Quality Management Practices

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Ideally, every clinical trial should have a Clinical Trial Quality Management Plan (QMP) describing the tools that will be used to ensure study quality. The extent and nature of monitoring may be determined based on various considerations such as trial design, complexity, size, risks to subjects, and endpoints of the trial.

One of the benefits of developing and implementing a QMP includes developing proactive communication among clinical trial team members. This benefits clinical trial teams by encouraging early identification and resolution of clinical trial problems and concerns. Implementing a Clinical Trial QMP can also encourage conformity with Standard Operating Procedure, Good Clinical Practice (GCP), Good Laboratory Practice, and UCLA policies and procedures. This leads to an overall reduction in external (Sponsor, FDA) and internal (UCLA) data queries, and helps reduce clinical trial closeout time.

Quality Management Plans include all the activities undertaken to verify that the requirements for quality of the trial related activities have been fulfilled. Listed below are several logs and checklists that might help with quality management plan development:

- Chart Audit Tool
- Regulatory File Review Tool
- Monitoring Log

Industry sponsored clinical trials usually have a comprehensive monitoring plan. Regular monitoring of a trial is very helpful to verify compliance of the trial with currently approved protocol, Good Clinical Practice and applicable regulatory requirements.

Source Data are defined as all information in original records or certified copies of clinical findings, observations, or other activities that are necessary for reconstruction and evaluation of the trial. The records that contain source data are called Source Documents. Source Document Verification is an important part of monitoring. Source data is verified by reviewing that all the data variables in the case report form accurately reflect information in the source documents.

Researchers may choose any option that is appropriate for the trial, some of the options include; a review of all data variables in the case report form for all enrolled subjects, a review of all CRF data for a percentage (e.g. 5%) of patients enrolled or even a review of only certain specified variables on all or some CRFs (for example, only the eligibility criteria).

?Essential Documents permit evaluation of the conduct of a trial and the quality of data produced. These documents serve to demonstrate compliance with standards of Good Clinical Practice and with all applicable regulatory requirements. Filing these documents in a timely manner can greatly assist in the successful CTQMP and management of a trial.

- Sample Quality Management Plan
- Sample Clinical Quality Management Regulatory File Review Tool
- Food and Drug Administration (FDA) Regulations
- Commonly Used QM Definitions

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