

Research Pharmacist : Binder  
Version: National



Canadian Adaptive Platform Trial of **Treatments** for **COVID** in Community Settings

**Principal Investigator:** Andrew D. Pinto MD CCFP FRCPC

**Contact Details:** Upstream Lab, MAP/Centre for Urban Health Solutions, Li Ka Shing Knowledge Institute, Unity Health Toronto, 30 Bond Street, Toronto, Ontario, Canada M5B1W8, [upstreamlab@smh.ca](mailto:upstreamlab@smh.ca), 416-864-6060 x76148

**Study Sponsor:** Unity Health Toronto

**Contact Details:** [researchethics@unityhealth.to](mailto:researchethics@unityhealth.to)

**Study Funder:** Canadian Institutes for Health Research (CIHR)

**Contact Details:** [mediarelations@cihr-irsc.gc.ca](mailto:mediarelations@cihr-irsc.gc.ca)

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## Contents

1. Project Summary
2. Research Pharmacist Training
3. Participant Encounter Procedure Manual

## **Project Summary**

CanTreatCOVID is an open-label, individually randomized, multi-centre, national trial. CanTreatCOVID aims to establish an adaptive platform trial aimed at evaluating the clinical- and cost-effectiveness, practical challenges, and outcomes of therapeutics for SARS-CoV-2 for non-hospitalized patients in Canada. Participants will be randomized to receive usual care (i.e. supportive care and symptom relief) or a study therapeutic, which will be determined by the Canadian COVID-19 Out-Patient Therapeutics Committee. The first intervention arm is nirmatrelvir 300 mg/ritonavir 100 mg BID (Paxlovid™) x 5 days.

## Training

The Research Pharmacist role is unique and was developed specifically to support CanTreatCOVID protocol execution. Training to prepare to assume the role will consist of clinical, ethics, jurisprudence and core application training. Researcher-specific training includes: The training pieces are compiled from a variety of sources, and should be completed within a 2 weeks period.

Domains : clinical, ethics, research, jurisprudence, technology

Table 1: Training to work as part of a research team in Canada (research involving human subjects)

Training Course	Remote or In-Person class	Link for training
Canada GCP Course: For Basic or Social Scientists involved with human research	Remote only	Collaborative Institutional Training Initiative (CITI Program) Email:support@citiprogram.org Phone: 888-529-5929 Web:https://www.citiprogram.org
Health Canada Division 5 - Drugs For Clinical Trials Involving Human Subjects	Remote only	Collaborative Institutional Training Initiative (CITI Program) Email:support@citiprogram.org Phone: 888-529-5929 Web:https://www.citiprogram.org
Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2022)	Remote only	Panel on Research Ethics <a href="http://www.pre.ethics.gc.ca">www.pre.ethics.gc.ca</a>  <a href="https://tcps2core.ca/course/dashboard">https://tcps2core.ca/course/dashboard</a>
Privacy Training related to accessing digital databases containing Personal Health Information	Remote but facilitated by an individual with responsibilities to train users – institution specific training	Specific to province/institution

Table 2: CanTreatCOVID Protocol

Training Protocol training	Remote only	<a href="https://cantreatcovid.org/study-materials/">https://cantreatcovid.org/study-materials/</a> Password: studyteam
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Table 2: Pharmacist Training Links

Item	Clin	Eth	Juris	Link for training
<p>Ontario College of Pharmacists – Dispensing and Prescribing Paxlovid – Patient Care</p> <p>Resources listed on the Ontario College of Pharmacists website meet many of the required training elements: jurisprudence around dispensing (specific to working with the Contracted Research Pharmacy), jurisprudence around documentation, clinical (drug interactions, clinical assessment, care plan and monitoring) and Virtual Care</p>	✓		✓	<p><a href="https://www.ocpinfo.com/regulations-standards/novel-coronavirus-covid-19-professionals/#faq13">https://www.ocpinfo.com/regulations-standards/novel-coronavirus-covid-19-professionals/#faq13</a></p> <p><a href="https://www.ocpinfo.com/regulations-standards/practice-policies-guidelines/virtual-care-policy/">https://www.ocpinfo.com/regulations-standards/practice-policies-guidelines/virtual-care-policy/</a></p>
Ontario College of Pharmacists - Initiating, Adapting and Renewing Prescriptions Guideline	✓	✓	✓	<a href="https://www.ocpinfo.com/regulations-standards/practice-policies-guidelines/adaptations-renewing-prescriptions/">https://www.ocpinfo.com/regulations-standards/practice-policies-guidelines/adaptations-renewing-prescriptions/</a>
Manufacturer Resources intended for use by Canadian Health Care Professionals	✓			<a href="https://www.paxlovid-hcp.ca/en">https://www.paxlovid-hcp.ca/en</a>
Therapeutics Initiative Best Evidence Webinar: Drug-drug interactions in older adults with polypharmacy prescribed nirmatrelvir-ritonavir for the treatment of COVID-19	✓			<p>Slide Deck available from Ontario hub pharmacist</p> <p>Webinar Recording <a href="https://www.ti.ubc.ca/2022/12/14/ti-best-evidence-registration-upcoming-dec-14-best-evidence-webinar-drug-drug-interactions-in-older-adults-with-polypharmacy-prescribed-nirmatrelvir-">https://www.ti.ubc.ca/2022/12/14/ti-best-evidence-registration-upcoming-dec-14-best-evidence-webinar-drug-drug-interactions-in-older-adults-with-polypharmacy-prescribed-nirmatrelvir-</a></p>

			<a href="#">ritonavir-for-the-treatment-of-covid-19/</a>
COVID-19 open access chapter published by Canadian Pharmacists Association	✓		<a href="https://www.pharmacists.ca/cpha-ca/function/utilities/pdf-server.cfm?thefile=/cpha-on-the-issues/COVID-19%20Chapter-EN-FINAL.pdf">https://www.pharmacists.ca/cpha-ca/function/utilities/pdf-server.cfm?thefile=/cpha-on-the-issues/COVID-19 Chapter-EN-FINAL.pdf</a>  (chapter also available as a PDF)
COVID-19 RCTs: Treatment of symptomatic outpatients at high risk for progression to severe COVID-19	✓		PDF (printout from rxfiles – do not share outside of CanTreatCOVID team)  Appendix 1

### Trial Procedures

Table 3: List of applications and permissions required for pharmacist to complete all the required documentation for CanTreatCOVID

Application	Link if available (bookmark recommended)
REDCap Academic	<a href="https://REDCap.smh.ca/REDCap/index.php">https://REDCap.smh.ca/REDCap/index.php</a>
REDCap Cloud	<a href="https://login.REDCapcloud.com/">https://login.REDCapcloud.com/</a>
Local / provincial drug database	Province specific
Master Linking Log Electronic	Citrix access to Unity Health Desktop, located on secure network drive
Telephone calling – local and long distance	Jabber
Fax application Rightfax	<a href="http://webfax">http://webfax</a>
Institutional email (Personal Health Information can be securely shared)	
Liverpool Drug Interactions Checker	<a href="https://www.covid19-druginteractions.org/checker">https://www.covid19-druginteractions.org/checker</a>

## Participant Encounter Procedures

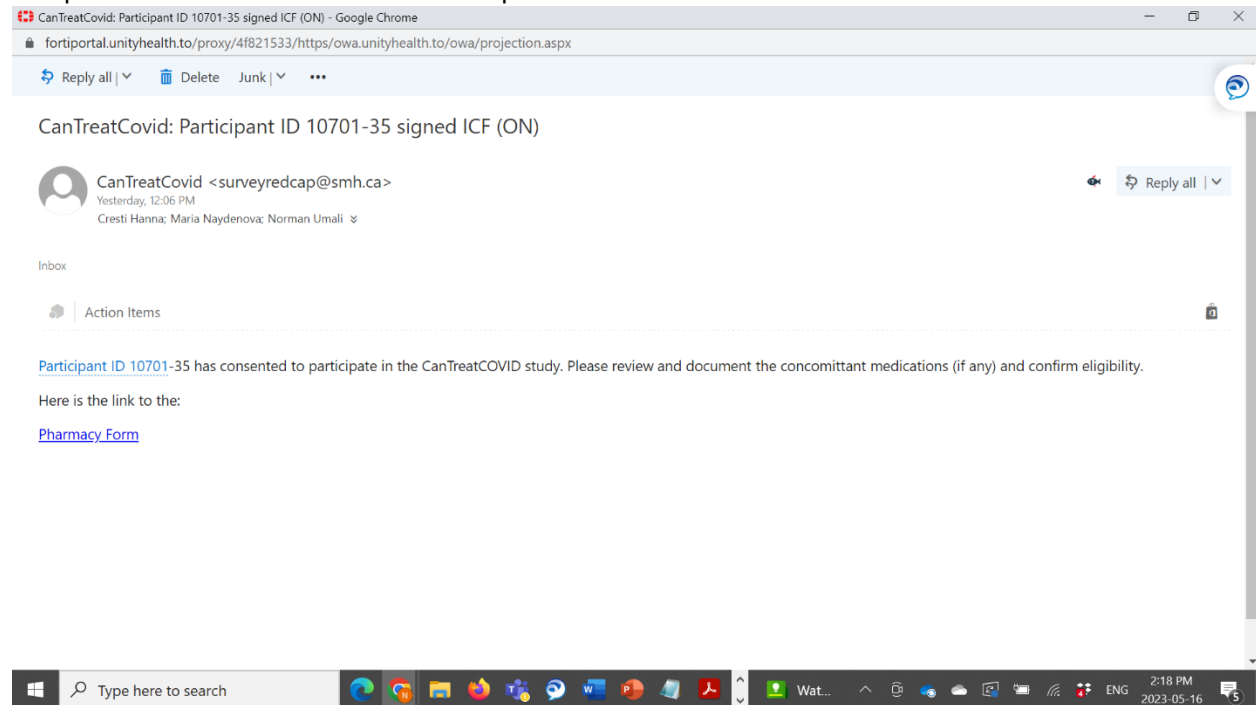
### Contacting potential participant

1. Upon successful participant screen by Research Assistant, research pharmacist will receive email notification from REDCap Academic with the following format:
  - a. **Subject:** CanTreatCovid: Participant ID XXXXX-XX signed ICF (ON)
  - b. **Body:** Participant ID XXXXX-XX has consented to participate in the CanTreatCOVID study. Please review and document the concomittant medications (if any) and confirm eligibility.

Here is the link to the:

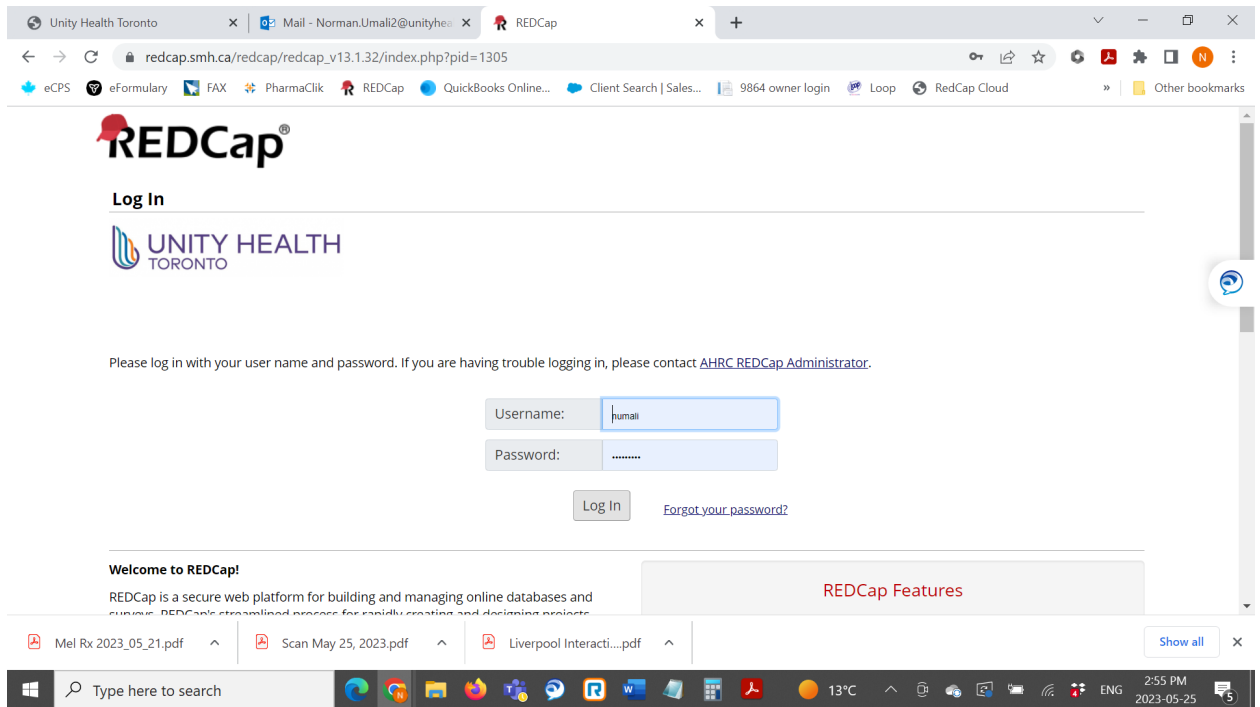
### Pharmacy Form

#### Sample Screen Shot of Email from REDCap:

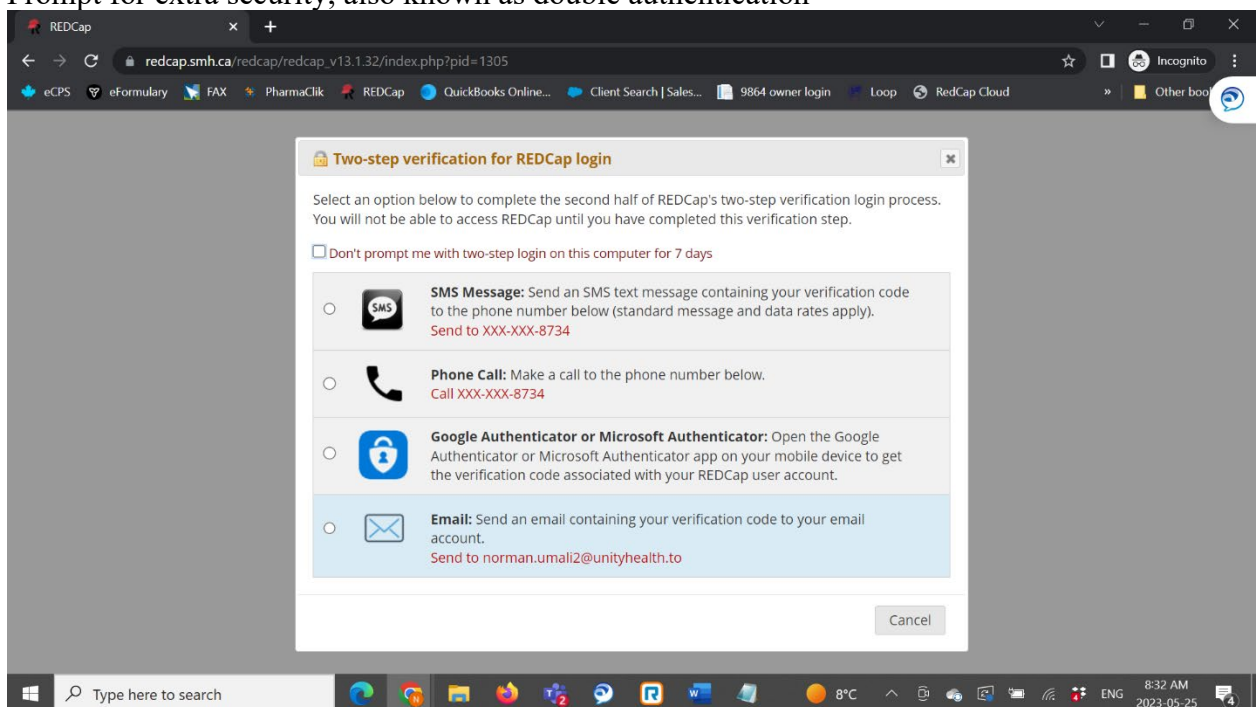


2. Open a CanTreatCOVID Pharmacist Assessment template Word document and assign to participant
3. **IMPORTANT: pharmacist will be concurrently directly documenting in the REDCap Academic database (4 to 29) and the Pharmacist Assessment document (30 to 43)**
4. Login securely to REDCap Academic, either using the link provided or Bookmark
  - a. clicking on the embedded link within the notification email, or
  - b. navigating to REDCap login page via bookmark
    - i. [https://REDCap.smh.ca/REDCap/REDCap\\_v13.1.32/index.php?pid=1305](https://REDCap.smh.ca/REDCap/REDCap_v13.1.32/index.php?pid=1305)
  - c. **IMPORTANT: Access to REDCap requires a consistent internet connection**

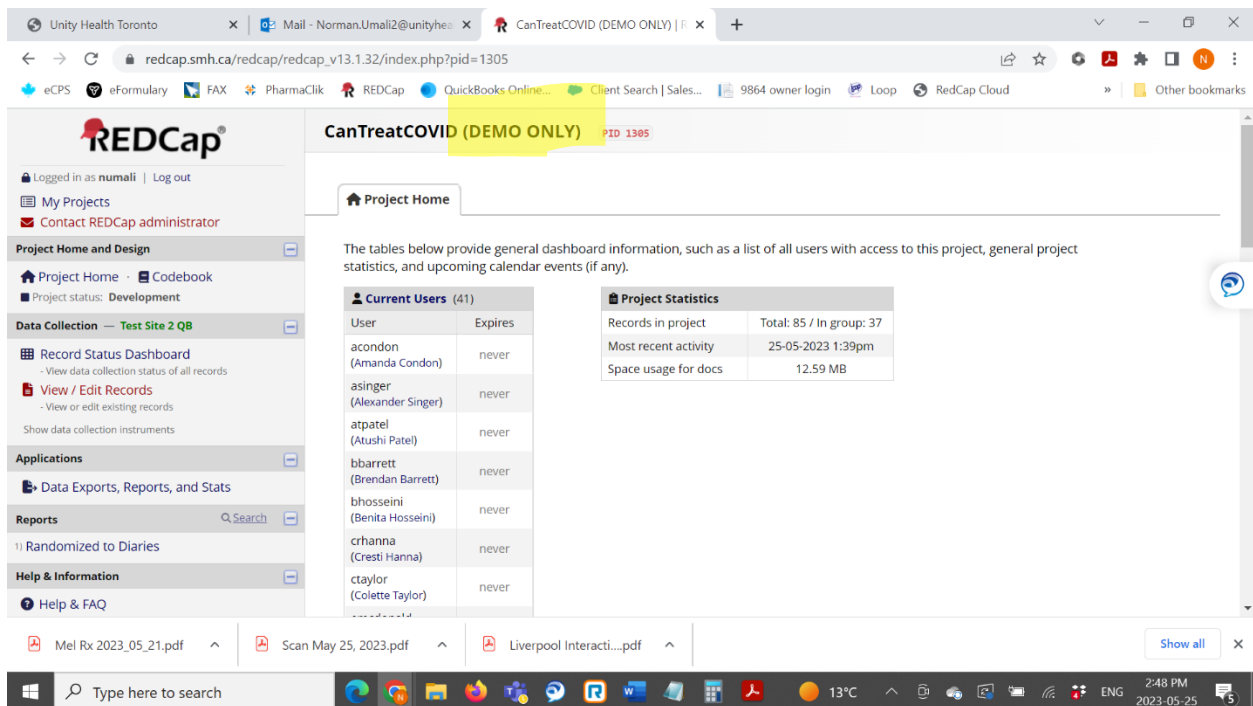




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- 
5. Prompt for extra security, also known as double authentication
6. Prompt for extra security, also known as double authentication



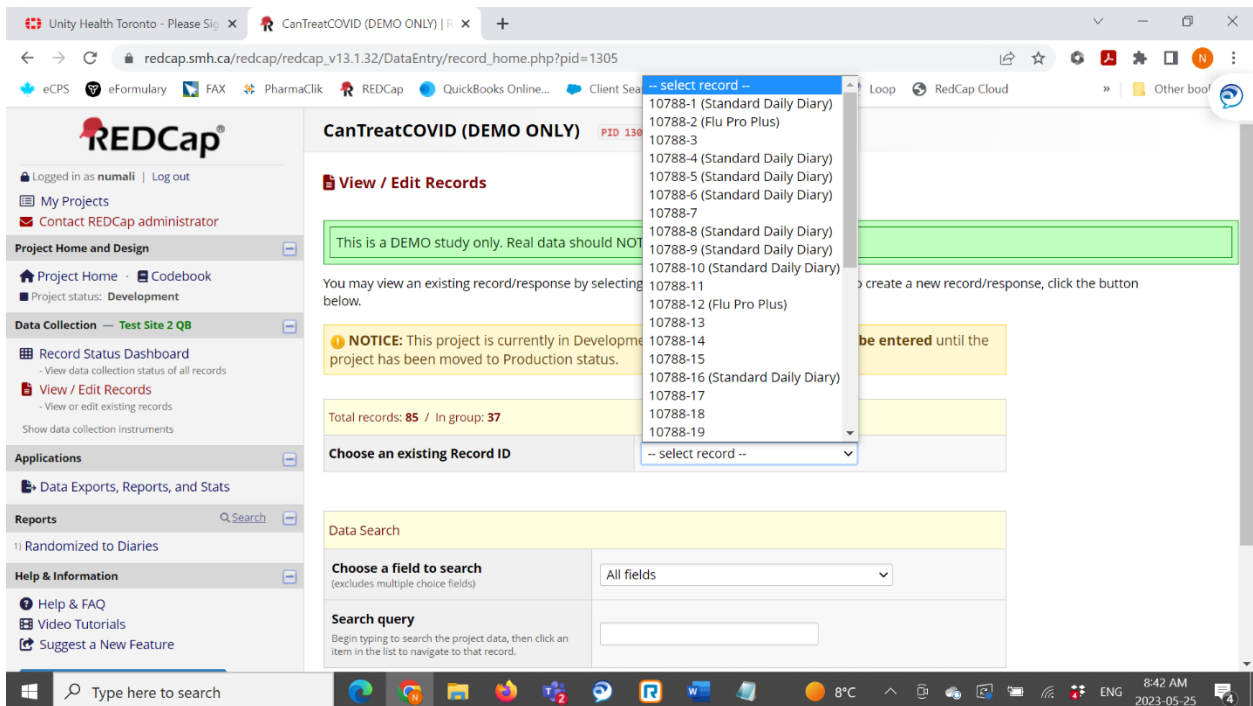
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- 
7. Selection authentication method and proceed to the REDCap project homepage
8. At REDCap Academic home page, ensure you are working within the CanTreatCOVID project
  - a. In this screenshot, "DEMO" is indicated, this is ONLY for purposes of training – you must be working within the non-DEMO version to access live participant files



9. Navigate to View/Edit records

10. Navigating to the Participant REDCap forms, utilizing the Participant ID from the notification email

a. Select from the Drop Down menu



b. Ensure the Participant ID matches from the REDCap notification email

11. Ensure that “Pharmacy Authorization Form – Complete by Research Coordinator” has been marked as Complete with a green indicator

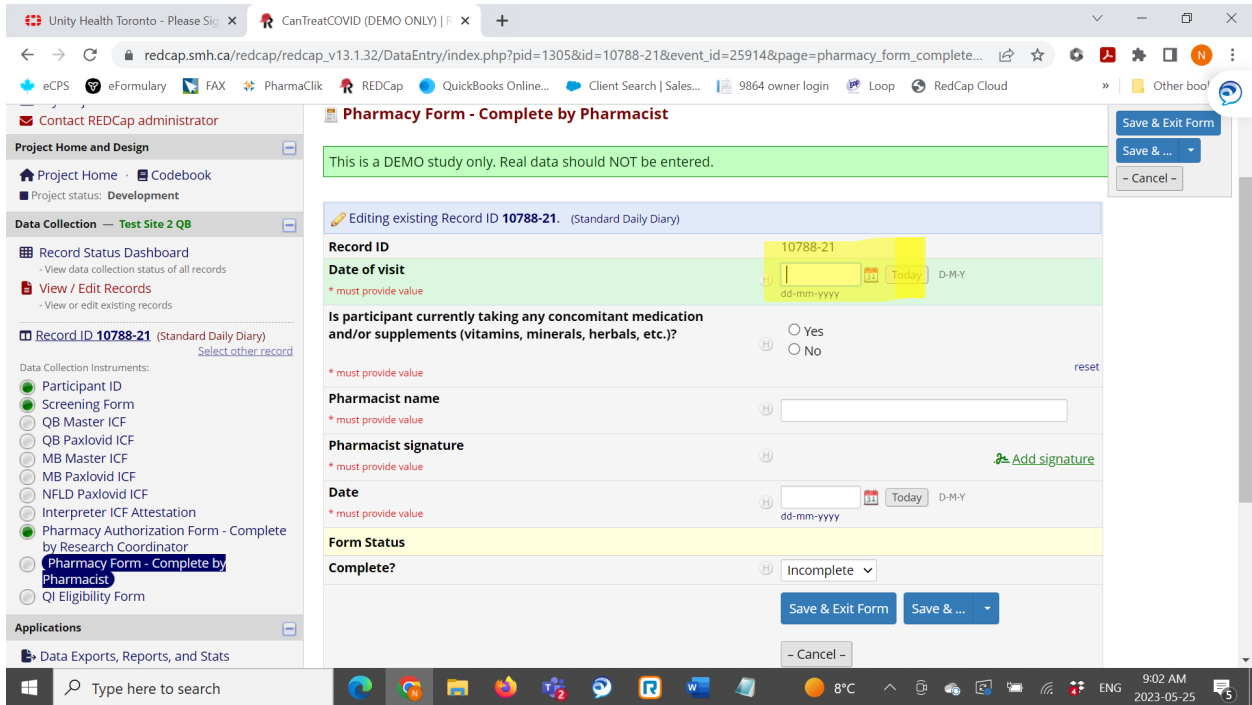
The screenshot shows the REDCap interface for Record ID 10788-21. A legend at the top right indicates that a green circle represents a 'Complete' status. In the 'Data Collection Instrument' table, the 'Pharmacy Authorization Form - Complete by Research Coordinator' row has a green circle in the 'Status' column. Other forms like 'Pharmacy Form - Complete by Pharmacist' and 'QI Eligibility Form' have grey circles.

Data Collection Instrument	Status
Participant ID	Complete (Green)
Screening Form	Complete (Green)
QB Master ICF (survey)	Unverified (Grey)
QB Paxlovid ICF (survey)	Unverified (Grey)
MB Master ICF (survey)	Unverified (Grey)
MB Paxlovid ICF (survey)	Unverified (Grey)
NFLD Paxlovid ICF (survey)	Unverified (Grey)
Interpreter ICF Attestation (survey)	Unverified (Grey)
Pharmacy Authorization Form - Complete by Research Coordinator	Complete (Green)
Pharmacy Form - Complete by Pharmacist	Unverified (Grey)
QI Eligibility Form	Unverified (Grey)

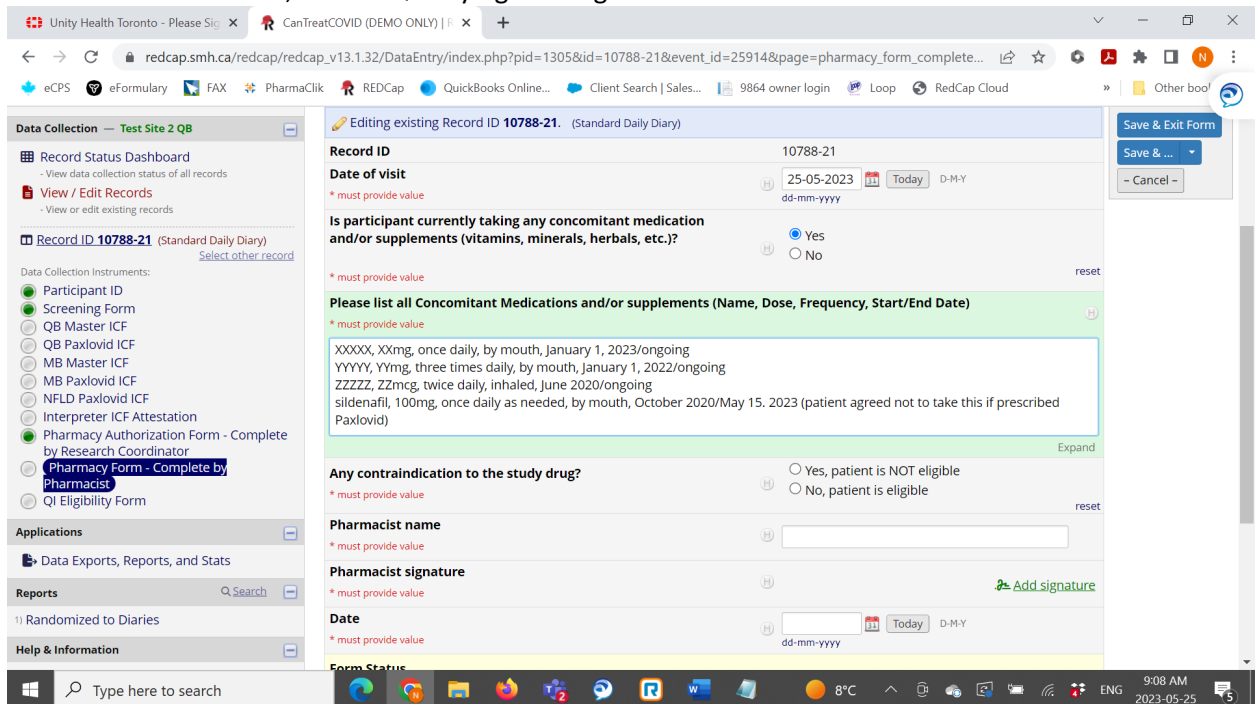
- 12.
13. Navigate to “Pharmacy Form – Complete by Pharmacist” by clicking on the blank indicator circle in the Status column

This screenshot is identical to the previous one, but the 'Pharmacy Form - Complete by Pharmacist' row in the table is highlighted with a yellow background, and its status indicator is a grey circle.

- 14.
15. Document “Date of Visit”. This refers to the Date of Assessment of the participant via telephone



16. REDCap question “Is participant currently taking any concomitant medication and/or supplements (vitamins, minerals, herbals, etc.)?”
  - a. If Yes, document in the free text box the medications
    - i. Data enter in the format outlined in REDCap
      1. Name, Dose, Frequency, route of administration, Start/End Date
17. The free text box is also a location where relevant findings related to renal or liver function can be data entered as well, for the Qualifying Investigator to review

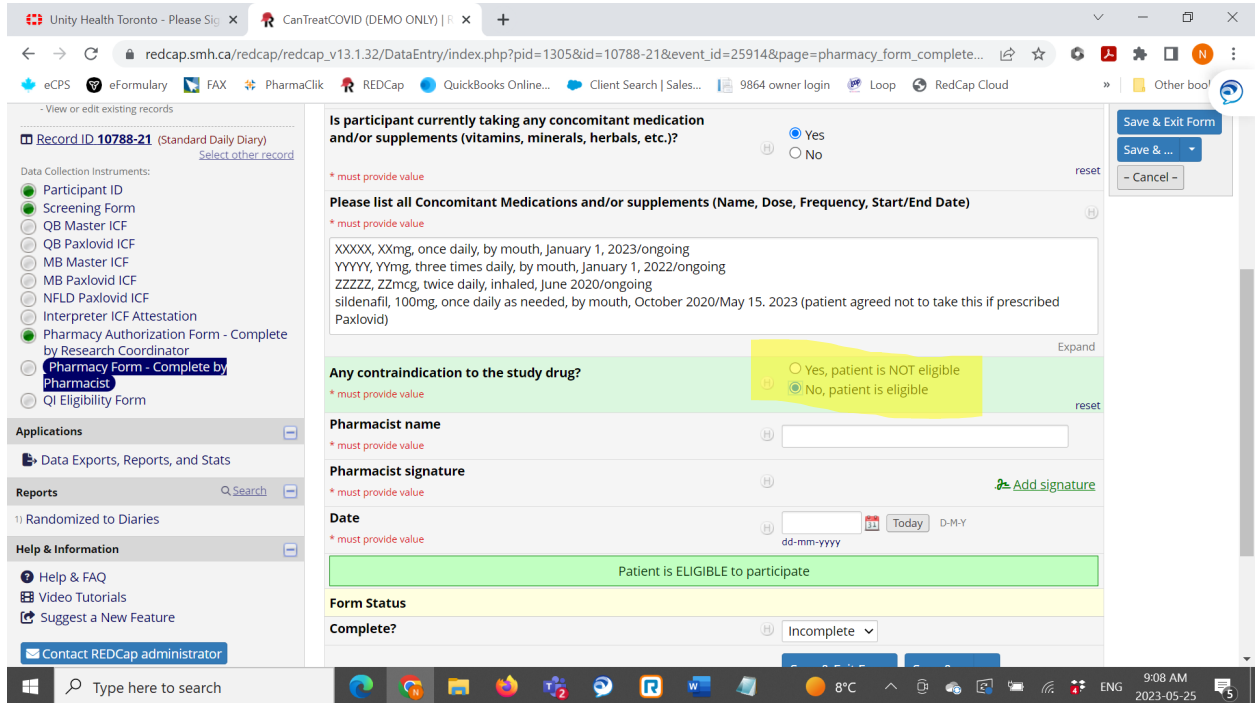


18.
  - a. If “No”, proceed to “Any Contraindication to the study drug?”

19. REDCap question “Any Contraindication to the Study Drug?”

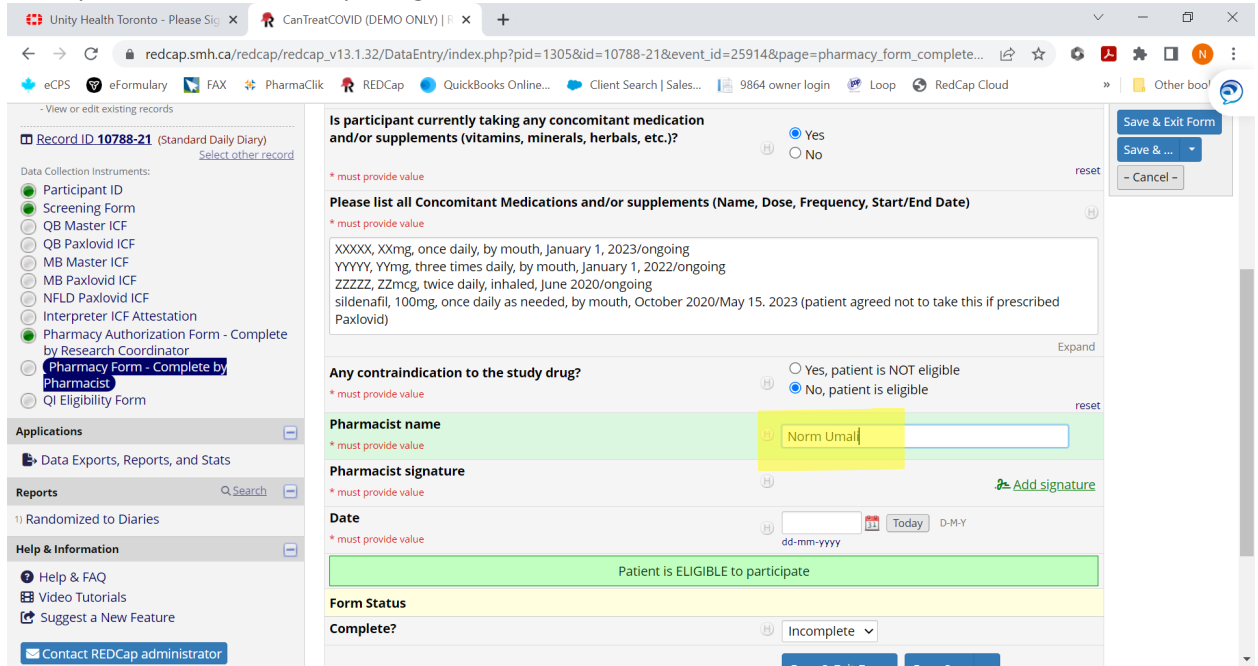
- a. This is a wholistic assessment including drug interactions and renal/liver function assessment

20. Document Yes or No



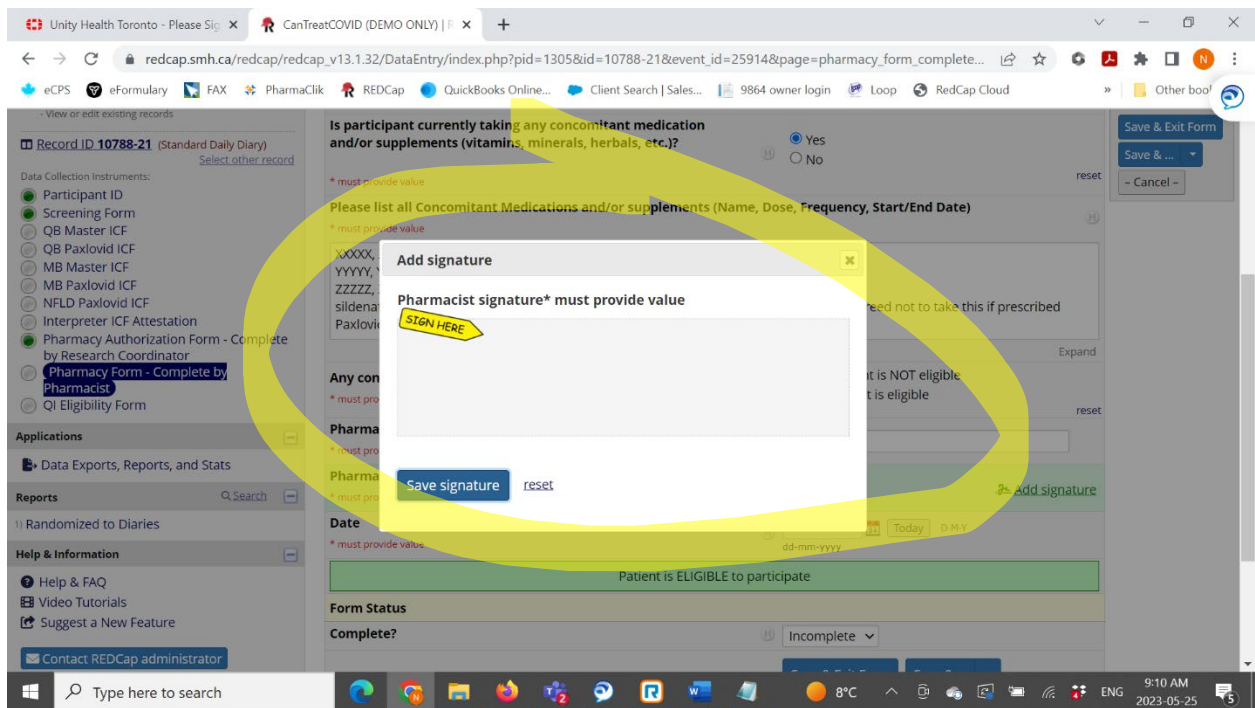
21.

22. Enter pharmacist name completing the assessment

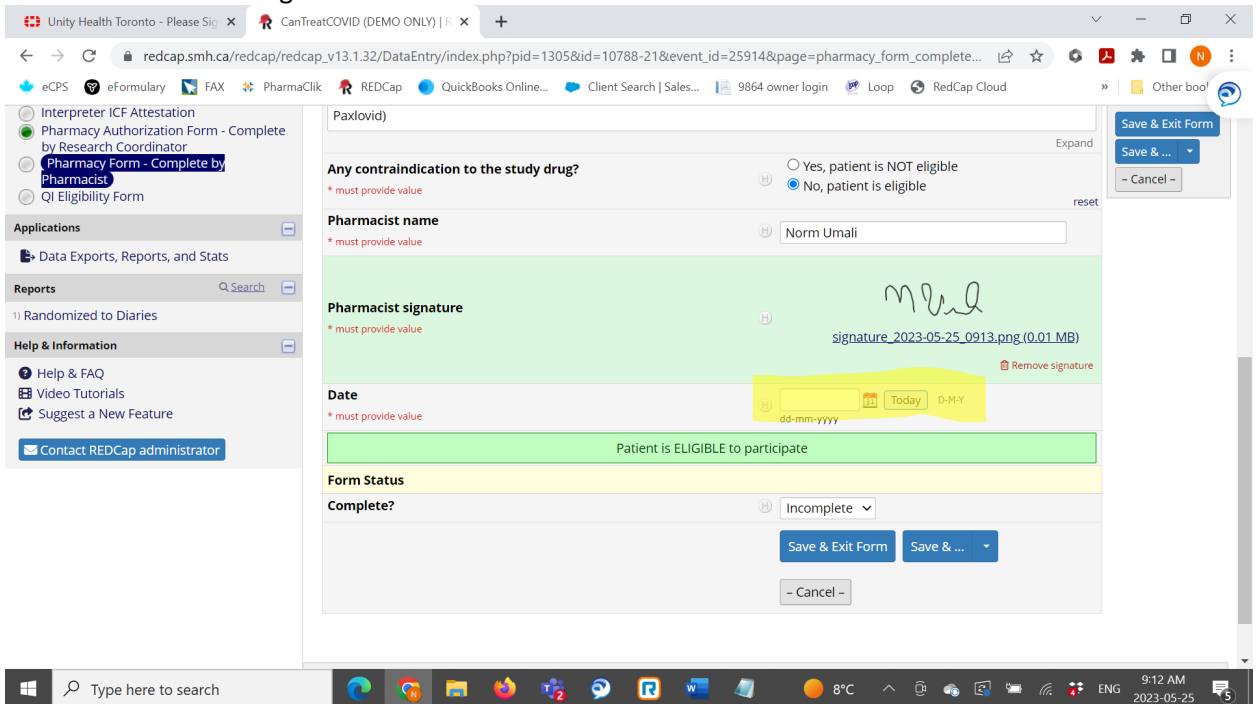


23.

24. Sign off by drawing signature either by using mouse/touchpad, or directly on active touch screen



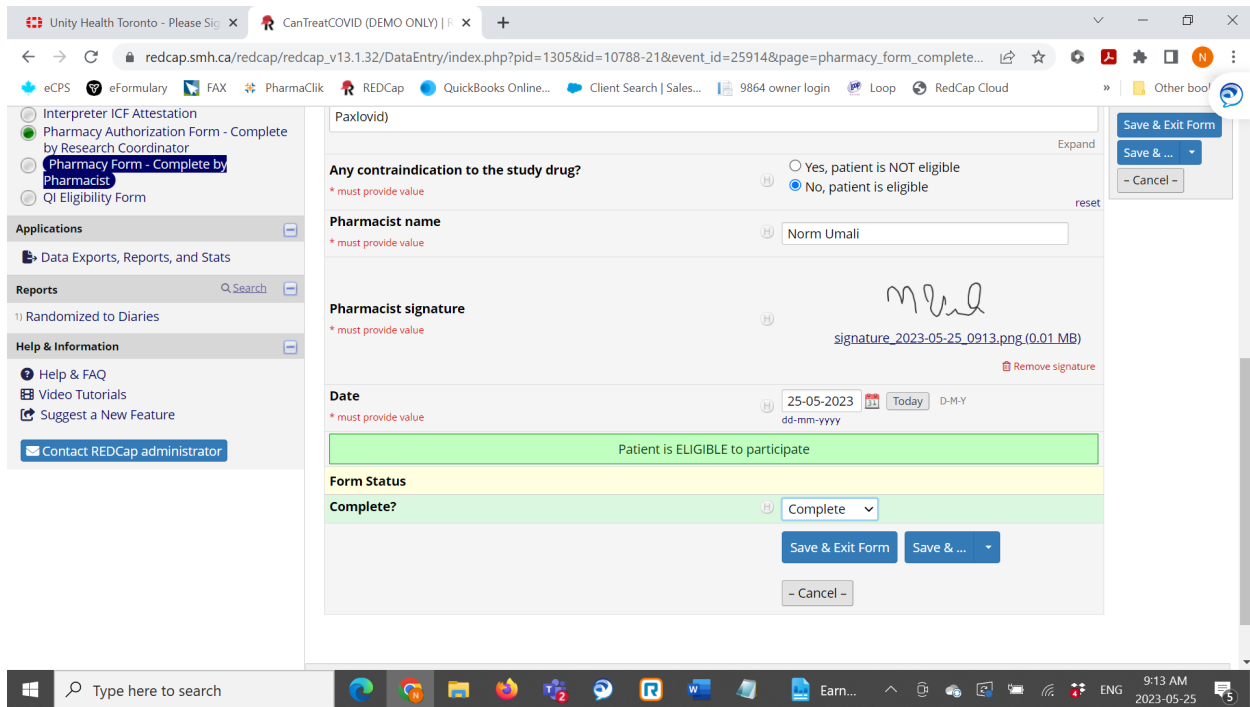
25. Document date form signed



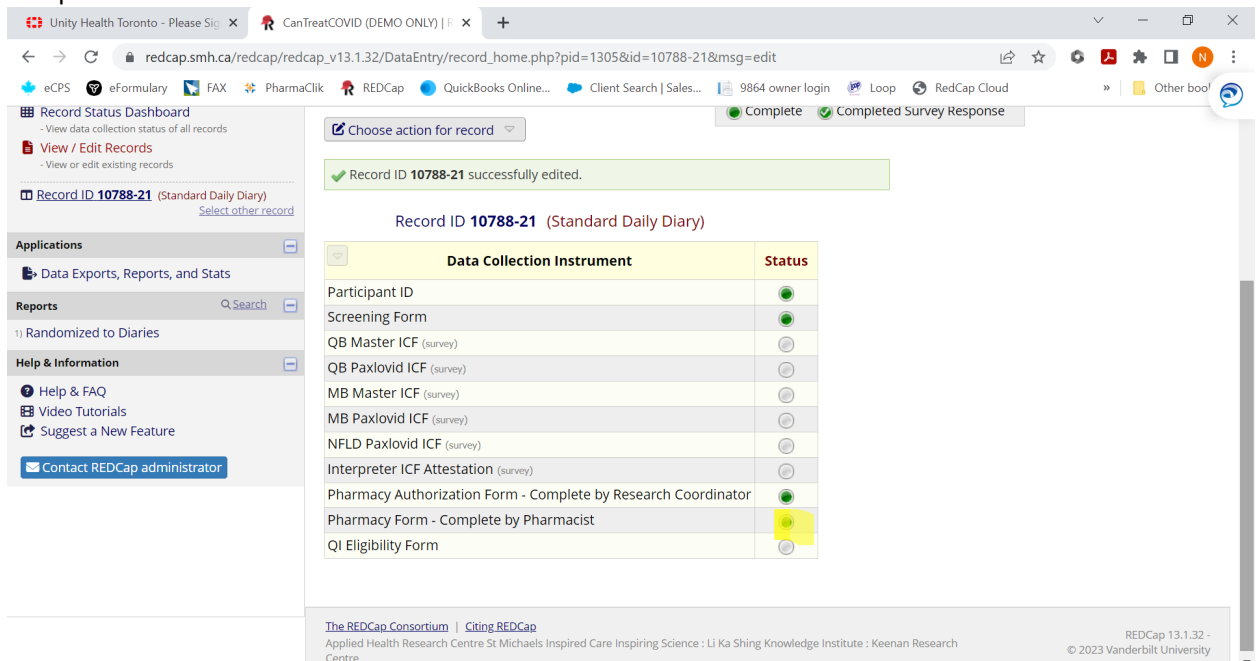
26.

27. mark Form as "Complete" and then "Save & Exit Form"





28. At Record Home page, green indicator next to “Pharmacy Form – Complete by Pharmacist” indicates that the research pharmacist REDCap Academic tasks have been successfully completed



29.

30. Access the Master Linking Log, and find the participant information to review, by matching the Participant ID
  - b. The Master Linking Log is a securely stored digital document that is accessed only by core project team staff (i.e., individuals who have completed the required training and have signed the hub delegation log) – access will vary depending on enrolment site and province
  - c. **IMPORTANT – be careful not to modify this file inadvertently, as this is the source documentation for all research participants. When closing file after use, make sure to NOT save changes. In the case that an error has been identified (e.g., wrong date of birth), then, contact Research Coordinator and jointly decide to update the Master Linking Log**
31. Open a Pharmacist Assessment Tool (see Appendix 2) and initiate tool population by retrieving information from the Master Linking Log
  - d. Remember: this tool will be a source document for inclusion in the Participant file
  - e. Fields
    - i. Participant Screening ID
    - ii. Full name
    - iii. Telephone number
    - iv. Health Number
    - v. Date of Birth
    - vi. Email
    - vii. Alternate contact telephone number, if needed
    - viii. Family doctor name
    - ix. Family doctor telephone number
    - x. Community pharmacy name
    - xi. Community pharmacy address
    - xii. Community pharmacy telephone number
32. Telephone call to participant – general script:
  - f. Hello, I am calling about the CanTreatCOVID research project, my name is XX. Can I please speak to Mrs/Mr XX? I am the pharmacist with the project, and I wanted to first thank you for volunteering to participate in this research. I am sorry to hear that you have acquired a COVID-19 infection. Recently, you have been speaking to one of our Research Assistants. My role is to review your medications to make sure you are safe to participate in this research project.
33. Proceed with starting a Best Possible Medication History (BPMH), documenting in the Pharmacist Assessment Tool.
34. Screen participant for “red flag symptoms” such as shortness of breath and cognitive disturbance such as confusion
35. In addition to BPMH interview, other relevant questioning to include:
  - g. Height
  - h. Weight
  - i. How many pharmacies being used
  - j. Ability to swallow oral dosage forms whole
  - k. Knowledge of other medical history, including renal and liver function
36. Important to confirm the local community pharmacy information, even though Research Assistant documents this detail
  - l. Sometimes, participants use multiple pharmacies, so capture this information and included those pharmacies when calling to complete the BPMH



37. Complete the telephone call to participant – general closing script:
  - m. Thank you for speaking to me and sharing these important details. I will contact your community pharmacy to make sure my list is complete. Unless I find some new information from the community pharmacy about your medications or health that will affect your participation, you will be contacted by one of our research team to confirm how you will be proceeding with participating in the research. If you have questions, reach out to the toll free number and you can ask for the pharmacist.
38. Contact community pharmacy to get more details about prescription history – general script:
  - n. Hello, I am a pharmacist working at XX and I am calling to review the medication history for one of your patients, Ms/Mr XX, date of birth XX.
39. Capture name of the staff spoken to at the community pharmacy, document in the Pharmacist Assessment Tool
40. Locate community pharmacy name, address and telephone number from Master Linking Log
41. Telephone call to the community pharmacy to review medication history
  - o. Validation procedures with community pharmacy to ensure comfortable sharing Personal Health Information
  - p. Utilize community pharmacy review as another source of medication information in completing BPMH
  - q. Inform the community pharmacist of the patient’s involvement in the research project, and that a fax update will be communicated in the case this patient is allocated to the group that receives investigational product
  - r. If medication list is lengthy, option to have community pharmacy fax to the research team, but this must be completed in a timely manner, keeping in mind the priority to ship investigational product the same day as enrolment
  - s. Document the name of the pharmacy team member
42. Upon completion of BPMH, navigate to Liverpool Drug Interaction Checker online website (this is a free online drug interactions assessment tool sourced from the United Kingdom and recommended for clinician use by Canadian public health authorities)
  - t. <https://www.covid19-druginteractions.org/checker>

- u.
- v. Under COVID Drugs heading, search up Paxlovid
- w. Under Co-medications heading, data enter the medications from the BPMH
- x. After analysis, towards bottom of the working screen there is a button to Download, and a field to enter data
  - i. In the field, enter the Participant Screening ID
  - ii. Download as PDF (do not print) and add to the source documentation for the participant

43. Qualifying Investigator procedures to confirm eligibility will be activated after Saving and Exiting Pharmacy Form
  - y. Send a text message to the Qualified Investigator to notify that a participant has been screen as eligible by the pharmacist
    - i. Text message step helps to notify the Qualified Investigator, who will likely be in other daily clinic or academic duties – this is to prevent any gaps in communication
    - ii. Remember: do NOT include any PHI in the text message, nor in team emails
44. If there are Contraindications, then participant is ineligible
  - a. Document Yes to Contraindications question
  - b. mark Form as “Complete” and then “Save & Exit Form
  - c. Telephone call to participant to communicate the reason for ineligibility
  - d. Send email to Research Assistant and Research Coordinator to communicate the finding of ineligibility, stating the reason as well, which will be documented by Research Assistant in Source Documentation
44. If No contraindications to the study drug, and after the Qualifying Investigator completes procedures to confirm eligibility, then Research Coordinator will assign the computer-generated randomization through REDCap Cloud function
45. REDCap Cloud will assign a Study ID
  - e. Study ID is distinct from Participant Screening ID
46. Match up the Screening ID to the Study ID using the Master Linking Log
47. Allocation Group will not be evident from REDCap Academic database; REDCap Cloud stores the information with respect to group assignment
  - f. Alternately, the Research Assistant and Research Coordinator will confirm via email the group allocation
48. If participant is randomized to group that receives the investigational product, then must prepare prescription to be faxed to the dispensing pharmacy
  - g. Qualified Investigator will be signing the prescription to authorize
49. Open the digital fax application
50. Fax the participant’s prescription to the dispensing pharmacy, including the following details that are important for shipments
  - h. Shipping address, including apartment or unit number, as well as building access number (i.e., buzzer code)
  - i. Email address
  - j. Telephone number
51. Telephone call to the dispensing pharmacy to clearly communicate the need to ship the prescription as soon as possible
  - k. Document the name of the staff member that was notified
52. Telephone call to the participant (randomized to the investigational product group) to perform medication counselling
  - l. Document the details of this patient encounter on the Pharmacist Assessment Form, Counselling section, including:
    - i. Counselling on red flag symptoms
    - ii. Participant’s questions, and resolution
    - iii. Any specific details regarding the management of drug interactions
53. Prepare a fax communication to be sent to the community pharmacy, notifying that the participant will be taking investigational product, including the anticipated start date

- m. This step is important because investigational product is being prescribed by a Qualified Investigator, not the primary care team, and the investigational product is being dispensed outside of common provincial Drug Utilization Review systems
54. Prepare a fax communication to be sent to the primary care provider, similarly notifying that the participant will be taking investigational product, including the anticipated start date

**Important notes on Procedures to Document during Participant Encounter**

Any information collected from verbal communication with a local pharmacy should be directly entered into the study database. Make sure to accurately record the details provided.

If additional information is required from the patient's medical record, such as lab data or medical history, it's important to file a screenshot of the portal (i.e Connecting Ontario) or email correspondence from the primary care provider. Save these screenshots/email correspondence within the patient's folder in a designated location.