



Cancer Clinical Trials

Data Management Plan Guide and Template

A guide to support researchers and trial coordinators to develop accurate and compliant Data Management Plans

Contents

1. Introduction	02
2. Data Management Plan (DMP) Preparation Checklist	03
3. Data Management Plan (DMP) Template	06

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The Regional Cancer Research Network NSW acknowledges the traditional custodians of the lands on which we work and live, and recognise their continuing connection to land, water and community. We pay our respect to Elders past and present.

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1. Introduction

A Data Management Plan (DMP) is an important research governance document that describes how research data will be collected, stored, secured, managed, shared, retained and disposed of throughout the research lifecycle. A DMP supports good research practice, data quality, regulatory compliance and the responsible management of research data. DMPs are required for many research studies, including clinical trials. The DMP should be completed as early as practicable in the project lifecycle and reviewed throughout the trial as required.

USEFUL TIPS

Before you start preparing a DMP:

- ✓ Review this guide
- ✓ Gather the required study documents
- ✓ Confirm data management responsibilities
- ✓ Identify data storage and security arrangements
- ✓ Review applicable governance requirements

FURTHER ASSISTANCE:

For support with developing a Data Management Plan, you may wish to consult:

Research Governance

- Ethics approvals, site governance, regulatory requirements, sponsor requirements

Biostatistics

- Data sources, collection and analysis

Data Governance

- Data storage, security, sharing, retention and archiving

2.DMP Preparation Checklist

This checklist outlines the information commonly required to complete a DMP. Gathering these details before you begin will help in developing an accurate and comprehensive DMP that is compliant with organisational, ethical and regulatory requirements.

You may wish to tick off items as you complete them and before you commence the DMP Template (see Section 3).

INFORMATION TO GATHER	COMPLETE
1.Study Protocol	
Have the most recent approved protocol available, including: ➤ Protocol title, identifying number, version number, and version date ➤ Principal Investigator, sponsor and trial coordinating centre ➤ Study design, objectives ➤ Key procedures relevant to data collection and management	☐ ☐ ☐ ☐
2.Ethics and Regulatory Requirements	
Have the most recent approved protocol available, including: ➤ Human Research Ethics Committee (HREC) approval number and approved documents ➤ Site governance authorisation details ➤ Standards, guidelines or regulatory obligations relevant to the study (e.g. security, privacy, retention, metadata standards) ➤ Operating procedures, manuals, or study-specific instructions related to data collection, storage, sharing and future use ➤ Institutional or sponsor-specific-data management policies	☐ ☐ ☐ ☐ ☐

3. Study Personnel and Responsibilities	
Identify who is responsible for key data management duties, including: ➤ Database design, build, and maintenance ➤ Data entry and quality assurance ➤ Reporting and monitoring ➤ Adverse event management ➤ Data analysis ➤ Data archiving	
4. Data Sources and Collection Processes	
Prepare information about the data to be collected and managed: ➤ Critical variables ➤ Data sources (e.g. medical records, external reports, existing datasets, participant-reported measures) ➤ Data capture systems (electronic or paper) ➤ Data linkage requirements ➤ Data classification (e.g. identifiable, re-identifiable, de-identified) ➤ Data dictionary ➤ Codebook ➤ File naming conventions	
5. Data Storage, Security, and Quality	
Confirm arrangements for: ➤ Storage locations for electronic and physical data ➤ User permissions and access controls ➤ Backup and recovery procedures ➤ Data validation, query management, and routine data quality checks ➤ Source document verification	
6. Data Sharing, Retention and Archiving	
Clarify requirements related to: ➤ Data sharing obligations ➤ Data retention and archiving timeframes	

3. Data Management Plan Template

The template on the following page is designed to support the systematic planning and management of research data throughout the lifecycle of a clinical trial.

It should be completed as early as practicable using project-specific information, and maintained as a living document throughout the trial.

Guidance is provided within each section of the template to assist completion. Where a section is not applicable to the trial, indicate "N/A" and provide a brief justification where appropriate.

A downloadable Microsoft Word version of this template is available at www.nswregionalcrrn.com.au/s/Cancer-Clinical-Trials-DMP-Template.docx. The template can be completed electronically or printed for manual completion.



DATA MANAGEMENT PLAN

Protocol identifying name/number	
Protocol full title	
Short title	
Protocol version	
Protocol date	
Project lead	
Sponsor	
Trial Coordination Centre	
DMP author	
DMP version	
DMP date	
Authorisation date	

1. STUDY OVERVIEW

Guidance: Provide a concise description of the study design, including the study type (e.g. observational, interventional), key design features (e.g. randomised, controlled, blinded/open-label, parallel-group, crossover), number of arms/groups, trial phase (if applicable), primary objective, target sample size, study population, and whether the study is conducted at a single-site or across multiple sites.

2. DATA OWNERSHIP and GOVERNANCE

Guidance: Identify who owns the study data and who is responsible for its governance. Include the name of the individual, organization or entity responsible for data ownership; role (e.g. Principal Investigator, Sponsor); institutional affiliation; any legal, contractual, funding or collaborative agreements affecting data ownership or access; intellectual property arrangements, and any governance bodies responsible for oversight of the data.

Duties and responsibilities related to data management	Responsible party/parties
Creation and ongoing maintenance of the Data Management Plan (DMP)	
Develop electronic Case Report Forms (eCRFs)	
Design and build trial database	
Perform system and performance testing of the database	
Perform user acceptance testing of the database	
Create and maintain Study Manual	
Create and maintain eCRF Completion Guidelines	
Provide initial and ongoing training to study and site staff on the trial protocol and implementation of the database	
Create database user accounts for study staff and participating trial site staff with appropriate user rights	
Enter and maintain data in the database in an accurate and timely manner	
Securely store all electronic or paper-based source materials not collected within the database	
Define type and content of reports required	
Create reports to review, export or present data	
Create data quality rules to routinely check for missing, out of range, or inaccurate data as needed	
Create dynamic dashboards to view data: e.g. enrolment, withdrawal, and completion counts that may be used to create CONSORT diagrams or similar	
Use dashboards to track recruitment and enrolment rates	
Use reports, dashboard, or data queries to review data quality, and liaise with sites to query/correct data as needed	

Enter and manage Adverse Event data	
Review Adverse Events reported; if needed, report to relevant ethics review board, governing body, Therapeutic Goods Administration (TGA)	
Identify and record protocol deviations or breaches, and report to appropriate governing bodies if required	
Identify any database issues, or requests for changes or improvements to the database	
Maintain the database e.g. implement changes, add eCRFs, address errors or unforeseen program faults, test scenarios that arise	
Develop a Statistical Analysis Plan	
Create reports and export data and perform interim (if applicable) and final Statistical Analysis Reports	
Create reports and export data and generate tables for Safety Committee review and Trial Management Committee oversight	
End of Study: Disable the data collection functionality of the database	
End of Study: Lock data/database	
End of Study: Download any relevant study-related documents, data, database structure and materials from the trial database for long-term storage	
End of Study: Store database structure on server for long-term storage. Delete the trial database from data collection systems	

In addition to the table above, the following policies, procedures, guidelines and standards apply to the management of data:

- Protocol (current, HREC approved)
- Ethics approved documents
- eCRF Completion Guidelines
- Study Manual
- Statistical Analysis Plan

3. DATABASE

3.1 SYSTEM AND DATABASE

Guidance: Describe the data collection system(s) and database(s) used for the study. Include the system/database name (e.g. REDCap), purpose, data capture methods (e.g. surveys, forms, data imports, eCRFs), user access controls, audit trail functionality, validation and quality control processes, storage and backup arrangements, and compliance with applicable regulatory and GCP requirements.

3.2 CASE REPORT FORM (CRF) DEVELOPMENT AND DATABASE TESTING

Guidance: Describe the processes for CRF development, testing, approval, and maintenance. Include validation and user acceptance testing procedures, version control arrangements, and how amendments and updates will be documented to ensure data quality and regulatory compliance.

3.3 PARTICIPATING SITES - USER TRAINING

Guidance: Describe how participating site staff will be trained to use the data capture system and complete CRFs accurately and consistently. Include training materials (e.g. manuals), training requirements (e.g. frequency) and documentation, training format (e.g. face-to-face, online, self-directed), and any additional resources or support available to site staff.

3.4 PARTICIPANT RECORD ID

Guidance: Describe how unique participant record IDs will be assigned and managed to maintain confidentiality and data integrity. Include the ID format, any site-specific numbering conventions, procedures to prevent duplicate IDs, and how the participant identification log will be maintained and secured.

4. ETHICS AND LEGAL COMPLIANCE

4.1 ETHICS APPROVAL

Guidance: Provide details of the ethics approval(s) for the study, including the name of the approving Human Research Ethics Committee, approval number/reference, approved protocol version, approval date, and whether approval covers all participating sites or site-specific approvals were required.

4.2 SECURITY, STORAGE AND BACKUP

Guidance: Describe the storage, security, and backup arrangements for study data. Include the database hosting environment and storage location, security measures (e.g. encryption, firewalls), user access controls, backup and recovery procedures, audit trails, and compliance with applicable ethical, privacy, and institutional requirements.

4.3 USER ACCESS AND ADMINISTRATION

Guidance: Describe how access to the study database and data will be managed. Include user roles and permissions, access control processes (e.g. role-based permissions), responsibilities for managing access, database administrator(s) and their responsibilities, and any exceptions to standard access arrangements.

4.4 USER ROLE NAMES AND RIGHTS

Guidance: Identify the main user roles with access to the study database and provide a reference to where detailed role permissions and privileges are documented.

5. DATA GENERATION AND COLLECTION

5.1 KEY DATA COLLECTED

Guidance: Describe the key data collected for the study, including the data source(s) (e.g. participants, medical records), collection methods (e.g. surveys, data imports, eCRFs), and where the complete list of data collection variables is documented (e.g. code book, data dictionary).

5.2 KEY VARIABLES IN THE DATABASE

Variable name	Outcome

5.3 DOCUMENTATION AND METADATA

Guidance: Describe the documentation and metadata maintained for the study database to support transparency, reproducibility, and data governance. Include data dictionaries, codebooks and data collection instruments (e.g. eCRFs, surveys); database structure; logic and validation documentation (e.g. branching logic, calculations, skip/display logic), audit logs, user access permissions, and where these documents are stored and maintained.

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6. DATA VALIDATION and QUERY RESOLUTION

6.1 DATA VALIDATION

Guidance: Describe the procedures used to ensure data quality and minimise errors and missing data. Include automated database validation checks (e.g. range checks, required fields), where validation rules are documented, and ongoing data review and query resolution processes.

6.2 REPORTS AND DASHBOARDS

Guidance: Describe any reports or dashboards that will be used to monitor study progress and data quality. Include the reports/dashboards to be generated, their purpose (e.g. recruitment monitoring, data completeness, overdue forms, protocol deviations), and how they will be used to support ongoing data quality.

6.3 DATA CLEANING

Guidance: Describe the processes used to identify, investigate, resolve and document data discrepancies, and prepare data for analysis. Include automated and manual data cleaning procedures, oversight of ongoing data cleaning activities, and responsibility for final data review and cleaning.

6.4 SOURCE DATA VERIFICATION

Guidance: Describe the source data verification process used to confirm the accuracy and completeness of eCRF data against source documents. Include the scope of source document verification, method of verification, frequency and timing, monitoring approach, requirements for source document review or upload, and roles and responsibilities for conducting source document verification.

7. DATA PREPARATION FOR ANALYSIS

Guidance: Describe the processes for final data review, database lock, and preparation for statistical analysis. Include final data quality checks, sign-off requirements prior to database lock, database lock procedures, compliance with the Statistical Analysis Plan (SAP), procedures for post-lock changes if required, and roles and responsibilities.

8. DATA USE and DISTRIBUTION

8.1 DATA USE

Guidance: Describe the governance arrangements for access and use of study data beyond the activities outlined in the protocol and DMP. Include permitted uses, approval requirements, who may access the data, and any restrictions on future or secondary use.

8.2 DATA PUBLICATION

Guidance: Describe how study results and related data will be disseminated or published. Include planned publications, results reporting requirements, sponsor or funder requirements, data or materials to be shared, and any restrictions on publication or disclosure.

9. DATA SHARING and ACCESS

Guidance: Describe how study data will be shared and accessed after collection. Include who approves access, where and how data will be shared (e.g. institutional repositories, metadata repositories), the access request process, measures to protect participant confidentiality, and any restrictions or data sharing agreements.

10. DATA RETENTION and DELETION

Guidance: Describe how long study data and related documentation will be retained, where they will be stored, and how they will be securely destroyed or deleted after the retention period. Include any regulatory, sponsor, or institutional requirements.

A downloadable Microsoft Word version of this template is available at www.nswregionalcrcn.com.au/s/Cancer-Clinical-Trials-DMP-Template.docx. The template can be completed electronically or printed for manual completion.