Category: Departmental SOP

Title: Remote monitoring/ Remote source data verification of Clinical studies conducted in the Department of Clinical Pharmacology, K.E.M. Hospital, Mumbai during the ongoing COVID-19 pandemic

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1) Introduction:

Monitoring of clinical trials / studies is necessary to assure adequate protection of the rights and the safety and well-being of all research participants and ensure the quality and integrity of the resulting data generated.

The objectives of the monitoring procedures are to:

- Ensure that the study is being carried out in accordance with the IEC approved protocol and as per GCP guidelines
- Identify any problems and suggest / seek solutions

In view of the pandemic situation and travel restrictions, it may be difficult for the Sponsor/CRO team to visit the site for monitoring. This SOP therefore covers conditions under which Remote Monitoring/ Remote source data verification can be done.

2) Purpose:

This Standard operating procedure has been developed in the Department of Clinical Pharmacology (DCP), Seth GS Medical College and KEM Hospital, Mumbai and aims to guide Remote monitoring and Remote source data verification during the ongoing COVID-19 pandemic. The responsibility for maintaining this operating procedure lies with delegated member of the research unit.

3) Scope:

This SOP is limited to the Remote Monitoring of clinical studies conducted in the Department of Clinical Pharmacology, K.E.M. Hospital, Mumbai. Its use is restricted to the context of the pandemic only.

4) Applicable rules, regulations and guidelines:

- Indian GCP Guidelines 2001
- Ethical Guidelines for Biomedical and Human Research involving Human Participants, Indian Council of Medical Research 2017
- ICH E6(R3) EWG Draft Guidelines dated 19th April, 2021.
- Drug Controller General of India guidelines for clinical trials in COVID-19, 30th March 2020

5) Responsibilities:

The Principal Investigator is responsible for complying with procedures necessary to secure the quality of every aspect of the trial. The Principal Investigator is responsible for determining the level of monitoring (remote or non remote) and for enabling monitoring activities at the study site. The Study Monitor from the Sponsor/ CRO is responsible for conducting the monitoring in accordance with the pre-decided monitoring plan, SOP and regulatory requirements.

6) Detailed Instructions:

In agreement with Sponsor and PI monitoring activities may take place remotely after prior intimation and when mutually convenient.

I. Pre-Visit Preparation

Sponsor (or CRO) should notify all involved trial personnel (i.e PI and/or CRC) of the intention to conduct a remote monitoring visit.

This notification should be at least 1 week (preferably 15 days) prior to the visit and include the following details:

- the planned dates of this activity
- the planned times this activity will be conducted each day (e.g. 9am -4pm)
- the documents required for review
- details of all the monitoring related activities planned

II. Monitoring Procedures

1) Documents which contain participant identifiers (i.e. Name, Address, Contact details) *will not be shown* to the Study Monitor. If at all such documents are shown, the identifiers will be covered with a tape/ paper
2) The monitoring may be done telephonically/ through an Online Platform as decided between the Sponsor and the PI. The responsibility of providing the online platform is with the Sponsor/ CRO
3) All the monitoring proceedings will be for the purpose of the Document Verification only and should not be recorded at all.
4) Once the pandemic situation improves, it will be the decision of the PI based on the current scenario and the travel restrictions whether to conduct a Physical Monitoring or permit a Remote Monitoring

Monitoring will focus on the following key processes of the study so as to ensure protection of rights, safety and well-being of study participants and integrity of data

i. Study eligibility criteria met for all participants

ii. Source data verification

iii. Completion of physical Study CRFs, eCRFs

iv. Accurate entry of data from clinical and laboratory forms.

v. Sample collection and handling in accordance to Protocol and SOP(s)

vi. Review of data management procedure i.e. data entry, handling of data discrepancies and data backup. (If applicable)

vii. Reporting of adverse events and protocols deviations and violations according to SOP(s)

viii. Investigational Product accountability

ix. Follow up assessments and procedures

x. Measures to ensure complete participant follow up.

xi. Maintenance and regular update of trial master file(s)

xii. Any other documents that are relevant to the study

- During each monitoring, the monitor will work according to an agreed schedule of tasks, including the following that will be given as specifics in the monitoring form

- Schedule a date with the study investigator/coordinator for the monitoring procedure and provide them with a list or shell of the study sections that will be monitored in the particular visit
- Review last monitoring report(s)
- Review the trial master file to ensure that it is updated
- Verify correct version of written informed consent documents were given for every subject enrolled into the study and obtained according to the consent SOP
- Review current status of the study participants enrolled vs. anticipated enrolled, lost to follow up, outstanding data issues, reported SAEs, outstanding laboratory issues
- Review the enrolled participants file to verify that the participants were eligible
- Review the safety issues and protocol violations or deviations (if any)

- Review the reports of all investigations done during study
- Review the screening and enrolment log
- Review all EC and sponsor (if applicable) communications
- Review laboratory documents: handling, storage and shipment of samples.
- Review IP accountability log: handling, storage, usage and shipment of IPs
- Source data verification - entry of data from clinical and laboratory forms.
- Temperature recording and logs

- During the initial visits the monitors will review 100% of the fields of all the study forms. All forms monitored during a visit will be detailed in the monitoring report
- After each monitoring visit the monitor will debrief the study team i.e. appreciate them where they are getting it right and highlight areas which need improvement

The monitor will then write up a detailed monitoring report citing all findings and relevant comments and send a copy [both soft copy and hard copy] to the PI via email within 15 days of monitoring.

Relevant SOPs

Sop No: D 26/05 SOP for Internal Monitoring of Clinical Clinical studies conducted in the Department of Clinical Pharmacology, K.E.M. Hospital, Mumbai

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