FREE LIVE WEBINAR PRESENTED BY:

ERIAH GROUP

CLINICAL TRIAL INSPECTIONS

ARE YOU READY?

Wednesday
Dec. 6, 2023

Robert Bilkovski, M.D., MBA
CLINICAL/MEDICAL SME

Donna Haire, M.S.
CEO & HOST

Sue Chase, B.S.N.
CLINICAL QUALITY SME

1pm-2pm EST

Our team of experts will:

- **Review:** Top clinical trial compliance challenges and the latest FDA BIMO Inspection Metrics.
- **Interpret:** What the data means for YOUR clinical trials.
- **Recommend:** How to prepare for a successful clincal inspection.

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Clinical Trial Inspections: Are You Ready?

Donna Haire, CEO

Moderator Overview

Our panel of experts will review top clinical trial compliance challenges in the industry

Key Takeaways from Today's Panel Discussion:

- Review common BIMO Inspection FDA 483 Observations
- Increase awareness of pitfalls that may impact your study’s compliance
- Provide recommendations for overcoming compliance hurdles, helping you better prepare for a BIMO Inspection

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Meet the Panel

Robert Bilkovski, M.D., MBA
Clinical & Medical SME

Dr. Bilkovski has over 25 years experience in leadership roles overseeing medical affairs and clinical development in the IVD, medical device, and pharmaceutical industries. Some of the companies where he worked include Hospira, GE Healthcare, Abbott Laboratories and Becton Dickinson. Dr. Bilkovski currently provides strategic consulting in the fields of medical and clinical affairs.

Donna Haire, M.S.
RA, QA & Clinical SME

Donna Haire is the CEO of The Eriah Group, Inc. She has over 25 years of experience in global regulatory, quality and clinical affairs in the healthcare, pharmaceutical, and medical device industries. She held executive and senior level positions at Bayer, On Target Laboratories, AngioDynamics, Philips Healthcare, and Medtronic. She was an adjunct professor of law and served as an AdvaMed board committee member.

Sue Chase, B.S.N.
Clinical Quality SME

Sue Chase has over 30 years experience in healthcare and served in upper management roles in a clinical research environment. She held leadership roles at Vertex Pharmaceuticals, ICON Government and Public Health Solutions (ClinicalRM) and the CCF Cardiovascular Coordinating Center (C5Research). She currently provides clinical research consulting in operations and clinical quality.

Background

BIMO Background

- FDA's Bioresearch Monitoring (BIMO) Program (founded in 1977) is a cornerstone of the FDA preapproval process for new medicines, medical devices, food and color additives, veterinary products and tobacco products
- The BIMO Program includes on-site inspections, data audits and remote regulatory assessments designed to monitor all aspects of the conduct and reporting of FDA regulated research
- The BIMO Program is implemented domestically and internationally resulting in over 1,000 inspections annually

BIMO Objectives

The objectives of the BIMO Program are to:

- Ensure the protection of the rights, safety and welfare of human subjects participating in clinical studies
- Ensure the quality, integrity, and validity of clinical, analytical and statistical data from clinical studies
- Ensure compliance with applicable FDA regulations and to identify significant deviations

FDA's BIMO Metrics – FY2022

- Each year, the FDA publishes the BIMO Inspection Metrics from the previous year
- FDA recently released the 2022 BIMO Metric results and it indicated a total of ***766 BIMO Inspections***
- Of the 766 BIMO Inspections performed, 717 inspections were performed by CBER (Biologics - 108), CDER (Drugs - 471), and CDRH (Devices - 138)
- Majority of 483 observations were for Clinical Investigators (504) and Sponsor/CRO (81)

BIMO Inspection Final Classifications by Center - FY2022*

Center	CI	IRB	S/M/CRO	S/I	GLP	BEQ	PADE	REMS	Total
CBER (Biologics)	80	10	10	0	8	0	0	0	**108**
CDER (Drugs)	311	7	48	9	7	42	35	12	**471**
CDRH (Devices/Radiological Health)	77	31	22	1	7	0	0	0	**138**
CFSAN (Food/Nutrition)	2	1	0	0	1	0	0	0	**4**
CTP (Tobacco)	2	0	0	0	0	0	0	0	**2**
CVM (Veterinary Medicine)	32	0	1	0	10	0	0	0	**43**
Total	**504**	**49**	**81**	**10**	**33**	**42**	**35**	**12**	**766**

*Includes both Domestic and Foreign inspections

Panel Session

Common Clinical Investigator Inspection 483 Observations

1. Failure to comply with Form FDA 1572 requirements, protocol compliance
2. Failure to follow the investigational plan; protocol deviations
3. Inadequate and/or inaccurate case history records; inadequate study records
4. Inadequate accountability and/or control of the investigational product
5. Safety reporting; failure to report and/or record adverse events
6. Inadequate subject protection; informed consent issues

Common Sponsor/CRO Inspection 483 Observations

1. Failure to ensure proper monitoring of the study and ensure the study is conducted in accordance with the protocol and/or investigational plan
2. Failure to meet the abbreviated requirements for investigational device exemptions (IDEs)
3. Failure to maintain and/or retain adequate records in accordance with 21 CFR 312.57; accountability for the investigational product; Investigator Statement (Form FDA 1572); Financial disclosures
4. Failure to submit an Investigational New Drug (IND) application; IND safety report
5. Failure to submit current list of all participating investigators to FDA at six-month interval after FDA approval of the study

Questions?

References

Bioresearch Monitoring (BIMO) Fiscal Year 2022 Metrics
https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/bimo-inspection-metrics

7348.810 Sponsors, Contract Research Organizations and Monitors

7348.811 Clinical Investigators and Sponsor Investigators

7348.809 Institutional Review Boards

Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors
- FDA Institutional Review Board Inspections, January 2006

FDA Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors
- FDA Inspections of Clinical Investigators, June 2010

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Thank you!