Title	2R2 website: site user's manual
SOP Code	2R2 SOP20_08Sep2020
Effective Date	15 September 2020

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1.0 Purpose(s)

The objective of this standard operating procedure (SOP) is to ensure users at study sites and at the coordinating center can correctly use the study website, for collection of study participants' data.

The SOP will ensure:

- data are collected in compliance with the standards of Good Clinical Practice and the study protocol;
- the safety and protection of study participants, as communication of adverse events is also done through the use of the study website;
- the quality of the data produced by the study.

2.0 Scope: Persons affected

This SOP concerns: coordinating center, site principal investigators, site coordinators and site research teams involved in conducting research with human subjects for the study entitled -2R² Higher dose Rifampin for 2 months vs Standard dose Rifampin for Latent TB: a 3-arm randomized trial.

3.0 Responsibilities.

The trial coordinating center is responsible for developing and maintaining this SOP and for making it available at the clinical research site. At the clinical trial site, the site principal investigator is responsible for adoption of the processes described in the SOP.

4.0 Definition(s) and abbreviations

- I. AE: Adverse event
- II. ATB: Active TB
- III. **Case Report Form (CRF)**: A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the coordinating center on each trial participant in this research study.
- **IV. Coordinating centre:** research staff involved in running the 2R² study who are based at Research Institute of McGill University Health Centre (RI-MUHC)
- V. CXR: Chest x-ray
- VI. **eCRF**: the electronic version of CRF. eCRFs are in the 2R2 website.

5.0 Procedures

5.1. Procedures to access the 2R2 online database

Access the database using an internet browser.

- 1. Open an Internet browser. Please use **Google Chrome**, as this is the preferred browser for 2R2 database.
- 2. Enter the URL https://2r2.crc.chus.qc.ca/

At the first access:

2R2 SOP20 Website site user's manual_ 08Sep2020 Higher dose Rifampin for 2 months vs Standard dose Rifampin for Latent TB: a 3-arm randomized trial.

- 1. Enter your username. Your username have been assigned to you by the coordinating center. Please contact the coordinating center if you do not have an username.
- 2. Click on "Forgot your password? / Mot de passe oublié?" (figure 1)

2R ²	user name / nom d'utilisateur password / mot de passe Log in Forgot your password? / Mot de passe oublié?
© Laboratoire de télématique biomédicale du RSRQ, 2019	9
RSROE Béseau de recherche en Santé Respiratoire du Québec	

Forgot your password? / Mot de passe oublié?

Your user name and your password will be sent to the email address you provide in the box below. Votre code d'utilisateur et mot de passe vous sera envoyé à l'adresse entrée plus bas.

email address / adresse courriel	
	Send
Return to login page / Retour au Log in	

This window will appear,

Type your work email (the one the coordinating center uses to contact you) and you will receive an email with your password.

For all subsequent accesses:

- 1. Open an Internet browser. The preferred browser for 2R2 database is Google chrome, please use this one if possible.
- 2. Enter the URL <u>https://2r2.crc.chus.qc.ca/</u>
- 3. Type your username
- 4. Type your password
- 5. Click on the "Log in" button

Figure 2	
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	user name / nom d'utilisateur password / mot de passe
	Log in Forgot your password? / Mot de passe oublié?
Laboratoire de télématique biomédicale du RSRQ, 2019	a
RSRQ Réseu de recherche en Bréseu de recherche en	

**Note**: data entered in the 2R2 website are linked to the username of person entering that case report form for the first time. Please do not share your password with anyone.

#### 5.2 General information on the main page

Once you completed the login to the website, you will see the home page (**figure 3**) From that page you can also have access to the contact for the coordinating center.

Figure 3	
2	la Home
	Welcome to the 2R2 database portal!
	This is the official website for the study: A 3-arm randomized clinical trial to assess completion and safety of higher dose Rifampin for 2 months vs Standard dose Rifampin for Latent TB infection (2R2).
Logged in as <b>demo</b> Connected at <b>24/08/2020 - 9:25:08 AM</b>	This website is indented to enter data collected in the paper Clinical Research Forms (CRFs)
[Sign out]	Please enter information on this website only after having completed the paper CRFs.
Home	The website is for use only by the 2R2 research personnel in the following study sites:
Data capture	Calgary (CAL)
E Dashboard	Edmonton (EDM) Indonesia (IND)
Add / Select records	Montreal (MTL)
Help	Vietnam (VIE)
(***) Frequently asked quest (FAO)	The entry of information will be linked to your username and password.
Glossary	Data in the website must be non-nominal: please remove names, date of birth or other identifying information from all narratives entered in the website.
	For any questions on the website use or if you are unable to connect, please contact the trial coordinating center federica.freqonese@mail.mcoill.ca
	IMPORTANT NOTE: This web application is optimized for use with Chrome, the Google browser. For best results, be sure to use this browser.
	© This application was made by the Laboratoire de Télématique Biomédicale of the QRHN and is protected by current copyright legislation. Director: Dr Eric Rousseau, PhD. Coding: Mrs Mina Dilgui, M. Yvan Fortier

Once you are into the website, you will see on the top left menu, under the study logo, your name, date and time. You can also sign out/disconnect at any time. You will be disconnected form the website after 20 minutes of inactivity. (figure 4)

# Figure 4

		in nome
		Welcome to the 2R2 database portal!
-Name of the person who is connected		This is the official website for the study: A 3-arm randomized clinical trial to assess completion and safety of higher dose Rifampin for 2 months vs Standard dose Rifampin for Latent TB Infection (2R2).
data and time of	Logged in as demo Connected at 24/08/2020 - 9:25:08 AM	This website is indented to enter data collected in the paper Clinical Research Forms (CRFs)
-date and time of	[Sign out]	Please enter information on this website only after having completed the paper CRFs.
connection	Home	The website is for use only by the 2R2 research personnel in the following study sites:
-sign out-disconnect	Data capture Dashboard Add / Select records Help	Calgary (CAL) Edmonton (EDM) Indonesia (IND) Montreal (MTL) Vancouver (VAN) Vietnam (VIE) The entry of Information will be linked to your username and password.
	Frequently asked quest. (FAQ) Glossary Note to file	Data in the website must be non-nominal: please remove names, date of birth or other identifying information from all narratives entered in the website.
	_	For any questions on the website use or if you are unable to connect, please contact the trial coordinating center federica.fregonese@mail.mcgill.ca
		IMPORTANT NOTE: This web application is optimized for use with Chrome, the Google browser. For best results, be sure to use this browser.
		© This application was made by the Laboratoire de Télématique Biomédicale of the QRHN and is protected by current copyright legislation. Director: Dr Eric Rousseau, PhD. Coding: Mrs Mina Diigui, M. Yvan Fortier

- 6 11-----

#### 5.3 Use of the website for site user

Site users are the site research coordinators at each study site, unless not differently agreed between site PI and coordinating center.

A site user can enter, review and modify only information for participants of that study sites. **Note**: remind to fill in the CRF in the 2R2 website only after having completed the paper CRFs.

# 5.3.1 Access to the main participant table

If you want to review a participant's file or if you want to add a new participant, click on "Add/select records" in the left menu (figure 5)

#### Figure 5



It will bring you to the main table to have access to the following lists of all participants' files of your site: (**figure 6**)

Director: Dr Eric Rousseau, PhD. Coding: Mrs Mina Dligui, M. Yvan Fortier

# Figure 6

	lacktrice and the select participant record	Version 1, last update October 2 2019
	Participant's file	
	AS1 Screening ongoing (1)	select record V
	AS2 Randomized (0)	select record V
Logged in as demo Connected at 24/08/2020 - 9:54:24 AM	AS3 Excluded (1)	select record
[Sign out]	AS4 Excluded post randomization(3)	select record 🗸 🕜
Data canture	Add a new participant Id	📭
Dashboard     Add / Select records	Follow-Up during treatment	
Help	Follow-Up during treatment (7)	select record V
🤒 Frequently asked quest. (FAQ)	Follow-Up post treatment	
Glossary	Follow-Up post treatment(1)	select record V
Note to me	Adverse events	
	Adverse events initial (4)	select record V
	Adverse events final (4)	select record V
	Active TB	
	Active TB initial(3)	select record
	Active TB final (3)	select record V

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Participants are here classified as

- Screening ongoing if they have started screening but did not complete it yet (i.e. they have started any parts of **CRF1**, **2** or **3** but they are not ready to be randomized yet);
- Randomized;
- Excluded (i.e. **CRF1**, **2** or **3** clearly met one of the exclusion criteria before randomization);
- Excluded post randomization (i.e. one of the exclusion criteria have been known after randomization took place and coordinating center has agreed to consider the participant "excluded after randomization").

You can click on the questions marks to see the meaning of these categories.

## 5.3.2 How to create a new participant ID

To add a new participant, click on "**show section**". You will have access to create a new participant ID (**figure 7**).

Figure 7

-						
2	📓 Add or select participan	t record		Version 1, last u	update October 2 2	2019
	Participant's file					
	AS1	Screening ongoing (1)	select record	~	0	
	AS2	Randomized (1)	select record	~	0	
gged in as <b>demo</b> innected at <b>24/08/2020 - 11:29:15 AM</b>	AS3	Excluded (2)	select record	~	0	
[Sign out]	AS4	Excluded post randomization(5)	select record	~	0	
ata canture	Add a new participant Id				(	
Deebboard						Show section
Add / Select records	Follow-Up during treatment					
elp		Follow-Up during treatment (7)	select record	~		
Frequently asked quest. (FAQ)	Follow-Up post treatment					
Glossary		Follow-Up post treatment(1)	select record	~		
	Adverse events					
		Adverse events initial (4)	select record	~		
		Adverse events final (4)	select record	~		
	Active TB					
		Active TB initial(3)	select record	~		
		Active TB final (3)	select record	~		

Then click on the "Create a new participant ID" button to have access to the CRF1: Initial screening form (figure 8).

### Figure 8

2	Add or select participant record		Version 1, last update October 2 2019				
	Participant's file						
	A51	Screening ongoing (1)	select record	~	(2)		
	AS2	Randomized (1)	select record	~	(?)		
in as <b>demo</b> ted at <b>24/08/2020 - 11:29:15 AM</b>	AS3	Excluded (2)	select record	~	0		
[Sign out]	A54	Excluded post randomization(5)	select record	~	0		
anture	Add a new partic	ipant ld			<b>-</b>		
apture		Center(s)	CAL	~			
Add / Select records		Create a new participant Id	Create a new partic	ipant Id			
requently asked quest. (EAO)	Follow-Up during	g treatment					
Glossary		Follow-Up during treatment (7)	select record	~			
Note to file	Follow-Up post t	reatment					
		Follow-Up post treatment(1)	select record	~			
	Adverse events						
		Adverse events initial (4)	select record	~			
		Adverse events final (4)	select record	~			
	Active TB						
		Active TB initial(3)	select record	~			
		Active TB final (3)	select record	~			

The CRF-1: Initial screening form will appear, and you can transcribe all the data that you already have on your paper copy of **CRF1**. (figure 9)

#### Figure 9

Home
Data capture
Add / Select records

E Glossary

Help

Logged in as ssenecal Connected at 21/08/2020 - 12:40:12 PP

Frequently asked quest. (FAQ)

[Log

J	Editing participant's Initial screening form					
so	Research staff completing the form (?)					
<b>S</b> 1	Date *			15	Today	dd-mm
Inc	lusion criteria					
<b>S</b> 2	Treatment of LTBI has been recommended, and the study participant, who is >= 10 years of age, has agreed to meet with the research personnel *	-	~			
\$3	Age *		yea	rs old		
54	Sex *	-		~		
55	Was TST testing done? *	-	~			
58	Is study participant a TST converter? *	-	~			
S10	Was QFT testing done? *	-	~			
Exe	clusion criteria					
S13	Was study participant a contact of a TB patient known to have TB resistant to RIF? *	-	~			
S14	Does study participant have a history of allergy/hypersensitivity to Rifampin, Rifabutin or Rifapentine? *	-	~			
S15	Is study participant pregnant? *	-	~			
S16	Does study participant have Active TB? *	-	~			
S17	Has study participant already started treatment for LTBI?* (?)	-	~			
<b>S18</b>	Does the participant take medications that the medical team judge not manageable with rifampin and that participant does not want to change? * (?)	-	۷			
S19	Study participant was already treated for TB disease or LTBI *	-	~			
S20	Study participant has AST or ALT at least 3 times higher than upper limit of normal *	-	۷			
Co	nfirmation of eligibility					
521	Is the participant eligible according to the 2R2 website?					
	NOTE: If participants is not eligible according to the website, but you think that eligible, review and revise information and if still non eligible, conta	study particip ot the coordin	ant sh nating	ould t	be con	sidere
		Save/Stay	on pa	ge		

2R2 SOP20 Website site user's manual_08Sep2020 Higher dose Rifampin for 2 months vs Standard dose Rifampin for Latent TB: a 3-arm randomized trial. Once you click on "Save/Stay on page" at the bottom of the page, an ID number for the participant is created and appear in the left menu and on the top of the form. (figure 10) Figure 10

2	Initial screening form	Version 1, last update September 18th 2019
	Editing participant's CAL-11 Initial screening form	
	so Research staff completing the form (?)	Utilisateur de test
Logged in as <b>demo</b>	si Date *	28-08-2020 Today dd-mm-yyyy
Connected at 28/08/2020 - 10:08:51 AM	Inclusion criteria	
[Sign out]	S2 Treatment of LTBI has been recommended, and the study participant, who is >= 10 years of age, has agreed to meet with the research personnel *	Yes 🗸
Data capture	ss Age *	45 years old
🕅 Dashboard	s4 Sex*	Male 🗸
Add / Select records	ss Was TST testing done? *	No 🗸
CRF1-3 for participant CAL-11 [Change]	ss Is study participant a TST converter? *	No 🗸
Initial screening	s10 Was QFT testing done? *	Yes 🗸
<ul> <li>Eligibility &amp; consent</li> <li>Randomization &amp; Study drugs</li> </ul>	s11 i If Yes, date of test	28-08-2020 Today dd-mm-yyyy
Help	s12 Results of QFT	Positive V
Frequently asked quest (EAQ)	Exclusion criteria	
Glossary	$_{\rm S13}$ Was study participant a contact of a TB patient known to have TB resistant to RIF? *	No 🗸
<ul> <li>Note to me</li> </ul>	Does study participant have a history of allergy/hypersensitivity to Rifampin, Rifabutin or Rifapentine? *	No 🗸
	S16 Does study participant have Active TB? *	No 🗸
	s17 Has study participant already started treatment for LTBI?* 🔞	No 🗸
	Does the participant take medications that the medical team judge not manageable with rifampin and that participant does not want to change? * 📀	No 🗸
	s19 Study participant was already treated for TB disease or LTBI $\star$	No 🗸
	Study participant has AST or ALT at least 3 times higher than upper limit of normal OR hematological abnormalities of Grade 3 or 4 ?*	No 🗸
	Confirmation of eligibility	
	s21 Is the participant eligible according to the 2R2 website?	Yes, this patient IS eligible
	NOTE: If participants is not eligible according to the website, but you think that s eligible, review and revise information and if still non eligible, contact	study participant should be considered ct the coordinating center
		Go to next form
		Save/Stay on page
		Save/Exit

**Note**: an ID will be created for all participant you enter data for, independently if this participant will be eligible or not.

Once you have clicked on "**Save/stay on page**", if a patient is eligible, S21 will show the answer automatically. If for 2R2 website the participant is eligible, the answer to S21 will be "Yes, this patient is eligible".

You can then continue by clicking on "Go to next form".

If the 2R2 Websites considers that the patient is NOT eligible, then answer to question S21 will appear to be "No, this patient is not eligible". (figure 11) Figure 11

	Initial screening form	Version 1, last update September 18th 2019
	Editing participant's CAL-12 Initial screening form	
	so Research staff completing the form @	Utilisateur de test
Logned in as demo	si Date *	28-08-2020 Today dd-mm-yyyy
Connected at 28/08/2020 - 10:08:51 AM	Inclusion criteria	
[Sign out]	S2 Treatment of LTBI has been recommended, and the study participant, who is >= 10 years of age, has agreed to meet with the research personnel *	Yes 🗸
Data capture	ss Age *	45 years old
Dashboard	54 Sex *	Male 🗸
Add / Select records	ss Was TST testing done? *	No 🗸
CRF1-3 for participant CAL-12 [Change]	ss Is study participant a TST converter? *	No 🗸
Initial screening	s10 Was QFT testing done? *	Yes 🗸
Randomization & Study drugs	s11 i If Yes, date of test	28-08-2020 Today dd-mm-yyyy
Help	s12 Results of QFT	Positive 🗸
Frequently asked quest. (FAQ) Glossary	Exclusion criteria	
Note to file	Was study participant a contact of a TB patient known to have TB resistant to RIF? *	Yes 🗸
	514 Does study participant have a history of allergy/hypersensitivity to Rifampin, Rifabutin or Rifapentine? *	No 🗸
	S16 Does study participant have Active TB? *	No 🗸
	s17 Has study participant already started treatment for LTBI? * 🔞	No 🗸
	Does the participant take medications that the medical team judge not manageable with rifampin and that participant does not want to change? *	No 🗸
	s19 Study participant was already treated for TB disease or LTBI $\star$	No 🗸
	Study participant has AST or ALT at least 3 times higher than upper limit of normal OR hematological abnormalities of Grade 3 or 4 ?*	No 🗸
	Confirmation of eligibility	
	s21 Is the participant eligible according to the 2R2 website?	No, this patient is NOT eligible
	NOTE: If participants is not eligible according to the website, but you think that s eligible, review and revise information and if still non eligible, conta	study participant should be considered ict the coordinating center
		Save/Stay on page Save/Exit

If you think that this patient should be consider eligible, review and revise information entered and if still non-eligible, contact the coordinating center.

# 5.3.3 How to randomize a new participant

If participant is eligible, continue to the Eligibility & Consent page and transcribe in this page the data you have collected in paper CRF2, then "save/stay on the page" (figure 12)

	2	Eligibility and Consent	Version 1, last update September 18th 2019
		Editing participant's CAL-11 Eligibility & Consent form	
		co Research staff who completed the form 🕐	
	Longed in as demo	Consent and participation	
	Connected at 31/08/2020 - 10:00:38 AM	Ls this participant a member of the same household as someone who has recently been randomized in this trial? *	- •
	Home	C4 Has study participant consented to participate, or if a minor, did his/her guardian signed consent ? *	- •
	Data capture		Save/Go to next form
	Dashboard Add / Select records		Save/Stay on page
			Save/Exit
	CRF1-3 for participant CAL-11 [Change]		
~	Initial screening     Elicibility & concent		
V	Randomization & Study drugs		
	Help		
	<ul> <li>Frequently asked quest. (FAQ)</li> <li>Glossary</li> <li>Note to file</li> </ul>		

Continue with the Demographics & TB history, Medication/allergies/Med. Eval., Initial investigations and Randomization & Study drugs pages from **CRF3** then "**save/go to next form**" (figure 13).

# Figure 13

2	Demographics and TB history	Version 1, last update September 18th 2019
	Editing participant's CAL-11 Demographics and TB history form	n
	Do Research staff completing the form	
	Demographics	
Connected at 31/08/2020 - 10:00:38 AM	D1 Height	m
[Sign out]	D2 Weight *	kg
Data capture	D3 In which Country were you born?	
E Dashboard	D4 If Country of birth is different from country of this study center, in which year did you arrive in country of this center?	9999
Add / Select records	D5 Immigration status	- •
E1-3 for participant CAL-11 (Channel	Medical history	
Initial screening	Risk factors	
Eligibility & consent	D7 HIV status *	- 🗸
Medications/Allergies/Med.eval Initial investigations Randomization & Study drugs	D13 Contact with a person who has active pulmonary TB *	
Elp	Does the study participant have any immunosuppressive     conditions or therapy? *	- •
Unssary	D25 Smoking status *	- 🗸
Note to file	D29 How often do you have a drink containing alcohol? *	- 🗸
	D32 Do you use any recreational drug more than once a month? *	- *
	History of TB	
	D36 Has the participant had BCG vaccination?	- *
	37 Was the participant treated before for active TB? *	- •
	D40 Was the participant treated for latent TB in the past? *	- •
	D43 Comments	
		Save/Go to next form Save/Stay on page

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

# 2R2 website: site user's manual

#### 2R2 SOP20_08Sep2020

**Note:** In "Initial investigations" page, under variable L2 there is the possibility to upload the CXR. <u>DO NOT upload the CXR done at randomization</u> for all participants. The CXR upload will be required ONLY for participants who will develop an Active TB during follow-up. The upload of CXR done at enrolment will then be required only once you have completed **CRF11** and **CRF12** (see **5.3.11 CRF12 Active TB Final** for more information) for participants with active TB.

While completing the forms you will see small coloured dots in the left menu, beside each page of the CRF. The dots indicate if a CRF (or a CRF page) is "completed", "ongoing" or "not yet started". (figure 14)

#### Figure 14

<b>2R</b> ²
Logged in as demo Connected at 31/08/2020 - 10:00:38 AM [Sign out]
Data capture
E Dashboard Add / Select records
CRF1-3 for participant CAL-11 [Change] Initial screening
<ul> <li>Eligibility &amp; consent</li> <li>Demographics &amp; TR history</li> </ul>
Medications/Allergies/Med.eval
Initial investigations     Randomization & Study drugs
Нејр
<ul> <li>Frequently asked quest. (FAQ)</li> <li>Glossary</li> <li>Note to file</li> </ul>

Green dots = form is completed; Yellow dots = form is ongoing, information is still missing;

Red dots = form is not started yet, no information entered

You will not be able to randomize a participant if one of the forms is in yellow or red. You will see an exclamation mark under "Status" for the incomplete form, in the Randomization page (figure 15) Figure 15

2	Randomization and study drug     Version 1, last update October 2 2019
	Editing participant's CAL-5 Randomization and study drug form
	R0 Research staff completing the form 🕐
Logged in as <b>demo</b>	Randomization status for this participant
Connected at 31/08/2020 - 12:37:03 PM	Forms Status Randomization criteria 🕜
[Sign out]	Initial screening S1 S2 S3 S4 S5 S6 S7 S8 S10 S11 S12 S13 S14 S15 S16 S17 S18 S19 S20
	Eligibility & consent C1 C2 C4 C5 C8
	Demographics & TB
Dashboard Add / Select records	Medications/Allergies M1 M2.2 M3 M4 M5 M12 M13 M14 M15 M16 M17 M18 M19 M20 M21 M22 M23 M24 M25
	Initial investigations 🛛 L1 L2 L8 L9 L14 L16 L18 L19 L20 L21 L26.1 L28 L30 L32
CRF1-3 for participant CAL-5 [Change]  Initial screening Eligibility & consent Demographics & TB history Medications/Allergies/Med.eval Initial investigations Randomization & Study drugs Help Frequently asked quest. (FAQ)	

Glossary
Note to file

Once all the forms are completed, they have a green dot on the menu on the left, and you can randomize the participant, by clicking on "Please randomize this participant" (figure 16) Figure 16

2	Randomization and study drug	Version 1, last update October 2 2019
	PEditing participant's CAL-11 Randomization and study drug form	
	R0 Research staff completing the form (?)	
Logged in as <b>demo</b>	Randomization status for this participant	
Connected at 31/08/2020 - 12:37:03 PM	Forms Status Random	nization criteria 🕜
Home	Initial screening S1 S2 S3 S4 S5 S6 S7 S8 S10	0 S11 S12 S13 S14 S15 S16 S17 S18 S19 S20
Data capture	Eligibility & consent C C1 C2 C4 C5 C8 Demographics & TB D2 D7 D10 D12 D13 D15 D16 D25 D22	9 D30 D32 D37 D40
Dashboard     Add / Select records	nist. Medications/Allergies M1 M2.2 M3 M4 M5 M12 M13 M14 M1	5 M16 M17 M18 M19 M20 M21 M22 M23 M24 M25
CRF1-3 for participant CAL-11 [Change]	Randomization and study drugs	
<ul> <li>Initial screening</li> <li>Eligibility &amp; consent</li> </ul>	R1 Are you ready to randomize this participant? Yes, I	please randomize this participant
<ul> <li>Demographics &amp; TB history</li> <li>Medications/Allergies/Medieval</li> </ul>	Save	ə/Exit
Initial investigations	Save/	Stay on page
Randomization & Study drugs	Save	Go to next form
Help		
Frequently asked quest. (FAQ)     Gossary     Note to file		

**Exception** : You can randomize a participant even if you have not completed the part reporting the results of the blood test, but you must enter a date for the lab test done. Fill in the results as soon as you have them (i.e. in the next 1-2 days after enrolment (**figure 17**).

igure 17		
2	Initial investigations form	Version 1, last update Septemb
	Editing participant's CAL-11 Initial investigations form	
	Lo Research staff completing the form (?)	Utilisateur de test
and is as down	Chest X Ray	
gged in as demo innected at 31/08/2020 - 2:41:26 PM	Li Date of chest-x ray *	31-08-2020 Today dd-mm-yyyy
[Sign out]	L2 Chest-x ray results *	Normal 🗸
ata capture	CXR uploaded file:	
Dashboard	L4 Other radiological tests	None 🗸
Add / Select records	Microbiology	
	Ls Microbiology *	Not required V
RF1-3 for participant CAL-11 [Change] Initial screening	Laboratory	
Eligibility & consent	L19 Date test was performed *	31-08-2020 1 Today dd-mm-vyyy
Demographics & TB history Medications/Allergies/Med.eval	L20 Alanine transaminase (ALT) (?)	
Initial investigations	L20.1 Upper Normal value for ALT	U/L
Randomization & Study drugs	L21 Aspartate aminotransferase (AST)	U/L
llow-Up during treatment CRF5	L21.1 Upper Normal value for AST	U/L
General information	Please fill at least one of the	a two between L20 and L21
End of treatment-CRF6	L22 Total bilirubin	umol/L
	L22.1 Upper normal limit (total bilirubin)	umol/L
AE initial evaluation-CRE9	L23 Hemoglobin	9/L
	L24 Hematocrit	L/L
tive TB	L25 White blood cells	10 ⁹ /L
ATB initial-CRF11	L26 Platelets	10 ⁹ /L
4p	L26.1 Is there any hematological abnormality of grade 3 or 4?	- 🗸
Prequently asked quest. (FAQ)	L27 If participant is HIV+, viral load 🕐	copies/ml
Note to file	HIV testing	
	$_{\tt L28}$ $$ Has treating team offered HIV testing to study participant? *	Not required, status is known
	L32 Pregnancy test	N/A 🗸
		Save/Go to next form
		Save/Stay on page
		Save/Exit

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

Until you do not complete all the information required in the forms, the dot beside the form in the left menu will remain yellow (**figure 18**).

#### Figure 18

2	Randomization and study drug	Version 1, last update October 2 2019
	Editing participant's CAL-11 Randomization and study drug form	
	R0 Research staff completing the form ?	
Looged in as <b>demo</b>	Randomization status for this participant	
Connected at 31/08/2020 - 12:37:03 PM	Forms Status Rando	omization criteria 🔞
(Sign out)	Initial screening S1 S2 S3 S4 S5 S6 S7 S8 S	10 S11 S12 S13 S14 S15 S16 S17 S18 S19 S20
Data capture	Eligibility & consent C1 C2 C4 C5 C8	
Dashboard	D2 D7 D10 D12 D13 D15 D16 D25 D	29 D30 D32 D37 D40
😹 Add / Select records	Medications/Allergies M1 M2.2 M3 M4 M5 M12 M13 M14 M Initial investigations M2 11 12 18 19 14 16 18 19 1	20 121 126 1 128 130 132
CRF1-3 for participant CAL-11 [Change]	Randomization and study drugs	
<ul> <li>Eligibility &amp; consent</li> </ul>	R1 Are you ready to randomize this participant? Yes	, please randomize this participant
<ul> <li>Demographics &amp; TB history</li> <li>Medications/Allergies/Med eval</li> </ul>	Sa	ve/Exit
Initial investigations	Sav	e/Stay on page
Randomization & Study drugs	Sav	e/Go to next form
Help		
Frequently asked quest. (FAQ) Glossary		
Note to file		

Note: Yellow dots will require review by the coordinating center if not resolved within 2 weeks.

Once the participant is randomized, the website will assign the duration of treatment at question R2 (i.e. 4 months of standard dose or 2 months of high dose rifampin) (figure 19) Figure 19

2	Randomization and study drug	Version 1, last update October 2 2019
	Editing participant's CAL-11 Randomization and study dr	ug form
	R0 Research staff completing the form 🔞	Utilisateur de test
Logged in as <b>demo</b>	Randomization status for this participant	
Connected at 31/08/2020 - 12:37:03 PM	Forms Status	Randomization criteria (2)
[Sign out]	Initial screening S1 S2 S3 S4 S5 S6 S	7 S8 \$10 S11 \$12 \$13 S14 S15 S16 S17 S18 \$19 \$20
Data capture	Eligibility & consent C1 C2 C4 C5 C8 Demographics & TB hist. D2 D7 D10 D12 D13 D15 D1	6 D25 D29 D30 D32 D37 D40
Add / Select records	Medications/Allergies M1 M2.2 M3 M4 M5 M12 M1	<b>3 M14 M15 M16 M17 M18 M19 M20 M21 M22 M23 M24 M25</b>
	Initial investigations 🔽 L1 L2 L8 L9 L14 L16 L1	8 L19 L20 L21 L26.1 L28 L30 L32
CRF1-3 for participant CAL-11 [Change]	Randomization and study drugs	
<ul> <li>Eligibility &amp; consent</li> </ul>	R1 Are you ready to randomize this participant?	Yes, please randomize this participant
<ul> <li>Demographics &amp; TB history</li> <li>Medications/Allergies/Med.eval</li> </ul>	R2 Study participant is randomized to	4 months of Rifampin standard dose
<ul> <li>Initial investigations</li> </ul>	R3 i Dose should be	600 mg/day
<ul> <li>Randomization &amp; Study drugs</li> </ul>	R7 Number of daily doses of study medication dispensed today	doses
Follow-Up during treatment CRF5	R8 How many days will these pills be for?	days
General information	R9 Suggested date of next visit is	25-09-2020
End of treatment-CRF6		Save/Exit
		Save/Stay on page
Adverse event     AE initial evaluation-CRF9		Save/Go to next form
Active TB ATB initial-CRF11		
Help		
Frequently asked quest. (FAQ)     Glossary     Note to file		

If participant is not randomized once you click on "**Yes, please randomize this participant**" but you think that he/she should be randomized, review and revise information and if still NOT able to randomize, contact the coordinating center.

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# 5.3.4 CRF5: Follow-up during treatment

### General notes for CRF5:

**1**. In the website, **CRF5** has been divided in 4 pages: "General Information", "Symptoms and physical exam", "Investigations during follow-up" and "Treatment Plan".

**2**. As each participants has more than one follow-up, different follow-ups for each participants are named and sorted by date of the follow-up. You can see all the follow-up forms done for one participant by scrolling down the window in the section "Follow-up during treatment" once the participant ID has been selected in the "Add/Select record" page (figures 20-21).

When you are ready to enter the data from the paper **CRF5** into the website, select the participant for whom you want to add the follow-up form by clicking on "Add/Select records" in the menu of the left.

Click on a participant who has been already randomized (by opening the scroll down list at "Randomized") and for whom you want to enter the follow-up form (**figure 20**)

#### Figure 20

2	Add or select participant record	Version 1, last update October 2 2019
	Participant's file	
	AS1 Screening ongoing (1) -select recom	d 🗸 🕜
Local data	AS2 Randomized (2 Vselect rect	ord 🖌 🕐
Connected at 03/09/2020 - 9:08:02 PM	AS3 Excluded (3 CAL-7	2 3
[Sign out]	AS4 Excluded post randomization(5)select recom	d 🗸 🔇
Data capture	Add a new participant Id	
Dashboard		
Add / Select records	Follow-Up during treatment	
Help	Follow-Up during treatment (8) -select record	I- <b>v</b>
🥮 Frequently asked quest. (FAQ)	Follow-Up post treatment	
Glossary	Follow-Up post treatment(1) -select record	I- <b>v</b>
Note to me	Adverse events	
	Adverse events initial (4) -select record	- *
	Adverse events final (4) -select record	I <b>~</b>
	Active TB	
	Active TB initial(3) -select record	I V
	Active TB final (3) -select record	

You can choose to complete a follow-up form already started (selecting the date of follow-up form you want to complete, by opening the scroll down window) or you can choose to add a new follow-up form, by clicking on "Add a new flw-up". (figure 21)

#### Figure 21

~~~?	🗋 Add or select parti	cipant record	Version	n 1, last up	pdate October 2 2
	Participant's file				
	A51	Screening ongoing (1)	select record	~	0
	A52	Randomized (2)	CAL-7	~	(Change)
gged in as demo nnected at 03/09/2020 - 9:08:02 PM	A53	Excluded (3)	select record	~	(?)
[Sign out]	A54	Excluded post randomization(5)	select record	~	(?)
n) Home	Add a new participant	d			(
Add / Select records	Follow-Up during treat	nent			
Add / Select records RF1-3 for participant CAL-7 [Change]	Follow-Up during treats	Follow-Up during treatment (0	'select record	Add a n	ew flw-up
Add / Select records KF1-3 for participant CAL-7 [Change] Initial screening Eligibility & consent	Follow-Up during treat	Follow-Up during treatment (0	-select record	Add a n	ew flw-up
Add / Select records RF1-3 for participant CAL-7 [Change] Initial screening Eligibility & consent Demographics & TB history Medications/Allergies/Med.eval	Follow-Up during treat	Follow-Up during treatment (0 Adverse events initial (0) Adverse events final (0)	select record	Add a n	ew flw-up ew AEI
Add / Select records F1-3 for participant CAL-7 [Change] Initial screening Eligibility & consent Demographics & TB history Medications/Allergies/Med.eval Initial investigations Reardenziations & Subki dates	Follow-Up during treat	Follow-Up during treatment (0 Adverse events initial (0) Adverse events final (0)	/select record	Add a n	ew flw-up
Add / Select records F1-3 for participant CAL-7 [Change] Initial screening Eligibility & consent Demographics & TB history Medications/Allergies/Med.eval Initial investigations Randomization & Study drugs	Follow-Up during treat	Follow-Up during treatment (0 Adverse events initial (0) Adverse events final (0) Active TB initial(0)	 select record / select record / select record select record 	Add a n	ew flw-up

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

You will be directed to the first page (General Information) (figure 22) Figure 22

2	General information	Version 1 - Last update Octo
	Editing participant's CAL-7 General information form	
	G0 Research staff completing the form	
Logged in as demo	General information	
Connected at 03/09/2020 - 9:08:02 PM	G1 Date of this visit *	Today dd-mm-yyyy
[Sign out]	GZ Is this the date on which this visit was originally scheduled?	- •
Data capture	G6 This visit is:	-
Dashboard	G10 Has contact information changed?	- *
Add / Select records	IMPORTANT NOTE: review contact in	formation at each visit
CRE1-3 for participant CAL-7 [Change]	Adherence to treatment	
 Initial screening 	G11 The participant was randomized to:	2 months of Rifampin high dose
 Eligibility & consent Demographics & TB history 	G13 Randomization code given	N4
Medications/Allergies/Med.eval	G14 Number of pills per day	3 pills/day
Initial investigations Randomization & Study drugs	G15 Did study participant bring their medication bottle?	- *
	G24 Comments	
Follow-Up during treatment CRF5 General information		
End of treatment-CRF6		
Adverse event AE initial evaluation-CRF9		
Active TB ACTB initial-CRF11		Save/Go to next form
Help		Save/Exit
🥦 Frequently asked quest. (FAQ)		

Note: On this page you can see the participant's treatment and check that it is correct (**figure 23**).

Figure 23

2	General information	Version 1 - Last update October 3 2019
	Editing participant's CAL-7 General information form	
	G0 Research staff completing the form	
Logged in as demo	General information	
Connected at 03/09/2020 - 9:08:02 PM	G1 Date of this visit *	Today dd-mm-yyyy
[Sign out]	GZ Is this the date on which this visit was originally scheduled?	- 🗸
Data capture	G6 This visit is:	- •
2010 Dashboard	G10 Has contact information changed?	- •
Add / Select records	IMPORTANT NOTE: review contact infor	mation at each visit
CRE1-3 for participant CAL-7 [Change]	Adherence to treatment	
Initial screening	G11 The participant was randomized to:	2 months of Rifampin high dose
 Eligibility & consent Demographics & TB bistory 	G13 Randomization code given	N4
Medications/Allergies/Med.eval	G14 Number of pills per day	3 pills/day
 Initial investigations Randomization & Study drugs 	G15 Did study participant bring their medication bottle?	- *
	G24 Comments	
Follow-Up during treatment CRF5 General information		
e End of treatment-CRF6		
Adverse event		
AE initial evaluation-CRF9		
Active TB		Save/Go to next form
ATB initial-CRF11		Save/Stay on page
Help		Save/Exit
🥦 Frequently asked quest. (FAQ)		

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

Once you finish completing the "General Information" page, click on "Save/Go to next form" and complete "Symptoms and physical exam" (figure 24) and "Investigations during follow-up" (figure 25). Click on "Save/Go to next form" at the end of each page once done. Figure 24

2	Current symptoms and Physical exam	Version 1 - Last update October 3 2019
	Editing participant's CAL-7 Current symptoms and	Physical exam form
	vo Research staff completing the form	Utilisateur de test
	Current symptoms and Physical exam	
Logged in as demo Connected at 08/09/2020 - 2:09:28 PM	Does the study participant have any of the followin	g symptoms TODAY?
[Sign out]	Y1 Fever/Night sweats?	No 🗸
ini Home	v3 Weight loss without dieting?	No 🗸
	Y5 Cough?	No 🗸
Add / Select records	Y7 Sputum production?	No 🗸
	v9 Skin problems? (?)	No 🗸
RF1-3 for participant CAL-7 [Change]	Y11 Gastrointestinal problems? (?)	No 🗸
Eligibility & consent	Y13 Neurological problems? (?)	No 🗸
Demographics & TB history	Y15 Other? (2)	No 🗸
Initial investigations	Y17 Physical exam is (?)	Not necessary
Randomization & Study drugs		Save/Go to next form
ollow-Up during treatment CRF5[Change]		Save/Stay on page
12 (04-09-2020) (Incomplete) General information		Save/Exit
Symptoms & physical exam		SaverExit
Investigations during follow-up		
investigations during follow-up		
- → C ▲ Not Secure 2r	2-demo.crc.chus.qc.ca/index.aspx?uc=24	
•	Investigations during follow-up	Version 1 - Last update October 3 20
	Editing participant's CAL-7 Investigations during for	llow-up form
	FO Research staff completing the form	Utilisateur de test
gged in as demo	Investigations	
nnected at 08/09/2020 - 2:09:28 PM	Note: at the 4 weeks FOLLOW-UP VISIT, the	following ARE REQUIRED, otherwise as clinically indicated
[Sign out]	F1 Date tests were performed	01-09-2020 T5 Today dd-mm-vyvy

U/L

U/L 30

umol/L

mg/dL

mg/dL

g/L

L/L 10⁹/L

10⁹/L

~

×

No

20

🟠 Home

Dashboard Add / Select records	Dashboard		F3	Aspartate aminotransferase (AST)
	Add / Select records		F4	Total bilirubin
		F5	Creatinine	
CRF1-3 for participant CAL-7 [Change]	ingel	F6	BUN (blood urea nitrogen)	
	 Eligibility & consent 	F7	F7	Hemoglobin

F2 Alanine transaminase (ALT)

F8 Hematocrit

F10 Platelets

F9 White blood cells

F11 Other investigations

F12 Does study participant require monitoring of other medications being taken?

F16 If this is the 4 weeks FOLLOW-UP VISIT: were samples for PK taken?

- Demographics & TB history
 Medications/Allergies/Med.eval
- Initial investigations
- Randomization & Study drugs
- Follow-Up during treatment CRF5 (Change) 12 (04-09-2020) (incomplete)
- General information
- Symptoms & physical exam
- Investigations during follow-up
- Treatment plan

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Note: There may be different types of follow-up appointments that participants can have, for example: in-person visits with a blood test done, in-person visits without blood test, phone calls, medication pick-ups, etc. For this reason, the follow-up form **CRF5** can be completed in all its parts (in visits in which all follow-up components are carried out) or just partially (for example during a call follow-up). The judgment if the form is completed or not will be based on a) final statement done by the site user; b) confirmation given by the coordinating center. At this purpose, there is a question at the end of **CRF5** in the 2R2 website (in page "Treatment plan") asking the site user if data entered for this specific follow-up appointment have to be considered completed or if are still pending.

This is question N8 (in the last page of **CRF5**, "Treatment Plan") which asks if the form has to be considered as "Complete" or "Incomplete". Choose incomplete if there are still information pending (in any part of **CRF5**) which will be entered as soon as they will become available to you. (**figure 26**)

Figure 26

.8				
CRF5 form status	CRF5 form status			
Please indicate in N8 if CRF 5 is now completed.				
N8 CRF5 form status is :	Incomplete ~			
	Save/Stay on page			

This can be, for example, if at a 1 month visit, blood test has been done and results are still pending when **CRF5** is entered in the website. By choosing "Incomplete", in this case, the site user can go back and fill in the pending information once available.

Once all information you can enter have been entered, choose "Complete". a message will appear above the question N8: "**CRF5** status will be confirmed by 2r2 coordinator". (**figure 27**) **Figure 27**

Logged in as demo Concict at 04/09/2020 - 103-203. MM (Sign out) (Sign out) (Sign out) <th>2</th> <th>Treatment plan</th> <th>Version 1 - Last update October 3 2019</th>	2	Treatment plan	Version 1 - Last update October 3 2019
Logged in as demo Concreted at 04/09/2020 - 10:32:01 AM (Sign out) (Note medications) Path Ame Data capture (Note medications) Note medications Note medication		🥖 Editing participant's CAL-7 Treatment plan form	
Logged in as demo Connected at 04/09/2020 - 10:32:03 LM (i) Is the study participant taking any NEW medications No Data capture (ii) Dashboard (iii) Add / Select records (iii) Dashboard (iii) Add / Select records (iiii) Streening Eliphility K somett Eliphility K somett (iii) Is the study and clast for Pollow-Up during treatment 1: (iii) Offer matilication Schrift pain (iii) Is the study and clast for Pollow-Up during treatment 1: (iii) Offer matilication Schrift pain (iii) Is the study medication continued as per protocol at same dose (iii) Is the study and clast for Pollow-Up during treatment 1: (iii) Is dashboard (iii) Is dashboard (iii) Is dashboard (iii) Is dashboard (iiii) Is dashboard		N0 Research staff completing the formResearch staff completing the form	Utilisateur de test
Connected at 04/09/2020 - 10:32:01 AM	Logged in as demo	Other medications	
Action regarding study medication Data capture Image: Dashboard Image: Dashboard </th <th>Connected at 04/09/2020 - 10:32:01 AM [Sign out]</th> <th>Is the study participant taking any NEW medications prescribed by a doctor?</th> <th>No 🗸</th>	Connected at 04/09/2020 - 10:32:01 AM [Sign out]	Is the study participant taking any NEW medications prescribed by a doctor?	No 🗸
Pate capture Ins Plas capture Instal Sudy medication continued as per protocol at same dose Instal Sudy medication continued as per protocol at same dose Instal Sudy medication continued as per protocol at same dose Instal Sudy medication continued as per protocol at same dose Instal Sudy medication continued as per protocol at same dose Instal Sudy medication continued as per protocol at same dose Instal Sudy medication continued as per protocol at same dose Instal Sudy medication continued as per protocol at same dose Instal screening Instal screening Instal screening Instal screening Instal screening Instal screening Instal investigations Instal investigations Instal investigation Suggested date for Follow-Up during treatment 1: Or0-02020 Suggested date for Follow-Up during treatment 2: 21-09-2020 Suggested date for Follow-Up during treatment 3: 19-10-2020 Instal investigations Instal investigations Instal investigations Instal investigation Study fugs Instal investigation Study fugs Instal investigation Suggested date for Follow-Up during treatment 3: 19-10-2020 Instal investigations Instal investigation Suggested date for Follow-Up during treatment 3: 19-10-2020 Instal investigations Instal investigations Suggested date for Follow-Up during treatment 3: 19-10-2020 Suggested date for Follow-Up during treatment 3: 19-10-2020 Suggested date for Follow-Up during treatment 3: 19-10-2020 Instal investigations Suggested date for Follow-Up during treatment 3: Instal investigations Instal i	🟠 Home	Action regarding study medication	
Dashboard Add / Select records Ns.1 Pills of study medication that were dispensed today for T2 pills Participant CAL-7 Charged Initial screening Eligibility & consent Demographics & TB history Medications/Allergies/Med.eval Initial investigations Randomization & Study drugs Vorgested date for Follow-Up during treatment 1: 07-09-2020 Suggested date for Follow-Up during treatment 2: 21-09-2020 Suggested date for Follow-Up during treatment 2: 10:03-09-2020) Vorgested date for Follow-Up during treatment 3: 11:03-09-2020) Suggested date for Follow-Up during treatment 3: 10:03-09-2020) Symptoms & physical exam Investigations during follow-up Treatment plan Population PK-CRF13 CRF5 form status CRF5 form status is :: Carbon-CRF6 Active TB • ATB initial-CRF11	Data capture	N5 Plan Study medication continued as per protocol at same do	use 🗸
CRF-1 3 or participant CAL-7 Changed Initial screening Eligibility is consent Eligibility is consent Demographics & TB history Medications/Allergies/Med.eval Initial integes/Med.eval Integes/Med.eval Integes/Med.eval	Dashboard Add / Select records	NS.1 Pills of study medication that were dispensed today for participant who is in 2 months high dose arm	72 pills
CRF1-3 for participant CAL-7 Chempel ● Initial screening Suggested date for next visit is ● Demographics & TB history Suggested date for Follow-Up during treatment 1: 07-09-2020 ● Medications/Allergies/Med.eval Suggested date for Follow-Up during treatment 2: 21-09-2020 ● Initial investigations Suggested date for Follow-Up during treatment 3: 19-10-2020 Suggested date for Follow-Up during treatment 3: 19-10-2020 Suggested date for Follow-Up during treatment 3: 19-10-2020 Initial investigations N° General information Sproptoms & physical exam ● Investigations during follow-up CRF5 form status CRF5 form status CRF5 form status is : CRF5 form status is : Complete Active TB Save/Stay on page Active TB Save/Stay on page Atte Initial-CRF11 Save/Stay on page		N5.3 How many days will the pills dispensed today be for?	18 days
Initial screening Suggested date for heat visit is Suggested date for follow-Up during treatment 1: 07-09-2020 Suggested date for Follow-Up during treatment 1: 19-10-2020 Suggested date for Follow-Up during treatment 2: 21-09-2020 Suggested date for Follow-Up during treatment 1: 19-10-2020 Suggested date for Follow-Up during treatment 3: 19-10-2020 Treatment CRF5 (Change) Follow-Up during treatment CRF5 (Change) Follow-Up during freatment CRF5 (Change) Follow-Up during freatment CRF5 (Change) Follow-Up during freatment CRF5 (Change) Follow-Up during follow-up Treatment plan Population PK-CRF13 CRF5 form status CRF5 form status is : CRF5 form status is : Complete Save/Stay on page Sa	CRF1-3 for participant CAL-7 [Change]		
Eligibility & consent Suggested date for Follow-Up during treatment 1: 07-08-2020 Medications/Allergies/Med.eval Suggested date for Follow-Up during treatment 2: 21-09-2020 Initial investigations Randomization & Study drugs N7 General comments General comments Follow-Up during treatment CRF5 (change) N7 General formation General formation Symptoms & physical exam CRF5 form status Investigations during follow-up CRF5 form status Population PK-CRF13 CRF5 form status is : CRF5 form status is : Complete Adverse event Save/Stay on page Active TB Save/Stay on page Attinitial-CRF11 Save/Exit	Initial screening	N6 Suggested date for next visit is	
Demographics & TB history Suggested date for Follow-Up during treatment 2: 21-09-2020 Suggested date for Follow-Up during treatment 3: 19-10-2020 Initial investigations Randomization & Study drugs Follow-Up during treatment CRF5 (Channel) General information Symptoms & physical exam Investigations during follow-up Treatment plan Population PK-CRF13 End of treatment-CRF6 Adverse event AtE initial evaluation-CRF9 Active TB Atti initial-CRF11 Suggested date for Follow-Up during treatment 2: 21-09-2020 Suggested date for Follow-Up during treatment 3: 19-10-2020 Suggested date for Follow-Up during treatment 4: CRF5 form status Suggested date for Follow-Up during treatment 4: CRF5 form status is : Suggested date for Follow-Up during treatment 5: Suggested date for Follow-Up during treatment 4: CRF5 form status is : Suggested date for Follow-Up during treatment 5: Suggested date for	Eligibility & consent	Suggested date for Follow-Up during treatment 1:	07-09-2020
Medications/Allergies/Med.eval Initial evaluation-CRF9 ArtB initial-CRF11 Suggested date for Follow-Up during treatment 3: 19-10-2020 Investigation & Study drugs Suggested date for Follow-Up during treatment 3: 19-10-2020 Investigation & Study drugs V General information Symptoms a physical exam Investigations Physical exam CRF5 form status CRF5 form status CRF5 form status CRF5 form status is : Complete Save/Stay on page Save/Stay on page	Demographics & TB history	Suggested date for Follow-Up during treatment 2:	21-09-2020
Initial investigations Randomization & Study drugs N7 General comments Follow-Up during treatment CRF5 (Changel 11 (03-09-2020) (incomplete) General information Symptoms & physical exam Investigations during follow-up Treatment plan Population PK-CRF13 CRF5 form status CRF5 form status will be confirmed by 2R2 coordinator. N8 CRF5 form status is : CRF5 form status is : Complete N9 CRF5 form status is : Complete Save/Stay on page Save/Stay on page Save/Exit	Medications/Allergies/Med.eval	Suggested date for Follow-Up during treatment 3:	19-10-2020
Randomization & Study drugs N ⁷ General comments Follow-Up during treatment CRF5 (Channel) General information Symptoms & physical exam Investigations during follow-up Treatment plan Population PK-CRF13 End of treatment-CRF6 Adverse event Ati initial evaluation-CRF9 Active TB Ati initial-CRF11	Initial investigations		
Follow-Up during treatment CRF5 (Channes) 11 (03-09-2020) (Incomplete) General information Symptoms a physical exam Investigations during follow-up Treatment plan Population PK-CRF13 End of treatment-CRF6 Adverse event A El initial evaluation-CRF9 Active TB Attien itial-CRF11	Randomization & Study drugs	N7 General comments	
General information Symptoms & physical exam Investigations during follow-up Treatment plan Population PK-CRF13 CRF5 form status CRF5 form status CRF5 status will be confirmed by 2R2 coordinator. No CRF5 form status is : Complete Complete Complete Save/Stay on page Save/Stay on page Save/Exit	Follow-Up during treatment CRF5[Change] 11 (03-09-2020) (Incomplete)		
Symptoms & physical exam Investigations during follow-up Treatment plan Population PK-CRF13 End of treatment-CRF6 Adverse event Active TB Atti initial evaluation-CRF9 Active TB Atti initial evaluation-CRF9	General information		
Investigations during follow-up Treatment plan Population PK-CRF13 End of treatment-CRF6 Adverse event Active TB ATB initial-CRF11 Save/Stay on page Save/Stay on page Save/Exit	 Symptoms & physical exam 		
	 Investigations during follow-up 		
Population PK-CRF13 End of treatment-CRF6 Adverse event • AE initial evaluation-CRF9 Active TB • ATB initial-CRF11	Treatment plan		
End of treatment-CRF6 Adverse event Adverse event Ative TB ATB initial-CRF11 CRF5 form status is : Complete Save/Stay on page Save/Exit	Population PK-CRF13		
CRF5 status will be confirmed by 2R2 coordinator. Adverse event Ative TB ATB initial-CRF11 Complete Save/Stay on page Save/Exit		CRF5 form status	
Adverse event • AE initial evaluation-CRF9 • ATB initial-CRF11 Complete • ATB initial-CRF11 Complete • ATB initial-CRF11 Complete Complete Complete Complete Complete Complete Save/Stay on page Save/Stay on page	End of treatment-CRF6	CRF5 status will be confirmed by 2R2 coordinator.	
AE initial evaluation-CRF9 Active TB ATB initial-CRF11 Save/Stay on page Save/Exit	Adverse event	N8 CRF5 form status is :	Complete ~
Active TB ACtive TB ACtive TB ACtive TB ACtive TB Save/Stay on page Save/Exit	AE initial evaluation-CRF9		
ATB initial-CRF11 Save/Exit	Active TR		Save/Stay on page
			Sauc/Evit
	ATB Initial-CRF11		Save/EAR

2R2 SOP20 Website site user's manual_08Sep2020

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

2R2 website: site user's manual

2R2 SOP20_08Sep2020

Note: you can choose complete for forms where all variables are entered or for forms which are not all filled out, but that have all the information that were expected to be collected for that appointment. For example: in a follow-up visit at 2 months after treatment started, where there is no routine blood test required, a **CRF5** form in which "Investigation during follow-up" remains blank (and therefore has a red dot) is still to be considered a complete follow-up form (as lab test were not requested and not done).



Figure 28

At this point, the word "incomplete" (in yellow) beside the name of this specific form (Follow-up During treatment (**CRF5**)), <date> in the left menu will remain, until the coordinating center confirms that this follow-up form in indeed considered completed.

If the coordinating center does not agree with classifying the form as complete, site user will be contacted for more information.

If the coordinating center agrees and confirms that this **CRF5** is to be considered completed, then the world beside the follow-up form will become "complete" (in green). (**figure 29**) **Figure 29**



Note: the dots on the left menu, besides the pages of **CRF5** which have not filled in all their variables, will remain yellow even when the **CRF5** is considered completed (as they reflect the status of all variables and will not be modified). These yellow dots will not require any further action, if the **CRF5** is classified as "complete" by the word in green beside the CRF name.

5.3.5 CRF6 End of treatment

The form End of treatment is visible at all times in the menu on the left when you select a randomized participant. You must click on "End of treatment **CRF6**" to fill out the **CRF6** form. (figure 30)

Figure 30		
~~?	End of treatment	Version 1 - Last update October 3 2019
	Editing participant's CAL-11 End of treatment form	
	TO Research staff completing the form	
Logged in as demo	End of treatment	
Connected at 04/09/2020 - 1:20:57 PM	T1 Reason for stopping *	
Home	•	~
Data capture	T5 General comments	
E Dashboard Add / Select records		
CRF1-3 for participant CAL-11 [Change]		
 Initial screening Eligibility & consent 		
 Demographics & TB history Medications/Allergies/Med.eval 		
 Initial investigations Randomization & Study drugs 	Study participant is now in post treatment follow-up	
	T6 Suggested date of 1st FOLLOW-UP CALL/VISIT for this participant is	
Follow-Up during treatment CRF5		Save/Go to next form
		Save/Stay on page
End of treatment-CRF6		Save/Exit

Note: while completing **CRF6**, if a sentence in **RED** appears when you select a Reason for stopping (T1), **pay attention!** This means that you must fill out another form, if not already done, beside completing the end of treatment form (see example in **figure 31**)

Figure 31

2	End of treatment	Version 1 - Last update October 3 2019
	Editing participant's CAL-11 End of treatment form	
	T0 Research staff completing the form	
Logged in as demo	End of treatment	
Connected at 04/09/2020 - 1:20:57 PM	T1 Reason for stopping *	
Home	Study medication stopped due to an adverse event	~
Data capture	REPORT Adverse Event Initial CRF 9, if not already done	
Dashboard	T4 Date of the last dose taken by participant 2 04-09-2020	Today dd-mm-yyyy
Add / Select records	T5 General comments	
CRF1-3 for participant CAL-11 [Change] Initial screening Eligibility & consent Demographics & TB history Medications/Allergies/Med.eval Initial investigations Randomization & Study drugs		
Follow-Up during treatment CRF5	Study participant is now in post treatment follow-up	
General Information	T6 Suggested date of 1st FOLLOW-UP CALL/VISIT for this participant is	
End of treatment-CRF6	Save/Go to next	form
Adverse event	Save/Stay on pa	ige
AE initial evaluation-CRF9	Save/Exit	

Complete **CRF6** only when you are sure participant stopped treatment permanently and you know the date of last dose taken (T4).

2R2 SOP20 Website site user's manual_08Sep2020 Higher dose Rifampin for 2 months vs Standard dose Rifampin for Latent TB: a 3-arm randomized trial.

5.3.6 CRF7 Follow-up evaluation post treatment

Once you have completed a form "End of treatment" and you did "Save/Exit", the section "Follow-Up post treatment" will appear. Then you can click on Post treatment follow-up-CRF7 on the left menu or click on "Add a new pst flw-up" in the "Add/select participant record" page. (figure 32) Figure 32

2	📓 Add or select participan	t record		Version 1, last update October 2
	Participant's file			
	A51	Screening ongoing (1)	select record	✓ ②
	A52	Randomized (2)	CAL-11	V 🕐 [Change]
gged in as demo onnected at 04/09/2020 - 1:20:57 PM	A53	Excluded (3)	select record	✓ ②
[Sign out]	A54	Excluded post randomization(5)	select record	✓ ②
n' Home	Add a new participant Id			
ita capture				
Add / Select records	Follow-Up during treatment			
		Follow-Up during treatment (1)	select record	✓ Add a new flw-up
F1-3 for participant CAL-11 [Change]	Follow-Up post treatment			
Eligibility & consent		Follow-Up post treatment(0)	select record	✓ Add a new ps.
Demographics & TB history Medications/Allergies/Med.eval	Adverse events			
Initial investigations		Adverse events initial (0)	select record	✓ Add a new AEI
Randomization & Study drugs	-	Adverse events final (0)	select record	~
low-Up during treatment CRF5	Active TB			
General information		Active TB initial(0)	select record	~
End of treatment-CRF6		Active TB final (0)	select record	~
low-Up post treatment				
Post treatment follow-up-CRF7				
End of post treat. follow-up-CRF8				
Death during post treatCRF14				

The form post treatment follow-up **CRF7** will appear (**figure 33**), fill out the form and click **"Save/Exit"** when it's complete.

Note: Don't forget to fill out the question P12 if you said yes to any of P8-P11.

2R2 website: site user's manual

2R2 SOP20_08Sep2020

Figure 33		
2	Post treatment follow-up	Version 1 - Last update September 23rd 2019
	Editing participant's CAL-7 Post treatment follow-up form	1
	P0 Research staff completing the form	
Longed in as demo	Post treatment follow-up	
Connected at 04/09/2020 - 2:03:52 PM	P1 Date of call/visit *	Today dd-mm-yyyy
[Sign out]	P2 Were you able to contact the study participant?	- ~
Data capture	P5 Has contact information changed?	- *
Tashboard	P6 Is study participant planning to move to a different address in the next 6 months?	- *
Add / Select records	P7 Comments	
CRF1-3 for participant CAL-7 [Change] Initial screening Eligibility & consent Demographics & TB history Medications/Allergies/Med.eval Initial investigations Randomization & Study drugs		
Follow-Up during treatment CRF5[Change] 11 (03-09-2020) (Incomplete)	Changes in health status since last call	
General information Symptoms & physical exam	P8 Has there been any change in study participant?s health status since the last call/visit?	- •
 Investigations during follow-up 	P9 Was the study participant hospitalized, for any reason, since	- *
Treatment plan	Did the study participant receive a new diagnosis (for any	- *
Population PK-CRF13	disease) since last call/visit? Was the study participant prescribed any new medications	
End of treatment-CRE6	since the last call/visit? If Yes to any of P8-P11 questions; get and document permiss	sion to obtain clinical, laboratory, treatment information, and
	P12 copies of relevant X-rays from their treating physician; AND p A Neuros of diagonal di	provide details in the narrative below, including:
Follow-Up post treatment	B. Treatment given	E. Dates of hospitalization
Post treatment follow-up-CRF7	C. Hospitals where participant has been hospitalized	•
End of post treat_follow-up-CRE8		
Death during post treat -CRE14		
	Current symptoms	
Adverse event	Does the study participant have any of the following sym	nptoms TODAY?
	P13 Fever/Night sweats?	- •
Active TB	P15 Weight loss without dieting?	- •
ATB initial-CRF11	P17 Cough?	- *
Help	P19 Sputum?	- ~
Frequently asked quest. (FAQ)	P21 Other?	- •
Note to file	P23 Physical exam is	- *
	Follow-up	
	P25 Is this the last follow-up call with this participant?	- •
		Save/Go to next form
		Save/Stay on page
		Save/Exit

5.3.7 CRF8 End of post treatment follow-up

The form "End of post treatment follow-up **CRF8**" is only visible once you have completed "End of treatment form **CRF6**". **CRF8** will appear in the menu on the left. Once the post-treatment follow-up is completed, you must click on "End of post treatment follow-up **CRF8**" and fill out the form (**figure 34**)

Figure 34 Version 1 - Last update September 23rd 2019 End of post-treatment follow-up Success The form has been saved. Editing participant's CAL-7 End of post-treatment follow-up form zo Research staff completing the form Logged in as demo Connected at 04/09/2020 - 2:03:52 PM End of post-treatment follow-up [Sign out] How many months post randomization was the last followmonths 28 Home up call/visit made? Data capture z2 Reason why the post-treatment follow-up for this participant is finished.* Dashboard Study participant completed post-treatment follow-up, i.e. last contact at about 25-27 months after randomization ~ 🚵 Add / Select records z4 General comments CRF1-3 for participant CAL-7 [Change] Initial screening Eligibility & consent Demographics & TB history Medications/Allergies/Med.eval Initial investigations Randomization & Study drugs Follow-Up during treatment CRF5[Change] STUDY PARTICIPANT HAS NOW COMPLETED THE STUDY 11 (03-09-2020) Save/Go to next form General information Symptoms & physical exam Save/Stay on page Investigations during follow-up Treatment plan Save/Exit Population PK-CRF13 End of treatment-CRF6 Follow-Up post treatment 3 (04-09-2020) [Change] Post treatment follow-up-CRF7 End of post treat. follow-up-CRF8 Death during post treat.-CRF14

Click on "Save/exit" when it's complete.

5.3.8 CRF9 Adverse event Initial evaluation

The form Adverse Event Initial **CRF9** is visible at all times in the menu on the left when you select a randomized participant. To enter a **CRF9**, click on **"AE Initial evaluation CRF9"** on left menu or click on **"Add a new AE"** in **"Add/Select participant record"** page. (figure35)

Figure 35

2	📓 Add or select p	participant record		Version 1, last update October 2 2019
	Participant's file			
	A51	Screening ongoing (1)	select record	< ⊘
	A52	Randomized (2)	CAL-11	V 🕐 [Change]
Logged in as demo Connected at 04/09/2020 - 2:03:52 PM	A53	Excluded (3)	select record	▼ ②
[Sign out]	AS4	Excluded post randomization(5)	select record	✓ ②
Home	Add a new particip	ant Id		
Add / Select records	Follow-Up during t	reatment		
		Follow-Up during treatment (1)	select record	✓ Add a new flw-up
CRF1-3 for participant CAL-11 [Change]	Follow-Up post tre	atment		
 Eligibility & consent 		Follow-Up post treatment(0)	select record	✓ Add a new pst flw-up
 Demographics & TB history Medications/Allergies/Med.eval 	Adverse events			
 Initial investigations 		Adverse events initial (0)	select re	Add a new AEI
Randomization & Study drugs	-	Adverse events final (0)	select record	*
Follow-Up during treatment CRF5	Active TB			
General information		Active TB initial(0)	select record	~
End of treatment-CRF6		Active TB final (0)	select record	~
-ollow-Op post treatment				
Post treatment follow-up-CRF7				
End of post treat. follow-up-CRF8				
Death during post treatCRF14				
Adverse event Adverse event AE initial evaluation-CRF9				
Active TB Active TB initial-CRF11				

The CRF9 form will appear, then you can fill it out, transcribing from the paper form (figure 36) Figure 36

2	Adverse event initial evaluation	Version 1 - Last update September 24th 2019			
	Editing participant's CAL-11 Adverse event initial evaluation	uation form			
	All Research staff completing the form				
Loosed in as demo	Adverse event initial evaluation				
Connected at 04/09/2020 - 2:03:52 PM	All Event number				
[Sign out]	AI2 Date of event *	Today dd-mm-yyyy			
Data capture	Regarding study medication status, please select one				
E Dashboard	- EIA	~			
Add / Select records	Description of adverse event and investigations done				
CRF1-3 for participant CAL-11 [Change]	Which was the most important reason for stopping study medication? (choose one or more, as applies)	Which of the following MANDATORY TESTS were undertaken for this event? (choose all that applies except if differently specified)			
 Eligibility & consent 	AI5 Death				
 Demographics & TB history Medications/Allergies/Med.eval 	AI8 Hepatotoxicity				
 Initial investigations 	AII7 🗌 Hematologic				
Kandomization & Study drugs	AI20 Drug interaction				
Follow-Up during treatment CRF5	AI22 Gastrointestinal intolerance				
General information	Al29 Pregnancy				
End of treatment-CRF6	AI32 🗌 Rash				
Follow Lin post treatment	AI35 O Possible active TB				
Pollow-Op post treatment	AI36 Other reason for stopping				
Post treatment follow-up-CRF7	AI39 Was any other investigation done (a part from the one already listed in AI5-AI37)?	- •			
End of post treat. follow-up-CRF8	AI41 Was the participant referred to other specialist?	- •			
Death during post treatCRF14	AI42 Was the participant hospitalized?	- •			
Adverse event	History of adverse event				
AE initial evaluation-CRF9	AI43 Date of onset of symptoms	Today dd-mm-yyyy			
Active TB	AI44 Date in which study participant took the last dose of study medication	Today dd-mm-yyyy			
ATB initial-CRF11	Describe the symptoms and the current history of the event using as much detail as possible. Make sure that all the points				
Help	1. Time at which medication is usually taken	7. If participant had any recent exposure to allergens or food			
Merce Frequently asked quest. (FAQ)	Number of hours between ingestion of medication and onset of symptoms	8. If participant had any past history of disease 🕐			

When you entered the information needed in CRF9, click first on "Save/stay on page"(figure 37) Figure 37

Reserved for the site user	
	Save/Stay on page
	SAVE & CLOSE

You will see an Event number appearing on the top of the form (**figure 38**). Use this number to add as event number on your <u>paper</u> form **CRF9**. **Figure 38**

	Adverse event initial evaluation	Version 1 - Last update September 24th 2019	
	Editing participant's CAL-7 Adverse event initial evaluation	ation form	
	AI0 Research staff completing the form	Utilisateur de test	
Logged in as demo	Adverse event initial evaluation		
Connected at 04/09/2020 - 3:28:42 PM	All Event number	1	
[Sign out]	AI2 Date of event *	04-09-2020	
Data capture	Regarding study medication status, please select one		
Dashboard	AI3 Study medication was stopped before the study participa	int completed the full course V	
😹 Add / Select records	Why was study medication stopped?		
CRF1-3 for participant CAL-7 [Change]	AI4 Treating team stopped medication due to potential ad	tverse event 🗸	
Initial screening	Description of adverse event and investigations done		
 Eligibility & consent Demographics & TB history Medications/Allergies/Med.eval 	Which was the most important reason for stopping study medication? (choose one or more, as applies)	Which of the following MANDATORY TESTS were undertaken for this event? (choose all that applies except if differently specified)	
 Initial investigations 	AI5 Death		
Randomization & Study drugs	AI8 Hepatotoxicity		
Follow-Up during treatment CRF5 All7 Hematologic			
General information	A120 Drug interaction		
End of treatment-CRF6	AI22 Castrointestinal intolerance		
Fallow I la part tractment	AI23 AI24 Specify	✓ Liver function test ✓ Complete blood count	
Pollow-Op post treatment	A125 A126	Amylase Pregnancy test	
Post treatment follow-up-CRF7	A127	Date of last menstrual period was asked	
End of post treat. follow-up-CRF8	A128	Abdominal/liver ultrasound (not mandatory)	
Death during post treatCRF14	A129 Pregnancy		
Adverse event 1(04-09-2020)	AI32 🗌 Rash		
AE initial evaluation-CRF9	AI35 Possible active TB		

When you are sure that your **CRF9** is complete, click on **"SAVE & CLOSE"** in the space reserved for site user (see **figure 37** above).

This action will submit the **CRF9** (AE Initial evaluation form) to coordinating center and will serve as an alert that a new AE has occurred in the trial. You will not be able to modify a **CRF9** once the **"SAVE & CLOSE"** button has been chosen.

The coordinating center will review the **CRF9** and get back to you if more information is needed. If no additional information is needed for the **CRF9**, you will have to complete the **CRF10** (AE Final evaluation form) for this AE once the event is resolved.

Figure 39 Dashboard

6	8 /100 /	0010001	coordo		
CR	F1-3 for	particip	ant CAI	-7	[Change
	Initial so	creening			
	Eligibilit	y & con	sent		
	Demog	raphics a	& TB his	story	
	Medical	tions/Alle	ergies/N	led.ev	al
	Initial in	vestigat	ions		
•	Randon	nization	& Study	/ drugs	5
Fol	low-Up (during tr	eatmen	t CRF	[Change
	12 (04-0	19-2020)	Incon		
•	Genera		ation		
•	Sympto	ms & pr	iysical e	xam	
-	Investig	ations d	uring to	llow-u	р
-	Treatme	ent plan			
•	Populat	ion PK-(CRF13		
•	End of t	reatmer	nt-CRF6		
Fol	low-Up (post trea	itment		
•	Post tre	atment	follow-u	p-CRF	7
•	End of p	oost trea	t. follow	/-up-C	RF8
•	Death d	luring po	ost treat	-CRF	14
Adv	verse ev	ent 1(04	-09-202	20)	[Change
	AE init	ial evalu	ation-C	RF9	
	AE final	evaluat	ion-CR	F10	
Act	ive TB				
	ATB init	ial-CRF	11		

As each participant can have more than one AE, each **CRF9** is named with the date in which is generated (**figure 39**)

Once a **CRF9** has been saved, an **"AE final** evaluation **CRF10**" will appear below the **"AE** initial evaluation **CRF9"** on the left menu. (figure 39)

The dot in the left menu for **CRF9** will remain yellow until the coordinating center reviews and approves the **CRF9** form. Once approved the dot will become green.

5.3.9. CRF10 Adverse Event Final evaluation

For each **CRF9** that has been entered in the website, a **CRF10** must be completed, as soon as all information needed are available.

A **CRF10** can be completed only after a **CRF9** has been completed (i.e, you have clicked on "**SAVE** & **CLOSE**") and the coordinating center has approved it (i.e. the dot beside **CRF9** is green).

To complete a **CRF10**: select the participant you want to add a **CRF10** for, from the "**Add/Select participant record**" page, then select the AE initial evaluation for which you want to add a Final AE form in the section "**Adverse Events**" of the same page, in this example, AE #1 is selected for participant CAL-7 (**figure 40**).

Participant's file				
\$1	Screening ongoing (1)	select record	~	0
52	Randomized (2)	CAL-7	~	(Change)
53	Excluded (3)	select record	~	?
54	Excluded post randomization(5)	select record	~	?
Add a new partic	ipant Id			

Follow-Up during treatment			
	Follow-Up during treatment (3)	select record	✓ Add a new flw-up
Follow-Up post treatment			
	Follow-Up post treatment(2)	select record	✓ Add a new pst flw-up
Adverse events			
	Adverse events initial (1	/select record	Add a new AEI
	Adverse events final (1)		4

You can now open **CRF10** from the left menu (**CRF10** will be below **CRF9**), and fill CRF10 (**figure 41**)

,	Adverse event final evaluation	Version 1 - Last update September 25th 2019	
	Editing participant's CAL-7 Adverse event final evaluation for	orm	
	AF0 Research staff completing the form		
Lower dia so dama	Adverse event final evaluation		
Connected at 04/09/2020 - 3:28:42 PM	AF1 Event number	1	
[Sign out]	AF2 Date of completion of CRF10 *	Today dd-mm-yyyy	
Data canture	AF3 Was this considered an adverse event by the study team?	- •	
	Final impression of treating team		
Add / Select records	AF9 Final impression of grading severity	- ~	
	AF10 Final impression of relationship to therapy	- *	
CRF1-3 for participant CAL-7 [Change] Initial screening	AF11 If study medication was permanently stopped, reason for stopping study medication	- •	
 Eligibility & consent Demographics & TB history 	NOTE If the study medication was already completed but the AB choose the most important reas	E occurred less than 30 days after completing study drugs, son for this adverse event.	
Medications/Allergies/Med.eval	Description of adverse event		
Initial investigations Randomization & Study drugs	Total number of visits the study participant had between the AF13 date of first evaluation for this adverse event and the date of resolution of this adverse event		
Follow-Up during treatment CRF5[Change]	AF14 Date of resolution of adverse event	Today dd-mm-yyyy	
General information	AF15 Description of adverse event and resolution		
 Symptoms & physical exam Investigations during follow-up 	Please provide details of what happened from the onset until the complete resolution of the adverse event. Make sure that all the following points below are mentioned in the narrative (If any of the points below are not known, please write "NOT DONE" or "NOT KNOWN")		
 Treatment plan 	1. Date treatment started and indication		
- Description DK 00544	2. Date of onset of AE including initial symptoms, and/or lab resi	ults	
Population PK-CRF13	What were the results of initial evaluation of the AE: history of etc.), symptoms, physical exam, lab tests, other specialists' con	f other possible causes (as food, other drugs, alcohol sultations	
End of treatment-CRF6	4. When was the study drug held		
	What happened - provide sequence of events especially hosp tests. Was a re-challenge made with the study drug? Was an all	pitalization, resolution of abnormalities - symptoms or lab ternative therapy given	
Best treatment fellow up CRE7	NOTE: Provide as much detail as possible without specifying the medication. Use exact dates (i.e. 19-Jan-2020) as much as poss	e planned duration (4 months or 2 months) of the study sible.	
End of post treat. follow-up-CRF8			
Death during post treatCRF14			
Adverse event 1(04-09-2020) [Change]			
AE final evaluation-CRF10			
Active TB ACT Initial-CRF11		SAVE	
Help			
 Frequently asked quest. (FAQ) Glossary Note to file 			

Once you are sure to have entered all the information, click on "SAVE & CLOSE", at the bottom of the form. Note: If you want just to save the form, to work on it later, click on "SAVE".

Once you clicked on **"SAVE&CLOSE"**, the from is submitted for review to the coordinating center and cannot be modified. The coordinating center will contact you if more information are needed.

Note: the dot in the left menu will be yellow until the coordinating center will approve the form. Once approved the dot will be green. If a **CRF9** and **CRF10** for an AE are approved, they are sent automatically to the AE panel for review. If the AE panel does not find agreement in the review, the coordinating center will contact you for more information. In that case the **CRF10** will be "reopen" for you to modify and add the additional information needed. Once modifications have been made, you can click on "**SAVE&CLOSE**" and then whole process will be repeated (i.e.

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the coordinating center will approved or ask for more info, once approved, the new **CRF10** will be sent to review to AE panel until an agreement is found).

5.3.10 CRF11 Active TB Initial

To enter **CRF11**: select, from the "**Add/select participant record page**, the randomized participant for whom you want to enter an "Active TB Initial evaluation" form; find the form at the bottom of the left menu.(**figure 42**)

Figure 42



Complete the form **CRF11** that will appear (figure 43)

Figure 43

Active TB initial evaluation	Version 1 - Last update November 8th 2019			
Editing participant's CAL-11 Active TB initial evaluation	on form			
TB0 Research staff completing the form				
Active TB initial evaluation				
TB1 Date *	Today dd-mm-yyyy			
TB2 Is the study participant suspected to have active TB?	- 🗸			
Potential symptoms of active TB				
Does the study participant have any of the following	symptoms?			
TB3 Night sweats/Fever	- •			
TBS Cough	- 🗸			
TB7 Sputum production	- 🗸			
TB9 Other	- 🗸			
TB11 Physical exam	- 🗸			
Description				
${\scriptscriptstyleTB15}$ Describe the symptoms and other relevant details of the	suspected active TB in as much detail as possible			
Treatment				
TB16 Treatment started -	×			

Note: at the bottom of the page you have a reminder of what needs to be collected when one participant is suspected to have active TB (figure 44) Figure 44

REMINDER	
Chest x-rays are needed at 3 time points (see below), send results for all 3 to the coordinating ce 1 - Randomization	nter
2 - Time of TB diagnosis (now) 3 - End of the TB treatment	
Culture at the time of the diagnosis is mandatory - at least 2 sputum samples for AFB smear and TB culture	must be done

Make sure you have the CXR done for the diagnosis of this suspected TB event and that you have the file of the CXR done at randomization for this participant. Both these two CXR (i.e. the one done at randomization and the one done now, at diagnosis) will be submitted, together with the final CXR (at end of treatment) to coordinating center via the 2R2 website, at the moment in which you will complete **CRF12** (ATB final evaluation report).

Once you are done with entering **CRF11**, you can click on **"SAVE&CLOSE"** at the bottom of the page. At this point the form cannot be modified any longer. **Note** : if you just want to save the page, and come back to work on it later, click on **"Save"**.

Once you clicked on "SAVE&CLOSE" the dot beside ATB initial-CRF11, on the left menu, will become yellow, and ATB Final-CRF12 will appear (figure 45).

Figure 45



An automatic message is also sent by the website to the coordinating center informing that there is a new ATB initial report to review. The coordinating center will review the **CRF11** and either ask you for more information (in that case the **CRF11** we be "reopen" and you will be able to modify it), or confirm it is complete. In this case the dot beside **CRF11** will become green (**figure 46**)

Figure 46



You need to complete a **CRF12** (ATB Final evaluation report) for each **CFR11** you have entered.

5.3.11 CRF12 Active TB Final evaluation

Once you are ready to enter information for **CRF12**, select the participant you want to enter **CRF12** for from the **"Add/Select participant records"** page, at the section "Active TB" (**figure 47**).

Add of select participan	record				
Participant's file					
\$1	Screening ongoing (1)	-select record-		~ 🕐	
S2	Randomized (2)	-select record-		~ 🕜	
S3	Excluded (3)	-select record-		~ 🕐	
S4	Excluded post randomization(5)	-select record-		~ 🕜	
Add a new participant Id					
Follow-Up during treatment					
	Follow-Up during treatment (11)	-select record-	~		
Follow-Up post treatment					
	Follow-Up post treatment(3)	-select record-	~		
Adverse events					
	Adverse events initial (5)	-select record-	~		
	Adverse events final (5)	-select record-	~		
Active TB					
	Active TB initial(5 🗸	select record			
	Active TB final (4	CAL-11 CAL-2	-		
		CAL-3			
		CAL-4	C		

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

Once you have selected the participant in the dropdown list of "Active TB Initial", you can click on CRF12 on the bottom of the left menu and CRF12 will open (figure 48). Figure 48

2	Active TB final evaluation	Version 1 - Last update November 8th 2019	
	Editing participant's CAL-11 Active TB final evaluation form		
	TF0 Research staff completing the form	Utilisateur de test	
Leased in an dema	Active TB final evaluation		
Connected at 10/09/2020 - 1:19:42 PM	TF1 Date *	10-09-2020 Today dd-mm-yyyy	
[Sign out]	${}^{_{TF1.1}}\ensuremath{Was}$ study participant diagnosed with (or died of) active TB?	- 👻	
Data capture	Description		
E Dashboard	${\scriptscriptstyle TF30}$ Describe the symptoms, the history of the illness and any unusual finding	ngs in as much detail as possible	
Add / Select records			
Initial screening			
Eligibility & consent	Eligibility & consent Diagnosis and Treatment		
Demographics & TB history	TF31 Site of TB	- •	
 Initial investigations 	TF32 Specify if Other		
 Randomization & Study drugs 	TF33 Method of diagnosis 🔞	Radiological	
Follow Lip during treatment CREE	TF34	Microbiological	
 General information 	TF35		
	TF36	Pathology	
End of treatment-CRF6	$_{\rm TF37}$ Is the date treatment started confirmed to be the one reported in CRF11?	- •	
Follow-Up post treatment	${}^{_{\rm TF39}}$ Did the treatment change since what reported in CRF11?	- 🖌	
Post treatment follow-up-CRF7	Response to treatment		
	TF41 Symptoms resolved	- 🗸	
End of post treat. follow-up-CRF8	TF42 Tolerability of the therapy		

Complete the form with all the available information, then click on **"Save"** at the bottom of the page (**figure 49**).

Figure 49

inguic 45		
Reserved for the site user	1	
	SAVE	
	SAVE & CLOSE	

At this point, after having save all information, you will be able to upload the CXR pictures for this ATB report.

Upload the <u>chest x-ray done at diagnosis of this Active TB event</u> in the section **"File uploaded"** after variable TF5 (**figure 50**).

Figure 50

Initial investigations	
TF4 Chest x-ray at the time of diagnosis	Yes 🗸
TFS L Date chest x-ray done	10-03-2020 Today dd-mm-yyyy
Send copy of film to the coordinating center	er by 2R2 website
File uploaded:	
Choose File No file chosen	Upload & save

First open the window on the right of the **"File uploaded"** section, then choose the file from your computer (Note: file must be an .jpeg format) then, click on **"Upload & save".**

Upload in the same way <u>other radiological test (if any</u>), in the section **"File uploaded"** after variable TF8 (**figure 51**).

Figure 51

-0		
TF6	Other radiological tests	Yes 🗸
TF7	i Date radiological test done	04-03-2020 Today dd-mm-yyyy
TF8	Name of the test	
	Send copy of film to the coordinating cent	er by 2R2 website
File	uploaded:	
Cł	oose File No file chosen	Upload & save

Upload the <u>CXR done at the end of treatment (for all participants with ATB)</u>, after variable TF57 (figure 52). Figure 52

Response to treatment	
TF41 Symptoms resolved	Yes 🗸
TF42 Tolerability of the therapy	good
TF43 Estimated adherence	good
TF44 Completed therapy	Yes 🗸
TF45 i Date completed	10-09-2020 Today dd-mm-yyyy
TF46 Treatment outcome	Cured V
TF48 Sputum for AFB and culture during treatment	Yes 🗸
TF49 AFB smear done	Yes 🗸
TF50 i Number done	2
TF51 Results	All negative V
TF52 Cultures done	Yes 🗸
TF53 i Number done	2
TF54 Results	All negative V
${}^{\mbox{\tiny TF56}}$ Chest x-ray or other imaging at the end of treatment for active TB	Yes 🗸
TF57 Date done	10-09-2020 Today dd-mm-yyyy
Send film to the coordinating center	by 2R2 website
File uploaded:	
Choose File No file chosen	Upload & save

Once you are done with entering **CRF12**, you can click on **"SAVE&CLOSE"** at the bottom of the page. At this point the form cannot be modified any longer. **Note** : if you just want to save the page, and come back to work on it later, click on **"Save"**.

Once you clicked on "SAVE&CLOSE" the dot beside ATB initial CRF12, on the left menu, will become yellow. An automatic message is also sent by the website to the coordinating center informing that there is a ATB final evaluation report to review. The coordinating center will review the CRF12 and either ask you for more information (in that case the CRF12 we be "reopen" and you will be able to modify it), or confirm it is complete. In this case the dot beside CRF12 will become green. The ATB panel members will independently review the CRF11 and CRF12 for this ATB report and evaluate. If there is agreement the report is consider final. If there is no agreement and more information are needed, the coordinating center will contact you for more information, CRF12 will be reopened and you will be able to modify it.

For participants who have an ATB report, please upload also the <u>CXR done before</u> <u>randomization</u>. To upload the CXR done before randomization, please go to **"Initial investigations" (in CRF3)**, choosing the page from the left menu for the participant for whom you just completed **CRF12 (figure 53)**.





- Medications/Allergies/Med.eval
- Initial investigations
- Randomization & Study drugs

The CXR done at randomization can be uploaded after variable L2 (Chest-x ray results).

Please note that, for all the CXR uploaded, a unique name, without nominal information, is automatically given by the website (see example in **figure 54**)

ingai e ba

Ch	est X Ray			
L1	Date of chest-x ray *	31-08-2020 📆 Toda	iy dd-mm-yyyy	
L2	Chest-x ray results *	Normal	~	
сх	R uploaded file: CAL-11_Xray_L1_31-08-2020.jpeg			-

5.3.12 CRF13 Population PK

When you are ready to enter data from the Population PK form **CRF13**, select the "Follow-up during treatment" visit in which the PK was done for that participant, from the **"Add/select participant record"** (figure 55)

Add or select participant record Version 1, last update Octo Participant's file As1 Screening ongoing (1) -select record • @	oer 2 2019
Participant's file As1 Screening ongoing (1)	
AS1 Screening ongoing (1)select record V	
As2 Randomized (2) CAL-7 V 🚱 Char	ge]
Logged in as demo Connected at 04/09/2020 - 2:03:52 PM	
[Sign out] A54 Excluded post randomization(5) -select record V	
Add a new participant Id	-
Dashboard Follow-Up during treatment	
Follow-Up during treatment (2 🗸select record	p
CRF1-3 for participant CAL-7 [Change] Follow-Up post treatment CAL-7-2020-09-03 CAL-7-2020-09-03	
Demographics & TB history Adverse events	
Add or select participant record Version 1, Coged in as demo Connected at 04/09/2020 - 2:03:52 PM [Sign out] Sign out] Image: Participant Call Data capture Data capture Data capture Data capture Image: Participant Call CRF1-3 for participant CAL-7 Changed Initial screening Eligibility & consent Demographics & TB history Medications/Allergies/Med.eval Initial investigations Randomization & Study drugs Follow-Up during treatment CRF5 General information Active TB Active TB Active TB	
Adverse events final (0)select record	
Follow-Up during treatment CRF5 Active TB	
Active TB initial(0)select record	

The population PK form **CRF13** will appear on the left menu, after the Follow-up form (**figure 56**) **Figure 56**

2	📓 Add or select participan	t record		Version 1, last u	pdate October 2 2
	Participant's file				
	A51	Screening ongoing (1)	select record	~	(2)
	AS2	Randomized (2)	CAL-7	~	[Change]
Logged in as demo Connected at 04/09/2020 - 2:03:52 PM	A53	Excluded (3)	select record	~	0
[Sign out]	A54	Excluded post randomization(5)	select record	~	0
Territoria	Add a new participant Id				0
Dashboard					
Add / Select records	Follow-Up during treatment				
		Follow-Up during treatment (2)	CAL-7-2020-09-03	✓ [Change]	
RF1-3 for participant CAL-7 [Change]	Follow-Up post treatment				
Eligibility & consent		Follow-Up post treatment(2)	CAL-7-2020-09-04	✓ [Change]	
Demographics & TB history Medications/Allergies/Med.eval	Adverse events				
Initial investigations		Adverse events initial (0)	select record	✓ Add a m	ew AEI
Randomization & Study drugs		Adverse events final (0)	select record	~	
ollow-Up during treatment CRF5[Change]	Active TB				
General information		Active TB initial(0)	select record	~	
Symptoms & physical exam	-	Active TB final (0)	select record	~	
 Treatment plan 					
Population PK-CRF13					
End of treatment-CRF6					

2R2 SOP20 Website site user's manual_08Sep2020 Higher dose Rifampin for 2 months vs Standard dose Rifampin for Latent TB: a 3-arm randomized trial. Click on it, and the **CRF13** will appear. Once the form is completed, click on "**Save/Exit**" (figure 57).

Figure 57							
2	Population P	к				Version 1 - Last u	pdate September 25th 2019
	🥖 Editing participa	ant's CAL-7 Po	opulation PK f	orm			
	ко Research staff o	completing the f	orm				
Longed in as demo	Data on PK samplin	ng					
Connected at 04/09/2020 - 2:03:52 PM	кі Date of sampling	g				15 Today dd-m	п-уууу
[Sign out]	ка When was the s	tudy drug taker	at home?		h	h:mm (24 hour clock)	
Data capture	Population PK Population PK Population PK Secure Population PK Secure Population PK Secure <						
Dashboard	к4 Is the participan	t taking other d	rugs?		- `	•	
Add / Select records	Name of other drug	is taken					
CPE1 2 for participant CAL 7	K5- Name		Date an	d time of last dose	dd-mm-yyyy - hh:m	m Daily do	se Unit
Initial screening	🕒 Click on the gre	en "+" sign to	add another m	nedication			
 Eligibility & consent Domographics & TB history 	Blood sampling						
Ata capture K3 Did the participant had anything to eat since midnight? - ~ Image: Solution of the participant taking other drugs? - ~ ~ Image: Solution of the participant taking other drugs? - ~ Image: Solution of the participant taking other drugs? - ~ Image: Solution of the participant taking other drugs? - ~ Name of other drugs taken - ~ Name of other drugs taken - ~ Initial screening Date and time of last dose dd-mm-yyyy - hhumm Daily dose Image: Solution of the participant taking other drugs taken - ~ Medications/Allergies/Med.eval Blood sampling - - Initial investigations Randomization & Study drugs Storage time sampling Operator Centrifuge Done by Storage time sampling Io (03-092-020) (Incompleto) Storage time sampling - - - Io (03-092-020) (Incompleto) Storage time sampling - - - Symptoms & physical exam K24 Comments - - Investigations during follow-up Trastrenet plan - - </th <th>age Done by</th>	age Done by						
 Randomization & Study drugs 	K10- H2		sampling				
	K17- H4						
10 (03-09-2020) (Incompleto)	K23						
General information Symptoms & physical exam	K24 Comments						
 Symptoms a physical exam Investigations during follow-up 	ites comments						
Treatment plan							
Population PK-CRF13							
End of treatment-CRF6							
Follow-Up post treatment [Change] 3 (04-09-2020)							
Post treatment follow-up-CRF7							
End of post treat. follow-up-CRF8					Save/Stay on p	age	
Death during post treatCRF14					Save/Exit		

Note: if the participant has not done the PK sampling at a follow-up visit in which he/she was supposed to (i.e. the 4 weeks visit), remember to write it in variable F16 of **CRF5**. In that case, no **CRF13** needs to be completed.

5.3.13 CRF14 Death in post treatment follow-up

The form **"Death during post treatment follow-up"** becomes visible in the left menu when you already completed a form **"End of treatment CRF6"** for the same participant. If you need to enter a **CRF14**, select the participant from **"Add/Select records"**; then click on **"Death in post treatment CRF14"** in the left menu and fill out the form. Click on **"Save/Exit"** when it's complete (figure 58).

liguie Jo		
2	Death during post-treatment	Version 1 - Last update September 23rd 2019
	Editing participant's CAL-7 Death during post-treatment for	orm
	H0 Research staff completing the form	
Longed in as damo	Death during post-treatment information	
Connected at 04/09/2020 - 2:03:52 PM	H1 Date form is completed	Today dd-mm-yyyy
[Sign out]	H2 Date of death of the participant *	Today dd-mm-yyyy
Data capture	H3 Was the participant hospitalized before dying?	- *
Dashboard	H4 Was Active TB likely the cause/contributor of death?	- •
😹 Add / Select records	Narrative	
CRE1-3 for participant CAL-7 (Change)	H6 Narrative that describes the circumstance of death	
 Eligibility & consent Demographics & TB history Medications/Allergies/Med.eval Initial investigations Randomization & Study drugs 	If any of the points below are not known, piease spect 1- Hospitals where participant has been hospitalized 2- Treating physicians and dates of hospitalization 3- List of symptoms and duration 4- Laboratory done and results 8- Ai 9- Ai	In the there were "NOT DONE" of "NOT KNOWN" elevant images done and results ames of disease diagnosed reatment received by participant utopsy results ny other relevant information
Follow-Up during treatment CRF5[Change] 11 (03-09-2020) (Incomplete) General information Symptoms & physical exam Investigations during follow-up Treatment plan		
Population PK-CRF13	Get and document permission to obtain clinical, laboratory	treatment information, and copies of relevant X-rays from
End of treatment-CRF6	participant's trea	ating physician.
Follow-Up post treatment [Change] 3 (04-09-2020) Post treatment follow-up-CRF7		Save/Go to next form Save/Stay on page Save/Exit
 End of post treat. follow-up-CRF8 Death during post treatCRF14 		

Note: if a sentence in **RED** appears when you select a Yes on the question H4, **pay attention!** This means that you must fill out the ACTIVE TB report form **CRF11** before or after completing the Death during post treatment form (**figure 59**).

Figure 59 rsion 1 - Last update September 23rd 2019 Death during post-treatment Editing participant's CAL-7 Death during post-treatment form H0 Research staff completing the form Death during post-treatment information Logged in as demo 04-09-2020 Today dd-mm-yyyy Connected at 04/09/2020 - 2:03:52 PM H1 Date form is completed [Sign out] 04-09-2020 Today dd-mm-yyyy H2 Date of death of the participant * Home H3 Was the participant hospitalized before dying? Yes v Data capture H4 Was Active TB likely the cause/contributor of death? Yes ~ Dashboard Add / Select records If Yes, please complete ACTIVE TB report CRF11 form Narrative CRF1-3 for participant CAL-7 [Change] H6 Narrative that describes the circumstance of death Initial screening Eligibility & consent Make sure that all the points below are mentioned in the narrative If any of the points below are not known, please specify that there were "NOT DONE" or "NOT KNOWN" 1- Hospitals where participant has been hospitalized 2- Treating physicians and dates of hospitalization 3- Relevant images done and results 3- Relevant images done and re Demographics & TB history Medications/Allergies/Med.eval Initial investigations 3- List of symptoms and duration 7- Treatment received by participant Randomization & Study drugs 4- Laboratory done and results 8- Autopsy results 9- Any other relevant information Follow-Up during treatment CRF5[Change] 11 (03-09-2020) (Incomplete) General information Symptoms & physical exam Investigations during follow-up Treatment plan Population PK-CRF13 Get and document permission to obtain clinical, laboratory, treatment information, and copies of relevant X-rays from End of treatment-CRF6 participant's treating physician Save/Go to next form Follow-Up post treatment 3 (04-09-2020) Save/Stay on page Post treatment follow-up-CRF7 Save/Exit End of post treat. follow-up-CRF8

5.3.14 "Note to file" form site

If a change needs to be made to a completed and saved CRF you need to fill a " 2R2 Note to file" (see **Appendix 1).** Please complete first a paper "Note to file" (see SOP folder in 2R2 drop-box), then enter the "Note to file" in the 2R2 website. **Note**: if you prefer, you can complete a "Note to file" directly in the 2R2 website, but then you need to print it out and add it to the participant's folder (in order to have a copy of the "Note to file" both in the participant's folder and in the website).

The "Note to file" form is the official and standardized way to communicate between sites and coordinating center when there are modifications needed in CRFs. In this way, all the changes made are stored in the website, with a record of why and when they were made.

Changes could be done for the following reasons:

1. A manual randomization was done, and you need to inform the coordinating center so that the website can be updated to match the randomization received by the envelope used for the manual randomization;

 A participant who has been randomized, meets one of the criteria for exclusion post randomization (see protocol, "Exclusion criteria post-randomization");
 An error has been made in any CRF that needs to be corrected.

In all these cases you need to describe briefly what made the changes necessary.

Note: all changes done in e-CRFs must reflect the changes done in the paper CRFs. In paper CRFs changes will be dated and signed by the person doing them.

The "Note to file" can be found at the bottom of the left menu, in the "Help" section (**figure 60**) **Figure 60**



After clicking on **"Note to file"**, select the participant for whom you would like to do the changes **(figure 61).**

Figure 61

Note to file		
		-
Study participan(1)	select record	
	CAL-2	
ParticipantID	CAL-3	- 1
CAL-2	CAL-4	•
CAL-2	CAL-5	s
CAL-3	CAL-6	a
CAL-4	CAL-7	-
CAL-4	CAL-8	s
= Submitted	CAL-10	et
	CAL-11	
	CAL-12	

Choose the reason why you need to make the change(s) for that participant among three choices given at variable NF1 (**figure 62**).

Figure 62 ✓ -Manual randomization was done Exclusion post randomization per protocol Other reason for a change in the database

Fill in the required information for the option you have chosen (figures 63-65) and click on "Add note to file" at the bottom of the form.

Figure 63

NF2	Which is the reason why changes to the database are required?		
	Manual randomization was done		
NF3	I manual randomization was done, explain briefly why you use manual randomi which access to website was not available):	zation (please i	nclude dates and time in
NF4	$\lim_{\ensuremath{}}$ Which is the number on the randomization envelope you used		
NFS	i With manual randomization, the participant has been randomized to	-	~
NF6	I If 2 months, please write the code given		
	Add note to file		

Figure 64

0.		
NF2	Which is the reason why changes to the database are required?	
	Exclusion post randomization per protocol	
NF7	Please state the reason why the participant should be excluded	
	Add note to file	

Note: if an exclusion post-randomization is necessary, please write down in NF7 which is the reason why that participant should be excluded. For example, write which are the result of the baseline lab test which are abnormal and which are the normal limit, etc.

2R2 SOP20 Website site user's manual_08Sep2020 Higher dose Rifampin for 2 months vs Standard dose Rifampin for Latent TB: a 3-arm randomized trial.

Figure 65

Other reason for a change in the	e database 🛛 💙	
If Other, please specify which c	of the following form(s) need(s) to be changed, how and why. Please check	all that ap
- *	-select record-	
Information currently in the we	ebsite that you would like to change (specify variable and value to change)	
Information that you would like	e to have instead (specify variable and value to change)	
i Information that you would like	e to have instead (specify variable and value to change)	
Information that you would like	e to have instead (specify variable and value to change)	
Information that you would like	e to have instead (specify variable and value to change)	
Information that you would like	e to have instead (specify variable and value to change)	

Note: if more than one CRF needs to be corrected for the same participant, all the CRFs to be modified can be communicated in the same **"Note to file"**. Once you have completed the information required for the first change, click on **"Add note to file"**, then select another CRF from the scroll down menu. Click on **"Add another CRF/changed needed for this Note to file"** when you have entered the required information for the second change you want to make **(figure 66)**.

Figure 66

-	-select record-	
CRF 1	surrently in the website that you would like to change (specify variable and value to change)	
CRF 2		_
CRF 3		
CRF 5		
CRF 6	hat you would like to have instead (appoint yorights and yolys to shappo)	
CRF 7	hat you would like to have instead (specify variable and value to change)	
CRF 8		
CRF 9		
CRF 10		
CRF 11	he change	
CRF 12		
CRF 13		
CRF 14		
	Add another CRE/changed needed for this Note to file	

When "Add Note to File" is clicked, an automatic message will be sent to the coordinating center who will process the required change. You will be contacted if more information is needed. Otherwise the note to file will be addressed, the required modifications will be made in the eCRF(s) and this "note to file" will be archived by the coordinating center. You can check the status of your notes on the "Note to file page" by clicking on "Note to file" in the left menu. You will see a summary table (figure 67)

Figure 67

•				
ParticipantID	Date note to file	Reason why changes to the database are required	Date of action	Status
CAL-2	20-08-2020	Other reason for a change in the database	20-08-2020	•
CAL-2	20-08-2020	Exclusion post randomization per protocol		•

The notes that have been taken care of have a green dot in the "Status" column, the ones which are still on treatment at the coordinating center have a black dot. In this example, for participant CAL-2 the note to change CRF for other reasons has been processed on August 20th, the note on exclusion post randomization is still under process.

5.3.15 Checking your site's participants status

To check the list of your participants and the forms you have completed for your site, you can go to Dashboard (on the left menu) and then click on **Show section** in the Participants forms status (**figure 68**).

Figure 68

Participants forms status	
	Show section

For each participant screened at your site (either randomized or not randomized yet), you will be able to see the status of each form.

Participants forms status													
Participant	Scr	Elig	Dem	Med	Invest	Rand	End Flup	End pst Flup	Death	ATB	Flw-up	Pst Flw-up	AE
CAL-5	-	-	-	-	-	•	•	•	•	•	0	0	0
CAL-7	•	•	•	-	•	-	•	-	•	-	3	2	1
CAL-11	•	•	-	-	-	-	•	•	•	-	1	0	0

Abbreviations used in this table:

Scr: CRF1
Elig: CRF2
Dem: CRF3-Demographic
Med: CRF3-Medical evaluation
Invest: CRF3-Initial investigations
Rand: CRF3-Randomization
End Flup: CRF6

End post Flup: CRF8 Death: CRF14 ATB: CRF11 Flw-up: Number of CRF5 entered Post Flw up: Number of CRF7 entered AE: Number of CRF9 entered

The status for each form is represented as following: Record status dashboard

= Not done - = Incomplete - Complete = Excluded

6.0. References

To practice you can access the demonstration site 2R2 demo at: <u>http://2r2-demo.crc.chus.qc.ca/index.aspx?uc=0</u> username: demo; password: demo

2R2 website: site user's manual 2R2 SOP20_08Sep2020					
<i>Appendix 1: 2R² Note to file Note this paper form can be found in the 2R2 drop-box</i>					
A1.Participant's Study ID number					
NF0. Research Staff completing the form					
NF1. Date D D M M Y Y Y Y					
NF2. Which is the reason why changes to the database are required?					
Manual randomization was done. If manual randomization was done: NF3: Explain briefly why you use manual randomization (please include dates and time in which access to website was not available):					
NF4: Which is the number on the randomization envelope you used:					
NF5: With manual randomization, the participant has been randomized to :					
4 months of Rifampin 10mg/kg/day					
2 months of Rifampin high dose, if 2 months, please write the code given (NF6)					
Exclusion post randomization per protocol, NF7. Please state the reason why the participant should be excluded:					
Other reason for a change in the database (see next page)					
2R2 SOP20 Website site user's manual_08Sep2020 Higher dose Rifampin for 2 months vs Standard dose Rifampin for Latent TB: a 3-arm randomized trial.					

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2R2 website: site user's manual						
			2R2 SOP20_08Sep2020			
NF8: If how and why.	Other, please specify which o Please check all that apply.	f the following form(s) ne	ed(s) to be changed,			
Form(s) to change	Information currently in the website that you would like to change (specify variable and value to change)	Information that you would like to have instead (specify variable and value to change)	Reason for the change			
CRF1						
CRF2						
CRF3						
CRF5						
date						
CRF5						
date						
CRF5						
date						
CRF6						
CRF7						
CRF8						
CRF14						
2R2 SOP20 Website site user's manual_08Sep2020 Higher dose Rifampin for 2 months vs Standard dose Rifampin for Latent TB: a 3-arm randomized trial.						
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7.0. SOP Revision history

SOP code	Effective date	Summary of changes	
SOP20_08Sep2020	15 September 2020	NA (original version)	