Good clinical practice (GCP) is an international ethical analysis and scientific quality standard for designing, conducting, and auditing clinical trials that involve the participation of human subjects. Investigators, sponsors, clinical research organizations (CROs), and institutional review boards (IRBs) must have a working knowledge of GCPs for assurance of the best protection of human subjects and the preservation of the quality, reliability, and integrity of the data.

The GCP audit is the interface for this assurance. It is carried out to assess compliance with regulatory requirements for the clinical trial protocol and the clinical quality management plan (CQMP) by the principal investigator and all of the site support personnel. The CQMP is an extension of a sponsor or CRO’s quality programs and standard operation procedures. During the site feasibility and qualification process, the sponsor or CRO personnel will not only be checking professional credentials but also the ability and resources available to carry out the assigned duties of the site, both professionally and administratively. Not being compliant can lead to failures, delays, unrecognized adverse events, and most importantly, loss of protocol and data integrity. This could lead to a challenge of the clinical trial results by regulatory authorities.

GCP audits can have different purposes relative to the clinical trial process. It is not always a site(s) and monitoring audit—a GCP audit can be a full clinical trial audit over systems and operations conducted by monitors and trial management, a full clinical trial audit over the clinical trial sites, or an audit of the CRO carrying out the clinical trial on behalf of the sponsor. A GCP audit can also be conducted for the qualification and selection of a CRO. Audit scope can be for the purpose of auditing data management and electronic data capture (EDC) systems, electronic medical records (EMR) integrity, interactive response technology (IRT) systems such as IVRS and IWRS, regulatory compliance for essential document collection and integrity throughout the study, for institutional review boards/international ethics committees, specialized Phase 1 unit compliance, Phase 1 SOP development and training, or over third party vendors.

Experienced auditors will help identify potential risks and help to ensure that the compliance issues do not jeopardize the study. It is obviously useful that the clinical trial auditor has a good understanding of the clinical trial process and objectives. Of particular
interest to a potential site is the site qualification process and compliance expectations before, during, and after the clinical trial. Of further importance to the site is the need to be transparent about the site responsibilities within the CQMP. Once selected, the site wants a clear and thorough study start-up process and an explanation of the potential for an audit by the sponsor or regulatory authority. That means that each member of the site team has obligations to fulfill with regards to the CQMP and GCP compliance.

CQMP requires each site to have a quality management coordinator. The quality management coordinator works closely with the principal investigator and the clinical study coordinator (CSC). The purpose of the CQMP is to identify and document the ongoing processes and activities that are used to monitor and facilitate quality protocol execution, including data collection and entry following study initiation. A good compliance organization can support the development of this CQMP for discussion during the clinical trial kick-off and initial investigator meeting.

The site CSC has the responsibility to see that all study personnel have completed all required institution-specific and protocol-specific trainings and that these trainings are documented appropriately in the training log. The site will maintain a delegation of responsibilities log. The CSC will verify that all training is current and appropriately documented on a quarterly basis.

Finally, the quality management coordinator will assure on a quarterly basis that a report is filed internally as a reference for the CRO clinical research associate and other external clinical trial responsible parties. This report will include assurance of integration of new personnel, consent process completion, source document completion and review, eCRF review to minimize correction of induced data entry errors, assurance of ongoing equipment calibration and maintenance, proper handling of investigative product and logs, and awareness of any protocol or study changes based on shared data with other investigators. The report will document other matters related to important events such as SAEs and AEs and note any corrective actions undertaken by the site independently or at the request of the CRA from the sponsor or CRO.

These site responsibilities are a serious part of the clinical trial process. The conduct of a thorough GCP audit will include the review of the information found in the CSC report. This CSC report is crucial to the GCP audit and contributes to a speedy site audit, but because the CSC requirement is not well understood with most sites and principal investigators, we will address this in a future blog.

A meaningful GCP audit of a clinical trial will focus on the integrity of this process and the compliance of the site with all aspects of the protocol and the actions of each person who handles some aspect of the clinical trial. With the 21st Century Cures Act calling for more patient-centric analysis and real world experience during and after the clinical trial, it behooves clinical trial sites to understand the necessary quality standards compliance and to be organized and prepared for the GCP audit that is sure to come.

Are you and your administrators ready to address these ongoing compliance aspects of the clinical trial process? Be an attractive site to work with. A little diligence to be ready will put you at the top.

Learn more about ProPharma Group’s Compliance services.
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