General Introduction of Research in Connect Care

December 20th, 2022 and January 9th, 2023

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Alberta Health Services
Connect Care

Welcome and Opening Remarks

They help keep Albertans healthy and independent

They improve the quality and safety of care for Albertans

They provide access to potentially life-changing treatments

They update or replace outdated treatments and technologies

They take good ideas and turn them into something even better

They shorten the pathways to diagnosis and treatment

They achieve more with the same or fewer resources

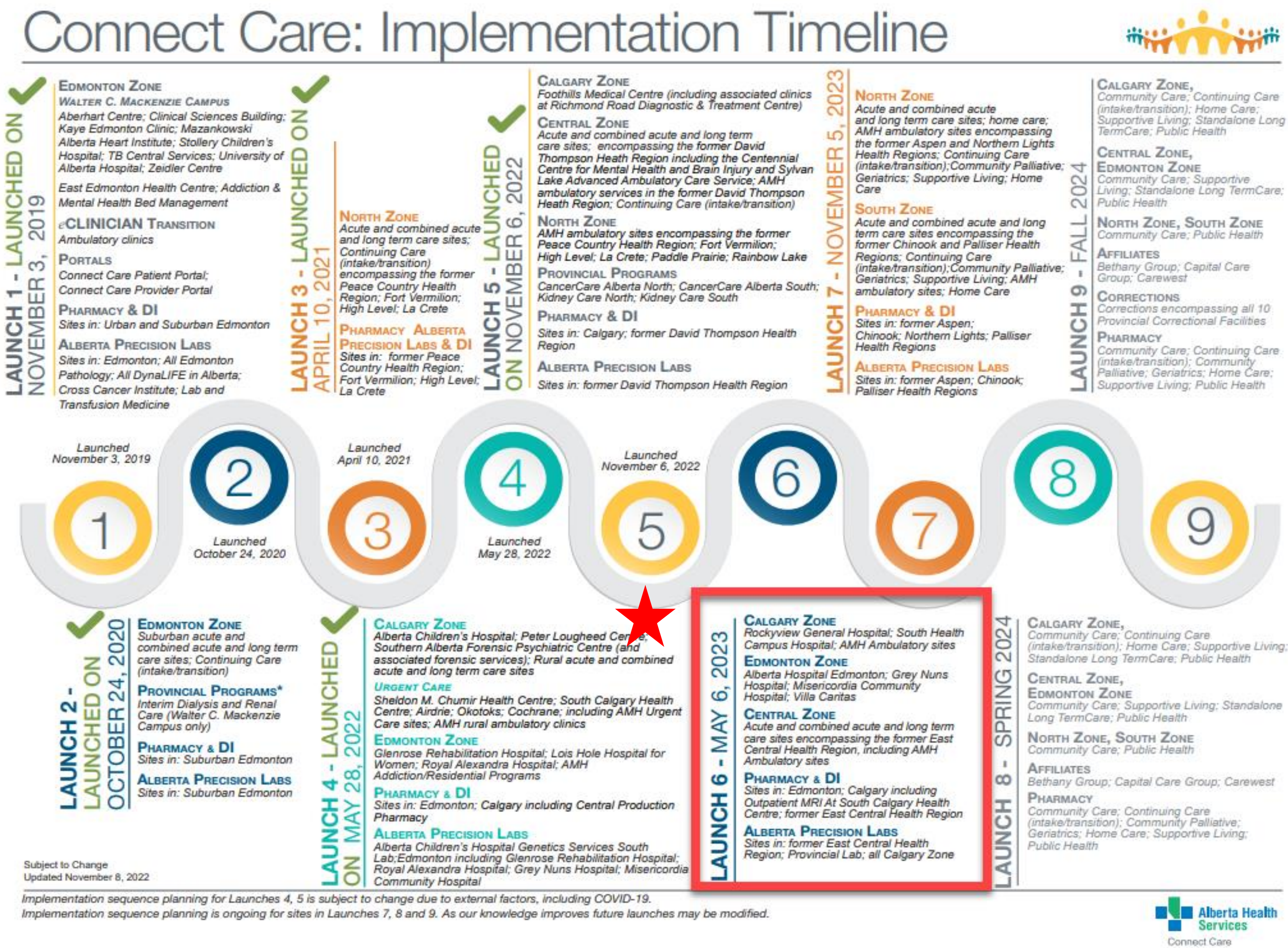
They improve conditions for the AHS workforce and other Albertans

They encourage highly qualified professionals to join AHS

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**

Research and Connect Care



Research in Connect Care

Current State: There are 1708 active studies currently in Connect Care.

- 1,337 Interventional studies
- 363 Observational studies
- 8 Unclassified

Patient Enrollment Statistics

- 10,121 patients enrolled in interventional studies
- 11,459 patients enrolled in observational studies
- 33 patient enrolled in unclassified studies

Research studies can take place in any location:

- Emergency departments
- Inpatient and Ambulatory clinics (including oncology)
- Surgery & transplant units
- Pediatric departments
- Diagnostic Imaging

AHS collaborates with university affiliated staff to integrate additional research teams into Connect Care.

Organizational Drivers for Research

- **Enhance Patient Safety**
  - This is achieved by increasing transparency of clinical care provided by linking and associating research studies to reflect patient research activities in Connect Care.

- **Integrate Inquiry & Research into Operations**
  - Create processes and workflows to perform, track, and report on inquiry and research

Research and Inquiry: Guiding Principles

One patient = One chart

- Research **is** part of patient care.
- Research **should be** a part of the patient record.
- Research teams have a role in ensuring **chart accuracy**.

Research Related Roles and Access

Primary Key Messages

- Your clinical role will always trump the research role; therefore, the research role is considered as a sub-role or sub-template that has been assigned.
- Research functionality in Connect Care will be primarily used with research team members who have Research Coordinator responsibilities. Relevant training will be offered.
- For the first time we are inviting in AHS **AND** university affiliated research team members to queue up clinical workflows. The individuals who know the research protocol best will, inform the process.

What Studies are In-scope for Launch?

Clinical research projects that meet any of the following criteria:

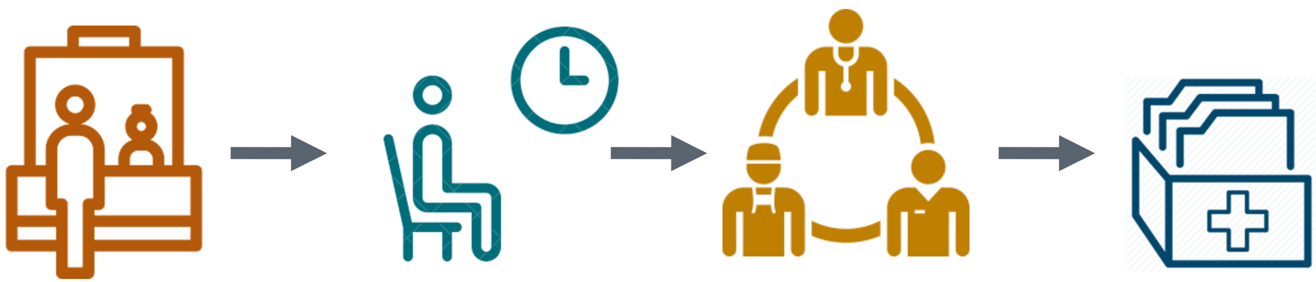
- Interventional drugs trials and investigational device studies
- Requires the use of recruitment tools, or research-study specific order entry or documentation
- Requires release of information to external study monitors
- Coordinators require notifications of ED arrivals or admissions
- Incorporates billable items (i.e., observational studies with labs or other testing)

What Studies are NOT In-scope for Launch?

Clinical research projects that may be excluded for a research (RSH) record in Connect Care:

- RSH record creation is **optional for non-interventional studies with minimal patient care impact requiring only a single research order** (such as a blood draw or urine sample for enrollment eligibility) where the service area can support non-Connect Care requisitions and where patient consent permits linkage of study participation to their medical record. This includes:
- An RSH record for these studies may be created if all the following apply:
    1. Principal investigators and study teams expressly request the use of Connect Care to manage their patients;
    2. Study staff agree to take Connect Care training;
    3. Study staff agree to comply with RSH record and patient association maintenance workflows;
    4. Research orders cannot be accommodated outside of Connect care;
    5. Patients have explicitly consented to their research participation linked to their medical record.

Research and Inquiry Workflows and Activities



ALERT

- Educate
- Empower
- Opportunities

APPROACH

- Consent
- Enroll
- Soliciting Interest
- Randomization

STUDY

- Research Protocol / Study Plan
- Intervention/Tx plans
- Research Operations (DI, Imaging, Pharmacy)
- Research Billing/Costing
- Scheduling/Orders

CAPTURE

- Research Data
- Secondary Use
- Data Disclosure/ Transfer
- Info requests

Use evidence to drive research and innovation

Research Aware Patient Care: Research Flag

Care Team

Nurse
Allied Health
Technicians
Physician
+
Research Study Coordinator (AHS/non)

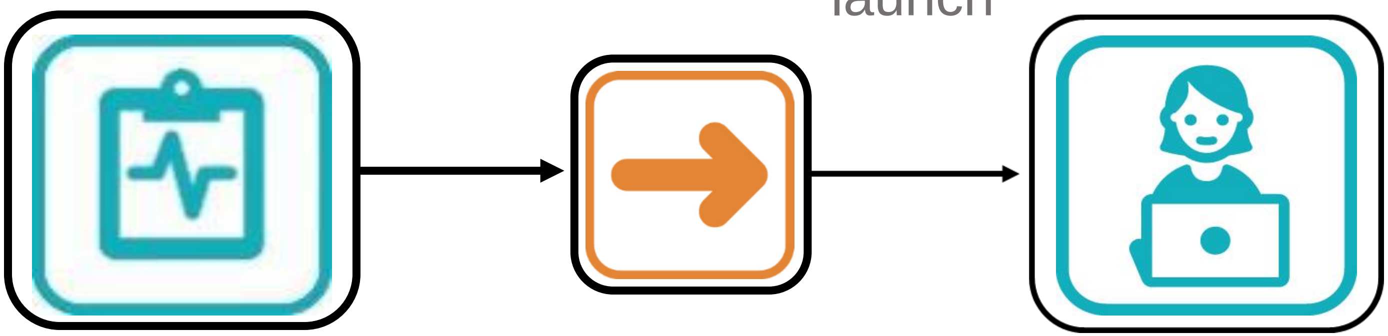
Research Module

- STUDY STATUS
- VISITS
- ORDERS
- RESULTS

What will or will not change?

If you're doing it on *paper* today…

…You'll be doing it *electronically in-system* at launch



- Access to data for research studies
- Enter information into Connect Care to replace other EHRs
- Research records and workflows will be integrated within Connect Care

Getting Ready – What You Should Know

Communication With You

Health System Access (HSA) Overview

- The HSA team supports the administration of clinical research studies (post-ethics approval) requiring access to AHS' provincial data or network resources such as Connect Care, administrative departments and/or operational areas.
- HSA helps researchers gain access to Connect Care resources required to support research that includes:
  1. Administrative elements to mitigate risk such as:
     a. Legal and Contracting or
     b. Biosafety Approval (note that the pathway that is currently in development).
  2. Requests to set up research accounts to house research funding
  3. Access to operational resources such as AHS facilities, patients or staff specifically for research purposes AND
  4. Access to AHS' vast data assets and data systems.

How do I Request Access for a Study?

1. Submit your study information including all the study team members associated with the study
2. Wait for an email request to submit preferred training dates → proceed to select your dates
3. Check your AHS email inbox for confirmation of training date and location
4. Attend training, complete the End User Proficiency Assessment (EUPA)
5. Test your access and confirm your study information at Conversion Lab

Even if you have already submitted your Research Conversion Intake form and you think your responses may have changed, you will have an opportunity to re-submit the form regarding the need of Connect Care access.

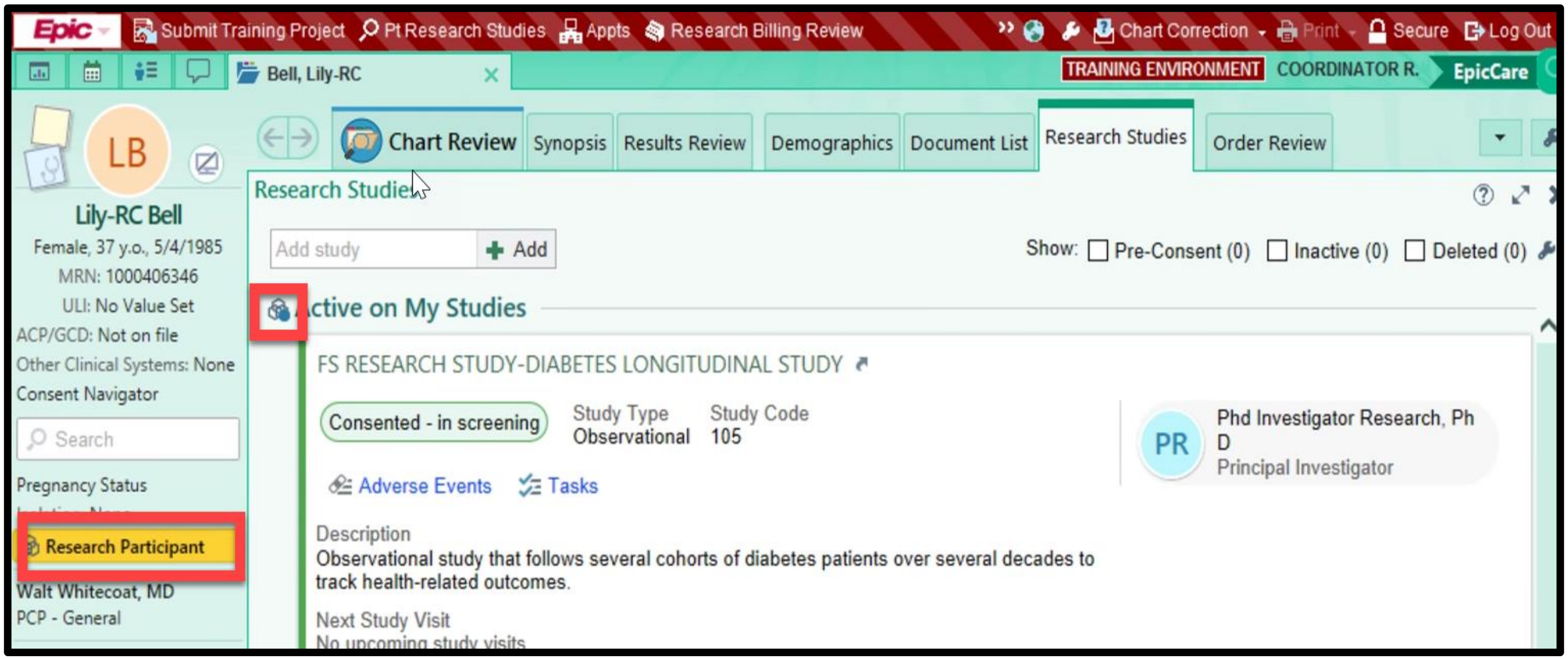
Visit the Provincial Health System Access - Home (albertahealthservices.ca) page for instructions.

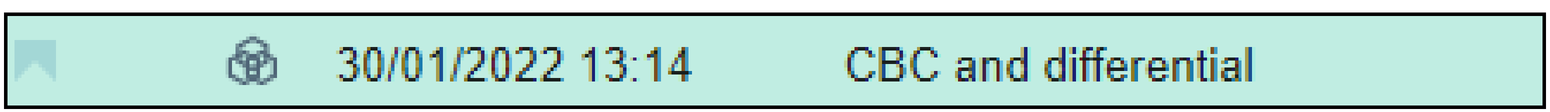
Research Workflows Managed in CC

EXPECTATION	DESCRIPTION	REASON
Study Information Management	Applicable information related to the research study is properly entered and maintained.	• Patient Safety • Integration • Visibility
Study Status Management	Study status in the CIS accurately reflects the current study recruitment stage.	• Integration • Recruitment enhancement
Patient Association & Recruitment Management	Study patients are linked to the respective research study, their recruitment status is up to date and Informed Consent Forms are scanned into their chart.	• Patient Safety • Visibility • Integration
Scheduling Management	Encounters and visits related to research are linked to the respective study.	• Visibility • Integration
Documentation, Safety Reporting & Ordering Management	Study related ordering (meds and tests) are done in-system and all clinically relevant information is available to the care teams.	• Patient Safety • Visibility • Integration
Service Charge Management	Charges are reviewed and reconciled.	• Transparency • Financial accuracy • Integration

Key Takeaways

Once Again, Integrated care: One Patient = One Chart!





Research and Inquiry – *Meeting Expectations for Day 1*

Teams and Users must be Identified

Individuals who previously did not have direct access to the patient chart, including university-employed **research coordinators**, will have access and responsibilities to **keep the patient record** (as it relates to research), **up-to-date**.

Training will be Provided **Training** in all CC research-related workflows will be **research role-specific**.

Information is required from research teams, please read and reply to the Connect Care emails.

Principal Investigator – *Responsibilities Key Messages*

- **Provide oversight** of the study
- **Clinical care workflows**
- **Respond to critical communications** from cc.research@ahs.ca and Health System Access (HSA)
- **Ensure time is available** for coordinators/team to train and get familiar with workflows, participate in conversion

Training Requirements & Sequencing

Connect Care

Research Training Requirements and Sequencing

The following information outlines the training requirements and sequencing for the Connect Care research roles. If you have any questions, please contact Health System Access at HSAResearchITAccess@ahs.ca.

Courses MUST be scheduled in the proper sequence. See the **Connect Care Roles & Training Course Catalogue** for the required sequence of training sessions for your research role. If multiple Instructor-Led Training (ILT) courses are required for a particular role, ensure that Track 1 is scheduled first; Track 2 is scheduled second, etc. You will not be permitted to attend ILT's scheduled out of sequence.

Research staff may also require Schegistrar training in order to schedule research-specific appointments within the ambulatory (outpatient) setting (please review item number 4 for more information).

In addition, training is available that provides information about reporting functionality within the Connect Care system (please review item number 5 for more information).

Please refer to the training sequence examples, below, for research staff. A complete list of research roles is available in the Connect Care Roles & TrainingCourse Catalogue.

Role: Research Staff – Ambulatory

Intended for Research Coordinators recruiting and carrying out a research protocol with patients visiting an outpatient (ambulatory) clinic.

1. **Epic – Ambulatory Nurse Shared ILT**
   Learn how to navigate Connect Care, including the patient chart, which will now include research.
2. **Epic – Research Staff ILT**
   Learn how to manage your research study and chart research activities in Connect Care.

Role: Research Staff – Inpatient

Intended for Research Coordinators recruiting and carrying out a research protocol with patients admitted into a hospital using Connect Care.

1. **Epic – Nurse Adult and Pediatric Medical Surgical ILT**
   Learn how to navigate Connect Care, including the patient chart, which will now include research. There will be additional learnings on how to time orders using phases of care (e.g. pre-surgery, post-surgery) in an inpatient setting.
2. **Epic – Research Staff ILT**
   Learn how to manage your research study and chart research activities in Connect Care.

Roles: Research Staff – Oncology/Hematology Research Nurse OR Research Staff - Oncology General (e.g. for Research Coordinators)

This is an example of a role where specialty training is required to fully perform a user's role in the clinic; in this case, being able to order and apply oncology/hematology treatment plans.

1. **Epic – Ambulatory Nurse Shared ILT**
   Learn how to navigate Connect Care, including the patient chart, which will now include research.
2. **Epic – Oncology/Hematology Clinic Nurse ILT**

Link to the resource can be accessed via: [CC Research Training Requirements and Sequencing_Jan2023.pdf (albertahealthservices.ca)]

Read-Write Training for Research

Training begins approximately 3 months prior to Connect Care implementation.

- Pre eLearning via *AHS My Learning Link (MLL)*:
  - ❖ Introduction to e-Safety (7 min)
  - ❖ On Our Best Behavior (30 min)
  - ❖ Module-specific e-learning
- Instructor Led Training (ILT):
  - ❖ Clinical Specialty (1-2 days)
  - ❖ Research Staff – 7.75h
  - ❖ Pass Simulation End User Proficiency Assessment (SEUPA)

Research Reporting and Clinical View-only Roles

- **Research Aggregate Reporting**
- **Clinical View Only**

Access to training catalogue on Insite as per the following hyperlink:
[Connect Care - Training Information]

Reporting and Analytics

Key takeaways:

- It is a self-serve opportunity to view clinically relevant information.
- Reporting content in Connect Care is readily available and more robust.
- Once AHS accounts have been provisioned, we recommend research end users self-register in the following three courses via MyLearningLink:
  - Epic – Basic Reporting User ILT
  - Epic – Reporting Power User ILT
  - Epic – Introduction to SlicerDicer ILT

Identification of Super Users

Ideal Research Super Users are trained in and familiar with research related workflows and clinical workflows. This is dependent on what area you work within.

Skills and Qualities

- Competency in basic computer skills, good communicators, and active listeners.
- Respected by peers and recognized as department/specialty area experts.
- Able to be released from regular duties based on time and resource commitments.
- Can solve problems and adapt to change.
- Previous training or adult education experience.

How is Study Information Converted into Connect Care?

- Research conversion is the **process of preparing research studies** that impact patient care for use in Connect Care. This includes:
  - **Loading and activating** research studies
  - **Building** research specific drugs and orderable items
  - **Linking patients** to research studies
  - **Linking research specific appointments** to studies
- Completing the Research Conversion activities will allow you and your team to be better prepared for Launch and be able to focus on your patients and your studies instead of the system during your Go-Live date.
- It's your chance to try the system before the "start date".

Support and Resources

Finding Help& Submitting Tickets

- **For urgent issues (including login or device concerns) or IT related issues call 1-877-311-4300** (Please visit: Insite IT Service Desk & Solution Center for more information).

- **For non-urgent issues**
  1. Ask a local research super-user first; your colleagues are your first best resource.
  2. You can also submit a Connect Care IT ticket for non-urgent research-specific system issues using our online concierge form – refer to Connect Care IT ticket. Under ‘Issue Type’, select ‘Research’.

Terminology & Documentation Reminders

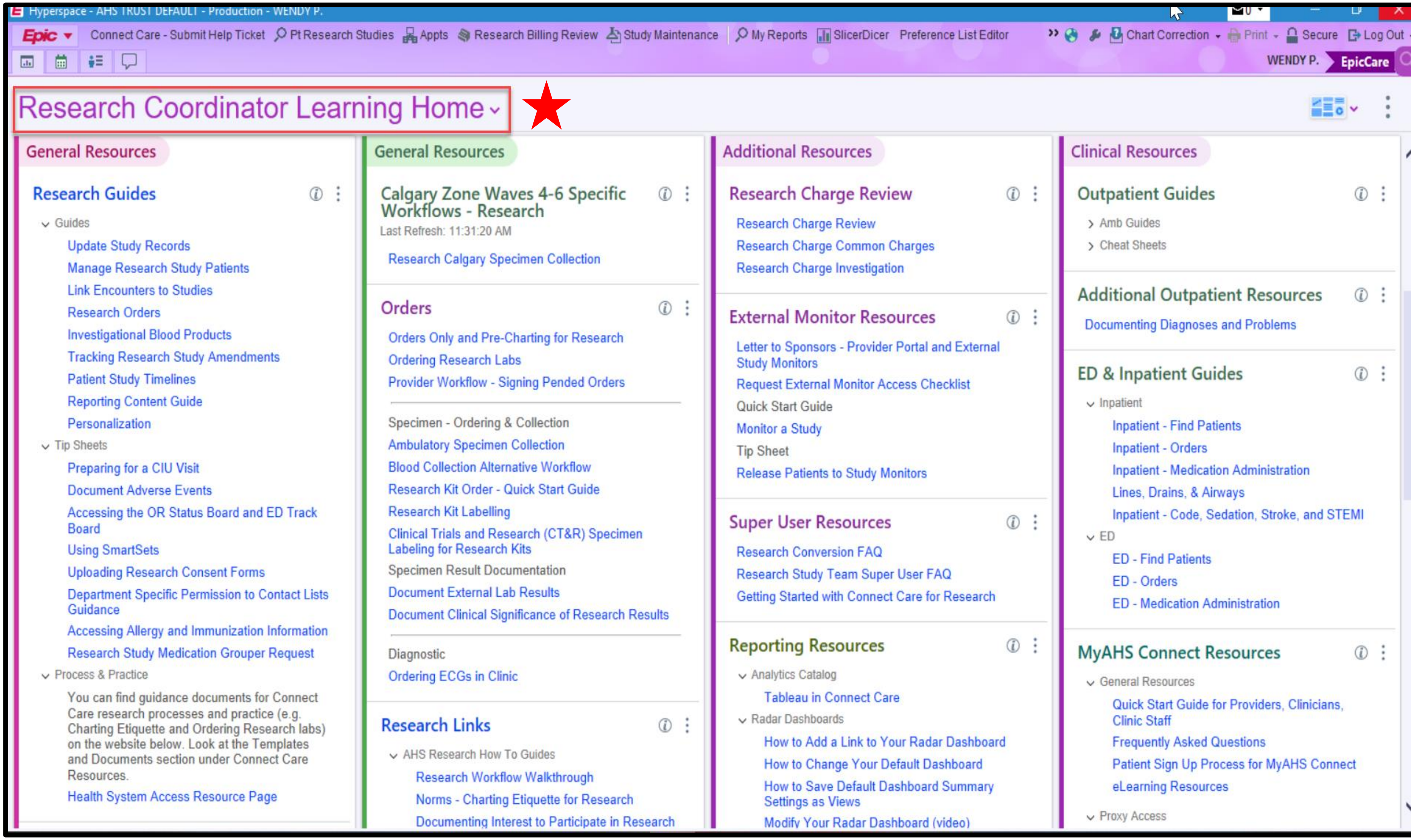
- We are all new to the language of Connect Care. In addition to your training, there are resources available to help:
  - Connect Care Glossary, available on AHS Insite at Connect Care Glossary (albertahealthservices.ca)

- Please refer to the charting etiquette document for more information related to expectations in Connect Care Connect Care Charting Etiquette (ahsnet.ca)
  - This document clearly defines expectations for research teams that engage in clinical workflows and in turn, how they should record information in the patient's chart.

Important Resources

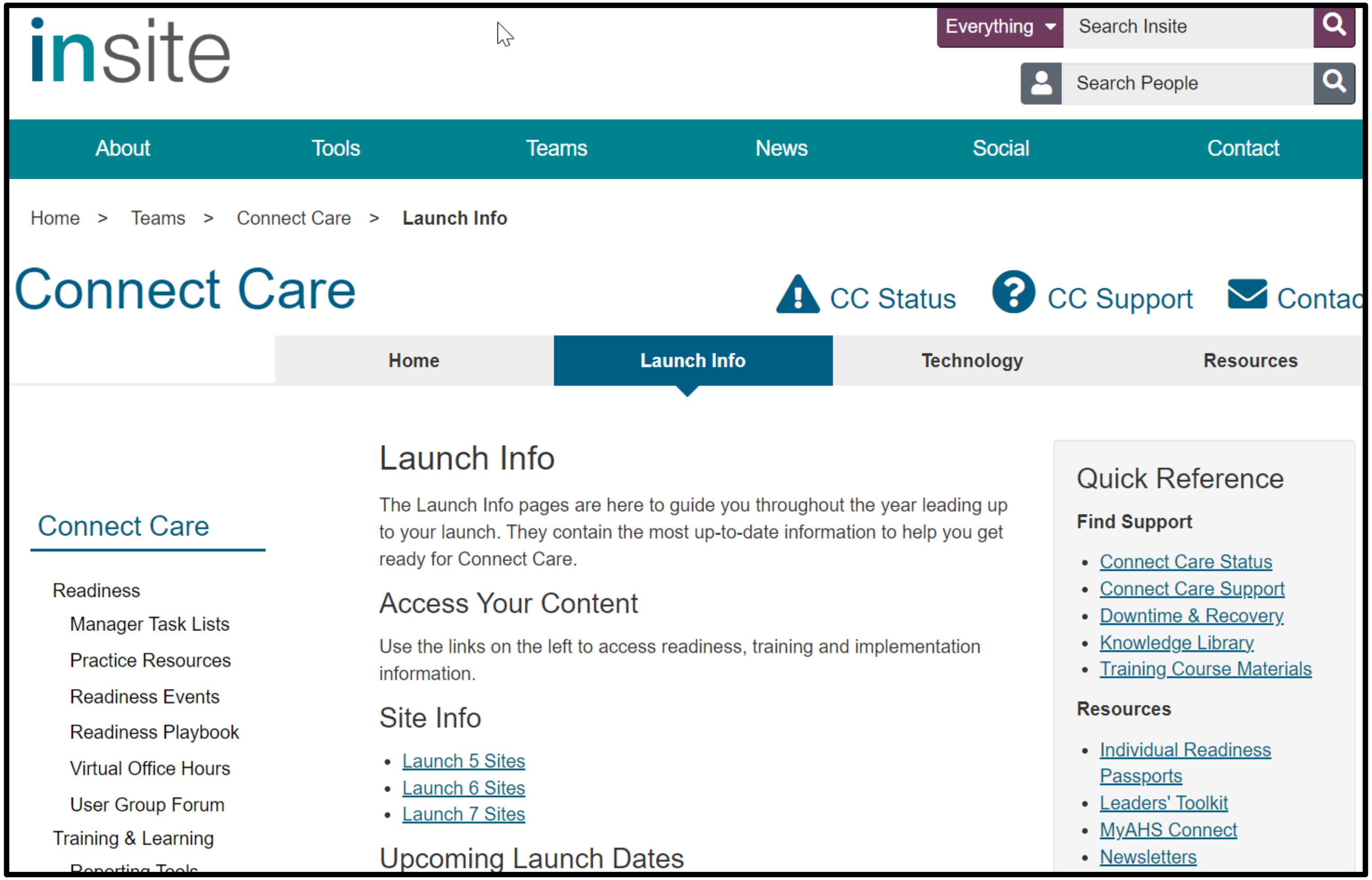
- Health System Access Webpage
- Getting Started with Connect Care
- CC Research Coordinator Checklist
- CC Research Training Requirements and Sequencing
- CC Research_Clinical Department and Service Area Tip Sheet
- Connect Care Charting Etiquette

Research and Connect Care



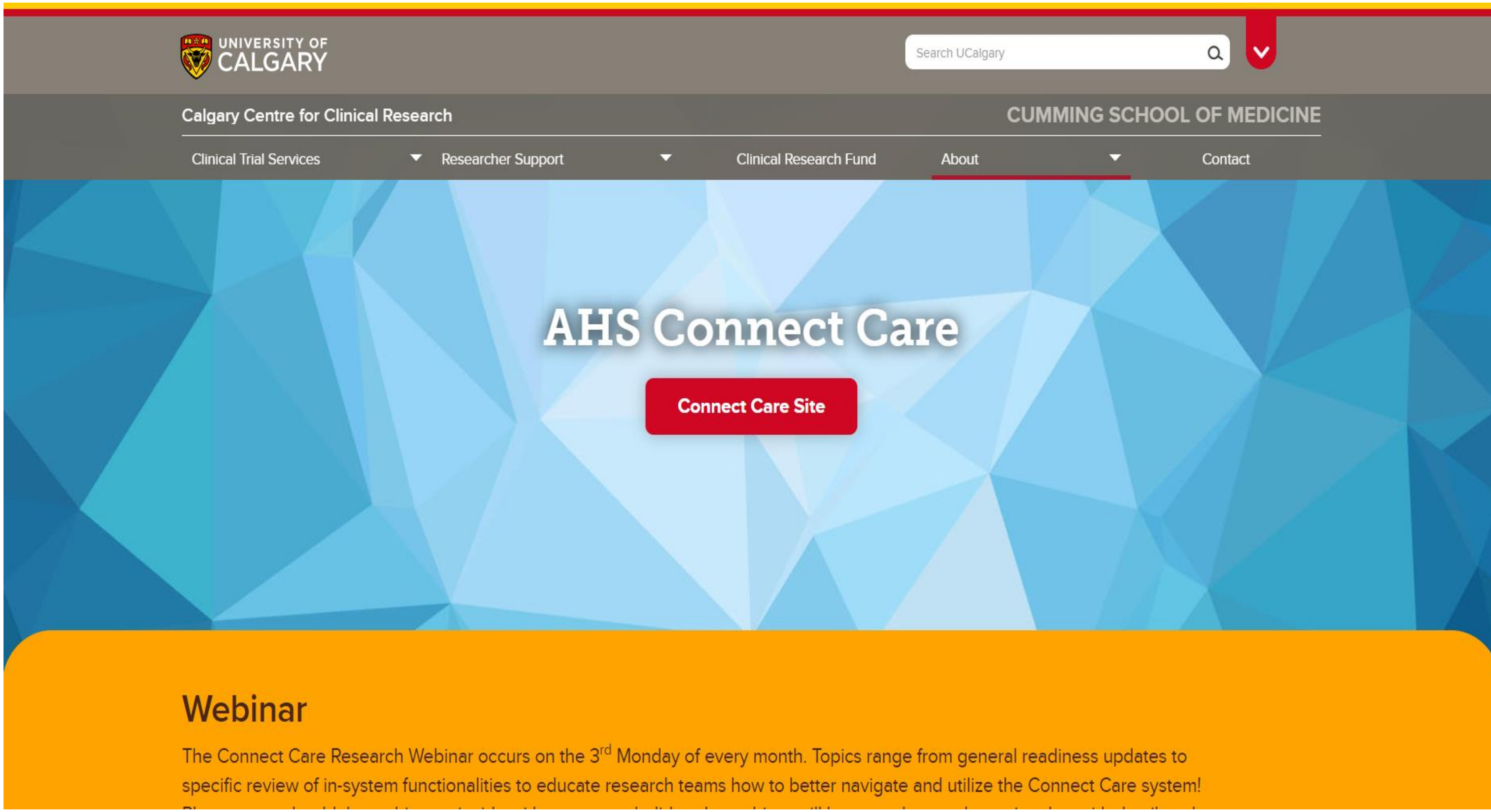
Staying Connected

Alberta Health Services Partners



[Connect Care | Insite (albertahealthservices.ca)]

University of Calgary Partners



[AHS ConnectCare Comms Archive | Cumming School of Medicine | University of Calgary (ucalgary.ca)]

Remember: Research is care!!

We are here to answer your questions!

- For general inquiries and to sign up for Connect Care Research Communications, including event invites, email **CC.Research@ahs.ca**
- For questions regarding the study intake process or approvals related to your study, contact **Research.Administration@ahs.ca**
- For questions related to training requirements and role assignment, contact **HSAResearchITAccess@ahs.ca**

Question and Answer Period

QUESTION #1: If we have submitted a study intake form, how will we be informed if we do not meet in-scope study criteria to be included as part of Connect Care?

- Answer: Study intake forms are still being processed by the Health System Access team. You will be contacted, if your study is ineligible. After this webinar, if you would like to re-enroll and complete a study intake form, please send an email to cc.research@ahs.ca and your request will be triaged for further assistance.

QUESTION #2: Will there be a walkthrough to help guide research teams on the study intake process, prior to training, similar to what is available on My Learning Link?

- Answer: Instructions on how to complete the study intake form is included within the email request sent to complete the form. Training will be dependent upon the role provisioned, once the study intake process is done.

Question and Answer Period

QUESTION #3: Can research team members start training early to get 'base access', in anticipation of multiple Connect Care studies and related work?

- Answer: All access and subsequent role assignment occurs once the study intake process has been completed. Scheduling of training will occur thereafter and is dependent on the assigned role individuals are assigned within Connect Care.

QUESTION #4: Will a patient's label show up for studies that are retrospective and/or if a 'waiver of consent' has been obtained?

- Answer: Research participants must consent to participate for a study that is eligible to be included in Connect Care. When study records are activated and consented patients are associated (linked) to the respective study in Connect Care, the research banner and icon will be visible on the patient story board (refer to slide #20).

Question and Answer Period

QUESTION #5: To build from the previous question (#4), for any retrospective study that includes a 'waiver of consent', does that mean those types of studies are not eligible for Connect Care?

- Answer: These types of studies may be eligible for clinical view-only (CVO) access to Connect Care, instead of write-access (refer to slides #23 to 25).

QUESTION #6: How do non-AHS employees (i.e., University employees) get access to My Learning Link?

- Answer: All non-AHS employees (research study team members) who have a role in maintaining a study record, for consented patients of their respective studies, will be provisioned with an AHS username and password, which permits access to My Learning Link and ability to sign up and complete all relevant courses.

Question and Answer Period

QUESTION #7: For clarification, what kind of research training is required for Principal Investigators (PIs) who already have completed clinical Connect Care training?

- Answer: PIs with clinical access to Connect Care are provisioned with the Investigator sub-role that requires viewing a short eLearning and completion of an end-user proficiency assessment (EUPA).

QUESTION #8: For clarification, will the Connect Care team contact research teams to notify them about the training required and how to register into the appropriate courses, once the intake form has been completed?

- Answer: The Health System Access team will contact you about the required courses for read-write access. Clinical view-only (CVO) access will be communicated shortly before launch.

Question and Answer Period

QUESTION #9: Will there be training available on how to use SlicerDicer and other reporting tool within Connect Care?

- Answer: There are various reporting courses available to users in Connect Care (refer to slide #26).

QUESTION #10: How long will AHS Insite access last?

- Answer: Your AHS Network access (username and password) will be valid for use, as long as you have active studies in Connect Care.

QUESTION #11: Will patients need to be re-consented for Connect Care (if they are already involved in a study)?

- Answer: Patients who are already consented to a study will not be required to re-consent if the study is eligible for Connect Care. Patients will have to be associated (linked) to the study record, which is part of research conversion.

Question and Answer Period

QUESTION #12: Some 'further readings' are not available to non-AHS staff. Is there a way to get a copy to read before? Is there an email we can request this from?

- Answer: Several documents are available directly from the external facing Health System Access Team page at Health Evidence & Innovation - Home (albertahealthservices.ca).

QUESTION #13: For studies that have Netcare and Connect Care access to complete blood draws and is entered on their Netcare profile, should study teams also include the results in Connect Care?

- Answer: For tests ordered in Connect Care for AHS services, the tests are resulted automatically to Connect Care. Any lab services provided by a third-party lab will not be automatically resulted to Connect Care (for example, when a research kit is ordered).

Question and Answer Period

QUESTION #14: How will connect care be used for the ordering/delivery of research-related medication and how will it differ from the current flow?

- Answer: If an investigational medication is being dispensed or administered to a patient inside an AHS or Covenant Health site, that order must be entered in system. This is similar to the way an order would be placed for a test and would be signed by the Principal Investigator or provider. If the study team is providing the medication, this will still be documented in Connect Care. One of the questions on the study intake form relates to investigational medications and instructions to follow to request a build for the medication if necessary.

NOTE: All Workflows will be reviewed in training.

Question and Answer Period

QUESTION #15: When blood work is ordered for the research participants who are admitted in the unit, a call to lab accession in the McCaig tower is made to send someone to do blood work. Is Connect Care needed to place the order or simply the current process continue? Specifically, the blood sample for the genetics research is through the U of C lab.

- Answer: If the blood is being collected inside an AHS or Covenant Health facility, and the study qualifies for a Connect Care record, then the order should be placed in Connect Care.

QUESTION #16: In follow up to question #15, is Connect Care needed for the payment of research invoices for the blood work done by APL?

- Answer: There is currently no in-system invoicing using Connect Care, it is more to assist in building an invoice.

Question and Answer Period

QUESTION #17: Where can research teams find all applicable resources to help prepare them for launch (i.e., the Research Coordinator Checklist, etc.)?

- Answer: All resources can be found by access the Health System Access webpage at Health Evidence & Innovation - Home (albertahealthservices.ca).

QUESTION #18: For team members that are also part of the clinical care team (i.e., RN, NP, RT, etc.), are they required to register into research specific Connect Care training even if they are already enrolled into Connect Care training specific to their role?

- Answer: If those clinical care team members are expected to perform study-specific workflows, they are required to take the Research Staff ILT training. Please ensure all team members are listed on the approved study REB/ethics ID, so they are not missed and in turn, take training.