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

Table of Contents

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).

2. ED Domain specific eCRFs

i. ED Sites

The ED local site has to be entered in the database

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 eligilibty determination on the database.

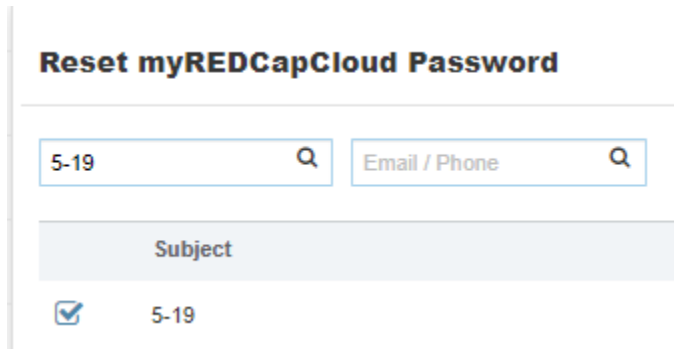ED Designee has to upload the QI's eligibility determination on the database

REDCAP CLOUD

1. Reset Participant password

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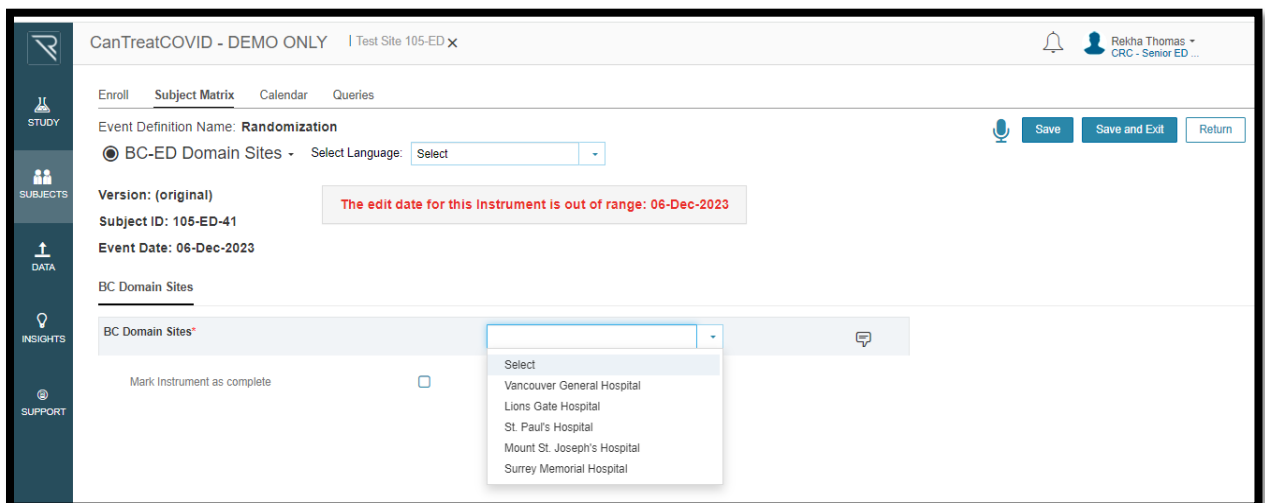

Then search for 5-19, select the subject

And press on Reset myREDCAP Cloud password.

2. ED Domain Sites

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

3. Emergency Department Log

Select where the participant was recruited from?

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?

For Participants recruited from <u>Non-ED setting</u>, 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 <u>ED setting</u>, 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 Provinical 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