**DATA MANAGEMENT PLAN**

|  |  |
| --- | --- |
| **Protocol Title:** |  |
| **Sponsor Number:** |    |
| **REC Reference:** |  |
| **Trial / Data Manager:** |  |
| **Version / Date:** |   |

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** |   |   |   |
| **Chief Investigator** | Signature:  |   | Date:  |
| **Name** |   |   |   |
| **Trial Statistician** | Signature:  |   | Date:  |
| **Name** |   |   |   |
| **Lead Clinical Trials Monitor** | Signature:  |   | Date:  |

|  |  |  |
| --- | --- | --- |
| **Version** | **Date** | **Summary of Revisions** |
| 1.0 | DD-MMM-YYYY | Initial creation |
|   |   |  |

*Sections should be adapted with trial specific details*. *Sections may be added or removed depending on the complexity of the trial. External data management vendors should use their own template documents as per their own SOPs.*

*Highlighted text should be replaced with trial-specific details.*

*Guidance text is included as a prompt and should be removed once appropriate text has been entered.*

# Contents

# List of Abbreviations

# Purpose

## The purpose of this Data Management Plan (DMP) is to define and provide instructions regarding the conduct of data management processes and the flow of data from source data to data release for the [enter study name].

## Updates to this document will be maintained throughout the life of the trial to reflect any changes in data management procedures.

# Scope

## This DMP applies to study personnel and roles involved with decision making, data collection and data handling.

# Study Overview

[Please provide a summary of the trial design and objectives, including critical data items (for example key information that is essential for the successful analysis of the primary and secondary endpoints and any variable the trial statistician feels is essential to the quality of the data). Please also include an indication of proposed study timelines, section below to be adapted per trial. This section can be copied from the study protocol.]

The proposed study timeline is mentioned below; however please note this may change over the course of the study.

|  |  |
| --- | --- |
| **Milestone** | **Timelines** |
| CRF Design Finalised |  |
| Database Validated  |  |
| Database Live  |  |
| First Data-in  |  |
| Final Database Clean |  |
| Interim Analysis  |  |
| Database Lock  |  |
| Analysis Start  |  |
| Analysis End  |  |

# Roles and Responsibilities

[Please provide a brief description of roles and responsibilities by key study personnel. Add/remove suggested roles below as applicable to the study].

## The CI or delegate is responsible for the creation and maintenance of the Data Management Plan (DMP) during the trial. The CI or delegate will ensure a DMP is in place before data collection begins.

The team members for this study are listed below:

|  |  |  |
| --- | --- | --- |
| **Role**  | **Person**  | **Email**  |
| Chief Investigator  |   |   |
| Trial Statistician  |   |   |
| Unblinded Statistician  |   |   |
| Trial Manager  |   |   |
| Data Manager  |   |   |
| Database Programmer / Analyst |  |  |
| Study Monitor  |   |   |
| Sponsor Representative |  |  |

The table below describes data management activities and responsible person for each task.

[Please update the below table with the responsible person marked as an X as appropriate]

| **Task** | **CI or delegate (e.g. TM)** | **Data Manager** | **Database Programmer** | **Site Research team** | **Statistician** | **Sponsor** | **[eCRF provider, if applicable] (3rd Party)** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| CRF Design  |  |  |  |  |  |  |  |
| Database Specification, Build & UAT  |  |  |  |  |  |  |  |
| Database Validation |  |  |  |  |  |  |  |
| Data Entry |  |  |  |  |  |  |  |
| Data Cleaning |  |  |  |  |  |  |  |
| Database Lock |  |  |  |  |  |  |  |
| Data Release |  |  |  |  |  |  |  |
| Data Analysis  |  |  |  |  |  |  |  |
| Data Archiving |  |  |  |  |  |  |  |

# CRF Design and Implementation

## The CRF design will incorporate all specifications required by the study protocol.

## CRF design is the responsibility of the CI. Input will be sought from other members of the research team including but not limited to the person responsible for the final statistical analysis.

## A paper / electronic CRF will be developed by [please state responsible person].

## Final approval of the CRF is granted by the CI and Sponsor, as per ACCORD SOP CR013.  Review of the CRF will be completed prior to final database validation.

## Amendments to the CRF will follow process defined in ACCORD SOP CR013. Changes to the dataset will be reviewed and approved by the CI and Trial Statistician. Minor administrative changes (e.g. spelling, formatting) do not require formal approval by the Trial Statistician and CI. All changes will be approved by the Sponsor prior to release.

## The final CRF will be available before the first patient is enrolled into the study.

# Database Setup and Validation

## The database contains all information taken from CRFs. In the case of an eCRF the database may be the same system. The database specification will be written after the protocol and CRF have been finalised.

## The software model selected for the eCRF and data entry processes for the [enter study title]study is [enter name of electronic data capture system (EDC)].

[Describe the EDC system proposed for use in this study, including its supplier, software version number or other identifying information and validation status.

Identify ancillary software packages associated with the EDC, such as underlying database software, statistical analysis software or other software used in the management of the trial data (e.g.: excel).

Describe any relationship to the server(s) used to house data (trial, statistical or otherwise) used by the project team. For example, is there an office Dropbox, OneDrive, Shared Drive or MS Sharepoint that is being used to store any trial data?

[Please also detail the back-up and recovery procedures. Provide details on which server the data is located, where the server is located, timelines for back-ups and disaster recovery plan including testing of the disaster recovery plan.]

## System edit checks (e.g. checking the data for elements such as logical consistency, missing, incorrect or implausible data) will be specified and built into the database where possible. These data validation rules will be configured by [enter responsible person] under approval of the CI, or designee.

## [Please list all computerised and manual data checks that will be carried out for the study and at what point. As a minimum, checks will be completed on all datapoints contributing to endpoint or safety data. If this is not yet known, please specify details in an associated database validation plan.]

## The validation of the eCRF will be done in compliance with ACCORD Policy POL007 (Computer System Validation). [Provide details of who will be responsible for validation of system setup]. Users will be given access to the database in the development environment for training and UAT purposes. The [state responsible person] will test data entry screens to ensure that data can be entered as efficiently as possible. Data validation rules will be checked by entering clean and erroneous test data. Each study specific feature will be tested with results being documented on a Test log.

## Once all stages of database development and UAT is documented and complete, the Sponsor will provide formal approval following processes defined in POL011 (Data Management). Any areas of non-compliance noted by the Sponsor during this review will be resolved before the computer system can go live and be used by the trial team.

## If any modifications are made to the database during its lifecycle these will be tested, re-validated and approved by the CI and Sponsor prior to implementation.

## Once all system testing has been carried out and approved by the Sponsor, the system will be released for use in the study by [state responsible person].

# Data entry

## Data entry of the CRF is the responsibility of the trial site staff. The delegation log outlines a list of individuals authorised for data entry and verification of CRF entries against source data. All trial site staff responsible for CRF completion will be trained appropriately.

[Please provide detailed information of data entry processes (e.g. types of data collected, how this data is generated, methods / tools used to capture and record data for the study) or if this information is captured in the source data plan, please reference.

Further include timelines for data entry and detail here if trial specific CRF completion guidelines are to be generated by the CI, or designee. These are recommended where the study is multicentre to facilitate consistency of data entry across sites or where the data collected is particularly complex].

# System user access

## Each user will be trained on the EDC system prior to being granted permission to access the live EDC system. A training log will be maintained by [state responsible person].

## All users require an account to allow them to access to the study database. Database access will be restricted to members of the research team that have been authorised and fully trained, and that have been assigned personal usernames and passwords. The [please state responsible person]will be notified of new user requests and these are forwarded to [please state responsible person]for action. Each user will have different level of access privileges to the study’s database depending on their role.

## To protect the security of data in the database, user accounts are issued for site staff only if the following documents are available:

## CV of the trial staff member

## Evidence of trial-specific training (e.g. attendance at the site initiation meeting or documentation of training conducted after the site initiation meeting).

## A signed Delegation log of the trial staff member.

## The exception to this is read-only/query/monitoring access which should be granted to the Monitor / Auditor at the beginning of the study.

## Site PIs will be instructed to contact [please state responsible person] if user details change or to remove access when site staff are no longer working on the study. The [please state responsible person] will review the user list periodically [please state timeframe] and liaise with PIs to remove user access where appropriate.

## An overview of the user roles and their associated access rights are described below.

## [Please add table specifying task (e.g. add participant, edit data, open / close data query, data export, view data etc.) and role (e.g. PI, Monitor, Trial Manager, Administrator, Site Staff etc.).

# Data Quality

# [Please describe the process for generating and resolving data queries including timelines for sending / answering queries and process for how unresolved queries are managed for example outline the query escalation process in a flowchart. If this process is defined in supporting documentation, please reference the appropriate documentation.]

## Inconsistencies in the trial data will be investigated using data queries that prompt the central trial team to clarify or confirm discrepant items.

## Automated data queries are raised in response to pre-defined data validation checks built into the database (see section 6.3). These are generated immediately after an eCRF page is saved as complete. Subject data that violates a validation rule will automatically trigger an edit check which is instantly visible to the user in the eCRF. Queries can be answered immediately by [state responsible person], or the subject data will either need to be corrected or missing information entered. Query reports will be shared with the PI for oversight.

## The Clinical Trials Monitor, or designee, will systematically check incoming trial data for consistency, omissions and compliance with the protocol and according to the Monitoring Plan. The study specific Monitoring Plan and Source Data Verification (SDV) Plan describe the monitoring and SDV activity in detail.  Manual queries can be raised on review of the data by [please specify delegated roles].

## The trial site staff will answer the queriesraised automatically or by [please specify delegated roles] and update the eCRF data when appropriate; submitting responses through the eCRF. The full audit trail will be available in the database.

## The [please specify responsible person] will be responsible for closing data queries that have been answered on the eCRF.

## Study data will be quality control (QC) checked by [please state responsible person].

## [Please further define the percentage of QC checking to be performed, the data points to be QC checked, the process for resolving QC queries and the acceptable error rate threshold. If this process is defined in supporting documentation, please reference the appropriate documentation].

## Data cleaning is an ongoing process throughout the lifecycle of the trial and will be finalised prior to final database lock at the end of the study (see section 12) or prior to any planned interim analyses [please state if applicable and timelines].

# Data Reconciliation

## The [please state responsible person] will request a line listing of SAEs and SARs from the ACCORD Pharmacovigilance Manager and reconcile this against the eCRF/database. Any inconsistencies will be flagged and investigated with the PV Manager.

## The [please state responsible person] will request line listings of study non-compliances (i.e. deviations/violations) from the ACCORD QA Coordinator for reconciliation and inclusion in final analysis. Any inconsistencies will be flagged and investigated with the QA Coordinator. A copy of the final protocol deviation / violation logs will be provided to the Trial Statistician for inclusion in analysis.

## Reconciliation of safety data and non-compliances will occur prior to [state whether there is a planned interim analysis or provision of data to the DMC/TSC] and prior to database lock.

# Medical Coding

[Please complete details of any medical coding (e.g. MedDRA) that will be performed for the study. List which coding will be performed, who will code the data, what coding system is used (if appropriate) and when the coding should be performed]

# Database Lock

## When the CI or designee, declare the database clean; the [please state responsible person] will be informed to lock the database and remove access rights to the database.

##

## The Database will be locked upon successful completion of the following:

* All clinical trial subjects have completed their final visit and any follow-up visit activities.
* All expected data has been received, entered, processed and validated for completeness and consistency.
* All coding of clinical events has been completed.

All expected eCRF data is SDV’d by the Clinical Trials Monitor, or designee as detailed in the Monitoring Plan.

All site close out visits are complete and data related actions addressed.

All outstanding queries are resolved, and the database has been updated.

All QC checks have been performed and issues resolved.

Final reconciliation of safety data and non-compliances has been completed.

All updates to the database have been completed.

All members of the trial team have been notified of the date of lock.

[Please specify if an interim analysis is planned, the process and responsibilities for a temporary database freeze to allow data extraction for a limited time].

### Unlocking of a locked database should be limited to important corrections (those that will have a significant impact on the reliability of the results e.g. missing data relating to the primary endpoint) and will be avoided where possible. Where there is a requirement to unlock the database, the CI, or designee, will provide written justification for the request to the Sponsor and Trial Statistician, including consideration of impact on statistical outcome. The Sponsor will provide written approval if appropriate.

## The [please state responsible person] is authorised to unlock the database and grant access rights to the database to the dedicated personnel responsible for updating of the database only.

## The CI or designee (e.g. dedicated personnel not responsible for updating of the database)will perform a documented final QC check to ensure that only the approved updating of the database was performed and a check of the audit trail will be made at re-locking.

## All details of any changes made to the locked database will be documented in the TMF and Clinical Study Report. [Please add details of how this process will be documented e.g. Database Lock/Unlock Approval form]

# Data Release

## [Please describe the process for releasing data to the Trial Statistician including any unblinding implications. If this process is defined in supporting documentation e.g. Statistical Analysis Plan, please reference the appropriate documentation].

## The statistician has read-only access to the eCRF system, and performs blinded data extractions during the study, to prepare and develop the analyses and reporting programs. Files are downloaded directly from the EDC system and contain blinded data in .csv or excel format [Please amend section as appropriate].

## Following a data release request from the CI, or designee to the [please state responsible person], all agreed data will be extracted and sent to the Trial Statistician. The report will be provided in an encrypted form (with passwords sent separately). The Trial Statistician will confirm receipt of the files.

[Please further detail if there are any pre-defined data transfers required for the study including description, responsible person producing / distributing report, methods to maintain participant data confidentiality, frequency, and recipient. If any ad hoc data requests are received by the CI, then guidance should be sought from the Sponsor. Please further detail how site specific patient data will be shared with PIs].

# Data Archiving

## All study data will be stored and archived according to the trial protocol and Sponsor SOPs.

## [Please further specify location of data archive including back-up, how access is restricted, whether external electronic storage media will be used with considerations for future-proofing, and archiving timelines].

[The site Principal Investigator (PI) must maintain a complete and independent copy of the data collected for their site participants. Where data will be collected centrally (e.g. patient reported outcomes sent directly to the trial management office/database by questionnaire or text message) a process must be in place to ensure PIs have access to this data for participants at their site during the course of the trial and a copy of this data is provided to the PI for archiving at the end of the trial. Please describe process here].

# Relevant SOPs / Guidelines

[Please detail here associated trial documents and SOPs to be followed.