Getting Ready for Connect Care

Getting Ready for Research Conversion





Zoom Etiquette



- Remain muted if you are not speaking
- Be mindful of allowing others to participate, where appropriate
- Leverage the chat window to ask questions
- Be mindful that you cannot be on a Skype, Microsoft Teams and Zoom call at the same time

Agenda

- In-scope studies and general process overview
- Required activities for Research Conversion
- Registration for Virtual Research Conversion Sessions
- Logging in to Hyperspace



What Studies are In-scope for Connect Care Launch?



Clinical research projects that meet these criteria:

- Interventional trials and device studies
- Other clinical studies that require:
 - Research-specific visits scheduled in Connect Care
 - Use of recruitment tools, or research-study specific order entry or documentation
 - Release of information to outside study monitors
 - Coordinator notifications of ED arrivals or admissions
 - Billable items to study (i.e. observational studies with labs or other testing)

Research Conversion Process



What happens in the Research Conversion Classroom?

- Study information is verified in Connect Care
- Patients and future encounters are associated to the correct studies
- Virtual Conversion Classroom sessions include live support and 'how-to' guides for staff as they complete study conversion in the virtual session
- Study conversion steps include:

Part 1: Verify Studies and Link Patients

Part 2: Link Encounters, Document Investigational Meds, and Personal Settings

Most coordinators will need from 1 to 2 hours to complete all classroom activities

□ 1 representative per study is required in the virtual classroom

The entire study team should view the Research Conversion eLearning on MLL

Research Conversion Preparation

- 1 representative per study is required in the virtual classroom (the person performing the steps to set-up the study)
- The entire study team should review the Research Conversion eLearning on MLL
- Follow your Research Conversion Guide
- Your team only needs to attend ONE virtual classroom session where you will convert at least one study in real-time
- Ensure all studies are converted prior to Launch 6 on May 6, 2023



Preparing for Part 1: What to Have Available

- Study information including (where applicable): study team members, REB approval and expiry dates, CTCAE version for adverse events, names of study arms.
- Your roster of patients actively enrolled or being recruited for your studies
 - Access to multiple patient identifiers (Name, DOB, ULI) so you can search for your patients
 - Be prepared to access any information that may be stored in a document or another system

Required	Required	Required	Optional	Required	Required	Required	Required	Required if Patient has Consented
Research Study Name (Short Title)	Site (Location)	REB Number	Beacon PRL	Patient ID Number (ULI preferred)	Patient Name	Patient DOB (DD/MM/YYYY)	Current Enrollment Status	Initial Consent Date (DD/MM/YYYY)
Sample Study	FMC CF Clinic	Pro00001234		123456789	Mouse, Mick	25/01/1955	Enrolled	14/02/2017
Sample Study	FMC Audiology	Pro00005678		456789123	Duck, Donal	14/02/1965	On Follow-Up	25/01/2016
								0

Template for Patient Data (to be sent via email following your registration to a virtual classroom session):

Step 1 – Find your List of Studies

What to check

- Verify all your studies are showing up on your "Coordinator Study Search" report
- Identify any studies that should be closed and notify the HSA Team
- Confirm the studies are properly marked as Interventional OR observational

Step 2 – Complete your study set-up using the Study Maintenance Activity

Sections you will review

- General Information
- Users and Providers
- Study Calendar
- Automated Actions
- Contraindicated Medications
- Adverse Events

General Information	User	s And Providers						
Users and Providers Studies Activity Setup Report Groupers Study Calendar Amendments Automated Actions Billing Setup Billing Notes Transactions History Review Settings Recruitment Contraindicated Medi	Study Users Principal Investigator RESEARCH, PHD INVESTIGATOR [E40118]							
	Study Coordinators			Nurses				
	1	RESEARCH, COORDINATOR [INTRC]		1				
	2							
	Other Providers				Research Contacts			
	1			1				

Research and Connect Care

What to check in each section

General Information section

- Study Name
- Description
- Ethics ID
- Update the Approval and expiration date
- Update the study status (It must be updated from 'Project in Set Up' to the most appropriate status)

Users and Providers section

• Verify the correct study personnel is listed in the correct field. Any changes will need to be requested of HSA. Please let the classroom support leads know.

Study Calendar

• Add study branches (if applicable)

Automated Actions

- Verify the required automated actions for your studies are properly set up
 - ✓ Interventional studies: the Procedure Result, Appointment, and ADT notifications are added for these studies
 - X Observational studies: the ADT Notifications are NOT added for these studies

Any change requests will need to be submitted to HSA.

Contraindicated Medications

 Select (as applicable) the study-specific medication grouper containing all medications that are considered contraindicated for your study (as per the study protocol)

OPTIONAL functionality – a study-specific medication grouper request will allow you to set up both specific drugs and/or drug class contraindications.

If you need a medication grouper built for your study, please submit a ticket using the instructions in the <u>Research Study Medication Grouper Tip Sheet</u> which can be found on the Research Coordinator Learning Home Dashboard.

Adverse Events

• Select the appropriate Adverse Events Term set

Step 3 - Patient Associations

What to check for studies with active enrollments

• Find your patients and associate your patients to their respective research studies adding the following:

✓ Status

✓ Consent Date

Review all your patients have been properly linked and have their 'start date'

- 1. Go to your Research Coordinator dashboard and run the report: Patient Associations on My Studies Ready to run
- 2. Verify all your patients have been properly linked to their studies and have the correct 'start date' and 'status' entered.

Preparing for Part 2: What to Have Available

- A list of the future, study-related visits
 - Know the department where patients will be seen.
 - Know who which provider will be seeing the patient.
- A list of medications details (INV or SOC) for your research studies
 - Document any patients currently taking INV meds at home.

Step 1 – Information about Booking Researchrelated Patient Appointments

What you need to check to make sure your study appointments are in system

- Research-related visits at AHS clinical spaces are ideally scheduled by AHS scheduling staff for the most consistent patient experience
- Clinical department setup includes a Research Visit Type
 - A 'Research Only' visit type is part of the standard build for specialty departments where your patients will be seen in an AHS clinical setting
 - The 'Research Only' visit means that everything in that encounter pertains to a research study
- You need to know who is booking your study appointments
 - Appointments may be booked by AHS scheduling staff or by Research Study Team members
- Research study team members require additional Schegistrar training before they will receive scheduling permissions in system

Step 2 - Linking Appointments & Admissions

What to check if study participants have research appointments within 2 weeks postlaunch

- You will use a report called 'Upcoming Appts for Patients Associated with (specify your study)'
 - Review upcoming visits for your study participants
 - Verify that all post-launch appointments were entered into Connect Care during appointment conversion
 - Verify research study-related visits scheduled for go-live and beyond are correctly associated with your study
- Make sure to link DI appointments for research which are converted by the DI service team prior to the research conversion classroom
- Check your profile to confirm you have been set up with a provider record if you are the person who will be booked to see a patient
- You can apply a similar workflow for the 'Upcoming/Current Admissions for Patients Associated with Your Study'

Step 3 - Investigational Medication Association

What to check if your studies involve an investigational medication and/or if any of your patients are taking it at home

All medication orders, including investigational medications, go through the system

- Add investigational medications to the patient chart
- Validate the INV build, that it is accurate and reflects either 'study dispensed' or 'pharmacy dispensed'

Step 4 - Research Coordinator User Settings

Dashboard options and other Personalization

• Many resources and links are available to you on your Research Coordinator Learning Home Dashboard and you can toggle between them, or choose another default option



• Take the opportunity to make your hyperspace work for you once familiar with the system

Research and Connect Care

Dates & Times for Conversion

Virtual Research Classroom Sessions:

- DATES: 4 days over two weeks
 - April 18-19
 - April 26-27
- **<u>TIME</u>**: Every session is 2 hours in length
 - 0830h to 1030h
- Maximum of 7 attendees per session
- Virtual office support 30 min after each session in the afternoon from 1400-1430h



Location: **Zoom** information provided in your session confirmation email

Virtual Research Conversion Session Registration

- 1) Ensure at least ONE team member signs up for a virtual conversion classroom session to complete conversion activities for your studies
 - Self-select your team's conversion delegate(s) to sign up to the classroom
 - We will send your team delegate(s) an email confirming the date and time for your session with Zoom details after they select a timeslot
 - The confirmation email will also contain a series of supporting materials that you will need to access during the classroom session - Make sure you have all listed information available during your virtual classroom session



Registration continued:

- 2) All team members must complete the self-directed Research Conversion eLearning on MLL
 - Your team **delegate(s) must complete the eLearning** prior to the virtual conversion classroom session date they selected
 - All other team members should complete the eLearning regardless of participation in the conversion classroom session

The eLearning teaches you what to do so you can complete these activities with new studies in the future, and to complete the conversion work if there are multiple studies your team must activate in Connect Care for launch 6



Registration continued:

- 3) Have a back-up plan in case your delegate is unable to attend the virtual conversion classroom
 - The COVID pandemic has impacted work for everyone; it is recommended that your team discuss who may substitute for your delegate if they are unexpectedly unable to attend the virtual conversion classroom date they selected
 - **Rescheduling the conversion classroom sessions is not an option** due to the other research users also registering for research conversion which may be affected by such changes.



Registration continued:

4) Test your Connect Care login

After you complete your training, test your login to the PRD environment in advance of your virtual conversion classroom session:

Connect Care

- Enter your AHS Network username and password
- Open Citrix



Connect Care

- Click on Applications
 - Folders icon (If you don't see the "PRD" icon let us know) Look for the CC
- **Do not** log into the training environments such as 'ACE'
- Enter your AHS Network username and password
- Select the role that you are attended training for ٠
- Select your department (see next slide for tips)



Department Naming – How to find yours

System Department Naming Formula:

- Large Acute Care Facilities (Multi Building)
 - [City Abbreviation] + [Campus/Hospital Abbreviation] + [Building Abbreviation] + [Specialty/Clinic Name]
 - Example [EDM] + [WMC] + [KEC] + Diabetes
- Single Hospital Facility/Location (Single Building)
 - [City Abbreviation] + [Hospital/Location Abbreviation] + [Specialty/Clinic Name]
 - Example [CGY] + [FMC] + Emergency
- Program Specific Naming
 - [City Abbreviation] + [Hospital/Location Abbreviation] + [Program Abbreviation] + [Specialty/Clinic Name]
 - Example [EDM] + [NC] + [AMH] + CYF Crisis

We are here to answer your questions.





QUESTION #1: For those of us whose clinics are not on Connect Care yet (i.e. we use Healthquest for our EMR), will this apply to us as well?

• Answer: Anyone who is going live with CC during launch 6 and located within an AHS space.

QUESTION #2: If we are not going live with CC yet, we do not need to enter our various clinical studies?

• Answer: Correct, you do not need to enter your studies in Connect Care until your site is live.

QUESTION #3 (Follow-up to question #2): What AHS site do you work at?

• Answer: Glen Sather Sports Medicine Clinic – we are in the KEC but we are under U of A. This is not an AHS site that is not going into Connect Care.

QUESTION #4: Will patients that were withdrawn from the study have to be added?

• Answer: No, only active patients

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QUESTION #5: For studies that has HREB approval and is now closed, what email address should be used to notify HSA that this study does not need conversion to CC?

Answer: <u>cc.research@ahs.ca</u>

QUESTION #6: There is a clinical trial that was intended to end in March 2023, and therefore, a study intake form was not completed. That said, there are ~70 patients enrolled and there may be a chance it will go until May 2023, sometime. Should a research team complete a study intake form, as there is a chance the trial may not be completed before the Launch 6 go-live date?

• Answer: Yes, please submit the intake form. If it closes before launch, you can let us know during virtual research conversion classroom.

QUESTION #7: Is attendance for the virtual research conversion classroom mandatory, if no study requires to be converted, or can research teams complete the eLearning session?

• Answer : If you do not have any active studies that need to be converted, no you do not need to attend the conversion session as you will not have any studies to convert.

QUESTION #8: We don't book any exclusive visits with just the researcher at our site. Our 'research appointments' always take place simultaneously with a clinic visit with the PI/Co-I. Do these still get added as research visits? Is there a difference?

 Answer: If your study qualifies for write-access to Connect Care, this would be considered a mixed visit and should be linked to your study. The clinic visit would be associated with the research study. If the study is just to complete surveys or questionnaires during a clinic visits, they wouldn't require write-access. Write-access would only be required if the study involves orders or needed to document in the chart.

QUESTION #9: If a project is read-only, when will research teams be contacted for training?

• Answer: The Connect Care Support for Research Team will send read-only training information closer to Launch 6 – likely mid-April. It involves short eLearnings that need to be completed.

QUESTION #10: Will there be an invite email to sign-up for the conversion and team delegate?
Answer: Yes, an invitation email will follow this webinar.

QUESTION #11: If a study a study needs to be converted during the virtual research conversion classroom for Launch 6, please confirm that study teams will receive an email with a link to registration for the conversion sessions. Will this process be automated through the NACTRC process after ethics approval?

• Answer: Research conversion virtual classroom registration information and links will follow in an email after this webinar. Provided that you indicate that access to AHS sites/resources in your ethics application, you will be able to apply for access to Connect Care in NACTRC, which is a separate process from your operational approvals. Our team will review the request and determine appropriate Connect Care access.

QUESTION #12: If a study is not being conducted in AHS space, but uses AHS lab or diagnostic imaging, should it undergo Research Conversion?

• Answer: If the study does not involve more than one lab test per patient then it likely does not qualify for write-access to Connect Care or need to undergo research conversion.

QUESTION #13: We recruit patients from AHS but their study visits are at the Matheson center in the CWPH building at FMC. Will our studies need to be converted as well? We use CC for confirmation of diagnosis only. Also, if approved by the REB, are we able to search for potential participants with a specific diagnosis on CC.?

• Answer: Still require a DDA for disclosure of health information and a waiver of consent from the REB. This study likely qualifies for read-only access but we will require the ethics ID to confirm.

QUESTION #14: Could you clarify what view-only studies would entail?

• Answer: You have permission to view the patient's chart but do not have the ability to document directly on their chart.