Investigator-Sponsored Multi-Center Trials
Information Sheet: Auditing versus Monitoring

Auditing and Monitoring are separate and distinct functions. A Data Safety Monitoring Plan (DSMP) is required for Investigator-Sponsored Multi-Center Trials per DF/HCC Policy MULTI-100, and must include appropriate language related to auditing and monitoring, among other DF/HCC requirements. Interventional trials are required to use the DF/HCC Multi-Center DSMP Template to fulfill this requirement.

Auditing

Auditing is a method of Quality Assurance and is, therefore, process focused. Through systematic and independent examination of research activities and documents, auditing verifies that research teams have successfully implemented processes that ensure appropriate research conduct of all protocols in accordance with DF/HCC Policies, Good Clinical Practice (GCP) and the Code of Federal Regulations. At the DF/HCC, independent and centralized auditing of clinical trials is performed by the Office of Data Quality.

Monitoring

Monitoring is a method of Quality Control and is; therefore, outcome focused. Through ongoing identification and remediation of errors and other non-compliance, monitoring oversees the progress of an individual clinical trial to ensure high quality research outcomes for that trial. Monitors ensure data are recorded and reported in accordance with the protocol, policies, Good Clinical Practice (GCP) and the Code of Federal Regulations. For DF/HCC Investigator-Sponsored clinical trials, monitoring is the responsibility of the Sponsor-Investigator.

References:

FDA Compliance Program 7348.810 Bioresearch Monitoring

…clinical trial quality control units (QAUs) are not required by the regulation. However, many sponsors have clinical QAUs that perform independent audits/data verifications to determine compliance with the study protocol clinical trials SOPs and FDA regulations. QAUs should be independent of, and separate from, routine monitoring or quality control functions". In addition, it notes that "findings that are the product of a written program of QA will not be inspected without prior concurrence of the assigning FDA Headquarters Unit….

21 CFR 312.50 General responsibilities of Sponsors

Sponsors are responsible for selecting qualified investigators, providing them with the information they need to conduct an investigation properly, ensuring proper monitoring of the investigation(s), ensuring that the investigation(s) is conducted in accordance with the general investigational plan and protocols…

21 CFR 312.56 Review of ongoing investigations.

(a) The sponsor shall **monitor** the progress of all clinical investigations being conducted under its IND.

ICH GCP E6(R2) Section 5.18.3-Extent and Nature of Monitoring

The sponsor should ensure that the trials are adequately monitored. The sponsor should determine the appropriate extent and nature of monitoring. The determination of the extent and nature of monitoring should be based on considerations such as the objective, purpose, design, complexity, blinding, size, and endpoints of the trial. In general, there is a need for on-site monitoring, before, during, and after the trial; however in exceptional circumstances the sponsor may determine that central monitoring in conjunction with procedures such as investigators' training and meetings, and extensive written guidance can assure appropriate conduct of the trial in accordance with GCP. Statistically controlled sampling may be an acceptable method for selecting the data to be verified.

The sponsor should develop a systematic, prioritized, risk-based approach to monitoring clinical trials. The flexibility in the extent and nature of monitoring described in this section is intended to permit varied approaches that improve the effectiveness and efficiency of monitoring. The sponsor may choose on-site monitoring, a combination of on-site and centralized monitoring, or, where justified, centralized monitoring. The sponsor should document the rationale for the chosen monitoring strategy (e.g., in the monitoring plan).

ICH GCP E6(R2) Section 5.19- Audit

The purpose of a sponsor's audit, which is independent of and separate from routine monitoring or quality control functions, should be to evaluate trial conduct and compliance with the protocol, SOPs, GCP, and the applicable regulatory requirements.