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1.0 PURPOSE

- 1.1 This policy sets the minimum standards that must be met for the Study Progress, Data, and Safety Monitoring Plan (SPDSMP) for all Division of AIDS (DAIDS) sponsored trials conducted within the National Institute of Allergy and Infectious Diseases (NIAID) Clinical Trials Networks. Responsibilities for creating, reviewing, and implementing the SPDSMP may differ in various settings, but must meet the requirements identified in this policy.
 - 1.1.1 Study progress, data, and safety monitoring is required for all clinical trials, to ensure the progress of the study, safety of participants, and quality of the data. The type and frequency of monitoring should be commensurate with the risks, size and complexity of the clinical trial.
 - 1.1.2 All NIAID/DAIDS sponsored clinical trials are subject to and must adhere to any applicable laws, regulations, guidelines, as well as National Institutes of Health (NIH), NIAID, and DAIDS policies, terms of award, or other requirements for study progress, data, and safety monitoring [See references].

2.0 SCOPE

- 2.1 This policy applies to NIAID/DAIDS sponsored clinical trials carried out within the NIAID DAIDS networks.

Note: Clinical on-site monitoring is outside the scope of this policy and is addressed in a separate DAIDS policy.

3.0 DEFINITIONS

For additional definitions, see [Glossary of Division of AIDS Clinical Research Policy Terms](#)

- 3.1 **SPDSMP:** The SPDSMP outlines the process for the creation, content, and distribution of data reports, including Independent Data-Monitoring Committee (IDMC) reports, for the following purposes:
 - To help ensure the safety of the study participants.
 - To verify that the appropriate data are collected to monitor safety and address the protocol objectives.
 - To ensure that the reports are made available in a timely manner.
- 3.2 **IDMC:** An independent data-monitoring committee that may be established by the sponsor (Data and Safety Monitoring Board), or the network (Safety Monitoring Board or Committee, or equivalent) to assess, at predetermined intervals or ad hoc if required, the progress of a clinical trial, the safety data, outcome measures, and the critical efficacy endpoints when applicable, and to recommend to the sponsor whether to continue, modify, or stop a trial.

3.3 **Data reports:** For the purposes of this policy, the term “data reports” is defined as follows – descriptive documents, tables, listings, and figures containing data (including safety) and analysis results generated according to the SPDSMP.

3.4 **DAIDS MO:** The DAIDS Medical Officer (MO) is the designated DAIDS Clinical Representative for the study.

4.0 RESPONSIBILITIES

4.1 Clinical Trials Networks

For NIAID, DAIDS sponsored clinical trials conducted within the Clinical Trials Networks, each Network, directly or through their Statistical and Data Analysis Center/ Data Management Centers (SDAC/DMC), is responsible for the following:

4.1.1 Developing, maintaining, and updating the study-specific SPDSMP.

4.1.2 Providing the initial study-specific SPDSMP to the DAIDS MO for review and approval, and ensuring that a final approved version of the SPDSMP is available prior to study opening.

4.1.3 Providing the SPDSMP to the DAIDS MO and the OPCRO Data Management Representative following the release of a full protocol amendment or a Letter of Amendment (LOA) to determine whether any SPDSMP updates are needed, when applicable (see section 5.3).

4.1.4 Ensuring that the SPDSMP is followed.

4.1.5 Ensuring that all appropriate documentation is maintained and made available for review by site monitors, program staff, protocol teams, and regulatory authorities, as appropriate.

4.2 DAIDS Medical Officer/Clinical Representative

4.2.1 The DAIDS MO and Program, in discussion with the Network and SDAC/DMC, will determine the specific reports to include in protocol SPDSMPs.

4.2.2 The DAIDS MO is responsible for reviewing the SPDSMP.

4.2.3 The DAIDS MO is responsible for ensuring that the SPDSMP is aligned with the protocol.

4.2.4 The DAIDS MO must provide approval of the initial SPDSMP prior to study opening.

4.2.5 The DAIDS MO will collaborate with Program, Office for Policy in Clinical Research Operations (OPCRO) staff, Office of Clinical Site Oversight (OCSO) staff, and Data Management Representative as needed for review and updates to the SPDSMP as per their program procedures.

4.3 DAIDS OPCRO Data Management Representative

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- 4.3.1 The OPCRO Data Manager is responsible for reviewing the SPDSMP.
- 4.3.2 The OPCRO Data Management representative is responsible for ensuring that the SPDSMP data management quality reports and summary table are aligned with the DMC generated reports and data source.
- 4.3.3 The OPCRO Data Management representative will collaborate with the DAIDS MO for review and updates to the SPDSMP.
- 4.3.4 The OPCRO Data Management representative must sign off on the SPDSMP as per the program procedures.

5.0 POLICY

- 5.1 All NIAID/DAIDS-sponsored trials conducted within the Clinical Trials Networks must have an SPDSMP.
- 5.2 The SPDSMP must be a separate document and must not be included in other documents such as, a network Manual of Operational Procedures (MOP), the study specific clinical Data Management Plan or a study-specific procedures (SSP) manual.
- 5.3 The SPDSMP must be reviewed and approved prior to study opening and, when applicable, after a protocol amendment. The initial SPDSMP and any revisions must be provided to the DAIDS MO and the OPCRO Data Manager for review and approval.

6.0 REFERENCES

- 6.1 [FDA regulations on Investigational New Drug Application at 21 CFR 312](#)
- 6.2 [ICH E6\(R3\): Guideline for Good Clinical Practice E6\(R3\)](#)
- 6.3 [FDA Guidance for Clinical Trial Sponsors, Establishment of Operation of Clinical Trial Data Monitoring Committees](#)
- 6.4 [FDA Data Integrity and Compliance with Drug CGMP Questions and Answers, Guidance for Industry](#)
- 6.5 [NIAID Policy on Data and Safety Monitoring Board \(DSMB\) Operations](#)
- 6.6 NIH: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html>
- 6.7 NIH: <https://grants.nih.gov/grants/guide/notice-files/not98-084.html>

7.0 APPENDICES

Not applicable

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8.0 REVISION SUMMARY

- 8.1 POL-A15-OPC-012.00 is the initial version of the Policy for Study Progress, Data, and Safety Monitoring submitted to the DAIDS QMS as version 00. There was one previous version of the Policy for Study Progress, Data, and Safety Monitoring, version 1.0 December 2006, published on the DAIDS Clinical Research Policies web page prior to the implementation of the DAIDS QMS in 2018.

The policy name was updated from Study Progress and Safety Monitoring to Policy for Study Progress and Safety Monitoring Plan to better reflect the contents of the revised policy. The scope of the policy has been modified to apply to all clinical trials that are sponsored by NIAID/DAIDS. All the appendices and information from the previous version that are out of scope with the revised version of this policy have been removed.

- 8.2 DAIDS-OPC-A15-POL-00012 rev 01 became effective on 11/29/2022 and is the first revision of this policy in MasterControl. The document format and numbering were updated to reflect the current requirements.
- 8.3 DAIDS-OPC-A15-POL-00012 rev 02 is the second revision of this policy in MasterControl. The document title, format, and numbering were updated to align with current requirements. Specifically, the title was revised from "*Policy for Study Progress and Safety Monitoring Plan*" to "*Policy for Study Progress, Data, and Safety Monitoring Plan*" to better reflect the scope and content of the policy. The summary of changes include:
- The purpose of this policy was revised for improved clarity and alignment with the updated policy title.
 - Several definitions were updated to ensure consistency with terminology used in the *Glossary of Division of AIDS Clinical Research Policy Terms*.
 - The *Responsibilities* section was revised to clarify the workflow, and expanded to include review and approval responsibilities of the OPCRO Data Management Team.
 - The *Policy* section was revised to incorporate a defined timeline for review and approval, and to include reference to the SS-DMP.
 - The References section was updated to include the NIAID *Policy on DSMB Operations* and the NIAID *Clinical Terms of Award* to reflect current guidance.
 - Minor grammatical and editorial changes were made throughout the document to improve readability and overall clarity.