**Title Data Management Plan**

**Version *Insert version number* 0.0**

**Author(s) Name:**

**Signature: ……………………**

**Date: ……………………**

**Approved by Name:**

**Signature ……………………**

**Date ……………………**

Revision History

| Version | Author | Date | Reason for Revision |
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1. Purpose

The purpose of this document is to outline the data management procedures at the and at site(s) and the related responsibilities for the ***insert trial title*** study.

1. Study Design & Objectives

The primary objective of the ***insert trial title*** clinical trial is to evaluate ***specify*.** The secondary objectives are:

1. To evaluate the impact ***specify***
2. To assess the safety of ***specify***

The Primary and secondary outcome measures, and the associated electronic Case Record Forms (eCRFs) are listed in Table 1. The trial includes ***insert***cohort and ***insert*** cohort. Only patients in the ***insert*** cohort are eligible to receive treatment. Patients in the ***insert*** cohort will receive standard care. For full details on the eligibility for, and allocation to, the cohorts see the Protocol.

The primary endpoint is ***specify***

Table 1. *Add trial title* outcome measures and associated data collection (eCRF form)

|  |  |  |
| --- | --- | --- |
| **Cohort** | **Outcome Measures** | **eCRF** |
|  | Primary: ***specify*** | ***specify*** |
|  | Secondary (effectiveness): ***specify*** | ***specify*** |
| Secondary (safety): ***specify*** | ***specify*** |
|  | Secondary: ***specify*** | ***specify*** |

1. Data systems

The flow of data from patients through to the study reports is shown in **Figure 1**. The ***insert data capture system e.g. MACRO*** database (developed by ***insert company***) is being used for data collection in ***insert trial title***. The database can be accessed for monitoring and review purposes through ***insert web link.*** Access to data is restricted and each user requires a username and password.

Following extraction of the data from the ***insert data capture system e.g. MACRO*** database, data processing and analysis are being conducted using ***insert statistical package e.g***. ***SPSS*** and ***Stata***. Data are extracted from ***insert data capture system e.g. MACRO*** as a single line of data for each patient.

Figure 1. Data flow in *insert trial title*

Patient data

Laboratory data

IMP data

eCRF

Trial title

Add data capture system MACRO sever

Data monitoring

ISF

TMF

IDMC

Statistician

Data Manager

Trial investigators

Study reports

1. Responsibilities
   1. Organisational Responsibilities

Table 2. RAPIDE-TKM Data Management Responsibilities

| **Data Management Responsibilities** | ***insert trial title*** Data Manager | External Collaborator 1 -***specify*** |
| --- | --- | --- |
| Creation of Data Management Plan |  |  |
| CRF design and maintenance |  |  |
| Database design (trial database) |  |  |
| Build, test and validate database |  |  |
| Database Lock |  |  |

* 1. Key Personnel

The roles and responsibilities in relation to data management are outlined in Table 3. The Data Manager (DM) is responsible for all day to day data management processes. The Clinical Project Manager (CPM)/Trial Manager (TM), has oversight of the data management processes. The DM and CPM/TM will report issues to the Trial Operations Group (TOG) as they arise. The DM is the first line of contact and will ensure tasks are carried out appropriately, and in consultation with the TM/CPM/TOG where necessary. The DM will liaise with the study Statistician to ensure routine reports are produced within the required timelines, providing data as required. Details of all personnel involved in data management at site can be found in the ***insert document*** (held by the DM).

Table 3. *Trial Title* Roles and responsibilities for data management

|  |  |  |  |
| --- | --- | --- | --- |
| **Role** | **Primary Personnel Responsible** | **Secondary Personnel Responsible** | **Timescale** |
| ***Data entry*** | ***insert e.g. data entry staff*** | ***insert e.g. chief investigator*** | ***insert e.g. daily*** |
| ***Data Transfer*** |  |  |  |
| ***Source data verification of primary endpoint data*** |  |  |  |
| ***Review of Day 14 outcome graph*** |  |  |  |
| ***Data extraction, preparation of data for interim reporting*** |  |  |  |
| ***Analysis of primary and secondary outcomes*** |  |  |  |
| ***Update data management plan*** |  |  |  |

* 1. Data management trial documents

This Data Management Plan (DMP) should be used as an overview for procedures undertaken within the ***insert trial title*** and should not be used in isolation.

This DMP should be used in conjunction with the related ***insert trial title*** documents listed in Table 4.

Table 4. *Trial Title* Additional documents required for data management

|  |  |
| --- | --- |
| **Document** | **Trial Master File Section -** |
| ***Insert trial title*** protocol | ***Insert*** |
| Contracts and Agreements |  |
| Risk assessment |  |
| Data Monitoring and Safety Plan |  |
| Independent Data Monitoring Committee (IDMC) Charter |  |
| Data Entry and Data Query Standard Operating Procedures (SOPs) |  |
| Case Report Forms (CRFs) |  |
| Study definition reports |  |

* 1. Updating the data management plan

The DMP should be reviewed at least annually, or as and when changes to data management working practices occur. Any changes will be detailed here, and the Data Manager is responsible for any updates. This will result in a new version of the document and the reasons for the revision must be listed on the document cover page.

When a Data Manager leaves the ***insert institution,*** moves between trials or changes roles, he/she must ensure the DMP is up to date before leaving.

1. Timescales of Key Activities
   1. Milestones

The dates of key milestones achieved in the trial are outlined in Table 5.

Table 5. Key data-related milestones in *insert trial title*

|  |  |  |
| --- | --- | --- |
| **Milestone** | **Predicted Date** | **Actual date** |
| Database Go-live | ***insert*** | ***insert*** |
| First participant recruited to trial |  |  |
| Last participant recruited |  |  |
| Last participant visit |  |  |
| Database Locked |  |  |

* 1. Frequency of recurrent activities

Those activities required for the timely and accurate collection of data for ***insert trial title***, and the frequency with which they must be conducted, are outlined in Table 6.

Table 6. Data-related activities and the frequency with which they must be undertaken

|  |  |  |
| --- | --- | --- |
| **Activity** | ***insert institution* Timescale** | **Site Timescale** |
| ***CRFs/data returned from site*** | ***insert*** | ***insert*** |
| ***Data Entry*** |  |  |
| ***Transfer of Data*** |  |  |
| ***Data Chase/Missing CRFs*** |  |  |
| ***Review, Raise and follow up of data query listings*** |  |  |
| ***Query resolutions added to trial database*** |  |  |
| ***Central source data verification of patient eligibility, drug accountabilty and day 14 primary endpoint data.*** |  |  |
| ***On site monitoring (e.g. consent)*** |  |  |
| ***Data extraction and reporting to internal groups:*** |  |  |
| ***Data extraction and reporting to external groups: Trial Steering Committee (TSC) and Independent Data Monitoring Committeee (IDMC)*** |  |  |
| ***Medical Data Review*** |  |  |
| ***Update Data Management Plan*** |  |  |
|  |  |  |

1. eCRF Design and Data Definitions
   1. eCRF Design

There are 16 eCRF forms. Table 7 outlines the availability of the eCRFs for different visits and whether these are mandatory (m) and non-mandatory eCRFs such as laboratory testing and SAR form.

Data on Serious Adverse Reactions (SARs) and Suspected Unexpected SARs (SUSARs) are collected outside of the ***insert data capture system e.g. MACRO*** database. Data collection on SARs and SUSARs is undertaken using the ***insert document.***

The trial database has been programmed by ***insert company*** and all project documentation relating to the database, including study definition reports, report specifications, database guides, CRFs, data management plan and SOPs can be found within section ***insert*** of the Trial Master File.

Table 7. Database design

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **CRF Name** | ***Screening*** | ***Days***  ***1 -13*** | ***Discharge*** | ***Day***  ***30*** | ***Month 3*** | ***Month 6*** | ***Month 12*** | **Database CRF Version** |
| ***Insert e.g. screening & randomisation*** | ***e.g X*** |  |  |  |  |  |  |  |
| ***Insert e.g. malaria*** | ***e.g X*** |  |  |  |  |  |  |  |
| ***Insert e.g. ebola PCR and sample Storage*** | ***e.g X*** |  |  |  |  |  |  |  |
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(m) = mandatory

1. Participant Management
   1. Screening

Patients with confirmed ***insert*** will be screened for trial eligibility and invited to give informed consent to participate in the trial. Staff will not discuss informed consent with patients (or the parents/representatives of patients <99 years old) who are not eligible for enrolment in any trial arm. Study dosing, sampling and data collection will begin only after enrolment.

For patients not enrolled in the study, only ***insert*** data will be collected. The screening and enrolment log and the ***insert*** eCRF should be completed on the ***insert data capture system e.g. MACRO*** database.

* 1. Randomisation/Registration

Please refer to the ***insert Trial Title\_SOP00\_Randomisation*** for further details.

* 1. Trial/Study Number/Participant ID

All patients (both those that are eligible to take part in the trial and screen-failures) will be allocated a unique patient identifier number (PIN). The identification number will consist of ***specify*** digits; the first ***specify*** digits correspond to the site number and the last ***specify***digits are the sequential patient number ***e.g. 201-001 is for the first patient at site 201***. The PIN will be in the same format for enrolled patients regardless of their cohort. For non-enrolled patients, the PIN will be prefixed ***by "S" (to denote "Screening ID"), e.g. S202-001.***

The PIN should be used in all correspondence; names should not be used in any data transmissions or correspondence.

* 1. Participant assessments

Patient demographic data and medical history will be collected for all patients at the time of enrolment in the trial. While a participant is an inpatient, information will be collected daily on signs and symptoms, medications and blood products received, and the results of non-trial blood samples. For patients who are receiving ***specify*** that day, detailed records of physiological monitoring and adverse event monitoring will be provided.

These data will be collected daily for participating patients up to ***specify, e.g. discharge, or death***, whichever occurs first. Patients who achieve discharge criteria before ***specify*** will stop the inpatient testing schedule upon discharge.

Discharge criteria are:

* ***specify***

Please see above section 5.2, table 7 eCRF Design for further information on the eCRFs that will be completed on the database.

* 1. Laboratory assessments

Laboratory data should be entered on the ***insert data capture system e.g. MACRO*** according to the schedule specified in section ***specify*** of the protocol.

Please refer to the ***insert Trial Title\_SOP00\_Data Entry*** for instructions on entering lab values, screening and discharge PCRs.

* 1. Follow-up assessments

***Specify*** is the primary end point of this trial, and defined as **specify**. Follow up assessments will be conducted for status on ***specify e.g. Days 00 and 00 or at 0, 0 and 00 months***. Patient status on follow-up assessment days will be collected (admitted, met discharge criteria or deceased). In addition, visits ***on specify e.g. 0, 0, 00 months*** will seek information on symptoms post recovery.

Primary/secondary outcome data for these visits can be collected at any point after the respective days.

* 1. Missed assessments

Missed assessments will be managed and tracked at site and are also highlighted through missing eCRF on the database. If information is deemed as missing (i.e. it has been requested from the site but they have been unable to locate it or if a patient has not attended their visit) the associated eCRF and/or field(s) should be indicated as such and amended to ‘unobtainable’ on the database. Please refer to the ***insert Trial Title\_SOP00\_Data Entry*** on how to do this.

* 1. Discontinuation of Trial Treatment

Each participant has the right to discontinue use of study treatment at any time. In addition, the Investigator may discontinue treatment at any time if the Investigator considers it necessary for any reason including:

***specify***

The reason for any discontinuation of treatment will be recorded on the ***insert eCRF.***

* 1. Withdrawal from the trial

Patients, or parents/guardians/representatives when they have given consent on behalf of the patient, are free to withdraw consent and stop study participation at any time for any reason. In this case, the patient’s clinical management will continue to be provided according to standard care and will not be affected by the decision to withdraw. Outcome data and the reason for withdrawal will be recorded when possible. Data collected up to the date of withdrawal will be used in study analysis.

1. Data Processes
   1. Data transfer

Electronic data transfer will be undertaken daily by the field teams to the central InferMed server.

In addition, the documents outlined in section 9.4 – Table 8 will be sent to the ***insert trial title*** Data Manager in order to complete central QC of eCRFs.

* 1. Data entry procedures

Data entry will be performed on an on-going basis, according to the timelines identified in section 5.2 Table 6 above. Data management, reporting and storage within this trial will comply with the requirements of European Union data protection laws, ICH Good Clinical Practice and FDA 21 CFR Part 11.

Please refer to ***insert Trial Title\_SOP00\_Data Entry*** for further details.

* 1. Accessing MACRO Database online

The online version of the database can be accessed using the following ***insert link***.

The login details for the ***insert trial title*** test database are as follows: ***insert web link.***

* 1. Data entry trouble-shooting

*If data entry falls behind*:

*If there is a daily non study medication not listed on the database drop down menu*:

1. Quality Management
   1. Staff training

New site staff who are responsible for data entry should receive eCRF specific training before being added to the delegation log, and being granted access to the database to begin data entry, data modifications or raise discrepancies.

* 1. MACRO user roles and access

There are two different ***insert trial title* &** ***data capture system e.g. MACRO*** database user profiles available and these are as follows:-

* Data Entry
* Data Review

In summary, staff with a ‘Data Entry’ profile will be able to enter and edit data on the database, respond to discrepancies, create and close SDVS and transfer data. Staff can also be given a separate ‘Data Review’ profile, which enables users to raise manual discrepancies. Each site will need at least one member of staff with a ‘Data Entry’ user profile and one member of staff with a ‘Data Review’ user profile (though it is possible for the same member of staff to have both user profiles). Staff will therefore need to complete the relevant training depending on the level of database access required.

In order to issue new trial staff with their database login details, the ***insert trial title and document*** should be completed and sent to – ***insert email address.***

When an existing member of staff leaves the study, the ***insert trial title*** Data Manager will send the ***insert document*** to – ***insert email address*** to remove the person’s access to the database.

* 1. QC of eCRFs at site

Following data entry of the eCRF onto the add data capture system, the data entered should be reconciled against the original case investigation form ***insert trial title*** daily review form/clinic notes/laboratory reports by another member of team who did not complete data entry. Any issues identified will be clarified with the person who completed the eCRF and any necessary corrections made using the data entry/review user profile login.

Please refer to the ***insert Trial Title\_SOP00\_Data Entry*** for further details regarding the process.

* 1. Central QC of eCRFs

Central QC activities are outlined in the ***insert trial title*** Monitoring Plan. ***Specify*** is the primary end point of this trial. It is important to ensure that data recorded on the ***insert trial title & specify graph and/or tables***, which will be presented at the IDMC meetings, are regularly monitored to ensure quality control. Data will also be evaluated for compliance with the ***insert trial title*** protocol and accuracy; ***specify percentage e.g. 100%*** source data verification of the following eCRFs will be undertaken:

* **s*pecify***

Site staff will be requested to send password protected zip files containing anonymised copies of the following forms/lab printouts on a weekly basis for checking by the ***insert trial title*** Data Manager:-

* **s*pecify***

Table 8. Documents required for central monitoring

|  |  |
| --- | --- |
| **Source Document** | **Frequency** |
| ***specify e.g. screening and enrolment log*** | ***specify e.g. weekly*** |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

1. eCRF and patient tracking
   1. Generating/identifying and sending reports overdue CRFs

Any expected CRFs which have not yet been received are identified in the missing eCRFs listing located on the homepage of the ***insert data capture system e.g. MACRO*** database.

Ideally, all data must be entered on the eCRF, and also uploads to the database performed, on a daily basis in order to ensure all information is up to date for **s*pecify***.

* 1. Missing data

If a CRF is deemed missing (e.g. the source document has been requested from the site but they have been unable to locate it or if a patient has not attended their visit) the associated missing form should be indicated as such on the database and amended to ‘unobtainable’.

1. Query Handling
   1. Errors on Source Data documents

Site staff should look at forms before data entry to check for mistakes. If any mistakes are noted the data entry staff should flag these on the eCRF and return to the clinic for correction or clarification.

* 1. Sending/Receiving queries

All MACRO queries, both manual and automated are compiled within the trial database. Queries generated from Source Data Verification conducted by the Data Manager will be listed on the Monitoring Log that will be regularly sent to the Site by the Data Manager. Sites should review and resolve all query listings on a weekly basis. Any concerns the ***insert trial title*** Data Manager may have with the efficiency of this process will be noted and discussed at the **s*pecify frequency*** weekly TOG meetings.

In addition, in the case of an approaching IDMC meeting the Data Manager/Trial Statistician will send a list of urgent queries need to be to be entered onto the database before the IDMC reports are compiled.

The ***insert trial title*** Data Manager will review the queries and provide further responses where necessary. Any further clarification needed (for example, if something on the listing is unclear) can be obtained via email communication (any information relevant to query resolution should be kept within the patient file alongside the associated source document). Any further information received will be reviewed by the Data Manager and entered on the database.

See ***insert Trial Title\_SOP00 Data Query*** for details on generating and identifying queries in ***insert data capture system e.g. MACRO.***

* 1. Handling query responses

The ***add trial title*** Data Manager will check all queries in the ***insert data capture system e.g. MACRO*** query listings and Monitoring Log have been appropriately responded to and further written feedback will be provided when this is not the case.

If necessary, any query responses can also be clarified via email with the site; it may be necessary to request a copy of the original form be sent, or a response may simply need written confirmation. Any emails containing information relating to query resolution should be stored in the patient file with the corresponding source document.

If a site is unsure how to answer a query, a comment should be added to the query on the database or Monitoring Log and the ***insert trial title*** Data Manager will provide further clarification.

Please refer to the ***insert Trial Title\_SOP00\_Data Query*** for further details.

1. Storage of patient-related documents
   1. Storage of source documents

All original source documents (paper documentation containing patient data), for example ***insert trial title*** CRFs, clinic notes, laboratory reports etc should be kept in a lockable drawer or cabinet, with restricted access wherever possible and when not in use.

1. Safety reporting

Please refer to ***insert Trial Title\_SOP00\_Safety Reporting*** for further information regarding the ***insert trial title*** safety reporting requirements.

1. Monitoring

Details of the overall monitoring plan for the trial can be found in the ***insert trial title*** data monitoring plan section of the ***specify*** Trial Master File. Monitoring will include Source Data Verification conducted by ***specify*** staff as well as a monitoring visit.

1. Reporting
   1. Regular Reports

The reports that are to be generated regularly, when these are to be produced, whom they are produced for and how these are used are shown in Table 9.

Table 9. Data reports – Regular reports

|  |  |  |  |
| --- | --- | --- | --- |
| **Listing** | **Frequency** | **Produced for** | **Purpose** |
| **e.g. visits** | **insert frequency e.g. daily/weekly/monthly** | **insert institution** | **insert e.g. follow up of patients** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

* 1. Ad-hoc Reports

Examples of Ad hoc reports, when these have been produced, whom they are produced for and how these are used are shown in Table 10. Further ad hoc reports will be generated as required.

Table 10. Data reports – Examples of ad-hoc reports

|  |  |  |  |
| --- | --- | --- | --- |
| **Listing** | **Frequency** | **Produced for** | **Used for** |
| **e.g. events listing** | **Insert frequency e.g. daily** | **insert institution** | **Insert e.g. review and recommendations** |
|  |  |  |  |
|  |  |  |  |

1. Data Extraction and Analysis

The Data Manager will extract data from the ***insert data capture system e.g. MACRO*** database. The Data Manager and other Trial members may produce data summaries and reports as required by the IDMC and Investigators. The ***insert statistical package e.g. SPSS*** syntax files used to compile the below data summary can be found at the following location:

|  |  |
| --- | --- |
| **File** | **Location** |
| ***Insert*** | ***Insert*** |

The ***insert statistical package e.g. SPSS*** syntax files must be updated with any new or additional ***insert trial title*** variables as they become available.

Interim data extractions will be undertaken on ***insert frequency e.g. weekly*** basis in order to compile ***specify*** for the IDMC meetings. This frequency maybe increased for the ***specify***.

The interim and final analyses will be performed by the Trial Statistician assigned to the study using ***insert statistical package e.g. STATA*** software. Documentation of this process can be found in the ***insert statistical document.*** The timing of data extraction and database lock will be agreed in advance with the TOG to ensure this is done when data entry and query resolution is as complete as possible. Password protected copies of all CSV files will be stored electronically within the IDMC folder at the following location: ***Insert***

Please refer to *i****nsert Trial Title\_ IDMC Charter*** for detailed information regarding the ***insert trial title*** IDMC reporting and meeting requirements.

1. Database Closure/Lock

The trial database will be locked before the final analysis. All data will be cleaned prior to database lock and queries resolved where possible. Any un-resolvable queries will be closed as ‘closed-unresolved/unobtainable’.

1. Archiving

The trial database will be archived by ***insert company*** and data extractions and listings held for a minimum of ***specify number*** of years after completion of the trial. Should access to the database be required following archiving, please contact ***insert email address***. Guidance will be provided on the correct procedures to undertake to be able to access the archived data.

Copies of all completed eCRFs/CRFs and source documents will be archived for a minimum of ***specify number*** of years following completion of the trial. Documents should be stored in such a way that documents are complete, accurate and remain legible. Any alterations made should be traceable.

CRFs and source documents should be archived in an appropriate locked room, cupboard or filing cabinet with adequate fire protection (sprinkler systems), protection from water, humid conditions and pests. The room, cupboard or filing cabinet should have secure access by authorised personnel only.

**Appendix 1 *Insert data capture system e.g. MACRO Database Function Keys and symbols***

**Appendix 2 *Insert data capture system e.g. MACRO database status icons***