Seminar Series

REGULATORY AFFAIRS

ANIMAL HEALTH

What is a DMP, and Why is it Important?

KANSAS STATE UNIVERSITY | Olathe

What is a DMP, and Why is it Important?

The Data Management Plan (DMP) is a document that outlines the flow of data for a *clinical* research project from data collection to data submission. If properly written, a DMP will ensure the integrity of the data collected making sure it is fit for purpose. The DMP is also an auditable document often asked for by regulatory inspectors.

What is a DMP, and Why is it Important?

Like a Protocol details the flow of a research project, the DMP details the flow of the data.

Study Protocol

Table of Contents

Title of the study
Identifier unique to the study
Study contacts
Identity of the sites
Objective(s)/purpose of the study
Justification
Schedule of events
Study design
Animal selection and identification
Inclusion/Exclusion and post-inclusion criteria
Animal management and housing
Animal feeds
Investigational veterinary and control product(s)
Treatments
Disposal of study animals, products of study animals and investigational and control vet product(s)
Assessment of effectiveness
Statistics/Biometrics
Handling of records
Adverse events
Supplements to be appended to the protocol
Changes to the study protocol
References

Data Management Plan

Table of Contents

Approval Page
Protocol Summary
Access Rights
Case Report Forms (CRFs) or Electronic Case Report Forms (eCRFs)
Database Details
Data Collection and Flow
Database Lock
Database Export/Storage/Archive
External Data Transfers
Data Validation and User Acceptance Testing
Dictionary Coding
Serious Adverse Event (SAE) Reporting and Reconciliation
Protocol Deviations
Quality Control/Quality Assurance/Audit Plans
Optional Miscellaneous Items (Timelines, Metrics, Reports, Definitions, Acronyms, Communication)

What is a DMP, and Why is it Important?

The DMP is the FOUNDATION

“You can’t build a house
without a good, solid foundation”

What is a DMP, and Why is it Important?

The DMP is also a ROADMAP

"Dictates the flow of the data from collection to submission"

What is a DMP, and Why is it Important?

So why is the DMP important?

- ***Consistency*** – consistent approach to the process and guidelines
- ***Reproducibility*** – process can be reproduced with no changes to outcome
- ***Accountability*** – provides a description of the flow and directly outlines who is responsible for process actions
- ***Transparency*** – to stakeholders and regulatory authorities

What is a DMP, and Why is it Important?

Should follow some minimum standards:

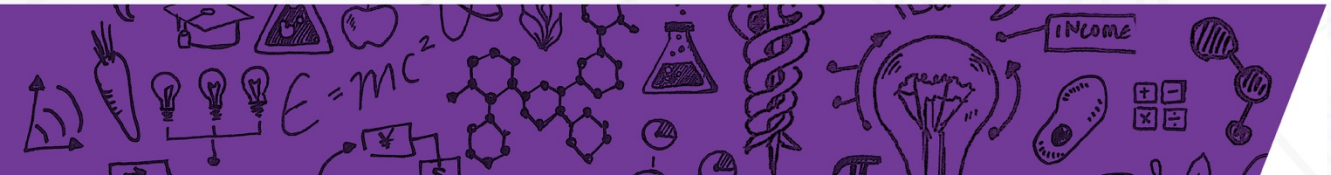
- Completed prior to enrollment of 1st Subject
- Supports applicable regulations and oversight agencies
- Identifies and defines personnel and roles – who is in charge of decision making, data collection, data handling, and data quality
- Contains key data items that define the flow from collection to submission

What is a DMP, and Why is it Important?

Key data items the DMP should contain*:

- Approval Page
- Protocol Summary
- Access Rights
- Case Report Forms (CRFs) or Electronic Case Report Forms (eCRFs)
- Database Details
- Data Collection and Flow
- Database Lock
- Database Export/Storage/Archive

* Reference to Society for Clinical Data Management's Good Clinical Data Management Practices October 2013 Edition



What is a DMP, and Why is it Important?

Key data items the DMP should contain*: (cont.)

- External Data Transfers
- Data Validation and User Acceptance Testing
- Dictionary Coding
- Serious Adverse Event (SAE) Reporting and Reconciliation
- Protocol Deviations
- Quality Control/Quality Assurance/Audit Plans
- Optional Miscellaneous Items

What is a DMP, and Why is it Important?

Approval Page

Official signatures and dates of key stakeholders of the data portions of the project. May include the signatures of the following team members:

- Data Manager (author)
- Clinical Operations Team Lead
- Product/Project Lead
- Statistician
- Data Coder
- Pharmacovigilance Team Lead

Provides official documentation to the agreement of the responsibility and accountability of data management of the project.

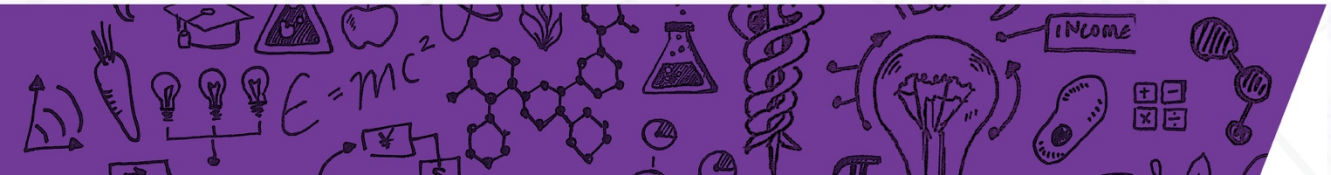
What is a DMP, and Why is it Important?

Protocol Summary

This is a brief description of the project that the DMP is supporting. Usually points taken directly from the protocol in which the DMP is following. Can include the following items:

- Protocol Title
- Protocol Number
- Objectives
- Primary/Secondary Endpoints/Critical Data Analysis
- Visit Schedule
- List of Protocol Revisions/Amendments and associated version numbers

The Protocol Summary is the official link of the DMP to a particular project.



What is a DMP, and Why is it Important?

Access Rights – Roles/Permissions/Security/Training

This section of the DMP should specify the key personnel with roles and responsibilities associated with the protocol, as well as the training requirements associated with each. This list includes the available database roles within the system being used. Each role should have a description of the associated privileges/permissions. Maintenance of database roles (possibly a corresponding company SOP) should be referred to as well.

Description of the network equipment/servers as well as security of electronic records within the system should be addressed here as well. It is a good idea to reference the company database backup SOP in this section.

What is a DMP, and Why is it Important?

Case Report Forms (CRFs) or Electronic Case Report Forms (eCRFs)

The CRF/eCRF design process, or reference to related company SOP, should be included in the DMP, along with a copy of the finalized CRFs/eCRFs.

Instructions for CRFs/eCRFs completion should be included as well.

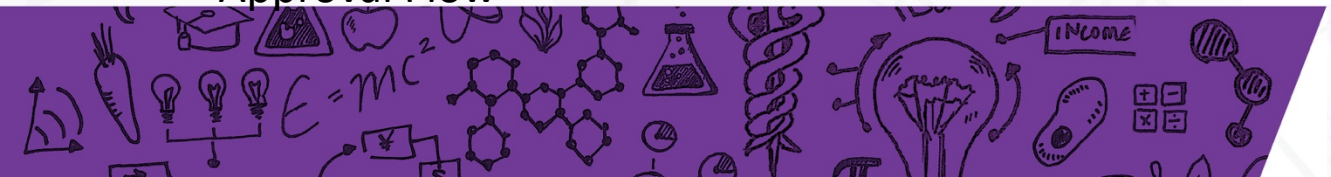
The process, or reference to the related company SOP, for handling changes to finalized CRFs/eCRFs should also be included in this section the DMP.

What is a DMP, and Why is it Important?

Database Details

This section of the DMP contains a description of how the database is designed, created and maintained. It should provide general information about the database system, as well as the following types of specific information directly related to the project:

- Annotated CRFs/eCRFs (Forms/Field Specifications/Visits)
- Sites/Treatment Groups
- Form Rules
- Code Lists
- Skip Logic
- Edit Check Specification
- Approval Flow



What is a DMP, and Why is it Important?

Data Collection and Flow

This section should include data entry and processing plans. This may include or reference the following:

- Data Entry Guidelines
- Data Handling Guidelines
- Data Discrepancy Conventions
- Data Receipt
- Data Processing
- Data Entry
- Data Review
- Self-evident Corrections

What is a DMP, and Why is it Important?

Database Lock

This section should include details defining the criteria for database lock:

- Who is responsible for database lock
- What processes will be used for database lock
- What processes will be used for database unlock and relock
- Reference to the related company SOP

What is a DMP, and Why is it Important?

Database Export/Storage/Archive

Should include specific details regarding extracting data from the database:

- Field/Form specifications
- Format
- Method or location
- Recipient of data
- Frequency
- QC/Validation steps performed to maintain integrity
- Reference to the related company SOP

What is a DMP, and Why is it Important?

External Data Transfers

Similar to export, should include specific details regarding transferring data to and from the database:

- Field/Form specifications
- Procedures for collecting and handling the data
- Format
- Method or location
- Recipient of data
- Frequency
- QC/Validation steps performed to maintain integrity

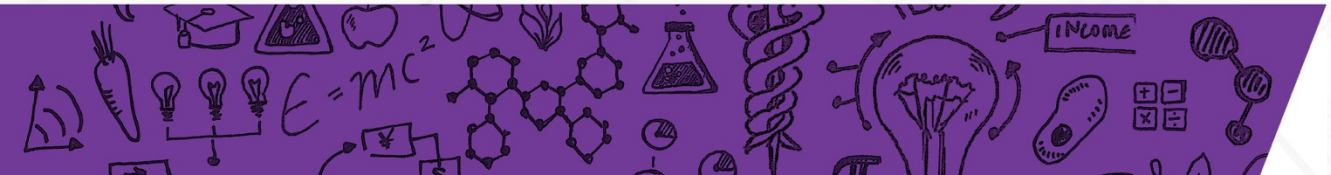
What is a DMP, and Why is it Important?

Data Validation and User Acceptance Testing

This section of the DMP should define the process, or refer to the related SOP, for ensuring the integrity (complete, correct, allowable, valid, consistent) of all related database programming. This includes, but not limited to:

- Data Entry/EDC Screens
- System Logic and Flow
- Edit Checks
- Security/Backup/Archiving

The documentation practice for validation and user acceptance testing should also be provided.



What is a DMP, and Why is it Important?

Dictionary Coding

This section of the DMP should list which medical coding dictionaries and versions of each dictionary will be used for the study. Instructions for updates or changes to the dictionaries should be included as well. Fields and forms associated with coding should be listed, indicating how the coding will occur (auto or manual) and by whom.

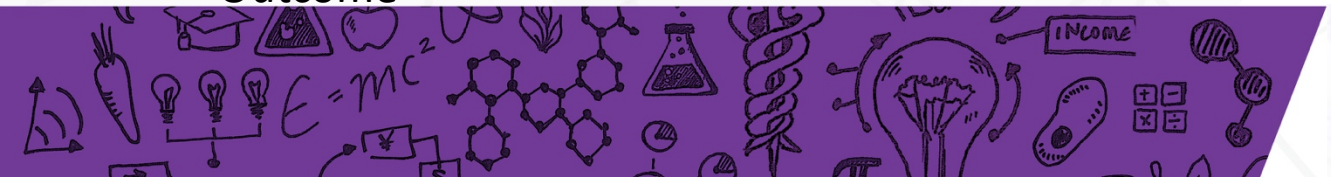
What is a DMP, and Why is it Important?

Serious Adverse Event (SAE) Reporting and Reconciliation

This section of the DMP should provide details about the data fields and external databases requiring reconciliation per the protocol. Should also indicate how the SAE reporting and reconciliation will occur, when it will occur and by whom.

Data fields typically included in Serious Adverse Event reconciliation:

- Clinical Signs/Diagnosis
- Start Date
- End Date/Ongoing
- Causality
- Action Taken
- Outcome



What is a DMP, and Why is it Important?

Protocol Deviations

This section of the DMP should provide details about how protocol deviations should be recorded and handled. As well as how they maintained ALCOA.

Per CVM, Protocol Deviations should include:

- Date of Deviation
- Description of Deviation
- Corrective Actions
- Impact of Deviations

What is a DMP, and Why is it Important?

Quality Control/Quality Assurance/Audit Plans

This section of the DMP should address the level of quality control (or verification that the requirements for quality have been fulfilled) that is going to be completed, as well as how this step is going to be executed and documented.

Quality Assurance (actions that are established to ensure data is in compliance with applicable regulatory requirements) or an audit plan should also be defined. If the QA steps are not detailed in the DMP, then there should be reference to related company SOP.

What is a DMP, and Why is it Important?

Optional Miscellaneous Items

- Timelines
- Metrics
- Reports
- Definitions
- Acronyms
- Communication
- Interim Analysis Requirements
- Business Rules
- Flowcharts
- Blind Data Review Specifications

Contact Information

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