Short, all-oral Regimens for Rifampicin-resistant Tuberculosis
ShORRT Research Package

Readiness checklist of the study site involved in patient recruitment and follow-up, and of the reference laboratory

About this document

The purpose of these ShORRT study site readiness and follow-up and reference laboratory readiness checklists is to verify that the sites have the appropriate characteristics to conduct the study.

These checklists are intended **to be used before the start of a ShORRT study to prepare the site(s) to conduct the study, or during the initiation visit to verify that everything is in place to initiate the study.**

These lists when completed should be kept in the investigator's file to document that this assessment was performed.

This document is comprised of three checklists:

- Patient recruitment and follow-up site readiness checklist ***(to be replicated for every study site)***
- Readiness checklist for the laboratory of the patient recruitment and follow-up site ***(to be replicated for every study site)***
- Readiness checklist of the reference laboratory

Please note that these checklists include those elements that are considered key to the conduct of ShORRT, but they are not exhaustive and each country should adapt them to their context, as appropriate.

Readiness checklist for patient recruitment and follow-up site

Country			
Name of study site			
Checklist			**Remarks and follow-up actions**
STUDY TEAM			
Focal person for the study	Has a study focal person been identified and appointed?	☐ Yes ☐ No	
Training of study team at the study site on GCP	Have staff received training in GCP principles (including the informed consent process)?	☐ Yes ☐ No	
Roles and responsibilities of the personnel involved in the study on site	Have the roles and responsibilities of the staff at the study site been defined? *Example: Is there someone dedicated to sending the samples to the lab?*	☐ Yes ☐ No	
Training and capacity building of the team on study procedures	Has the study team been trained on the procedures? *Example:* Has the clinician been trained in the tests involved in the study (according to the study follow-up schedule)?	☐ Yes ☐ No	
Communication between the staff at the site involved in the study and between the study site and the study coordinator	Is the communication flow between all study actors and the coordination team well defined (i.e. everyone knows who to contact if there is a problem)? *Example: In the event of an adverse event, has the communication flow been defined?*	☐ Yes ☐ No	
EQUIPMENT			
Weight scale	Is a weight scale available at the study site and is it working?	☐ Yes ☐ No	
Tape measure	Is a tape measure available?	☐ Yes ☐ No	
ECG	Is an ECG machine available and functioning?	☐ Yes ☐ No	*If no, a referral system should be in place*
Snellen test	Is the Snellen test available?	☐ Yes ☐ No ☐ NA	*If no but required for the follow-up of the patient, a referral system should be in place*

Ishihara test	Is the Ishihara test available?	☐ Yes ☐ No ☐ NA	*If no but required for the follow-up of the patient, a referral system should be in place*
Audiometer	Is an audiometer available?	☐ Yes ☐ No ☐ NA	*If no but required for the follow-up of the patient, a referral system should be in place*
Electricity	Is there electricity at the study site? Is it stable?	☐ Yes ☐ No	
Internet	Is there an internet connection for online data entry on tablets/laptops?	☐ Yes ☐ No	*If there is no internet connection, consider using tablets instead of laptops to enter data "offline"*
STUDY DOCUMENTATION			
Consent form	Have copies of the informed consent form been printed and are they available at the study site?	☐ Yes ☐ No	
Protocol	Does the study site have the latest version of the study protocol?	☐ Yes ☐ No	
Ethics approval	Is a copy of the ethics approval available at the study site?	☐ Yes ☐ No	
Key study procedures	Are the key study procedures available at the study site?	☐ Yes ☐ No	
If data collection is paper-based, case report form at the study sites	Have the data collection forms been printed and are they available at the study site?	☐ Yes ☐ No	
Data source documents checklist	Is the list of the source documents available? *(Please note that this checklist indicates in which document study staff can find each piece of information)*	☐ Yes ☐ No	
Secure place for the study documentation	*Is there a secure place at the study site where the study documentation can be stored?*	☐ Yes ☐ No	
OVERALL CONCLUSION OF THE ASSESSMENT			
Is the study site ready to commence the study?		☐ Yes ☐ No	
If "No", please list the recommended activities to perform for the site to be ready?		• _____ • _____ • _____ • _____ • _____	

Date: ___ / ___ /___

Completed by: _____

Readiness checklist of the laboratory at the study site

THIS SECTION SHOULD BE COMPLETED AT THE Xpert MTB/RIF SITE *(you should duplicate this table according to the number of sites involved in the study)*			
Country:			
Name of laboratory:			
Checklist			**Remarks and follow-up actions**
1.	***Tests carried out***	☐ Microscopy ☐ Xpert MTB/RIF	
2.	***Correct identification of samples (labelling, verification of conformity)?***	☐ Yes ☐ No	
3.	***Microscopy***		
3.1	*Optimal quality control of colorants (new batch, routine, process)?*	☐ Yes ☐ No	
3.2	*Colorants well preserved?*	☐ Yes ☐ No	
3.3	*Smears well done (size; thickness; homogeneity)?*	☐ Yes ☐ No	
3.4	*Optimal staining (drying and fixation of smears, staining time)?*	☐ Yes ☐ No	
3.5	*Acceptable previous quarter review results (0HFN, 0HFP, +/-EQ)?*	☐ Yes ☐ No	
4.	***Xpert MTB/RIF machine & functioning***		
4.1	*Is an Xpert MTB/RIF machine available?*	☐ Yes ☐ No	
4.2	*Is the Xpert MTB/RIF used in a temperature-controlled environment?*	☐ Yes ☐ No	
4.3	*Is the algorithm for reporting resistant cases in line with WHO recommendations?*	☐ Yes ☐ No	
4.4	*Method employed for detecting Rifampicin resistance?*	☐ Xpert MTB/RIF ☐ Xpert Ultra ☐ Other	*If other, please specify the number of days to have a result?* [_____]
4.5	*Is the storage of cartridges correct?*	☐ Yes ☐ No	

4.6	*What is the type of machine available?*	4 modules: [_____] 16 modules: [_____]	Other (please specify) : [_____]
4.7	*Regular and adequate maintenance (daily, weekly, monthly, quarterly and annually)?*	☐ Yes ☐ No	
4.8	*Number of functioning modules out of total number of modules*	[_____]	
4.9	*Is the handling correct?*	☐ Yes ☐ No	
5	***Usage of Xpert MTB/RIF for the detection of rifampicin resistance***		
5.1.	*Is the study data management system in place?*	☐ Yes ☐ No	
5.2.	*Number of RRs screened / Number of RRs sent to the clinic?*	[_____]	
5.3.	*Person responsible for the study identified and trained?*	☐ Yes ☐ No	
8.Xpert MTB/RIF performance			
8.1	*Period:*	[_____]	
8.2	*Number of tests conducted:*		
8.3	*Error: ____ is _ %. Probably due to improper handling of samples (2008, 5006, 5007) :*	_____%	
8.4.	*% Invalid:*	_____%	
8.5.	*% No results :*	_____%	

Date : ___ / ___ /___

Completed by: _____

Readiness checklist for the reference laboratory

Country:			
Name of the reference laboratory:			
1.Tests of hybridisation on strips (Hain Test*)*			
1.1	*Are the reagents available?*	☐ Yes ☐ No	*If not, please reconsider the start date of the study*
1.2	*Optimal quality (no expired) of consumables and reagents?*	☐ Yes ☐ No ☐ Not evaluated	
1.3	*Correct storage (in the refrigerator / freezer and at monitored temperature) of the reagents?*	☐ Yes ☐ No ☐ Not evaluated	
1.4	*Is the molecular biology infrastructure well-adapted with an adequate organization of work (3 rooms respecting the front step)?*	☐ Yes ☐ No	
1.5	*Correct handling procedure (please complete the activity report presented at the end of the document)?*	☐ Yes ☐ No	
1.6	*Test performed on clinical samples (and not on strains)?*	☐ Yes ☐ No	
1.7	*Is the interpretation of the results correct (see interpretation of already validated strips)?*	☐ Yes ☐ No	
1.8	*Is the deadline for rendering results (collection of samples - rendering of results) satisfactory?*	☐ Yes ☐ No	*If Yes, please specify the number of days* *[_____] days*
1.9	*Is the channel for transmitting results to clinicians efficient? (Availability of results)*	☐ Yes ☐ No	
1.10	*Is resistance to the following drugs being tested?*	RIF ☐ Yes ☐ No INH ☐ Yes ☐ No INJ ☐ Yes ☐ No FQ ☐ Yes ☐ No	*If FQ Hain tests are not performed, another rapid test should be available to quickly detect FQ resistance. This is a requirement before starting a shorter all oral regimen containing FQ drugs.*

1.11	*Are the results of the external quality control for the previous year satisfactory?*	☐ Yes ☐ No ☐ Not done	*If Yes, please specify the results of the performance* *RIF: Se……. Sp…… Concordance…..* *INH: Se……. Sp…… Concordance…..* *INJ: Se……. Sp…… Concordance…..* *FQ: Se ……. Sp…… Concordance…..*
2. Phenotypic sensitivity tests			
2.1	*Which method is utilised?*	☐ Proportion method ☐ Other	*If Other, please specify* _____
2.2	*Medium*	☐ LJ ☐ MGIT ☐ Other	*If Other, please specify* _____
2.3	***LJ medium*** ☐ Not applicable (please go to Section 2.4)		
2.3.1	*List of antibiotics tested (1st and 2nd line)*	[_____] [_____] [_____] [_____]	
2.3.2	*Culture media (incorporated with 1st and 2nd line ATB) prepared on site?*	☐ Yes ☐ No	
2.3.3	*Are culture media available?*	☐ Yes ☐ No	
2.3.4	*Internal quality control results (sterility and fertility) of the prepared media monitored and acceptable*	☐ Yes ☐ No ☐ Not done	
2.3.5	*Is the handling procedure correct?* ***(please complete the activity report presented at the end of the document)***	☐ Yes ☐ No	
2.3.6	*Is the interpretation of the results correct?*	☐ Yes ☐ No	
2.3.7	*Handling time after acceptable culture positivity (less than eight weeks)?*	☐ Yes ☐ No	*If Yes, please specify the number of days:* *[_____] days*
2.4	***MGIT medium*** ☐ Not applicable (please go to Section 3)		

2.4.1	*List of antibiotics tested by MGIT medium*		
2.4.2	*Are the inputs (reagents, consumables) necessary to perform the test available?*	☐ Yes ☐ No	
2.4.3	*Has the calibration been done?*	☐ Yes ☐ No	*If Yes, date of the last calibration : [__ / __ / __]*
2.5	*Adapted infrastructure (negative pressure laboratory, certified class II PSM) for carrying out the tests?*	☐ Yes ☐ No	
2.6	*Is the channel for transmitting results to clinicians efficient? (Availability of results)*	☐ Yes ☐ No	
2.7	*Ability to introduce new drugs? (Equipment, reagents, consumables)*	☐ Yes ☐ No	*Please list the new drugs that can be tested in the lab*
2.8	*Are the results of the external quality control for the previous year satisfactory?*	☐ Yes ☐ No ☐ Not done	*RIF: Se……. Sp…… Concordance…..* *INH: Se……. Sp…… Concordance…..* *INJ: Se……. Sp…… Concordance…..* *FQ: Se ……. Sp…… Concordance…..*
2.9	*Are the results of the comparison of local results with results of samples sent to the reference laboratory satisfactory?*	☐ Yes ☐ No ☐ Not applicable	*RIF: Se……. Sp…… Concordance…..* *INH: Se……. Sp…… Concordance…..* *INJ: Se……. Sp…… Concordance…..* *FQ: Se ……. Sp…… Concordance…..*
3. Samples			
3.1	*Is there an efficient sputum transport system from treatment centres to the national reference laboratory in place?*	☐ Yes ☐ No	
3.2	*Is there an efficient transport system for strains from the national reference laboratory to the supranational laboratory in place?*	☐ Yes ☐ No	
3.3	*Are the system and inputs (Cryoboxes, cryotubes, freezer) retention of baseline samples and in case of relapse in place? (culture strains and pellets)*	☐ Yes ☐ No	
4. Data management			
4.1	*Is there a register of available data?*	☐ Yes ☐ No	

4.2	*Is there a patient data storage system in place?*	☐ Yes ☐ No	
4.3	*Circuit for performing the tests (microscopy, Xpert MTB/RIF and culture)*	[_____]	
5. Personnel			
5.1	*Is there a focal person for the study in the lab?*	☐ Yes ☐ No	***If No, this is a must for conducting the study***
5.2	*The list of tasks for this focal person is defined - someone is appointed to replace this person in case it is required*	☐ Yes ☐ No	***If No, this is a must for conducting the study***
5.3	*This person has been trained on the ShORRT study and knows the key study procedures related to the lab*	☐ Yes ☐ No	***If no, this is a must for conducting the study***
5.4	*A procedure for regular reporting of laboratory activities to the study coordinator is in place*	☐ Yes ☐ No	*If Yes, every week? Every two weeks? Please specify ……* ***If No, this is a must for conducting the study***

Activity report

Period: [___ | ___ | ___]

Number of tests conducted: Invalid/ not interpretable: _____ %

	Conducted N (%)	Valid N (%)	Invalid N (%)	Not interpretable N (%)
LPA 1st line				
LPA 2nd line				

Period: [___ | ___ | ___]

	Conducted N (%)	Valid N (%)	Contaminated N (%)	In progress N (%)
DST 1st line				
DST 2nd line				

Date: ___ / ___ /___

Completed by: _____