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. It is the responsibility of the Data Management Lead, with an overview by the Clinical Project Manager.

The DMP is divided into three sections: ***prior to build start***, ***prior to going live***, ***prior to locking***. The relevant section of the DMP should be approved by the Clinical Project Manager and /or the Chief Investigator (CI) prior to starting on the work it describes.

The DMP should be kept current by the data management lead, and all responsible parties should be aware of, and agree to, the current content.

The ***DMP prior to build start*** should be signed by the Clinical Project Manager and/or the CI and the ***DMP prior to going live*** and ***prior to locking*** should be signed off by the CI. Any major changes to the DMP after this time point (e.g. coding of variables, changes to importing data) for CTIMP and Interventional Studies should be approved by the CI and minor changes (for example administrative changes) can be approved by the study's Clinical Project Manager. If the Clinical Project Manager deems it necessary, they should escalate any amendments for approval by the CI. For all other study types, the Clinical Project Manager can approve all parts of the DMP but can escalate any amendments for approval by the CI.

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

The DMP FRM046 is currently stored within eForms on OpenClinica, and each section is a separate eCRF. This allows for the updating of the DMP throughout the trial. The DMP should be checked by the Data Management Lead for completeness and marked complete at the end of the trial.

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

1. ***Prior to build start***
    a. Roles: this allows the full history of responsibilities to be retained.
        i. Role - the following responsibilities should be recorded: Data Management Lead, Chief Investigator, Clinical Data Lead, and Clinical Project Manager.
        ii. Name - the individual responsible for said role.
        iii. Start date - start date of responsibility.
        iv. End date - end date of responsibility.
    b. Study details: the basic study details should be documented; these are not expected to change throughout the study.
        i. Study P0 Number - the study P0 number in the following format: P0XXXX
        ii. Study name (short title) - the short title of the study.

iii. Current protocol version - the current protocol version when the build was started. This should only be updated if the protocol was updated before the trial goes live.
iv. Current protocol version date - the date this version was approved.
v. Study type - the following response options are available: CTIMP, Device Study, Interventional, Observational.
vi. Is this a multi-centre study? – Yes/No, (e.g. whether the study is a single centre or multi-centre).

c. Data: this section documents the chosen data repository and how the data is going to be collected.
    i. Data repository - the following response options are available (select all that apply): OpenClinica, REDCap, SharePoint, Excel, PostgreSQL, Other.
    ii. If multiple options are selected, explain choice.
    iii. Specify - if Other is selected as a data repository, please specify exactly what will be used.
    iv. Data gathering options - 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).
    v. If multiple options are selected, explain choice - if multiple options are selected the reasoning should be provided.
    vi. Specify -If Other data (e.g. Lab data) is selected, the data gathering method should be specified.
d. Security *: this section documents how security is maintained (the measures that are used to block unauthorised access to data from outside the unit).
    i. Summarise how security is maintained - how security is maintained (this refers to the measures that are used to block unauthorised access to data from outside the unit).
e. Backups *: this section documents the procedures in place that ensure the data is adequately backed up (how, how frequently and by whom the backups will be undertaken). This may be an automatic or manual process.
    i. How will data backups be undertaken? - how is the data being backed up?
    ii. How frequently will data backups be undertaken? - how often is the data being backed up?
    iii. Who will undertake backups? - who will do the backups?
f. Audit trail *: this section documents how the audit trail will be recorded (e.g. which system will keep a record of any changes that have been made to the data repository). This could be the inbuilt audit trial as in OpenClinica, a manual one or none at all.
    i. How will an audit trail be recorded? - document how and where the audit trail will be recorded, if at all.
g. Version control *: this section documents the procedures in place for version control. This is how different versions of the CRFs will be managed.
    i. How will version control be undertaken? - how will the CRF versions be managed, and how will each version be saved?

h. User access: this section documents how the user access will be controlled. This will show who will give access to the system with the data.
    i. How will user access be controlled? - how will each user access the data, and who will control this?

2. Prior to going live

a. User access: this section documents how user access is recorded for the study.
    i. How will user access be recorded? - the following response options are available (select one): FRM052 Database Access, Other.
    ii. Specify - FRM052 Database Access is the standard way of recording user access, if this is not being used the alternative method should be specified.
b. Data entry guidelines: this section documents which data entry guidelines are provided to the users.
    i. 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.
    ii. 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.
    iii. Specify - if users are required to enter test data, record details of what will be required to be entered.
c. Data timeline: this section documents the data entry timeline that have been agreed.
    i. 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.
    ii. Provide reason for data entry timeline - if the timeline is 3+ weeks after data is captured a reason should be provided.
d. Blinding: if the study is blinded, a list of who is blinded / unblinded is detailed in FRM042 Project Management Responsibilities Log which can be found in the electronic sponsor folder.
    i. Is the study blinded? - record whether the study is blinded.
    ii. 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.
e. Validations: this section details the data validation specification (DVS) completion, UAT and query management.
    i. Has a DVS been completed? - record whether a data validation specification (DVS) has been completed.
    ii. Explain choice - if a DVS has not been completed a reason should be provided.
    iii. Validation methods - the following response options are available (select all that apply): On entry validation, AECs.
    iv. Type of UAT - record the type of UAT being completed. The following response options are available (select one): Fast track, Full.
    v. Explain choice - if a fast track UAT is selected, a reason should be provided.

vi. How are data queries being handled? - the following options are available (select one): OpenClinica, Within Data Repository, Paper.
vii. Please explain why data queries are being handled on paper - if the data queries are being handled on paper, a reason for this should be provided.

f. Coding: this section documents any fields that will be coded.
   i. Will any fields be coded? - record whether any fields will be coded.
   ii. Version Number – record the version number(s) of coding systems being used. E.g. MedDRA 27.0.
   iii. 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.
   iv. Coding review (undertaken by and frequency) - if fields are being coded, the plan for coding review (undertaken by whom and frequency) should be detailed.

g. Reporting: this section is how AE/SAE will be recorded.
   i. How are AEs being reported? - record how AEs are being reported. The following response options are available (select one): OpenClinica, within Data Repository*, Paper, N/A.
   ii. *Approval required from Clinical Project Manager (CPM) and Senior Clinical Trial Data Manager before AEs/SAEs can be recorded within a Data Repository other than OpenClinica.
   iii. How are SAEs being reported? – record how SAEs are being reported. The following response options are available (select one): OpenClinica, within Data Repository*, Paper, N/A.
   iv. *Approval required from Clinical Project Manager (CPM) and Senior Clinical Trial Data Manager before AEs/SAEs can be recorded within a Data Repository other than OpenClinica.
   v. 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.

   NB: Where the method of reporting refers to paper, this can be physical paper and also Docusign.

3. Prior to locking

a. PI signatures: this section documents how PI (Principal Investigator) signatures are being recorded.
   i. How are PI signatures being recorded? - the following options are available (select one): OpenClinica, Data Repository, Paper or file note.
   ii. If not using OpenClinica. A reason should be provided.

b. Database lock: this section covers requirement for any interim lock and database lock.
   i. Is an interim lock required? - record whether an interim lock is required.
   ii. 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.

iii. 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.

c. SAE reconciliation: this section documents if SAE reconciliation is required.
   i. Is SAE reconciliation required? - record whether SAE reconciliation is required.
   ii. SAE reconciliation plan - if SAE reconciliation is required, detail the plan.

   NB: Where the method of reporting refers to paper, this can be physical paper and also Docusign.

d. Lock Log: This section logs the dates and types of locks for the study. This is so there is one place of reference for these dates. These are not considered revisions to the DMP, and therefore any changes to this log do not need any signing of the revision log. This is because this information is being signed off by on forms 017, 019 and 053 (FRM017 Database Lock Form, FRM019 Database Unlock Request Form and FRM053 Interim Database Lock Form.)
   i. Date – This is the date of the database lock/unlock, for interim lock which might take multiple days to lock, this is the date the last participant/event is locked.
   ii. Lock type – Which lock was performed. The options available are Interim, Full, Full unlock. If a database is being relocked after an unlock, the Full option would be used again.
   iii. Comments – For Interim this should include which participants and events, for Full unlock this should include the reasons, for both this would probably be a summary of the details on their respective forms.