Ph.1 SOP B22

DEPARTMENT OF CLINICAL PHARMACOLOGY
SETH GSMC AND KEMH, MUMBAI – 400012

Ph.1 SOP B22: Training Members of Data Safety Monitoring Board (DSMB) for a Phase 1 Clinical Trial with an Investigational Product

Version 2.0 dated 1st January2026
Effective date: 3rd January 2026
Revision due date: 31st of December 2026

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Ph.1 SOP B22: Training Members of Data Safety Monitoring Board (DSMB) for a Phase 1 Clinical Trial with an Investigational Product

1. Purpose: The purpose of this Standard Operating Procedure (SOP) is to provide guidelines for the training of members appointed to the Data Safety Monitoring Board (DSMB) for a Phase 1 clinical trial involving an investigational product.

2. Scope: This SOP applies to all individuals appointed as members of the DSMB for a Phase 1 clinical trial with an investigational product. The training described in this SOP should be completed before the DSMB members begin their duties.

3. Responsibilities:

The responsibilities for ensuring implementation of this SOP lies with the Principal Investigator

4. Applicable rules, regulations and guidelines:

- Ethical Guidelines for Biomedical and Health Research involving Human Participants,ICMR(2017)
- ICH E6 (R3) Integrated Addendum to ICH E6 (Rl), Current Step 4 version dated May, 2023
- Medical Devices Rules, 2019
- New Drugs and Clinical Trials Rules, 2019

5. References (to other SOPs)

None

6. Detailed instructions

S.No	Task	Person responsible
1.	Appoint Chairperson of the DSMB.	PI or the Sponsor
2.	Provide both administrative and scientific leadership for the Board	DSMB Chairperson
3.	Selection of DSMB members and ensure that all DSMB members receive appropriate training and maintain the necessary qualifications to serve on the DSMB.	DSMB Chairperson
4.	Ensure that the training materials are up-to-date and relevant to the specific trial.	Sponsor/PI
5.	Active participation in the training activities and acquiring the knowledge and skills necessary to fulfill their role effectively.	DSMB Members*
6.	Develop - DSMB charter	Sponsor/ PI.
7.	Administrative responsibilities such as scheduling the training , meeting, arranging telecommunications for the meeting (telephone, video or web conferencing), as well as distributing data and serious adverse event reports prior to the meeting (preferably 2 weeks prior)	Executive secretary
8.	Transcript Minutes, Agenda and recommendations to the PI, or Sponsor, and study team members as identified in the DSMB charter.	Executive secretary
9.	Reviews and approves the DSMB charter.	DSMB Chairperson
10.	Maintain proper documentation (Records of attendance, Training materials)	Executive secretary
11.	Investigate and report safety events to the DSMB and to the IEC in a timely manner as specified by the DSMB charter and IEC guidelines	PI

12.	Convey relevant recommendations from the DSMB to the IEC, sponsor, and funding agency in a timely manner	PI

*** Composition of DSMB:**

Minimum 3 members out of Subject-experts, Clinical-Trial Specialists, Biostatisticians, Administrators)

[Special members: Ethicists, Epidemiologists, Lawyers]

Training Content:

A. The training for DSMB members should cover the following topics:

1. Overview of the Investigational Product

Provide a comprehensive overview of the investigational product, including its mechanism of action, intended therapeutic indication, potential risks, and anticipated benefits.

2. Clinical Trial Protocol

Review the Phase 1 clinical trial protocol in detail, including the study design, inclusion and exclusion criteria, study endpoints, and planned statistical analyses.

3. Safety Monitoring and Reporting

Educate DSMB members on the specific safety monitoring procedures and adverse event reporting requirements for the trial. This includes guidance on how to identify and classify adverse events, assess their severity, and determine their relationship to the investigational product.

4. Data Review and Analysis

Provide training on the procedures for reviewing and analysing trial data. This includes guidance on data quality assurance, data monitoring, and the interpretation of safety and efficacy outcomes.

5. DSMB Meetings and Decision-Making

Outline the purpose, format, and frequency of DSMB meetings. Train DSMB members on their roles and responsibilities during these meetings, including the evaluation of trial progress, data review, and making recommendations regarding trial continuation, modification, or termination.

B. Training Methods

The training can be conducted through a combination of the following methods:

1. In-person or Virtual Presentations

Presentations by subject matter experts to deliver training content and facilitate discussions.

2. Workshops and Case Studies

Interactive workshops and case studies to enhance understanding and application of the knowledge acquired.

C. **Training Materials**

Provide DSMB members with comprehensive training materials, including relevant documents, guidelines, and reference materials, to supplement the training sessions.

D. Training Documentation

Maintain proper documentation of the training provided to each DSMB member. This should include records of attendance, training materials used, and any assessments or evaluations conducted during the training process.

E. Training Assessment

Conduct assessments or evaluations to ensure the effectiveness of the training. This may include quizzes, case studies, or other methods to gauge the understanding and competence of DSMB members.

F. Training Frequency

The initial training should be conducted before DSMB members assume their responsibilities. Additionally, on-going training and updates should be provided periodically throughout the trial to keep DSMB members informed of any relevant changes or new information.

Based on the risk on the study participant - frequency of DSMB meeting is planned.

- Minimal Risk Annual DSMB meeting
- Greater than Minimal Risk Every 6 months
- Greater than Minimal Risk, high enrolment Every 3 months
- High Risk, high enrolment Every 3 months

Note:Each training has to be completed 1 month prior to every DSMB meeting.

G. Deviations and Amendments

Any deviations from this SOP or amendments to the training procedures should be documented, approved, and communicated to all relevant parties.

H. Training Records Retention

Maintain all training records in accordance with applicable regulations and guidelines. These records should be securely stored for the duration specified by regulatory authorities.

7. Abbreviations

Co-I	Co-investigator
DSMB	Data and Safety Monitoring Board
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICMR	Indian Council of Medical Research
IEC	Institutional Ethics Committee
SOP	Standard Operating Procedure
PI	Principal Investigator

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Signature with date Rparida 01/Jan/2026

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APPENDIX

OUTLINE OF A TYPICAL DSMB CHARTER

1. Title page
    a. Includes version, version date, study title, PI
    b. Page footers should include: DSMB charter version and date, study title or abbreviation, and page number (x of y pages)
    c. A table of contents is helpful for longer documents
2. Introduction
    a. The purpose of the DSMB
    b. Optional protocol summary
3. DSMB functions and responsibilities
    a. Safety monitoring
    b. Monitor performance of the trial
    c. Stopping rules for safety, efficacy, and/or futility (if applicable)
4. Principal Investigator responsibilities
5. Sponsor responsibilities (if applicable)
6. DSMB membership and role-specific responsibilities
    a. All members: Conflict of interest, confidentiality, communications
    b. Responsibilities of the chairperson
7. Structure and conduct of DSMB meetings
    a. DSMB meetings
    b. Quorum and voting
    c. DSMB recommendations
    d. Ad hoc meetings
8. DSMB operations
    a. Data to be reviewed
    b. Disbanding the DSMB and destruction of documents
    c. Procedures for replacing a member

9. Reports
    a. Minutes
    b. DSMB recommendations
    c. Reports to PI for IRB review
10. Signature page
11. Appendices
    a. DSMB membership, affiliations and contact information
    b. Template for recommendations from the closed (executive) DSMB session
    c. Stopping rule