Category: Departmental SOP

Title: Internal monitoring of Clinical studies conducted in the Department of Clinical Pharmacology, K.E.M. Hospital, Mumbai.

SOP No.: D 26/07 **Total pages**: 11

Date first effective: 1 Jan 2025 **Next Review date:** 31 Dec 2025

Version: 07

Author: Dr. Rupali Mishra
DM Resident

Signature with date 30/Dec/2024

Reviewer: Dr. Mahesh Belhekar

Associate Professor

Dr. Mahesh N. Belhekar
Associate Professor
Department of Clinical Pharmacology
New MS Building, First Floor,
Seth GS Medical College and KEM Hospital
Acharya Donde Marg, Parel,
Mumbai - 400 012. India

Signature with date 30.12.2024

Approved by: Dr. Nithya Gogtay

Professor and Head

Signature with date 30/12/24

Dr. Nithya Gogtay
Professor & Head
Department of Clinical Pharmacology
1st Floor, MS Building,
Seth GS Medical College & KEM Hospital,
Parel, Mumbai - 400 012.

Category: Departmental SOP
Title: Internal monitoring of Clinical studies conducted in the Department of Clinical Pharmacology, K.E.M. Hospital, Mumbai.
SOP No.: D 26/07
Date first effective: 1 Jan 2025 **Review date: 31 Dec 2025**
Department of Clinical Pharmacology, 1st floor, New MS building Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

Table of Contents

No.	Contents	Page no.
1.	Introduction	3
2.	Purpose	3
3.	Scope	3
4.	Applicable rules, regulations and guidelines	4
5.	Responsibilities	4
6.	Detailed Instructions	4
7.	Glossary	8
8.	Appendices	9

Category: Departmental SOP
Title: Internal monitoring of Clinical studies conducted in the Department of Clinical Pharmacology, K.E.M. Hospital, Mumbai.
SOP No.: D 26/07
Date first effective: 1 Jan 2025 **Review date: 31 Dec 2025**
Department of Clinical Pharmacology, 1st floor, New MS building Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

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

Overall the monitor should be seen as a supportive extension of the study team. Therefore, the monitor should not be perceived as an outside threat but part of the team and there to identify any problems affecting the conduct and quality of data collected.

2) Purpose:

The purpose of this SOP is to describe the principles of the monitoring services provided by the site and the monitoring procedures in clinical studies conducted at the site. The operating procedure has been developed in the Department of Clinical Pharmacology (DCP), Seth GS Medical College and KEM Hospital, Mumbai and aims to harmonise monitoring procedures. The responsibility for maintaining this operating procedure lies with delegated member of the research unit.

3) Scope:

This SOP is limited to the internal monitoring of clinical studies conducted in the Department of Clinical Pharmacology, K.E.M. Hospital, Mumbai.

4) Applicable rules, regulations and guidelines:

- ICMR's Ethical Guidelines for Biomedical and Health research involving Human Participants, ICMR(2017)
  http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf
- International Conference on Harmonization, Guidance on Good Clinical Practice

(ICH GCP) ICH E6 (R3)
https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf (Adopted on 06 January 2025)

- Indian GCP guidelines 2001
https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MzM5NQ (Last accessed 20 Dec 2024)
- New Drugs and Clinical Trials 2019
https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdfdocuments/NewDrugs_CTRules_2019.pdf (Last accessed 20 Dec 2024)

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 and for enabling monitoring activities at the study site. The Study Monitor is responsible for conducting the monitoring in accordance with the pre-decided monitoring plan, SOP and regulatory requirements.

6) Detailed Instructions:

1) Internal Monitoring Schedule:

A pre-study, routine and close out monitoring is planned and conducted for the study. The pre-study monitoring will be conducted as soon as:

- All the necessary approvals have been obtained
- Staff recruited
- Investigational product has been delivered to site (is about to be delivered to site)
- CRF and source documents are ready
- Laboratory is ready to start storing study samples

The first routine monitoring visit will occur as soon as the first participant is enrolled or within 2 weeks of enrolment of the first participant. The subsequent monitoring should be done prior to sponsor/CRO monitoring in case of pharma sponsored trial or as per recruitment rate in case of investigator initiated study (IIS). The monitoring frequency may be increased if recruitment rate

is faster, or at times of data entry deadlines such as interim analysis or if the DSMB request a safety report.

1. Monitoring Procedures:

- All the team members will be informed through email before approximately a week before the scheduled monitoring visit with detailed objectives of 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. Informed consent process and documents

ii. Study eligibility criteria met for all participants

iii. Source data verification

iv. Completion of Study CRFs.

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

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

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

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

ix. Investigational Product accountability

x. Follow up assessments and procedures

xi. Measures to ensure complete participant follow up.

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

- 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.

- 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 (See appendix 2)
- 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 monitoring report citing all findings and status of such findings (resolved or not) and forward the copy [both soft copy and hard copy] to the PI
- The follow up monitoring will be conducted within four days to ensure that the findings arise during the previous monitoring are resolved

- For IIS, at close out visit(s) the monitor will ensure all queries are resolved and study documents are properly archived. The comprehensive list of activities during this visit(s) will be detailed in a study close out SOP.

7) Glossary:

a) Monitoring

The act of overseeing the progress of a clinical study, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, SOPs, Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

b) Trial Master File (TMF):

The repository for the essential documents for the conduct of a clinical trial. These documents individually and collectively permit evaluation of the conduct of the study and the quality of the data produced. These documents demonstrate the compliance of the sponsor-investigator and of the monitor with standards of GCP and with all applicable regulatory requirements.

c) SOP (Standard Operating Procedure)

Standard Operating Procedures (SOP) are detailed, written instructions, in a certain format, describing activities and actions undertaken by an organisation to achieve uniformity of the performance of a specific function. The aim of the SOPs and their accompanying checklists and forms is to simplify the functioning, whilst maintaining high standards of Good Clinical Practice.

8) Appendices:

1) Checklist for monitoring:

Sr. No.	Issues reviewed/discussed during visit	Yes	No	N/AP
1	Screening & Enrolment log			
2	Subject-Informed Consent form and narrative			
3	CRFs and source documents verification			
4	Protocol deviations/violations			
5	Trial Master File			
6	Study medication, Randomisation & Blinding Codes-if Applicable			
7	AE / SAE Reporting.			
8	Amendments in study documents			
9	Study team			
10	Site Facilities			
11	Laboratory Issues			
12	Collections of CRFs			
13	Queries			
14	Miscellaneous			
15	Follow-up action points previous visit(s)			
16	IP accountability log			

2) Monitoring report format:

Study Title	
Protocol ID	
Investigator Name	
Institution Address	
Monitor Name	
Date of visit	
Study staff seen	

Sub 1. Subject Screening & Enrollment

Sub 2. Subject Informed Consent

Sub 3. CRFs and source documents verification

Screening No / Subject ID	Findings	Correction Done (Yes / No)	Follow Up Required (Yes / No)

Sub 4. Site Master File

SI No:	Findings	Correction Done (Yes / No)	Follow Up Required (Yes / No)

Prepared by:

_____ _____

Name Signature & Date

Category: Departmental SOP
Title: Internal monitoring of Clinical studies conducted in the Department of Clinical Pharmacology, K.E.M. Hospital, Mumbai.
SOP No.: D 26/07
Date first effective: 1 Jan 2025 **Review date: 31 Dec 2025**
Department of Clinical Pharmacology, 1st floor, New MS building Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

Reviewer: Dr. Mahesh Belhekar

Associate Professor

Dr. Mahesh N. Belhekar
Associate Professor
Department of Clinical Pharmacology
New MS Building, First Floor,
Seth GS Medical College and KEM Hospital
Acharya Donde Marg, Parel,
Mumbai - 400 012. India

Belhe
30-12-2024

Signature with date

Approved by: Dr. Nithya Gogtay

Professor and Head

Signature with date

Dr. Nithya Gogtay
Professor & Head
Department of Clinical Pharmacology
1st Floor, MS Building,
Seth GS Medical College & KEM Hospital,
Parel, Mumbai - 400 012.
30/12/24