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Short Communication Open Access

Monitoring of Clinical Trial in Current Scenario

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Short Communication

Monitoring is always considered an important step to conduct a clinical trial to ensure the quality of data with compliance with Protocol; Local Regulation of Country where trial country and International Conference of Harmonization-Good Clinical Practice (ICH-GCP). According to ICH-GCP we can say, "Clinical Trial Monitoring is an activity of overseeing the progress of a clinical trial and ensuring that it is conducted, recorded and reported in accordance with protocol, Standard Operating Procedure (SOP), Good Clinical Practice (GCP) and applicable Regulatory Requirements" [1].

During the Onsite Monitoring Clinical Research Associate (CRA) or Monitor perform following activity onsite:

- Review the Informed Consent Form and Documentation for Newly Enrolled or Consented Subjects
- Eligibility Criteria of recruited subjects with comply of Inclusion/ Exclusion Criteria as per Protocol
- Review the Adverse Events and Serious Adverse events
- Perform the Investigational Product Accountability
- Review the Essential Documents
- Protocol Deviation
- Assess the Investigator Involvement in Clinical Trial
- Check the Site team understanding with Protocol and study Procedures
- Discuss the identified Issue and protocol Deviation with Investigator and Team with Corrective Action and Preventive Action to avoid same issue in future.

The Main objective of Monitoring of Clinical Trial is to ensure 100% source data verification(SDV) to avoid errors e.g. Protocol Deviation and subject safety issue because outcome of clinical trial is depend on quality of data collected from various site of clinical trial.

"Monitoring Guidance Document (1988)" has been replaced with "Guidance for Industry: Oversight of Clinical Investigations-A Risk Approach to Monitoring". Risk Based Monitoring (RBM) explained "strategies for monitoring activities that reflect a modern, more risk-based approach that focuses on critical study parameters and relies on a combination of monitoring activities to oversee a study effectively."

According to FDA guideline Centralized Monitoring is a remote evaluation carried out by Sponsor Personnel or representative (Central Monitor; Data Management or Statisticians) at location other than sites at which the Clinical Investigation is being conducted. Centralized Monitoring processes can provide many capabilities of on-site monitoring as well as additional capabilities [2].

During the Centralized Monitoring we can perform following activities:

- Perform the Data Checks for completeness and consistency
- Review the inconsistency of data for whole study globally for all sites.
- Perform the Regulatory Review requirements for study globally for all sites.
- Trigger the risk on data integrity based on remote review of data of site.
- Trigger the training deficiency of site staff in real time based on remote review of data.

Centralized Monitoring processes are cost effective and reduce the need of on-site visit and allow real time monitoring. To use remote monitoring effectively, risk assessments must be performed and should include in monitoring plan prior implementation in any clinical trial. Thus we can say the Monitoring Risk Assessments is an approach for Adequate Protection of rights, Safety and Welfare of enrolled subject in clinical trial along with quality and integrity of data collected from trial site [3].

The risk assessments should be perform for on-site and remote monitoring because onsite monitoring concentrate on study aspects which defined in risk plan as critical for integrity of clinical trial study such as Informed Consent Form; study endpoints, drug accountability and source data verification, however Remote Monitoring should concentrate the review and monitor remotely such as data completeness, trends in enter data of system(eCRF; lab reports; eTMF etc.) and trigger the risk on integrity of data.

Thus Study Monitoring Plan should be designed to cover frequency and cover the centralized monitoring activities along with communication and co-ordination between centralized monitor and other stakeholders of study team. It should cover the training requirement of study team also.

Though Centralized Monitoring has lots of positive points however we can't denied the negative impact of centralized monitoring, based on data collection from one survey conducted by trusted firm the major concern come in picture that Centralized Monitoring can't prepare the site for audits or inspection because this process only trigger the risk but to maintain the quality at site onsite monitoring play important role and make the site ready for audit or inspection [4].

In Current Scenario maximum company are in process of developing the centralized monitoring process with appropriate system and training of staff for effective implementation of centralized monitoring system to improve the quality, safety and timelines for better outcomes of study.

References

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