; dose 4 on 3/8/21. This seemed odd to me.
6/21/2022 15:02:06	125742_S1_M5_CRF_c4591001-1007-10071124	43, 78, 235-260,262	forms	Adverse Effects - Other	Subject received dose 1 on 8/15/20; dose 2 on 8/26/20; dose 3 on 9/23/20. She was UNBLINDED on 2/14/21 and received V3 on 1/19/21 and V4 on 2/9/21. Between 2/10/21 and 2/12/21 the following adverse events occurred (p235 -p260): generalized myalgia; chills; auxiliary lymphadenopathy, headache, pain at injection site.
6/21/2022 17:51:04	https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=646	Page 646	Subject # 10091213	Efficacy	This 15-year-old subject had 1 injection and then was excluded for not getting the 2nd dose. There is no other data found. So, were subjects wrongly excluded from the study due to adverse events which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or "test positive" for Sars Cov-2 after getting the shot and then are excluded would skew the results. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.
6/21/2022 17:57:55	https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=646	Page 646	Subject 10091216	Efficacy	This 12-year-old subject had the 1st injection, then was excluded for not receiving 2 doses. So, were subjects wrongly excluded from the study due to adverse events which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or "test positive" for Sars Cov-2 after getting the shot and then are excluded would skew the results. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.
6/21/2022 18:00:17	https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=647	Page 647	Subject # 10091218	Efficacy	This 13-year-old subject had the 1st injection, then was excluded for not receiving 2 doses. So, were subjects wrongly excluded from the study due to adverse events which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or "test positive" for Sars Cov-2 after getting the shot and then are excluded would skew the results. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.

6/21/2022 18:02:30	https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=647	Page 647	Subject # 10091220	Efficacy	This 15-year-old subject had the 1st injection, then was excluded for not receiving 2 doses. So, were subjects wrongly excluded from the study due to adverse events which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or “test positive” for Sars Cov-2 after getting the shot and then are excluded would skew the results. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.
6/21/2022 18:08:28	https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=647, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_c4591001-A-c4591001-subject-list-for-12-25-immuno-analysis-27jan2021.pdf#page=3	First doc pg 647, second doc pg 3	Subject # 10091221	Efficacy	This 15-year-old subject had the 1st injection, then was excluded for not receiving 2 doses. So, were subjects wrongly excluded from the study due to adverse events which would make these mRNA gene altering therapy shots look bad? If the subject is excluded, then why was an Immuno Analysis was done? It would seem subjects who experience adverse events and/or “test positive” for Sars Cov-2 after getting the shot and then are excluded would skew the results. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.
6/21/2022 18:13:27	https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=647	Page 647	Subject # 10091223	Efficacy	This 14-year-old subject had the 1st injection, then was excluded for not receiving 2 doses. So, were subjects wrongly excluded from the study due to adverse events which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or “test positive” for Sars Cov-2 after getting the shot and then are excluded would skew the results. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.
6/21/2022 18:19:30	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=763, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=687	First doc pg 763, second doc pg 687	Subject # 10091224	Data Discrepancy	Excluded: Claimed did not get 2 doses or within the prescribed time. But data shows subject did get 2 within time frame. This 17-year-old is on the exclusion form list of 2-Dec-20 stating the subject did not receive the second dose. However, the subject did indeed receive the 2nd dose on 10-Nov-2020, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated on the 01- April 2021 form, both clearly state the subject did in fact receive the study doses 1 & 2. So, were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or “test positive” for Sars Cov-2 after getting the shot(s) are then excluded. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.
6/21/2022 18:29:13	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=763	Page 763	Subject # 10091224	Data Discrepancy	I didn't get a copy of what I had filed and I may have forgotten to include the doc for this 17-year-old subject that shows he did receive 2 doses.
6/21/2022 18:33:55	https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=763, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=647	First doc pg 763, second doc pg 647	Subject # 10091226	Data Discrepancy	Excluded: Claimed did not get 2 doses or within the prescribed time. But data shows subject did get 2 within time frame. This 15-year-old is on the exclusion form list of 2-Dec-20 stating the subject did not receive the second dose. However, the subject did indeed receive the 2nd dose on 9-Nov-2020, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated on the 01- April 2021 form, both clearly state the subject did in fact receive the study doses 1 & 2. The question is were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or “test positive” for Sars Cov-2 after getting the shot(s) are then excluded. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.
6/21/2022 19:49:19	125742_S1_M5_5351_c4591001-fa-interim-severe-adverse-events.pdf	790	case #10801002	Adverse Effects - Other	The SAE happened within 1 day after the 1st shot and was assessed as not related to the treatment and was downgraded. The subject (16-55)received the vaccine on August 10,2020 (p.1151, 125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive (1)). On August 11,2020 he/she developed a bleeding ulcer of the stomach that was assessed as toxicity grade 2 and not related to the vaccination. The subject must be excluded from the trial because he/she met exclusion criteria #10, condition associated with prolonged bleeding. However, the investigator didn't consider the condition to be serious. It wasn't resolved. Nevertheless, the subject received the 2nd shot on August 31,2020. The case outcome is unknown due to unavailability CRF.
6/21/2022 20:08:22	125742_S1_M5_CRF_c4591001-1013-10131517.pdf	136	N/A	Data Missing	For this subject they note: "SAE RECON 2: Outcome is still recovering/resolving in SDB. Per PSSR confirmation, no follow up form was received. Please submit a follow up AEM form to update outcome in Safety database." Further down on the same page it notes that this is correct that follow up is "pending." In the last remaining 8 pages after that I do not see anything pertaining to follow up being completed. I am not sure if this is elsewhere in additional documents but I don't see anything in this document. The patient had suffered a noted heart attack.
6/21/2022 20:09:57	125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf	1088	Case #11561006	Adverse Effects - Other	The subject (16-55) within 12 days after the treatment developed a pulmonary embolism that wasn't considered by the site investigator as SAE. She/he also had DVT, deep vein thrombosis, that was assessed as SAE. Both events had a toxicity grade of 3 that was downgraded. The subject received the vaccine on August 20,2020 (p.2669, 125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive(1)). She/he developed the SAE on August 31,2020. It was resolved on September 2,2020. Also The Listing of Adverse Events doesn't have any comorbidities that could worsen if the SAE weren't related to the vaccine. The CRF for this case isn't available to fully assess SAE. The subject was withdrawn from the trial based on exclusion criteria #5 (p.47, 125742_S1_M5_5351_c4591001-fa-interim-discontinued-patients(1).pdf).
6/21/2022 20:20:31	125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf	1099	case #11671175	Adverse Effects - Other	The subject (16-55) had a "Cerebrovascular accident" after the 2nd treatment that was assessed as toxicity grade of 3 and not being related to the vaccine. The subject received the vaccine on September 10 and September 29,2020 (p.2817, 125742_S1_M5_5351_c4591001-fa-interim--randomization-sensitive(1)). On October 21,2020 he/she had a SAE. In spite of the severity of the adverse event, the subject wasn't withdrawn from the study and his diagnosis and preexisting conditions weren't updated. The CRF for this case isn't available to fully assess the SAE.
6/21/2022 20:34:57	125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf	1044	case #11461200	Adverse Effects - Other	The subject (16-55) had a cardiac SAE within 3 days after the 2nd treatment. However, the investigator concluded that the SAE wasn't related to the vaccine. The subject received the vaccine on September 3 and September 25, 2020 (p.2523, 125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive(1)). He/she had AV-block of 1 degree, acute bradycardia, and lost of consciousness on September 27,2020.The subject probably was hospitalized and had installed a pacemaker. The conditions were marked as resolved. The CRF isn't available for this case to assess the subject's medical history and preexisting conditions.
6/21/2022 20:46:10	125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf	641	Case #10161245	Adverse Effects - Other	The subject (16-55) had to be removed from the trial due to worsening depression within 7 days after the 1st shot , on September 10,2020. The event was assessed as not related to the treatment. It wasn't resolved. However, the subject received the 2nd shot on September 24,2020 (p.1435, 125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive(1)). The CRF isn't available for this case to fully assess the adverse event.
6/21/2022 21:02:57	125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf	1023	Case #11411227	Adverse Effects - Other	The subject (16-55) had to be excluded from the study after the 1st treatment due to worsening depression. However, he/she received the 2nd shot that again caused the depression to worse. The subject developed the adverse event within 2 days after the 1st shot, on September18,2020. According to the site investigator, the adverse event was resolved on September 21,2020 and it was related to the treatment. On October 9,2020 the subject received the 2nd shot (p.2461, 125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive(1)). His/her condition worsened again on October 24,2020. At this time it was assessed by the investigator as not being related to the vaccine. The subject had not recovered. The CRF for this case isn't available to fully assess the adverse event.
6/21/2022 21:11:40	125742_S1_M5_5351_c4591001_fa-interim-adverse-events.pdf	788	case #10771054	Adverse Effects - Reproductive Issues	The subject developed "Polycystic ovarian syndrome" after 2 treatments. She received the vaccine on August 17 and September 9, 2020 (p.1099, 125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive(1)). She was diagnosed on October 1,2020 with toxicity grade of 1 that wasn't related to the treatment. The toxicity of the adverse event was downgraded by the investigator. The condition wasn't resolved. The CRF for this case isn't available to fully assess the event.
6/21/2022 21:23:59	125742_S1_M5_5351_c4591001fa-interim-adverse-events.pdf	1089	case #11561018	Adverse Effects - Reproductive Issues	The subject (16-55) on the 18th day after the 1st shot developed "dysfunctional uterine bleeding" that had a toxicity grade of 2 which was not related to the vaccine according to the site investigator. However, she received the 2nd shot while her adverse event had not been resolved. The subject received the vaccine on August 24 and September 15,2020 (p.2671, 125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive(1)).She had the adverse event on September 10,2020. The CRF for this case isn't available to fully assess the event.

6/21/2022 21:42:00	125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf	1097	Case #11631069	Adverse Effects - Other	The subject (16-55) had worsening depression within 23 days after 1st shot. According to the site investigator , the adverse event wasn't related to the vaccine and wasn't resolved. The subject had not received the 2nd shot. He/she also wasn't discontinued from the study. It is unclear what had happened with the subject. He/she received the 1st and the only shot on August 10,2020 (p.2782, 125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive(1)). The CRF isn't available for this case to fully assess the adverse event.
6/22/2022 13:56:26	r18hs017045-lazarus-final-report-2011.pdf	6	3	Other	The VAERS data (from HHS/AHRQ report) show under-reporting rate of 99% for vaccines
6/22/2022 18:24:43	125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf	813	Case #10891261	Adverse Effects - Other	The subject(16-55) developed "Herpes Zoster" infection after the 1st shot. However, according to the site investigator he/she had recovered within 5 days after onset of the symptoms. Also the subject received the 2nd shot in a week after the recovery. The subject received the 1st shot on September 8,2020 (p.1440, 125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive(1)). On September 19,2020 she/he was diagnosed with Herpes Zoster . According to the investigator, the subject's condition wasn't related to the vaccine .On September 23,2020 the subject recovered. There are two possibilities in this case either the diagnosis of Herpes Zoster wasn't correct or the recovery date was wrong(it takes average 3-5 weeks to recover). The subject received the 2nd shot on September 30,2020. The CRF isn't available for this case to fully assess the adverse event.
6/22/2022 18:57:42	125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf	1100	Case #11681073	Adverse Effects - Other	The subject probably had Herpes Zoster infection which was hiding under "Intermittent body rash" symptom. The subject(16-55) received two shots , on August 21 and September 11,2020 (p.2830, 125742_S1_M5_c4591001-fa-interim-randomization-sensitive(1)).Within 3 days after 2nd shot she/he developed the" upper body rash "which lasted 2 days and was related to the shot. However, on September 18,2020 she/he developed again the "intermittent body rash" which was also related to the shot. The body rash resolved on October 12,2020. Considering the presence of long-lasting rash in upper body and the course of the disease, the diagnosis of Herpes Zoster is very likely. The CRF for this case isn't available to fully assess the event.
6/22/2022 19:11:26	125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf	1084	Case #11521046	Adverse Effects - Other	Another case where Herpes Zoster infection is hiding under the "body rash" adverse event . The subject (16-55) received two shots, on August 13 and September 1,2020 (p.2616, 125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive(1)). Within 3 days after the 2nd shot the subject developed the "body rash" which was related to the vaccine. The condition was not resolved. The CRF for this case isn't available to fully assess the event.
6/22/2022 19:23:20	125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf	942	Case #11281005	Adverse Effects - Other	Herpes Zoster infection is hiding under the "rash of upper torso" adverse event. The subject (16-55) received two treatments, on July 31 and August 19,2020 (p.2135, 125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive(1)). On September 12,2020 the subject developed the upper torso rash which wasn't related to the vaccine. The condition didn't resolve. The CRF for this case isn't available to fully assess the adverse event.
6/22/2022 20:25:37	125742 MS CRF c4591001-10 10081056	40	#9 of Adverse Event Report	Adverse Effects - Other	Complaint:Shortness of breath (listed on previous page. pg 39) #9 Is this event related to study treatment: answered as not related, event due to : OTHER if Other, specify, No explanation is given listed as unknown-this does not explain how it can be justified as unrelated to the vaccine
6/22/2022 20:32:42	https://phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_5351_c4591001-fa-interim-protocol-deviations-sensitive.pdf	2471-2506	multiple	Study Protocol	I noticed when reviewing the documents that in 16.2.7.5.4 Listing of Serious Adverse Events - All subjects (pp 2471-2506) that the majority of serious events (I concentrated on Cardiac, Respiratory, and Nervous System, which includes MI, PE and stroke) are listed as Vaccine related - "No" and Cause O (other). Do we already know or if not, can we find out how the reviewers were selected (were they biased) and what criteria they used? I came across "The Bradford Hill Criteria" when looking at other studies. Does this (or anything similar) appear in their design?
6/22/2022 22:25:28	125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf	1173	case #11771418	Adverse Effects - Other	The subject(16-55) had a new onset Herpes Zoster infection 2 days before the 2nd shot. However, the subject received his/her 2nd shot while he/she had been sick. The subject received the 1st shot on September 22,2020 (p.2983, 125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive(1)). Within 20 days after 1st shot, on October 11,2020, he/she developed shingles which weren't related to the vaccine according to the site investigator. The subject received the 2nd shot on October 13,2020. The outcome of the adverse event is unknown due to unavailability CRF for this case.
6/23/2022 6:57:26	Pfizer)02/08/2022) "Fourth Quarter 2021 Earnings Teleconference"	Slides 13 and 14	Relevant point - about 2/3 down the Dr. Malone article referenced below beginning "SAE is an abbreviation..."	Data Missing	Slide 14 title refers to Pfizer's mRNA strategy road map, not their "synthetic" mRNA road map. Slide 15 mentions four recent collaboration projects with BioNTech (mRNA shingles), CODEX DNA ("synthetic DNA", Acuitas (LNP), and Beam (rare CNS, muscular, and liver) Dr. Robert Malone pointed out in his "Pfizer and Moderna Analysis Re-do" article discussing Peter Doshi's and colleague's heroic attempt to take another look at the Phase 3 trials that the "synthetic mRNA that is not really mRNA lasts for about sixty days, as does the spike protein produced from that mRNA..." This raises two questions. 1. Has Pfizer misrepresented to investors the nature of the synthetic mRNA which was used. 2. Are the collaboration agreements mentioned in Q4 2021 being driven by known adverse events that were not publicly disclosed or presented to the FDA for early EUA approval(s). Pfizer does not appear to disclose the use of any "synthetic" mRNA.
6/23/2022 14:11:13	https://phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf#page=263, https://phmpt.org/wp-content/uploads/2022/05/125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf#page=763, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-excluded-patients-sensitive.pdf#page=688, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_c4591001-A-c4591001-subject-list-for-12-25-immuno-analysis-27jan2021.pdf#page=3	First doc pg 263 , second doc pg 763 , third doc pg 688, fourth doc pg 3	Subject 10091235	Data Discrepancy	This 16-year-old is on the exclusion form list of 2-Dec-20 stating the subject did not receive the second dose. This is not factual! It is documented that the subject did receive the 2nd dose on 11-Nov-2020, documented on form "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age" dated 24-Nov-2020 & 01- April 2021 form, both clearly state the subject did in fact receive the study doses 1 & 2. Also if the subject is excluded, then why was an Immuno Analysis was done? So, were subjects wrongly excluded from the study due to adverse events happening which would make these mRNA gene altering therapy shots look bad? It would seem subjects who experience adverse events and/or “test positive” for Sars Cov-2 after getting the shot(s) are then excluded. It seems they cherry picked the results they wanted to justify the EUA for these experimental gene therapy drugs.
6/23/2022 15:06:10	125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf	1330	Case #12311315	Adverse Effects - Reproductive Issues	Rare cancer with a bad prognosis was developed after the 2nd shot. The subject (16-55) received two treatments one on August 15 and the other on September 3, 2020 (p.3435, 125742_S1_M5_5351_4591001-fa-interim-randomization-sensitive(1)). On September 25,2020 she was diagnosed with " Pigmented epithelioid melanoma of the vagina". According to the site investigator, the adverse event wasn't related to the vaccine. The adverse event had a toxicity grade of 2. The grade had been significantly downgraded. The woman probably was hospitalized and underwent surgery because the event was marked as SAE. Only 500 cases of this kind of cancer have been described in the literature since 1887. This type of cancer is more common in women in their 60s and 70s (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5354139). The CRF for this case isn't available to fully assess the SAE.
6/23/2022 17:22:30	125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf	1318	case #12262104	Adverse Effects - myocarditis	The subject(16-55) within 3 days after the 2nd shot developed "Costochondritis in the sternal region" which might be misdiagnosed. The toxicity of the adverse event was 3 and it wasn't related to the vaccine according to the site investigator. The subject received 2 shots, the 1st on October 7 and the 2nd on October 28,2020 (p.3337, 125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive(1)). The subject also had other symptoms after the shots, such as fever, headache, injection site pain, chills which were related to the vaccine according to the investigator. Those symptoms resolved quickly. However, the "Costochondritis" was marked as " recovering". The localization of the pain and prolonged the course of the disease without presence of trauma, surgery or infection ,and toxicity grade of 3 can't exclude myocarditis. The CRF for this case isn't available to fully assess the adverse event.

6/23/2022 18:48:33	125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf	1177	Case#11781061	Adverse Effects - myocarditis	The subject (16-55) within 2 days after 2nd shot developed "Sternum pain". The adverse reaction wasn't related to the treatment according to the investigator. The subject received 2 shots, the 1st on September 1 and the 2nd on October 14,2020 (p.3003, 125742_S1_M5_5351_c4591001-fa interim-randomization-sensitive(1)). The gap between two shots was 45 days which was considered as the protocol deviation (p.87-88, 125742_S1_M5_5351_c4591001-fa-interim-protocol.pdf). However, the subject wasn't included in the Listing of Important Protocol Subjects Deviations (125742_S1_M5_5351_c4591001-fa-interim-protocol-deviations-sensitive.pdf). He also had adverse reactions after the 1st shot such as injection site pain, chills, myalgia, and headache. The symptoms had resolved within 2 days after the 1st shot. The reason for 2nd shot delay is unknown due to unavailability the CRF. Nevertheless, on October 15, 2020 he became experience "sternum pain" that hadn't resolved according to the site investigator. Localization of the pain and prolonged course of the disease can't exclude myocarditis.
6/23/2022 20:15:03	125742 MS CRF c4591001-10	18	#8 Actual Dose	Data Missing	If a blinded study shouldn't the dosage be stated regardless of placebo or vaccine being injected.
6/24/2022 11:28:03	Mary Glazer	1 through 435	all	Other	Mary Glazer
6/24/2022 14:02:57	125742_S1_M5_5351_C4591001-fa-interim-adverse-events.pdf	1369	Case #12313175	Adverse Effects - myocarditis	The subject(16-55) developed "Nonspecific chest pain" within 8 days after the 1st shot. He/she received the 1st and the only one shot on August 22,2020 (p.3614, 125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive(1)). According to the site investigator the adverse event wasn't related to the treatment and had a toxicity grade of 1. Also it had resolved within 3 days , on August 31,2020. However, the subject refused to receive the 2nd shot and was discontinued from the trial on September 22,2020 (p.63, 125742_S1_M5_5351_c4591001-fa-interim-discontinued-patients(1)). The CRF for this case isn't available to fully assess the adverse event.
6/24/2022 14:23:52	125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf	1357	Case #12312593	Adverse Effects - Other	The subject(16-55) within 6 days after the 2nd shot developed "Acute Coronary Syndrome without ST elevation". He/she received the treatment on August 20 and September 11,2020(p.3559, 125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive(1)). According to the site investigator the event wasn't related to the vaccine. The SAE had resolved on September 19,2020. There is no comorbidities that make worse the subject's condition, except the "Right bundle branch block" which could be a consequence of the Acute Coronary Syndrome but can't cause it. The CRF for this case isn't available to fully assess the SAE.
6/24/2022 14:38:12	125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf	1357	Case #12312577	Adverse Effects - Other	The subject (16-55) with unknown neoplasma developed "Brain metastasis" within 9 days after the 1st shot. He/she received the 1st and the only one shot on August 20,2020 (p.3558, 125742_S1_M5_5351-c4591001-fa-interim-randomization-sensitive(1)). The subject 's condition wasn't related to the shot according to the site investigator. He/she was discontinued from the study on August 28,2020 (p.3558, 125742_S1_M5_5351_c4591001-fa-interim-discontinued-patients(1)). The CRF for this case isn't available to fully assess the SAE.
6/24/2022 14:54:59	125742_S1_M5_5351_c4591001-fa-interim- adverse-events.pdf	1411	Case #12315359	Adverse Effects - Reproductive Issues	The subject(16-55) within 19 days after the 1st shot developed "Amenorrhea". According to the site investigator her condition wasn't related to the vaccine. She received two treatments, on August 29 and September 17,2020 (p.3823, 125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive(1)). The outcome of the adverse event was marked as "recovering". However, it's not possible in this case. There are only two possible outcomes either the adverse event hadn't resolved or it had resolved. The CRF for this case isn't available to fully assess the adverse event.
6/24/2022 16:30:34	Pfizer 10-Q financial filings and Teleconference Earnings slides Q1 2019 - Q1 2022	All	All	Other	FDA Future Framework Pfizer 10-Q (Q1 2019 t – Q1 2022) There is no mention of FDA Future Framework in Pfizer Q-10 reports from Q1 2019 through Q1 2022. I will explore different definitions of “Future Framework” as there are numerous FDA references, which is not unusual. The point being they may have historically called the Future Framework concept FDA “X” or something else. Pfizer Quarterly Earnings Teleconference Slides (Q1 2019 – Q1 2022) There is no mention of FDA Future Framework in Pfizer Earnings Teleconference slides from Q1 2019 through Q1 2022.
6/24/2022 21:14:11	A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY INDIVIDUA	Pg 35	2.3 Benefit Risk assessment	Other	Lie regarding therapeutics and preventions for virus
6/24/2022 21:26:07	A Tissue Distribution Study of a Labelled Lipid Nanoparticle - mRNA	Pg 21	Chart on pg 21. Values expressed over 48hours	Adverse Effects - Reproductive Issues	There is a clear multiplication of drug not only outside injection site, but the concentration through 48 hours is multiplied significantly. (Ovaries for example) These concentrations signal further monitoring of this trend!
6/25/2022 10:41:17	125742_S1_M5_CRF_c45910011008 10081337	1-182	181	Data Missing	Exposure during pregnancy without follow up as to outcome
6/25/2022 11:24:02	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1012-10121163.pdf	4, then 133	line 1	Other	Subject withdrew consent on 9/24/20
6/25/2022 11:28:55	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1012-10121163.pdf	7	whole page	Other	Subject has following on-going conditions: Allergic Atopic Dermatitis, Penicillin allergy, Codeine allergy, Iodine allergy, Cat Scratch Disease
6/25/2022 11:31:49	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1012-10121163.pdf	9	line 6	Other	Subject is not pregnant.
6/25/2022 11:33:55	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1012-10121163.pdf	150	section 3	Data Missing	Was the recording error mentioned ever corrected?
6/25/2022 11:35:16	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1128-11281009-reissue.pdf	all	all	Other	The blue hotlinks are not working.
6/25/2022 14:14:02	125742_S1_M5_CRF_c46910011013 10131165	191	1	Adverse Effects - Other	PE coded as unrelated to vaccine. also from correspondence it looks like they were trying to attribute it to Covid instead
6/25/2022 14:19:12	125742_S1_M5_CRF_c45910011013 10131229	157	1	Adverse Effects - Reproductive Issues	Patient was originally in control group but was then vaccinated when study became unblinded. After she received the vaccine she became pregnant and then had a miscarriage. This was documented as exposure during pregnancy rather than as miscarriage
6/25/2022 14:29:10	125742_S1_M5_CRF_c45910011009 10091123	161	1	Adverse Effects - Other	Patient received both doses of the vaccine then developed a polyp that turned out to be tubular adenoma of the ascending colon. It looks like this was classified as not related to vaccine and they possibly tried to add it to medical history so that it would appear that it was preexisting
6/25/2022 19:36:06	STN 125742-0-0-Sect 2.5-Clinical overview reissue.pdf	#152	#9	Adverse Effects - Other	Systemic events
6/25/2022 19:39:44	STN 125742-0-0-Sect 2.5-Clinical overview reissue.pdf	#153	#1-2-3	Adverse Effects - Other	Systemic adverse events
6/25/2022 23:26:05	na	na	na	Adverse Effects - Other	
6/26/2022 1:01:46	125742_S1_M5_5351_c4591001 fa interim adverse events.pdf	2525	16.2.7.7.4	Fatality	6 deaths reported
6/26/2022 21:39:55	125742_S1_M5_CRF_c4591001 1081 10811194 reissue.pdf	71, 72, 98, 353	NA - Adverse event report	Adverse Effects - myocarditis	This subject 108111194 was the victim of an adverse event (death) which was not explained in a previous document. Their cause of death was listed as death. More defined in this document - cannot find the other unknown causes of death (yet), but this is one more cardiac related death now.
6/27/2022 22:41:53	125742_S1_M5_CRF_c4591001-1007-10071101.pdf	pp 49, 50	last	Fatality	adverse event was fatal heart attack. conclusion was NR to study, but no reasoning other than "Occurred 2 months after last receipt of study agent"
6/28/2022 13:29:23	Interim 3 Lab Measurements - Part 1 & 5 - BNT162b2	excel spreadsheet	mulitple	Other	The attached pdf summarizes my findings. The excel spreadsheet is the source for the analysis

6/28/2022 16:38:38	125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf 125742_S1_M5_CRF_c4591001 1013 10131176.pdf	1681-1682	case #10131176	Adverse Effects - Other	The subject wasn't properly screened for preexisting conditions. Then after the 1st shot he developed 13 SAE the majority of which were downgraded by Pfizer as the adverse events. Due to the severity of the adverse reactions, he had to discontinue the study. However, he received the 2nd shot. The 2nd shot was given 55 days later after the 1st shot (p.323, 125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive(1)) which is considered as a protocol deviation. However, on the page 22 in the CRF the answer to the question "Was there a temporarily delay of vaccination?" was "No". The subject also wasn't included in the Listings of Important Protocol Subjects Deviations (125742_S1_M5_5351_c4591001-fa-interim-protocol-deviations-sensitive.pdf). This isn't the first case when the subject wasn't included in the deviation protocol. I reported earlier the case # 11781061 with the same issue. Pfizer's deviation protocol doesn't have the subjects which had a delay with the 2nd shot due to SAE after the 1st one. The subject's condition "hypertension" wasn't included in his medical history originally. It was added later, on November 25,2020 (p.495, CRF). However, the causes of the adverse events such as Congestive Heart Failure and Mild Concentric Left Ventricular Hypertrophy weren't corrected. They were caused by high blood pressure and were not related to the prior surgery or had an unknown cause as it was written in the CRF. Within 17 days after the 1st shot the subject developed "Small Bowel Obstruction" that is considered the SAE and was related to his previous surgery. He underwent a surgery (p.427, CRF). After the surgery he developed many complications such as Sepsis, Anemia, Acute Renal Failure, Acute Respiratory Failure, Altered Mental Status, Hypokalemia, Hyponatremia. On November 11,2020 (3 days before cut off data) Pfizer gave recommendations to "Change(to non-serious) for all 5 (CHF, Sepsis, Anemia, Hypokalemia, Acute renal failure) as a safety update, so SAE report will also have non-serious" (p. 447, CRF).
6/28/2022 18:44:04	125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf 125742_s1_M5_CRF_c4591001-1007-10071101	1645	case #10071101	Adverse Effects - Other	The subject, female, 57, had a heart attack within 60 days after her 2nd shot. She died from cardiac arrest 4 days later(p.1645). However, her medical history doesn't have any heart conditions except Supraventricular Tachycardia which ongoing status was unknown. She had suffered obesity for 20 years and sleep apnea for 7 years (p. 9-10, CRF). Those conditions indicate that she had preexisting heart conditions which weren't screened properly. Also her medical history did not have a list of medication that she was taken prior her heart attack, in spite of her diagnosis of asthma, hypothyroidism, and depression(p.199,CRF). In addition, the subject had had SAE for 4 days. It is unclear from CRF where she had been for 4 days. On page 50 , the question " Did this serious event require or prolong hospitalization?" was answered "No". There is no mention about hospital admission, hospital records or treatment in the CRF. The diagnosis of the heart attack was mention only in causality of the SAE and was added probably later. On page 195 of CRF there is a remark on November 6,2020 from Pfizer that "Causality recorded as UNRELATED in Safety database but was left blank in AE CRF". UNRELATED was highlighted by Pfizer because according to Pfizer's protocol paragraph 8.3.4. Regulatory Reporting Requirements for SAEs 8.3.6. Cardiovascular and Death Events - Not applicable (p.78, 125742_S1_M5_5351_c4591001-fa-interim-protocol.pdf). In other words, if there is a cardiovascular SAE or death, Pfizer doesn't obligate to report it as related to the experimental product.
6/28/2022 20:09:55	125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf 125742_S1_M5_CRF_c4591001-1006-10061020.pdf	1642-1643	case #10061020	Adverse Effects - Other	The subject, male, 76, wasn't supposed to be enrolled in the study based on his medical history and current health. The subject had 3 heart attacks (1989,2004,2017) and Cardiovascular accident on March 6,2019. In addition, he had 2 strokes (2016, 2018) . Also he has Factor V Leiden (inherited) which increases the risk of blood clots, heart attack, and stroke. He had had SAE every year since 2016(pp.7-13, CRF). He received placebo shot on August 12,2020 (p.112, 125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive(1)). Within 10 days after the 1st shot he developed unstable angina that resulted in myocardial infarction (p.1642-1643). However, on page 160 of CRF there is a remark that the "subject reported angina 2 weeks prior hospitalization on August 25 ,2020". That means that the subject had ongoing angina on August 12,2020 ,the date of completed screening (p.6, CRF). He was discontinued from the study on September 16,2020 (p.81,CRF). However, he wasn't included in the Listing of Discontinued Subjects (125742_S1_M5_5351_c4591001-fa-interim-discontinued-patients(1).pdf).
6/29/2022 7:34:34	Interim 3 Lab Measurements - Part 1 & 5 - BNT162b2	all	all	Other	Resubmitting excel form uploaded yesterday. Some of the worksheets were hidden.
6/29/2022 21:08:47	125742_S1_M5_5351_c4591001 fa interim discontinued patients.pdf	4-112	16.2.1.4	Study Protocol	125742_S1_M5_5351_c4591001 fa interim discontinued patients.pdf was converted to .xls by one of the Daily Clout Pfizer Campaign volunteers. The data shows 810 People withdrew from the study – enclosing an excel version of this file for your further review. Here's some initial highlights: 78 of these subjects got COVID between vaccine 1 and 2, no longer met study criteria and were withdrawn from the study 12 withdrawn for heart related issues (to include death) – interestingly 4 of the deaths were people who were in the Placebo group. The site with the most withdrawals was 1231 see attached bar graph. Hard to tell the magnitude of this comparison without knowing how many people were at each site. I will keep looking for that to update, for now, this bar graph shows an alarming trend there.
6/29/2022 21:33:32	125742_S1_M5_CRF_c4591001-1013-10131653.pdf	45	N/A	Other	Participant had a serious AE of a DVT (blood clot in leg) and it was noted as not related to the to the study, but noted secondary to a fracture the participant had the month before. I do not see anywhere in the documents that display how they know it is definitively from the fracture and not potentially from the study treatment. Additionally, the participant was noted as "recovering/resolving" and throughout the document when they submit queries re: if they got better or what the outcome was, it says they're still waiting for additional info. Not additional info is noted by the end of the document.
6/29/2022 21:55:01	125742_S1_M5_CRF_c4591001-1013-10131653.pdf	40	N/A	Adverse Effects - Other	Participant noted with left lymph node swelling, noted as related to the study treatment.
6/30/2022 1:09:10	125742s1_m5_4591001-interim-mth6-randomization	47,	It's a graph no paragraphs.. on 06/22 she got vaccinated 06/24&29 she returned for blood work but didn't state reason for blood work.	Data Missing	Pages 93-106 and 107-110 not filled out
7/1/2022 15:59:22	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1012-10121112.pdf	3, 7-9	whole pages	Other	Note the age and condition of this subject. Born 1940, prostate cancer, squamous cell carcinoma, ongoing hyperlipidemia, heart arrhythmia, loop recorder implant, mitral valve prolapse.
7/1/2022 16:06:06	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1012-10121112.pdf	15	line 1	Other	No E-Diary collected for this subject
7/1/2022 16:08:08	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1012-10121112.pdf	17	section 2	Other	Subject's body temp is slightly low.
7/1/2022 16:14:14	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1012-10121112.pdf	23	4b, 4d, 4e, 4h	Adverse Effects - Other	signs and symptoms of covid-19
7/1/2022 16:21:19	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1012-10121112.pdf	29	1f	Data Missing	What was reason for visit? What type of visit was it?
7/1/2022 16:22:44	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1012-10121112.pdf	32	line 3	Other	toxicity grade 1
7/1/2022 16:24:34	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1012-10121112.pdf	39-42	whole pages	Data Missing	No vital signs recorded. None taken?
7/1/2022 16:26:32	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1012-10121112.pdf	49, link to 179	line 3	Other	Did the subject get Covid?
7/1/2022 16:37:00	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1012-10121112.pdf	54	whole page	Data Missing	

7/1/2022 17:04:39	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1012-10121112.pdf		55 whole page	Data Missing	
7/1/2022 17:05:31	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1012-10121112.pdf		56 whole page	Data Missing	
7/1/2022 17:08:10	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1012-10121112.pdf		57 lines 1-7	Adverse Effects - Other	several symptoms said to be adverse events
7/1/2022 17:10:29	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1012-10121112.pdf		58 whole page	Adverse Effects - Other	paroxysmal atrial fibrillation
7/1/2022 17:13:31	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1012-10121112.pdf		59 line 9	Other	a fib deemed not related to vaxx
7/1/2022 17:16:19	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1012-10121112.pdf	60-65	whole pages	Adverse Effects - Other	Adverse Effects are recorded then crossed out. Also see eCRF Audit Trail History and Form Audit Trail related to these pages.
7/1/2022 17:18:42	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1012-10121112.pdf		66 line 3	Adverse Effects - Other	Body chills started 2/3/21, ended 2/6/21.
7/1/2022 17:21:21	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1012-10121112.pdf		210 section 2/9/21	Adverse Effects - Other	reactogenicity took place after vaxx #4
7/1/2022 17:22:58	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1012-10121112.pdf		68 line 3	Adverse Effects - Other	body sweats
7/1/2022 17:26:16	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1012-10121112.pdf		70 line 3	Adverse Effects - Other	back pain, same dates and body chills and body sweats
7/1/2022 17:30:01	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1012-10121112.pdf		88 line 1	Other	Subject agrees to vaccination #3. #1 and #2 were placebo.
7/2/2022 20:31:47	125742_S1_M5_5351_bnt162-01_20242.pdf		90 2nd row	Adverse Effects - Other	2 episodes of syncope, considered severe, not considered related to the treatment
7/3/2022 5:27:45	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1012-10121097.pdf	P88,	Not noted	Study Protocol	Participant 10121097 got the placebo for doses 1 & 2. (P88) Then got BNT162b2 for the 3rd dose. The participant got COVID after the first 2 doses. After the BNT162b2 injection (Feb 2nd 2021) he got vertigo (Feb 3rd 2021) and was hospitalized with a laceration to the head needing a CT scan & 7 stitches. This was reported as related to the injection (P59) but not Serious. (P.65) However, on P237 it is reported as Serious. ***We know Pfizer gave both placebo & also product injections to participants. SO - WHERE DID THEY THEN place the participants when they reported the trial results? What logic did they use to place them in the product arm or the placebo arm?*** For example, did they report Participant 10121097 as being in the placebo group or the vaccinated group?
7/3/2022 6:42:36	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1012-10121097.pdf	P88 & others	Not noted	Study Protocol	Was it ethical to enroll an 82 year old man with a history of prostate cancer, skin cancer, allergies, osteoarthritis, heart arrhythmia, knee replacement, mitral valve prolapse & other health problems? Participant 10121112 is recorded as having placebo injections on September 2nd 2020 & September 21st 2020 (P88.). He was unblinded on January 11th & had doses of BNT162b2 on January 13th 2021 & February 2nd 2021. He got covid at the start of December 2020. In December he also suffered arrhythmia, dizziness, rapid heartbeat, muscle pain. No AEs are reported for the period after he had the product. However, if trial participants have multiple serious health problems, AEs can be attributed - by the trial reporters - to their medical history/condition & not the product. Surely participants should be in good health.
7/4/2022 13:53:46	"125742 S1 M5 5351 c4591001 interim mth6 randomization sensitive.pdf" 125742_S1_M5_CRF_c4591001 1013 10131517.pdf	pp 37,13,18,37,21,22,23,24 , 67,68,69	information appears within Forms on the denoted page numbers	Study Protocol	safety and long-term protection I reviewed Document # 6 "125742 S1 M5 CRF c4591001-1013 1013157" from the June 1 document release. Document # 6 is the CRF (Case Report Form) for Phase 3 trial subject, # 1013157, who is a White Male, born in 1950. His medical history included the following: Vitiligo, Asthma, Myocardial Infarction 2/14/2016 with Stent Insertion, Hypothyroidism, and CAD (Coronary Artery Disease) since 2005. I also accessed Document "125742 S1 M5 5351 c4591001 interim mth6 randomization sensitive.pdf" from the May 2 release. This document is entitled "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received - Subjects > and equal 16 Years of Age." The document confirms this subject did receive 2 doses of BNT162b2 30 ug vaccine, not placebo. (p 3003) Was this subject monitored as per Study Procedure for long-term protection and safety after the second dose? Background Pfizer's "A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY INDIVIDUALS" (cdn.pfizer.com.) outlines protocols/procedures for the c4591001 clinical trials. Section 8.11 (Study Procedures) of this document outlines the required visits for those participating in the Phase 3 trials. Section 8.11.2. Phase 2/3 8.11.2.1. Visit 1- Vaccination 1: (Day 1) 8.11.2.2. Visit 2 - Vaccination 2: (19-23 Days after Visit 1) 8.11.2.3. Visit 3 - 1-Month Follow-up Visit (After Vaccination 2): (28 to 35 Days after Visit 2) 8.11.2.4. Visit 4- 6-Month Follow-up Visit: (175-189 Days after Visit 2) 8.11.2.5. Visit 5- 12 Month Follow-up Visit (350-378 Days after Visit 2) 8.11.2.6. Visit 6- 24-Month Follow-up Visit (714 to742 Days after Visit 2) (pp 85-92) A Pfizer Press Release related to the status of the ongoing clinical vaccine trials released on 11/8/2020 assured the public that trial subjects would be followed for 2 years, stating the following: "Pfizer and BioNTech are continuing to accumulate safety data and currently estimate that a median of two months of safety data following second (and final) dose of the vaccine candidate - the amount of safety data specified by the FDA in its

7/4/2022 23:24:31	125742_ S1_ M5 _CRF_c4591001-1013 1013157.pdf, 125742_ S1_ M5_ 5351 _c4591001 interim mth6 randomization sensitive.pdf	CRF document pp46-47, 126, 135; randomization document p3003	p 46-47, p 126 presented within form, p135, presented within form	Adverse Effects - Other	was also documented that it was “NOT LIFE THREATENING” Was this serious adverse event sufficiently investigated? Was it reported and documented sufficiently to fulfill protocol requirements? I reviewed Document # 6 “125742 _S1_ M5_ CRF_ c4591001-1013 1013157” from the June 1 document release. Document # 6 is the CRF (Case Report Form) for Phase 3 trial subject, # 1013157, who is a White Male, born in 1950. His medical history included the following: Vitiligo, Asthma, Myocardial Infarction 2/14/2016 with Stent Insertion, Hypothyroidism, and CAD (Coronary Artery Disease) since 2005. I also accessed Document “125742 _S1_ M5_5351_ c4591001 interim mth6 randomization sensitive.pdf” from the May 2 release.This document is entitled “16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received - Subjects > and equal 16 Years of Age.” The document confirms this subject did receive 2 doses of BNT162b2 30 ug vaccine, not placebo. (p 3003) I also accessed Pfizer’s “A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY INDIVIDUALS” (cdn.pfizer.com.) which outlines protocols/procedures for the c4591001 clinical trials. Background The CRF lists three Adverse Events: 1. “injection site pain,” 2. “fatigue,” and 3. “STEMI” A STEMI is an “ST Elevation Myocardial Infarction.” The subject suffered a STEMI on November 8, 2020, 39 days after receiving his second vaccination. He required hospitalization. The STEMI occurred after Visit #3 and before Visit #4 was due to occur. According to the clevelandclinic.org website, a STEMI is described as follows: “Blockages in the arteries that supply blood flow to your heart muscle are what cause most heart attacks. Usually, the blockage happens because plaque, a fatty, waxy buildup accumulates on the inside of your arteries. A blood clot can form on the plaque deposits, rapidly closing the artery and interrupting blood flow to the heart muscle.”...“The key characteristic that identifies a STEMI is the ST –segment elevation, ST-segment elevation usually indicated a total blockage of the involved coronary artery and that the heart muscle is currently dying. Non-STEMI heat attacks usually involve an artery with partial blockage, which usually does not cause as much heart muscle damage.”...“Among heart attacks, STEMIS are typically more severe. Between 2.5% and 10% of people who have one die within 30 days.” On September 22, 2020, Tom Shimabukuro, MD, MPH, MBA CDC of the COVID-19 Vaccine Planning Unit (VPU) Vaccine Safety Team gave a presentation entitled “Enhanced safety monitoring for COVID-19 vaccines in early phase vaccination.” On a slide entitled “Preliminary list of VAERS AESIs,” “acute myocardial infarction” is listed. Although the VAERS would be the monitoring system utilized to identify adverse events once the vaccine rollout began under EUA, acute myocardial Infarction was already being identified as an adverse event of special interest (AESI)
7/5/2022 11:32:58	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1128-11281009-reissue.pdf	P5 et al	Various	Study Protocol	***SURELY people with multiple medical conditions should not be in trials - it is too easy to say any AE is unassociated with the product, but related to the participant's documented ill health.*** Trial participant 11281009, 68 years old, was listed as healthy: "determined by medical history, physical examination & clinical judgment of the investigator to be eligible for inclusion in the study". (P5) But he had: high blood pressure; a heart attack in 2017; high cholesterol; anxiety; bilateral hip pain; Type 2 diabetes; fluid retention; angina; restless leg syndrome; cough; Vitamin D deficiency; & tobacco dependency. He had also had a vasectomy - even if effect on sperm had been assessed, this man could have shed no light on the matter. He was injected on 31st July 2020, 19th August 2020. He appears to have died on 28th November 2020 after having a heart attack & pneumonia 27-28th October 2020. It was noted as a life-threatening event which was "Recovered/Resolved." (AE Number: 2020482043.) An odd entry on P301 says: "Death is entered as 28Nov2020. Please consider updating the date of visit to 28Nov2020 since the date entered (14Dec2020) could not be after the date of Death." The same page notes "cough & shortness of breath" should be added as AEs because he is listed as having a cough on 23Feb2021 - obviously impossible. P321 notes "site not notified of illness until after death". P332 notes "death was reported as 28Nov2020 in Safety database but 04Dec2020 in AE CRF. Please confirm correct date of death." P336 notes: "There is an event of Myocardial Infarction listed in Medical History that was from Jan2017 and ended Jan2017." And P340 says the death was "NOT RELATED" to the injections but was due to a failed cardiac stent. P344 adds "the event was covid pneumonia however site has no records that state covid so the term cannot be updated." Cause of death was noted as Pneumonia (unrelated to the injections.) (P360.)
7/5/2022 17:00:20	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	709	9	Adverse Effects - Other	ABNORMAL RBC MORPHOLOGY INCLUDING SICKLE CELLS
7/5/2022 17:10:42	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	729	8	Adverse Effects - Other	Lymphadenopathy/ Bilateral axillary adenopathy
7/5/2022 17:16:10	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	735	5	Adverse Effects - Other	Neutropenia
7/5/2022 17:49:23	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	739	4	Adverse Effects - Other	Subarachnoid haemorrhage/
7/5/2022 17:52:47	125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf	42	1	Adverse Effects - Other	Patient withdrew from study due to facial pain and paralysis after first dose of the vax. Narrative comment concluded: "In the opinion of the investigator, there was no reasonable possibility that the facial pain and facial swelling were related to the study intervention, but rather they were related to an allergic reaction to an unknown agent." How do they know if it's unrelated to the vax if the causative agent is unknown? To paraphrase, they seem to be saying "since we don't know what caused this, we know it wasn't our product".
7/5/2022 17:54:50	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	745	6	Adverse Effects - Reproductive Issues	INTRAMURAL AND SUBSEROUS LEIOMYOMA OF UTERUS
7/5/2022 17:57:32	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	749	2	Adverse Effects - Other	Lymph node pain/ Lymph node pain, under left arm
7/5/2022 19:18:22	125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf	124	1	Adverse Effects - Other	49 year old male with no cardiac history had heart attack 7 days after vax. Investigator concluded that "there was no reasonable possibility that the acute myocardial infarction was related to the study intervention, but rather it was related to undiagnosed obstructive coronary artery disease". No acknowledgement of the possibility that vax could have contributed to or exacerbated the obstruction . . . assuming that one actually existed prior to the man's being vaxxed.
7/6/2022 4:11:25	https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.5-Clinical-Overview.pdf	P119	Para 3	Efficacy	**FDA knew efficacy waned, in April 2020.** Not 100% sure about this - an immunologist would need to confirm - but the document notes: "For the majority of participants, the strong S-specific IFNg+ and IL-2+ CD8+ T cell responses and Th1 CD4+ T cell responses contracted by Day 43 (3 weeks after Dose 2), and plateaued at a lower level towards Day 85 (approximately 2 months after Dose 2). This observation held true for all dose groups analyzed, with varying response magnitudes between individuals." It seems their calculation here indicates that interferon, interleukin, CD8+ & T Cells were reduced 42 days after they were generated? That is, they were detected 3 weeks after Dose 2 - a day which they refer to as Day 43 - but waned to a "lower level" by Day 85.

7/6/2022 5:23:58	https://phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf	P9 & following	many	Adverse Effects - Other	Pfizer reports 93,473 of AEs up to 28 Feb 2021. They identify ANAPHYLAXIS as an Important Identified Risk & Vaccine-Associated Enhanced Disease is an Important Potential Risk. (They report 1,833 cases of Anaphylaxis.) The general public were not given this information before getting the injections. They report 317 'potential cases' of VAED: 38 people died & 65 cases were not resolved at the time of reporting. (P11.) Pfizer also reports Missing Information on Use in Pregnancy & Lactation and Missing Information on Vaccine Effectiveness. (I believe many reports have been filed on the content of this Post-marketing document.)
7/6/2022 13:21:32	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	84-3283	1	Adverse Effects - Other	I found #60 incidences of appendicitis listed as an AE or SAE (pages 84-3283). Of these, #10 occurred after vaccine dose 1, #48 occurred after dose 2, and #2 occurred after dose 3. None were coded as vaccine related and the cause of the AE was coded "O" (other) in all cases. Considering appendicitis in the US occurs in 1.1/1000 people, finding #60 cases in the vaccine study population seems significant.
7/6/2022 15:16:58	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf	3-6	noted in explanation section	Fatality	USA subject (C4591001 1007 10071101) [pg,3, para.1], a 56 yr. old white female w/ present sleep apnea (2013), present Gastroesophageal reflux disease (2018), past Gastric sleeve Gastrectomy (SEP2019), past Supraventricular tachycardia (08OCT2019) [pg.3, para.4]. Subject DIED 18 oct 20 [pg.3,para.4] 2 mos. after last dose; given BNT162b2 30 ug on 30Jul20 and 20 Aug 20 [pg.3, para 1]. Subject experienced cardiac arrest and went to ER and ICU; , a magnetic resonance imaging showed anoxic brain injury and possible herniation and an electroencephalogram showed absent brain activity. [pg.6, para 1] Pfizer data recorder noted this AE was NOT RELATED as it occurred 2 months after last study agent. [pg,3, para 3]
7/6/2022 15:22:22	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2430	16.2.7.4.1	Adverse Effects - Other	Pneumothorax, Pulmonary Embolism, Deep Vein Thrombosis Toxicity Grade 4,3
7/6/2022 15:23:55	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2430	16.2.7.4.1	Adverse Effects - Other	Cardiac Arrest, Tox grade 4
7/6/2022 15:25:26	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2430	16.2.7.4.1	Adverse Effects - Other	Cardiac arrest 0 Tox Grade 4 (23 Nov 2020)
7/6/2022 15:29:11	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2433	16.2.7.4.1	Adverse Effects - Other	Squamous cell carcinoma (25 Jan 2021)
7/6/2022 15:30:12	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2433	16.2.7.4.1	Adverse Effects - Other	Worsening of Type 2 Diabetes
7/6/2022 15:31:58	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2434	16.2.7.4.1	Adverse Effects - Other	Basal Cell Carcinoma (10 Sep 2020)
7/6/2022 15:33:52	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2435	16.2.7.4.1	Adverse Effects - Other	Worsening of hypertension (2 Dec 2020)
7/6/2022 15:35:43	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2436	16.2.7.4.1	Adverse Effects - Other	Haematemesis/Vomiting Blood TG3, 6 Mar 2021
7/6/2022 15:38:57	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2440	16.2.7.4.1	Adverse Effects - Other	Breast Cancer (11 Feb 2021)
7/6/2022 15:40:11	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2440	16.2.7.4.1	Adverse Effects - Other	Cerebrovascular accident/Stroke (2 Nov 2020)
7/6/2022 15:43:06	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf	7-10	noted in explanation section	Fatality	58 yr. old white USA male subject (C4591001 1066 10661350) administered first PLACEBO dose on 19OCT2020 [pg. 7, para 1]. Present conditions: drug hypersensitivity 1980; morphine allergy Drug hypersensitivity 1985; Anxiety 1990; GERD Gastrooesophageal reflux disease 2000;Hypertension 2000 ; Insomnia 2000; Hyponatraemia 2015; Cardiomyopathy/infarction; Past: Seizure 2015; Alcohol abuse 2018, L4-L5 laminotomy with diskectomy 2012; Spinal stenosis 2012. [pg.7, para 4], subject DIED FROM MYOCARDIAL INFARCTION 03 Nov 20 during sleep, ONE DAY AFTER RECEIVING PLACEBO DOSE. [pg. 10, para 1] Concomitant medications 2 weeks prior to the onset of myocardial infarction: omeprazole (Protonix) for gastroesophageal reflux disease, trazodone for insomnia, Depade and acamprosate calcium (Campral) for alcohol dependence , and levetiracetam (Keppra) for seizures. No autopsy. "In the opinion of the investigator, there was no reasonable possibility that the myocardial infarction was related to the study intervention, concomitant medication, or clinical trial procedures, but rather it was related to disease progression. Pfizer concurred . . "
7/6/2022 15:43:44	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2441	16.2.7.4.1	Adverse Effects - Other	Worsening of osteoarthritis, TG3
7/6/2022 15:44:40	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2442	16.2.7.4.1	Adverse Effects - myocarditis	Heart Palpitations
7/6/2022 15:46:04	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2442	16.2.7.4.1	Adverse Effects - myocarditis	Chest Pain/Dizziness
7/6/2022 15:51:45	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2453	16.2.7.4.1	Adverse Effects - Other	Syncopal Episode, TG3
7/6/2022 15:54:01	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2454	16.2.7.4.1	Adverse Effects - Other	Hypersensitivity pneumonitis
7/6/2022 15:55:01	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2454	16.2.7.4.1	Adverse Effects - Other	Atrial fibrillation
7/6/2022 15:56:43	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2459	16.2.7.4.1	Adverse Effects - Other	Hepatitis C antibody positive
7/6/2022 15:58:50	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2461	16.2.7.4.1	Adverse Effects - Other	Squamous cell carcinoma on scalp
7/6/2022 16:01:40	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2467	16.2.7.4.1	Adverse Effects - Other	Acute Myeloid Leukemia, TG3
7/6/2022 16:02:40	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2467	16.2.7.4.1	Adverse Effects - Other	Deep vein thrombosis
7/6/2022 16:04:31	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2469	16.2.7.4.1	Adverse Effects - Other	COVID-19 Infection, TG4 (after dose 2)
7/6/2022 16:05:54	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2469	16.2.7.4.1	Adverse Effects - Other	Acute Respiratory Failure, TG4 - Fatal
7/6/2022 16:07:29	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2469	16.2.7.4.1	Adverse Effects - Other	Covid-19, Fatality (after Dose 2) - Onset 12 Jan, died 13 Feb 2021)
7/6/2022 16:11:49	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2480	16.2.7.4.1	Adverse Effects - Other	Atrial Fibrillation
7/6/2022 16:13:20	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2480	16.2.7.4.1	Adverse Effects - Other	Acute kidney injury
7/6/2022 16:15:34	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2481	16.2.7.4.1	Adverse Effects - Other	Herpes Zoster
7/6/2022 16:17:03	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2481	16.2.7.4.1	Adverse Effects - Other	Lung adenocarcinoma, Metastases to lymph nodes

7/6/2022 16:19:54	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2487	16.2.7.4.1	Adverse Effects - Other	Hepatitis C
7/6/2022 16:24:12	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2496	16.2.7.4.1	Adverse Effects - Other	COPD exacerbation
7/6/2022 16:25:46	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2497	16.2.7.4.1	Adverse Effects - Other	Acute Ischemic stroke
7/6/2022 16:28:53	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2499	16.2.7.4.1	Adverse Effects - myocarditis	Hypertensive heart disease, Arteriosclerosis - FATALITY (18 Nov 2020)
7/6/2022 16:31:53	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2506	16.2.7.4.1	Adverse Effects - Other	Malignant melanoma,
7/6/2022 16:35:01	125742 S1 M5 5351 c4591001 interim mth6 adverse events.pdf	915, 3323 and 3350	multiple	Adverse Effects - Other	I found 3 instances of Psoriasis as an AE on pages 915, 3323 and 3350. Of interest, on page 915, psoriasis of subject C4591001-1134-11341151 was considered VAX RELATED but psoriasis of subject C4591001-1231-12312234 on page 3323 and subject C4591001-1231-12314401 on page 3350 was NOT. All three showed the AE after dose 2. Patient C4591001-1134-11341151 was in the 16-55 age group and the other two were in the >55 group. What criteria was used to determine cause of psoriasis?
7/6/2022 16:35:39	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2517	16.2.7.4.1	Adverse Effects - Other	Lung adenoidscarcinoma. Not resolved
7/6/2022 16:37:25	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2518	16.2.7.4.1	Adverse Effects - myocarditis	Chest Pain
7/6/2022 16:40:27	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2520	16.2.7.4.1	Adverse Effects - Other	Iron Deficiency Anemia, TG3
7/6/2022 16:42:08	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2522	16.2.7.4.1	Adverse Effects - Other	RESP - upper airway cough syndrome/post nasal drip
7/6/2022 16:48:31	125742 S1 M5 5351 c4591001 interim mth6 adverse events.pdf	96, 654, 3427, 3459, 3518	multiple	Adverse Effects - Other	I found 3 instances of Psoriatic Arthritis arthralgia/flare AE in the 16-55 age group and 2 in the >55 age group. Of the 3 in the 16-55 age group, 2 were listed as VAX RELATED (pg. 96, 654, 3518), and one had no entry in that column. Of the 2 in the >55 age group, one was listed as VAX RELATED (pg.3427, 3459) the other was not. What criteria were used to determine that the psoriatic arthritis arthralgia/flare was VAX induced?
7/6/2022 16:56:16	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2534	16.2.7.4.1	Adverse Effects - Other	
7/6/2022 16:58:14	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2540	16.2.7.4.1	Adverse Effects - Other	Syncope/Vagal Response
7/6/2022 17:00:05	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2544	16.2.7.4.1	Adverse Effects - myocarditis	CARD - Acute coronary syndrome
7/6/2022 17:06:59	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2560	16.2.7.4.1	Adverse Effects - Other	CARD - Atrial fibrillation
7/6/2022 17:08:56	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2562	16.2.7.4.1	Adverse Effects - myocarditis	aortic valve incompetence TG4
7/6/2022 17:10:15	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2562	16.2.7.4.1	Adverse Effects - Other	Subacute endocarditis/subacute bacterial endocarditis
7/6/2022 17:10:58	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2562	16.2.7.4.1	Adverse Effects - myocarditis	
7/6/2022 17:16:13	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2587	16.2.7.4.1	Adverse Effects - Other	Malignant melanoma
7/6/2022 17:19:03	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2590	16.2.7.4.1	Adverse Effects - myocarditis	CARD = Tachycardia
7/6/2022 17:20:43	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	766	7	Adverse Effects - Other	Syncope
7/6/2022 17:21:54	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2598	16.2.7.4.1	Adverse Effects - Other	REPRO - Testicular Pain
7/6/2022 17:24:57	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	773	1	Adverse Effects - Other	Vitamin D deficiency/
7/6/2022 17:26:15	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2614	16.2.7.4.1	Fatality	Myocardial infarction
7/6/2022 17:28:38	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2622	16.2.7.4.1	Adverse Effects - Other	Meningitis bacterial
7/6/2022 17:32:22	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	792	7	Adverse Effects - Other	Vulvovaginal candidiasis. There are a great number of people who had vaginal discharge and UTI's.
7/6/2022 17:44:21	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2640	16.2.7.4.1	Adverse Effects - myocarditis	Acute myocardial infarction, TG4; Coronary Artery Disease, Acute Chest Pain
7/6/2022 17:46:12	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2641	16.2.7.4.1	Adverse Effects - Other	Worsening hypertension
7/6/2022 17:47:45	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2642	16.2.7.4.1	Adverse Effects - Other	Cerebrovascular Accident (2 cases on this page), hypertension
7/6/2022 17:49:05	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2644	16.2.7.4.1	Adverse Effects - myocarditis	CARD - Atrial Fibrillation
7/6/2022 17:50:02	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2645	16.2.7.4.1	Adverse Effects - Other	Breast Cancer
7/6/2022 17:51:04	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2646	16.2.7.4.1	Adverse Effects - Other	Worsening of hypertension
7/6/2022 17:54:33	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2648	16.2.7.4.1	Adverse Effects - myocarditis	Atrial fibrillation
7/6/2022 17:57:13	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2654	16.2.7.4.1	Adverse Effects - Other	Prostate Cancer
7/6/2022 17:58:01	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2654	16.2.7.4.1	Adverse Effects - myocarditis	Atrial fibrillation
7/6/2022 17:59:26	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2655	16.2.7.4.1	Adverse Effects - myocarditis	Myocardial Infarction
7/6/2022 18:00:22	16.2.7.4.1	2655	16.2.7.4.1	Adverse Effects - myocarditis	Atrial Fibrillation
7/6/2022 18:02:11	16.2.7.4.1	2656	16.2.7.4.1	Adverse Effects - myocarditis	Atrioventricular block - Intermittent Complete Heart Block, also on this page Angina Pectoris & Non-cardiac chest pain
7/6/2022 18:03:23	16.2.7.4.1	2658	16.2.7.4.1	Adverse Effects - Other	
7/6/2022 18:04:04	16.2.7.4.1	2658	16.2.7.4.1	Adverse Effects - Other	Prostate Cancer
7/6/2022 18:05:02	16.2.7.4.1	2658	16.2.7.4.1	Adverse Effects - Other	Breast Cancer

7/6/2022 18:05:55	16.2.7.4.1		2658	16.2.7.4.1	Adverse Effects - myocarditis	Cardiac failure congestive
7/6/2022 18:07:17	16.2.7.4.1		2661	16.2.7.4.1	Adverse Effects - myocarditis	Atrial Fibrillation
7/6/2022 18:09:54	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)		2663	16.2.7.4.1	Adverse Effects - myocarditis	Atrial fibrillation
7/6/2022 18:11:02	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)		2664	16.2.7.4.1	Adverse Effects - Other	Prostate Cancer
7/6/2022 18:13:52	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)		2674	16.2.7.4.1	Adverse Effects - Reproductive Issues	Ovarian cyst; Uterine Prolapse
7/6/2022 18:15:16	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)		2678	16.2.7.4.1	Adverse Effects - myocarditis	Atrial Fibrillation
7/6/2022 18:16:38	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)		2680	16.2.7.4.1	Fatality	Multiple Organ Dysfunction Syndrome
7/6/2022 18:18:15	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)		2680	16.2.7.4.1	Fatality	Covid-19
7/6/2022 18:19:21	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)		2681	16.2.7.4.1	Adverse Effects - myocarditis	Acute Myocardial Infarction
7/6/2022 18:20:47	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)		2682	16.2.7.4.1	Adverse Effects - myocarditis	Myocardial Infarction; Congestive Heart Failure
7/6/2022 18:22:18	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)		2686	16.2.7.4.1	Adverse Effects - Other	Acute Toxic Metabolic Encephalopathy
7/6/2022 18:23:41	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)		2686	16.2.7.4.1	Adverse Effects - Other	New Onset Deep Vein Thrombosis
7/6/2022 18:28:29	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)		2687	16.2.7.4.1	Adverse Effects - myocarditis	Acute coronary syndrome; Unstable Angina
7/6/2022 18:30:24	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)		2691	16.2.7.4.1	Adverse Effects - Other	Squamous Cell Carcinoma, Malignant Melanoma
7/6/2022 18:32:05	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)		2694	16.2.7.4.1	Adverse Effects - myocarditis	Atrial Fibrillation; Congestive Heart Failure
7/6/2022 19:45:56	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf	13-16	noted in explanation section		Fatality	USA subject ID (C4591001 1081 10811194); , received 2 doses of PLACEBO on 10SEP2020 and 29SEP2020; DIED 01 Nov 2020; deemed Not related to dose/unknown cause of death; no prohibited concomittant meds. [pg.12, para 104]. Subject was 51 yr. old white female with hypothyroidism (1995); allergy to sulfa drugs and oral NSAIDS, chronic obstructive pulmonary disease and hypertension (both since 2015), attention deficit hyperactivity disorder (2017), osteoarthritis and postmenopause (both since 2018). When subject was a no-show for convalescent visit, family found her at home, deceased, apparently for 3 days. Subject spoke to family 3 days earlier; he'd taken a shower, was going to lay down due to stomach pains. No autopsy. Despite that, cause of death was unknown, Pfizer investigator opined the death was unrelated to the clinical trial. [pg. 13, para 3]. Subject was 42 yrs. old white female. Medical history: Present - Chronic sinusitis (2000), Seasonal allergy (2000), breast cancer 2001 w/lumpectomy left breast Breast conserving surgery (2001), Breast cancer (2017), lumpectomy left breast Breast conserving surgery (2017); [pg. 14, para 4]; Subject was given PLACEBO 26 Aug 2020; toxicity grade 4. Death determined to not related to study but form also notes "waiting on death certificate." [pg. 15] Autopsy performed but results pending at time of report. Day 7 after dose, subject had no AE, normal evening, went to bed and died during the night. "In the opinion of the investigator, there was no reasonable possibility that the death was related to the study intervention. The investigator further stated that although the full autopsy report was pending and determining cause of death at this time was essentially an educated guess, the subject had possible risk factors. She possibly had a thromboembolic event related to a history of breast cancer, or there was a potential toxicity related to the Essure permanent birth control device. Essure implant for permanent birth control was taken off the market in the United States by the Food and Drug Administration (FDA) in 2018. A brief review revealed almost 50,000 reports to the FDA regarding the device and approximately 50 deaths. Pfizer commented that there was not enough evidence to suggest a causal relationship between the study intervention and the subject's death." [pg. 16, para 3].
7/6/2022 20:01:08	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf	17-19	noted in explanation section		Fatality	DEATH of USA 60 yr. old male subject (C4591001 1162 11621327) in vax study group w/ BNT162b2 (30 µg).[pg. 17, para 1] Med Hist. Autoimmune thyroiditis 2010 Present, Obesity 2010 Present; traumatic brain injury Craniocerebral injury 2011, Depression 2011; Hip arthroplasty 2015, Corrective lens user 2017 [pg. 17, para 3] Dose given 10 Sep 20; 3 days after dose subject had AE- Atherosclertotic Disease and DEATH on 13 Sep 2020. No prohibited concomittant meds. [pg. 18, para 1-3].Concomitant medications reported within 2 weeks prior to the onset of arteriosclerosis included venlafaxine hydrochloride (from 2015) and aripiprazole (from 2011), both for depression. Police found deceased by conducting a welfare check. No autopsy results available. Pfizer investigator opined death unrelated to vaccine but due to underlying disease. Pfizer concurred. [pg. 19, para 2]
7/6/2022 23:00:37	125742_S1_M5_5351__C4591001 interim mth6labmeasurementssensitive.pdf	Page 9 as an example of all pages	page 9 as an example of all pages		Adverse Effects - Other	Using page 9 , FDA-CBER-2021-5683-0220593 Documented adverse event after first dose noted in both the Placebo group and BNT162b2 group. Is it possible, after reviewing similar adverse events symptoms, that the everyone got the same injection and just documented some individuals as being in the Placebo group? How is it possible that so many in the Placebo group had covid symptoms after the Dose 1 injection? How is it possible to have covid symptoms from a saline injection in the Placebo group? So, did both groups get the BNT162b2 injection?
7/6/2022 23:24:46	FDA-CBER-2021-5683-0220781	197/430 Example of all the pages	graph		Adverse Effects - Other	From 16.2.8.1 Listing of Subjects With First COVID-19 Occurrence After Dose 1 Visit 1 and 2 N-Binding Assay results mostly Negative in the Placebo group as well as BNT162b2 group. The Central or Local lab swab results generally come back Positive in both groups. Signs and symptoms, even in the Placebo group are: fever, chills, new or increased cough, muscle pain, loss of taste or smell are the main examples. How is it possible for the Placebo group who allegedly are injected with saline get these symptoms? Did everyone get the same BNT162b2 injection and no saline injection?
7/7/2022 1:45:01	16.2.7.2.1 Listing of Severe and Grade 4 Local reactions	17 and 18 of 3645		1	Other	FDA-CBER-2021-5683-0216742 and 48 Page 17 and 18 paragraph "Cutoff date: 13Mar 2021,Snapshot Date: 25Mar 2021, unblinded/c4591001 Does this mean everyone got the BNT162b2 injection and there was no longer a Placebo group? From 16.2.7.2.1 Listing of Severe and Grade 4 Local Reactions
7/7/2022 8:02:59	https://docs.google.com/forms/d/e/1FAIpQLSefx2Lh1cMQHbp-rIXG_Yr5mM1c9akRdXt9nRVANoFFXle1Sw/viewform	20-22	noted in explanation section		Fatality	DEATH of 61 yr. old Hispanic female from Argentina (subject ID C4591001 1231 12313972) with hist of arterial hypertension given 2 doses of PLACEBO on 25AUG2020 and 13SEP2020 [pg. 20. para 1-3], DIED from haemorrhagic stroke on 20 Sep 2020, fifteen days after 2nd shot; toxicity grade 4. [pg. 21, para 1-2]. On 27 Sep 2020 (Day 34), the subject complained of "severe headache and incoercible vomiting" and went to ER; placed on ventilator and pharmacological support (inotropics, unknown drugs and doses); moved to ICU; imaging showed subarachnoid hemorrhage, intraventricular hemorrhage, and right cerebral hemisphere hematoma (Fisher Scale 4). A brain angiography showed cerebral circulatory arrest, unable to establish location of aneurysm. Negative swab for SAR-COV-2. Subject had been on losartan (since 2017) for arterial hypertension. Investigator opined there was no reasonable possibility that the hemorrhagic stroke was related to the study intervention, concomitant medications, or clinical trial. Pfizer concurred. [pg. 22, para 2]

7/7/2022 8:38:50	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	851	6	Adverse Effects - Other	Cardio-respiratory arrest
7/7/2022 8:40:56	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf	23-26	specific paras noted in explanation	Adverse Effects - Other	Injury to 30 yr. old Asian USA female (ID C4591001 1015 10151047). [pg. 23, para 1] Subject had hist of migraines from 2018; given 2 does of BNT162b2 (30 ug) on 17 Aug 2020 and 09 Sep 2020. [pg. 23, para 3-4]. Subject had AE's: Right corneal irritation 17AUG2020 and shoulder injury related to Vax, which was "ongoing." on 09 sep 2020. In the AE chart, the doc notes that the AE shoulder injury was related to the study treatment. [pg. 24, para 2]. Doc does not indicate death; chart is unclear whether or not sububject was withdrawn from the trial study as it states vaccination on 07 Oct 2020 in column "withdrawal/completion date"; not same date as last vax. [pg.25, para 1] lengthly narrative; subject was on cetirizine hydrochloride for allergies for unknown period; experienced upper L arm pain and restricted range of motion (ROM) w/burning down the arm, initially w/tingling when typing. Examined 15 sep 20, continued limited ROM; subject referred to neurology when med issue suspected as related to vax. started phys therapy; underwent additional testing. 03 Nov 2020, subject completed 5 weeks phys therapy w/ significant improvement. Investigator opined likely shoulder injury related to vax. Pfizer concorred but also noted a report (source unstated) that vax was erroneously administered into or near the shoulder jount capsule; consistent with med literature re: unintentional injection into shoulder joint synovial tissues may result in an immune-mediated inflammatory reaction causing shoulder injury. Narrative does not explicitly state subject was withdrawn from study. [pg.26, para 1]
7/7/2022 11:10:02	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf	156-159	noted in the explanation	Adverse Effects - Other	38 yr old Amer. Indian or Alaskan subject (ID C4591001 1127 11271022); vaxed with BNT162b2 (30 µg) Med hist: Myopia 1988; Astigmatism 2014; Vitamin D Deficiency 2015; Depression JAN2016; Cholelithiasis JUN2016; Diffuse Cellulitis MAR2019; Trichomoniasis Jan 2020 [pg. 156, para 3] Vax given 30JUL2020; AE's joint pain, headache, flu like symptoms, SCHIZOPHRENIA (onset 24 Aug 2020), sinus infection. [pg. 157, para 3] SCHIZOPHRENIA deemed not related to study despite onset was 24 days after vax. [pg. 158, para 1]. Narrative comment opinion by investigator; no reasonable possibiliy that SCHIZOPHRENIA was related to study but rather to ongoing psych disease. Withdrawn from study by physician's decision. [pg. 159, para 1] Implication is that 24 days after vax, depression incredibly morphed into Schizophrenia.
7/7/2022 12:52:55	FDA-CBER-2021-5683-0221182 to 0221184	4/149 to 6/149	entire	Fatality	History of obesity, sleep apnea, and SVT BNT162b2 30 mcgs on 7/30/2020, second dose 8/2/2020. Had cardiac arrest on Oct 18 2020. Grade 4 Tox. Died on Oct 21, 2020. "In the opinion of the investigator, there was no reasonable possibility that the cardiac arrest was related to the study intervention or clinical trial procedure, as the death occurred 2 months after receiving Dose 2. Pfizer concurred with the investigators causality assessment." From page 6 of 149.
7/7/2022 13:34:05	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	708	5	Adverse Effects - Reproductive Issues	Abortion spontaneous
7/7/2022 14:20:46	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.pdf	2885, 2944, 2990, 3036, 3112, 3344, 3362, 3421	Tables	Fatality	These pages are under the title of "adverse events". All subjects are 55 years old or older. These events are labeled "not vaccine related" and the outcome is "F" fatal. This sounds serious to me, but I cannot tell by the information tabulated if it is actually likely that the event is vaccine related. The conditions listed under the heading "Preferred Term" are: Cardiac Arrest, Pneumonia, Aortic Stenosis, Cardiopulmonary arrest, Shigella sepsis, Hemorrhagic stroke, Covid-19, Septic shock, Covid 19 pneumonia. "Relative Day" or days after vaccination + 1 ranges from 15 (p 3344) to 117 (p 3036). A physician should be able to deduce more from the data
7/7/2022 14:44:56	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.pdf	2433, 2457, 2972, 3123, 3461 & 3462, 3465	Table	Adverse Effects - Other	p 2433 Urticaria, Rel Day = 1, not resolved; p2457 Chest pain, Rel Day = 2, not resolved; p2457 Myalgia and headache, Rel Day =2, not resolved; p2972 Dysgeusia, Parosmia, Rel Day = 3, not resolved; p3123 Erectile Dysfunction, Rel Day = 3, not resolved; p 3461 & 3462 Eczema, Pruritus, rash, Rel Day =16, not resolved; p3465, Rel Day = 2, Fatigue, Chills, Myalgia, headache, not resolved. My concern is that these adverse events are not resolved.
7/7/2022 14:47:40	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	1071	1	Adverse Effects - Reproductive Issues	Abortion spontaneous/
7/7/2022 16:19:17	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.pdf	3521 & 3522, 3523, 3524, 3525, 3526, 3527, 3530, 3532, 3534, 3535, 3538, 3544, 3546, 3548, 3549, 3550, 3559, 3560, 3562, 3563, 3565, 3566, 3567, 3569, 3570, 3671, 3574, 3575, 3577, 3579, 3591, 3594, 3595, 3596, 3597, 3601, 3602, 3606, 3612, 3616	Table	Adverse Effects - Other	Under "Severe" adverse events, those listed below are "not vaccine related", but some sound like they might be vax related. p3521-3522 Breast Cancer, Rei Day = 52; attempted suicide, not resolved; p 3522 breast cancer, Rel Day = 15, not resolved; p 3523 breast cancer, Rel Day = 71, not resolved; p 3544 Adenocarcinoma gastric, Rel Day = 23, not resolved; p3525 Myocardial Infarction, Rel Day = 37, Fatal; p 3526 Malignant melanoma, Rel Day = 63, not resolved; P 3527 Meningioma, Rel Day = 6, not resolved; p 3527 Psychosis, Rel Day = 34, not resolved; p 3530 Microcytic Anemia, Rel Day = 75, not resolved; p 3532 Lung cancer, Rel Day = 67, Fatal; p 3532 Cardio pulmonary arrest, Rel Day = 86, Fatal; p 3534 Anxiety, Major depression, suicide attempt, Rel Day = 21, not resolved; p 3535 B-cell lymphoma, Rel Day = 101, not resolved; p 3538 Breast Cancer, Rel Day = 90, not resolved; p 3544 diabetes mellitus, Rel Day = 68, not resolved; p 3544 Covid-19 pneumonia, Rel day = 72, Fatal; p 3546 Breast cancer, Rel Day = 70, not resolved; p 3548 metastases to central nervous system, Rel Day=9, not resolved; p 3549 Papillary thyroid cancer, Rel day=137, not resolved; p 3550 Clear cell renal carcinoma, Rel day = 32, not resolved; p 3559 Cardiac arrest, Rel Day=60, Fatal; p 3560 Prostate cancer, Rel day=7, not resolved; p 3560 breast cancer, Rel day = 3, not resolved; p 3562 Cardiac stress test abnormal, Rel day= 8, not resolved; p 3563 Liver cancer, Rel day= 36, Fatal; p 3565 Breast cancer, Rel day = 2, not resolved; p 3565 Covid 19 respiratory failure, Rel day= 103, Fatal; p 3566 hypertensive hear disease, Rel day= 71, Fatal; p 3567 Arteriosclerosis, Rel day= 71, Fatal; p 3567 Lung adenocarcinoma, Rel day= 145, not resolved; p 3569 malignant melanoma, Rel day= 53, not resolved; p 3570 Myocardial infarction, Rel day=16, Fatal; p 3571 Bilateral kidney stones, Rel day = 59, not resolved; P 3571 retinal occlusion, Rel day = 1, not resolved; p 3574, prostate cancer, Rel day= 43, not resolved; p 3574 breast cancer, Rel day=6, not resolved; p 3575 Emphysematous Cholecystitis, Rel day= 51, Fatal; P3575 multiple organ dysfunction, Covid 19 infection, Rel day = 72, Fatal; p 3577 Cardiac arrest, Rel day= 70, Fatal; p 3577 Metastases to lung, Rel day = 133, Fatal; p 3577 chronic obstructive pulmonary disease, Rel day = 70, Fatal; p 3579 Covid 19 pneumonia, Rel day= 61, Fatal; p 3591 Breast cancer, Rel day= 80, not resolved; p 3591 Oropharyngeal cancer, Rel day= 64, not resolved; P 3594 pulmonary embolism, aortic aneurysm, deep vein thrombosis, Rel day= 175, not resolved; p 3594 Breast cancer, Rel day= 76, not resolved; P 3595 Cardiac arrest, Rel day=26, Fatal; P 3596 Adrenal gland cancer, Rel day= 27, not resolved; P 3597 breast cancer, Rel day= 168, not resolved; P 3597 Thyroid cancer, Rel day=25, not resolved; P 3597 Cardiac arrest, Rel day= 117, Fatal; P 3597 Brain neoplasm, Rel day= 5, not resolved; P 3601 Shigella sepsis, Rel day=20, Fatal; P 3602 Arteriosclerosis, Rel day= 4, Fatal; P 3602 Aortic rupture, Rel day= 65, Fatal; p 3606 Adenocarcinoma, Rel day=36, not resolved; P 3612 Covid 19, Rel day=99, Fatal; P 3616 Covid 19 pneumonia, Rel day= 109, Fatal;

7/7/2022 17:00:49	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.pdf	1-75	see chart in explanation	Adverse Effects - Other	first 5 of 20 subjects in the first 75 pages of this doc who had prolonged AE-HEADACHES for more than 6 days after vax Subj. Dose# Date Days' duration Pg. in document C4591001 1006 10061040 #1 14Aug20 8 19 C4591001 1057 10571362 #1 30Oct20 7 24 C4591001 1071 10711039 #2 04Sep20 16 24 C4591001 1071 10711065 #2 09Sep20 9 24 C4591001 1079 10791039 #2 25Aug20 8 24
7/7/2022 17:56:36	125742_S1_M5_5351_c4591001-int...	1889	Listing in table	Adverse Effects - Reproductive Issues	AE listing for pregnancy exposure 10Sep2020, "R" (resolved?) on 14Sep2020: with next event "retained product of conception" starting 14Sep2020 and end date listed as "R", but no date. Is this a creative way to hide a baby that died in utero?
7/7/2022 18:07:07	125742_S1_M5_5351_c4591001-int...	1820, 1844, 1882, 1898, 1929, 1956	Listing of adverse events	Data Missing	Several listings (spread out, peppered through) for pregnancy exposure with a start date, but all list end date as UNK (unknown?)
7/7/2022 20:01:48	125742_S1_M5_5351_c4591001-interim-mnth6-adverse-events.pdf	1-75	see explanation	Adverse Effects - Other	2nd set of 5 subjects (20 total) in the first 75 pages of this doc who had prolonged AE-HEADACHES for more than 6 days after vax subj. Dose # Date Days' duration pg. in doc. C4591001 1079 10791115 #1 12Aug20 7 25 C4591001 1082 10821036 #1 04Aug20 8 25 C4591001 1090 10901043 #2 24Aug20 7 27 C4591001 1127 11271022 #1 30Jul20 17 32 C4591001 1140 11401045 #2 24Aug20 7 35
7/7/2022 20:15:02	125742_S1_M5_5351_c4591001-interim-mnth6-adverse-events.pdf	1-75	see explanation	Adverse Effects - Other	3rd set of 5 subjects (20 total) in the first 75 pages of this doc who had prolonged AE-HEADACHES for more than 6 days after vax Subj. Dose# Date Days' duration Pg. in document C4591001 1163 11631036 #2 25Aug20 7 39 C4591001 1205 12051079 #1 11Nov20 8 43 C4591001 1208 12081020 #1 01Nov20 10 44 C4591001 1213 12131037 #2 24Nov20 7 47 C4591001 1229 12291105 #2 26Oct20 9 52

7/7/2022 20:25:19	125742_S1_M5_5351_c4591001-interim-mnth6-adverse-events.pdf	1-75	see explanation	Adverse Effects - Other	4th set of 5 subjects (20 total) in the first 75 pages of this doc who had prolonged AE-HEADACHES for more than 6 days after vax Subj. Dose# Date Days' duration Pg. in document C4591001 1230 12301129 #1 05Oct20 8 53 C4591001 1231 12311179 #1 14Aug20 7 55 C4591001 1247 12471121 #1 30Sep20 7 61 C4591001 1007 10071127 #1 05Aug20 7 64 C4591001 1231 12311390 #1 15Aug20 8 75
7/8/2022 8:06:33	125742_S1_M5_5351_c4591001-interim-mnth6-adverse-events.pdf	26-75	noted in explanation section	Adverse Effects - Other	List of 17 vaxed subjects who experienced AE- FATIGUE for a duration of more than 8 days. (counting down along right side column "Dur days" for line numbers.) 15 days [pg.26, line 8] 10 days [pg.26, line 14] 17 days [pg.32, line 6] 14 days [[pg. 14 line 12] 10 days [pg.42, line 10] 12 days [pg.54, line 15] 5 days [pg. 59, line 5] 12 days [pg.60, line 10] 14 days [pg. 62, line 7] 29 days [pg. 63, line 6] 20 days [pg. 63, line 15] 17 days [pg. 69, line 5] 9 days [pg. 69, line 8] 9 days [pg. 70, line 2] 8 days [pg. 72, line 2] 9 days [pg. 75, line 7]
7/8/2022 11:02:38	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	1-18	Inport ID# 14,19, 21, 61(>21), 70, 80, 123, 311, 316, 340, 347, 352, 355, 360, 384, 387, 390, 434, 442, 449, 481, 493, 496, 520, 525, 533, 540 (>21), 566, 571, 574, 577, 580, 585, 613, 625	Adverse Effects - Other	The issue I noted was redness at injection site rated at 21 caliber units (cu) or greater which is the highest measurement in a lot of patients.
7/8/2022 12:02:22	interim-mth6-adverse-events.zip	143, 190, 272, 423, 446, 537	0	Adverse Effects - Other	On each page is a vaginal infection, in one case a vaginal lesion, all listed as NOT being related to the shot and having resolved. The lesion and one infection listed as grade 1 and all other grade 2 and one infection being less than 10 days one being 47.
7/8/2022 12:48:05	interim-mth6-adverse-events	78 x3, 80, 125, 159, 533, 580, 590, 99, 315, 543, 551, 552, 575, 292, 554, 562	0	Adverse Effects - myocarditis	On each page is a cardiac event. Tachycardia: 78 (3 times), 80, 125, 159, 553, 580, and 590. In each instance it is listed as grade 1 and related to the shot with the exceptions of: 125 (grade 2); 553 (grade 2 and listed as NOT related) and 590 (grade 2 and NOT related). Cardiac: 99-non related non cardiac chest pain grade 2; listed as SAE 543 - non related non cardiac chest pain grade 1 315 - non related congestive heart failure grade 4; fatal and withdrawn and listed as SAE Myocardial infarction: 551- listed twice and both as grade 4: one recovery with sequelae and the other fatal, NEITHER listed as related to the shot but both listed as an SAE 552 - also grade 4 and not related, recovered; listed as SAE 554- grade 1 and not related, recovered 575 - grade 2 not related, recovered; listed as SAE Atrial fibrilation: 292 - grade 2 not related, recovered; listed as SAE 554 - grade 3 not related, but 'P' was coded for "investigational product withdrawn" and listed as SAE 562 - grade 2 not related continuing symptoms; listed as SAE

7/8/2022 14:20:55	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2703	16.2.7.4.1	Adverse Effects - Other	worsening of hypertension
7/8/2022 14:23:16	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2706	16.2.7.4.1	Fatality	Cardiac arrest; coronary artery disease
7/8/2022 14:26:06	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2706	16.2.7.4.1	Fatality	Metastases to lung
7/8/2022 14:27:08	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2706	16.2.7.4.1	Adverse Effects - Other	COVID-19 - Unknown outcome, TG4
7/8/2022 14:28:20	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2706	16.2.7.4.1	Adverse Effects - Other	Retinal artery occlusion,
7/8/2022 14:29:34	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2706	16.2.7.4.1	Adverse Effects - Other	Metastatic pancreatic cancer, unresolved
7/8/2022 14:31:04	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2708	16.2.7.4.1	Fatality	Chronic obstructive pulmonary disease
7/8/2022 14:31:55	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2708	16.2.7.4.1	Fatality	Dementia Alzheimer's type
7/8/2022 14:33:33	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2709	16.2.7.4.1	Adverse Effects - Other	Cystitis, Kidney infection, nephrolithiasis in both kidneys
7/8/2022 14:34:23	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2709	16.2.7.4.1	Adverse Effects - myocarditis	Atrial fibrillation, TG3
7/8/2022 14:36:44	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2721	16.2.7.4.1	Adverse Effects - Other	Anaphylactic shock - TG4
7/8/2022 14:41:18	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2751	16.2.7.4.1	Adverse Effects - myocarditis	Atrial fibrillation
7/8/2022 14:42:29	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2753	16.2.7.4.1	Adverse Effects - Other	Dermatitis - Rash from neck to knees
7/8/2022 14:43:22	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2754	16.2.7.4.1	Adverse Effects - myocarditis	Atrial fibrillation
7/8/2022 14:47:48	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2759	16.2.7.4.1	Adverse Effects - Other	Same case - UTI, Vertigo, Nausea, + Blood pressure, hypokalemia, STROKE (TIA)
7/8/2022 14:58:22	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2772	16.2.7.4.1	Adverse Effects - Other	Deep vein thrombosis
7/8/2022 15:00:49	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2773	16.2.7.4.1	Adverse Effects - myocarditis	Palpitations
7/8/2022 15:01:37	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2773	16.2.7.4.1	Adverse Effects - Other	Pulmonary embolism
7/8/2022 15:02:51	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2773	16.2.7.4.1	COVID Testing	Tested positive
7/8/2022 15:03:29	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2773	16.2.7.4.1	COVID Testing	Tested positive
7/8/2022 15:05:33	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2774	16.2.7.4.1	Adverse Effects - myocarditis	Severe chest pain
7/8/2022 15:07:06	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2774	16.2.7.4.1	COVID Testing	Positive test
7/8/2022 15:08:57	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2774	16.2.7.4.1	Adverse Effects - Other	Breast Cancer
7/8/2022 15:13:40	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2775	16.2.7.4.1	Adverse Effects - Other	Dysphemia/stutter
7/8/2022 15:15:31	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2776	16.2.7.4.1	Adverse Effects - myocarditis	Palpitations
7/8/2022 15:16:44	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2776	16.2.7.4.1	Fatality	COVID-19 Infection/Pneumonia/Acute Respiratory Failure
7/8/2022 15:18:01	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2777	16.2.7.4.1	COVID Testing	Positive test
7/8/2022 15:21:48	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2780	16.2.7.4.1	Adverse Effects - Other	Pulmonary embolism

7/8/2022 15:23:53	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip	2780	16.2.7.4.1	Adverse Effects - myocarditis	Tachyarrhythmia/dizziness
7/8/2022 15:26:56	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip	2783	16.2.7.4.1	Adverse Effects - Other	Cardiac Arrest, TG4
7/8/2022 15:28:52	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip	2785	16.2.7.4.1	Adverse Effects - Other	Bladder Cancer
7/8/2022 15:30:10	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip	2788	16.2.7.4.1	Adverse Effects - Other	Pneumonia
7/8/2022 15:31:17	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip	2789	16.2.7.4.1	Adverse Effects - Other	Metastatic prostate Cancer
7/8/2022 15:34:35	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip	2796	16.2.7.4.1	Adverse Effects - Other	Pneumonia/Acute Respiratory Failure, Acute myocardial infarction, coronary artery disease, arteriospasm coronary, coronary blood stasis
7/8/2022 15:37:44	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip	2805	16.2.7.4.1	Adverse Effects - Other	Pneumonia TG 3
7/8/2022 15:40:04	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip	2806	16.2.7.4.1	Adverse Effects - myocarditis	Tachycardia at rest
7/8/2022 15:40:36	125742_S1_M5_5351_c4591001-interim-mth6-lab-measurements-sensitive.pdf (phmpt.org)	1-224	noted in explanation section	Other	16.2.8.1 Listing of Subjects With First COVID-19 Occurrence After Dose 1 – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population. This section of the 430 pg. doc runs from pg. 1-224. Rough count of vaxed subjects who got Covid were 141 persons (11 -from Germany, 31-Argentina, 14-Brazil, 3-Turkey, 82-USA). The date of the first dose is not provided in this chart. Observation: There are many, many times over, more Placebo covid subjects in the data as compared to the vaxed covid subjects. Thoughts: 1) The grossly uneven numbers of vaxed covid subjects to placebo covid subjects ought to skew the overall structure and analysis of comparative study badly. 2) The important numbers are the "Rel Day" column in the middle from left to right. That indicates the number of days since the first dose when the subject developed Covid. 3) If a statistician calculated an average number of relative days for the placebo covid subjects and compared it to the average days before covid onset for the vaxed covid subjects, it may show a much longer or shorter time for one of the groups. Pfizer would definitely have an interest in data which showed a longer time before covid onset among the vaxed subject group.
7/8/2022 15:40:44	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip	2806	16.2.7.4.1	Fatality	Septic shock
7/8/2022 15:41:30	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip	2806	16.2.7.4.1	Adverse Effects - myocarditis	Acute myocardial infarction, TG3
7/8/2022 15:42:58	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip	2807	16.2.7.4.1	Adverse Effects - Other	STROKE, TG3
7/8/2022 15:44:14	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip	2808	16.2.7.4.1	Adverse Effects - Other	Acute kidney injury, TG3
7/8/2022 15:45:09	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip	2808	16.2.7.4.1	Adverse Effects - Other	Cardiac failure congestive/congestive heart failure
7/8/2022 15:46:15	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip	2809	16.2.7.4.1	Adverse Effects - myocarditis	New onset persistent Atrial Fibrillation
7/8/2022 15:46:59	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip	2809	16.2.7.4.1	Adverse Effects - Other	Bacterial sepsis
7/8/2022 15:48:43	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip	2811	16.2.7.4.1	Adverse Effects - Other	Angina Unstable, cardiac failure congestive, chest pain, pneumonia, dizziness, COPD
7/8/2022 15:50:04	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip	2816	16.2.7.4.1	Adverse Effects - Other	Basal Cell Carcinoma
7/8/2022 15:51:32	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip	2821	16.2.7.4.1	Adverse Effects - Other	Covid-19 Pneumonia, TG4
7/8/2022 15:52:43	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip	2822	16.2.7.4.1	Adverse Effects - Other	Malignant Melanoma, TG4
7/8/2022 15:54:08	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip	2824	16.2.7.4.1	Adverse Effects - Other	Deep Vein Thrombosis, TG4
7/8/2022 15:55:26	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip	2825	16.2.7.4.1	Adverse Effects - Other	Cerebrovascular accident/STROKE
7/8/2022 15:56:20	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip	2826	16.2.7.4.1	Adverse Effects - Other	Acute appendicitis with necrosis, TG4
7/8/2022 15:57:41	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip	2829	16.2.7.4.1	Adverse Effects - Other	Deep vein thrombosis
7/8/2022 15:58:57	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip	2831	16.2.7.4.1	Adverse Effects - Other	Exacerbation of COPD, TG3

7/8/2022 16:00:44	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2832	16.2.7.4.1	Adverse Effects - Other	Uncontrolled Diabetes Mellitus Type 2
7/8/2022 16:02:24	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2837	16.2.7.4.1	Adverse Effects - Other	Chest Pain
7/8/2022 16:03:40	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2838	16.2.7.4.1	Adverse Effects - Other	Transient Ischemic Attack - TIA
7/8/2022 16:06:51	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2845	16.2.7.4.1	Adverse Effects - Other	Acute kidney injury, acute respiratory failure, lung cancer, clostridium difficile infection
7/8/2022 16:08:25	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2847	16.2.7.4.1	Adverse Effects - Other	Pulmonary embolism, occlusive thrombosis
7/8/2022 16:09:21	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2848	16.2.7.4.1	Adverse Effects - Other	Malignant melanoma
7/8/2022 16:11:06	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2852	16.2.7.4.1	Adverse Effects - Other	Basal cell carcinoma
7/8/2022 16:11:37	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2852	16.2.7.4.1	Adverse Effects - myocarditis	Chest pain
7/8/2022 16:12:25	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2853	16.2.7.4.1	Adverse Effects - Other	Acute Pancreatitis
7/8/2022 16:13:30	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2855	16.2.7.4.1	Adverse Effects - myocarditis	Tachycardia
7/8/2022 16:14:51	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2861	16.2.7.4.1	Adverse Effects - myocarditis	Ventricular tachycardia
7/8/2022 16:15:52	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2862	16.2.7.4.1	Adverse Effects - Other	Pulmonary embolism
7/8/2022 16:16:37	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2862	16.2.7.4.1	Fatality	Sudden cardiac death
7/8/2022 16:17:39	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2863	16.2.7.4.1	Adverse Effects - myocarditis	Chest pain
7/8/2022 16:19:42	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2871	16.2.7.4.1	Adverse Effects - Other	Pulmonary Embolism/blood clots in upper right lobe
7/8/2022 16:25:33	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2876	16.2.7.4.1	Adverse Effects - myocarditis	Atrial fibrillation
7/8/2022 16:26:30	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2877	16.2.7.4.1	Adverse Effects - Other	Myocardial Infarction, TG3
7/8/2022 16:27:33	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2877	16.2.7.4.1	Adverse Effects - Other	Cardiac Failure, Congestive
7/8/2022 16:28:33	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2878	16.2.7.4.1	Adverse Effects - Other	Basal cell carcinoma
7/8/2022 16:29:49	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2880	16.2.7.4.1	Adverse Effects - Other	Pulmonary Embolism, Deep Vein Thrombosis
7/8/2022 16:32:37	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2882	16.2.7.4.1	Adverse Effects - Other	Angina pectoris/cardiac chest pain
7/8/2022 16:33:42	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2884	16.2.7.4.1	Adverse Effects - Other	Idiopathic acute pancreatitis
7/8/2022 16:34:26	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2884	16.2.7.4.1	Adverse Effects - Other	Squamous cell carcinoma
7/8/2022 16:35:31	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2885	16.2.7.4.1	Fatality	Cardiac arrest
7/8/2022 16:36:14	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2886	16.2.7.4.1	Adverse Effects - Other	Breast Cancer
7/8/2022 16:37:35	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2890	16.2.7.4.1	Adverse Effects - Other	Worsening of pancreatitis
7/8/2022 16:38:10	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2890	16.2.7.4.1	Adverse Effects - Other	Basal Cell Carcinoma
7/8/2022 16:39:06	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910-01-interim-mth6-adverse-events.zip	2891	16.2.7.4.1	Adverse Effects - Other	Pancreatic carcinoma, TG4

7/8/2022 16:41:07	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910 01-interim-mth6-adverse-events.zip	2900	16.2.7.4.1	Adverse Effects - Other	Deep vein thrombosis
7/8/2022 16:42:13	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910 01-interim-mth6-adverse-events.zip	2904	16.2.7.4.1	Adverse Effects - Other	Lyme disease
7/8/2022 16:43:46	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910 01-interim-mth6-adverse-events.zip	2912	16.2.7.4.1	Adverse Effects - myocarditis	Atrial fibrillation
7/8/2022 16:45:41	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910 01-interim-mth6-adverse-events.zip	2919	16.2.7.4.1	Adverse Effects - Other	Basal cell carcinoma
7/8/2022 16:49:36	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910 01-interim-mth6-adverse-events.zip	2943	16.2.7.4.1	Adverse Effects - Other	Basal cell carcinoma
7/8/2022 16:50:56	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910 01-interim-mth6-adverse-events.zip	294416.2.7.4.1	16.2.7.4.1	Fatality	Myocardial infarction/Pneumonia
7/8/2022 16:52:12	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910 01-interim-mth6-adverse-events.zip	2947	16.2.7.4.1	Adverse Effects - Other	Worsening of Coronary Artery Disease
7/8/2022 16:53:04	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910 01-interim-mth6-adverse-events.zip	2947	16.2.7.4.1	Adverse Effects - Other	Recurrence of Oropharyngeal Cancer, TG3
7/8/2022 16:54:28	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910 01-interim-mth6-adverse-events.zip	2952	16.2.7.4.1	Adverse Effects - Other	Breast Cancer
7/8/2022 16:55:16	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910 01-interim-mth6-adverse-events.zip	2953	16.2.7.4.1	Adverse Effects - Other	Squamous Cell Carcinoma
7/8/2022 16:57:38	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910 01-interim-mth6-adverse-events.zip	2963	16.2.7.4.1	Adverse Effects - Other	Squamous cell carcinoma, metastatic
7/8/2022 16:58:51	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910 01-interim-mth6-adverse-events.zip	2966	16.2.7.4.1	Adverse Effects - Other	Basal cell carcinoma
7/8/2022 17:00:01	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910 01-interim-mth6-adverse-events.zip	2968	16.2.7.4.1	Adverse Effects - Other	Sepsis
7/8/2022 17:01:52	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910 01-interim-mth6-adverse-events.zip	2976	16.2.7.4.1	Adverse Effects - Other	Worsening of rectal cancer
7/8/2022 17:02:57	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910 01-interim-mth6-adverse-events.zip	2978	16.2.7.4.1	Adverse Effects - Other	Transient Ischemic attack/TIA
7/8/2022 17:05:41	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910 01-interim-mth6-adverse-events.zip	2988	16.2.7.4.1	Adverse Effects - Other	Basal cell carcinoma
7/8/2022 17:06:36	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910 01-interim-mth6-adverse-events.zip	2988	16.2.7.4.1	Adverse Effects - Other	Atrioventricular block complete; cardiomegaly
7/8/2022 17:07:35	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910 01-interim-mth6-adverse-events.zip	2990	16.2.7.4.1	Fatality	Cardio-respiratory arrest
7/8/2022 17:09:15	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910 01-interim-mth6-adverse-events.zip	2997	16.2.7.4.1	Adverse Effects - Other	Acute pancreatitis
7/8/2022 17:11:26	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910 01-interim-mth6-adverse-events.zip	3007	16.2.7.4.1	Adverse Effects - Other	Worsening coronary artery disease & hypertension
7/8/2022 17:13:22	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910 01-interim-mth6-adverse-events.zip	3017	16.2.7.4.1	Fatality	Suicide
7/8/2022 17:16:04	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910 01-interim-mth6-adverse-events.zip	3023	16.2.7.4.1	Adverse Effects - myocarditis	Atrial Fibrillation
7/8/2022 17:16:51	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910 01-interim-mth6-adverse-events.zip	3023	16.2.7.4.1	Adverse Effects - Other	Lung Cancer Stave IV, Atrial fibrillation
7/8/2022 17:17:33	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910 01-interim-mth6-adverse-events.zip	3023	16.2.7.4.1	Adverse Effects - Other	Prostate Cancer
7/8/2022 17:19:36	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910 01-interim-mth6-adverse-events.zip	3031	16.2.7.4.1	Fatality	Cardiac arrest
7/8/2022 17:20:30	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910 01-interim-mth6-adverse-events.zip	3032	16.2.7.4.1	Adverse Effects - Other	Breast Cancer
7/8/2022 17:21:40	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c45910 01-interim-mth6-adverse-events.zip	3033	16.2.7.4.1	Adverse Effects - Other	Coronary artery dissection TG4

7/8/2022 17:54:57	125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf 125742_S1_M5_CRF_c4591001-1008-10081184	1654	case #10081184	Adverse Effects - Other	Male, 62, had had elevated PSA since 20019. He was diagnosed with prostate cancer after 2nd placebo shot. However, it wasn't clear from the medical history if PSA elevation was due to benign hyperplasia or stable malignancy (p.7,CRF). The subject was supposed to be unblinded and withdrawn from the trial due to SAE. However, he was administered the flu vaccine on October19,2020 (p. 39,CRF) within 20 days after his cancer diagnosis (p.35,CRF). It is unknown if the subject received any therapy for his cancer. Furthermore, he was unblinded in January and received two vaccines shots on January 13,2021 and February 4, 2021 (pp.60,66, CRF) .Within 19 days after his 2nd shot he had started the radiation therapy for his cancer(p.44,CRF). Also it wasn't clear from the CRF if the radiation therapy was planned or due to cancer worsening .The outcome of the case is unknown.
7/8/2022 18:55:51	125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf 125742_S1_M5_CRF_c4591001-1009-10091135	1666	case #10091135	Adverse Effects - Other	Female,63 years old, was diagnosed with breast cancer within 3 days after her 1st placebo shot. Her medical history indicates that she has MTHFR- gene mutation (p.8,CRF). This mutation can cause many conditions, including anxiety, depression, food and drug intolerance (pp.8-9, CRF). Also people that carry MTHFR mutation are in a high risk group of developing cancer (https://doi.org/10.1186/bcr2462). It is unclear from the medical history when the subject was diagnosed with this mutation. In addition, on September 2,2020 she was diagnosed with two conditions at the same time (Right Breast Ductal Carcinoma and Right Breast Lump) which is impossible due to length of pathology diagnosis. Based on the fact that the pathology diagnosis was known on September 2,2020 , I would suggest that her right breast lump was found at least a week earlier, before her 1st shot. In other words, she was enrolled in the trial having a mass suspicious for malignancy. In spite of the fact, that the breast cancer is considered a severe adverse reaction, the subject wasn't withdrawn from the trial and proceeded with the 2nd shot (p.255, 125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive(1)). It seems to me that the subject knew that she will receive the placebo. She was formally unblinded on February, 25,2020 (p.93, CRF).
7/8/2022 19:50:35	125742_S1_M5_CRF_c4591001-1003-10031065.pdf	108-111 and 394-398	in the form	Adverse Effects - Other	Vaccination of white female, birthdate 6/1968, 52. Vaccination 6/24/20, 7/15/20. 7/20/2020 Pt. Report: mild fever of (100.4 -101.1 degree F), mild pain at injection site, severe fatigue and moderate headache. PI determined no site visit is clinically needed. Adverse event reports 7/29/20: Adverse event 1 - right arm pain, rated not serious, not considered related to study treatment, cause unknown, not resolved. Adverse event 2 - ongoing neuritis right arm, rated serious, resulting in persistent or significant disability/incapacity. First recorded as related, then unrelated, to study treatment. 3rd vaccination 3/3/21.
7/8/2022 21:23:45	125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf	621	1	Adverse Effects - Other	The lady got an Undiagnosed Mental Disorder. In another document which group 2 was given to read, 66 in the 600 pages, people came down with mental disorders.
7/8/2022 22:34:21	125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive	various	Compound: PF-07302048; Protocol: C4591001 Page 1 of 149	Study Protocol	16 subjects from site 4444 listed in the 125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf document (https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf#page=3612) . There is not a site 4444 listed in the comprehensive list of all clinical sites https://phmpt.org/wp-content/uploads/2021/11/5.2-listing-of-clinical-sites-and-cvs-pages-1-41.pdf#page=2 Wouldn't it be FRAUD to list poor COVID outcomes from sites that don't exist on paper officially? Site 4444 is said to be in Argentina.
7/9/2022 0:39:37	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events	various	16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age	Study Protocol	377 subjects listed with adverse events at site 4444 in the subject document. There is no site 4444 listed site in the following document. This is data fraud. https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf#page=3612
7/9/2022 12:46:00	https://www.phmpt.org/wp-content/uploads/2022/07/125742_S1_M5_5351_c4591001-interim-mth6-lab-measurements-sensitive.pdf	226-416	noted in explanation section	Data Missing	Section of this doc is designated 16.2.8.2 [pg. 226-416 of the total 430 pgs] Section lists subjects with 1st Covid Occurring from 7 days after Dose #2. It id not take out any subject who showed evidence of infection prior to 7 days after Dose #2. In other words, some subjects may have developoed Covid within the first week after Dose #2 or earlier but Pfizer did not record that. The data is charted in colums [L to R, subj.country/age/sex; Vax group; Dose # and relative days from dose to Covid symtoms; Start and Stop date of symptoms, a colulm of physical symptoms and 2 more columns of test results 9N-binding Assay and SARS-CoV-2 NAAT] By my quick count, there were 867 placebo subjects who developed Covid, and 109 vaxed subjects who developed Covid. Also, if my first count is right, the vaxed Covid subjects were overwhelmingly from the US (82, 11 from Brazil and 16 from Argentina). What is absent from the way this data is reported is whether the vaxed subjects previoulsy develped Covid after Dose #1 or within 1st 7 days of Dose#2. The vaxed covid subjects could well be on their 2nd or higher round of Covid. The data leaves the impression that the placebo/un-vaxed group got Covid in significant higher numbers, so a sloppy analyst might say the vax data shows it protects from covid. However, without the study beginning with a close to equal number of vaxed and placebo subjects (which we do not have), the narrowly reported results here can be very misleading. Thus, the data reported as-is is inherently subject to question. We know Pfizer allowed many of the placebo subjects to leave that group and get vaccinated early on and this may well have permanently skewed the entire study. Are the vaxed covid subjects really comparable to the placebo covid subjects in a proper scientific study structure? We do not know but there is reason to think it is not so. Here, vaxed subjects might have already gotten covid and have gotten it again but that info is not provided. If Pfizer asserts this evidence shows the vax works, it may be challenged readily because more info may either be inconclusive or show exactly the opposite. A statistician could calculate the average number of relative days for the placebo group to have developed Covid and compare it to the vaxed covid group. The same probable incongruity might be present. The column itemizing symptoms seems almost irrelevant to me for the focus of this listing.
7/9/2022 13:47:43	125742_S1_M5_5351_c4591001 interim mth6 excluded patients sensitive.pdf	1-198	all	Other	I counted the number of patients excluded by site number (broken out into vaccine dose and placebo).

7/9/2022 18:02:47	125742_S1_M5_5351_c4591001 interim mth6 lab measurements sensitive.pdf	Page 216-430	General review and comments	Adverse Effects - Other	the placebo group. The symptoms, across test centers and countries are remarkably consistent. The ratio among test centers and countries appears to be similar (I didn't count). In short there are too similar in outcomes. 125742_S1_M5_5351_c4591001 interim mth6 lab measurements sensitive.pdf (pages 216-430) Page 216 .pdf 1. Everyone is in the placebo group. All have COVID symptoms (increased cough, shortness of breath, short of breath, chills, sore throat, AND loss of taste) suggesting they may have caught COVID between the beginning of the trail and after the first placebo. 2. Or that something is terribly wrong with the placebo testing. 3. Most, all but three are placebo AEs or testing positive. 4. There are no Serious Adverse Events, not one. The same symptoms after dose 2. 5. The ages are younger and include teenagers. 6. The symptoms are too consistent, all are similar to #1 above. There aren't any outliers symptoms or AEs, even if they aren't severe per #4 above. 7. All of these are in the fall of 2020, well before Omicron. 8. Almost all of dose two are placebo cases. 9. The stop date of all symptoms is around a week to ten days. Serious Adverse Events would appears immediately or well after they closed the review. 10. There are substantially more adverse reactions after the second dose. 11. So all of these placebo folks tested positive between dose 1 and 2 with mild symptoms which supports the need for more vaccines? 12. I didn't count but the increase in placebo infections between dose 1 and dose has got to be >30 to 1. 13. Any almost none from the vaccinated group had symptoms? 14. Why the seven-day windows for measurement? There is no way to pick up a longer term adverse event. You would think that is what they should be primarily concerned about. 15. The vaccinated show only one or two symptoms. The placebo generally show four or some (which are all the same few symptoms). Wouldn't they show the same consistency in symptoms is the have the virus? With or without the vaccine? Especially early? 16. The Brazil and Argentina "signs and symptoms" are exactly like the U.S. ones. Wouldn't there be some diversity in reporting among different countries? 17. Per my note above the vaccinated "signs and symptoms" are also similar in that there are only one (typical) and maybe two, but never more. 18. Per my note above, the ratio of vaccinated to placebo is similar (rough eyeball), in BR and AG to the US. 19. 16.2.8.3 severe listing begins on page 417 out of 430. 20. Low oxygen or high flow oxygen therapy or hospitalized due to COVID (not the vaccine) or admission without comment to the ICE. Per CDC or protocol definitions – notice how vague they are. Wouldn't one want to get specific with a severe event? 21. All are over forty, most over fifty years old. No teenagers. 22. Oddly most are placebo patients?
7/9/2022 21:45:14	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf	619	2	Adverse Effects - Other	The person developed type 2 diabetes with out having any pre conditions
7/9/2022 21:48:37	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf	622	2	Adverse Effects - Other	The person developed a mental disorder. Pfizer did not agree with the investigator that it wasn't the jab.
7/9/2022 21:53:42	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf	629	2	Adverse Effects - Other	The person developed a bleed under the skull. Pfizer did not agree with the investigator that it wasn't the jab
7/10/2022 0:31:58	125742_S2_M5_5354_wi235284-protocol.pdf	9	4th para on the page	Adverse Effects - Reproductive Issues	The Advisory Committee on Immunization Practices (ACIP) noted that "potential risks of mRNA vaccines to the pregnant person and the fetus are unknown because these vaccines have not been studied in pregnant people." They advised that "If pregnant people are part of a group that is recommended to receive a COVID-19 vaccine (e.g., healthcarepersonnel), they may choose to be vaccinated." This passage states clearly they don't know what this will do to pregnant people. This document is dated March 2021. The OBGYN medical societies started recommending the vaccine to pregnant people in July 2021. Where is the data to say it's safe? They wanted the data about antibodies from the cord blood.
7/10/2022 11:29:27	125742_S1_M5_CRF_c4591001 1007 10071443.pdf	133-140, 55-56, 154	p 136: 1 & 3, p 56: 1	Adverse Effects - Other	grand mal seizure Subject ID 10071443 white female, 17, birthdate 2003 vax1 11/4/20, vax2 11/25/20, vax3 2/24/21 pp 133-140 Adverse Event: Grand Mal Seizure 12/1/20; some debate on whether the event was serious (she was not hospitalized) and whether it was related to the study treatment. Mother denies any history of seizure. p55 12/25/20 unscheduled contact on Christmas? p56 says vax1 and vax2 were placebos. Treatment unblinded 2/10/21 to assess eligibility for additional vaccination. p154 vax3 2/24/2021
7/10/2022 13:58:26	https://www.phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1008-10081056.pdf	40, 138, 147	p40 para 1 & 3, p138 para 1, p147 para 1	Adverse Effects - Other	shortness of breath, deemed serious, deemed not related to study treatment white male birthdate 1959 age 61 vax1 8/18/20 p114 vax2 9/8/20 p122 blinded therapy vax3 1/20/21 p65 vax4 2/10/21 p71 p35 adverse event report adverse event 1: injection site pain 1/20/21, end 1/24/21 - not serious, related to study treatment, recovered p40 adverse event 2: 3/?/2021 shortness of breath, serious, required hospitalization, not related to study treatment, med given, resolved, did not cause subject to be discontinued from study paragraph 1, 3 p66 treatment unblinded: 1/5/21 p78 further vaccination - open label treatment 3/10/21 p138, paragraph 1: 3/11/21 per protocol, shortness of breath symptom should have triggered potential COVID illness visit, please complete forms p141 paragraph 1 & 2 adverse event serious, required hospitalization p143 paragraph 1 due to "other, unknown"; paragraph 2 deemed not related to study treatment p147 paragraph 1 1/7/21 participant is willing to return for vax3, eligible, confirmed to have received only placebo at vax1, vax2

7/10/2022 14:31:54	125742_S1_M5_CRF_c4591001-1008-10081184.pdf	7, 35, 36, 53	p7 para 1.c, p35 para 3 & 7, p36 para 9 & 13, p53 para 1	Adverse Effects - Other	prostate cancer, not considered related to study treatment white male birthdate 1958, age 62 p7 general medical history includes elevated PSA para 1.c vax1 9/3/20 p12 vax2 9/24/20 p17 vax3 1/13/2021 p54 vax4 2/4/2021 p66 p35 adverse event report 9/30/20 - prostate cancer paragraph 3; medically important serious event paragraph 7 p36 paragraph 9: not related to study treatment; paragraph 13: not resolved p44 radiation treatment 2/22/2021 paragraph 4 p52 1/11/21 paragraph 1 - potential re-vax p53 1/11/21 paragraph 1 - participation is willing to return for vax3; eligible and confirmed to have received only placebo at vax1 and vax2
7/10/2022 19:41:25	125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf	10	case# 10661350	Adverse Effects - Other	Male,58 , died after 1st placebo shot. However, he is not listed in the adverse events-all subjects (pp.1813-1814, 125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf). In addition, his medical history includes hypertension, myocardial infarction, and cardiomyopathy. However, the narrative doesn't describe any medications for those conditions(p.10). His health condition prior to death is hard to evaluate due to unavailability of the CRF.
7/10/2022 21:05:17	125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf	647	4	Adverse Effects - Other	The person with no previous health problems developed heart problems and Thrombocytopenia. The big question is he was given a placebo.
7/10/2022 21:09:04	125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf	663	1	Adverse Effects - myocarditis	Acute myocardial infarction
7/10/2022 21:13:42	125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf	667	2	Adverse Effects - Other	Invasive ductal breast carcinoma, Pfizer and the investigator both agreed this could have been caused by the jab
7/10/2022 21:14:36	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2110, 2419	Not applicable	Adverse Effects - Other	Bell's Palsy. On page 2110 the palsy is attributed to the vaccine
7/10/2022 21:17:35	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	1829, 2312	Not applicable	Fatality	Fatality due to cardiac arrest
7/10/2022 21:27:49	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	1828, 2307	Not applicable	Adverse Effects - myocarditis	On page 2307 the patient had a cascade of effects after the first dose and was withdrawn from the study
7/10/2022 21:29:36	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2405	Not applicable	Adverse Effects - Other	Patient developed Covid-19 9 days after the third dose
7/11/2022 8:37:30	Labeling update 6/17/22 (scroll down to chart), EUA Fact Sheets for >6mos to 4YO, and >12YO	Pages 1 and 4 color-coded boxes.	Multiple	Other	https://www.cvdvaccine-us.com/. https://labeling.pfizer.com/ShowLabeling.aspx?id=14471&format=pdf https://labeling.pfizer.com/ShowLabeling.aspx?id=17227&format=pdf Damn I just noticed that the vial cap color for >6 mos. to 4 years is maroon and 3mcg. The color for >12 years old is purple at 30 mcg. Both are for the “dilute before use”. Where I come from maroon is a shade of purple. What could go wrong?
7/11/2022 18:24:17	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	1836, 1871, 1885,1892,2147,2203,2225,2236,2171,2256,2281	Not applicable	Adverse Effects - Reproductive Issues	Irregular menstrual cycle. Page 2236 post-menopausal bleeding
7/11/2022 18:26:58	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2208, 2217	Not applicable	Adverse Effects - Other	Page 2208: shingles, page 2217: herpes
7/11/2022 18:32:56	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	2178	Not applicable	Adverse Effects - Other	Encephalopathy, in the context of cascade of events 37 days after the 4th dose (fall, ankle fracture, urinary tract infection, encephalopathy)
7/11/2022 20:15:42	125742_S1_M5_5351_c4591001-fa-interim- adverse-events.pdf CRFs-for-site-1081(1).pdf	793	case #10811194	Adverse Effects - Other	The adverse events are missing in the list of the adverse events-all subjects. The only adverse event which was listed is a death on November 1, 2020. However, the subject visited the site on October 12,2020. She complained of increasing coughing, sore throat, and fatigue .These symptoms had started on October 9,2020 and had been continuing (p.30, CRF). In other words, she had worsening health 3 weeks before her death. In spite the fact that the subject had COPD and hypertension since 2015, the CRF (p.60) and the death narrative (p.13, 125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf) don't contain any medications which the subject were taken.
7/11/2022 20:21:10	125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pd	3, 4, 5, 6	Chart	Fatality	Investigator and Pfizer found no correlation between vaccine and death!
7/11/2022 23:10:10	125742_S1_M5_5351_c4591001-fa-interim-narrative.pdf	77	case #10711023	Adverse Effects - Other	The narrative description of the adverse event seems to omit the important facts. The narrative describes the event as a planned check up by a doctor. However, the subject went to the emergency room on day 7 after the 1st shot. After that she was admitted to the hospital. She wouldn't go to the ER if she didn't have any symptoms. Probably, her tests were also abnormal in the ER that's why she was hospitalized for further evaluation. In the hospital the angiography probably showed severe blockage of the coronary arteries. Then she underwent the bypass surgery. The whole story rises a question : When had the subject been examined by the doctor the last time before the SAE? From her medical history we know that she had a stroke in February 2020, and 6 stents placement in September 2019. Considering her comorbidities (diabetes, hypertension, CHF, hypercholesterolemia) she should be checked every 3 months. There are two possibilities in this case : first, she was enrolled in the trial in unstable condition and second, the shot might exacerbate her condition. The CRF isn't available for this case.
7/12/2022 14:10:09	FDA-CBER 2021-5683-0220377	5	2	Other	In bold capital letters it's written PFIZER CONFIDENTIAL STDM then creation is in small print went is anything confidential when it comes to putting vaccines in our bodies
7/12/2022 15:07:29	FDA-CBER-2021-5683-02210515/FINAL	2-68	All	Data Missing	They say it was a delicious administration error that the people were giving wrong amounts what were their amounts they were given what was the result after giving the wrong amounts they have no information on it whatsoever just what subject got the wrong amount
7/12/2022 17:27:52	FDA-CBER-2021-5683-0221091	3 and 9	Pg9 para 5 Pg3 para.2	Other	About the modified plans in the protocol say that any other missing data will not be imputed in the safety analysis then it says any missing antibody results won't be imputed and then immunogenicity below LLOQ will be set to 0.5 X LLOQ page 9 is marked confidential
7/12/2022 17:38:51	125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf	255-260 (3059-3064)	case #11691007	Other	The case is an example how to make placebo group sicker. Female,28, no medical history, received 2nd placebo shot on September 29,2020. She didn't have any adverse events after the 2nd shot. On October 8,2020 she received the flu vaccine. Within 3 days after the flu shot she developed a loss of smell and shortness of breath. She had positive Covid test on October 13,2020.

7/12/2022 19:25:50	125742_S1_M5_5351_c4591001-fa-interim-narrative.pdf	3124-3130	case #12091013	Adverse Effects - Other	The subject , 32, male, no medical history, developed the chest pain within 7 days after 1st shot. However, there is no record about his adverse event in the listing of adverse events-all subjects (should be on page 1214, 125742_S1_M5_5351_c4591001-fa-interim-adverse-events.pdf). In addition, the subject had positive Covid test on the day of the 1st shot (p.3126). It is unclear whether the subject had any Covid symptoms on November 2,2020, on the day of the shot. According to the narrative, he developed the Covid symptoms on November 7 and 8, 2020. He also developed the chest pain on November 8,2020 and it resolved on November 9,2020. The cause of the chest pain was a "harsh climate conditions"(p.3125). The site 1209 is located in Istanbul, Turkey (p.31, 5.2-listing-of-clinical-sites-and-cvs-pages-1-41.pdf). The weather check in Istanbul on first week of November, 2020 didn't confirm the "harsh climate conditions". The temperatures and precipitations were in average range for this time of the year.(https://weatherspark.com/h/m/95434/2020/11/Historical-Weather-in-November-2020-in-%C4%B0stanbul-Turkey#Figures-Temperature). The CRF isn't available for this case to fully assess the event.
7/12/2022 19:56:24	125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf	6/3611	2	Fatality	How is it possible that we don't know if an autopsy was performed? And, with no autopsy information, how could the investigator conclude that there was no "reasonable possibility" that the death was related to the drug study?! This is unacceptable in a serious drug study protocol.
7/12/2022 20:30:46	FDA-CBER-2021-5683-0225021	Throughout	throughout	Other	I see throughout the document that patients were withdrawn from the study due to prior infection with Covid. How then could they recommend the vaccine to those who had Covid if they did not seek valid data through trials for those who had previous infections?
7/12/2022 21:49:39	125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf	3251-3257	case #12312130	Data Discrepancy	Female,64, received the placebo shot on August 18,2020 at 19:50. On the same day she was tested positive for Covid (p.3251). Considering the time of the injection, I suggest that the subject was found Covid- positive and then enrolled in the study. Furthermore, her first Covid symptom started on August 20,2020 (p.3253).However, on the page 3255 there is a note that the subject was hospitalized with bilateral pneumonia from August 20,2020 to August 27,2020. According to the narrative, she developed pneumonia at the same day with onset of the first Covid symptom which is very unusual for Covid progression. Another mismatch is her visit to the site on August 26,2020 while she had been in the hospital. She was tested on the site and had a positive Covid test (p.3254)
7/12/2022 22:25:05	125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf	3323-3329	case #12312805	Study Protocol	The subject had to be withdrawn from the study after the 1st shot due to Covid. However, he received the 2nd shot. Male, 33, no medical history, received the 1st vaccine on August 21,2020. He had positive Covid test on September 8,2020 (p.3326). 20 days later he received the 2nd vaccine (p.3323).
7/13/2022 9:40:11	125742_S1_M5_5351_c4591001-interim-mth6-	10MAR2021, Page 21 of 60	3.2.2 Vaccinations	Other	Indication of government issued passports forthcoming.
7/13/2022 17:13:32	125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf	3447-3454	case #12314477	COVID Testing	The subject was tested for Covid before the 1st shot on August 27,2020. His nasal swab was negative .However, his serum was positive for antibodies(p.3449). It means that he had Covid before and had to be withdrawn from the study. In spite of that, he received the 2nd placebo shot on September 18,2020. On October 6, 2020 he was tested positive for Covid (p.3450).
7/13/2022 17:46:33	125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf	3499	case #12411688	Other	The subject shouldn't be enrolled in the study due to Cachexia or Wasting Syndrome. He is 29 years old, with the only allergic sinusitis history. His BMI is 12 kg/m^2 . The BMI calculation is correct with given weight and height :(36.8 kg /175^2 cm)x 10,000=12 The CRF isn't available for this case.
7/13/2022 18:03:38	125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf	3513-3519	case #12411885	COVID Testing	The subject had to be withdrawn from the study due to previous Covid infection. On September 18,2020 he was screened for Covid and had negative nasal swab. However, his serum was positive for antibodies that means he had had Covid before(p.3514). In spite of that, he received the 2nd shot on October 9,2020 (p.3513).On October 23,2020 he was tested positive for Covid (p.3516).
7/13/2022 18:21:12	125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf	3536	case # 12412568	COVID Testing	The subject was tested for Covid before the 1st shot. However, there is only the nasal swab result which was negative. There is no serum test result. It isn't clear whether the subject had or didn't have Covid before the screening.
7/13/2022 18:52:10	125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf	3585-3590	case # 44441253	COVID Testing	The subject had a positive serum test before the 1st shot on September 21,2020(p.3585). He had to be withdrawn from the study due to previous Covid infection. Furthermore, he developed another Covid after the 1st placebo shot and was tested positive on October 2,2020(p.3587). However, he wasn't withdrawn from the study (p.110, 125742_S1_M5_c4591001-fa-interim-discontinued-patients.pdf). On October 22,2020 he received his 2nd placebo shot. Also the status of the case is unknown (p.3590).
7/13/2022 19:07:47	125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf	3598-3604	case #44441787	COVID Testing	The subject had a positive serum test before his 1st shot. He had to be withdrawn from the study due to previous Covid infection(p.3599). Furthermore, he was tested positive for Covid after the 1st placebo shot, on September 26,2020 (p.3601). After that he hadn't been withdrawn from the study either. On October 13,2020 he received his 2nd shot. The status of the case is vaccination completed (p.3604).
7/13/2022 19:51:23	125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf	3605-3611	case #44442188	COVID Testing	The subject was Covid positive during the whole period of the study. Male, 24 years old, no medical history, was screened for Covid on September 27,2020.His nasal swab was positive and serum test was negative(p.3606). He received his 1st vaccine shot on the same day. Then, on October 5,2020 he developed first Covid symptoms and was tested again positive on 13th day, October 9,2020 (pp.3607-3608).He had the only one symptom, cough, and didn't seek professional medical help(pp. 3607,3609). He hadn't been withdrawn from the study after Covid diagnosis. On October 15,2020 he received his 2nd shot in spite of having Covid positive test again before the 2nd shot (p.3606). There is no record in the narrative which indicates that the subject was ever tested negative for Covid. He had never been withdrawn from the study and the status of the case is vaccination completed (p.3611).
7/14/2022 0:11:26	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.pdf	Tables 16.2.7.8, 16.2.7.6 and 16.2.7.4.1	Multiple	Adverse Effects - Reproductive Issues	I compared overlapping data on pregnancy exposure across those 3 tables. There were 101 unique pregnancies of which 18 ended in miscarriage, spontaneous abortion or loss, an average of 52 days after the pregnancy was first reported. The remaining 83 pregnancies had no information on outcome (including a 62 year-old woman!) 19 women discontinued the trial due to the pregnancy, but one still lost her baby. It was unclear how the reported date of the pregnancy related to the actual date of conception. If the reports were ~8 weeks into the pregnancy, the miscarriages would be occurring on average at 108 days, which seems late for miscarriage. On the other hand, if the first exposure reports referred to the date of conception, the miscarriages are occurring fairly early ~6-7 weeks.
7/14/2022 0:19:56	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.pdf	3644	Table 16.2.7.8	Adverse Effects - Reproductive Issues	A 62 year-old Black woman from Tennessee is listed as being pregnant, with a Feb 8, 2021 pregnancy date (is this the date of conception or just when the pregnancy was diagnosed?) The randomization file shows she got BNT162b2 (30ug) on Sep 4 and 23 (not even 3 weeks apart!?). It seems unusual for a woman to conceive at age 61 and one wonders if the injection could have contributed to the pregnancy. There is no data on the outcome of her pregnancy.
7/14/2022 4:38:56	Fosun Pharma, 40th Annual JP Morgan Healthcare C	Slide 18	mRNA BNT162b2 infectious disease reference	Data Missing	This presentation from Fosun Pharma USA ties off the connection with the BNT162b2 vaccine. Does this connect the vaccine to the CCP? Does that connection to the CCP violate the terms of the OTA from the DoD that originally funded the $1.9 billion contract with Pfizer.
7/14/2022 4:58:09	Fosun Pharma USA web site	News & Media web site page	Fosun Pharma Signs Agreement with Medicines Patent Pool	Other	This Press Release ties Fosun to the MPP and Pfizer's oral COVID19 product
7/14/2022 9:25:46	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events-	22	1 (as listed by cases)	Data Missing	New or worsened muscle and joint pain for 2 days, no ratings listed on days 3-7, with last rating as severe
7/14/2022 10:09:28	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events	26	7 (by case)	Adverse Effects - Other	Had severe fatigue, moderate to severe muscle pain with first dose. (15 and 11 days respectively) Was given second dose in same month (August). Severe fatigue, moderate to severe headache reported. No duration (number) given for how long symptoms lasted after second dose.
7/14/2022 13:09:48	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events-	39	5 (by case)	Data Missing	Person had 7 severe symptoms over a period of 7 days. On some of those days the symptoms were not rated or categorized.
7/14/2022 16:43:47	125742_S1_M5_5351-c4591001-fa-interim-narrative-sensitive.pdf	192-194	case #11521497	Fatality	The subject had probably different diagnosis than that of described in the narrative. The narrative states that that the subject was experienced a vasovagal syncope ,fainting , at night and then he was hospitalized in ICU(p.194).The diagnosis of vasovagal syncope isn't require hospitalization unless the subject has more serious conditions. The medical history revealed that the man had type 2 diabetes and hypertension(p.192).These conditions could cause fainting (low blood sugar or arrhythmia).The condition of the subject was severe because he was admitted to the ICU. However, the narrative doesn't describe how long the subject was in the hospital and results of the tests which had been performed there. The only test of the investigator's concern was Covid that was negative. I'm sure that the diagnosis after the hospital was different and wasn't updated in the narrative.
7/14/2022 18:00:54	125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf	207-210	case #12241012	Adverse Effects - Other	The subject initial diagnosis of Suspected TIA (Transitional Ischemic Attack) was removed from the final adverse events lists from April 1,2021 (p.3266, 125742_S1_M55351-c4591001-interim-mth6-adverse-events). Female, 75, within 6 days after the 1st shot developed the muscles weakness in the legs. She fell and got fractured her left ankle. According to the narrative , she was under the care of the PCP. However, there is no indication that she was going to be evaluated by a specialist about her suspected TIA(p.210). All the adverse events were evaluated as not related to the shot and not serious(p.2127, 125742-S1_M5_5351_c4591001-fa-interim-adverse-events.pdf). However, the subject was withdrawn from the study probably due to limited mobility (p.210). From the available documents it is unclear what evidence Pfizer had to remove her initial diagnosis from the final document. The CRF isn't available for this case.
7/15/2022 8:17:16	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events	41	6 (by case)	Data Discrepancy	Person had symptoms for 14 days. A recording of symptoms is only available for 7 days.
7/15/2022 8:35:42	125742_S1_M5_5341_c491001_interim-mth6-adverse-events	42	6 (by case)	Data Missing	10 days of symptoms listed, only 7 days recorded

7/15/2022 8:45:28	125741_S1_M5_5351_c491001-interim-mth6-adverse-events	43	2 (by case)	Data Missing	Person's duration of symptoms (chills) was 8 days. Last recording of symptoms was day 6 as severe.
7/15/2022 9:34:18	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events	44	5 (by case)	Data Discrepancy	duration of headache 10 days. Only 6 days of data were noted, with symptom severe on the last recorded day.
7/15/2022 9:47:34	12572_S1_M5_5351_c491001-interim-mth6-adverse-events	47	7 (by case)	Data Discrepancy	Person had 6 days duration of headache. Only 2 days of symptom are reported, with the last date noted as severe.
7/15/2022 10:04:11	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events	49	7 (by case)	Data Discrepancy	Fatigue was reported at 5 days duration. Only 3 days of symptom are noted, with no notation on the last day designated.
7/16/2022 11:59:19	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf#page=2529	2529-2535	All	Efficacy	Clearly this is evidence of fraud. This subject after having the 1st exposure to BNT162b2 became ill, so he was removed from the study and even before a swab test was done, as if it was known to be caused by the shot and then the excuse was used that he didn't have 2 doses as the reason for his withdrawal from the study. Subject's 1st exposure 10/22/20, then on 10/31/20 10 days after 1st exposure he presented with AEs(fever, headache, runny nose, 2 days later on 11/02/20 an at home nasal swab was taken, sent to the lab which said was positive. But the subject was withdrawn from the study on Oct 31, 2020 stating "NO LONGER MEETS ELIGIBILITY CRITERIA" and is then listed in Nov 24, 2020 doc., "16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations" as "Did not receive 2 vaccinations".
7/16/2022 17:25:16	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.pdf	3634 and others	entire page	Data Discrepancy	For the most part the adverse events such as chills, headache, soreness, fatigue etc are YES related to vaccine but NONE of the deaths recorded are. They are all assumed as NOT RELATED. funny how that works.....
7/16/2022 17:39:13	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.pdf	2993	EYE	Adverse Effects - Other	Eye - vitreous floaters - says not related to vax yet my husband has since complained of them since his injections, never complained about them in the past. Also has had flashing occurring in peripheral vision since
7/16/2022 17:52:52	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.pdf	3638	a couple graphs indicated	Fatality	Septic shock seems to be quite a few incidences - but of course, not related as caused by injection
7/16/2022 20:11:47	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.pdf	1501-1821 VASC	n/a	Adverse Effects - Other	
7/16/2022 21:40:24	125742_S1_M5_CRF_c4591001-1008-10081337.pdf	42, 65, 78, 164, 167	p42 1-4, p65 3, p78 1, p164 4, p167 4	Adverse Effects - Reproductive Issues	White female, birthdate 1981, age 39. She received vax1 9/16/20, vax2 10/7/20, vax3 11/3/20. Got positive pregnancy test 12/23/20. Adverse events: 1. injection site pain 9/16/20 ended 9/17/20 - not serious, related to study treatment; 2. injection site pain 10/7/20 ended 10/8/20 - not serious, related to study treatment; 3. body aches 10/7/20 ended 10/9/20 - not serious, related to study treatment; 4. exposure during pregnancy 12/23/20 ongoing - not serious, not related to study treatment, subject not discontinued from study. p42 para 1-4 adverse events p65 para 3 vax3 completed p78 para 1 willing to return for vax3; eligible and NOT confirmed to have received only placebo at vax1 & vax2 p164 para 4 1/29/21 Clinical As per CRF CG 8.50.2.5, the toxicity grade for "Exposure During Pregnancy" is reported as Not Applicable. p167 para 4 2/22/21 study outcome UNKNOWN. No further information after 2/22/21.
7/17/2022 0:19:29	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.zip (pdf)	4	16.2.7.1	Adverse Effects - Other	Patient 10901043 had severe Pain at the injection site for 70 days! THIS is not normal. All other severe and grade 4 reactions ranged from 1-22 days
7/17/2022 0:37:30	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events	1-3645	16.2.7.2.1 Listing of Severe and Grade 4 Local Reactions (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population	Adverse Effects - Other	There were 65 people who had severe redness and swelling with measurements noted at the maximum noted as 21 and >21 Since 1 caliper unit is = 0.5cm, a grade of >21 would be > 10.5 cm!!
7/17/2022 8:48:56	Combo of Tables 16.2.7.2.1 and 16.2.7.3.1-Severe	1 (by sheet)	1-4 (same subject)	Data Discrepancy	Same subject had 4 symptoms after 1st dose. Only 2 days of rating are noted with no indication on duration of symptoms. New or worsened muscle pain is listed, but has an N notation for both days. The other 3 symptoms have either mild or moderate rating for the last day listed (2), with no follow up explanation after day 2 on when the symptoms ceased.
7/17/2022 9:00:47	combo of tables 16.2.7.2.1 and 16.2.7.3.1 -Severe	sheet 1	5 (by line)	Data Missing	For the second dose, the subject had a headache, which was severe on the second day. No follow up is noted for the duration of symptoms.
7/17/2022 9:10:58	Combo of Tables 16.2.7.2.1 and 16.2.7.3.1	sheet 1	6 (line)	Data Missing	For dose 2, there is a severe reaction of headache on day 2. There is no noted duration of symptoms or follow up after that.
7/17/2022 9:18:18	Combo of Tables 16.2.7.2.1 and 16.2.7.3.1	sheet 1	7 (line)	Data Discrepancy	After second dose, there was a severe symptom of fatigue. There is no notation for duration of symptoms or follow up after that.
7/17/2022 9:28:03	16.2.7.2.1 and 16.2.7.3.1-Severe_Grade4_Reactions_and_Events.1	sheet 1	8-9 (line)	Data Missing	After second dose, the subject had severe symptoms of fatigue and chills. No follow up is noted after the second day for when this subsided or how many days the subject had the symptoms.
7/17/2022 10:57:33	Combo of tables 16.2.7.2.1 and 16.2.7.3.1	sheet 1	10 (line)	Data Discrepancy	The subject had symptom of chills after the second dose. It was severe on the second day. There was no follow up noted after that or duration of symptom noted.
7/17/2022 11:03:46	Combo of Tables 16.2.7.2.1 and 16.2.7.3.1	sheet 1	11 (line)	Data Missing	No further follow up after symptom of severe fatigue on second day (notation).
7/17/2022 11:22:52	Combo of Tables 16.2.7.2.1 and 16.2.7.3.1	sheet 1	12 (line)	Data Missing	Severe fatigue reaction, no follow up found after second notation of symptom.
7/17/2022 16:57:18	125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf	all	NA	Adverse Effects - Other	For group 6 assignment the notes said look at the comorbities of dead patients. Within this ENTIRE document (not just the assigned pages for group 6) there were 6 patients that died. Here are their ID numbers and comorbities: Subject Number Comorbitities 10071101 Obesity, Sleep Apnea, Gastroesophageal reflux disease, Gastrectomy, Supraventricular tachycardia 10661350 Drug hypersensitivity (morphine / sulfa), Anxiety, Gastroesophageal reflux disease, Hypertension, Insomnia, Spinal Laminectomy, Spinal Stenosis, Hyponatraemia 10811194 Hypothyroidism, Drug hypersensitivity (sulfa / NSAIDs), COPD, Hypertension, ADD, Osteoarthritis, Postmenopause 11521085 None 11521497 Lithotripsy, Nephrolithiasis, Food Allergy (celery / mango), hearing loss, osteoarthritis, Type II diabetes, hypertension, prostatism 11621327 Autoimmune thyroiditis, Obesity, Craniocerebral injury, Depression, Hip replacement, Corrective Lens 12313972 Arterial Hypertension
7/17/2022 18:04:20	125742_S1_M5_5351_c4591001 interim mth6 discontinued patients.pdf	119,165,180,227	Not applicable	Fatality	Death due to Covid-19, between 76 and 135 days after the second dose
7/17/2022 18:29:04	125742_S1_M5_5351_c4591001 interim mth6 discontinued patients.pdf	37,175,201	Not applicable	Fatality	Death due to myocardial infarction, in particular page 175 death 16 days after the 1st dose
7/17/2022 18:33:22	125742_S1_M5_5351_c4591001 interim mth6 discontinued patients.pdf	##################	Not applicable	Fatality	Death due cardio/respiratory or cardiac arrest between 31 days and 124 days after the second dose
7/17/2022 18:35:35	125742_S1_M5_5351_c4591001 interim mth6 discontinued patients.pdf	222	Not applicable	Fatality	Death due to emorrhagic stroke 16 days after the 1st dose
7/17/2022 18:37:22	125742_S1_M5_5351_c4591001 interim mth6 discontinued patients.pdf	211	Not applicable	Fatality	Death due arteriosclerosis 4 days after the 1st dose
7/17/2022 18:39:10	125742_S1_M5_5351_c4591001 interim mth6 discontinued patients.pdf	226	Not applicable	Adverse Effects - Other	Cerebral infarction 22 days after the 1st dose
7/17/2022 18:40:18	125742_S1_M5_5351_c4591001 interim mth6 discontinued patients.pdf	228	Not applicable	Adverse Effects - Other	Pulmonary embolism 61 days after 1st dose

7/17/2022 18:43:41	125742_S1_M5_5351_c4591001 interim mth6 discontinued patients.pdf	200,215	Not applicable	Fatality	Death due to pneumonia 102 and 76 days respectively after the 2nd dose
7/17/2022 18:47:20	125742_S1_M5_5351_c4591001 interim mth6 discontinued patients.pdf	182	Not applicable	Adverse Effects - Other	Congestive cardiac failure, 22 days after 1st dose
7/17/2022 18:49:14	125742_S1_M5_5351_c4591001 interim mth6 discontinued patients.pdf	166	Not applicable	Fatality	Death due to hypertensive heart disease and arteriosclerosis 71 days after the 2nd dose
7/18/2022 13:04:01	Combo of Tables 16.2.7.2.1 and 16.2.7.3.1	sheet 1	19 (line)	Data Missing	Did not find dosage or placebo listed at end of grid.
7/18/2022 13:10:30	Combo of Tables 16.2.7.2.1 and f16.2.7.3.1	sheet 1	20 (line)	Data Missing	Did not find dosage or placebo at end of grid.
7/18/2022 13:15:24	Combo of Tables 16.2.7.2.1 and 16.2.7.3.1	sheet 1	21 (line)	Data Missing	no placebo or dosage found at end of grid
7/18/2022 13:18:16	Combo of Tables 16.2.7.2.1 and 16.2.7.3.1	sheet 1	22 (line)	Data Missing	No dosage or placebo listed at end of grid
7/18/2022 14:14:18	file:///C:/Users/user/Downloads/125742_S1_M5_5351_c4591001-interim-mth6-excluded-patients-sensitive.pdf	all	all	Other	1766 subjects excluded from the trial. If we sum the number of statements it's 2753.
7/18/2022 15:38:54	125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf	14-16	all	Fatality	A 42 yo woman got the placebo. History of breast cancer. Had an implantation of Essure permanent birth control device. Rec'd 1st dose of the placebo on Aug 19. Died 6 days later. Here's the investigator's conclusion: "Subject C4591001 1152 11521085, a 42-year-old white female with a pertinent medical history of recurrent breast cancer (in 2001 and 2017) and lumpectomy (left breast; in 2001 and 2017) and implantation of an Essure permanent birth control device (implanted in 2017), received Dose 1 on 19 Aug 2020. The subject was not taking any concomitant medications. The subject's husband stated that the subject had no adverse events after receiving Dose 1. She had a normal evening and went to bed on 25 Aug 2020 (Day 7). By the next morning (26 Aug 2020), the subject had died (Day 8). An autopsy was performed and the results are still pending at the time of this report. In the opinion of the investigator, there was no reasonable possibility that the death was related to the study intervention. The investigator further stated that although the full autopsy report was pending and determining cause of death at this time was essentially an educated guess, the subject had possible risk factors. She possibly had a thromboembolic event related to a history of breast cancer, or there was a potential toxicity related to the Essure permanent birth control device. Essure implant for permanent birth control was taken off the market in the United States by the Food and Drug Administration (FDA) in 2018. A brief review revealed almost 50,000 reports to the FDA regarding the device and approximately 50 deaths. Pfizer commented that there was not enough evidence to suggest a causal relationship between the study intervention and the subject's death." The woman gets the placebo, dies 6 days later & it's from the birth control device related to her BC, of course, bc there were 50 deaths associated with that BC. I see other places where death occurs after the placebo (will submit those). Just Doesn't make sense to me. What's in the placebo?
7/18/2022 15:50:04	125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf	7-10	all	Fatality	58 yo male died from a heart attack 16 days after receiving the placebo. He had a bunch of comorbidities which made me ask, "Why was this guy included in this study?" I also ask myself what might have been in the placebo that could have caused this man to have a heart attack? here's the summary: "Subject C4591001 1066 10661350, a 58-year-old white male with a pertinent medical history of hypertension (since 2000), gastroesophageal reflux disease (since 2000), insomnia (since 2000), hyponatremia (since 2015), seizures (in 2015), alcohol abuse (from 2010 to 2018), myocardial infarction (in Mar 2018), and cardiomyopathy (coronary angiography, left ventriculography, and left heart catheterization; since Mar 2018), received Dose 1 on 19 Oct 2020. The subject died because of a myocardial infarction on 03 Nov 2020, 15 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of myocardial infarction included omeprazole (Protonix) for gastroesophageal reflux disease (since 2015), trazodone for insomnia (since 2015), Depade and acamprosate calcium (Campral) for alcohol dependence (since 2018), and levetiracetam (Keppra) for seizures (since 2018). When the subject did not return for Visit 2 on 09 Nov 2020 (Day 22), the subject's wife was contacted on the same day and she stated that the subject suffered a heart attack and died in his sleep on 03 Nov 2020 (Day 16). An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the myocardial infarction was related to the study intervention, concomitant medication, or clinical trial procedures, but rather it was related to disease progression. Pfizer concurred with the investigator's causality assessment and additionally considered that the myocardial infarction was mostly coincidental and associated with underlying cardiac conditions.
7/18/2022 15:59:22	Filename: 125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf	11-13	all	Fatality	Subject died 33 days after receiving the 2nd dose of the placebo. She complained of stomach pain, went to bed, and did not wake up. She had a bunch of comorbidities which made me question the appropriateness of her being in the study. No autopsy was performed & cause of death is unknown. I wonder if there was anything in the placebo that could have caused death. here's the investigator summary: Subject C4591001 1081 10811194, a 51-year-old white female with a medical history of hypothyroidism (since 1995), drug hypersensitivity (allergy to sulfa drugs since 2002 and allergy to oral NSAIDs since 2007), chronic obstructive pulmonary disease and hypertension (both since 2015), attention deficit hyperactivity disorder (since 2017), and osteoarthritis and postmenopause (both since 2018), received Dose 1 on 10 Sep 2020 and Dose 2 on 29 Sep 2020 (Day 20). The subject was scheduled for her convalescent visit on 11 Nov 2020 but did not show up for her appointment. The family was contacted and it was reported that the subject was found deceased in her home on 04 Nov 2020 and likely died 3 days prior. A family member had spoken with the subject on 01 Nov 2020 and the subject told her family member that she just got out of the shower and was going to go lay down due to having "stomach pains". This was the final conversation with the subject before she died. No autopsy was performed. A copy of the death certificate was requested. The cause of death was reported as unknown. In the opinion of the investigator, there was no reasonable possibility that the death was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment, and considered that the death was not related to concomitant medications and was most likely coincidental and associated with underlying clinical conditions. The closing paragraph occurs in many places & looks like a canned response.

7/18/2022 16:08:50	Filename: 125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf	20-22	all	Fatality	A 61 y.o. woman died from a brain hemorrhage 14 days after receiving her 2nd placebo dose. She had a history of hypertension, but no other comorbidities. Is there anything in the placebo that could have caused her to stroke out? Here is the investigator summary: Subject C4591001 1231 12313972, a 61-year-old white female with a pertinent medical history of hypertension (since 2017), received Dose 1 on 25 Aug 2020 and Dose 2 on 13 Sep 2020 (Day 20). The subject was diagnosed with a hemorrhagic stroke on 27 Sep 2020, 14 days after receiving Dose 2. Concomitant medication reported within 2 weeks before the onset of the hemorrhagic stroke included losartan (since 2017) for arterial hypertension. On 27 Sep 2020 (Day 34), the subject contacted the medical team complaining of a severe headache and incoercible vomiting, and she was advised to call the emergency system. The subject arrived at the emergency room unconscious (unknown Glasgow score) on the same day (Day 34) with nonreactive intermediate pupils and requiring life support measures including invasive mechanical ventilation and pharmacological support (inotropics, unknown drugs and doses). The subject's son informed the site that the subject was admitted to the intensive care unit at the hospital. A computed tomography of the brain on the same day (Day 35) showed subarachnoid hemorrhage, intraventricular hemorrhage, and right cerebral hemisphere hematoma (Fisher Scale 4). A brain angiography showed cerebral circulatory arrest, and therefore the location of the aneurysm could not be established. Per protocol, a PCR SAR-COV-2 swab test was performed and the results were negative. The subject did not respond to life support measures and died of hemorrhagic stroke on 28 Sep 2020 (Day 35). In the opinion of the investigator, there was no reasonable possibility that the hemorrhagic stroke was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment and considered the hemorrhagic stroke as most likely related to the subject's underlying arterial hypertension. Given the timing, it doesn't make sense to me
7/18/2022 16:10:30	https://www.phmpt.org/wp-content/uploads/2022/07/125742_S1_M5_5351_c4591001-interim-mth6-discontinued-patients.pdf	25	Subject 1056	Study Protocol	"Subject couldn't be reached. Caregiver states he left the house and nobody knows where he is." Caregiver?! Was this subject in a residential care facility (drug rehab, etc) & walked away? If that is the case, did the subject give consent?
7/18/2022 16:17:24	https://www.phmpt.org/wp-content/uploads/2022/07/125742_S1_M5_5351_c4591001-interim-mth6-discontinued-patients.pdf	61	subject 11101380	Study Protocol	"WITHDRAWAL BY PARENT/GUARDIAN: Parent discontinue subject because he states subject is too busy with school." I just find it so disturbing that a parent signed the consent for this child. Do we know that this child was NOT in foster care?
7/18/2022 16:25:52	https://www.phmpt.org/wp-content/uploads/2022/07/125742_S1_M5_5351_c4591001-interim-mth6-discontinued-patients.pdf	66	subject 11201104	Study Protocol	"Subject states no longer wishes to be in study about to have weight lost surgery" Isn't weight loss surgery for the obese? Obesity is excluding criteria #6.
7/18/2022 16:28:24	https://www.phmpt.org/wp-content/uploads/2022/07/125742_S1_M5_5351_c4591001-interim-mth6-discontinued-patients.pdf	79	subject 11331138	Study Protocol	"Subject stated she is not happy with the study number of visits, number of vaccines, payments." PAYMENTS?!!!
7/18/2022 16:31:21	https://www.phmpt.org/wp-content/uploads/2022/07/125742_S1_M5_5351_c4591001-interim-mth6-discontinued-patients.pdf	117	subject	Study Protocol	"Subject has missed visits and does not have a telephone. He is lost to followup." Doesn't have a phone?! Is subject homeless?
7/18/2022 16:35:50	https://www.phmpt.org/wp-content/uploads/2022/07/125742_S1_M5_5351_c4591001-interim-mth6-discontinued-patients.pdf	132	subject 12313376	Study Protocol	"being written phase 2/3 does not assure you that the safety of the product has been fully evaluated" A smart one got away....not assured that safety of product has been fully evaluated!
7/18/2022 16:39:12	https://www.phmpt.org/wp-content/uploads/2022/07/125742_S1_M5_5351_c4591001-interim-mth6-discontinued-patients.pdf	133 & 135	subjects 12314439 & 12313534	Study Protocol	"Subject refused to receive the second dose due to the previous medication dosis error." Was there follow-up on these subjects after they refused dose 2?
7/18/2022 16:42:37	https://www.phmpt.org/wp-content/uploads/2022/07/125742_S1_M5_5351_c4591001-interim-mth6-discontinued-patients.pdf	172	subject 10561079	Study Protocol	"SUBJECT STATED SHE IS SCARED OF THE VACCINE AFTER WATCHING NEWS REPORT ABOUT SAFETY CONCERNS." Was there information on the possible affects of the vax when subject enrolled in study? Subject found out from news report that the vax might be unsafe?! INFORMED consent might have been missing?
7/18/2022 16:46:51	https://www.phmpt.org/wp-content/uploads/2022/07/125742_S1_M5_5351_c4591001-interim-mth6-discontinued-patients.pdf	223	subject 12314920	Study Protocol	"It's not interested in participating in the study if the research product is not brought to Argentin" Why such a large cohort of subjects if vax wasn't going to be in Argentina?
7/18/2022 19:59:27	https://www.phmpt.org/wp-content/uploads/2022/07/125742_S1_M5_5351_c4591001-interim-mth6-discontinued-patients.pdf	all	general observation	Fatality	The information I have doesn't tell if the subjects were given placebo or Pfizer product. Of the approx 2000 subjects who didn't return for Dose 2, 38 were due to death: 10 heart-related, 3 cancer, 4 covid, 2 pneumonia, 3 respiratory failure, 3 cardiac/respiratory failure, 4 sepsis, 4 artery problems. From site to site, it's hard to know if death determinants were applied consistently. Could the respiratory failures, covid & pneumonia be grouped together? One death was attributed to dementia/Alzheimers. How was this person able to give consent?
7/18/2022 20:02:19	https://www.phmpt.org/wp-content/uploads/2022/07/125742_S1_M5_5351_c4591001-interim-mth6-discontinued-patients.pdf	all of them	general observation	Study Protocol	Of the approx 2000 subjects, at least 1/3 were LOST TO FOLLOW UP. How many of these are deaths?
7/20/2022 20:29:22	Combo of Tables 16.2.7.2.1 and 16.2.7.3.1 - Severe_Grade4_Reactions_and_Events.xlsx	Summary count of events in the table	all	Other	This file is supposed to contain severe AEs. The only severe AEs they seem to find are: Fatigue Headache New or worsened muscle pain New or worsened joint pain Chills Vomiting Oral temperature (°C) Diarrhea Pain at the injection site Redness (cu) Redness (svt) Swelling (cu) Swelling (svt) I've seen subjects with heart problems & cancer that were dismissed as not relevant. Doesn't make sense. What are the standards for determining AEs noted & their severity.
7/20/2022 21:35:24	Codexis SEC filing	1	All	Other	Pfizer canceled a large order for enzymes produced by Codexis for use in their oral COVID solution PAXLOVID.
7/21/2022 12:26:38	Combo of Tables 16.2.7.2.1 and 16.2.7.3.1-Severe	sheet 1	23 (line)	Data Discrepancy	Subject had new or worsened muscle pain a duration of 12 days. There are only 7 days of rating for the symptom.

7/21/2022 12:35:33	Combo of Tables 16.2.7.2.1 and 16.2.7.3.1_Severe_Grade 4	sheet 1	31 (line)	Data Discrepancy	Did not find either dosage or placebo recorded at the end of the grid.
7/21/2022 12:39:16	Combo of Tables 16.2.7.2.1 and 16.2.7.3.1-Severe_	sheet 1	32 (line)	Data Discrepancy	Did not find dosage or placebo at the end of the grid.
7/21/2022 13:08:47	Combo of Tables 16.2.7.2.1 and 16.2.7.3.1-Severe	sheet 1	47 (line)	Data Missing	Severe new or worsened muscle pain. None reported first day. Second day reported as severe, with no ratings after that. Duration of symptom listed as 2 days.
7/21/2022 13:15:39	Combo of Tables 16.2.7.2.1 and 16.2.7.3.1-Severe	sheet 1	48 (line)	Data Missing	Had severe rating for new or worsened joint pain, with no ratings after that. (some blank)
7/21/2022 17:00:51	https://pdata0916.s3	4	3	Fatality	cardiac arrest
7/21/2022 17:03:43	https://pdata0916.s3	6	1	Other	unknown if autopsy performed
7/21/2022 17:05:35	https://pdata0916.s3	7	3	Other	several present conditions
7/21/2022 17:06:52	https://pdata0916.s3	7	3	Other	past spinal laminectomy and spinal stenosis
7/22/2022 13:46:40	Combo of Tables 16.2.7.2.1 and 16.2.7.3.1-Severe	sheet 1 (C45910011016)	61 (line)	Adverse Effects - Other	Had a severe reaction of fatigue to a placebo.
7/22/2022 14:06:14	Combined 16.2.7.2.1 and 16.2.7.3.1-Severe	sheet 1 (ID 10441244)	68 and 69 (by line)	Data Missing	Subject had two reactions (fatigue, new or worsened muscle pain). It was not recorded whether the subject had a dosage or placebo.
7/22/2022 20:51:09	125742_S1_M5_5351_c4591001 interim mth6 excluded patients.pdf	1-6	N/A	Other	Instructions were to count how many patients were excluded in total; Tally sites based on # of patients excluded/Match the 'excluded' patients to sites. I have included a table with the tallies for both. 118 patients were excluded based on this document.
7/23/2022 10:20:26	pdata0916.s3.us-east-2.amazonaws.com/070122	17	3	Other	present conditions- autoimmune thyroiditis, obesity, depression
7/23/2022 10:22:06	pdata9016.s3.us-east-2.amazonaws.com/070122	17	3	Other	past conditions- craniocerebral injury (2011), hip arthroplasty (2015)
7/23/2022 10:25:42	pdata0916.s3.us-east-2.amazonaws.com/070122	18	3 & 4	Fatality	death was due to atherosclerotic disease- 3 days after first dose
7/23/2022 10:47:56	pdata0916.s3.us-east-2.amazonaws.com/070122	20	3	Other	present condition- hypertension
7/23/2022 10:51:08	pdata0916.s3.us-east-2.amazonaws.com/070122	20	4	Other	
7/23/2022 10:54:15	pdata0916.s3.us-east-2.amazonaws.com/070122	21	1 & 2	Fatality	investigator said fatality was due to hemorrhagic fever
7/23/2022 12:37:11	16.2.7.2.1 and 16.2.7.3.1-Severe	sheet 1	70 by line (ID 10441245)	Data Missing	Does not show whether subject had a dosage or placebo.
7/23/2022 12:42:29	Combo of Tables 16.2.7.2.1 and 16.2.7.3.1-Severe	sheet 1	line 71 (ID 10441287)	Data Missing	Did not find a dosage or placebo given.
7/23/2022 12:52:16	Combo of Tables 16.2.7.2.1 and 16.2.7.3.1-Severe	sheet 1	Line 76 (ID 10571362)	Adverse Effects - Other	3 days of fever are noted for when a placebo was given.
7/23/2022 13:03:05	Combo of Tables 16.2.7.2.1 and 16.2.7.3.1-Severe	sheet 1	Lines 76-79 (ID 10571362)	Adverse Effects - Other	Subject had 4 different reactions to a placebo.
7/23/2022 13:15:43	Combo of Tables 16.2.7.2.1 and 16.2.7.3.1- Severe	sheet 1	Line 82 (ID 10711039)	Adverse Effects - Other	Was given a placebo and had a headache for 16 days.
7/24/2022 9:53:03	Combo of Tables 16.2.7.2.1 and 16.2.7.3.1- Severe	sheet 1	83 (by line) (ID 10711065)	Data Discrepancy	Subject had headache for 9 days. Only 7 days are rated, with the last rating as mild.
7/24/2022 10:02:44	Combo of Tables 16.2.7.2.1 and 16.2.7.3.1-Severe	sheet 1	line 90 (ID 10771013)	Data Discrepancy	Subject had symptoms of fatigue for 5 days. Some rating days were blank, and only 3 days showed an adverse reaction rating.
7/24/2022 10:11:40	Combo of Tables16.2.7.2.1 and 16.2.7.3.1- Severe	sheet 1	line 92 (ID 10791039)	Data Discrepancy	Subject shows 8 days of headache. Last rating is severe, with no rating noted on the last designated day on the grid.
7/24/2022 15:07:06	Combo of Tables 16.2.7.2.1 and 16.2.7.3.1- Severe	sheet 1	line 93 (ID 10791040)	Adverse Effects - Other	Severe reaction of headache after subject was given a placebo.
7/26/2022 14:54:37	125742_S1_M2_26_pharmakin-written-summary	page 6	sorry, didn't get one	Other	LPN accumulation in the ovaries and consequences for female reproduction
7/26/2022 15:48:23	1_125742_S1_M5_5351_c4591001-interim-mth6-adverse-events%20(1).zip/125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.pdf	1501-1821	N/A	Adverse Effects - Other	I tabulated Muscular System AE's for these pages & found the following totals & notes: 460 total Muscular System AE's 57 from Arthralgia w/an average of 13.8 days that the AE lasted 41 for Back Pain w/an average of 3.96 days it lasted 278 for Myalgia w/an average of 2.45 days it lasted 28 for Pain in Extremities lasting for average of 2.22 days 11 for Neck Pain, lasting for average of 15.4 DAYS!!! All but 1 case noted as NOT RELATED. Then of note: 9 cases of muscular contracture w/all being noted as unrelated to the vax. 3 cases of muscular chest pain - all noted as unrelated. I have excel sheets for all of my data; feel free to email me if you would like me to send those for reference.
7/26/2022 15:51:37	1_125742_S1_M5_5351_c4591001-interim-mth6-adverse-events%20(1).zip/125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.pdf	1501-1821	N/A	Adverse Effects - Other	I tabulated all AE's for Nervous System Class for pages 1501-1821 & found: 398 total Adverse Events 320 Headaches, lasting for average of 2.36 days (OF NOTE: I found cases, which I left out of my average, that lasted these many days: 20, 63, 26, 45, 52, 94, 80, 38 & 50, as well as some that were "continuous" so it seems to signal a larger issue here related to the symptom of headaches.
7/26/2022 16:02:36	1_125742_S1_M5_5351_c4591001-interim-mth6-adverse-events%20(1).zip/125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.pdf	1501-1750	N/A	Adverse Effects - Other	I tabulated all GENERAL Adverse Events for these pages & found the following: Total GENERAL reactions: 1464 Chills: 151, lasted 1.9 days on average Injection Site Edema: 10, lasted 3 days on average Injection Site Erythema: 21, lasted 3.25 days on average Fatigue: 227, lasted 2.237 days on average Injection Site Pain: 735, lasted 2.5 days on average Malaise: 30, lasted 2.3 days on average Pain / Body Aches: 49, lasted 2.34 days on average Pyrexia / Fevers: 191, lasted 1.89 days on average Injection Site Swelling: 7, lasted 3.28 days on average *I have excel sheets for all the data if you would like, just email me.
7/26/2022 16:28:27	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events	3107	case #11521260	Adverse Effects - Other	The subject was enrolled in the study placebo group being diagnosed with suspicious malignancy. The subject's diagnosis of melanoma was confirmed within 5 days after the 1st placebo shot. She/he probably knew that and continued with the 2nd placebo shot following the schedule. The CRF for this case isn't available to fully assess the subject's condition and therapy. However, the subject received the vaccine on January 22,2021 and February 12,2021 (p.3843, 125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive).
7/27/2022 22:43:29	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.pdf	3177	case # 11771012	Adverse Effects - Other	Pulmonary Embolism doesn't consider a serious adverse event. The subject received two placebo shots. Within 29 days after the 2nd shot he/she developed Right Lower Lobe Pulmonary Artery Embolus. At the same time the subject was diagnosed with Aortic Aneurysm. These conditions can be diagnosed only in inpatient setting. However, the events weren't considered severe that indicates that the subject wasn't hospitalized. Also both conditions hadn't resolved. If aortic aneurysm may not require surgical treatment and be chronic condition, the pulmonary embolism is always acute condition. The adverse event happened on October1,2020. The data were collected till April 1,2021. There is no update about the subject's condition. The CRF of this case isn't available. However, the subject received two vaccine's shots on December 21,2020 and January 11,2021 being in unstable condition (p.3938, 125742_S1_M5_5351_c4591001-interim-randomization-sensitive.pdf).In addition, the vaccine's shots after placebo were administered in less than 90 days after the 2nd placebo shot(September 24,2020) which is a violation of the protocol. The vaccine should be administered at least 175 days after the 2nd placebo (p.145, 125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf).
7/27/2022 23:16:38	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.pdf	3177	case# 11771063	Adverse Effects - Other	The subject was diagnosed with neoplasma after the 2nd placebo. It wasn't considered as the SAE. She/he wasn't withdrawn from the study due to the AE and had received the treatments earlier than is required by the protocol. The subject was diagnosed with upper back melanoma on September 29,2020, within 22 days after the 2nd placebo. His/her condition resolved on January 15,2021. The CRF isn't available for this case to assess the cancer treatment that had been received by the subject. However, in 4 days after recovery, on January 19,2021, the subject received the vaccine. He/she received the 2nd shot on February 8,2021 (p.3941, 125742_S1_M5_5351_c4591001-interim-randomization-sensitive.pdf). The protocol states that the vaccine should be administered at least 175 days after the 2nd placebo. The subject 2nd placebo was on September 8,2020 . He/she received the vaccine 2 months earlier than is required by the protocol.

7/28/2022 13:18:40	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.pdf	3178	case #11771164	Adverse Effects - Other	The subject received the vaccine being not fully recovered from the adverse events. The subject received two placebo shots. After the 2nd shot within 75 days he/she developed Aortic root aneurysm and later, on January 5,2021(112 day) was diagnosed with Esophageal Ulcer. The CRF for this case is unavailable. It is unclear if the subject was hospitalized and received a surgical treatment for Aortic aneurysm. His/her both adverse events marked as "recovering". In 2 weeks after the esophageal ulcer diagnosis, on January 19,2021 the subject received the treatment. He/she received the 2nd vaccine on February 9,2021 (p.3946, 125742_S1_M5_5351_c4591001-interim-randomization-sensitive.).The condition of the subject hadn't been updated till cut off data on April1,2021.There is also a violation of the protocol for administer vaccine in the placebo group. The subject received the vaccine 2 months earlier than is required by the protocol.(p.145, 125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf)
7/28/2022 13:43:06	125742_S1_M5_5351_c4591001-interim-mth6-adverse events.pdf	3178	case #11771204	Adverse Effects - Other	The subject hadn't been fully recovered from cancer but received the vaccine. The subject received two placebo shots. After the 2nd shot within 34 days he/she was diagnosed with bladder cancer. His/her condition was marked as "recovering" after SAE. The subject received the vaccine on February 4,2021 and February 25,2021 while he/she had been recovering(p.3948, 125742_S1_M5_5351_c4591001-interim-randomization-sensitive.pdf). His/her condition hadn't been updated till cut off data on April 1,2021. There is also a violation of the protocol for vaccine administration in the placebo group. The subject received the vaccine 1.5 months earlier than is required by the protocol (p.145, 125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf).
7/28/2022 13:52:22	https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine	1	9	Data Missing	As you know Pfizer has two vaccines, one approved and one under EUA. In this press release they do not share the study results for the one approved with an efficacy of 91%, they only provide the results for the one under EUA with an efficacy of 95%. Are all of the files from the one under EUA? Where is the trial data from the one they approved? In this document they one under EUA is called modRNA https://www.fda.gov/media/144245/download "Pfizer-BioNTech COVID-19 Vaccine (BNT162b2) 4.1. Vaccine Composition, Dosing Regimen The Pfizer-BioNTech COVID-19 Vaccine is a white to off-white, sterile, preservative-free, frozen suspension for intramuscular injection. The vaccine contains a nucleoside-modified messenger RNA (modRNA) encoding the viral spike glycoprotein (S) of SARS-CoV-2" In this document they one approved is called mRNA https://www.fda.gov/media/152176/download "COMIRNATY contains a nucleoside-modified messenger RNA (mRNA) encoding the viral spike glycoprotein of SARS-CoV-2 that is formulated in lipid particles. During clinical development, the vaccine was called BNT162b2. COMIRNATY is the only vaccine or medical product that is FDA approved for prevention of COVID-19." Why the different names modRNA vs mRNA?
7/28/2022 14:06:17	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.pdf	3179	case# 11771317	Adverse Effects - Other	The subject was diagnosed with breast cancer and while she still had been recovering received the vaccine. The subject was diagnosed with Breast Cancer stage I on October 24,2020 after her 2nd placebo shot, on September 30, 2020.Her condition was marked as "recovering" and SAE. On January 18,2021 and February 8,2021 she received the vaccine while being recovering (p.3953, 125742_S1_M5_5351_c4591001-interim-randomization-sensitive.pdf). Her condition hadn't been updated till cut off data on April 1,2021. There is also a violation of the protocol for vaccine administration in the placebo group. She received the vaccine 2 months earlier than is required by the protocol (p.145, 125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf)
7/28/2022 14:36:12	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.pdf	3192	case#11781122	Adverse Effects - Other	The subject received the vaccine while being in unstable condition. The subject received two placebo shots. After the 2nd placebo, on September 28,2020, he/she was diagnosed with worsening of paroxysmal atrial fibrillation on January 14,2021. The adverse event was marked as SAE and the subject had recovered on February 4,2021. However, on January 19,2021, within 5 days of diagnosis, the subject received the vaccine. Probably the condition of the subject became more serious after the shot and he/she was hospitalized. However, the CRF isn't available for this case. Furthermore, his/her 2nd vaccine shot was administered in 40 days, on March 1,2021 which is a protocol deviation (p.3970, 125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf).There is also a violation of the protocol for vaccine administration in the placebo group. The subject received the vaccine 2 months earlier than is required by the protocol (p.145, 125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf).
7/28/2022 15:03:09	125742_S1_M5_5351_c4591001-interim-adverse-events.pdf	3193	case#11781138	Adverse Effects - Other	The subject had severe adverse event after placebo shot. However, he/she wasn't withdrawn from the study and received the vaccine which was a violation of the study protocol. The subject received two placebo shots. After the 2nd shot within 10 days he/she developed myocardial infarction. The condition was marked as SAE and the subject had recovered on October 19,2020. The CRF isn't available for this case to evaluate if the condition of the subject was stable before enrollment to the study. Furthermore, the subject received two vaccine shots on January 27,2021 and February 22,2021 (p.3970, 125742_S1_M5_5351_c4591001-interim-randomization-sensitive.pdf). The vaccine was administered 2 months earlier than is required by the protocol for the placebo group (p.145, 125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf).
7/28/2022 20:22:29	125742_S1_M5_5351_c4591001-interim-adverse-events.pdf	3641	case #11351033	Data Discrepancy	According to the document the subject received 3 doses (2 placebo and 1 treatment) before his death. However, there is no records that the subject received the treatment (p.3771, 125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf).There is only the record that the subject received 2 placebo (p.2336, 125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf). Another document, the list of discontinued subjects indicates that he received 2 shots and death happened on 156 day after the 2nd shot(p.205, 125742_S1_M5_5351_c4591001-interim-mth6-discontinued-patients.pdf) that contradicts the listing of deaths - 3rd shot and 5 days. There is no cause of death in the listing. However, in the discontinued patients it states that it was a suicide. The CRF isn't available to fully assess this case.
7/28/2022 21:21:53	125742_S1_M5_5351_c4591001_fa_interim_narrative_- sensitive pdf	article	article	Adverse Effects - Other	Article on Naturalnews.com by Mike Adams non 7/22/2022: "Self-assembling vaccine clot biostructures harvest conductive metals from your blood- preliminary ICP-MS analysis results' . pictures of clots removed from dead individuals by embalmers. Initial laboratory analysis describing various clots and differences in chemicals in blood clots and the synthetic "biostructures' Increase in Tin noted in these structures. 7/28/22 article by Belle Carter on naturalnews.com is second article entitled; ' Health Ranger Report: Post-vaccine clots taken from deceased individuals contain surprising amounts of metals".
7/28/2022 21:36:52	125742_S1_M5_5351_c4591001_fa_interim_narrative_sensitive pdf	video	video	Adverse Effects - Other	Video interview with Dr Jane Ruby and Mike Adams on the Dr Jane Ruby Show 7/27/2022. " Post-vaccine clot mysteries revealed with new lab results-Dr Jane Ruby and Health Ranger Mike Adams. He used an ICP-MS instrument to look at the composition of clots removed from deceased human beings who had been given the Covid-19 injection. Very interesting initial results.
7/29/2022 12:58:34	Combo of Tables 16.2.7.2.1 and 16.2.7.3.1-Severe	sheet 1	box comes up as though blocking access	Other	site appears blocked
7/30/2022 16:38:21	125742_S1_M5_5351_c4591001mth6adverseevents table16.2.7.4.1	1	1	Adverse Effects - Other	Why does it only have the 1st AEs start and end date where the data for the other AEs
7/30/2022 16:41:32	125742_s1_m5_5351_c4591001mth6 adverse events table 16.2.7.4.1	322	Bottom of page	Other	Went is the subjects info in red ink
7/30/2022 20:53:18	125742_S1_M5_5351_C4591001-fa-interim-narrative-sensitive.pdf	7-10	case # 10661350	Fatality	The subject's cause of death was Myocardial Infarction. However, he died in his sleep and the autopsy wasn't performed. Male, 58 years old, had suffered hypertension and insomnia since 2000(p.7). In 2018 he had Myocardial infarction and developed Cardiomyopathy. He received placebo shot on October 19,2020 and died within 16 days in his sleep. His wife reported that he had a heart attack. (p.10) and Pfizer concluded that it was a progression of his heart disease. However, the list of medication that the subject had been taking the last 2 weeks before the death didn't include any medicines to control hypertension or heart problems (p.10). On the contrary, it included two drugs (omeprazole and trazodone) which could cause cardiotoxicity if they are used for long time together (he had been taking both since 2015). The subject had alcohol abuse in his medical history, so the trazodone overdose cannot be excluded either. To exclude possibilities of overdose and cardiotoxicity, at least toxicology report should be performed. There is also possibility that the subject was in unstable health condition before enrollment to the study because he didn't take any medications to control high blood pressure. The narrative doesn't state how severe was his heart attack and cardiomyopathy in 2018.The CRF isn't available for this case.
7/31/2022 18:35:40	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.pdf	table 16.2.7.5	n/a	Adverse Effects - Other	For all adverse events of "Cardiac Arrest" 3 were after placebo and 8 were after vaccination.

7/31/2022 18:38:46	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.pdf	table 16.2.7.5	analysis of cardiac adverse events	Adverse Effects - Other	For all Cardiac adverse events r/t Heart Failure 4 were after placebo and 8 were after vaccination. (double the number in vaccinated vs. placebo)
7/31/2022 18:43:44	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.pdf	table 16.2.7.5	Analysis of cardiac adverse events	Adverse Effects - Other	For all adverse events labeled "Angina and or Coronary Artery Disease" 8 occurred after placebo and 18 occurred after vaccination. (this is most likely statistically significant)
7/31/2022 18:46:38	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.pdf	Table 16.2.7.5	Analysis of Cardiac Adverse Events	Adverse Effects - Other	For all Cardiac Adverse Events Labeled as "Myocardial Infarction, Acute Myocardial Infarction or Acute Coronary Syndrome" 14 were after Placebo and 19 were after vaccination. (may not be statistically significant)
7/31/2022 18:51:00	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.pdf	Analysis of Cardiac Adverse Events	Table 16.2.7.5	Adverse Effects - Other	For all Cardiac Adverse Events labeled as "VT, Ventricular Tachycardia, PVCs Premature Ventricular Contractions" zero were after placebo and all 5 were after vaccination. (is this related to sudden adult death syndrome?)
7/31/2022 19:07:03	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.pdf	Table 16.2.7.5	Analysis of Cardiac Adverse Events	Adverse Effects - Other	For all Cardiac Adverse Events excluding Tachycardia and Palpitations (which are generally benign and subjective) 59 were after placebo and 89 were after vaccination
7/31/2022 19:11:41	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.pdf	Table 16.2.7.5	Analysis of all cardiac adverse events	Adverse Effects - myocarditis	As it has now been established in the literature that myocarditis is correlated with Covid vaccination it is suspicious that within the grouping of cardiac adverse events there were only 2 cases of myocarditis, and these were in the placebo group? Maybe it is elsewhere and not grouped under cardiac adverse event?
8/1/2022 11:55:55	125742_S1_M5_5351_c4591001-interim-mth6-adverse-events	Multiple	Multiple	Adverse Effects - Other	Two points about the reporting of AEs in this document on "Adverse Events." 1). Over 32,000 AEs reported. Only mild AEs are "related to the vaccine." All bar a handful are reported as Resolved. Those reported as not related to the vaccine include: miscarriages, sudden cardiac death, stroke, hemorrhage, coagulopathy, pulmonary embolisms, AFib, thrombosis, cancers, severe dyspnoea, shingles, tremors, chest pain, thyroid dysfunction, bradycardia & tachycardia. (A couple of the tachycardia cases are "related" to the vaxx.) This is almost all Pfizer guesswork - how would they know many mild AEs are vaxx related & virtually none of the serious ones are? (To see the 'mild vaxx related' AEs, just search for the word Yes in this document. R beside it means al the AEs were resolved.) 2). Over 100 "exposures during pregnancy" are noted with outcomes 'UKNOWN'. So, as we have already asked, what happened to those babies? (To see these AEs just search for the three letters UNK in this documents.)
8/4/2022 11:14:51	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/080122/125742_S2_M5_54_ezeanolue-e-2019.pdf	176, 178, 30-34	noted in explanation section	Other	CDC doc: General Best Practice Guidelines for Immunization (ACIP)Advisory committee on Immunization and Practices. This document was undated. It did not include any references to mRNA covid vaccines. However, within the doc, the latest-dated reference is to a 2020 publication, HEALTHY PEOPLE (pg. 176 and 178). Thus, this document was updated or at least as late as 2020 without any inclusion of mRNA vaccines and adverse events reported to VAERS. No mRNA listed in table 3-2, Recommended Minimal Ages and Intervals Between Vaccine Doses, (pg. 30-34) despite CDC releasing info to the public about vaccine schedules during the pandemic.
8/4/2022 11:18:16	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/080122/125742_S2_M5_54_ezeanolue-e-2019.pdf	191	noted in explanation section	Other	CDC doc: General Best Practice Guidelines for Immunization (ACIP)Advisory committee on Immunization and Practices. This doc includes definitions of ADVERSE EVENT (AE) and ADVERSE REACTION (AR) at Pg. 191. An AE is an untoward event that might be caused by the vaccine or vaccine process. This undercuts Pfizer's other documents which note numerous AE's and Serious AE's and records its investigators concluding all or most of the time no relationship to the vaccine. Pfizer (in collusion with CDC??) are engaging in a word game. Per CDC, if an adverse event is observed and noted, then it might be caused by the vaccine. The doc distinguished ADVERSE REACTION as an established demonstrated causally related medical condition to a vaccine. Given this definition and IF the CDC relied upon Pfizer's repeated cursory conclusions that AE's and SAE's were not related to the vaccine, there would likely be no inquiry into the reported AEs and SAE's at all. Carried to its most narrow absurd end, there would never be any established adverse reactions to the Pfizer Covid vaccine, if CDC simply took the word of Pfizer's AE investigators. No relationship to the vaccine -- ever.
8/4/2022 11:26:45	https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/080122/125742_S2_M5_54_ezeanolue-e-2019.pdf	3, 9	noted in explanation section	Other	CDC doc: General Best Practice Guidelines for Immunization (ACIP) Advisory committee on Immunization and Practices. This document does not include any reference to mRNA covid vaccines. In June 2015, the ACIP voted on the best practices, which apparently is reflected in this doc. (pg. 9) There are vague references to docs that have been moved onto the CDC web site. There is an online version updated as of March 15, 2022, https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf even though the text of the online document is still "undated." Different individuals are listed in the online doc as authors: Kroger A, Bahta L, Hunter P, so CDC did take the time to update the named authors. The online doc looks to be substantially the same as the Pfizer doc produced in the court ordered tranche. mRNA is not listed as a vaccine in the Pfizer court ordered document or the "updated" online version. At the very least, this online 3/2022 'updated' online doc is inaccurate, not fully updated. It also is noteworthy that the 3/2022 'updated' online version of this doc, includes the older definition of vaccine ("A suspension of live (usually attenuated) or inactivated microorganisms (e.g., bacteria or viruses) or fractions thereof administered to induce immunity and prevent infectious disease or its sequelae…") News stories in January 2022 reported that CDC had made a second modification to the definition. https://www.cnsnews.com/article/national/susan-jones/cdcs-definition-vaccine-has-changed-over-time-protection-vs-immunity. The most recent revised definition of vaccine seems to conflict with the one of the stated purposes of this doc: to help "communicate the importance of vaccination to reduce the effects of "vaccine-preventable disease." (last para., pg. 3). CDC is saying the vax prevents disease and it doesn't. The definition discrepancies as of 2022 are evidence of CDC being disingenuous at best and at worst legally evasive.
8/4/2022 15:51:24	Other Local radio station advertising Pfizer covid vaccine Comirnaty in PA>	Other	Other	Other	False advertisement of product NOT available in the US. not FDA approved

8/4/2022 17:14:44	3 - 125742_S1_M5_5351_c4591001-interim-mth6-adverse-events Table16.2.7.4.1.xlsx	Not applicable	Not applicable	Fatality	I ran a spreadsheet analysis of Table 16.2.7.4.1 sorting for fatalities from the July data drop. Sorry, I had intended to submit this mid-July but family responsibilities had to come first. The results showed 48 fatal outcomes. I then created a summary file of the 48 fatalities and analyzed for when the fatalities occured vs. Dose. Found that 8% occurred after Dose 1; 88% after Dose 2; and 4% after Dose 3. I then checked for causes of death and broke down by category. Categories were chosen based on I had noted in numerous publications on adverse vaccine events. Results indicate: Cardiovascular related 35%; Respiratory related 31%; COVID-19 related 13%; Cancer related 8%; Sepsis related 8%; Stroke related 2%; Multiple organ dysfunction syndrome 2%; and Other Causes 15%. I will include the fatality sorted spreadsheet (3-125742_S1_M5_5351_c4591001-interim -mth6-adverse-events_Table 16.2.7.4.1-formatted_FATAL SORT.xlsx) and the summary file (Table 16.2.7.4.1 - FATAL Sort Results.xlsx) in the dropbox.
8/7/2022 6:14:48	16.2.7.2.1 and 16.2.7.3.1 from 125742_s1_m5_5351_c4591001	15-90-95-115-145	Charts	Adverse Effects - Other	Why is HIV LISTED FOR TH SUBJECTS ON THE ABOVE MENTIONED PAGES HIV IS NOT LISTED ON THE PAGES ABOVE THE MENTIONED
8/7/2022 6:17:59	16.2.7.2.1 and 16.2.7.3.1 from 125742_s1_m5_5351_c4591001	119	Graph	Other	Why were a few subjects given 100 instead of the usual 30
8/7/2022 6:19:42	16.2.7.2.1 and 16.2.7.3.1	169-170-174-175-189-190	Graphs	Data Missing	THOSE pages are blank
8/7/2022 6:38:01	Original unparsed data	4	Graphs last subject on page	Other	There's no way on God's green earth a 62 year old woman is pregnant
8/7/2022 6:40:27	Original unparsed data 16.2.7.7	7 and 9	First	Other	Both those pages says confidential SDTM CREATED
8/7/2022 6:42:06	Original unparsed data 16.2.7.7	3 and 6	All	Fatality	Both pages states all subjects died
8/8/2022 14:28:10	125742_S2_M5_54_ezeanolue-e-2019.pdf	193/195	2	Other	Usage of classic definition of vaccine, vaccinate, and immunization - substantially different from current CDC definitions.