

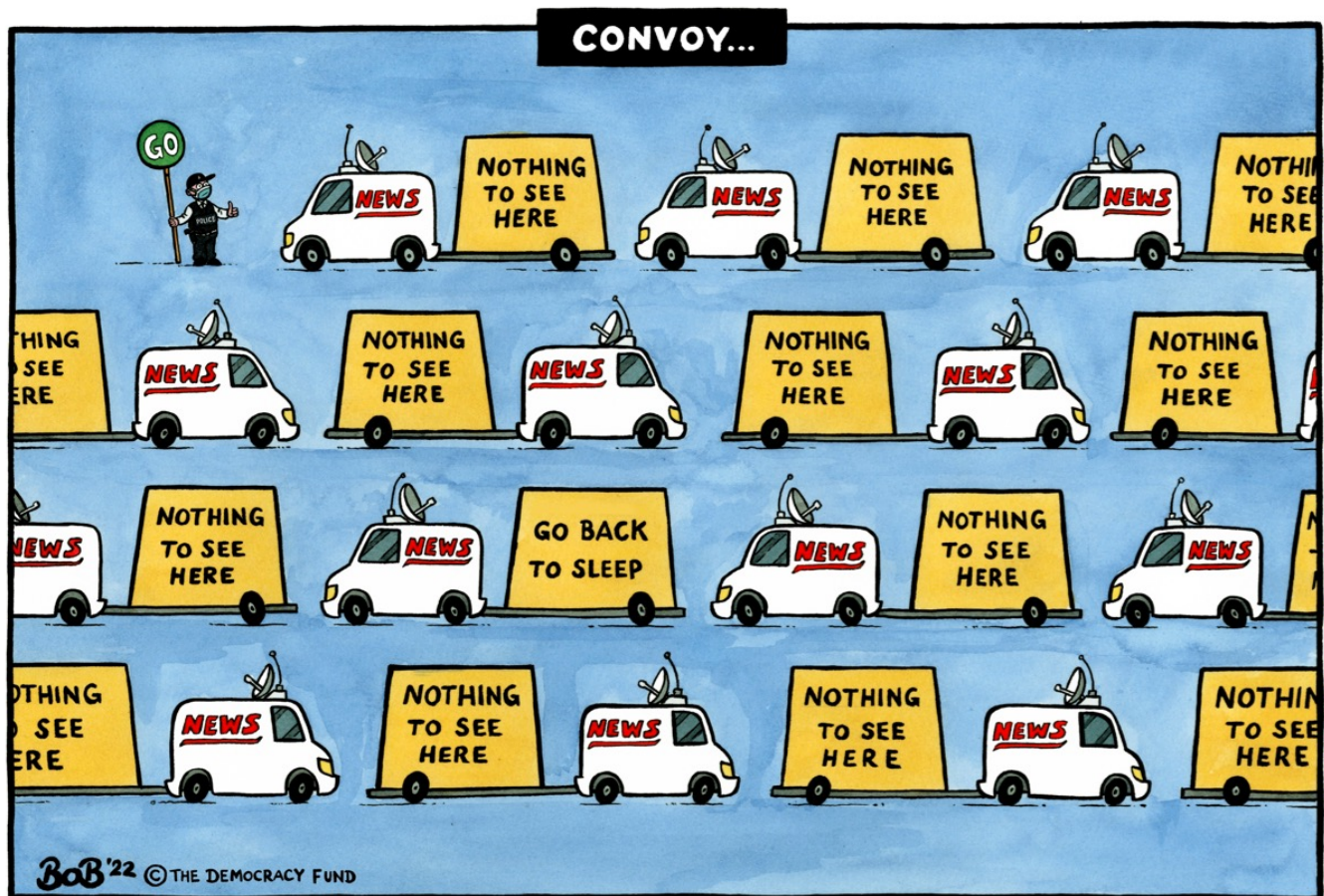
Exhibit 486

The story of patient 11281009 in the Pfizer trial

<https://www.hartgroup.org/the-story-of-patient-11281009-in-the-pfizer-trial/>

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March 11, 2022 (<https://www.hartgroup.org/the-story-of-patient-11281009-in-the-pfizer-trial/>)



Some disturbing findings hidden in the reluctantly released data

After a Texan court ordered the FDA to release the documents used to approve the covid vaccine the first 150 documents have now been published (<https://phmpt.org/pfizers-documents/>). These include the medical notes for a selection of patients at five different trial sites. Sonia Elijah has carried out part 1 of a forensic analysis of the patient notes and

noted some disturbing findings (<https://trialsitenews.com/a-first-look-at-the-newly-released-pfizer-papers-part-1-the-errors-and-anomalies-of-the-case-report-forms/>), for a number of patients.

The story of patient 11281009 (<https://phmpt.org/wp-content/uploads/2022/02/CRFs-for-site-1128.pdf>) is just one example. Patient 11281009 was a white male who would have turned 66 years of age in 2020. By piecing together the entries in the system and the audit log querying errors in those entries it is possible to recreate a timeline of events (see below).

In summary, after two doses of either vaccine or placebo by 9th August, he presented to the emergency room with cough and shortness of breath. This presentation was recorded as suspected covid. He had a myocardial infarction and developed a pneumonia during his stay. No details of covid testing were recorded but the family reported a single negative test taken during his hospital stay. He was discharged home where he died sometime between the end of October and beginning of February. No explanation was given for why hospital treatment was abandoned; remember you had to be “healthy” to enroll in the trial. The death certificate was said to have recorded the cause of death as “pneumonia”.

His last contact with the trial site was 16th September 2020. The trial protocol included participants having an app on their device to enter any covid-like symptoms but there is no entry of this in trial medical record. His family phoned the site on or around 8th December and relayed the details of his last weeks. These were entered in a “potential covid 19 form” by the site. However, the date of this entry was after death. For this reason all the details of the clinician’s concerns around him having had covid were expunged retrospectively from his records in the trial.

To reiterate, this patient had a cough, shortness of breath and presented to hospital with suspected covid, developed pneumonia, died of it and all records of this presentation except hospitalisation then death from “due to infection” were removed from the trial.

The inability to ensure accurate records are kept and to test people with suspected covid raises real concerns about the accuracy of the trial data. Even after 6 months (<https://www.medrxiv.org/content/10.1101/2021.07.28.21261159v1.full.pdf>), up to March 2021, only 2.2% of people enrolled in the trial were said to have had covid. However, there

were 3410 (<https://www.fda.gov/media/144245/download#page=42>) (<https://www.fda.gov/media/144245/download#page=42>) cases of “suspected covid” (7.3% of the vaccine arm and 8.4% of the placebo arm). For comparison, Public Health England estimated that 15% (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/973174/Weekly_Flu_and_COVID-19_report_w12.pdf) of the population had had covid over the year up to end of March 2021, based on antibody testing which may underestimate the total. Why enroll 44,000 people into a trial and then fail to diagnose the disease of interest? How much bias was introduced by failure to test?

We recommend you read the timeline of events below. It tells a disquieting story and as yet, we do not know how many other details of the trial might ultimately be seen as ‘troubling’ at best. With billions of dollars at stake, involving the company who once paid a fine of \$2.3 billion (<https://www.reuters.com/article/us-pfizer-settlement-idUSTRE5813XB20090902>), \$1.3 billion of which was a criminal fine, let us not be naive enough to think that ‘health and well-being of the nations’ was Pfizer’s primary goal in their rushed product roll-out.

TIMELINE

27th July 2020: Pfizer selects molecule (<https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-choose-lead-mrna-vaccine-candidate>) for testing.

31st July 2020: He was screened, consented, enrolled, randomized, swabbed and injected with a first dose. This may have been placebo or vaccine. Something odd happened with his consent which was described as “unknown or N/A” (see pg 352 (<https://phmpt.org/wp-content/uploads/2022/02/CRFs-for-site-1128.pdf>)) but marked a “obtained” eventually.

19th August 2020: He had a further nasal swab and received a second dose.

Nothing is then entered in the record until 8th December. When this entry appears:

27th October 2020: He had a Myocardial Infarction and was hospitalized. This was recorded as a serious adverse event. In response to the question “Is this event related to treatment?” was the response “Not related. Due to – other – failed cardiac stent.”

28th October 2020: The following day he remained in hospital with life threatening pneumonia. In response to “Is this event related to treatment?” was the response “Not related. Due to – other – infection.”

At some point between the end of October and 9th December 2020 the patient died at home (pg 333). The entry saying he died at home is still in the audit trail but the form where this information was uploaded is not present in the patient record. The cause of death was entered on 13th January 2021 as “pneumonia”. There is no record of the length of hospital stay or why he was discharged before death.

18th Nov 2020: Pfizer published (<https://www.nejm.org/doi/pdf/10.1056/NEJMoa2034577?articleTools=true>) a press release claiming over 94% efficacy of the vaccine.

2nd December 2020: MHRA authorises (<https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-achieve-first-authorization-world>) vaccine for emergency supply.

8th December 2020: Four issues were raised.

1. That the adverse event had been recorded as “fatal” but no death form was recorded (pg 349).
2. No serious adverse event number had been entered for either the myocardial infarction or the pneumonia (pg 345)
3. It was suggested that the myocardial infarction entry should be changed from a serious adverse event to a “worsening adverse event” on the basis that he had had a previous myocardial infarction in 2017 (pg 337).
4. It was noted that the serious adverse event had been marked as “recovered or resolved” in the safety database despite the death of the patient (pg 341).

9th December 2020: The file is marked as “discontinued”.

13th December 2020: The gentleman's relatives telephone the centre to tell them about the lead up to his death (pg 301 to 303). It seems someone is unsure how to enter this information and is advised:

“Potential COVID-19 related PNEUMONIA should have please triggered a COVID Illness Visit irrespective of perceived etiology or clinical significance. Please complete the COVID-19 CRF forms. Please complete the potential COVID-19 Illness Visit CRF forms with all information available. Should be captured only on the SOD CRF form and a NASAL SWAB will not be collected. Please the data should still be captured on the appropriate CRF pages (as for any late data, we will still capture it and not ignore it) but a swab will not be required” (pg 345-6)

14th December 2020: The person wanting to record this information opens up a “potential covid 19 visit form”. The audit trail then spits out a complaint that no swab was taken, no sign or symptom form was completed and this form was dated after the file had been discontinued. Someone patiently filled out the explanation that the patient was deceased and these were not possible for each of these entries.

The audit trail shows that the data entered on this date included that the patient had a cough, shortness of breath but no loss of smell or taste, diarrhoea or vomiting, (pg 308) and had been seen in the emergency room (pg 324) for a “potential covid 19 illness” (pg 329).

31st Dec 2020: Pfizer released their NEJM (<https://www.nejm.org/doi/pdf/10.1056/NEJMoa2034577?articleTools=true>) paper of the trial results. No covid deaths were reported to have taken place.

19th January 2021: Query raised that the covid illness form was dated 14th December 2020 after the subjects death. The site responded to this saying,

“The symptoms were reported to site after subject's death via subject's family, per medical monitor, this data is to be entered.”

22nd January 2021: He was due to be unblinded in the trial and offered a vaccination if he had been in the placebo arm.

26th January 2021: The site were told:

“There cannot be a date later than the date of death. Please remove data from the COVID Illness visit and add COUGH and SHORTNESS OF BREATH as AEs...COVID_A visit should then be marked as ERRONEOUS.”

28th and 29th January 2021: Attendances for nasal swab and antibody testing were marked up individually as “not applicable” and then an entry stated that he had “withdrawn consent” presumably to prevent these repeated requests for more data.

15th February 2021: The site were told:

“For correct attribution of Pneumonia; please update AE term to COVID Pneumonia or Pneumonia secondary to COVID-19 else clarify as per guidance from Clinical Monitor” (pg 344)

And

“We need to remove the COVID Illness visit which was originally requested. Please mark Erroneous and remove the data from within the visit using FORM Level comments of NOT APPLICABLE.” (pg 299)

27th February 2021: The site responded:

“SITE HAS NOT BEEN MADE AWARE THIS EVENT WAS COVID PNEUMONIA. PER PI PNEUMONIA WAS RELATED TO INFECTION, HOWEVER SITE HAS NO RECORDS THAT STATE COVID, THEREFORE TERM CANNOT BE UPDATED TO SUCH.” (pg 344)

2nd March 2021: ***“Site has not received MR (medical record) and cannot confirm a COVID test was done, however per family of subject, there was a negative COVID done, sometime during hospital stay, not sure which day or which test.” (pg 316)***

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