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| A Comparative Multicentric Non-Infireority Clinical Trial of WHOMBMDT with a New Monthly Chemotherapy Regime containing Rifampicin, Moxifloxacin and Clarithromycin (RMC) on Multibacillary patients from IndiaStandard Operating Procedure 12End-of Study | | | |
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**1.** **PURPOSE**

This document outlines the process of termination of the study.

### 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 SOP applies to the process of ending the study

**4. Responsibilities**

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| **Role** | **Responsibility** |
| RMC Principal  Investigator | * Ultimately responsible for ensuring RMC study procedures obtain ethics approval and that ICH GCP guidelines and this SOP are adhered to by all staff. |
| Local Study researcher/ Clinician | Responsible for:   * Counselling participant regarding care after the end of the study * Assuring all participant will be cared for after the end of the study. * Providing referral and guidance to all participants at the end of the study. * Documenting end of the study procedure. |
| Clinical Trial Co-ordinator | Responsible for:   * Ensuring appropriate staff members are trained on the procedures of this SOP. * Following up on the efficiency of data collection flow. |

### 5. PROCEDURE

The end-of-the study is defined as the date of the last subject’s last scheduled visit or the actual date of the follow-up contact, whichever is longer.

All data will be registered on the electronic data collection tool (Easy research) and on the Investigator Site File (ISF).

All participants will receive guidance regarding care after the study termination and will be referred to appropriate care.

Data and all appropriate documentation will be stored for a minimum of 5 years after the completion of the study, including the follow-up period.

### 6. TRAINING

Each staff member has direct access to applicable SOP.

Each staff member reviews the applicable SOP once a year.

All SOP training is documented and tracked in the training log located in the ISF.

New staff are trained on applicable SOP within 30 days of employment and all SOPs within 90 days of employment.

Staff members whose duties fall within this SOP scope are retrained within 14 days of the approval of each SOP revision.

### 7. REFERENCES

1. RMC Protocol