



RePORT International Long TB – User Guide to Frontier Science Utilities

REPORT LONG TB REFGD001

Version 1.1

October 21, 2025

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About

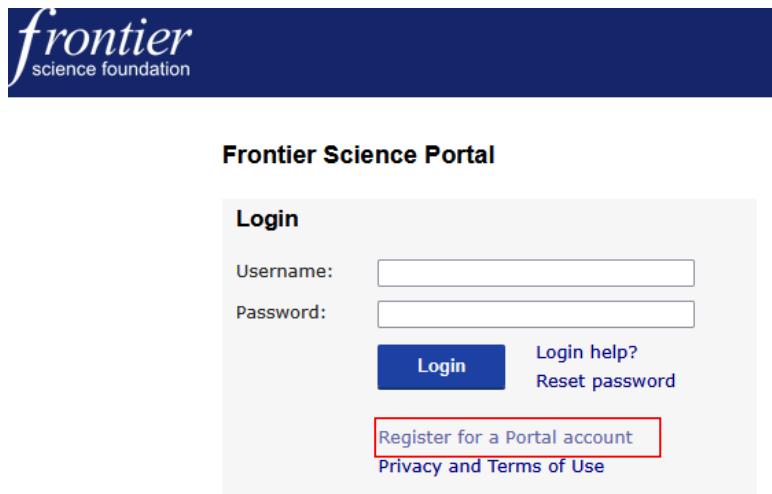
The RePORT International Long TB project will collect data in a variety of ways.

1. A central REDCap build hosted at Frontier Science. All sites must register for accounts to access this central REDCap build to log participant data.
2. The File Exchange Utility (FEU) hosted at Frontier Science. All sites must register for accounts to access this utility to upload de-identified DIACOM scan files.
3. The Data Submission System (DSS) hosted at Frontier Science. All sites must register for accounts to access this utility to upload information about specimen storage and availability.

This guide includes instructions for registering for accounts and for accessing and using these tools.

Registering for Access to Frontier Science Utilities

All users must first register for a Frontier Science portal account. Begin by navigating to www.frontierscience.org and clicking on the Portal link and then on the Register for a Portal account link.



Frontier Science Portal

Login

Username:

Password:

Login [Login help?](#) [Reset password](#)

[Register for a Portal account](#) [Privacy and Terms of Use](#)

Figure 1: File Exchange Utility link

Complete the Frontier Science portal registration form, including setting your password, and click **Next>**.

On the following page request access for the RePORT project.

- **Site IDs have been assigned as follows. Please be sure to enter the 2-digit ID corresponding to your site:**
 - 12- Christian Medical College (CMC), Vellore
 - 13- Byramjee-Jeejeebhoy Government Medical College (BJGMC), Pune
 - 14- Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Pondicherry
 - 15- University of Cape Town (UCT)
 - 16- Stellenbosch University, Cape Town
 - 17- University of the Philippines, Manila
 - 18- Makerere University, Kampala
- If you require access to the RePORT International central REDCap build for the Long TB project, select REDCap

access.

- If you also require access to the File Exchange Utility, which will be used to transfer the de-identified DIACOM files for CT, X-ray, and other scans, select File Exchange Utility access.

Once you have completed and submitted your registration, Frontier Science User Support will notify you of your account creation and User Name within 2 business days.

NOTE: Your Frontier Science portal account password will automatically be set to the password you chose during account registration.

About the File Exchange Utility (FEU)

The Frontier Science File Exchange Utility is a web based, secure file transfer tool. The RePORT International Long TB project will use this utility to transfer all scan files collected from participants.

NOTE: All scan files must be transferred in DIACOM format.

NOTE: All scan files must be de-identified before they are uploaded to the File Exchange Utility.

To access the File Exchange Utility, first log into the Frontier Science portal. From the TB RICC tab select the File Exchange Utility link found under the Utilities heading.



Figure 2: File Exchange Utility link

Complete the required information regarding the scan you will be uploading, including:

1. Participant ID – in LTB-01-001 format
2. Scan Type – Choose between MDCT, CXR, Echocardiogram, or Carotid Ultrasound
3. Study Visit – Choose between Baseline 0M, End of Treatment (EOT), 6 Month Post EOT (EOT +6M), Tx Failure/Relapse/Withdrawal.

Each participant scan must be uploaded individually. Do not bulk upload scans. It is recommended scans are de-identified and uploaded to the File Exchange Utility the same day the scan is completed.

About the Data Submission System (DSS)

The Frontier Science DSS is a web based, secure file transfer tool. The RePORT International Long TB project will use this utility to transfer information regarding the storage and availability of specimens.

Each site is responsible for tracking the ongoing storage and availability of specimens collected and processed for the Long TB study. Each site will use the specimen tracking system they are comfortable with, for example FreezerPro or LDMS. Sites must minimally track the storage location of each available specimen within their freezers along with the information needed to link the specimen to the participant it was collected from. This information must be transferred to the Long TB project team and must include key details about each specimen, like:

1. Participant ID in LTB-AAA-001 format
2. Storage location
3. Specimen type
4. Specimen volume

5. A unique identifier used to locate the specimen within the site's specimen tracking tool

Each site must provide line listings of this specimen information to the Long TB project team. These line listing specimen files are transferred using the Frontier Science DSS.

Access to the DSS is granted to individuals who have registered for and received a Frontier Science portal account. First log into the Frontier Science portal. From the TB RICC tab select the Data Submission System link found under the Lab Data Programs heading.

Laboratory Data Programs
Data Submission System (DSS)

Figure 3: Data Submission System link

Select the TB RePORT project from the project drop down and complete the remaining information about your file upload. When prompted, browse for and select the specimen information data file you will be submitting regarding Long TB project specimen storage and availability at your site.

About REDCap

REDCap Academic (REDCap) is a user-friendly web-based data collection tool that you can access from any browser or through a Mobile App. Built-in prompts and help resources provide guidance at every step. This guide describes how to login to the central REDCap build at Frontier Science for the RePORT Long TB project and how to perform data entry.

REDCap Training Acknowledgement

All users must complete the REDCap Training Acknowledgement before Frontier Science User Support will grant them access to the central REDCap build at Frontier Science for the RePORT International Long TB project. Accessing the link to the REDCap Training Acknowledgement requires a Frontier Science portal account. Begin by signing into the Frontier Science portal and then locating and clicking the REDCap Training Acknowledgement link found on the TB RICC tab. You are then prompted to read and acknowledge the REDCap User Guide. After doing so, enter your Frontier Science portal username and password into the REDCap Academic Training Acknowledgment popup window. Following completion of this process, Frontier Science User Support will issue you an account to access the RePORT Long TB central REDCap.

NOTE: If you need assistance locating the REDCap Training Acknowledgement or have signed the REDCap Training Acknowledgment and received confirmation from User Support, but are experiencing difficulties logging in, contact Frontier Science User Support by email at user.support@frontierscience.org or by phone at (716) 834-0900, x7302. Use the **Forgot your password?** link if your access challenges are related to a forgotten password.

Initial REDCap Access

When your REDCap account is created you will receive an email prompting you to create a username and password.

NOTE: Your Frontier Science portal and REDCap accounts will be different accounts.

REDCap access granted Inbox x 🖨️ ✉️

↪ Reply ↗ Forward

user.support@frontierscience.org 11:08 AM (1 minute ago) ☆ ↪ ⋮
to me ↗

[This message was automatically generated by REDCap]

A REDCap account has been created for you in which your REDCap username is "[User@REDCapUserManual.org](#)". Click the link below to set your new password and log in.

[Set your new REDCap password](#)

Figure 4: REDCap Access Granted Email

Click **Set your new REDCap password** and enter a password.



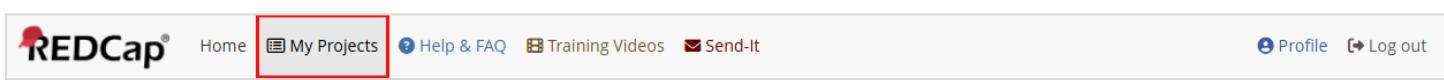
REDCap®
Set Your Password

Your password has not been set yet or has been reset. You will need to set your password here to whatever value you wish. Please enter your desired password below and click the 'Submit' button. Once your password has been set, you may use it with your username whenever you log in to REDCap. Please make sure that you write down or remember your new password for future use. **The new password entered must be AT LEAST 9 CHARACTERS IN LENGTH and must consist of AT LEAST one lower-case letter, one upper-case letter, and one number.**

Username:
Password:
Re-type password:

Figure 5: Set Your Password

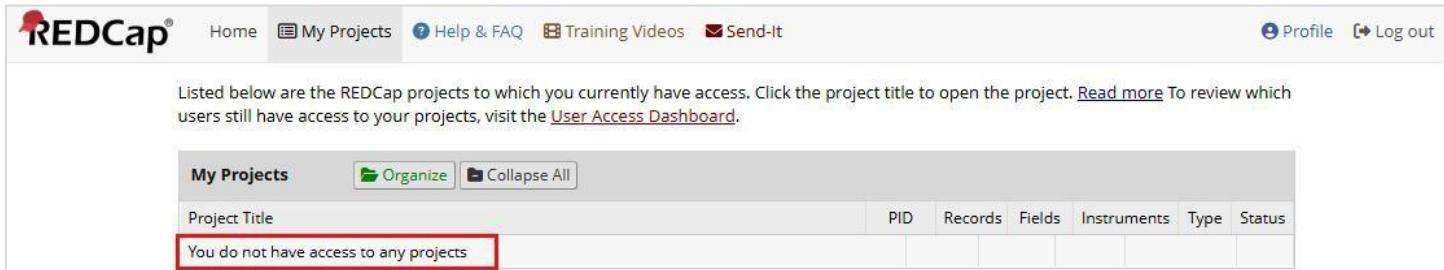
After you create your username and password, you will be logged into REDCap. Click on the **My Projects** link.



REDCap Home My Projects Help & FAQ Training Videos Send-It Profile Log out

Figure 6: My Projects

If you see a message stating that you do not have access to any projects, it means you have not been invited to a project yet.

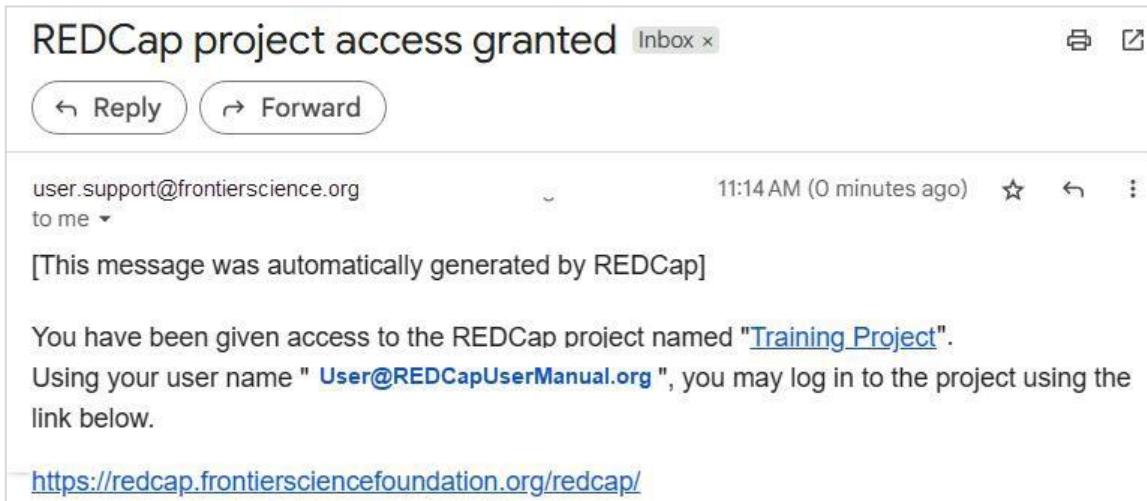


The screenshot shows the REDCap 'My Projects' page. At the top, there are navigation links: Home, My Projects, Help & FAQ, Training Videos, and Send-It. On the right, there are Profile and Log out links. A message below the navigation states: "Listed below are the REDCap projects to which you currently have access. Click the project title to open the project. [Read more](#) To review which users still have access to your projects, visit the [User Access Dashboard](#)." Below this message is a table with the following columns: Project Title, PID, Records, Fields, Instruments, Type, and Status. A single row in the table contains the text "You do not have access to any projects".

Figure 7: You do not have access to any projects

RePORT International Long TB Project Access

Check your inbox for an email with the subject line **REDCap project access granted**. This typically comes shortly after the REDCap account setup email. The link located at the bottom of the email will take you to the RePORT International Long TB project. Clicking the link will take you to REDCap. (**NOTE:** You may need to login again with your REDCap credentials.)



The screenshot shows an email inbox with a single message titled "REDCap project access granted". The message is from "user.support@frontierscience.org" and was sent "11:14 AM (0 minutes ago)". The message content is as follows:

[This message was automatically generated by REDCap]

You have been given access to the REDCap project named "[Training Project](#)".

Using your user name " [User@REDCapUserManual.org](#) ", you may log in to the project using the link below.

<https://redcap.frontiersciencefoundation.org/redcap/>

Figure 8: REDCap project access granted

You will then see that you have access to the RePORT International Long TB project when you click on **My Projects**. Click on the link to open the project.



REDCap® Home My Projects Help & FAQ Training Videos Send-It

Logged in as [REDACTED] Profile Log out

Listed below are the REDCap projects to which you currently have access. Click the project title to open the project. [Read more](#) To review which users still have access to your projects, visit the [User Access Dashboard](#).

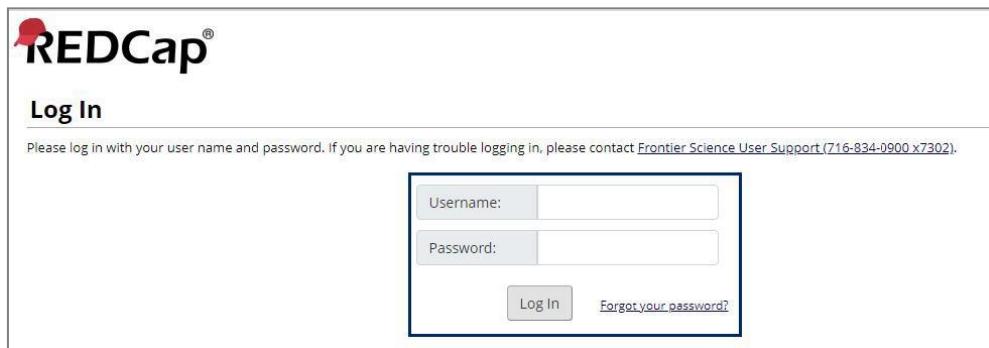
My Projects		Organize	Collapse All	Filter projects by title					
Project Title		PID	Records	Fields	Instruments	Type	Status		
RePORT International Long TB		16	7	1712	27 forms				

Figure 9: Project Access

Logging In

After your initial REDCap account and project login, moving forward you will access to REDCap by navigating to RePORTInternationalREDCap.org.

Login with your REDCap Username and Password. You will be automatically directed to the **Project Home** page.



REDCap®

Log In

Please log in with your user name and password. If you are having trouble logging in, please contact [Frontier Science User Support \(716-834-0900 x7302\)](#).

Username:	<input type="text"/>
Password:	<input type="password"/>
<input type="button" value="Log In"/> Forgot your password?	

Figure 10: REDCap Academic Login Screen

Accessing a REDCap Project

The **My Projects** page displays a list of REDCap projects to which the user has access. Click the RePORT International Long TB project link to access the **Project Home**.



My Projects Organize Collapse All Filter projects by title

Project Title PID Records Fields Instruments Type Status

RePORT International Long TB (DEV) 16 7 1712 27 forms

Figure 11: My Projects

All projects have the same general layout, consisting of the Menu on the left and the workspace on the right.

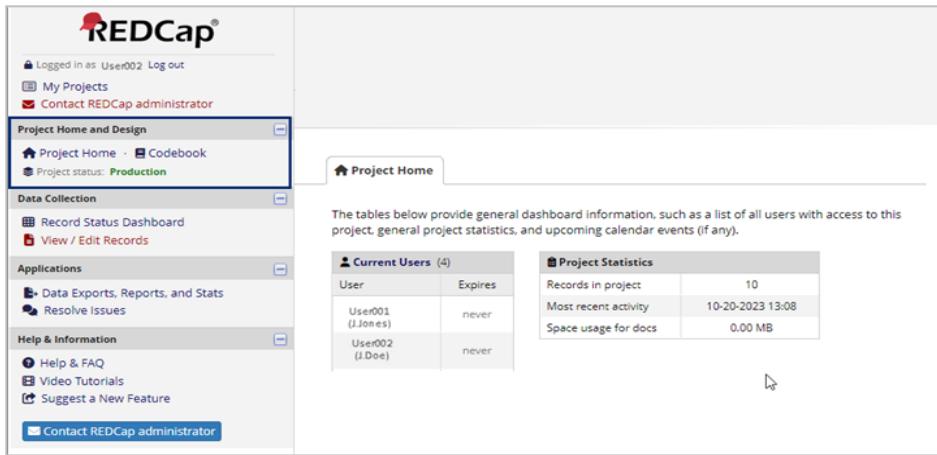


Figure 12: REDCap Menu and Project Home

Data Collection

To enter or view individual records, navigate to the **Data Collection** section of the REDCap menu.

Record Status Dashboard

Clicking the **Record Status Dashboard** link displays a table listing of all existing records/responses and their status for each record. This dashboard can be used to locate an existing Participant ID and to view, edit, or complete additional data collection instruments.



Figure 13: Record Status Dashboard

The **Record Status Dashboard** table is displayed by **Participant ID** (first column) in each row, with data collection **Instruments** organized under **Event** categories.

Participant ID:	Instruments										Event	Baseline OM		
	IE - Inclusion and Exclusion Criteria	VT - Visit Tracking	DM - Demographics	PE - Physical Exam	SU - Substance Usage	HI - HIV Status	PT - Pregnancy Test	MH - Medical History	HS - Health Seeking Behavior	TS - TB Symptoms		CH - Blood Chemistry	BC - Complete Blood Counts	MM - Multi Res
LTB-01-001	●	●	●	●	●	●	●	●	●	●	●	●	●	●
LTB-01-002	●	●	●	●	●	●	●	●	●	●	●	●	●	●

Figure 14: Record Status Dashboard table

The Legend for status icons contains helpful information to assist the user in understanding the status of the record. Click the  (question mark) icon to learn additional information.

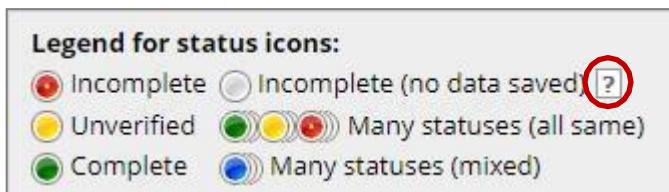


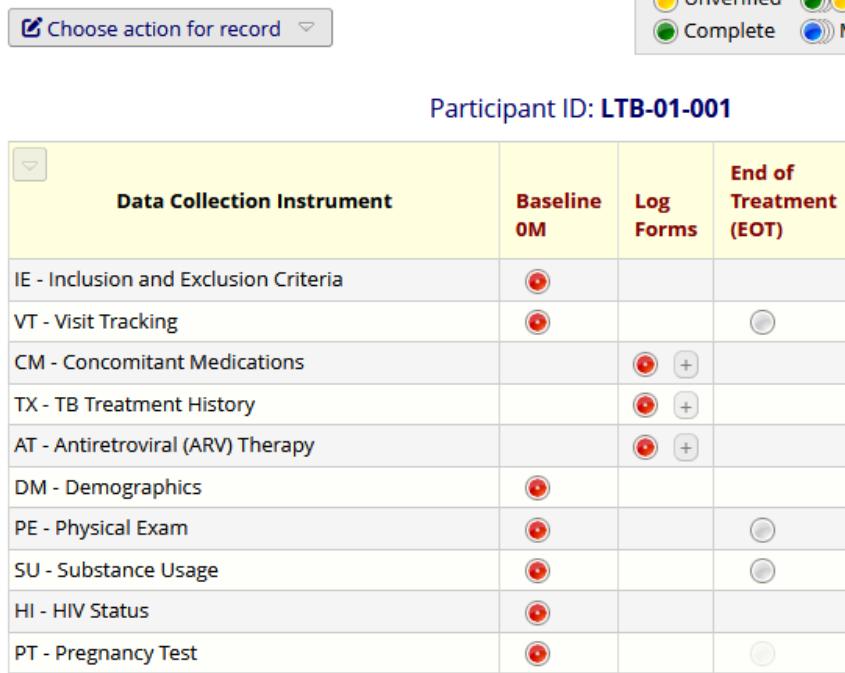
Figure 15: Legend for Status Icons

There are two ways to navigate to the data collection instruments for a participant via the Record Status Dashboard table.

1. Clicking on a single **Participant ID** link (in first column) to open a **Record Home Page** for the selected **Participant ID**. This page includes a table of data collection instruments and their associated statuses for the participant.

Record Home Page

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event.



Choose action for record ▾

Legend for status icons

- Incomplete (Red)
- In Progress (Grey)
- Unverified (Yellow)
- Complete (Green)

Participant ID: LTB-01-001

Data Collection Instrument	Baseline 0M	Log Forms	End of Treatment (EOT)
IE - Inclusion and Exclusion Criteria			
VT - Visit Tracking			
CM - Concomitant Medications		+	
TX - TB Treatment History		+	
AT - Antiretroviral (ARV) Therapy		+	
DM - Demographics			
PE - Physical Exam			
SU - Substance Usage			
HI - HIV Status			
PT - Pregnancy Test			

Figure 16: Record Home Page accessed via the Record Status Dashboard table

2. Clicking on a single status icon (radio button) in the cell for the desired PID and data collection instrument to open the corresponding data collection instrument. Users may edit the fields on the data collection instrument, adjust the Form Status field, and choose the desired Save option.

 **DM - Demographics**

Editing existing Participant ID: **LTB-01-001**.

Event: **Baseline 0M**

Participant ID:	LTB-01-001	CRFv1.0 xxx
Is the participant's exact date of birth known?	<input checked="" type="radio"/> Yes	
What is the date of birth?	1999-07-01	Y-M-D
Calculated age at baseline visit:	26	years
What is the participant's sex at birth?	<input checked="" type="radio"/> Female	
What is the participant's current dwelling location?	<input checked="" type="radio"/> Town/suburb	
What is the participant's marital status?	<input checked="" type="radio"/> Married/living together	
What race does the participant most closely identify with?	<input checked="" type="radio"/> White	
Has the participant ever attended school?	<input checked="" type="radio"/> Yes	
How many years of education did the participant complete?	16	
What is the approximate total monthly household income?	50,000	
Currency:	<input checked="" type="radio"/> Other	
Other type of currency:	<input checked="" type="radio"/> usd	
How many wage earners are there in the household?	2	
Please include/count research participant.		
How many members are there in the household?	4	
Please include/count research participant.		

Figure 17: DM- Demographics data collection instrument accessed via the Record Status Dashboard table.

When a data collection instrument is open, the REDCap menu displays a **full listing of selectable data collection instruments** within the same event for the participant. Users can click on the status icons in the REDCap menu display to view/edit other data collection instruments for the participant.

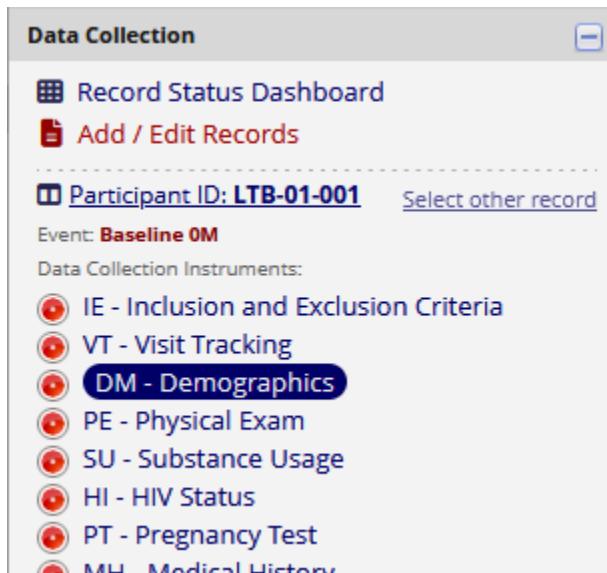


Figure 18: Available Data collection instruments

View/Edit Records vs. Add/Edit Records

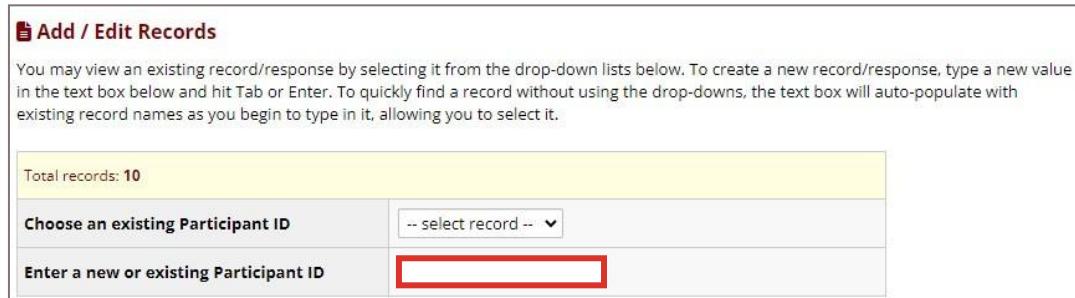
Use the **Add/Edit Records** link to create new Participant IDs and view or edit existing data collection instruments for enrolled participants.



Figure 19: Add/Edit Records

Type the assigned Participant ID into the **Enter a new or existing Participant ID** field and click **Enter**.

NOTE: To ensure the uniqueness of Participant IDs assigned by each of the RePORT Long TB sites, the RePORT International Coordinating Center (RICC) has established a required Participant ID format. Each site is required to adhere to this format when assigning Long TB Participant IDs and entering records to the Long TB REDCap. All Participant IDs must begin with the LTB prefix, followed by a hyphen (-), followed by a 3-character Site ID, followed by a hyphen (-), followed by a 3-digit participant number. Refer to the RePORT Long TB MOP for further details, including the assigned 3-character Site IDs.



You may view an existing record/response by selecting it from the drop-down lists below. To create a new record/response, type a new value in the text box below and hit Tab or Enter. To quickly find a record without using the drop-downs, the text box will auto-populate with existing record names as you begin to type in it, allowing you to select it.

Total records: 10

Choose an existing Participant ID	-- select record --
Enter a new or existing Participant ID	<input type="text"/>

Figure 20: Enter a new or existing Participant ID field, Add/Edit Records

To create the record and begin entering data, click any gray status icon. Once data are entered and the form is saved, the newly-added participant record will display in the Record Status Dashboard.

Record Home Page

Record "LTB-01-003" is a new Participant ID: To create the record and begin entering data for it, click any gray status icon below.

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event.

Legend for status icons:

- | | |
|--|--|
|  Incomplete |  Incomplete (no data saved) ? |
|  Unverified |  Many statuses (all same) |
|  Complete |  Many statuses (mixed) |

NEW Participant ID: LTB-01-003

Data Collection Instrument	Baseline 0M	Log Forms	End of Treatment (EOT)	6 Month Post EOT (EOT+6M)	Tx Failure/ Relapse/ Withdrawal	Off Study
IE - Inclusion and Exclusion Criteria						
VT - Visit Tracking						
CM - Concomitant Medications						
TX - TB Treatment History						
AT - Antiretroviral (ARV) Therapy						
DM - Demographics						
PE - Physical Exam						
SU - Substance Usage						
HI - HIV Status						
PT - Pregnancy Test						

Figure 21: New Participant ID Record Home Page

To view or edit data collection instruments for an existing PID, select a PID from the **Choose an existing Participant ID** list.

Add / Edit Records

You may view an existing record/response by selecting it from the drop-down lists below. To create a new record/response, type a new value in the text box below and hit Tab or Enter. To quickly find a record without using the drop-downs, the text box will auto-populate with existing record names as you begin to type in it, allowing you to select it.

Total records: 3	
Choose an existing Participant ID:	<input style="width: 150px; height: 25px; border: 1px solid #ccc; border-radius: 5px; padding: 2px;" type="button" value="-- select record --"/> <div style="border: 1px solid #ccc; padding: 5px; width: 150px; height: 100px; margin-top: 5px; background-color: #fff; display: none;"> -- select record -- LTB-01-001 LTB-01-002 LTB-01-003 </div>
Enter a new or existing Participant ID:	<input type="text"/>
Data Search	
Choose a field to search (excludes multiple choice fields)	<input style="width: 150px; height: 25px; border: 1px solid #ccc; border-radius: 5px; padding: 2px;" type="button" value="All fields"/>
Search query	<input type="text"/>

Figure 22: Choose an existing Participant ID dropdown list, Add/Edit Records

On the participant's **Record Home Page**, click a single status icon in the cell for the desired data collection instrument to open the corresponding instrument.

Participant ID: LTB-01-001					
Data Collection Instrument	Baseline 0M	Log Forms	End of Treatment (EOT)	6 Month Post EOT (EOT+6M)	
IE - Inclusion and Exclusion Criteria	<input checked="" type="radio"/>				
VT - Visit Tracking	<input checked="" type="radio"/>		<input type="radio"/>	<input type="radio"/>	
CM - Concomitant Medications		<input checked="" type="radio"/> <input type="radio"/>			
TX - TB Treatment History		<input checked="" type="radio"/> <input type="radio"/>			
AT - Antiretroviral (ARV) Therapy		<input checked="" type="radio"/> <input type="radio"/>			
DM - Demographics	<input checked="" type="radio"/>				
PE - Physical Exam	<input checked="" type="radio"/>		<input type="radio"/>	<input type="radio"/>	
EU - Substance Use	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>	

Figure 23: Data collection instrument table on participant's Record Home Page

Note: Editing existing Participant ID message displays at the top of the data collection instrument.

DM - Demographics

 Editing existing Participant ID: **LTB-01-001**.

Event: Baseline 0M	
Participant ID:	LTB-01-001
Is the participant's exact date of birth known?  Yes 	
What is the date of birth?  1999-07-01  31 Y-M-D	
Calculated age at baseline visit: 26  View epi	

Figure 24: Editing existing Participant ID

Click or Tab on your keyboard to navigate to the desired field(s) and enter data, as required. Required questions are indicated by the *** must provide value** text below each question.

What is the visit/contact start date?  <input type="text"/>  Today Y-M-D	
<small>* must provide value</small> If missed visit, record scheduled visit date	

Figure 25: Required question example

NOTE: If responses are not provided to all required questions, an error message displays upon saving the data collection

instrument.

NOTE: Additional questions may dynamically display based on the responses provided to previous questions.

Form Status

After completing data entry, select one of the appropriate options from the **Form Status** dropdown at the bottom of the form to indicate the status of the data collection instrument.

Form Status dropdown options include:

- **Incomplete:** Further data entry is needed.
- **Unverified:** All data have been entered but internal review has not yet occurred (as applicable).
- **Complete:** Data entry is complete, even if values are missing.

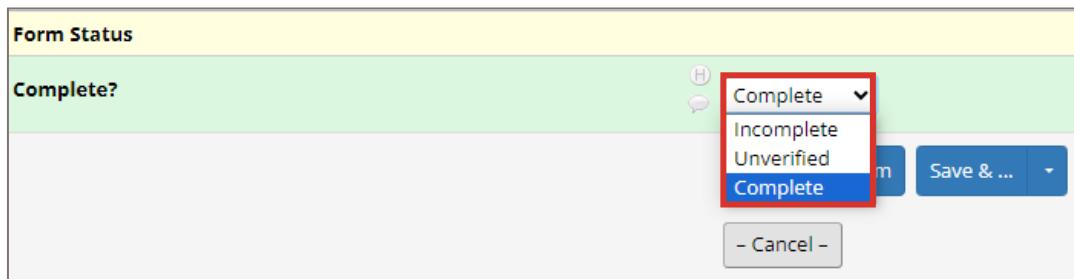


Figure 26: Form Status Options

Save Options

After a **Form Status** dropdown option is selected, save the data collection instrument before navigating away from the page.

Select the desired **Save** dropdown option.

- **Save & Exit Form:** Save any progress made on the data collection instrument and go back to the Record Home Page.
- **Save & Stay:** Save any progress made on the data collection instrument and stay on the current data collection instrument.
- **Save & Go To Next Form:** Save any progress made on the data collection instrument and move to the next data collection instrument for the current participant.
- **Save & Exit Record:** Save any progress made on the data collection instrument and go to View/Edit Records.
- **Save & Go To Next Record:** Save any progress made on the data collection instrument and move to the next PID.

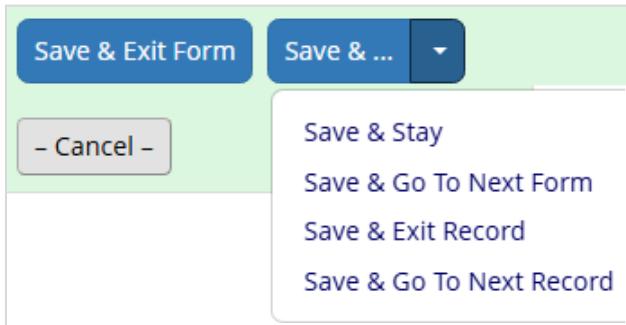


Figure 27: Save Options

Repeating Forms

Repeating forms may be used where a second instance of the form is needed. For example, some test results may need a repeating form if the results initially came back as Indeterminant. If this test is run a second time, a new instance of the form can be added to enter those results. Click the + sign next to the form to add another instance of the form. You can now complete the second form as needed to track the second set of results.

Participant ID: LTB-01-001

Data Collection Instrument	Baseline OM	Log Forms	End of Treatment (EOT)	6 Month Post EOT (EOT+6M)	Tx Failure/Relapse/Withdrawal	Off Study
IE - Inclusion and Exclusion Criteria	<input checked="" type="radio"/>					
VT - Visit Tracking	<input checked="" type="radio"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
CM - Concomitant Medications		<input checked="" type="radio"/> +				
TX - TB Treatment History		<input checked="" type="radio"/> +				
AT - Antiretroviral (ARV) Therapy		<input checked="" type="radio"/> +				
DM - Demographics	<input checked="" type="radio"/>					
PE - Physical Exam	<input checked="" type="radio"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
SU - Substance Usage	<input checked="" type="radio"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
HI - HIV Status	<input checked="" type="radio"/>					
PT - Pregnancy Test	<input checked="" type="radio"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
MH - Medical History	<input checked="" type="radio"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
HS - Health Seeking Behavior	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
TS - TB Symptoms	<input checked="" type="radio"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
SS - Specimen Storage	<input checked="" type="radio"/>		<input type="radio"/>	<input type="radio"/>		
CH - Blood Chemistry	<input checked="" type="radio"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
BC - Complete Blood Counts	<input checked="" type="radio"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
MT - MTB Culture Results	<input checked="" type="radio"/>		<input type="radio"/>		<input type="radio"/>	
GX - GeneXpert MTB/RIF Ultra	<input checked="" type="radio"/> +					
DS - Drug Susceptibility Testing (DST)	<input checked="" type="radio"/> +		<input type="radio"/>			
SG - St. George's Respiratory Questionnaire (SGRQ)	<input checked="" type="radio"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Figure 28: Repeating Forms

Log Forms

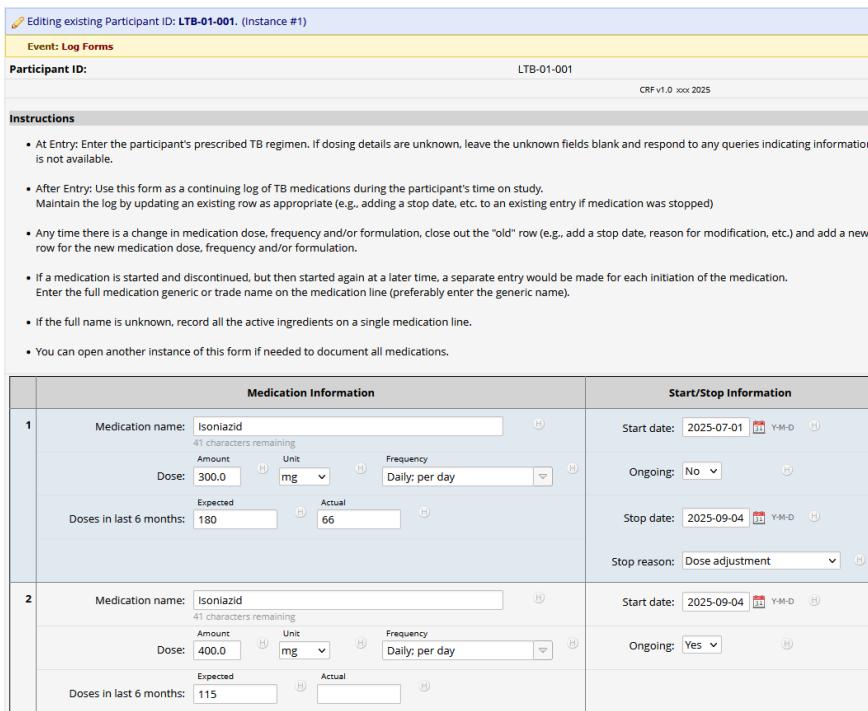
The Long TB central build makes use of Log forms to track a participant's medication history over the course of the study. The log forms must be reviewed and maintained at each participant visit, noting any changes to a participant's medication information. Medication information is split into 3 different Log forms: TX- to track a participant's TB medication, AT- to track ARV therapy for participants living with HIV, and CM- to track any other relevant concomitant medications.

At the entry visit, simply enter the participant's TB medications. Enter the name, dose, frequency, expected number of doses, and start date.

At the first visit it would be expected that treatment is Ongoing, and the ongoing field should be set to Yes.

After entering rows for each prescribed TB medication, set the form status to Incomplete and Save & Exit.

At each subsequent visit, you must open the Log forms and enter any changes to these medications or add rows for new medications. For example, at the EOT visit, the participant may no longer be on active TB treatment and medications on the TX form would need to change Ongoing to No and enter a Stop Date and Stop Reason.



Medication Information		Start/Stop Information	
1	Medication name: Isoniazid 41 characters remaining Amount: 300.0 Unit: mg Frequency: Daily: per day Doses in last 6 months: 180 Expected: 66 Actual:	Start date: 2025-07-01 Y-M-D Ongoing: No Stop date: 2025-09-04 Y-M-D Stop reason: Dose adjustment	
2	Medication name: Isoniazid 41 characters remaining Amount: 400.0 Unit: mg Frequency: Daily: per day Doses in last 6 months: 115 Expected: Actual:	Start date: 2025-09-04 Y-M-D Ongoing: Yes	

Figure 29: Log Forms

Obtaining Blank CRFs for Data Collection

If blank CRFs are required for data collection which will later be transcribed into the RePORT International central REDcap, do not download the blank data collection instruments directly from REDCap.

The appropriate blank CRFs needed for data collection can be provided to you by the RePORT International Long TB protocol team. Please reach out to request these forms.

Resolving Issues/Queries

The **Resolve Issues** page displays a list of queries and allows users to manage and document the resolution of data issues.



Figure 30: Resolve Issues

Anyone with respond privileges will be able to respond to an open query (even if it is assigned to a specific person). The

responder may select a response type (e.g., typographical error) and provide a descriptive comment with the ability to also attach a file (optional). Once a query has been responded to, a data manager will review the response and either ask for further clarification or close the query, after which it will be considered resolved.

Data Quality

[Resolve Issues \(2\)](#) [Resolution Metrics](#)

[VIDEO: Data Resolution Workflow](#) or [Read introduction to Data Resolution Workflow](#)

This page displays all data queries that are currently unresolved or have already been resolved using the Data Resolution Workflow. Some issues may have been initiated by users on data collection instruments, and others may have been initiated after executing Data Quality rules on the Find Issues tab. The table lists the name of the record and the specific field or Data Quality rule to which the data query belongs, as well as the user assigned to the query (if applicable), the number of days the data query has been open, and a brief snippet of the query's first and last comment. The results in the table can be filtered by the query status type (e.g., open, closed), by certain fields or Data Quality rules, and also by users assigned to it. Each data query may be viewed by clicking the button to its left.

Data Resolution Dashboard		Filters: Open / unresolved issues (2)				
Export		All fields and rules	All events	User assigned (all users) or not assigned		
Click button to view data query	Record	Data Quality rule and/or Field	User Assigned	Days Open	First Update	Last Update
1 comment	100001 Visit 1	Field: vld1 (Serum Prealbumin (mg/dL))	-	0	riservat (09-08-2025 08:38): "Please verify serum prealbumin value"	[same as first update]
1 comment	100002 Enrollment	Field: date_enrolled (Date subject signed consent)	-	0	riservat (09-08-2025 08:39): "This date does not seem correct based on other participant data"	[same as first update]

Figure 31: Resolve Issues

This page serves as a dashboard that neatly organizes all queries (both open and closed) so that they may be reviewed and so that any open queries may be easily responded to and closed. That page can serve as a nice to-do list for addressing all open queries.

A table lists the name of the record and the specific field or Data Quality rule to which the data query belongs, as well as the user assigned to the query (if applicable), the number of days the data query has been open, and a brief snippet of the query's first and last comment. The results in the table can be filtered by the following:

- Query status type (e.g., open, closed)
- Certain fields or Data Quality rules
- Event
- Users assigned

Click the button in the first column to view details of the data query. The **Data Resolution Workflow** displays for the specified record for a given field and/or Data Quality rule. Note the query **Status of Open / Unresolved (unresponded)**.

Opened data queries may be responded to by users with appropriate privileges, and then they may be closed once the issue has been resolved. All data queries can also be viewed on the **Resolve Issues** page in this project.

Data Resolution Workflow

[VIDEO: Data Resolution Workflow](#)

This pop-up displays the Data Resolution Workflow for the specified record for a given field and/or Data Quality rule. Users with appropriate user privileges may open data queries to begin a documented process of resolving an issue with the data. Opened data queries may thus be responded to by users with appropriate privileges, and then they may be closed once the issue has been resolved. All data queries can also be viewed on the Resolve Issues page in this project.

Study ID: **100001**

Event: Visit 1

Field: **vld1 ("Serum Prealbumin (mg/dL)")**

Status: **Open / Unresolved (unresponded)**

Date/Time	User	Comments and Details
09-05-2025 05:50	riservat	Data Changes Made: vld1 = '3.14'
09-08-2025 08:38	riservat	Action: Opened query Comment: "Please verify serum prealbumin value"
09-08-2025 08:48	wojcik	Reply with response: <input type="button" value="-- choose response --"/> Upload file (optional): <input type="button" value="Upload file"/> Comment: <input type="text"/>

Respond to query **Cancel**

Figure 32: Data Resolution Workflow

1. Select the most appropriate query response from the **Reply with response** listing.
2. The **Upload file** option may be available.
3. Complete the **Comment** field. If data are not corrected, indicate why.
4. Click **Respond to query**. The query Status changes to Open / Unresolved (responded). The DataResolution Dashboard will reflect the updates.

A data manager will be able to view the query response and ask for further clarification or close the query.

Data Resolution Workflow

VIDEO: Data Resolution Workflow

This pop-up displays the Data Resolution Workflow for the specified record for a given field and/or Data Quality rule. Users with appropriate user privileges may open data queries to begin a documented process of resolving an issue with the data. Opened data queries may thus be responded to by users with appropriate privileges, and then they may be closed once the issue has been resolved. All data queries can also be viewed on the Resolve Issues page in this project.

Study ID: **100001**
 Event: **Visit 1**
 Field: **vld1** ("Serum Prealbumin (mg/dL)")
 Status:  **Open / Unresolved (responded)**

Date/Time	User	Comments and Details
09-05-2025 05:50	riservat	Data Changes Made: vld1 = '3.14'
09-08-2025 08:38	riservat	Action: Opened query Comment: "Please verify serum prealbumin value"
09-08-2025 10:47	wojcik	Response: Corrected - Wrong source used Comment: "data corrected"

⚠ Awaiting action by user with sufficient user privileges.

Figure 33: Open / Unresolved (responded) Query

Data Resolution Dashboard

Filters: **Open / unresolved issues (2)**

 **Export**

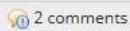
Click button to view data query	Record	Data Quality rule and/or Field	User Assigned	Days Open	First Update	Last Update
 2 comments	100001 Visit 1	Field: vld1 (Serum Prealbumin (mg/dL))	-	0	riservat (09-08-2025 08:38): "Please verify serum prealbumin value"	wojcik (09-08-2025 10:47): "data corrected"
 1 comment	100002 Enrollment	Field: date_enrolled (Date subject signed consent)	-	0	riservat (09-08-2025 08:39): "This date does not seem correct based on other participant data"	[same as first update]

Figure 34: Updated Data Resolution Dashboard

Resolution Metrics

It can sometimes be useful to view metrics with regard to your data queries, such as a count of how many queries are open or closed, the average response time, or the average time to query resolution. The **Resolution Metrics** page provides some useful statistics and some helpful bar charts for viewing progress and activity.

Resolution Metrics displays **General Statistics** regarding query management at each site. These include:

- **Number of open/unresolved queries**
- **Number of closed/resolved queries**
- **Average time for query response**
- **Average time to query resolution**

Charts are provided for each metric as you scroll down the page.

Data Quality

[Resolve Issues](#) [Resolution Metrics](#)

[VIDEO: Data Resolution Workflow](#) or [Read introduction to Data Resolution Workflow](#)

This page displays various statistics and metrics regarding all data queries that are currently unresolved or have already been resolved via the Data Resolution Workflow in this project. The 'average time for query response' refers to the time lapse between when a query was opened and the time it was first responded to by a user (includes both open and closed queries). The 'average time to query resolution' refers to the time lapse between when a query was opened and the time it was closed (includes only closed queries). NOTE: Since you belong to a Data Access Group, you will not be able to view the charts for comparing the resolution metrics of all groups. Only users that do not belong to a group will be able to view such charts.

Figure 35: Resolution Metrics

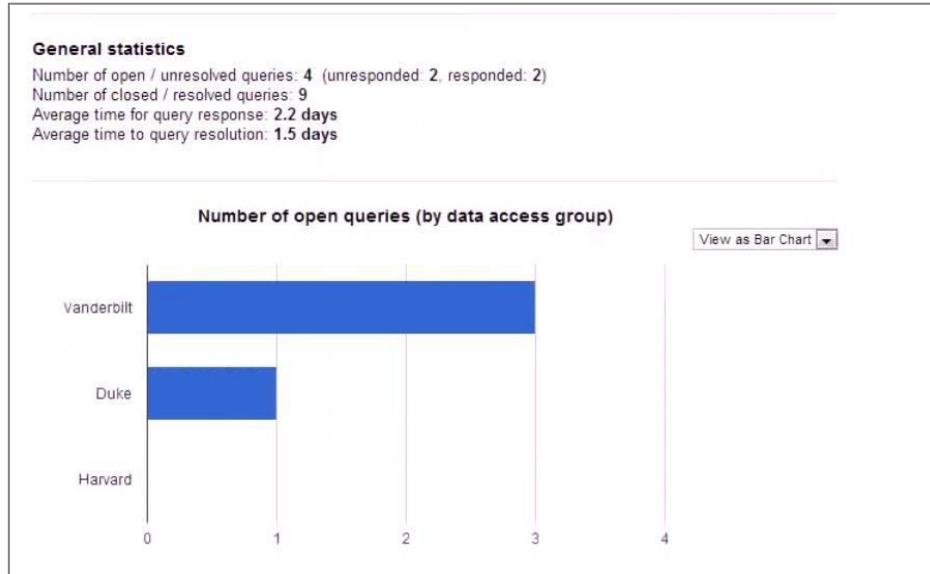


Figure 36: General Statistics

REDCap Video Tutorials

In addition to video tutorials available within the REDCap system, there are a few listed in the **Help and FAQ** section of the menu that you may find helpful as you enter data and utilize the available applications:

- [Data Entry Overview](#)
- [Applications Overview](#)

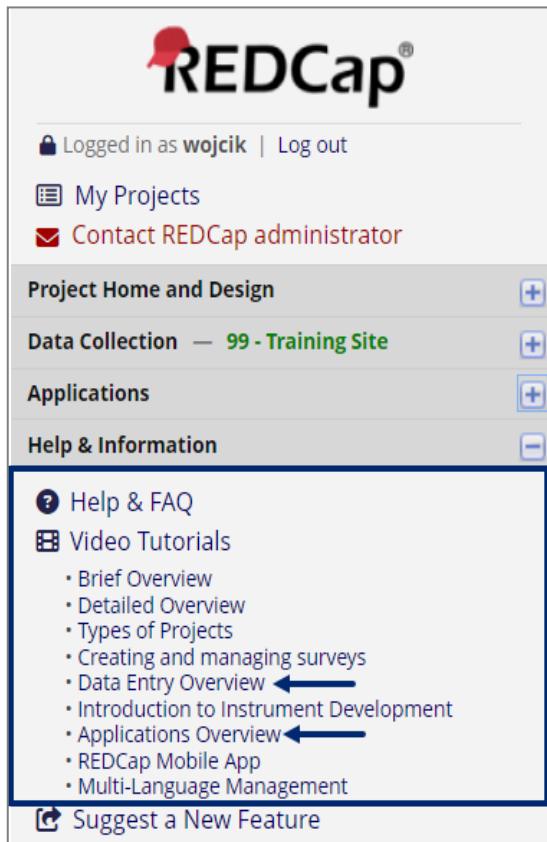


Figure 37: REDCap Overview materials

Collecting Data Using the REDCap App

In addition to the standard web-based data collection tool, REDCap also allows for data to be collected within the REDCap App. The App can be downloaded and installed on various devices, including tablets, and allows for offline data collection.

When using the App, please keep in mind that any records you enter must be synced to the main project build server when internet connectivity allows.

NOTE: It is critical that each RePORT International Long TB participating site assigns Participant IDs following the format established in the Long TB MOP. When using the REDCap App, if a duplicate Participant ID is entered that will conflict with a previously existing Participant ID, the data will be unable to sync. It is critical that each site maintain a proper log of assigned Participant IDs to prevent duplicate assignment and conflicts when multiple users are entering data in offline situations.

Configuring a Tablet for Use with the REDCap App

To configure a tablet for use with the REDCap App, you must be logged in to REDCap on both the App and on a desktop/laptop.

On the desktop/laptop:

- On the left-hand side menu bar, under 'Applications', click on 'REDCap Mobile App' and the 'Set Up Project' tab and locate the QR Code.

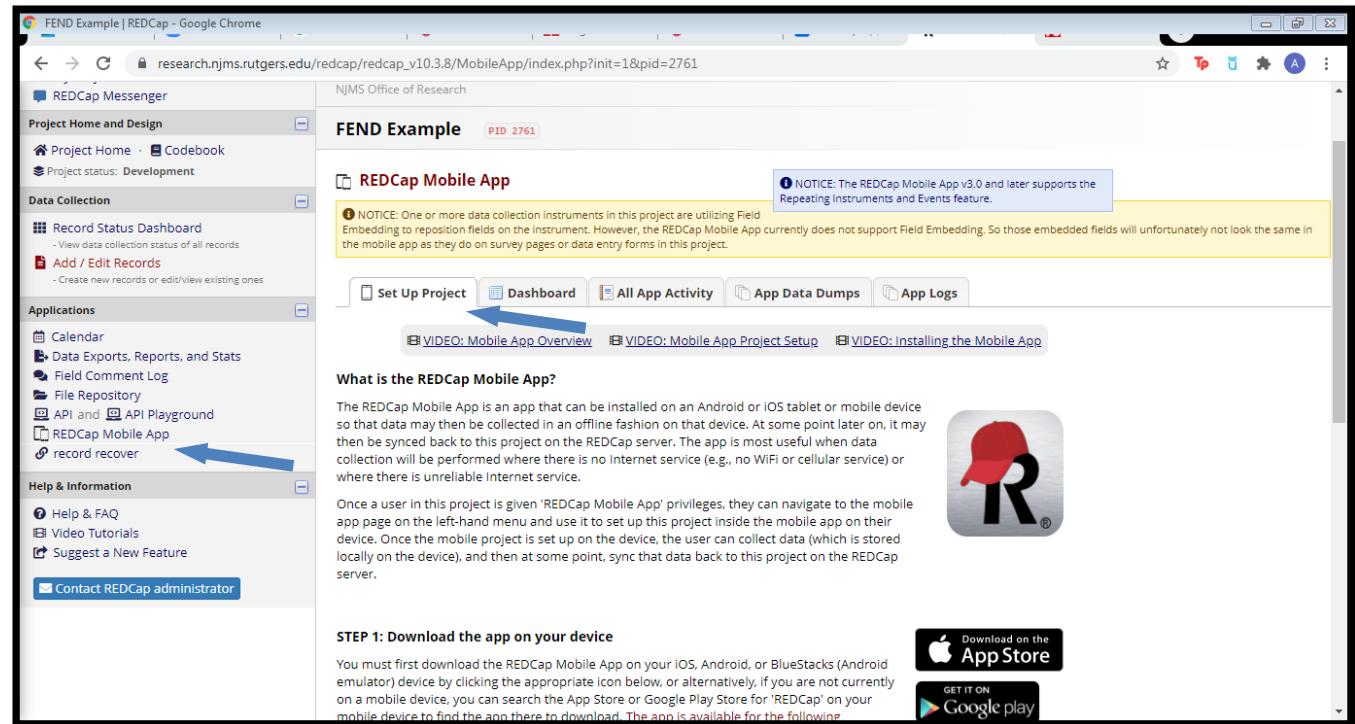


Figure 38: REDCap Mobile App page

On the tablet / device in the REDCap App:

- Click 'Set Up Mobile Project' and then 'Scan QR Code' to scan the QR Code from the laptop/desktop to begin downloading the RePORT International Long TB project to the App.



Figure 39: REDCap Mobile App Configuration

Collecting Data Using the REDCap App

After downloading the RePORT International Long TB project to the App, be sure to click 'Download All Records' to properly initialize any existing data to the device.

To enter new data to the REDCap App for project, first locate and select the RePORT International Long TB project from 'My Projects'. Once selected, the project will have the following options:

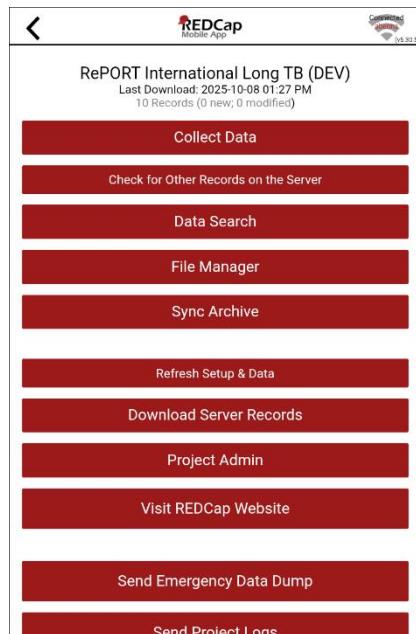


Figure 40: REDCap Mobile App Data Collection

- Collect Data
 - Allows for entry of new records and updates to existing records.
- Send Data to Server (note: this will only appear once Records are created on the app)
 - At the end of each day that the REDCap App is used, make sure to 'Send Data to Server'
 - When online, send the data to the project's REDCap server. This will coordinate the mobile device's data with the main REDCap project
 - If record names or data values conflict, you will be given the opportunity to adjust before completing the upload
 - If the instruments have been modified significantly in the main REDCap project since REDCap Mobile App project set up, you will not be able to complete the upload
 - After the data was sent to the server, verify the data is on the web browser (RePORTInternationalREDCap.org) in the Record Status Dashboard