<<insert short trial name>> Data Management Plan

**<<insert trial full title>>**

**Trial Identifier: << >>**

**EudraCT no: << >>**

**Version Number: 0.0 (DRAFT)**

**Author: <<insert name>>, Data Manager**

**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_**

**Approver: <<insert name>>, Trial Manager**

**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_**

**Approver: <<insert name>>, Trial Statistician**

**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_**

**Approver: <<insert name>>, Chief Investigator**

**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |
| --- | --- |
| **Version** | **Description of Changes** |
|  |  |

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# Scope

This document sets out the Data Management Plan (DMP) for the <<trial short name>> trial. The purpose of the DMP is twofold:

1. To outline and detail all data management processes used in the trial
2. To summarise the key data management milestones

The Data Manager (DM) is responsible for the implementation of the DMP. The DM will lead and co-ordinate the activities described here. This document is a working document and will need to be continuously updated throughout the trial, for example to reflect Data Monitoring Committee (DMC) recommendations. This DMP provides study specific requirements in validating and checking data integrity for electronic data submitted to the trial database.

***Abbreviations***

|  |  |
| --- | --- |
| CI | Chief Investigator |
| CDMS | Clinical Data Management System |
| CRFs | Case Report Forms |
| CTIMP | Clinical Trial of an Investigational Medicinal Product |
| DM | Data Manager |
| DSMB | Data Safety Monitoring Board |
| DMP | Data Management Plan |
| eCRF | Electronic Case Report Form |
| MTP | Move to Production |
| pCRF | Paper Case Report Form |
| SAP | Statistical Analysis Plan |
| STU | Swansea Trials Unit |
| TM | Trial Manager/Trial Co-ordinator/Project Manager |
| TMF | Trial Master File |
| TMG | Trial Management Group |

# Study overview

This section contains a summary of key trial information particularly with respect to data management activities (Table 1) and also includes the study primary and secondary aims and visit schedule.

**Table 1: Trial information**

|  |  |
| --- | --- |
| **Type of trial** | <<CTIMP/non CTIMP>> |
| **Phase of trial (if applicable)** | << >> |
| **Blinded** | <<Yes/No>> |
| **Level of blinding (if applicable)** | <<Single/Double>> |
| **Blinded personnel roles (if applicable)** | <<patient/investigator/pharmacist/trial manager/data manager/trial statistician>> |
| **Randomised** | <<Yes/No>> |
| **Type of randomisation** | <<Web /Automated telephone/Manual telephone>> |
| **In-house randomisation?** | <<Yes/No>> |
| **Name of CDMS** | <<MACRO4/REDCap/other>> |
| **Number of patients** | <<>> |
| **Data collection tools** | Eg. Paper CRFs remotely entered on to database |
| **Number of proposed sites** | <<>> |
| **Recruitment period** | <<MMM-YYYY to MMM-YYYY>> |
| **Follow up period** | <<>> |
| **Treatment duration** | <<>> |
| **Study duration** | <<>> |
| **# Interim analyses** | <<e.g. how many interim analyses are planned>> |
| **Data for interim analyses** | <<Clean /Dirty>> |
| **Frequency of TMG meetings** | <<>> |
| **Frequency of DMC meetings** | <<>> |

***Primary Aim: <<>>***

***Secondary Aim(s): <<>>***

***Tertiary Aim(s): <<>>***

***Exploratory Aim(s): <<>>***

***Visit Schedule: <<>>***

# Data management study milestones

This section contains key study milestones essential to data management. Table 2 shows dates for when key milestones should be, and have been reached, and can help to organise day to day data management activities in order to relate them to the planned deadlines.

**Table 2: Data management study milestones**

| **Activity** | **Planned date** | **Achieved date** |
| --- | --- | --- |
| Final protocol approved |  |  |
| Final CRF approved |  |  |
| Database Specification Document approved |  |  |
| Study database testing |  |  |
| Study database move to production |  |  |
| First site open |  |  |
| Interim analyses 1 *(add additional rows for 2nd, 3rd analyses)* |  |  |
| DSMB 1st meeting *(add additional rows for 2nd, 3rd meetings)* |  |  |
| Last patient's last visit |  |  |
| Database locked |  |  |
| Final clinical study report (CSR) due |  |  |

# Study Documents

The project specific documents detailed in Table 3, should be read in conjunction with the DMP.

**Table 3: Study Specific Documents**

| **Document** | **Storage Location** |
| --- | --- |
| Protocol | <<specify location>> |
| CRFs | <<specify location>> |
| Data Entry Instructions (DEI) | <<specify location>> |
| CRF Completion Guidelines (CCGs) | <<specify location>> |
| Study database specification | <<specify location>> |
| Randomisation Specification/Instructions | <<specify location>> |
| Site contact list | <<specify location>> |
| DSMB Charter | <<specify location>> |
| Statistical Analysis Plan | <<specify location>> |
| Monitoring Plan | <<specify location>> |
| Risk Assessment | <<specify location>> |
| Vendor Contracts | <<specify location>> |

# Study contacts

This section contains contact details of key study contacts.

**Table 4: Study contacts**

| **Role** | **Contact Information** |
| --- | --- |
| **Sponsor:** | **Name:** |
|  | **Email:** |
|  | **Phone:** |
|  | **Location:** |
| **CI:** | **Name:** |
|  | **Email:** |
|  | **Phone:** |
|  | **Location:** |
| **Trial Co-ordinator/Trial Manager:** | **Name:** |
|  | **Email:** |
|  | **Phone:** |
|  | **Location:** |
| **Trial Statistician:** | **Name:** |
|  | **Email:** |
|  | **Phone:** |
|  | **Location:** |
| **Data Manager:** | **Name:** |
|  | **Email:** |
|  | **Phone:** |
|  | **Location:** |
| **IT Manager:** | **Name:** |
|  | **Email :** |
|  | **Phone:** |
|  | **Location:** |
| **QA Representative:** | **Name:** |
|  | **Email:** |
|  | **Phone:** |
|  | **Location:** |

# Data Entry

Data entry must be performed according to the specific data entry guidelines for the study. The DM is responsible for compiling a study specific CRF completion guideline (see STU AD039).

## QC of data entry

Double data entry is a process that allows the quality of the data to be monitored. This is not the preferred method of data entry within STU but it may be used in some studies. Two individuals should carry out data entry independently of each other and then the two datasets are compared.

Visual checks may be performed by a second person to confirm that what is recorded on the paper CRF matches what has been entered to the database. This is not possible where data is entered remotely.

Where data is entered remotely the monitoring plan will be followed.

## Amendments to Data

Amendments to data recorded on CRFs and eCRFs should always be handled at the local site. DMs, IT Managers and Trial Management personnel must not amend data themselves. The database will contain an audit trail which will document the previous value and the current value along with the date and reason why changed. Corrections to the paper CRFs should be performed in accordance with guidelines in STU-AD039, CRF Completion Guidelines.

## Self-Evident Correction

A list of self-evident corrections to be kept for each study. This will allow data to be corrected where a data correction is self-evident. The type of self-evident correction will differ for whether data entry is completed in-house or data entry is completed remotely. <<to be provided as a separate document to site if appropriate>>

|  |  |
| --- | --- |
| ID | Self-Evident Correction |
| 01 | Patient has entered the year of questionnaire as the previous year as the year has recently changed. |
|  |  |
|  |  |
|  |  |

## Data Entry Training

All person(s) entering data must be appropriately trained on the data entry system and delegated that duty on the delegation log. For site data entry personnel, training will be included in the Site Initiation Visit (SIV) and subsequently as required when a new member staff is assigned to the study.

The table below lists the personnel who are authorised to provide data entry training for this study.

|  |  |
| --- | --- |
| **Name** | **Role** |
|  |  |
|  |  |

# Data flow

<<insert flow chart to summarise the path of the data>>

# Data Coding

List terms coded, dictionaries used, versions, who is responsible for coding, who is responsible for medical review.

# Query Management

Data queries will be raised for data discrepancies identified during data review. This would normally be done via the CDMS. Where an issue lies with an external vendor the ‘External Data Transfer’ table will highlight the process in resolving the issue. <<if CDMS will not be used to manage data queries then please describe the process here>>

List who will be responsible for SAE, medical coding, lab, general data management queries.

# Critical variable List

List the variables that are important to the final analysis. Checks should then be made to ensure that these variables are complete as possible.

# Data review

Manual review will be conducted of the listings below as well as the programmed checks in the database as per the Study specification. *Below are suggested reports please amend as per study requirements.*

|  |  |  |
| --- | --- | --- |
| ***Listing ID*** | ***Listing name*** | ***Listing description*** |
| *001* | Triangular Review (MH) |  |
| *002* | Triangular Review (AE) |  |
| *003* | Triangular Review (CM) |  |
| *004* | Visit windows |  |
| *005* | Lab reconciliation |  |
| *006* | SAE reconciliation |  |
| *007* | PE abnormal |  |
| *008* | IMP reconciliation |  |
| *009* | Drug accountability |  |
| *010* | MH review |  |
| *012* | AE review |  |
| *013* | CM review |  |
| *014* | Visit dates in chronological order |  |
| *015* | Withdrawal vs. visit dates |  |
| *016* | Pregnancy Outcome |  |
| *017* | Primary outcome |  |
| *018* | Secondary Outcome |  |
| *019* | Missing data |  |

# Study Metrics reporting

*These are reports to trial oversight groups (e.g. TMG, DMC) which help monitor the health of the study and check for data completeness. Below are suggested reports please amend as per study requirements.*

|  |  |  |
| --- | --- | --- |
| ***Name of report*** | ***Reporting group*** | ***Report description*** |
| Baseline characteristics | DMC |  |
| Eligibility report | DMC /TMG |  |
| Recruitment Report | DMC /TMG/Trial team |  |
| DCF Report (open, responded, and closed) | DMC /TMG/Trial team/Site (specific) |  |
| CRF completion rates | DMC /TMG |  |
| Missing Forms/data | DMC /TMG/Trial team/Site (specific) |  |
| Scheduling Report | *Site(s)* |  |
| Questionnaire Compliance Report | DMC /TMG/Trial team |  |
| Withdrawal/Deaths | DMC /TMG/Trial team |  |
| Outcome | DMC /TMG/Trial team |  |
| SAE report | DMC /TMG/Trial team |  |
| AE report | DMC /TMG/Trial team |  |
| Protocol Deviations | DMC /TMG/Trial team |  |

# Data cleaning strategy

*This section provides the data cleaning strategy for the study. There are two data cleaning methods a. per patient b. by subset. The latter is the preferred method and this section should state the number of participants per subset and the time points in which subsets will be cleaned. The strategy should also take account of any DMC reporting and interim analyses.*

*Clean Database is defined as below -*

* *All data entered*
* *Data review complete*
* *Coding complete (including medical review)*
* *SAE reconciliation complete (including medical review)*
* *SDV complete (where applicable)*
* *Labs reconciled*
* *All queries resolved*
* *Data frozen*

# Central Statistical Monitoring

The purpose of central statistical monitoring is to reduce 100% source data verification and to be able to identify sites for on-site monitoring by using techniques such as distribution comparisons, identification of outliers and looking at the variability of data within and across sites which may be able to identify fraud.

Is Central Statistical Monitoring required for this study?

Choose an item.

Please remove table is no central statistical monitoring is required.

|  |  |
| --- | --- |
| ID | Central Statistical Monitoring Check |
|  |  |
|  |  |
|  |  |
|  |  |

# Data Export

List data that requires blinding

List the variables for the export if a full export is not required. List multiple exports if required.

List the analyses time points and highlight whether clean or dirty data is required

# Security

List method of secure data transfer

# Patient identifiable data

List patient identifiable data fields.

# User Access Control

Access to the CDMS is role based and this will be documented in the study delegation log.

# Data Transfer

The table below lists the data that is going to be transferred to STU for analysis.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **1** | **2** | **3** | **4** | **5** | **6** | **7** |
| **1** | **Data sharing agreements in place?**  **Y/N**  **Date of agreement** | **Vendor type e.g. ECG, central lab, IVRS.** | **Vendor data details** | **Vendor contact for transfers and query resolution** | **Fields to be included on data transfer (as per contract)** | **Fields to be reconciled with the CDMS** | **Frequency of transfer**  **(When would labs be transferring their findings back to study team, e.g. end of trial / key stages?)** | **Process to query discrepancies between database and vendor data transfers** |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |