**Clinical data management plan – Template**

**Version 1.0**

**About EDCTP**

The [European & Developing Countries Clinical Trials Partnership (EDCTP)](https://www.edctp.org/) is a public– public partnership between 14 European and 16 African countries, supported by the European Union.

EDCTP’s vision is to reduce the individual, social and economic burden of poverty-related infectious diseases affecting sub-Saharan Africa.

EDCTP’s mission is to accelerate the development of new or improved medicinal products for the identification, treatment and prevention of infectious diseases, including emerging and re-emerging diseases, through pre- and post-registration clinical studies, with emphasis on phase II and III clinical trials. Our approach integrates conduct of research with development of African clinical research capacity and networking.

**About TBVI**

The [Tuberculosis Vaccine Initiative (TBVI)](https://www.tbvi.eu/) aims to support, integrate, translate, and prioritise R&D efforts to discover and develop new TB vaccines that are accessible and affordable for all. In an effort to optimise the discovery and development of new TB vaccines and biomarkers, TBVI facilitates and supports the generation of new knowledge and exchange among R&D partners. TBVI creates an enabling environment for consortium members to promote knowledge sharing through scientific meetings and workshops, publication in scientific and non-scientific journals, formal and informal networking.

This document was developed by TBVI, in collaboration with Patrick O’Meara and Richard Liwsky (C-Path), as one of the deliverables of the project ‘Development of tools and documents to support coordination of EDCTP TB-vaccine funded research’, which is part of the EDCTP programme support by the European Union. The document reflects the views of the authors. The European Union is not liable for any use that may be made of the information contained herein.

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For more information about this document, please contact the EDCTP Secretariat at info@edctp.org.

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Document approval

Authored by:

|  |  |
| --- | --- |
| Signature |  |
| Date | <dd-MMM-yyyy> |
| Print Name /Role | *<insert name / Role>* |
| Organisation | *<insert organisation name>* |

 Approved by:

|  |  |
| --- | --- |
| Signature |  |
| Date | <dd-MMM-yyyy> |
| Print Name /Role | *<insert name / Role>* |
| Organisation | *<insert organisation name>* |

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| --- | --- |
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# Introduction

The purpose of the Data Management Plan (DMP) is to present all key activities conducted by the data management (DM) team and the contribution of other relevant functional groups that support the DM processing activities for the *<insert study name>* study.

The initial approved version of the DMP should be made available prior to the commencement of data processing activities, and it is to be updated regularly and periodically throughout the lifecycle of the study.

The DMP will address any procedural or protocol updates that are made during the conduct of the study. At a minimum, the DMP will be reviewed and updated on a *<insert agreed frequency>* basis. Updates over the course of the study will occur whenever significant changes arise, such as (but not limited to):

* Changes in data flow and/or processes
* Significant amendments to study protocol
* Requests or requirements from other functional groups and/or sponsor

All changes to the DMP will be tracked and recorded within the revision history of this document. In the event of the DMP not requiring an update during the agreed review cycle, this will be noted within the revision history.

In the event of any deviations from the procedures described within the current effective version of the DMP, such deviations should be documented within an updated version of the DMP or as per <*refer to relevant procedure*>.

All activities described herein are conducted in accordance with all relevant regulatory requirements including ICH-GCP, GDPR and organisational Standard Operating Procedures (SOPs).

# Study protocol overview

The table below provides a summary of the <study>. The full clinical study protocol and associated materials are accessible to the study team at the following location *<insert location link>.*

|  |  |
| --- | --- |
| **Title of Study** | *<insert title>* |
| **Clinical Registry Identifier /Link** | *<insert identifier> /<insert URL Link>* |
| **Phase of Clinical Trial** | *<insert phase>* |
| **Study Drug** | *<insert study drug name, including active ingredient(s)>* |
| **Indication** | *<insert indication>* |
| **Recruitment Overview** |  **Countries:** *<insert number or list of countries participating>***Number of Sites:** *<insert number of sites>***Subject Enrolment:** *<insert number of treated subjects>* |
| **Study Objectives** | **Primary Objective:***<insert objective(s)>***Secondary Objectives:***<insert objective(s)>***Additional/Exploratory Objectives:***<insert objective(s)>* |

To date the study has had *<insert number>* protocol amendments, where applicable the table below provides a list of protocol amendments that have had a direct impact to DM activities (e.g. database design updates, new data sources etc.) including a brief summary of the impact/changes applied.

| **Protocol Version** | **Approval Date** | **Changes to DM Activities** |
| --- | --- | --- |
| *x.y* | *<dd-MMM-yyyy>* | *<provide a summary of key changes to DM activities>*   |

# Roles and responsibilities

The table below provides a summary of the tasks that the DM service are involved in and other functional group or vendors who collaborate with the DM team on a specified task/activity. In the event that the roles and responsibilities change during the course of the study, such changes will be reflected in an updated version of the DMP.

Further details regarding the scope and responsibilities of the DM team can be found in the *<specify document>* located internally at *<insert location>*.

| **Task/Activity** | **DM** | **Sponsor** | **Vendor** | **<Other>** | **<Other>** | **Additional Comments** |
| --- | --- | --- | --- | --- | --- | --- |
| *<Insert Activity>* |  |  |   |   |   |   |

# Training

All assigned members of the DM team have been trained in accordance with *<specify procedure or document>*.

Formal records of all study specific training conducted per assigned DM team member are reported in accordance to *<specify procedure or document>* and are maintained at *<specify platform or location used to maintain staff training records>* by *<specify role/group>.*

Prior to the commencement of study specific activities, the baseline training requirements per role can be found in the table below.

| **Role** | **Study Specific Training Required? (Y/N)** | **Study Specific Training Requirements** |
| --- | --- | --- |
| *<insert role>* | *<insert Y or N>* | *<specify training topics if study specific training is not required then specify reason >*   |

# Timelines

The table below represents the current and anticipated dates for the task or milestone specified. These dates may be adjusted during the course of the study due to varying factors (e.g. recruitment rate), and where applicable such dates may be modified in a subsequent version of the DMP.

***<table below provides examples; additional milestones can be added (e.g. interim locks) subject to the requirements of the study in question>***

|  |  |
| --- | --- |
| **Task/Milestone** | **Date** |
| Protocol Approval |   |
| Case Report Form (CRF) Approval |   |
| Database Go – Live |   |
| First Patient Screened |   |
| First Patient Enrolled |   |
| Last Patient Last Visit |   |
| Data Entry Complete |   |
| Last Query Out |   |
| Database Lock |   |
| Final Data Transfers |   |
| Archival Complete |   |

In addition to the tasks or milestones specified above, more detailed project plans can be found in the following locations:

* <insert Task/Milestone> : < insert location>
* <insert Task/Milestone> : < insert location>
* <insert Task/Milestone> : < insert location>

# CRF design and development

The case report form (CRF) design activities are conducted in accordance with *<specify procedure or document>*.

The design of the CRF is conducted by the *<specify role>* once the *<specify document(s)>* have been received. Where applicable, the CRF design process will utilise the *<specify library or standard>* in creating the initial draft version of the CRF.

The draft version of the CRF is subsequently shared for review to the following parties:

* <specify role>
* <specify role>
* <specify role>

All review findings/inputs are centrally reported within the *<specify document>* which is stored at *<insert location>* . Upon all findings/inputs have been appropriately addressed, the CRF version in question is formally approved by *<specify role(s)>.*

In the event of an update or amendment to the CRF, all changes are formally tracked using <*specify document>* and done in accordance with *<specify procedure or document>.*

# CDMS set-up and maintenance

## Clinical database

The *<specify platform and version>* platform is being utilised as the clinical data management system (CDMS) for this study. The set up and testing of the clinical database is done in accordance with *<specify procedure or document>.*

The design of the database commences once the *<specify document(s)>* has been finalised. Upon creation of the initial version of the database the following steps are conducted:

* <insert step>
* <insert step>
* <insert step>

The testing and review of the database is done using *<specify testing plan or equivalent*>, all database issues/findings are documented and tracked using the *<specify document>* which is centrally stored at *<insert location>.*

## Data integration

***<Please select one of the following>***

For this study there are no external sources of data integrated into the CDMS.

**<or>**

The table below provides an overview of the sources of data integrated into the CDMS, the testing of these data sources is done in accordance with *<specify procedure or document>.*

| **Data Type** | **Provider/****Vendor** | **Integration Method** | **Transfer Frequency** | **Data Integration Specification Reference** |
| --- | --- | --- | --- | --- |
| *<insert data type, e.g. IVRS, ECG, Imaging>* | *<insert data provider>* | *<e.g. Web Services, Batch Upload>* | *<insert frequency>* | *<insert document reference>* |

All data integration testing issues are centrally reported within the *<specify document>* which is stored *at <insert location>*. Once all findings have been appropriately addressed, the updated data integration specification or database specification in question is formally approved by *<specify role(s)>* when applicable. All testing outputs and reports are centrally stored at *<insert location>.*

## System edit checks

### Specification development

The system edit checks are defined within *<specify document>* which is centrally located at *<insert location>*. The edit check specification document is developed by the *<specify role(s)>* once the *<specify milestone(s)>* has been achieved.

The draft version of the edit check specification document is then subsequently shared for review to the following parties:

* <specify role>
* <specify role>
* <specify role>

All review findings/inputs are centrally reported within the *<specify document>* which is stored at *<insert location>*. Once all findings/inputs have been appropriately addressed, the edit check specification document in question is formally approved by *<specify role(s)>.*

### Programming and testing

The commencement of edit check programming starts once *<specify milestone>* has been achieved. The edit checks are tested by *<specify role(s)>* utilising the following:

* <specify document>
* <specify document>
* <specify document>

All review issues are centrally reported within the *<specify document>* which is stored *at <insert location>* . Once all findings have been appropriately addressed, the updated edit check specification in question is formally approved by *<specify role(s)>* when applicable. All testing outputs and reports are centrally stored at *<insert location>.*

## User acceptance testing

User acceptance testing (UAT) is done in accordance with *<specify procedure or document>*. The activity of UAT commences once *<specify milestone>* has been achieved. The clinical database is tested by *<specify role(s)>* utilising the following:

* <specify document>
* <specify document>
* <specify document>

All review issues are centrally reported within the *<specify document>* which is stored *at <insert location>* . All testing outputs and reports are centrally stored at *<insert location>.* The UAT is considered formally approved once *<specify role(s)> have signed the <specific document>.*

In the event of an issue(s) not being resolved as a result of time or technical constraint, but the issue being considered minor enough to not affect the release of the clinical database, such instances are formally documented with *<specify document>* at the end of the UAT process.

## CDMS go live

The formal release of the current version of the clinical database is conducted once the following milestones have been successfully achieved.

* *<specify milestone>*
* *<specify milestone>*
* *<specify milestone>*

The release of the database into production is formally documented using *<specify document>* which is signed off by *<specify role(s)>* .

## Post-production changes

### General

In the event of the clinical database requiring changes after the initial version has been released into production (e.g. as a result of protocol amendments), such changes are documented in the *<specify document>* and the activity is conducted in accordance with *<specify procedure or document>*. The development and testing activities will follow the processes as described in **Sections 7.1 – 7.4**.

### Database migration

***<Please select one of the following>***

For this CDMS platform a database migration is not required as part of the post-production change process.

***<or>***

*<Provide a description on the database testing migration procedure>*

### Database version tracking

***<Please select one of the following>***

For this study, the tracking of separate clinical database versions during the course of this study will not be required.

***<or>***

*<If the platform in question may involve having to track multiple versions of the database for different subsets of subject (e.g. protocol amendment), the process to ensure that the subject is in the correct version of the clinical database is described including the process to correct any errors>*

# Non-system validation checks/reports

In addition to the system edit checks, external reports/listings are generated to detect discrepancies which cannot be programmed within the CDMS platform itself. These data checks are defined within *<specify document>* which can be found at *<insert location>*. The development, programming and testing of these checks are done in accordance with *<specify procedure or document>.*

## Specification development

The specification document(s) for these checks are developed by the *<specify role(s)>* once the *<specify milestone(s)>* has been achieved.

The draft version of the edit check specification document is then subsequently shared for review to the following parties:

* <specify role>
* <specify role>
* <specify role>

All review findings/inputs are centrally reported within the *<specify document>* which is stored at *<insert location>*. Upon all findings/inputs have been appropriately addressed, the specification document in question is formally approved by *<specify role(s)>.*

## Programming and testing

The commencement of edit check programming starts once *<specify milestone>* has been achieved. The report/listing outputs are tested by *<specify role(s)>* utilising the following:

* <specify if Test or Production Data is being used>
* <specify document>
* <specify document>

All review issues are centrally reported within the *<specify document>* which is stored *at <insert location>* . Once all findings have been appropriately addressed, the updated edit check specification in question is formally approved by *<specify role(s)>* when applicable. All testing outputs and reports are centrally stored at *<insert location>.*

## Output review

The outputs of these checks are generated on a *<specify frequency>* basis and are reviewed by the *<specify role(s)>*. Any issues/discrepancies detected during the review will result in a *<specify query type>* being generated within the CDMS platform.

All ongoing issues/discrepancies detected during this review process is tracked via *<specify method of tracking ongoing issues>*.

# Data workflow

## CRF tracking

### Paper CRF (pCRF)

**<Please select one of the following>**

For this study there is no data collection being conducted using a paper CRF (pCRF), all data is collected electronically.

**<or>**

The pCRFs are collected from site by the *<insert role>* on a *<insert frequency>* basis and are sent to *<insert role or organisation>* for processing. All pCRF are tracked via *<specify method/system>*. Missing or overdue pages are identified by using *<specify report or method>*. An electronic copy of the pCRF is scanned and indexed via *<specify platform>* and are centrally stored at *<specify location>.*

**<NB: In the event of a hybrid CRF study, specify what data/forms are being reported on the pCRF>**

### Electronic CRF (eCRF)

**<Please select one of the following>**

For this study there is no data collection being conducted using an electronic CRF (eCRF), all data is collected on paper CRFs (pCRF).

**<or>**

The eCRFs are reported by *<insert role(s)>* using the *<insert CDMS platform>* EDC system. Users are expected to enter the data *<insert value>* days after the study visit has been conducted. Missing or overdue forms are identified and tracked using <*<specify report or method>*. A copy of the eCRF is generated and are centrally stored at *<specify location>.*

## Data entry

The completion of the CRF is conducted in accordance with the current Date Entry conventions document which is centrally located at *<specify location>,* the parties responsible for entering data are trained in accordance with *<specify procedure or document>* and are formally certified prior to the commencement of the data entry activities.

### pCRF entry

**<Please select one of the following>**

For this study there is no data collection being conducted using a paper CRF (pCRF), all data is collected electronically.

**<or>**

The pCRFs are accessed at *<specify platform/location>* by the *<specify role>* and is entered into the *<specify platform>* database.

The entry process involves a *<specify if single- or double-data entry>* entry process into the database. The quality/accuracy of pCRF data transcription into the database is verified by <describe process to ensure data is transcribed correctly, the responsible parties conducting this process and how the review is documented>.

### eCRF entry

**<Please select one of the following>**

For this study there is no data collection being conducted using an electronic CRF (eCRF), all data is collected on paper CRFs (pCRF).

**<or>**

The eCRFs are reported by *<insert role(s)>* using the *<specify platform>* EDC platform. To ensure completeness and accuracy of entry, the study site monitor/CRA reviews the source information at site to ensure that the data entered into the EDC platform is reflective of the source information. Any inaccuracies detected are highlighted to site via *<specify method of communication, e.g. CRA raises query in EDC system>.*

Further details of the site monitoring process can be found in the Monitoring Plan located at *<specify location>.*

### Self-evident corrections (SECs)

**<Please select one of the following>**

For this study there are no SECs being applied to the data entered in the clinical database.

**<or>**

In an effort to reduce the number of queries, and to efficiently clean/process the data collected from study trial sites, this study will be applying SECs where the applicable scenario arises. The full list of approved SECs that can be applied for this study are listed and found at *<insert location>.*

These SECs can be applied by the *<specify role(s)>* within the clinical database. Prior to applying these on data for a specific site, the list of SECs is formally approved by *<specify role(s)>* and all signed copies are tracked, stored, and maintained at *<insert location>*.

During the course of the trial a list of all SECs applied are maintained and made available at *<insert location>*. To ensure that SECs were correctly applied by the *<specify role(s)>* , these changes are verified/reviewed as per the steps below:

* <insert step>
* <insert step>
* <insert step>

These review steps above are formally documented and centrally stored at *<insert location>.*

## Query processing

The table below provides a list of the different categories of queries generated within the clinical database and responsible parties involved with the raising, answering, and resolving the query raised. Additional details regarding the query workflow configuration can be found in the *<specify document>* located at *<insert location>*.

| **Query Type/Name** | **Raised by** | **Answered by** |  **Closed by** | **Cancelled by** | **Associated Procedure(s)** |
| --- | --- | --- | --- | --- | --- |
| *<specify query >* | *<specify role(s)>* | *<specify role(s)>* | *<specify role(s)>* | *<specify role(s)>* | *<Specify process/activity related to this query type>* |

**<NB: In the event of paper Data Clarification Forms (DCFs) being used in a study, specify the process of generating, sending, and tracking the paper DCF, including the responsible personnel involved in each step>**

## Status review tracking

**<Please select one of the following>**

With the exception of data entry and query status, no additional processes are being tracked within the clinical database platform.

**<or>**

The table below provides a list of the different review activities which are tracked within the clinical database and responsible parties involved with indicating or tracking the status of each review type within the clinical database platform. Additional details regarding the query workflow configuration can be found in the *<specify document>* located at *<insert location>*.

| **Review Type** | **Tracked/Reviewed by** | **Associated Procedure(s)** |
| --- | --- | --- |
| *<specify review type, e.g. SDV >* | *<specify role(s)>* | *<Specify process/activity related to this query type>* |

# Access management

## Clinical database

Access to the clinical database is managed by *<specify role(s)>* and is done in accordance with <specify procedure or document>. The access request process involves the following steps:

* <insert step>
* <insert step>
* <insert step>

The access request, review and approval process are tracked via *<specify platform and/or document(s)>*.

## Internal directories

Access to the internal study directories is managed by *<specify role(s)>* and is done in accordance with <specify procedure or document>. The access request process involves the following steps:

* <insert step>
* <insert step>
* <insert step>

The access request, review and approval process is tracked via *<specify platform and/or document(s)>*. The list of internal directories used by the DM team for this study are listed in the table below.

| **Name** | **Server Location** | **Purpose** |
| --- | --- | --- |
| *<specify name >* | *<specify server location>* | *<Provide an overview on the purpose of this directory>* |

## Access review

To ensure that the database and directory access is representative of the current resources involved in the study (including role type where applicable), a review of the list of users is conducted by *<specify role(s)>* at a *<specify frequency>* basis.

In the event that a user should no longer have access or an incorrect role has been assigned, the following steps will be applied:

* <insert step>
* <insert step>
* <insert step>

For studies providing access to external parties (e.g. site users, vendors), a list of users is to be shared at a *<specify frequency>* basis with any required update applied as per the steps described above. All reviews and actions are formally tracked at *<specify document>* which can be found at *<insert location>.*

# Safety data reconciliation

## Data reconciliation overview

|  |  |
| --- | --- |
|  | **Output/File Location** |
| **Safety data****Specification reference** | *<insert document reference>* |
| **Safety data files** | *<insert storage location>* |
| **Data reconciliation specification document** | *<insert document name> /**<insert storage location>* |
| **Data reconciliation program** | *<insert storage location>* |
| **Data reconciliation listing output** | *<insert storage location>* |
| **Issue tracker** | *<insert document name> /**<insert storage location>* |

The table below provides a summary of the variables reconciled between the safety database and the clinical database. The development, programming and testing of these reconciliation checks are implemented as per the steps outlined in **Section 8**.

**<NB: If the development of the reconciliation listings/checks differ to the information described in Section 8, then add a dedication subsection to describe this activity>**

More detailed information regarding the data reconciliation checks can be found in the reconciliation specification document.

| **External Dataset(s)** | **CDMS Dataset(s)** | **Variable** | **Match Type** |
| --- | --- | --- | --- |
| *<specify dataset(s)>* | *<specify dataset(s)>* | *<e.g. Sample Collection date>* | *<e.g. Exact or Comparable>* |
| *<specify dataset(s)>* | *<specify dataset(s)>* | *<e.g. Sample Collection date>* | *<e.g. Exact or Comparable>* |
| *<specify dataset(s)>* | *<specify dataset(s)>* | *<e.g. Sample Collection date>* | *<e.g. Exact or Comparable>* |
| *<specify dataset(s)>* | *<specify dataset(s)>* | *<e.g. Sample Collection date>* | *<e.g. Exact or Comparable>* |
| *<specify dataset(s)>* | *<specify dataset(s)>* | *<e.g. Sample Collection date>* | *<e.g. Exact or Comparable>* |
| *<specify dataset(s)>* | *<specify dataset(s)>* | *<e.g. Sample Collection date>* | *<e.g. Exact or Comparable>* |
| *<specify dataset(s)>* | *<specify dataset(s)>* | *<e.g. Sample Collection date>* | *<e.g. Exact or Comparable>* |
| *<specify dataset(s)>* | *<specify dataset(s)>* | *<e.g. Sample Collection date>* | *<e.g. Exact or Comparable>* |
| *<specify dataset(s)>* | *<specify dataset(s)>* | *<e.g. Sample Collection date>* | *<e.g. Exact or Comparable>* |

## Data reconciliation process

The data reconciliation outputs are being ran and reviewed by the data manager on a *<specify frequency>* basis and are conducted as per *<specify procedure or document>* . Upon completion of review the data manager conducts the following steps:

* <insert step>
* <insert step>
* <insert step>

All reconciliation issues/ findings are maintained with the *<specify document/tracker>* which is maintained.In the event that a discrepancy is considered irresolvable, such cases are documented within the *<specify document/tracker>* for reporting purposes.

Prior to *<specify deliverable(s)>,* the final reconciliation outcome for this deliverable requires a formal approval by *<specify roles(s)>* in accordance with *<specify procedure or document>.*

# External data

## Data sources

The table below provides a list of all non-CRF (i.e. external data sources) being received by the DM team. Data sources which are reconciled against the CDMS data will be further described in section *12.<x>* to *12.<y>*.

| **Data Type** | **Provider/****Vendor** | **Data Reconciliation Required** **Y/N** | **Transfer Frequency** | **Data Specification Reference** |
| --- | --- | --- | --- | --- |
| *<insert data type, e.g. ECG, Imaging>* | *<insert data provider>* | *<insert Y or N>* | *<insert frequency>* | *<insert document reference>* |

All data sources are acquired and processed as per *<specify procedure or document>*. Prior to further downstream use of the data, the following structural/quality checks are applied:

*<provide summary of structural and quality checks applied once data has been acquired>*

## <insert source> Data reconciliation

**<NB this section can be repeated for each data source being reconciled>**

### Data reconciliation overview

|  |  |
| --- | --- |
|  | **Output/File Location** |
| **External dataset(s)** | *<insert storage location>* |
| **Data reconciliation specification document** | *<insert document name> /**<insert storage location>* |
| **Data reconciliation program** | *<insert storage location>* |
| **Data reconciliation listing output** | *<insert storage location>* |
| **Issue tracker** | *<insert document name> /**<insert storage location>* |

The table below provides a summary of the variables reconciled between *<insert source>* and the clinical database. The development, programming and testing of these reconciliation checks are implemented as per the steps outlined in **Section 8**.

**<NB: If the development of the reconciliation listings/checks differ to the information described in Section 8, then add a dedication subsection to describe this activity>**

More detailed information regarding the data reconciliation checks can be found in the reconciliation specification document.

| **External Dataset(s)** | **CDMS Dataset(s)** | **Variable** | **Match Type** |
| --- | --- | --- | --- |
| *<specify dataset(s)>* | *<specify dataset(s)>* | *<e.g. Sample Collection date>* | *<e.g. Exact or Comparable>* |
| *<specify dataset(s)>* | *<specify dataset(s)>* | *<e.g. Sample Collection date>* | *<e.g. Exact or Comparable>* |
| *<specify dataset(s)>* | *<specify dataset(s)>* | *<e.g. Sample Collection date>* | *<e.g. Exact or Comparable>* |
| *<specify dataset(s)>* | *<specify dataset(s)>* | *<e.g. Sample Collection date>* | *<e.g. Exact or Comparable>* |
| *<specify dataset(s)>* | *<specify dataset(s)>* | *<e.g. Sample Collection date>* | *<e.g. Exact or Comparable>* |
| *<specify dataset(s)>* | *<specify dataset(s)>* | *<e.g. Sample Collection date>* | *<e.g. Exact or Comparable>* |
| *<specify dataset(s)>* | *<specify dataset(s)>* | *<e.g. Sample Collection date>* | *<e.g. Exact or Comparable>* |
| *<specify dataset(s)>* | *<specify dataset(s)>* | *<e.g. Sample Collection date>* | *<e.g. Exact or Comparable>* |
| *<specify dataset(s)>* | *<specify dataset(s)>* | *<e.g. Sample Collection date>* | *<e.g. Exact or Comparable>* |

### Data reconciliation process

The data reconciliation outputs are being ran and reviewed by the data manager on a *<specific frequency>* basis and are conducted as *<specify procedure or document>* . Upon completion of review the data manager conducts the following steps:

* <insert step>
* <insert step>
* <insert step>

All reconciliation issues/ findings are maintained with the *<specify document/tracker>* which is maintained and located at *<insert location>*.In the event that a discrepancy is considered irresolvable, such cases are documented with *<specify document/tracker>* for reporting purposes.

# Local laboratory data

**<Please select one of the following>**

For this study there is no local laboratory data being collected.

**<or>**

The reference range information for local laboratories is reported by *<specify role(s)>*  into the <specify document or platform>. Upon the data being made available to the DM team, the following key review steps are conducted:

* <insert step>
* <insert step>
* <insert step>

In the event of an issue or finding being detected the DM team will notify *<specify role(s)>* via *<specify method of communication (e.g. manual query in database, e mail etc.)>*. All issues/findings are maintained within the *<specify document/tracker>* which is located at *<insert location>*.In the event that a discrepancy is considered irresolvable, such cases are documented within the *<specify document/tracker>* for reporting purposes.

Further details on the review checks applied are included in *<specify document>* which can be found at *<insert location>.* The development, programming and testing of these review checks are implemented as per the steps outlined in **Section 8**.

**<NB: If the development of the local laboratory checks differs to the information described in Section 8, then add a dedication subsection to describe this activity>**

# Medical coding

## Overview

Medical coding will be applied to the following forms/modules as per table below in accordance with *<specify procedure or document*>. The dictionary and versions specified in the table are updated on a *<specify frequency or indicate if dictionaries are not updated during the course of the study>* basis.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Form/ Module** | **Form Variable** | **Coding Variable(s)** | **Dictionary** | **Versions** | **Specification Reference** |
| *<insert form>* | *<insert variable>* | *<insert variable(s)>* | *<insert dictionary>* | *<insert version>* | *<insert document reference or describe programming logic here>* |
|   |   |   |   |   |   |
|   |   |   |   |   |   |
|   |   |   |   |   |   |
|   |   |   |   |   |   |

The development, programming and testing of these coding programs are implemented as per the steps outlined in **Section 8**.

**<NB: If the development of the coding programs differs to the information described in Section 8, then add a dedication subsection to describe this activity>**

## Coding process

Coding activities are conducted on a *<specify frequency>* basis by the *<specify role(s)>* . The process involves the following steps:

* <insert step>
* <insert step>
* <insert step>

In the event of a term being ambiguous or incorrect, the *<specify role(s)>* will notify *<specify role(s)>* via *<specify method of communication (e.g. manual query in database, e mail etc.)>* . All issues/findings are maintained within the *<specify document/tracker>* which is located at *<insert location>*.In the event that a discrepancy is considered irresolvable, such cases are documented within the *<specify document/tracker>* for reporting purposes.

The generated coded outputs can be found at *<insert location>*.

## Coding review

The medical coding assignments are reviewed by the *<specify role(s)>* on a *<specify frequency>* basis. The output generated for review is as per *<specify document>* and is made available at <insert location> for review.

The reviewer identifies if there are further queries or clarification needed, in the event of further actions, additional queries are raised by <specify role(s)> for site users to address, all issues/findings identified in this step are maintained within the *<specify document/tracker>* which is located at *<insert location>.*

Prior to a database lock or interim lock deliverable (if applicable), a final output is generated for review. Once the content is deemed appropriate for analysis, the *<specify role(s)>* will approve the coding assignment via the *<specify document>.*

# Status reporting

The table below provides a list of reports generated by the DM team. Where the output is external programmed, the development, programming and testing of these reports are implemented as per the steps outlined in **Section 8**. The outputs of these reports are centrally stored at *<insert location>*.

**<NB: If the development of the reports differs to the information described in Section 8, then add a dedication subsection to describe this activity>**

| **Report Name** | **Description** | **Frequency** | **Delivered To** | **Specification Reference** **(if applicable)** |
| --- | --- | --- | --- | --- |
|  <specify name> | <Provide a summary of the contents of the report |  <Specify frequency> |  <specify the groups/roles the reports will be delivered to> |  <Specify document or refer to platform that generates the output> |

# Protocol deviations

## Reporting

All detected protocol deviations (PDs) are reported by *<specify role(s)>* into the *<specify platform or document>* and are detected as part of the process described in the Monitoring Plan.

The updated information is made available to the DM team on a *<specify frequency>* basis at *<insert location>*.

## Programmatic detection

In addition to the deviations identified during on-site activities (i.e. site monitoring), programmatic outputs highlighting suspected PDs are generated by *<specify role(s)>* on a *<specify frequency>* and sent to *<specify role(s)>* for review and follow up.

The suspected PDs are programmed as per *<specify technical document>* and is located at *<insert location>*. The development, programming and testing of these reports are implemented as per the steps outlined in **Section 8**. The outputs of these reports are centrally stored at *<insert location>*.

**<NB: If the development of the PD programs differs to the information described in Section 8, then add a dedication subsection to describe this activity>**

## Subject classification

The subject classification process (i.e. determining the assigned analysis population(s) for each randomised subject), is managed by the *<specify role(s)>* and is conducted at *<specify milestone>.*

The PD data is made available by *<specify role(s)>* in a *<specify data structure format>* to support classification meeting. The PD output to support the classification will be stored at *<insert location>.*

# Unblinded data

## Overview

**<Please select one of the following>**

This is an open label study, there is no data blinding applied to this study.

**<or>**

The table below provides a list of data with the potential to be unblinded, the data will not be accessible to the DM team until the specified data release milestone has been formally achieved. For the data sources marked as “Y” for data reconciliation, further details on this activity are available in **Section 12. <x>** of the DMP. All data listed below will be securely stored by the DM team upon release at the follow location *<insert location>*.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Data Type** | **Data Provider / Vendor** | **Data Reconciliation Required? Y/N** | **Data Release Milestone** | **Data Specification Reference** |
| *<specific data type>* | *<specify group or vendor>* | *<indicate if data reconciliation is required>* | *<specify milestone >* | *<insert document reference>* |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

## Accidental unblinding

*<Where the study is blinded, please provide details on how inadvertent/accidental unblinding are managed if a team member(s) has been exposed to data which has effectively unblinded them.>*

# Data transfers

## Overview

The outbound delivery of data is done in accordance with *<specify procedure or document>*. The table below provides the list of scheduled data deliveries expected during the course of the study’s duration. All generated outputs are stored internally at *<insert location>.*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Delivery Name** | **Delivery Purpose** | **Frequency** | **Recipient** | **Data Cleaning status** | **Data Structure/Format** | **Reference Specification Document** |
| *<insert name>* | *<describe purpose of data delivery>* | *<insert frequency>* | *<specify group/role>* | *<e.g. Clean or Dirty>* | *<e.g. SDTM or raw>* | *<insert transfer specification document reference>* |
|   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |

## Transfer specifications

The specification document(s) as referenced in **Section 18.1** are developed by the *<specify role(s)>* once the *<specify milestone(s)>* has been achieved.

The draft version of the edit check specification document is then subsequently shared for review to the following parties:

* <specify role>
* <specify role>
* <specify role>

All review findings/inputs are centrally reported within the *<specify document>* which is stored at *<insert location>* . Upon all findings/inputs have been appropriately addressed, the specification document in question is formally approved by *<specify role(s)>.*

## Programming and testing

The commencement of data transfer programming starts once *<specify milestone>* has been achieved. The outputs are reviewed/tested by *<specify role(s)>* doing the following:

* <specify if Test or Production Data is being used for review>
* <insert step>
* <insert step>

All review issues are centrally reported within the *<specify document>* which is stored *at <insert location>* . Once all findings have been appropriately addressed, the updated data transfer specification in question is formally approved by *<specify role(s)>* when applicable. All testing outputs and reports are centrally stored at *<insert location>.*

# Database lock

The locking of the database is done in accordance with *<specify procedure or document>*, the table below provide a list of the expected database lock deliverables on this study.

|  |  |  |
| --- | --- | --- |
| **Milestone Name** | **Data Cleaning Level** | **Target Milestone Date** |
| *<insert name>* |  | *<dd-MMM-yyyy>* |
|   |   |   |
|   |   |   |
|   |   |   |
|   |   |   |

## Clean data definitions

## <Insert Milestone Name>

**<NB this section can be repeated for each milestone if the data cleaning definitions differ>**

For this deliverable the following levels of completeness’ are required as per the table below.

|  |  |  |
| --- | --- | --- |
| **Task/Activity** | **Completeness Definition** | **Status Confirmation Reference** |
| *<e.g. Data Entry, Safety Reconciliation, PI Signature etc.>* | *<provide a succinct overview of the level of expected cleanliness/completeness of this task>* | *<specify report or source of information to verify the cleaning level for this task has been achieved>* |

## Database lock procedure

Once the requisite cleaning level has been achieved as defined in **Section 19.1**, the database lock will involve the following steps:

* <insert step>
* <insert step>
* <insert step>

All approval documents and supplemental information supporting the database lock milestone are stored at *<insert location>*.

## Database unlock

In the event of a database unlock being required (e.g. a significant data error was found during statistical analysis), the unlock process will follow the following steps:

* <insert step>
* <insert step>
* <insert step>

All approval documents and supplemental information supporting the unlock and relocking of the database are stored at *<insert location>*.

# Data quality assurance

*<Please provide details of data QA activities being conducted for this study, details should include the following:*

* A list and description of quality checks being conducted
* Frequency of running and reviewing these quality checks
* Definition of thresholds or quality gates to determine that the overall quality of data is considered acceptable
* Describe how remedial actions for cases which fail the accepted threshold or quality gate are handled and documented.>

# Data storage and backup

*<Please provide details on the storage and back up of storage process within your organisation, including references to standard operating procedures. Details should include measures on how to mitigate data loss and ensuring a robust disaster recovery protocol>.*

# Data archival

<Please provide details on the generation of subject PDFs /data and the process to distribute this information to the relevant site. Details should include:

* Define the rate limiting factors in initiating the data archival process
* Reference specification documents that define the configuration or design of the outputs being generated (if applicable)
* Indicate responsible parties in generating and conducting QC of the outputs generated
* Describe the method (e.g. CD) and responsible parties in disseminating the relevant data to a specific study site.
* Describe how site confirmation of receiving the files and verifying opening of files is tracked and documented
* Where a database is being decommissioned (e.g. by an EDC vendor), the criteria for initiating decommissioning should be described.>

# Study documentation

<*Please provide details on how the DM study files are maintained, details should include:*

* Information whether a paper TMF (pTMF) or an electronic TMF (eTMF) is being utilised for the storage of key DM documentation
* Details on the eTMF platform that is being utilised for file storage (if applicable)
* In the event of a pTMF being maintained, details regarding where scanned copies of the originals are maintained as back-ups.
* Provide or refer to the filing structure being adhered to by the DM Service group
* Described the QC process to ensure that all relevant sections of the TMF have been appropriately fulfilled with correct documentation and that any gaps found have been addressed.
* Where the pTMF is being transferred periodically or at study end to an agreed recipient (e.g. Sponsor), the process to document the delivery of the pTMF should also be described.>

# Appendix I – abbreviations/acronyms

*<if applicable please insert any additional abbreviations/acronyms related to this study>*

|  |  |
| --- | --- |
| **ADAM** | CDISC Analysis Data Model (https://www.cdisc.org/standards/foundational/adam) |
| **AESI** | Adverse Event of Special Interest |
| **CDASH** | CDISC Clinical Data Acquisition Standards Harmonization (<https://www.cdisc.org/standards/foundational/cdash>) |
| **CDISC** | Clinical Data Interchange Standards Consortium ([https://www.cdisc.org/)](https://www.cdisc.org/) |
| **CD** | Compact Disc |
| **CDMS** | Clinical Data Management System |
| **CFR** | Code of Federal Regulations |
| **CRF** | Case Report Form |
| **CRA** | Clinical Research Associate |
| **CRO** | Contract Research Organisation |
| **DBL** | Database Lock |
| **DCF** | Data clarification form |
| **DM** | Data Management |
| **DMP** | Data Management Plan |
| **DVS** | Data Validation Specification |
| **ECG** | Electrocardiogram |
| **eCRF** | Electronic Case Report Form |
| **EDC** | Electronic Data Capture |
| **EMA** | European Medicines Agency |
| **ePRO** | Electronic Patient Reported Outcomes |
| **eTMF** | Electronic Trial Master File |
| **FDA** | Food and Drug Administration |
| **FPI** | First Patient In |
| **GCP** | Good Clinical Practice |
| **GDPR** | General Data Protection Regulation ([https://gdpr.eu/)](https://gdpr.eu/) |
| **HIPAA** | Health Insurance Portability and Accountability Act  |
| **ICH** | International Conference on Harmonisation (<https://www.ich.org/>) |
| **ICF** | Informed Consent Form |
| **IVRS** | Interactive Voice Response System |
| **LQO** | Last Query Out |
| **LPLV** | Last Patient Last Visit |
| **MedDRA** | Medical Dictionary for Regulatory Activities (<https://www.meddra.org/>) |
| **pCRF** | Paper CRF |
| **PD** | Protocol Deviation |
| **PK** | Pharmacokinetic |
| **PMDA** | Pharmaceuticals and Medical Devices Agency |
| **PRO** | Patient Reported Outcomes |
| **pTMF** | Paper Trial Master File |
| **QA** | Quality Assurance |
| **QC** | Quality Control |
| **SAE** | Serious Adverse Event |
| **SAP** | Statistical Analysis Plan |
| **SDTM** | CDISC Standard Data Tabulation Model for Clinical Data (<https://www.cdisc.org/standards/foundational/sdtm>) |
| **SDV** | Source Data Verification |
| **SEC** | Self-Evident Correction |
| **sFTP** | Secure File Transfer Protocol |
| **SOP** | Standard Operating Procedure |
| **TMF** | Trial Master File |
| **UAT** | User Acceptance Testing |
| **WHO DD** | World Health Organisation Drug Dictionary |