

CanTreatCOVID DATABASE(S) UPDATES

This document enlists the new Database updates for the respective database(s) as available in the production version as of 07 December 2023

REDCap Academic

REDCap Cloud

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NOTE: These instructions will be updated in the next iteration of the Manual of Operations. In the meanwhile, please retain this communication as reference for this update.

[ED Domain Sub-protocol](#)

The ED Domain participants are those recruited from the Emergency Department setting. These participants are screened in-person from the study approved Emergency department setting and if eligible enrolled into respective Provincial ED domain site.

The Screening activities will be completed and entered into ED domain database on REDCap Academic.

The Enrolment activities will be completed and entered into the ED site group on REDCap Cloud. The Enrolment no. will include the Provincial site – ED suffix (e.g. 1-ED, 2-ED, 3-ED, 4-ED, 5-ED, 6-ED).

[REDCAP Academic](#)

Informed Consent form obtained via?

- E-consent / Verbal Consent Setup:
 - Site specific ICFs setup
 - RC attestation
 - Witness attestation
 - Interpreter attestation

ICFs, RC attestation and Interpreter attestation will be uploaded in the Consent Form Info eCRF

- No E-consent /Verbal Consent setup
 - No ICFs on database
 - RC attestation
 - Witness attestation
 - Interpreter attestation

RC attestation and Interpreter attestation can be completed but will not be uploaded since the Consent Form Info eCRF is not setup

1. [Send ICF feature](#)

Note: This updated feature in the REDCap Academic database to [Send the ICFs](#) to the participant (those to be enrolled and previously enrolled) replaces the previous process detailed in Manual of Operations V2.0 – 31Aug2023.

The 'Send ICF' feature now indicates version date of the ICF beside it (see image below). This update also includes:

1. For newly enrolled participants: If using the 'e-consent' option to send out the ICFs enter the participants email address and check off 'Send ICF (version date)'
2. For previously enrolled participants: the initially checked off 'Send ICF' is hidden and updated with feature to '**Send ICF (version date)**', hence this checkbox will appear unchecked for participants consented on an earlier ICF. However the original signed ICFs are available as PDF in the 'Consent Form Info' eCRF.
3. To re-consent participants: If you wish to re-consent participants via the database, please check the 'Send ICF (version date)' from the 'Contact Information' eCRF to send ICF. Additionally, the Re-consent

Research Coordinator Attestation should also be completed. The complete signed ICF + attestation can be found in the 'Consent Form Info' eCRF but will have to be sent manually. The instruction for manually sending the updated ICF package via the database is detailed in the Manual of Operations; Section (Pg. 51-56).

This is a DEMO study only. Real data should NOT be entered.

Editing existing Record ID 10789-36.

Record ID 10789-36

Please enter participant email address ONLY if the participant will complete e-Consent

Consent to contact by email?
(note that email is an unsecure method of contact; please record email address on Participation log)
 Yes
 No
 * must provide value

Would you like to be contacted about other future studies?
 Yes
 No
 * must provide value

Informed Consent was obtained via?
 E-consent
 Emailed out to participant (hardcopy retained in ISF)
 Verbal consent
 * must provide value

Participant

Participant Email Address: rekha.thomas@unityhealth.to

Retype Participant Email Address: rekha.thomas@unityhealth.to
 retype the participant's email

Please select the box to send the Alberta Master and Paxlovid ICFs to the participant
 SEND ICFs V2.1 (11 October 2023) V2.0 (16 June 2023)
 * must provide value
 (Please note that this form must be completed and saved)

Updated 'Send ICF (version #)' feature.
 To re-consent participants check off the 'Send ICF' option to send the updated ICFs

2. ED Domain specific eCRFs

i. ED Sites

The ED local site has to be entered in the database

REDCap

Logged in as rthomas | Log out

My Projects
 Contact REDCap administrator

Project Home and Design
 Project Home Codebook
 Project status: Development

Data Collection — Test site 5 ED BC

Survey Distribution Tools
 Get a public survey link or build a participant list for inviting respondents

Record Status Dashboard
 View data collection status of all records

Add / Edit Records
 Create new records or edit/view existing ones

Record ID 12465-2 Select other record

Data Collection Instruments:
 Participant ID
 ED Sites
 Screening Form
 Contact Information
 Witness ICF Attestation
 Pharmacy Authorization Form - Complete by Research Coordinator
 Pharmacy Form - Complete by Pharmacist or QI
 QI Eligibility Form
 Research Coordinator Confirmation/Flu Pro Plus Assign

CanTreatCOVID ED Domain (DEMO ONLY) PID 1455

Actions: Download PDF of instrument(s) Video: Basic data entry

ED Sites

This is a DEMO study only. Real data should NOT be entered.

Editing existing Record ID 12465-2

Record ID 12465-2

BC Local Sites
 * must provide value
 Vancouver General Hospital

Form Status
 Vancouver General Hospital
 Lions Gate Hospital
 St. Paul's Hospital
 Mount St. Joseph's Hospital
 Surrey Memorial Hospital
 Save & Exit Form Save & ...

Complete?

- Cancel -

ii. Pharmacy Form

If the Pharmacy Form is completed by the Pharmacist/QI/ED physician on the paper CRF, it should be entered on the database by the ED designee. The Concomitant medication listing (if any) should be entered in the appropriate section and the paperCRF uploaded in the QI Eligibility form.

ED Designee should enter the information as indicated by the Pharmacist/QI/ED Physician on the Pharmacy paperCRF and upload the paperCRF in the QI eligibility form

iii. QI Eligibility Form

If the QI Eligibility form is completed by the QI or ED Physician on the paper CRF then the ED Designee can input the eligibility determination on the eCRF as provided by the QI or ED Physician. However, it is essential to upload a copy of the QI's eligibility determination on the database.

ED Designee has to upload the QI's eligibility determination on the database

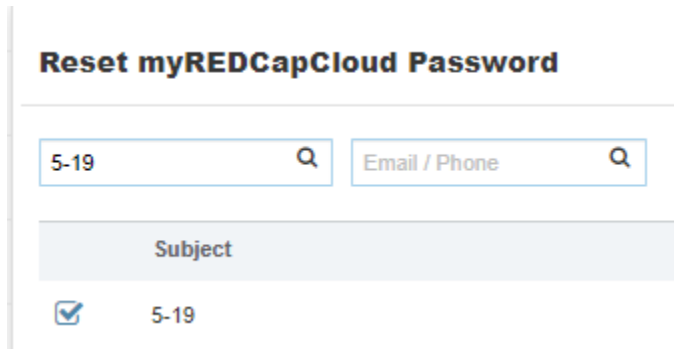
REDCAP CLOUD

1. Reset Participant password

Choose Subjects on left panel, then top right corner select the lock



Then search for 5-19, select the subject

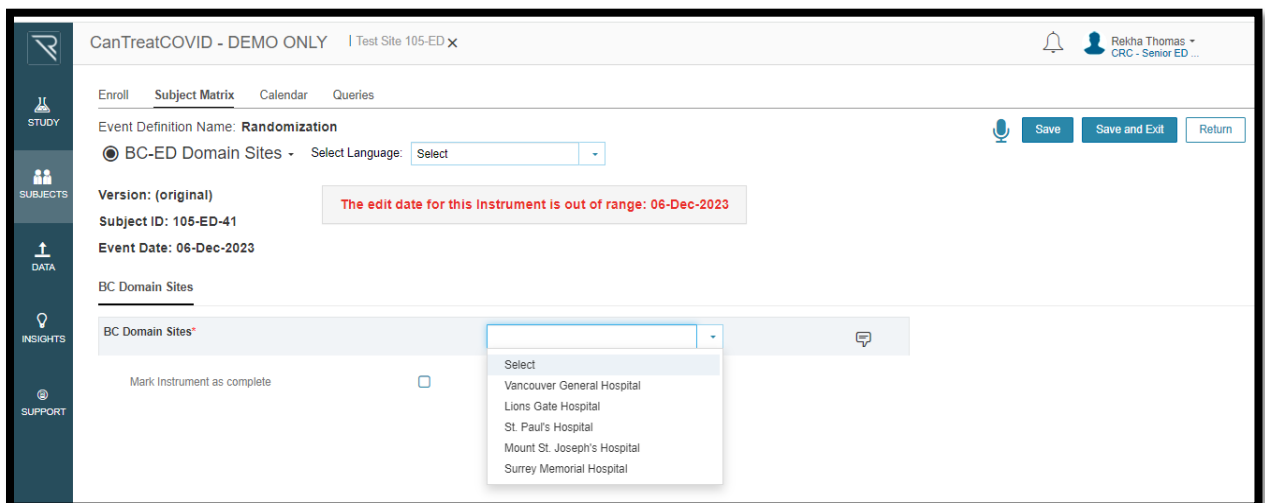
A form titled 'Reset myREDCapCloud Password'. It has two search input fields: one containing '5-19' and another labeled 'Email / Phone'. Below the fields is a table with a header 'Subject' and one row containing a checked checkbox and the text '5-19'.

And press on Reset myREDCAP Cloud password.

A blue rectangular button with the text 'Reset myREDCapCloud Password' in white.

2. ED Domain Sites

Select the Provincial-ED Domain Sites eCRF to indicate the local site that the participant was recruited from:

A screenshot of the REDCap interface for 'CanTreatCOVID - DEMO ONLY'. The 'SUBJECTS' tab is active. The 'BC-ED Domain Sites' dropdown menu is open, showing a list of hospitals: Vancouver General Hospital, Lions Gate Hospital, St. Paul's Hospital, Mount St. Joseph's Hospital, and Surrey Memorial Hospital. A red error message is visible: 'The edit date for this Instrument is out of range: 06-Dec-2023'.

3. Emergency Department Log

Select where the participant was recruited from?

CanTreatCOVID - DEMO ONLY | Test Site 105-ED x

Enroll Subject Matrix Calendar Queries

Event Definition Name: **As Needed Forms**

Emergency Department Visit Log1 - Select Language: Select

Version: (original)

Subject ID: 105-ED-41

Event Date: 06-Dec-2023

Emergency Department Visits

To only be completed for any Emergency Department visits after randomization

Where was the participant recruited from? Non-ED ED
 Reset

Mark Instrument as complete

For Participants recruited from **Non-ED setting**, the following fields should be completed as reported by the participant at any the follow-up data collection time points or an unscheduled phone visit.

- Date of presentation
- Site Location (name of the Emergency Department that the patient visited)
- Was the participant under observation for > 12 hours?
- Chief complaint?
 - Other symptoms (if selected)
- Reason for ER visit?
- Description of event
- Participant’s understanding of discharge diagnosis
- Was the participant hospitalized following the emergency visit?

For Participants recruited from **ED setting**, the following fields should be completed by the ED research coordinator for any emergency department visit (occurring after randomization) as obtained from the chart review at Day 28 time point.

All participant reported fields will be completed by the Provincial research coordinator at any of the follow up visits.

- Date of presentation
- Site Location (name of the Emergency Department that the patient visited)
- Chief complaint?
 - Other symptoms (if selected)
- Oxygen supply
- Did the patient receive any supplemental oxygen during the ED visit?
- Was a chest x-ray performed?
- First chest x-ray findings?
- Was a CT chest performed?
- CT chest findings?
- ED Discharge diagnosis? Other discharge diagnose (if selected)?
- Was the participant hospitalized following the emergency visit?

4. Hospitalization Log

Select where the participant was recruited from?

The screenshot shows the CanTreatCOVID - DEMO ONLY interface. The top navigation bar includes 'Enroll', 'Subject Matrix', 'Calendar', and 'Queries'. The main content area is titled 'Event Definition Name: As Needed Forms' and shows 'Hospitalization Log 1' selected. A 'Select Language' dropdown is set to 'Select'. Below this, the form displays 'Version: (original)', 'Subject ID: 105-ED-41', and 'Event Date: 06-Dec-2023'. The 'Hospitalization Forms' section contains a blue banner with the text 'To only be completed for any Hospitalizations after randomization'. Below the banner, the question 'Where was the participant recruited from?' is followed by two radio button options: 'Non-ED' and 'ED'. A 'Reset' link is positioned below the 'ED' option. At the bottom of the form, there is a checkbox labeled 'Mark Instrument as complete'.

For Participants recruited from Non-ED setting, the following fields should be completed as reported by the participant at any the follow-up data collection time points or an unscheduled phone visit.

- Admission date at facility
- Site location (name of the hospital that patient was admitted)
- Chief complaint
 - Other symptoms specify
- Reason for hospitalization
- Description of the event
- Participant understanding of discharge diagnosis
- Is hospitalization ongoing
- End date of hospitalization

For Participants recruited from ED setting, the following fields should be completed by the ED research coordinator for any hospitalization visits (occurring after randomization) as obtained from the chart review at Day 28 time point.

All participant reported fields will be completed by the Provincial research coordinator at any of the follow up visits.

- Admission date at facility
- Site location (name of the hospital that patient was admitted)
- Chief complaint
 - Other symptoms specify
- Reason for hospitalization
- Description of the event
- Participant understanding of discharge diagnosis
- Hospital admitting diagnosis
 - Other hospital admitting diagnosis, specify

- During hospital admission, did the patient receive supplemental oxygen
- During hospital admission, did the patient receive any of the following treatments?
- During hospital admission, was a chest x-ray performed?
- X-ray findings
- Was a CT chest performed?
- CT chest findings?
- Hospital discharge diagnosis (primary)
 - Other discharge diagnose (primary)
- Hospital discharge diagnosis 2
 - Other discharge diagnose 2
- Hospital discharge diagnosis 3
 - Other discharge diagnose 3
- Is hospitalizations ongoing
- End date of hospitalization