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2017 FDA Inspections

Findings for Clinical Investigators

The FDA recently released the Bioresearch Monitoring (BIMO) inspection metrics for the 2017 fiscal year.[1] The purpose of the BIMO program is to ensure the protection of the rights, safety and welfare of human research subjects and the integrity of the study data in FDA-regulated clinical trials.

The BIMO metrics summarize results from both domestic and international inspections and include all branches of the BIMO program: Clinical Investigators, Institutional Review Boards, Sponsors, Contract Research Organizations, and Monitors, the In-Vivo Bioequivalence Compliance Program, and Good Laboratory Practice.

The inspection statistics represent findings from 1,324 clinical research audits of Clinical Investigators, Sponsor/Monitor/CROs, and IRBs conducted during the 2017 fiscal year. Findings are classified as no action indicated (NAI), voluntary action indicated (VAI) and official action indicated (OAI). For reference:

NO ACTION INDICATED	No objectionable conditions or practices were found during the inspection.
VOLUNTARY ACTION INDICATED	Objectionable conditions were found but the problems do not justify further regulatory action. Any corrective action is left to the investigator to take voluntarily.
OFFICIAL ACTION INDICATED	Objectionable conditions were found and regulatory and/or administrative sanctions by FDA are indicated.

FOR CLINICAL INVESTIGATORS,

73% of these audits had no action indicated (NAI)

26% resulted in voluntary action indicated (VAI)

1% resulted in official action indicated (OAI)

Overall, the common Clinical Investigator deficiencies in 2017 included:

- Failure to follow the investigational plan/agreement or regulations, or both
- Protocol deviations
- Inadequate record keeping
- Inadequate subject protection—informed consent issues, failure to report adverse events
- Inadequate accountability for the investigational product
- Inadequate communication with the IRB
- Investigational product represented as safe/effective

The Warning Letters posted to the FDA website[2] in 2017 include the common findings. Of the six letters posted to Clinical Investigators in 2017, the following deficiencies were included:

You failed to ensure that the investigation was conducted according to the investigational plan

Examples:

- Enrolling subjects that did not meet eligibility criteria
- Failure to perform protocol-related testing at specific times
- Failure to ensure discontinuation of prohibited medications
- Failure to conduct follow-up as prescribed in the protocol

You failed to maintain adequate and accurate case histories

Examples:

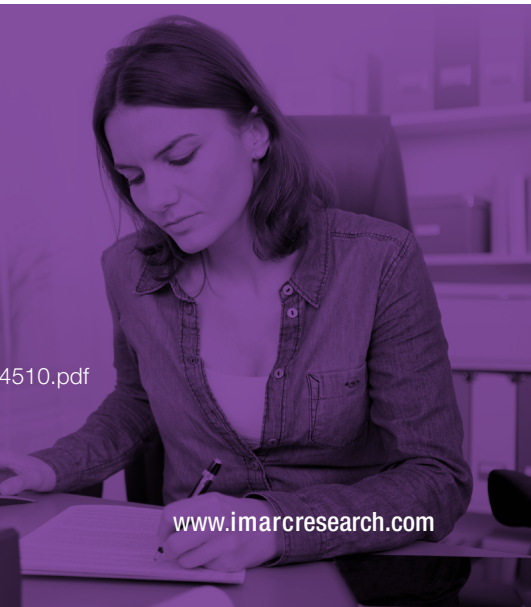
- Failure to maintain case histories that contain specific study-related data
- Source documents were not completed; however, despite the blank forms, electronic case report forms (eCRFs) included data submitted to the Sponsor

You failed to maintain adequate records of the disposition of the study product, including dates, quantity, and use by subjects

Examples:

- The amount of drug dispensed did not match the amount of drug taken, according to the eCRFs. In addition, the amount of drug returned did not match the amount of drug that should have been returned, based on the reported drug dosing records.
- Failure to document the disposition of unused supplies of study drug through the study drug accountability logs
- Failure to produce the unused supply of study drug with no other records indicating the use or disposal of the unused supply of study drug

Year after year, the common deficiencies remain the same. What can we learn to avoid these deficiencies? **If your study was inspected, would you have findings? What would they be?**



References:

1 https://www.fda.gov/downloads/ScienceResearch/SpecialTopics/RunningClinicalTrials/UCM604510.pdf

2 https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm