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Audits and maintaining clinical trial compliance

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Clinical research is the very reason for a multitude of medical breakthroughs discovered by researchers, doctors, nurses, and other medical professionals throughout history. The singular purpose is for the benefit of the health and wellbeing of individuals. Compliance and protecting human subjects are at the center of conducting clinical research. Audits are an inevitable part of clinical trial compliance; therefore, it is necessary to remain vigilant and up to date in the dynamic healthcare environment. Regardless of industry type, the majority of all professional organizations, big or small, participate in the process of internal and external audits. The clinical trial industry and, more specifically, research sites that conduct clinical trials participate in audits on a regular basis.

The amount of regulatory data and the importance of data accuracy inherent in oncology clinical trials are significant. Proactively, conducting internal audits is necessary in preparing for external audits and ensuring compliance in following protocol-specified Good Clinical Practice (GCP) guidelines^[1] and regulatory requirements. "GCP is the universal ethical and scientific quality standard for conducting clinical trials."^[2] Sponsors are responsible to abide by the International Conference on Harmonisation (ICH) guidelines to maintain quality assurance and quality control.^[3] This process dates back to the establishment of federal standards for conducting and monitoring clinical trials. In 1962, the United States Food and Drug Administration's (FDA) Investigational New Drug (IND) regulations went into effect, establishing the Bioresearch Monitoring Program (BIMO). This program helps ensure the protection of research subjects and the integrity of data submission.^[4]

Types of audits

There are two types of audits to be aware of, sponsor-based audits that occur at least once throughout the cycle of an open clinical trial and FDA lead audits that could occur at any time. It is essential that research sites are prepared at every level in the event of an audit and should regularly conduct internal audits. Having an organized and seamless internal auditing process will help avoid any potential major deviations during a sponsor-based or FDA lead audit.

First, it is necessary to establish a continual internal audit process that works for the investigation site. Patient case charts and regulatory charts should be audited internally on a regular basis to ensure all GCP guidelines are followed. As specified in the American Society of Clinical Oncology (ASCO) statement, "on minimum standards and exemplary attributes, implementation of internal quality assurance (QA) programs help ensure adherence to GCP guidelines and contribute to the ability of a clinical trial site to produce first-rate data."^[5] It is essential for these programs to include internal (self) audits, updating standard operating procedures (SOPs), protocol deviation reporting, quality assurance, and educational standards for clinical trial sites.

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