

Policy  
**Policy for Study Progress, Data, and Safety Monitoring Plan**

Effective Date: 07/15/21

Document No.: **POL-A15-OPC-012.00**

## 1.0 PURPOSE

This policy sets the minimum standards that must be met for the Study Progress, Data, and Safety Monitoring (SPDSM) plan 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 SPDSM plan may differ in various settings, but must meet the requirements identified in this policy.

- 1.1 This policy sets the requirement for the SPDSM plan for each individual trial sponsored by NIAID, DAIDS.
- 1.2 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 of monitoring should be commensurate with the risks, size and complexity of the clinical trial.
- 1.3 All NIAID (DAIDS) sponsored clinical trials are subject to and must adhere to any applicable laws, regulations, guidelines, 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 Terms](#)

- 3.1 **SPDSM plan:** The Study Progress, Data, and Safety Monitoring Plan (SPDSM plan) is a document created by the Statistical Data Analysis Center (SDAC)/Data Management Center (DMC). The purpose of the SPDSM plan is to outline the process for creation of IDMC data reports, including content, distribution schedules, and recipients 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 **Independent Data-Monitoring Committee (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

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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 For the purposes of this policy, the terms “data reports” and “summary reports” are defined as follows:
- 3.3.1 **Data reports** are descriptive documents, tables, listings, and figures containing data (including safety) and analysis results generated for the review by the designated IDMCs.
- 3.3.2 **Summary reports** are the synopsis of the observations and recommendations of the designated IDMCs.
- 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 SDAC/DMC, is responsible for the following:

- Ensuring that the SPDSM plan is followed.
- Developing, maintaining and updating the study-specific SPDSM plan
- Ensuring that all appropriate documentation is maintained and made available for review by site monitors, program staff, and regulatory authorities, as appropriate.
- Providing the various IDMC data reports and summary reports as applicable for IDMC reviews.
- Providing the SPDSM plan for DAIDS MO review within 30 days of release of a final version of the protocol, protocol amendment or a Letter of Amendment (LOA), as applicable.

##### **4.2 DAIDS Medical Officer/Clinical Representative**

- The DAIDS MO is responsible for receiving the SPDSM plan, authored by the SDAC/DMC
- The DAIDS MO is responsible for ensuring that the SPDSM plan is aligned with the protocol.
- The DAIDS MO will provide approval of the SPDSM plan to the SDAC/DMC

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- The DAIDS MO will collaborate with the appropriate parties to ensure that the SPDSM plan is updated as needed and followed for the given protocol.
- If needed, the DAIDS MO will collaborate with the DAIDS Network Leadership Grant Program Officer (PO) to ensure that the study specific SPDSM plan and this policy are followed

## **5.0 POLICY**

- 5.1 All NIAID/DAIDS-sponsored trials conducted within the Clinical Trials Networks must have an SPDSM plan.
- 5.2 The SPDSM plan must be a separate document and must not be included in other documents such as, a network manual of operational procedures (MOP) or a study-specific procedures (SSP) manual.
- 5.3 The SPDSM plan must be reviewed at least once a year and/or every time the protocol is amended and updated if needed. The initial SPDSM plan and any revisions must be provided to the DAIDS MO for review and approval.

## **6.0 REFERENCES**

- 6.1 [FDA regulations on Investigational New Drug Application at 21 CFR 312](#)
- 6.2 [ICH Harmonized Guideline, Integrated Addendum to ICH E6\(R1\): Guideline for Good Clinical Practice E6\(R2\)](#)
- 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 NIH: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html>
- 6.6 NIH: <https://grants.nih.gov/grants/guide/notice-files/not98-084.html>

## **7.0 APPENDICIES**

Not applicable

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**8.0 REVISION HISTORY**

- 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 webpage prior to the implementation of the DAIDS QMS in 2018.

The policy name was updated from Study Progress and Safety Monitoring to Study Progress, Data, 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 the (NIAID) Division of Acquired Immunodeficiency Syndrome (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.