Study Initiation Checklist

Short, all-oral Regimens for Rifampicin-resistant Tuberculosis

ShORRT Research Package

Version June 2020

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1. Purpose of this document

When to use this check list?

This checklist:

1. Is intended to be used when preparing for the conduct of a ShORRT study in order to plan for all key aspects of such study.
2. should be checked again prior to commencing the study to ensure that everything is in place to start.
3. should be stored in the investigator file to document that this check was done.

Please note that this is a generic document and it should be adapted to the study setting.

1.1. More on ShORRT

The Special Programme for Research and Training in Tropical Diseases (TDR) in close collaboration with the Global TB Programme at WHO and technical partners is leading the development of ShORRT (Short, all-Oral Regimens for Rifampicin-resistant Tuberculosis), an operational research package to assess the effectiveness, safety, feasibility, acceptability, cost and impact (including on health-related quality of life) of the use of all-oral shorter drug regimens for adults and children with MDR/RR-TB.

By providing a standardised methodology, ShORRT aims to facilitate the conduct of operational research on all-oral shorter MDR/RR-TB treatment regimens by countries, and to generate data that are harmonised across different settings.

ShORRT includes a master protocol, data collection tools and key study procedures that investigators can adapt. The generic protocol is currently available in English, French, Spanish and Portuguese.

Evidence from this research can play a key role in informing programmatic implementation at the country level, and also provide important data to the global TB community to strengthen the evidence base and inform treatment guidelines.

A number of essential requirements need to be in place before initiating the study. These include, for example, the procurement and in country availability of the drugs under investigation, receipt of ethics approval, organisation of the study team and governance. The purpose of this document is to provide country investigators with a checklist of key aspects to consider before launching their study, and to aid them in planning the study activities.

This document complements the Country Preliminary Assessment document which country investigators may have employed when developing their study protocol.

Key resources

- 2020 WHO Consolidated guidelines on tuberculosis: Module 4 – Drug-resistant TB treatment
- 2020 WHO Operational Handbook on tuberculosis: Module 4 – Drug-resistant TB treatment
- 2014 WHO *Companion Handbook to the WHO guidelines for the programmatic management of drug-resistant tuberculosis*

2. The checklist

The following table summarises key areas of the research project that investigators should consider before starting the study. It is not intended to be an exhaustive list and it should be adapted to the study setting.

Country	
Protocol title	
Institution	

CHECKLIST			**Remarks and further actions**
DRUGS UNDER INVESTIGATION			
In-country availability of drugs under investigation	*Are the drugs under investigation been procured and are they available in the country?*	☐ Yes ☐ No	If No, expected/tentative in-country availability: [___|___] **If this cannot be determined, you should reconsider the start date of your study**
LABORATORY			
Laboratory capacity for detecting Fluoroquinolones resistance	*Is there capacity to test all patients for resistance to Fluoroquinolones?*	☐ Yes ☐ No	**If No, please reconsider the start date of your study**
Sputum transportation	*Has sputum transportation from the health facility to the national reference laboratory been arranged for FQ resistance testing for RR and MDR-TB patients?*	☐ Yes ☐ No	**If No, please reconsider the start date of your study**
Storage of baseline and recurrent samples?	*Did you define the procedure to store baseline samples to differentiate relapses and re-infections if a recurrence occurs?*	☐ Yes ☐ No	If No, please consider discussing this with technical partners and the reference lab
Paired samples (baseline and recurrent) analysis	*Did you define where the paired samples (baseline and recurrent) will be analysed?*	☐ Yes ☐ No ☐ NA	This might not be applicable (NA) if you didn't decide to differentiate re-infections and relapses
Specimen shipment	*If the molecular test for paired samples analysis are not done in the country, has sputum shipment to the collaborating laboratory (e.g. SRL) been arranged?*	☐ Yes ☐ No ☐ NA	
ETHICS APPROVAL PROCESS			
National ethics approval	*Has approval from the national ethics review committee been obtained?*	☐ Yes ☐ No	If No, expected approval date: [___|___] **Until ethics approval has been obtained, you should not enrol patients in the study**
	Has notification of approval been reported to relevant technical partners and funders?	☐ Yes ☐ No	
Informed consent form	*Has the informed consent form been translated in the local language(s), as appropriate?*	☐ Yes ☐ No ☐ NA	If No, is this because there is no need? If the case tick NA

	Did you define where to archive the signed informed consent forms?	☐ Yes ☐ No	If no, please plan to file them in a dedicated folder(s) as signed informed consent forms are key documents to archive
Informed assent form	*Has the informed assent form been piloted to make sure it can be easily understood by children?*	☐ Yes ☐ No ☐ NA	NA if children are not recruited in your study
STUDY GOVERNANCE			
Project steering committee	*Has the project steering committee been established with clear roles and responsibilities?*	☐ Yes ☐ No	The study steering committee provides overall supervision of the study and monitors progress.
Study coordinator	*Has the survey coordinator been identified ?*	☐ Yes ☐ No	
Coordination team	*Has the coordination of the study been established?*	☐ Yes ☐ No	The coordination team deals with the day-to-day activities of the study.
Responsibilities	*Have the roles and responsibilities of the study team been defined?*	☐ Yes ☐ No	
Meetings	*Have the frequency and modality (e.g. face to face, remote) of the meetings of the steering committee been agreed?*	☐ Yes ☐ No	
ON SITE STUDY TEAM			
Roles & responsibilities of key staff members	*Have the roles and responsibilities of staff involved in the study been defined?*	☐ Yes ☐ No	
Training and capacity building of study team on study procedures	*Have the study team been trained on the study procedures?*	☐ Yes ☐ No	
Training on GCP principles	*Have staff been trained on GCP principles (including the informed consent process)?*	☐ Yes ☐ No	
Communication	*Is the communication flow between all study actors and the coordination team well defined (i.e. everyone knows whom to contact in case of issues)?*	☐ Yes ☐ No	

DATA COLLECTION & MANAGEMENT			
Piloting of the data collection tool	*Has the data collection tool(s) been piloted?*	☐ Yes ☐ No	
	Is a final version that takes into account your feedback available to you?	☐ Yes ☐ No	
Data management staff	*Has the data manager been identified and employed on the study?*	☐ Yes ☐ No	
If paper-based data collection	*Has the data flow been defined from where data are written on paper CRF to where data is captured electronically?*	☐ Yes ☐ No ☐ NA	NA if electronic data collection
If electronic data collection, Internet connectivity	*Has internet connectivity at the study sites been checked?*	☐ Yes ☐ No ☐ NA	NA if paper-based data collection
	How often will data be uploaded online?	[_____]	
Devices for data collection or data entry	*Have devices for data collection (tablets/laptops) been purchased and set up with the most recent version of the data collection software?*	☐ Yes ☐ No	
Data validation	*Did you define what key data that have been collected should be validated?*	☐ Yes ☐ No	Key data are data that are critical for the study and for which no errors can be accepted such as (1) drug resistance profile, (2) treatment regimen, (3) treatment outcome
MONITORING AND QUALITY ASSURANCE			
M&E plan (internal quality control)	*Is the plan for the study monitoring and evaluation and daily/periodic supervision roles spelled out?*	☐ Yes ☐ No	
Frequency	*Is frequency of monitoring considered appropriate to the number of study sites and recruitment rate?*	☐ Yes ☐ No	
Recruitment rate	*Did you define a monthly recruitment rate?*	☐ Yes ☐ No	
Safety monitoring, management, reporting and recording	*Is there capacity to monitor patients for adverse events, including ECG, as needed?*	☐ Yes ☐ No	
	Have safety monitoring, management and reporting procedures been defined?	☐ Yes ☐ No	
	Have job aids been developed?	☐ Yes ☐ No	

FUNDING			
Availability of funding	*Is funding available to ensure management (treatment, lab tests, X-ray, ECG, etc.) and follow up of all patients recruited?*	☐ Yes ☐ No	**If No, please reconsider the start date of your study**
TECHNICAL ASSISTANCE			
Support and technical assistance required	*Is there a need for technical assistance?*	☐ Yes ☐ No	
	If yes, what areas of the study require technical assistance? 1. Project management 2. Data management 3. External monitoring 4. Data analysis, reporting and writing up	☐ ☐ ☐ ☐	
	Have the terms of reference for technical assistance been developed?	☐ Yes ☐ No	
	Has the funding source for technical assistance been defined?	☐ Yes ☐ No	
General comments	Is everything in place to start enrolling patients?	☐ Yes ☐ No ☐ With conditions:	If conditions, please list them here:

Date: ___ / ___ /___

Checklist completed by: _____