

Policy No:

Responsible OfficeOffice of Research Compliance and Assurance

Last Review Date June 2021

Next Required Reviewable 2026

Data and Safety Monitoring Board

1. Purpose

An independent Data and Safety Monitoring Board (DSMB) will be convened to assess the progress of a clinical study, the safety data, and critical efficacy endpoint point point provide recommendations to the PI. The members of the DSMB serve in an individual capacity and provide their expertise and recommendations. The DSMB will review cumulative study data participating sitesto evaluate safety, study onduct, and scientific validity and data integrity of the study.

2. Applicability

Not all studies require the use of a DSMB. All studies should be evaluated by ORCA and the IRB to determine the need for a DSMB based on the study design, risk to pathending agency, and other concerns. A study with any of the following criteria should utilize a DSMB:

- x Multi-site clinical trials with interventions that entail greater than minimal risk(s) to participants
- x If the trial is evaluating mortality or anotherajor endpoint, such that inferiority of one treatment arm has safety as well as effectiveness implications.
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Data Safety and Monitoring Plan (DSMP): a specifien, developed by the local principal investigator (PI), that outlines how study progress will be monitored throughout the course of the research to ensure the safetyof subjects as well as the integrity and confidentiality defa.

Institutional Review Board (IR)Ban administrative body established to protect the rights and welfare of human research subjects recruited participate in research activities conducted under the auspices of the institution with which it is affiliated.

Office of Research Compliance and Assurance (ORDA) ffice thatworks with research oversight committees, boards and offices responsible specific components of research compliance to ensure compliance with all regulatory requirements related to research activity. The office is responsible for monitoring regulatory changes and recommending institutional responses to ensure compliance, an the oversees development and implementation of policies, procedures, programs and educational activities which satisfy federal, state and institutional regulations governing the conduct of research

Quorum:

- x To review all documents submitted to the DSMB for review
- x To review the conduct of the study, including protocol violations
- x To review data on participant recruitment, accrual, and retention, as well as assessments of data quality, completeness, and timesin
- x Protect the confidentiality of the study data and the DSMB discussions
- x To make recommendations to continue, modify, or terminate the study
- 4.3.3 DSMB Chair Responsibi (t)Inr-3 (n)2.MC /LBody <.3 (i)10.6n Th (n)2. following r (n)2.MC /4 (p)13

- x Disseminate documents to DSMB prior to the scheduled meeting
- x Maintain confidentiality of documents submitted for DSMB rex; open Session minutes, and DSMB correspondence
- x Distributes Open Session minutes to DSMB members
- x Facilitates the meetings, assists in the development of the agenda, and ensures that the meeting minutes and recommendation(s) are appropriately documented

4.6 Meeting of the DSMB

4.6.1 Charter Meeting

The first meeting of the DSMB for each new protocol will be a Charter Meeting. This meeting will formally establish the DSMB and begin to acquaint the DSMB members with the protocol or types of protocols thathis DSMB will be charged with monitoring. It affords the DSMB an opportunity to recommend final revisions to the Data Safety Monitoring Plan, Protocol, statistical analysis, etc.

The PI must be present of the Open Session of Charter Meeting.

DSMB approval must be received rior to any study related activities.

At the beginning of the DSMB meeting, the Chair will initiate the charter session of the meeting, which will include calling the meeting to order and assuring a duly constituted Board.

Meeting objectives will include:

- x The introduction of the DSMB members and an establishment of qualifications for quorum.
- x A review of the protocol and DSMP to offer feedback as necessary
- x Establishment of meeting frequency based on the risk profile, recruitment practical design, etc.
- x Confirmation and recording of any conflict of interest, if applicable.

As needed, the Charter may be revised after the interiereting, with the Chair providing signoff. Changes to the Charter will be clearly delineated in a document, and this document will be associated with the new version.

4.9 Completion of DSMB Activities

The DSMB will remain active until written notification is received from ORCA office that the study has completed.

5.2 Interim Review by the DSMB

5.2.1 Submission of Materials for Interim Meetings

Submit the following materials to Office of Research Compliance and AssurateCO

- x Informed Consent
- x DSMB Report for Open Session
- x DSMB Report for Closession if applicable
- 5.2.2The ORCA will work with the DSMB members to schedule a convenient date and time to hold the interim meeting.
- 5.2.3 After the DSMB meeting, an ORCA representative will draft the minutes and a letter Routhe The DSMB Chair is required to review the minutes and the letter to PI.
- 5.2.4The letter to the PI will be sent to the PI and any applicable parties.
- 5.2.5The PI is responsible for submitting a copy of the letter to the IRB of record per the IRB's reporting requirements.

5.3 Closure by the DSMB

- 5.3.1The Investigatorwill notify the Office of Research Compliance that thestinady is closing
- 5.2.2The ORCA will work with the DSMB members to schedule a convenient date and time to hold a closeout meeting.
- 5.2.3The Investigator will submit a summary of all datgardless of if the study completed or ended prematurely.
- 5.2.4After the convened DSMB meeting, the ORCAswild the Investigator an administrative letter demonstrating that t

7.1 Related Regulations and/or Policies

- x FDA Guidance: Establishment and Operation of Clinical Trial Data Monitoring Committees.
- x 21 CFR 50.24(a)(7)(iv)

7.2 Other Related Documentand/or Procedures

- x DSMB Report FornMultisite-Open Session
- x DSMB Report FormMultisite-Closed Session
- x DSMB Report FornSingle SiteOpen Session
- x DSMB Report FornSingle SiteClosed Session