A guideline for the research team to follow

In today's world of cut-throat competition, it is not merely a matter of providing quantitative results; the ones with qualitative work lead the pack. A look at how companies can achieve the best.

Good Clinical Practice (GCP) is a set of guidelines for biomedical studies, which encompasses the design, conduct, termination, audit, analysis, reporting and documentation of studies involving human subjects. It aims to ensure that the studies are scientifically and ethically sound and that the clinical properties of the pharmaceutical substances under investigation are properly documented. So adherence to GCP by clinical research organisations is of utmost importance and here are some compliance tips for the same. MPh

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1 Tips & Tricks

Protocol and study requirement: A well-written protocol with a clearly defined study objective and study requirements is primary requirement for the success of the clinical trial. The protocol should ensure that it takes care of patient safety and well being, collecting enough preclinical and clinical data (in case of late phase trial) to suggest the justification to conduct the present study. Every stake holder should be convinced with the design and outcome of the protocol which in turn will lead to better compliance, both at investigator as well as patient level. The data generated at the end of the trial is beneficial for research purpose and might lead to further development of the investigational product.

2 Tips & Tricks

Local regulation: One of the key stake holders of the clinical trial are the regulatory agencies and the Institutional Ethics Committees. These group of members should be knowledgeable enough to weigh the scientific rational against the risk and benefits of conducting a clinical trial before issuing an approval to conduct the trial. They should be unbiased in their decision and have a close oversight during the conduct of the trial to ensure patient safety.

3 Tips & Tricks

Research team and infrastructure: Each and every stake holder of the clinical trial; be it sponsor, investigator site staffs or data management and statisticians should be well trained, experienced and qualified research team, to carry out the trial with a clearly defined standard operating procedure for each activity. This automatically will lead to organised and accurate documentation.

4 Tips & Tricks

Need of a robust infrastructure: There is also a need for a robust infrastructure to carry out any clinical trial. These may include the production of the investigational product in a controlled environment in compliance with GMP requirements, well-controlled storage and administration of investigational product and other clinical trial supplies. A state-of-the-art clinical and data management team supported by IT infrastructure to track various activities in the clinical trial and also to capture and manage the data generated from the investigational sites.

5 Tips & Tricks

Quality control system : Every trial should have a group of personnel who are responsible to monitor the clinical trial and ensure the proper consenting of eligible subjects, adherence to the protocol, timely and complete adverse event reporting /subject's safety management and maintenance of good medical records and documentation practice. The key qualities of a good monitor are eye for detail, excellent written and oral communication skills, assertiveness, domain knowledge and most importantly to identify issues and subsequently applying logic and common sense to resolve/prevent them to satisfaction.

6 Tips & Tricks

Audit: Another independent team of personnel called the auditors / inspectors are needed to finally attest that trial data can be accepted world over. Their main aim is to establish the credibility of the data and see to it that the trial conclusions presented in the final report are traceable to the raw data generated at the site level. Ultimate goal for any clinical research team is to have a successful audit at the end of the day with no critical or major finding, which might otherwise lead to rejection of the data and in turn all the efforts might go in vain.