

SPDSMP Considerations

This document can be utilized when developing a Study Progress, Data, and Safety Monitoring Plan (SPDSMP). The document is divided into seven content sections: Designation of study review mechanism, review process, preparation and distribution of data reports, type of data reports, meetings, pause and stopping rules, and communication plan. Each section lists the elements to consider addressing in the SPDSMP. Hyperlinks to DAIDS policies, Appendices, and other relevant documents with additional information are included, when applicable.

Note: For purposes of this document, the terms data reports and summary reports are defined as follows:

Data reports are documents containing data related to study progress, data, and safety monitoring generated for the review by the designated monitor(s).

Summary reports are the synopsis of the observations and recommendations of the designated monitor(s).

Items in **bold** indicate mandatory content for SPDSMP. All other content is optional, as applicable.

	Options as listed in policy and Other considerations	Resources, for additional information
Designation of Study Review Mechanism		
Which type of monitoring will be used?	DSMB, SMC, Study Team, ISM Include other monitoring body(ies) that will be utilized (e.g., clinical monitoring committee, toxicity review group, endpoint verification committee)	DAIDS SPDSMP Policy, section 6.2, DAIDS PD Manual, section 15.8, NIH Policy for Data and Safety Monitoring, NIAID Clinical Terms of Award, Safety and Monitoring Issues, Data and Safety Monitoring Requirements
Development of formal charter	Required for DSMBs	NIAID Policy on DSMB Operations, section 6.1
Process for selecting reviewer(s) and Chair		DAIDS SPDSMP Policy, section 6.2.2, DAIDS SMC Guidelines, section 2, DAIDS ISM Guidelines, section A1, NIAID Policy on DSMB Operations, section 6.2 Charter for the DSMB of the DAIDS NIAID, membership and appointment procedures FDA Guidance for Clinical Trial Sponsors, Establishment of Operation of Clinical Trial Data Monitoring Committees, section 4
Terms of appointment	Limited term or for duration of study	
Number of reviewing (voting) members		DAIDS PD Manual, section 15.8
Type(s) of reviewing members expertise		DAIDS PD Manual, section 15.8
Reviewing members affiliation(s)	Identify if there will be nonvoting members, including if DAIDS staff will be included as nonvoting members	DAIDS PD Manual, section 15.8

	Process for adding ad hoc members		DAIDS SPDSMP Policy, section 6.2.1.1
	Process for avoiding reviewer(s) with COI		DAIDS SMC Guidelines, section 2.1, DAIDS ISM Guidelines, section A2 and B2, NIAID Policy for Identifying Potential Conflict of Interest for Individuals Serving on Advisory Committees or Independent Safety Monitors Responsible for Data and Safety Monitoring of Clinical Trials
	Process for DAIDS approval of PI-selected reviewer(s)		DAIDS SMC Guidelines, section 2.2, DAIDS ISM Guidelines, section A1
	Process for identifying and mitigating member COI that arise after member selected and approved		DAIDS SMC Guidelines, section 2.1, DAIDS ISM Guidelines, section A2 and B2, NIAID Policy for Identifying Potential Conflict of Interest for Individuals Serving on Advisory Committees or Independent Safety Monitors Responsible for Data and Safety Monitoring of Clinical Trials
	If ISM will be designated in addition to DSMB or SMC, how will ISM be identified?	May be designated by DSMB, SMC, DAIDS, or PI	DAIDS SMC Guidelines, section 2, DAIDS ISM Guidelines, section A2 and B2
	Responsibilities of reviewer(s) and Chair		DAIDS ISM Guidelines, section B1
Review Process			
	Who convenes meetings and develops agenda	DAIDS, Other Include who will set up conference call; who will make arrangements/pay for meeting travel	DAIDS SMC Guidelines, section 3, Charter for the DSMB of the DAIDS NIAID, meeting planning
	Review of SPDSMP by monitoring body/committee/monitor	DSMB should review overall interim monitoring plan and template for data	DAIDS SPDSMP Policy, section 6.2.1.1 and 6.2.2

	reports before first scheduled study review	
Frequency of reviews	Monthly, Quarterly, Semi-annually, Annually, ad hoc, Other Identify criterion that would trigger ad hoc review	DAIDS SPDSMP Policy, section 6.2.2, Charter for the DSMB of the DAIDS NIAID, meeting planning
Who makes reviewer assignments and when the assignments are communicated to reviewer, if applicable	If specific member will be asked to review select aspects of the data report, include a description of this process	Charter for the DSMB of the DAIDS NIAID, meeting planning
Preparation and Distribution of Data Reports		
Who prepares each data report	Data Manager, Statistician, Laboratory Data Coordinator, Other If approval by someone other than preparer is needed, describe approval process	DAIDS ISM Guidelines, section A3 and B3, Charter for the DSMB of the DAIDS NIAID, meeting conduct and data reports
How data reports are distributed	Email, mail, link to secure website	
When data reports are distributed relative to the meeting	Dependent on the frequency of review, providing sufficient time for data report preparation and review	Charter for the DSMB of the DAIDS NIAID, meeting conduct and data reports
Who receives data report	Describe who will receive open data reports and who will receive both open and closed data reports (if applicable)	Charter for the DSMB of the DAIDS NIAID, meeting conduct and data reports, FDA Guidance for Clinical Trial Sponsors, Establishment of Operation of Clinical Trial Data Monitoring Committees, section 4.2.2
Other material that is provided to reviewer(s) (e.g., Protocol, amendments, IB)		DAIDS SMC Guidelines, section 4, DAIDS ISM Guidelines, section A3 and B3
Type of Data Reports		
Describe all data reports that will be reviewed and timing of review	Not all data reports will necessarily be reviewed at every meeting. State which	DAIDS SPDSMP Policy, section 6.1.1 DAIDS SMC Guidelines, section 4, NIAID Policy on DSMB Operations, section 6.4,

	<p>data reports will be reviewed at each meeting.</p> <p>Describe process for data report format and content</p> <p>Describe which data reports will be open and which will be closed. For closed data report, describe if report data will be by treatment group, or be blinded/masked.</p>	Charter for the DSMB of the DAIDS NIAID, meeting conduct and data reports
Screening		
Enrollment		
Retention		
Safety (AE by relationship, severity/grade)		
Data quality (including timeliness)		
Procedure completion		
Protocol Deviations & Violations		
Endpoints	Specify if endpoints will be reviewed, and if so, which meeting(s)	
Other protocol-specific issue		
Meetings		
Convened meeting format	Video, Conference call, face-to-face, email, other	DAIDS SMC Guidelines, section 3
Meeting session(s) type	Identify if meeting includes open session, closed session, executive session, other	DAIDS SMC Guidelines, section 3.1, Charter for the DSMB of the DAIDS NIAID, meeting conduct and data reports, NIAID Policy on DSMB Operations, section 6.4, FDA Guidance for Clinical Trial Sponsors, Establishment of Operation of Clinical Trial Data Monitoring Committees, section 4.3.1
How quorum is attained		DAIDS DSMB Charter, membership and appointment procedures

How recommendation is reached	General consensus, simple majority, other	DAIDS SMC Guidelines, section 3.2
Pause and Stopping Rules		
Statistical analysis rules for pausing study enrollment	Specific statistical techniques and their operating characteristics (e.g., probability of stopping under different safety event rates), and associated number of participants that would be enrolled. Include whether rules pertain to entire study, specific study arms, participant subgroups, or other components of study	DAIDS PD Manual, section 15.8.1.1
Statistical analysis rules for pausing study product(s)/intervention(s) administration for safety	Specific definitions of proposed study stopping guidelines. Include whether rules pertain to entire study, specific study arms, participant subgroups, or other components of study	Charter for the DSMB of the DAIDS NIAID, meeting conduct and data reports, DAIDS PD Manual, section 15.8.1.1
Proposed permanent stopping guidelines associated with statistical interim analyses	Include criteria for stopping guidelines that address operational futility and efficacy futility	Charter for the DSMB of the DAIDS NIAID, meeting conduct and data reports, DAIDS PD Manual, section 15.8.1 and 15.8.1.2
Communication Plan		
Verbal summary reports- Which member(s) will discuss committee/board findings and recommendations, with whom		DAIDS SMC Guidelines, section 5.1, Charter for the DSMB of the DAIDS NIAID, DSMB Recommendations
Written summary reports- Who is responsible to prepare summary report,		DAIDS SPDSMP Policy, DAIDS SMC Guidelines, section 5.2, DAIDS ISM Guidelines, section A4.1 and B4.1,

review and approve written summary report for distribution, timeframe for distributing summary report, who will receive summary report		Charter for the DSMB of the DAIDS NIAID, DSMB Recommendations, FDA Guidance for Clinical Trial Sponsors, Establishment of Operation of Clinical Trial Data Monitoring Committees, section 4.4.3.1
Confidential minutes- Who is responsible to prepare minutes, who will receive		DAIDS SMC Guidelines, section 5.3, FDA Guidance for Clinical Trial Sponsors, Establishment of Operation of Clinical Trial Data Monitoring Committees, section 4.4.3.1
Immediate action summary reports- Format for communicating findings/ recommendations of a serious and immediate nature, whom will receive summary report, timeframe for communicating summary report		DAIDS SMC Guidelines, section 5.4, DAIDS ISM Guidelines, section A4.2, Charter for the DSMB of the DAIDS NIAID, DSMB Recommendations, NIAID Policy on DSMB Operations, section 6.5,
Additional Reporting		
Description of all required AE reporting	Specify reporting to IRB/EC, DAIDS, and FDA, when applicable. Note that there are reporting requirements to the IRB/EC, DAIDS and the FDA which are outside the scope of this document, and which are fully described in the FDA regulations, and the DAIDS EAE Policy and Manual.	DAIDS Expedited Adverse Events Reporting Policy, Manual for Expedited Reporting of Adverse Events to DAIDS, NIH Further Guidance on Data and Safety Monitoring for Phase I and Phase II Trials, monitoring plan