Summary Report for Data Safety Monitoring Board Meeting

Meeting Date:

Report Date:

Principal Investigator (PI):

IRB Control #:

Insert Study Title

Table of Contents

Please add any sections relevant to the particular study e.g. pharmacokinetics, unanticipated problems, manufacturing issues

1. Agenda
2. Attendees
3. DSMB Charter and Charge
4. Overview: Study Enrollment, Demographics, and Status
	1. Summary of study
	2. Enrollment by age, sex, race
5. Adverse Event Reporting
	1. Serious Adverse Events
	2. Adverse Events
	3. IND Safety Reports
	4. Participant drop out summary
6. DSMB Deliberations
7. Agenda (These categories of topics are merely suggestions. Please revise to suit study. Other potential categories include relevant pre-clinical studies, manufacturing issues)
8. Protocol status
9. Overview of subjects

 Enrollment, demographics and status

 Statement of any deviation from protocol

1. Review of data

Executive summary – all subjects

1. DSMB summary/recommendation
2. Decision to continue enrollment or not
3. Meeting Attendees
4. DSMB Charter and Charge

The committee consists of \_\_\_\_\_\_\_\_\_\_ members who have collective and individual expertise in \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. The committee members are independent of the sponsor, regulatory agencies, IRB/ECs, and investigators.

The DSMB will be provided reports that summarize demographics, enrollment and safety information. Specialized reports requested by the DSMB will be prepared as required.

Plan for DSMB meetings including timing (timepoints, enrollment triggers, DLT considerations, etc.) and mandate (safety review, enrollment continuation, dose escalation, etc).

Charge:

1. Upon completion of the DSMB review, a formal report containing the recommendations for the study will be sent to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.
2. If the DSMB recommends continuation of the study, the minutes and report for continuation are shared with \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ no later than \_\_\_\_\_\_\_\_\_\_ business days after the meeting.

If the DSMB recommends modifications, pause, or termination of the study, the minutes and report will be shared with the TJU IRB and \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ no later than \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_business days after the meeting.

In addition, any findings considered to be serious and potentially consequential that require immediate action are promptly shared with the TJU IRB and \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

1. Overview: Subject Enrollment, Demographics, and Status

Summary of the study:

Primary Endpoints:

Secondary Endpoints:

Participant population (# to be enrolled, demographics, randomization schedule):

Current Enrollment:

|  |  |  |
| --- | --- | --- |
|  | Females | Males |
| Total |  |  |
| Ages (median) |  |  |
| Hispanic |  |  |
| Non-Hispanic |  |  |
| Indigenous (American Indian or Alaskan Native) |  |  |
| Black or African American |  |  |
| Native Hawaiian or Pacific Islander |  |  |
| Caucasian |  |  |
| Other (Including Multiple Races) |  |  |
| Race/Ethnicity Unknown |  |  |

|  |  |  |
| --- | --- | --- |
|  | Females | Males |
| Completed |  |  |
| Discontinued/Withdrawn |  |  |
| Screen Failed |  |  |
| Active |  |  |

1. Adverse Event Reporting

Serious Adverse Events (include event, description, relationship, outcome):

Adverse Events Summary (include event, severity, relationship)

IND Safety Report:

Participant Deaths:

1. DSMB Deliberations and Recommendations