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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 14Research Staff training | | | |
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| **Table of Contents** | **Page** |
| 1. Purpose | 3 |
| 2. Background | 3 |
| 3. Scope | 3 |
| 4. Responsibilities | 4 |
| 5. Procedure | 5 |
| 7. Appendices  Appendix 1 | 6  Separate document |

**1.** **PURPOSE**

This document sets out the procedures to be followed by all The Leprosy Mission Trust, India (TLMTI) staff who are involved in research.

### 2. Background

Current WHOMDT does not kill 100% bacteria even after a full course of treatment in a subset of patients harboring a large bacterial load thus continuing transmission of the disease responsible for endemicity in some countries. The duration of MDT is long and promotes noncompliance. MDT continues to be controversial with limited evidence support resulting in multiple reformulations since the last 40 years. This calls for a search for newer, more efficacious drugs with shorter duration of action evidenced with well-designed clinical trials. Relapse, advocated as the key outcome measure of efficacy of MDT, has its drawbacks. Relapse studies require long years of follow up. The gold standard test for viability was Mouse foot pad studies which is costly and time consuming. Hence, we propose Molecular Viability Assays as outcome measure of efficacy which are newer and better techniques to test viability faster.

In this study, we propose to conduct a Randomized Controlled study comparing WHO MBMDT with a monthly regime consisting of currently most bactericidal and safe drugs of Rifampicin, Moxifloxacin and Clarithromycin in MB leprosy patients.

**3. Scope**

This document applies to all employee involved with clinical research including, but not limited to, Unit Heads, Principal Investigators (PI), Co-Investigators, Consultants, Clinicians, Clinical Trial Pharmacists, Physiotherapists, Statisticians, Research Nurses, Allied Health Professionals and all members of the Research & Development team.

**4. Responsibilities**

**4.1 Responsibilities of the Trust**

TLMTI is responsible for ensuring all research staff receive appropriate training and develop the necessary competencies. Staff members must complete all mandatory training required by their employers to meet these responsibilities and must comply with all relevant policies and procedures.

**4.2 Responsibilities of the Sponsor**

The Sponsor is responsible for ensuring appropriate management and documentation clinical trials to meet ethical and regulatory requirements. Specifically, the Sponsor should ensure that:

* Each individual involved in conducting a trial is qualified by education, training, and experience to perform their respective tasks (ICH, GCP).
* Employers of staff engaged in health and social care research are responsible for fostering and promoting a quality research culture within their organizations. This includes supporting their staff in maintaining professional conduct in research and holding them accountable for it. Attention must be given to training, career planning and development, and the implementation of clear codes of practice. Additionally, systems must be in place for monitoring compliance, addressing non-compliance or misconduct, and learning from errors and complaints.

**4.3 Responsibilities of the Principal Investigator (PI)**

The Principal Investigator (PI) is responsible for ensuring that all research staff involved in their study receive appropriate protocol-specific training and are competent to perform their assigned roles. Additionally, the PI must ensure that all staff members participating in each clinical trial have completed Good Clinical Practice (GCP) training within the past 2 years. The PI must also ensure that research staff without GCP training do not participate in obtaining consent for clinical trial-related activities.

**4.3 Responsibilities of the Research Staff**

All research staff working on research projects must demonstrate their competency in the areas required by their roles. Each research staff member is responsible for maintaining their own training records (as outlined in Appendices 2 and 4) and must provide evidence of such training when requested by the Trust, the Sponsor, or regulatory authorities.

### 5. PROCEDURE

**5.1 Induction Research Training**

Each individual's line manager is responsible for implementing formal training plans tailored to the specific needs of clinical trial personnel and their roles. These formal training plans should cover key training requirements and be regularly reviewed by both the individual and their line manager to ensure that training needs are being met.

**5.1 GCP Training**

**Mandatory for:** All employees/any other staff (or staff likely to provide cover) involved in performing trial-related procedures in Clinical Trial hosted by TLMTI. This also includes all staff in support departments within the Trust who are performing research specific investigations (outside of their usual role) for Clinical trial.

GCP training courses are available, please contact the RMC clinical trial team.

For staff without formal GCP training, staff should enroll and work through the Introduction to Good Clinical Practice (GCP) eLearning modules, available online through the London School of Hygiene and Tropical Medicine e-learning course.

For staff who have attended GCP training within the last 2-3 years and require an update, they should refresh e-learing course. Attached is a list of the topics covered in the online GCP training course (Appendix 3).

**5.2 Audit of GCP Training**

Original copies of GCP certificates should be maintained securely in the individual’s training file. Out of date certificates should be kept and not destroyed. Access to individual training files may be requested by the RMC Clinical trial team, the Trust, the Sponsor or the regulatory authorities as part of an audit or routine GCP inspection.

**5.2 SOP Training**

Prior to the implementation of new Standard Operating Procedures (SOPs), the RMC clinical trial team will organize targeted training sessions for all relevant research staff. These sessions may be integrated into research team meetings or held separately. RMC clinical trial team will also produce an attendance log after each SOP training session.

In addition to attending SOP training sessions, all staff must read and complete the SOP Signature Sheet (Appendix 6). This signature sheet confirms that each staff member has read and understood the contents and requirements of the SOPs and agrees to follow the outlined procedures once implemented. Depending on the individual’s role, SOPs must be read and acknowledged within 3 months of the Trust start date for new starters or the SOP roll-out date.

All original copies of the signed agreement signature page should be filed in the staff member's training file. It is recommended that these are reviewed during yearly appraisals. Each staff member is responsible for maintaining a record of this training.

If a staff member feels they are not competent in a particular area essential to their research role, additional training and support can be provided by the RMC team.

After the implementation of all SOPs, the RMC trial team will deliver refresher training sessions to research staff as needed on an ongoing basis.

**5.3 SOP/Policy non-compliance**

Where a significant and/or persistent deviation from research SOPs/Policy is identified the Escalation Plan (Appendix 7) and, as necessary, the Trust competency/disciplinary process will be followed.

**5.4 Trial specific training**

The Principal Investigator (PI) is accountable for ensuring that all research staff engaged in their research study have undergone appropriate protocol-specific training and are capable of fulfilling their delegated roles. Trial-specific training must be completed before initiating any trial-related activities or intricate trial assessments. It is mandatory for all staff to receive adequate training to enable them to execute their trial-related responsibilities, with consideration given to the training needs of staff joining a trial team after the trial commencement. All records of trial-specific training must be retained as trial supporting documents, either at the individual trial site or centrally, for as long as they are necessary to support the historical reconstruction of the trial.

**6. APPENDIX**

Appendix 1- Definitions

Appendix 2-Guidance note on staff training files

Appendix 3-Topics covered in full day GCP training

Appendix 4-Staff Training Log

Appendix 5-Training Attendance Log

Appendix 6- SOP Signature Sheet

Appendix 7- Escalation Plan

**Appendix 1**

**Definitions**

**Principal Investigator (PI)**

The investigator with overall responsibility for the research. In a multi-site study, the PI has co-ordinating responsibility for research at all sites. All applications for ethical review should be submitted by the PI.

**Clinical Trial**

A clinical study in which participants are assigned to receive one or more interventions (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study protocol. Participants may receive diagnostic, therapeutic, or other types of interventions.

**Good Clinical Practice (GCP)**

Good Clinical Practice is a set of internationally recognised ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects.

**International Conference on Harmonisation (ICH)**

International Conference for Harmonisation, a collaboration between regulators and the pharmaceutical industry in Europe, the United States and Japan to establish common standards for clinical trials. ICH GCP is a widely recognised standard for Good Clinical Practice in clinical trials.

**Investigational Medicinal Products (IMP)**

A pharmaceutical form of an active substance or placebo being tested, or to be tested, or used, or to be used, as a reference in a Clinical Trial, and includes a medicinal product which has a marketing authorisation but is, for the purposes of the trial - a) used or assembled (formulated or packaged) in a way different from the form of the product authorised under the authorisation, b) used for an indication not included in the summary of product characteristics under the authorisation for that product, or c) used to gain further information about the form of that product as authorised under the authorisation.

**Mandatory**

Training which must be completed by all employees and any other staff involved in clinical trials and is therefore compulsory.

**Appendix 2**

**Guidance notes on staff training files**

**PURPOSE**

To adhere to the principles of Good Clinical Practice (GCP), and TLMTI Policy, staff involved in clinical research trials must furnish evidence of qualification and training. Each member of the research staff should possess a training file, either maintained individually or centrally within units.

Acknowledging Principal Investigators, and Co-Investigators have access to suitable clinical research training, such as Good Clinical Practice, these professional groups will be accountable for managing their own training needs and upkeep of training records and related documentation.

The Principal Investigator (PI), or their designated representative, is responsible for ensuring that:

* All research staff involved in the research adhere to all relevant RMC Trial SOPs and/or unit-level guidance documents.
* Staff members receive adequate training and are kept informed about the current RMC Trial SOPs and guidance documents.

Each individual's line manager is tasked with conducting an assessment of the individual's needs upon appointment to establish a baseline framework of skills and competencies.

Within units, both central and/or individual training records must be maintained for research staff, with reference made in the Trial Master File (TMF) or Site File.

All training activities undertaken by research staff should be documented in a training log and regularly reviewed to ensure that all training needs remain current.

Adequate arrangements should be in place to ensure that a training file and/or related documentation are readily accessible for regulatory and/or other audit and monitoring activities.

New staff members entering clinical research and requiring assistance with establishing and maintaining a Trial Master File (TMF), as well as guidance on Good Clinical Practice, other regulatory, and ethics requirements, can seek guidance and training from the RMC Trial team.

The following are suggested minimum contents for training files:

**Curriculum Vitae (CV):** Provide evidence of education, training, qualifications, and experience to date, including the level of experience in clinical trials (e.g., numbers, phases, and therapy areas of trials). Dates of GCP training should be listed. CVs should be regularly updated. Additionally, CVs should be personally signed and dated to confirm the document's date and ownership by the named individual.

**Confirmation of GCP Training:** Provide evidence of completion of GCP training.

**Training Records Logs (Role-specific training records):** Maintain current and previous training record logs detailing all internal and external training received while in the post. This should encompass all training that enables the individual to competently perform their job and delegated duties in a clinical trial. At minimum, the training record log should document GCP training, mandatory training, and other courses attended. A sample copy of the training record log can be found in Appendix 4.

**Standard Operating Procedures (SOP):** Keep evidence of having read the SOPs. All staff participating in clinical research must adhere to applicable TLMTI policies and SOPs issued by the Standard Operating Procedures Working Group (SOPWG). It is mandatory to read, understand, and adhere to all SOPs. Training sessions on SOPs will be provided by the RMC trial team.

**Publication Details:** Maintain details of all publications and abstracts.

For each trial an individual is involved with, there must be documentary evidence that they have received relevant trial-specific and, where required, therapeutic area training. These records must be maintained as trial supporting documents, either at the individual trial site or centrally, for as long as they may be needed to support historical reconstruction of the trial.

**Appendix 3**

**Topics covered during GCP training**

* *Introduction to Good Clinical Practice*
* *Roles and Responsibilities- Key Players*
* *Informed Consent*
* *Essential Documents*
* *Data Management*
* *Monitoring, Auditing and Inspections*
* *Investigational Medicinal Products*
* *Safety Reporting*
* *End of the Study and Archiving*

**Appendix 4: Staff Training Log**

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| **NAME: TRAINING PERIOD:** |
| **JOB TITLE:** |

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| --- | --- | --- | --- | --- |
| **Title of the course/study day** | **Dates from/to** | **Organised by** | **Key objectives** | **Qualification**  **/Certificate achieved** |
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**Appendix:5**

**Training Attendance Log**

**Research Training Attendees List**

**Date:**

**Trainer:**

**Location:**

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| --- | --- | --- | --- |
| **Name** | **Department** | **Email** | **Phone** |
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**Appendix 7: SOP Signature Sheet**

**Please complete and sign this document then retain within your training files**

**Initial the boxes**

1. I have read and understood the contents and requirements of the SOP for patient recruitment (RMC\_SOP\_1\_Patient recruitment) and accept to follow Trust policies implementing it.
2. I have read and understood the contents and requirements of the SOP for patient informed consent form (RMC\_SOP\_2\_Patient informed consent form) and accept to follow Trust policies implementing it.
3. I have read and understood the contents and requirements of the SOP for randomisation (RMC\_SOP\_3\_Randomisation) and accept to follow Trust policies implementing it.
4. I have read and understood the contents and requirements of the SOP for slit skin smear (RMC\_SOP\_4\_Slit skin smear) and accept to follow Trust policies implementing it.
5. I have read and understood the contents and requirements of the SOP for skin biopsy and histopathology (RMC\_SOP\_5\_Skin biopsy and Histopathology) and accept to follow Trust policies implementing it.
6. I have read and understood the contents and requirements of the SOP for Molecular viability assay (MVA) (RMC\_SOP\_6\_MVA) and accept to follow Trust policies implementing it.
7. I have read and understood the contents and requirements of the SOP for Mouse Footpad (MFP) (RMC\_SOP\_7\_MFP) and accept to follow Trust policies implementing it.
8. I have read and understood the contents and requirements of the SOP for Data Management (RMC\_SOP\_8\_Data Management) and accept to follow Trust policies implementing it.
9. I have read and understood the contents and requirements of the SOP for patient follow up (RMC\_SOP\_9\_Follow up) and accept to follow Trust policies implementing it.
10. I have read and understood the contents and requirements of the SOP for adverse event (RMC\_SOP\_10\_adverse event) and accept to follow Trust policies implementing it.
11. I have read and understood the contents and requirements of the SOP for patient withdrawal (RMC\_SOP\_11\_Patient withdrawal) and accept to follow Trust policies implementing it.
12. I have read and understood the contents and requirements of the SOP for End of study (RMC\_SOP\_12\_End of study) and accept to follow Trust policies implementing it.
13. I have read and understood the contents and requirements of the SOP for drug disposal (RMC\_SOP\_13\_Drug disposal) and accept to follow Trust policies implementing it.