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| A Comparative Multicentric Non-Inferiority Clinical Trial of WHOMBMDT with a New Monthly Chemotherapy Regime containing Rifampicin, Moxifloxacin and Clarithromycin (RMC) on Multibacillary patients from IndiaStandard Operating Procedure 1Data Management | | | |
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**1.** **PURPOSE**

This document describes the process of Data management for the RMC study.

### 2. Background

This Standard Operating Procedure (SOP) outlines procedures for managing RMC clinical trial study data on paper and in electronic systems. It covers the entry, validation and management of clinical trial data according to the principles of GCP and applicable regulations in order to support statistical analysis and subsequent reporting.

**3. OBJECTIVES AND Scope**

This document summarizes the requirement for data management and entry procedures for all RMC study data, including paper and electronic forms, ensuring all data is collected, verified, validated and reconciled, ensuring the integrity of the research.

**4. ROLES AND Responsibilities**

*Principal Investigator*

* The principal investigator (PI) is responsible for providing oversight of all data management activities throughout the RMC clinical trial*.*
* Co-ordinating with the RMC clinical trial team to establish clear procedures for data collection, entry, verification, and monitoring.
* Identifying and addressing potential risks to data integrity and implementing strategies to mitigate such risks.
* Serving as the primary point of contact for communication with the sponsor regarding data management issues, including data queries and audit findings*.*
* Implementing continuous improvement initiatives to enhance data management processes and ensure the highest standards of data quality and integrity throughout the clinical trial*.*

*Clinical Trial Co-ordinator*

Define and document all data management activities for the study, including:

* The full range of data items defined in the electronic case report form (eCRF).
* Maintenance of blinding.
* Guidelines and protocols for handling situations where blinding codes need to be revealed on a case-by-case basis.
* Data entry requirements.
* Data verification requirements.
* Data validation and consistency checks as defined in the eCRF.
* Requirement and contents for reports on progress in recruitment and data entry and completeness or otherwise of available data.
* Timing and frequency of reported serious adverse effects.
* Procedures for data backup and retrieval.
* Reporting of numbers recruited, delayed or no show at scheduled visits, outcomes and serious adverse events (SAEs) along with overall progress in timely completion of follow-up to date.

The Clinical trial co-ordinator jointly with the Statistician will define, prepare and validate the data management system to be used by the project – specifically in relation to the data requirement as defined in the eCRF. They will be responsible for validating the data entry procedure in relation to data entry forms prepared for use in each participating centre.

*The Clinical trial co-ordinator’s responsibilities in relation to each participating centre:*

* Create and circulate a written guide for data entry procedures and provide training for the same.
* Develop and oversee individual user accounts tailored to each centre, granting appropriate access levels to relevant data sections.
* Ensure that all users of the data entry system to be appropriately trained, specifically when the centres become operational. Additionally, provide training for new research team members upon their arrival.
* Configure tablets for data entry purposes at each centre.
* Train staff comprehensively in utilizing the complete array of data management procedures.
* Execute and oversee procedures for data upload and hardware security in each participating centre, focusing on securely exporting data to the central repository within TLMTI
* Track the advancement of data entry at each participating centre, assessing both the thoroughness of data input and the pace of recruitment of the RMC trial.
* Throughout the research process, ensure transparent communication by sharing comprehensive updates regarding the data entry system with each participating centre.
* Prepare and submit a written report detailing findings derived from a randomly chosen 10% of patients locally recruited for the study.
* Mandate dual data entry for a subset of cases at each centre, stipulating that all data must be re-entered if the initial entry does not meet a predefined level of reliability.

Single data entry is sufficient. However, accuracy standards dictate no more than one error or omission per enrolled patient. Data entry accuracy will be evaluated after the recruitment of the initial ten patients at each centre and again after the last ten patients are enrolled until the project's conclusion. Centres unable to meet this accuracy standard will be instructed to re-enter all patient data.

### 5. DATA ENTRY AND HARDWARE

Individuals responsible for data entry will be identified in each Centre. User access will be strictly limited by password according to role.

The project will supply one tablet per center solely dedicated to data entry and is to be kept in a secure location. No personal mobile phones or tablets are to be used for data entry.

**6. DATA VALIDATION AND CLEANING**

Mostly, data validation will be automated through internal consistency checks written on to the database. Additional validation will be carried out on a quarterly basis and any actionable point will be communicated back to each Centre. These may pertain to missing, inconsistent or unexpected data or failure to follow the study protocol. They will extend to include broader issues in relation to management of the following:

* Actions in relation to missed or overdue visits.
* Actions in relation to SAEs.
* Actions in relation to outcomes.
* Actions in relation to entire data areas missing.

Each centre is required to respond to the listed data issues and report back on actions taken in response. Corrections to data entry may be made locally only up to the time at which the data record is flagged as “Complete”. For each correction the data entry system will add an entry to an audit trail.

A log of any unresolved data issues to be maintained by the Trial Manager and shared with the centres.

**7. Electronic data transfer**

The EasyResearch system includes secure uploading of data to a central data store managed by TLMTI which will be responsible for data security.