



1. Purpose

The purpose of this SOP is to define the most important aspects of the data management process for research studies:

1. Identify the work to be performed;
2. Identify the individuals (or group) responsible for the work;
3. Identify applicable procedures and guidelines;
4. Outline required documentation or output to be collected or produced.

2. Responsibilities

Methods Centre: The Methods Centre is responsible for documenting data management practices for a particular clinical trial in a Data Management Plan.

3. Procedures

- 3.1 The Data Management Plan (DMP) documents the framework for the management of data for a particular clinical trial. Refer to SOP 401: Data Management for further detail concerning the various aspects of data management.
- 3.2 Each study should have a DMP.
- 3.3 The DMP should be written at the beginning of the study.
- 3.4 The DMP for a study should provide direction regarding the following topics:
 - 3.4.1 Responsibilities and scope of work
 - 3.4.2 Data Analysis Plan
 - 3.4.3 CRF design
 - 3.4.4 Study setup
 - 3.4.5 CRF workflow
 - 3.4.6 Data entry
 - 3.4.7 Data cleaning
 - 3.4.8 Handling safety data (AEs and SAEs)
 - 3.4.9 Data coding
 - 3.4.10 Creating reports
 - 3.4.11 Transferring data
 - 3.4.12 Closing studies
 - 3.4.13 Security
- 3.5 Refer to Appendix 4.1 for a DMP template (including topic descriptions).
- 3.6 The DMP should be revised whenever significant changes to existing processes are implemented (e.g. process change or computer application change).

4 Appendix



Data Management Plans
402-00

4.1 Sample DMP Template

5 **References**

- 5.1 Prokscha, S. (2007). CRF Design Considerations. In: Practical Guide to Clinical Data Management. FL: Taylor & Francis Group. 9-18.

<Study Logo>

Data Management Plan

Protocol Title:	
Protocol No./Trial Registry No.:	
Principal Investigator:	
Written By:	
Approved By:	
Version:	Version <date>, replaces version <date>



**Clinical Evaluation
Research Unit**

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1. Introduction

The purpose of the Data Management Plan (DMP) is to define and provide instruction regarding the conduct of data management processes. The DMP will identify:

- The work to be performed
- Responsible individuals/groups
- Applicable SOPs and guidelines
- Required documentation to be produced

Definition of terms and abbreviations to be used in this plan:

AE = Adverse Event

CRF = Case Report Form

DMP = Data Management Plan

PI = Principal Investigator

SAE = Serious Adverse Event

<<Study Acronym>> = <<Study>>

2. Responsibilities and Scope of Work

1. *Lead Data Manager*
2. *Suppliers*
3. *Other relevant team members*

Team Member	Role	Contact Details
	Lead Data Manager	
	EDC System Developers	

Refer to Appendix A for allocation of data management responsibilities.

3. Data Analysis Plan

1. *Written by the Sponsor in consultation with the biostatistician (attached as an appendix). Completed prior to initiation of the trial.*
2. *Outlines each data element and corresponding analysis*
3. *Addresses primary outcomes and secondary outcomes*

Refer to Appendix B for the data analysis plan.

4. CRF Design

- 1. Who is responsible for design*
- 2. Who needs to sign-off and when*
- 3. How revisions are made, approved, and filed*

5. Study Setup

- 1. Who will design and build the study*
- 2. Computer system to be used (hardware and software)*
- 3. Data Dictionary (outlining each data element, database references and validation)*
- 4. Database design output: annotated CRF, printouts of database structures*
- 5. Entry screen design output: printouts of entry screens*
- 6. File loading outputs: specification, printout of code or configuration*
- 7. Other systems to be configured (e.g. imaging systems, CRF tracking systems)*

6. CRF Workflow

- 1. Study specific handling, if any, for this study*

7. Data Entry

- 1. Study specific entry guidelines (can reference Implementation Manual).*

8. Data Cleaning

- 1. Edit check specifications (can reference data validation plan)*
- 2. Data management self evident corrections*
- 3. Study specific discrepancy (query) handling guidelines*
- 4. Query flow and tracking including process for editing data*

Refer to Appendix c for Data Verification Strategy Flowchart.

9. Handling Safety Data

- 1. AE/SAE reconciliation*
- 2. Refer to DSMC procedures*

10. Data Coding

- 1. All dictionaries and specific versions being used (medications and AEs)*
- 2. Autocoding process and relevant algorithms*
- 3. Workflow for uncoded terms*

4. *Coding conventions specific to this protocol or drug*

11. Creating Reports

1. *List of standard reports*
2. *Frequency of reports*

11. Transferring Data

1. *List of transfers expected or frequency of transfers, if any.*
2. *Process for transfers*

12. Closing Studies

1. *Study closeout checklist*
2. *Database audit plan*
3. *Approval process needed to lock*

13. Security

1. *Access to application by users*
2. *Signatures*
3. *Special security for transfers*

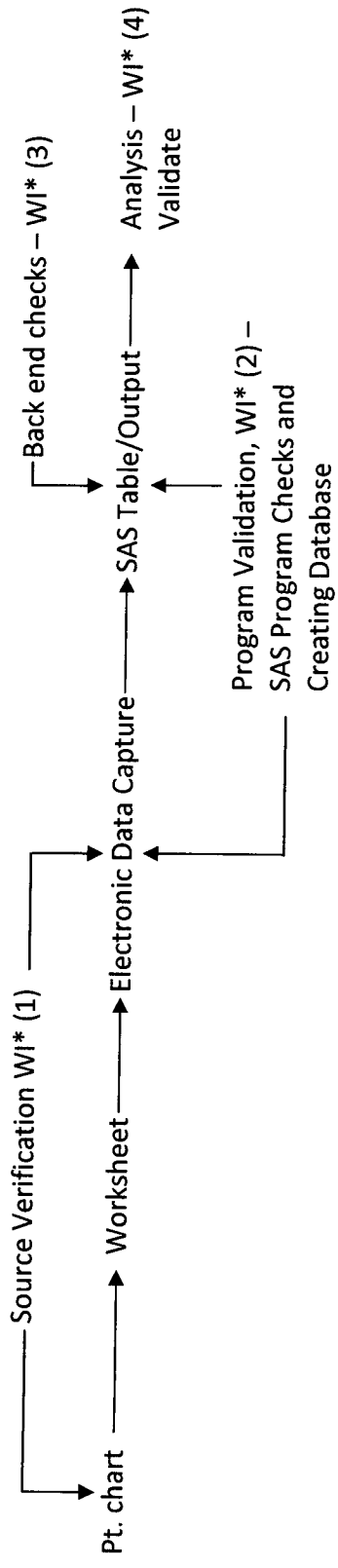
Sample

Data Management Allocation of Responsibilities

Task Description	MC	Stats	IT Developers
Study Start-up			
Define Data Elements	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Develop Data Dictionary (incl. edit checks)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Develop the CRF	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Write Data Management Work Instruction	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Database design and validation	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Programming and validation of edit check programs	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Study Implementation			
Query management and resolution	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CRF tracking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Reports	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Interim and Final Analysis			
Database audit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Data transfers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Coding	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Change Control	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Database Back-up and Recovery	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Study Close-out			
Approve study lock	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Database storage and archiving	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Sample

Data Verification Strategy (SOP)



*WI = work instruction