Title	**Study Initiation Monitoring Site Visit**
SOP Code	2R2 SOP12_06Jul2020
Effective Date	06 July 2020

One study initiation monitoring site visit should

APPENDIX 1

Example of an agenda/schedule and training points for visit

[*include dates & times, if the site has several clinics to be visited a list of the times & dates for each clinic visit should be included. The order of the agenda will be dependent upon availability of staff and timing of visit]*

Meet with the site investigator & study coordinator if applicable
- Review administrative
- Review questions/issues at site
- Discuss primary objective of visit

Review essential documents, Master binder (regulatory review as required)

Facilities visit (research office, clinics, radiology (if applicable), Laboratory and PK facilities, study medications storage and dispensing facilities)

Presentation of the overview of the study

CRFs and SOP training

Training on study medication blinding and dispending in clinics

Any other topics, issues, questions can be added to the agenda

Summary meeting (findings, recommendations, next step, etc)

TRAINING POINTS

Protocol review & questions
Primary & Secondary outcomes

Review Site Start-up Procedures & Requirements
Review Good Clinical Practice
Master binder & essential documents

Screening & recruitment procedures for potential patients
Screening - Inclusion & exclusion criteria
Inform consent/assent/parental
Data collection – case report form (CRF) & website
Contact information (identification form)
Randomization on website & Manual randomization

Follow-up during treatment
Medical examination and investigations needed during follow-up
Data collection – case report form (CRF) & website
Maintenance of contact information

Compliance, Adverse events, Other medications

Adverse event management & reporting
Data collection – case report form (CRF) & website

Follow-up post treatment
Screening for active TB
Maintenance of contact information

End of treatment
Data collection – case report form (CRF) & website

Follow-up post treatment
Data collection – case report form (CRF) & website

Active TB management & reporting
Data collection – case report form (CRF) & website

Death management & reporting
Data collection – case report form (CRF) & website

End of follow-up post treatment
Data collection – case report form (CRF) & website

PK sub-study
Population, blood collection, storage & shipping
Data collection – case report form (CRF) & website

Summary & next steps

RESOURCES
1. Resources/procedures: study medication blinding and storage, laboratory testing, medications, dispensing, internet access
2. Facility tour (research room, clinic, pharmacy, Lab, CXR if applicable)

APPENDIX 2 - Summary of site initiation training session for <*Name of the site*>

SITE INTITIATION TRAINING

Task and supportive documents	Action

APPENDIX 4 - Master Binder review - Essential documents for the study at <*Name of the site*>

APPENDIX 6

MONITORING SITE VISIT LOG

2R2: Higher dose Rifampin for 2 months vs Standard dose Rifampin for Latent TB: a 3-arm randomized trial.

Site name:
Site investigator:
Study Coordinator:

Site Visit Date		Type of monitoring visit	Names/ Signatures	
From	To		Monitor	Site Personnel