SOP 003_01

Title	Data Management Plan
SOP Code	SOP 003_01
Effective Date	30-June-2023

Site Approval/Authorization to Adopt

Name and Title of Local Personnel (Type or print)	**Signature**	**Date dd/Mon/yyyy**
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1.0 PURPOSE

This Standard Operating Procedure (SOP) identifies the need for a Data Management Plan (DMP) and describes which parties are applicable, the purpose, the process for creating a DMP, and the essential components.

2.0 SCOPE

This SOP is applicable to all Data Management personnel, or other research team members, who are responsible for authoring or versioning a Data Management Plan.

3.0 RESPONSIBILITIES

The Sponsor-Investigator, Qualified Investigator (QI)/Investigator, and applicable Data Management personnel are responsible for ensuring that all study data management activities at the site meet all of the applicable regulatory, International Conference on Harmonisation (ICH) Good Clinical Practice (GCP), Sponsor, and local requirements.

Any or all parts of this procedure may be delegated to appropriately trained study team members, but remain the ultimate responsibility of the Sponsor, Sponsor-Investigator and/or Qualified Investigator (QI)/Investigator.

4.0 DEFINITIONS

See “CDISC Clinical Research Glossary, Version 8.0” and “N2 Glossary of Terms”.

5.0 PROCEDURE

5.1 Purpose of the DMP

5.1.1 The Data Management Plan is a study-specific document that:

• Details all of the data management processes from study start to database lock and archive.
• Helps to ensure conformity to local, national, and international regulations and guidelines and documents the study-specific practices used to achieve this.
• Serves as a reference document, set of instructions, and a communication tool usable by all parties, throughout the study, explaining the processes by which data are to be handled under all situations.
• Ensures a common understanding of how the data management aspects of the study are conducted; typically achieved by providing training on the DMP.
• Identifies all of the functional roles within the data management process and the personnel who fulfill those roles.

5.2 Authoring the Initial Version

5.2.1 The Data Manager or designate authors a new DMP for each new study, based on the protocol, the scope of work, the contract agreement, analysis plans, dataflow, paper and/or electronic case report forms (CRFs), and any other applicable documents.

5.2.2 The development of the DMP is a collaborative effort between all of the applicable research study parties. Different parties' opinions are solicited, as needed, according to their specialty.

5.2.3 The DMP must be identified on every page by characters such as the study code and title that clearly associate the DMP with its respective study.

5.2.4 The draft document is organized into sections that may include, but are not limited to, the following:

• Approvals page: provide detail regarding the key parties who review and authorize the document and the dates of their approvals.
• Protocol summary: provide a brief summary of the research study protocol and refer the reader to the actual study protocol for more detailed information. Include a list of major protocol revisions and their associated version numbers.
• Study specific notes: state any assumptions that affect the data management of the study.
• Definitions and acronyms: a list of definitions and acronyms.
• Functional role identification: identify the key study personnel and their respective roles, responsibilities and activities.
• Communications: describe the communication plan, including frequency and methods to be used for the study.
• Timelines: list the expected date of the study's milestones and deliverables.
• Database roles and privileges: include database user roles and privileges information.
• Case Report Forms (CRFs): include CFR/eCRF development, description of CRF/eCRF design, and approval process. Develop and approve the completion instructions referred to in the DMP (i.e. form specific data entry direction).
• Database design, creation and maintenance: describe the database validation/testing plan, the creation and maintenance of the database, the data management system that contains the database, the variable names and table structure, the specifications and timeline for data listings, database change control methods, and the audit trail (if applicable).
• Data entry and processing: include the data entry guidelines for data entry personnel (both CRF and eCRF), the data query process and associated timelines, data processing procedures, CRF delinquency/reminder process, list of the data entry personnel, type of data entry, and database lock process.
• SAE data reconciliation: describe the SAE reconciliation processes to be used for the study.
• Lab data handling: process for capturing lab normal ranges or reference ranges and associated data.

• Dictionary and coding management: specify which coding dictionaries will be used in the study as well as the version numbers of those dictionaries.
• External data handling: describe the data being transferred, list the location/vendor that is providing and/or receiving the data. Include the quality control (QC) process, acceptance criteria, error reporting, any applicable agreements, formatting information, frequency of transfer, and contact information.
• QC: describe the level, frequency, and type of checks involved and ensure that there is a documentation process.
• Data validation: identify data validation and test procedures for the data management system and the database, as well as management of data discrepancies.
• Protocol deviations and violations: Specify the process for handling and reporting.
• Reports: include a list and description of all reports that are available throughout the study.
• Database security: describe network, server, and electronic record security measures.
• Quality assurance (QA) and audit plans: define the timing and procedure for all database audit and action plans.
• Regulatory documents: list external regulatory documents that apply to the study such as Sponsor, Sponsor-Investigator, Qualified Investigator, and CRO SOPs.
• Study closure: provide an outline of the data management procedures to be followed at the end of the study.
• Database archive: include procedures for the archiving system.

5.2.5 Other documents and plans (e.g. SOPs, additional project planning documents, or additional data management documents) may be referred to, in lieu of process descriptions within the DMP.

5.2.6 It is of great value to the research team that the initial version of the DMP is finalized, approved, signed, and available, before the work that it describes begins.

5.3 Version Control

5.3.1 Maintain the DMP in a current state throughout the study, using appropriate versioning techniques, including protocol changes and addendums as well as procedural changes that occur.

5.3.2 Note the author, date of change, reason for the change and the new version number for each new version of the DMP.

6.0 REFERENCES

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US Department of Health and Human Services. Food and Drug Administration. Office of the Commissioner. Guidance for Industry, Computerized Systems Used in Clinical Investigations. Guideline. May 2007.

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