Royal Papworth Hospital
NHS Foundation Trust

GD016

Data Management Plan

SOP078 - Data Management Plan describes the Trust's procedures for the responsibilities in the development review and approval of the FRM046 Data Management Plan (DMP). This document gives instructions on how to complete the form. Appendix 1-3 contains guidance for each individual item.

The DMP is divided into three sections: prior to study build, prior to study live, prior to study lock. The relevant section of the DMP should be approved prior to starting on the work it describes.

The DMP should be kept current and all responsible parties should be aware of, and agree to, the current content. Any major changes to the DMP should be approved by the CI and any minor changes should be approved by the study project manager. If the project manager deems it necessary they should escalate any amendments for approval by the CI.

At the end of each section there is a form for revision history which should detail the revision date, revision notes, amendment type (minor or major) and who the revision was authorised by. The first entry of this form should be that the section was approved.

Items marked with * will be auto populated if the standard data repository (currently OpenClinica) is selected.

1. Prior to study build
    a. Roles
        i. The following responsibilities should be documented: Data Management Lead, Chief Investigator, Principal Investigator, and Clinical Data Lead. Each responsibility should have a start and end date.
        ii. The full history of responsibilities should be retained.
    b. Study details
        i. The basic study details should be documented; these are not expected to change throughout the study.
    c. Data
        i. This section documents the chosen data repository and how the data is going to be collected.
        ii. The user may be prompted to provide details explaining their choices depending on the options selected.
    d. Security *
        i. This section documents the measures that are used to block unauthorised access to data from outside the unit.
    e. Backups *
        i. This section documents the procedures in place that ensure the data is adequately backed up. This may be an automatic or manual process.
    f. Audit trail *

i. This section documents the system which keeps a record of any changes that have been made to the data repository.

g. Version control *

This section documents the procedures in place for version control.

2. Prior to going live
    a. User access *
        i. This section documents how user access is controlled and recorded for the study.
        ii. The standard way of recording access is using FRM052 Database Access, if this is not being used the method should be specified.
    b. Data entry guidelines
        i. This section documents which data entry guidelines are provided to the users.
        ii. If the users are required to enter test data it should be specified here.
    c. Data timeline
        i. This section documents the data entry timeline that have been agreed.
    d. Blinding
        i. This section documents whether the study is blinded.
        ii. If the study is blinded list who is blinded and how this will be controlled.
    e. Validations
        i. This section documents whether a data validation plan (DVP) has been completed, if it has not then an explanation is required.
        ii. Record validation methods here.
        iii. Type of UAT is detailed here, if Fast track UAT is selected the user will be required to explain their choice.
        iv. Detail how data queries will be handled; an explanation should be given if OpenClinica is the selected repository but will not be used to handle data queries.
    f. Coding
        i. This section documents any fields that will be coded.
        ii. If coding is to be used, detail the coding plan (which terms will be coded, which dictionaries will be used) and plans for coding reviews (undertaken by whom and the frequency).
    g. Reporting
        i. Document how SAEs will be recorded; an explanation should be given if OpenClinica is the selected repository and it is not being use to record SAEs.
3. Prior to locking
    a. PI signatures
        i. This section documents how PI signatures are being recorded.
    b. Database lock
        i. This section documents if an interim lock is required.
        ii. If an interim lock is required, it will also detail the requirements for the interim lock.

iii. This also documents the requirements for a hard lock. The following is always required for a hard lock: Source data verification (SDV) review, PI Signature, Authorisation to lock obtained from all parties.

c. SAE reconciliation
   i. This section documents if SAE reconciliation is required.
   ii. If SAE reconciliation is required the plan is also documented here.

Appendix 1 - DMP Prior to build start

Item	Guidance
Role	The following responsibilities should be recorded: Data Management Lead, Chief Investigator, Principal Investigator, and Clinical Data Lead.
Name	The individual responsible for said role.
Start date	Start date of responsibility.
End date	End date of responsibility.
Study P0 Number	The study P0 number in the following format: P0XXXX
Study name (short title)	The short title of the study.
Protocol version	The current protocol version.
Protocol version date	The date this version was approved.
Is the study a CTIMP?	CTIMP: Clinical Trial of an Investigational Medicinal Product
Is the study a multisite?	Whether the study is a single site or multisite.
Data repository	The following response options are available (select one): OpenClinica, Formic, Excel, PostgreSQL, Other
Specify	If Other is selected as a data repository, please specify exactly what will be used.
Data gathering method	The following response options are available (select all that apply): Paper CRFs followed by entry into data repository, Direct entry into data repository, Importing into data repository, Other data (e.g. Lab data)
If multiple options are selected, explain choice	If multiple options are selected the reasoning should be provided.
Specify	If Other data (e.g. Lab data) is selected, the data gathering method should be specified.

Appendix 2 - DMP Prior to going live

Item	Guidance
How will user access be controlled?	How user access will be controlled for the data repository. If OpenClinica is the data repository this field will be auto-populated.
How will user access be recorded?	The following response options are available (select one): FRM052 Database Access, Other
Specify	FRM052 Database Access is the standard way of recording user access if not being used the alternative method should be specified.

What data entry guidelines will be provided to users?	The following response options are available (select all that apply): Generic guidelines for data repository, Study specific guidelines
Are users required to enter test data?	Record whether users are required to enter test data prior to being given access to the live site.
Specify	If users are required to enter test data, record details of what will be required to be entered.
What has the data timeline been agreed to?	The following response options are available (select all that apply): Instant (direct entry), 1 week after data is captured, 2 weeks after data is captured, 3+ weeks after data is captured
Provide reason for data entry timeline	If the timeline is 3+ weeks after data is captured a reason should be provided.
Is the study blinded?	Record whether the study is blinded.
Specify who will be blinded and how this will be controlled	If the study is blinded, specify the level and how this will be controlled.
Has a DVP been completed?	Record whether a data validation plan (DVP) has been completed.
Explain choice	If a DVP has not been completed a reason should be provided.
Validation methods	The following response options are available (select all that apply): Double entry, On entry validation, AECs.
Type of UAT	Record the type of UAT being completed.
Explain choice	If a fast track UAT is selected, a reason should be provided.
How are data queries being handled?	The following options are available (select one): OpenClinica, Paper
Please explain why data queries are not being handled in OpenClinica	If OpenClinica is the data repository and data queries are not being handled within OpenClinica, a reason for this should be provided.
Will any fields be coded?	Record whether any fields will be coded.
Coding plan (which terms will be coded, which dictionaries will be used)	If fields are being coded, the coding plan (which terms will be coded, which dictionaries will be used) should be detailed.
Coding review (undertaken by and frequency)	If fields are being coded, the plan coding for coding review (undertaken by whom and frequency) should be detailed.
How are AEs and SAEs being reported?	Record how AEs and SAEs are being reported.
Please explain why AEs and SAEs are not being reported in OpenClinica	If OpenClinica is the data repository and SAEs are not being reported within OpenClinica, a reason for this should be provided.

Appendix 3 - DMP Prior to locking

Item	**Guidance**
How are PI signatures being recorded?	The following options are available (select one): OpenClinica, Paper
Is an interim lock required?	Record whether an interim lock is required.

Requirements for interim lock	The following response options are available (select all that apply): Case Report Form (CRF) completion review, Data query review, Automatic edit check (AEC) review, Source data verification (SDV) review, Serious adverse event (SAE) reconciliation, Coding, PI Signature, Authorisation to lock obtained from all parties, Discrepancy Note
Requirements for hard lock (the following is always required for a hard lock: Source data verification (SDV) review, PI Signature, Authorisation to lock obtained from all parties)	The following response options are available (select all that apply): Case Report Form (CRF) completion review, Automatic edit check (AEC) review, Serious adverse event (SAE) reconciliation, Coding
Is SAE reconciliation required?	Record whether SAE reconciliation is required.
SAE reconciliation plan	If SAE reconciliation is required, detail the plan.