UAMS
TRANSLATIONAL RESEARCH INSTITUTE
UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES

# Data Safety Monitoring Boards (DSMBs)

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# Learning Objectives

- Define data safety monitoring.
- Discuss DSMB operations.
- Explore when using a DSMB is necessary.

# Monitoring

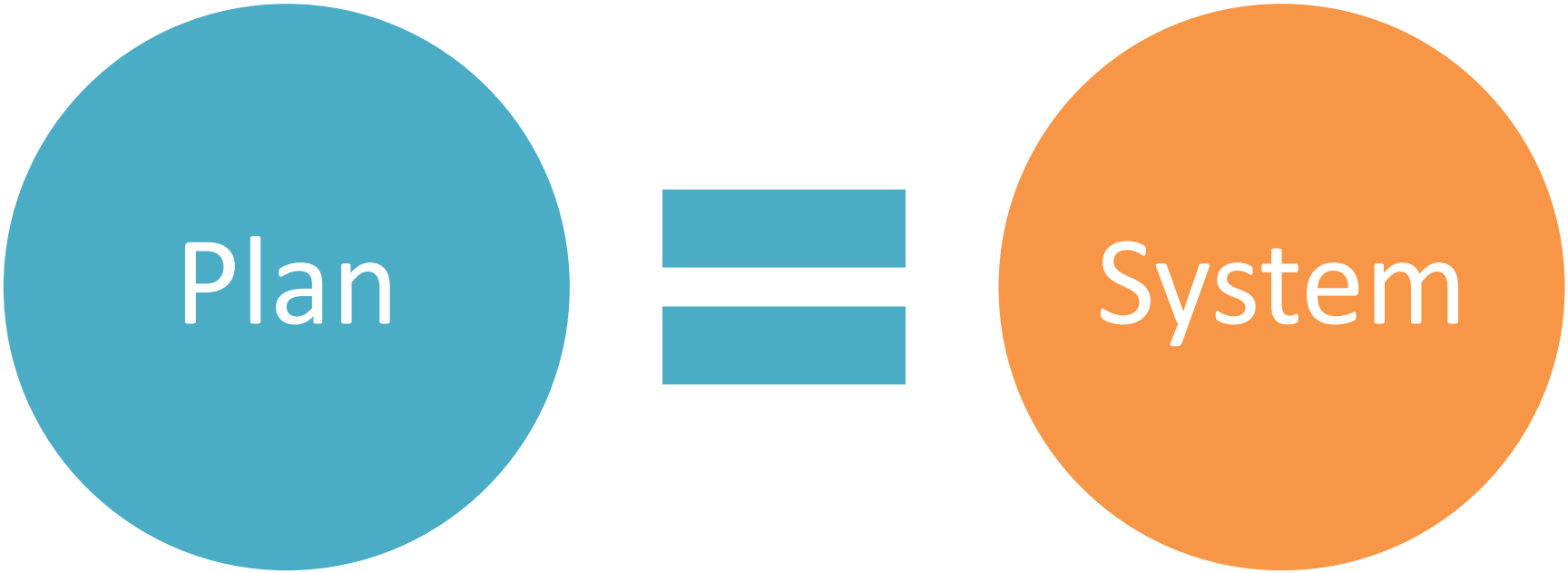

Sponsor
QA
Data Safety
Treatment Effects
Investigator Oversight
Individual Subject

# Data and Safety Monitoring

## DSMP

- **D**ata
- **S**afety
- **M**onitoring
- **P**lan

# Data and Safety Monitoring Plans



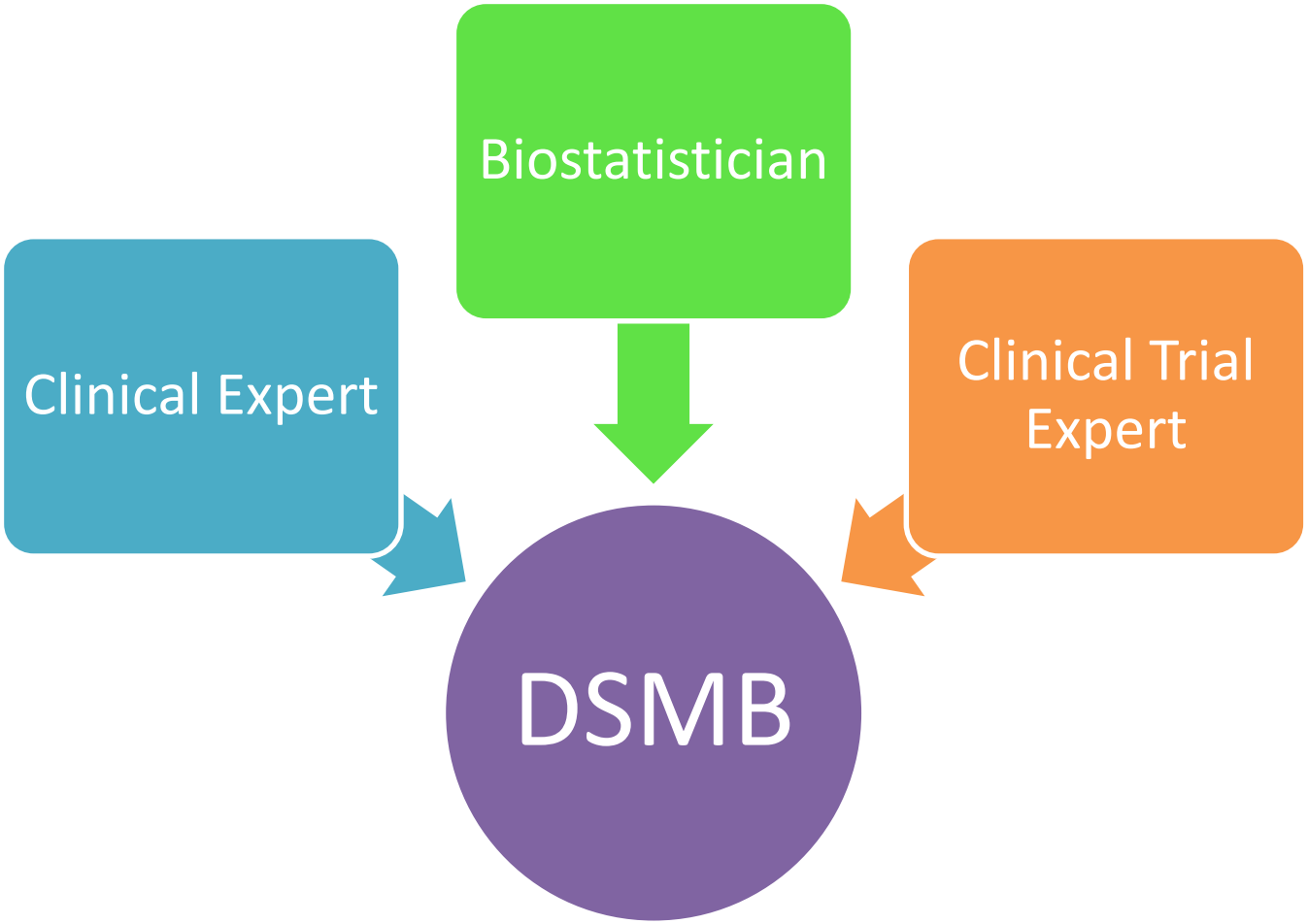
# Data and Safety Monitoring

## DSMB

- **D**ata
- **S**afety
- **M**onitoring
- **B**oard

# Data and Safety Monitoring Boards

# Membership


Biostatistician
Clinical Expert
Clinical Trial Expert
DSMB

# What is reviewed?

- Similar to what you might submit to the IRB at a continuing review.
- May submit interim analysis reports.
- DSMB members can request additional information. This can be provided in writing or answered directly by the investigator(s) during the meeting.

# Data and Safety Monitoring Report

**Protocol Title:** _____

**Principal Investigator:** _____

**Co-Investigators:**_____

**IRB#:** _____ **Date of Last IRB Review:** _____

**Date of this report:** _____ **Date of previous DSM report:**_____

Please fill out this reporting form and return to the RSA office at least ten (10) business days before the meeting of the Data and Safety Monitoring Board that will review your compliance with your DSMP in order for board members to have a chance to review and ask for clarification ahead of time if necessary.

**Accrual of Subjects**

| Category | Since Last Report | Since Initial Approval |
|---|---|---|
| 1. Date the first subject was consented | | |
| 2. Total number of subjects enrolled (= number signing consent form) | | |
| 3. Number of subject that were consented but failed screening | | |
| 4. Number of subjects completed the study and no further intervention with the subject is planned | | |
| 5. Number of subjects still on active treatment or extended follow-up | | |
| 6. Number of subjects voluntarily withdrawn (= number subjects who asked to be removed from the study | | |
| 7. Number of subjects whose participation was terminated by the PI | | |
| 8. Number of subjects who have been lost to follow-up | | |
| 9. Number of subjects who died before completing the protocol | | |

B. In the current reporting period, number of adverse events that have occurred ___
Please complete the attached Adverse Event Log and send with this report.

C. In the current reporting period, number of Serious Adverse Events (SAEs): ___
Please attach the SAE reports sent to the IRB.

D. In the current reporting period, number of protocol deviations: _____
What measures have been instituted to address the problem(s), if any? _____
Please complete the attached Protocol Deviation Tracking Log and send with this report.

E. In the current reporting interval, is there any reason to believe data integrity or confidentiality has been corrupted? _____
If so, what happened and what measures have been instituted to restore data integrity and/or confidentiality? _____

F. In the current reporting interval, how is study safety being monitored? What are the PI or coordinator(s), etc. doing to assure subject safety? (Here you may address changes and improvements in your DSMP, if any, and provide additional details not in your DSMP.) _____

_____
**PI Signature**

**Email completed copy to ajjenkins@uams.edu.**

# Meetings

**COI**

- Members must openly state any conflicts that may be present.

**Open**

- PI and study staff present to discuss updates and answer questions from DSMB members.

**Closed**

- DSMB members and invited guests only.

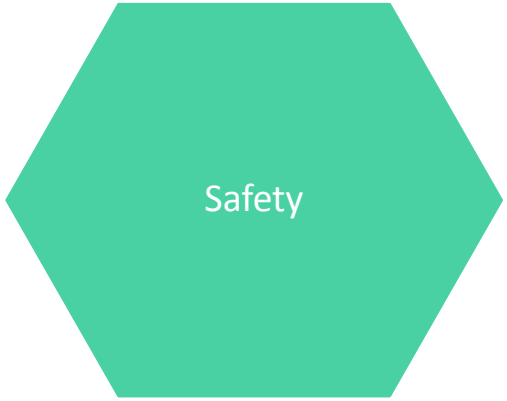
**Recommend**

- Continue with no modifications; Continue with modifications; Suspend study pending additional information; Termination

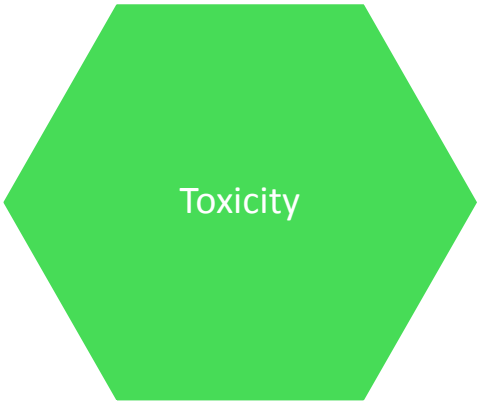
# When is a DSMB necessary?


FDA Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees (http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127073.pdf)

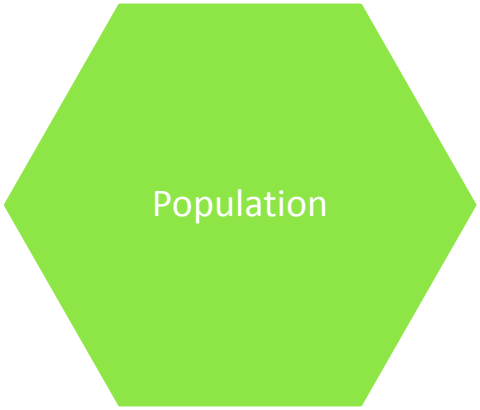

A highly favorable or unfavorable result, or even a finding of futility, at an interim analysis might ethically require termination of the study before its planned completion.




There are *a priori* reasons for a particular safety concern. (Ex: procedure for administering the treatment is particularly invasive)



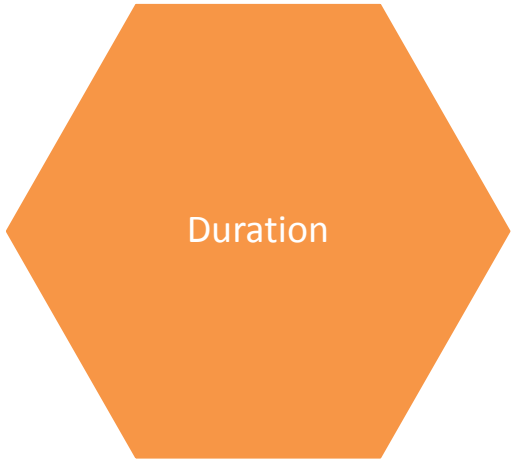

There is prior information suggesting the possibility of serious toxicity with the study treatment.




The study is being performed in a potentially fragile population (Ex: children, pregnant women, very elderly, terminally ill, of diminished capacity (45 CFR 46)).

The study is being performed in a population at elevated risk of death or other serious outcomes, even when the study objective addresses a lesser endpoint.

Large (hundreds+), multicenter




Long (years)

# Who decides if I need an DSMB?

- For investigator-initiated research:
  - Principal Investigator
  - FDA
  - IRB
  - Sponsor

- For other research, you will likely be provided with instructions.

# Finding a DSMB

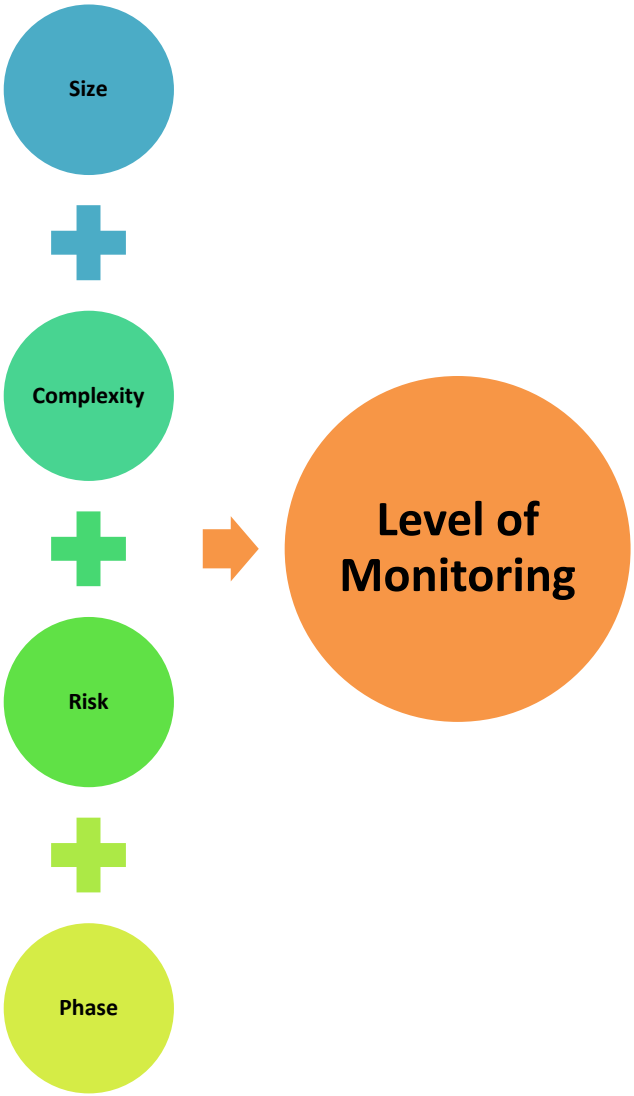
Funding Agency

Sponsor

Institution

Organize your own!

# Safety Monitoring Committees



# Safety Monitoring Committees

- Example:
  - Members (at least 2): Independent Investigator, Biostatistician, Independent Data Monitor, Consultant (if necessary)
  - Meet no less than once yearly
  - Recommendations
  - Summary letter to PI

# Questions?

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