

Charles Drew University RSA Program

Data Safety Monitoring Board (DSMB) Charter

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Data and Safety Monitoring Board Charter

Table of Contents

Introduction

Organization

 Overview

 Committee Structure

 DSMB Functions and Activities

 Guidelines for Members

Process

 Eligibility

 Reporting

 Relation to Institutional Review Board and CRC Director

Protocol Review and Data Monitoring

 Monitoring and Reporting Requirements

 Data Review by the DSMB

 Release of DSMB Recommendations

Appendices

 Appendix 1: Current members of the DSMB

Abbreviations

AE	Adverse event
DSMB	Data and Safety Monitoring Board
DSMP	Data and Safety Monitoring Plan
CRC	Clinical Resource Center
PCIR	Participant and Clinical Interaction Resource
IRB	Institutional Review Board
NIH	National Institutes of Health
PI	Principal Investigator

Introduction

1. The CDU RSA Program is committed to the safety of patients participating in clinical trials at our institution. In addition, it is committed to data accuracy and protocol compliance. The DSMB committee has established an institutional plan to provide data safety and monitoring all clinical trials conducted at PCIR.. This plan is designed to comply with policies and guidelines regarding data and safety monitoring from the National Institutes of Health ([://grants.nih.gov/grants/guide/notice-files/not98-084.html](http://grants.nih.gov/grants/guide/notice-files/not98-084.html); [://nih.gov/grants/guide/notice-files/NOT-OD-00-038.html](http://nih.gov/grants/guide/notice-files/NOT-OD-00-038.html)).

This charter is for the Data Safety and Monitoring Board (DSMB) of CDU charter contains the following:

- A description of the composition and organization of the DSMB
- Details the roles and responsibilities of DSMB members
- Outlines the responsibilities of the Principal Investigators and Sponsors
- Lists important contact persons

Organization

Overview

The DSMB functions as a committee within the Regulatory Core of the AXIS grant. The charge to the DSMB is review clinical trials to assure patient safety both by evaluating adverse events (AEs) and interim analyses of both safety and efficacy.

Committee Structure

The DSMB Chair, currently Dr. Naureen Tareen has the overall responsibility for chairing the DSMB committee and reporting its findings to the IRB. The Committee will function under the Office of Integrity and Compliance, The Committee will consist of a chair, an epidemiologist (if available), a biostatistician, and one or more clinical researchers. Committee members will serve for 3-year terms, but may be reappointed. Members will be appointed to the Committee by the Chair, Director or designated representative. A member of the DSMB can be removed due to poor attendance, inadequate demonstration of effort, unprofessional conduct and /or failure to act in accordance with the objectives of the DSMB. A list of current DSMB members can be found in Appendix 1.

PROCESS

Eligibility

A clinical trial is defined as “a prospective study involving human subjects designed to answer specific questions about the effects or impact of particular biomedical or behavior interventions; these may include drugs, treatments, devices, or behavior or nutritional strategies.” Studies that include nutritional, behavioral, and psychosocial interventions are considered to be clinical trials. Studies evaluating diagnostics (imaging, etc.) in which findings alter the patient’s clinical care are also considered to be clinical trials. Observational studies, epidemiologic studies, studies of diagnostics that do not effect patient care, and studies that do not test interventions are not considered to be clinical trials.

DSMB Functions and Activities

The DSMB is responsible for reviewing data from clinical trials approved by the IRB. Investigators with commercially or governmentally sponsored trials will normally work with their sponsor’s DSMB. The DSMB will review data from the following types of trials, when review is deemed necessary by the IRB or requested by the Principal Investigator (PI), in order to ensure the safety of participating subjects.

- Phase I, I/II, II, and II/III trials when such review is deemed necessary by CDU Institutional Review Board and the Principal Investigator.
- Phase III clinical trials (single site trials where the PI is a CDU faculty member and for which CDU is the sponsor)
- Phase IV clinical trials (single site trials where the PI is a CDU faculty member and for which CDU is the sponsor)

- Select multicenter clinical trials in which CDU is the coordinating center or the PI of the study is a CDU faculty member IF the DSMB determines that it has adequate resources to conduct the monitoring required of the study.

The DSMB will meet to review reports submitted by clinical investigators and has the following responsibilities.

- Assessing risk and complexity of clinical trials submitted for review
- Determining the appropriate level of data and safety monitoring
- Reviewing serious adverse events (SAEs) reports when requested.
- Reviewing yearly data and safety monitoring reports when requested. Recommending appropriate actions (closure, increased monitoring, etc.) to the Principal Investigator and the CDU Institutional Review Board (IRB). or designated representatives.
- Communicating its finding with the IRB
- Preparing minutes for all meetings

DSMB-Investigator Communications

The DSMB will make available to investigators the following:

- An Annual Data Reporting form for annual reporting of all AEs
- A Data Safety Monitoring Plan template

Principal Investigators shall make available to the DSMB the following information:

- A copy of the approval letter from the CDU Institutional Review Board
- Reports at the designated times stated in the IRB application
- All adverse event reports using the most current reporting form

Relation to (IRB) Institutional Review Board and (CRC) Clinical Resource Center

The DSMB will report its findings and make recommendations to the IRB. Trials required to have an independent DSMB as defined in this charter are expected to use the CDU DSMB instead of establishing their own independent board, unless outside expertise not available on the DSMB is necessary to adequately monitor the trial. Notice of a recommendation of early closure or suspension will be reported directly to the Principal Investigator, the IRB and the Office of Integrity and Compliance. **For research conducted by the CRC/PCIR, the DSMB will also report any suspension or closure of the study to the Director of the CRC/PCIR** or the designated representative. The Chair of the IRB in conjunction with the Director of the Office of Integrity and Compliance are responsible for seeing that these trials are closed to accrual.

Guidelines for Members

In order for the DSMB to fulfill its responsibilities, the member will observe the following guidelines:

- Members are free of apparent conflicts of interest involving financial, scientific, or regulatory matters. In case of any question of conflict of interest, standards used by NIH in determining conflict of interest for advisory committee members and investigators shall apply and such members must recuse themselves from participation in such studies;
- Members should assess trial objectives and design in an unbiased way;
- Members are guided both by pre-specified study performance criteria, such as early stopping rules, and also by a masked and, if necessary, unmasked review of all data prior to making decisions;
- The DSMB members will review data and pertinent procedures in order to be confident that the data on which the decisions are based are accurate and complete;
- All decisions of the DSMB shall be independent.

PROTOCOL REVIEW AND DATA MONITORING

Monitoring and Reporting Requirements

Reporting requirements will be stipulated by the Principal Investigator in the IRB application. The DSMB may also have face-to-face meeting(s) as prompted by unplanned interim analyses deemed necessary

because of safety concerns. The DSMB staff or chair will prepare minutes of each meeting within ten (10) working days of each meeting. These minutes will be circulated and approved at the next regularly scheduled meeting of the DSMB.

The Principal Investigator and study biostatistician will work with the DSMB for appropriate preparation of reports to be viewed at DSMB meetings and resolution of questions arising during data analysis. If requested by the DSMB, the Principal Investigator will turn over to the chairperson of the DSMB evidence of validation of all computer programs used to generate reports and analyses for each DSMB meeting. The documents will be made part of the minutes of each meeting. All formal reports will be circulated to the DSMB members no later than one week prior to each DSMB meeting.

Data Review by the DSMB

DSMB meetings will consist of an open and a closed session. The open session will provide a forum for exchange of information among DSMB members, Principal Investigator, and study biostatistician. During the open session, the Principal Investigator may present a brief summary report of the study progress, including enrollment rates, data collection, and data quality. There will be an opportunity for the Principal Investigator to ask advice from the DSMB on any matter concerning conduct of the trial. During the open session the DSMB members may ask the Principal Investigator to provide them with data that is partially unmasked (i.e., treatment A or treatment B without revealing what treatment A and B represent) or completely unmasked (i.e., identify treatment group).

Only members of the DSMB will attend the closed session. During this session, the DSMB will address issues regarding the following: 1) safety concerns, 2) efficacy concerns, 3) termination of the trial due to pre-specified stopping criteria, and 4) ethical concerns. The DSMB will be furnished with relevant information by the Principal Investigator to make these decisions.

In addition to the open and closed sessions, the voting members of the DSMB may meet in an executive session at their discretion. If necessary the DSMB will:

- Review the protocol and any protocol amendments;
- Review the interim analysis monitoring plan, make recommendations, and give approval (or not);
- Review interim analysis reports;
- Communicate recommendations in writing to the Principal Investigator

If there are any concerns about reviewed material (such as safety, efficacy, ethics, and stopping rules), the DSMB will take appropriate action. This may involve a request for additional information, or a request for an early, unscheduled meeting of the DSMB with the Principal Investigator and study biostatistician.

At each meeting that includes review of interim data, the DSMB will recommend one of the following actions to the Principal Investigator, the IRB, and when appropriate, to the Office of Integrity and Compliance.

- Continue the study according to the protocol
- Modify the study protocol. Modifications may include such items as changes in the inclusion/exclusion criteria, nature and frequency of safety monitoring, study procedures, study drug/intervention dosing, consent form changes, subject re-notification, and any other changes deemed necessary
- Discontinue one or more study arms
- Discontinue the study

The DSMB may request additional data, analyses or meetings to address specific concerns. The DSMB may hold additional meetings without knowledge of the sponsor or Principal Investigator.

Release of DSMB Recommendations

The DSMB will refrain from revealing to the sponsor, Principal Investigator, or any other party information that would lead to compromising the integrity of the trial unless such a release is required to protect

subject safety. In particular, the following guidelines will be followed with respect to the dissemination of the DSMB interim analysis results.

- Individual patient treatment assignments will not be revealed
- Individual center results will not be revealed
- The magnitude of treatment differences in efficacy will not be revealed
- Study results will not be communicated to investigators
- The DSMB will not make any public disclosures of its discussions and decisions
- The DSMB will complete a brief report documenting decisions and rationale behind its decisions. The report will be conveyed confidentially to the Principal Investigator and sponsor, who in turn, will forward it to appropriate regulatory agencies. A copy of the report will also be made available to the CDU Institutional Review Board, in form that does not contain information that could compromise the integrity of the clinical trial.

When appropriate a copy of the report will also be made available to the Office of Integrity and Compliance

Appendix 1 DSMB Members, Year 2010 – 2013

Member	Department	Phone	Email
Naureen Tareen, M.D	Internal Medicine	310-668-4161	<u>@aol.com</u>
Mayer B. Davidson, M.D,	Endocrinology	323-357-3439	<u>@cdrewu.edu</u>
Matthew H. Ho, MD, Ph	Endocrinology	325-357-3673	<u>@gmail.com</u>
Magda Shaheen, Ph D	Ophthalmology	310-761-4727	<u>@cdrewu.edu</u>
Dulcie Kerman, MPH		323-249-5710	<u>@cdrewu.edu</u>
Connie Dzekov, BA, CCRP	Endocrinology	323-568-3504	<u>@cdrewu.edu</u>