Research in Connect Care

A Day in the Life of a Principal Investigator

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They update or replace outdated treatments and technologies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

Research in Connect Care Current State

There are over 900 active studies currently in Connect Care.

Future State: After Wave 4, there will be over 1300 active studies being conducted in Connect Care.

Research studies can take place in any location:

- Emergency depts.
- Inpatient and Ambulatory clinics
- Surgery & transplant units
- Pediatric depts.
- Diagnostic Imaging

AHS is collaborating with U of A and U of C staff to integrate additional research teams into Connect Care.

Organizational Drivers for Research

- **Enhance Patient Safety**
  - Flag patient records by linking patients to research studies
- **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

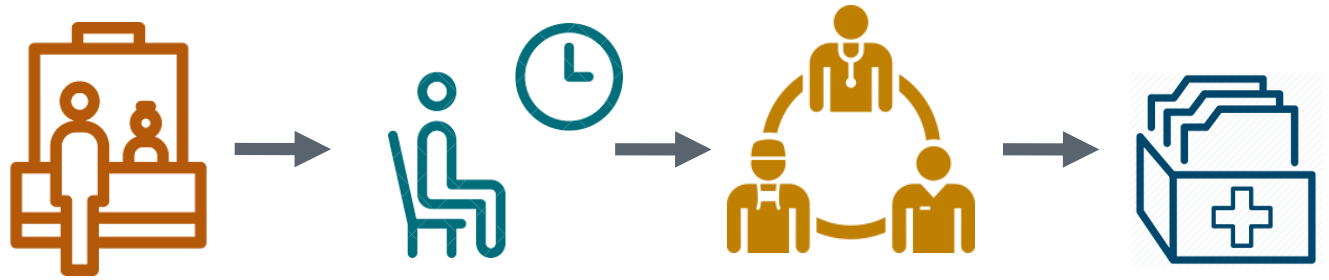
Primary Key Messages

- Your clinical role will always trump the research role; therefore, the research role is a considered a sub role. Clinical investigators will do most of their PI role using their clinical role.

- In reality, the research management tools in Connect Care are mostly geared towards the role of Research Coordinators which is why we offer research staff instructor led training.

- For the first time we are inviting in AHS **AND** university affiliated research team members to queue up clinical workflows. The individuals that know the research protocol best will inform the process.

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

You and your teams need to know how to use various features related to: studies; patients; encounters; orders; billing

Connect Care – Read/Write Access

Principal investigator with research coordinator

- Clinician
  - Primary role: clinical
    - Investigator sub role
    - E-Learning module available via MyLearningLink (MLL) [**25 minutes**]
    - 8191-L Research Investigator Module

- Non-clinical
  - Assigned non-clinical PI research role
    - Instructor led research staff course [7.75h]

Connect Care – Read/Write Access

Principal Investigator without research staff

- Clinician
  - Primary role: clinical
    - Investigator sub role
    - E-Learning module available via MyLearningLink (MLL) [**25 minutes**]
    - 8191-L Research Investigator Module
      - **Strongly recommended**: Take the instructor led research staff course [7.75h]

- Non-clinical
  - Assigned non-clinical PI research role
    - Research staff instructor led training [7.75h]

Secondary Key Messages

- Not all studies will go into Connect Care.

- Research roles are available that reflect the different needs for research studies; this includes:
  - Chart reviews
  - Surveys
  - Questionnaires
  - Clinical trials
  - Etc.

What Studies are In-scope for Launch?

Clinical research projects that meet any of the following criteria:

- Interventional trials and 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)

Research Reporting and Clinical View-only Roles

- **Research Aggregate Reporting**
- **Clinical View Only**
- **Research Reporting & Chart View-only**

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

Important Reminders!!!

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 CIS research-related workflows will be research role-specific.

Information is required from research teams

Research Workflows: Expected to be in-system

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

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".

Pulling it Altogether

Principal Investigator – *What is Your Role?*

A Principal Investigator is the **leader** of a research team who is **responsible for the conduct** of the research and for the **actions** of any member of the research team.

(Tri-Council Policy Statement, version 2)

✓ Required to provide sign-off or approval for research activities, as laid out in the Delegation Log and required by International Conference on Harmonization Good Clinical Practice (ICH/GCP).

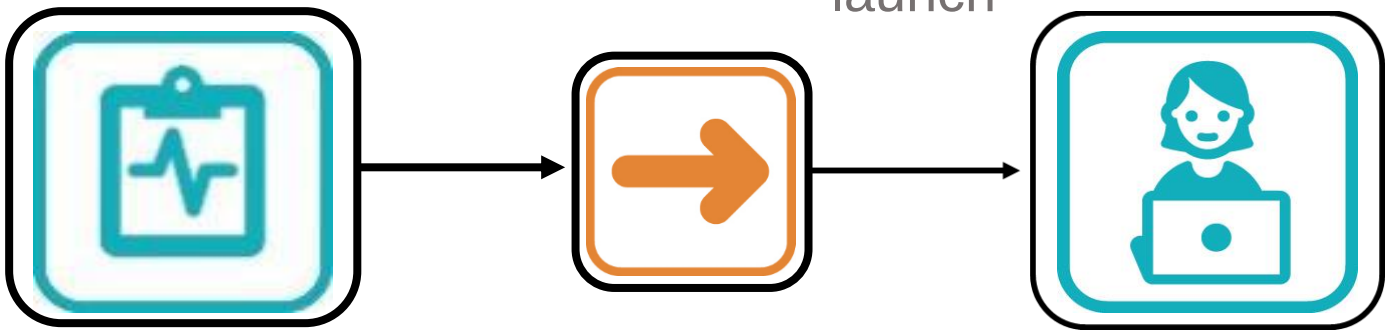
Principal Investigator – *Responsibilities Key Messages*

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

Post Launch: What will or will not change?

If you're doing it on *paper* today…

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



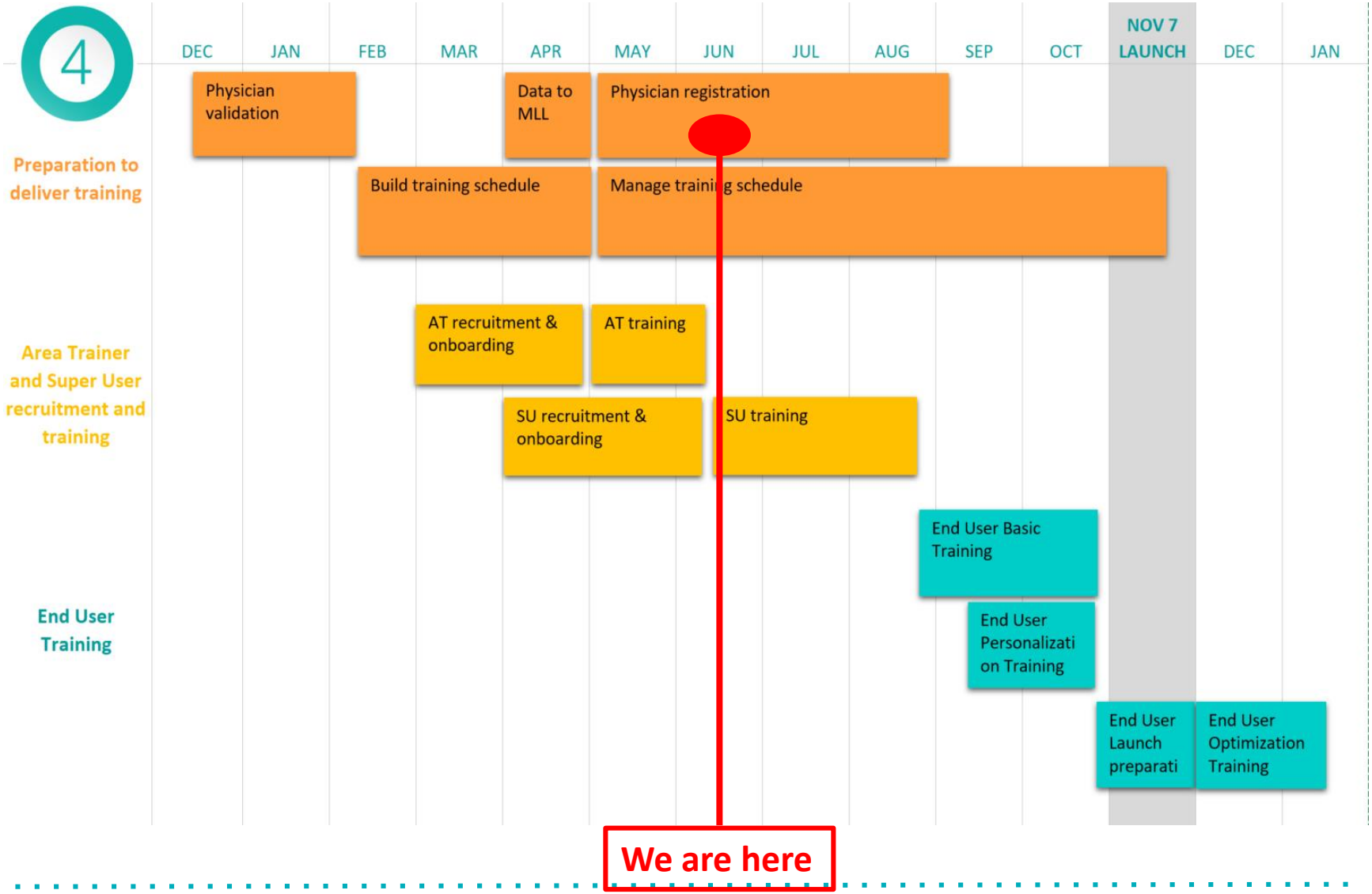
- Access to data for research studies
- Enter information into Connect Care to replace other EHRs
- Research records and workflows will be integrated within Connect Care
- PI messages and approvals will be electronic

Terminology & Training 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.

Research and Connect Care



What does Physician Training Look Like?

CMIO Training Tracks

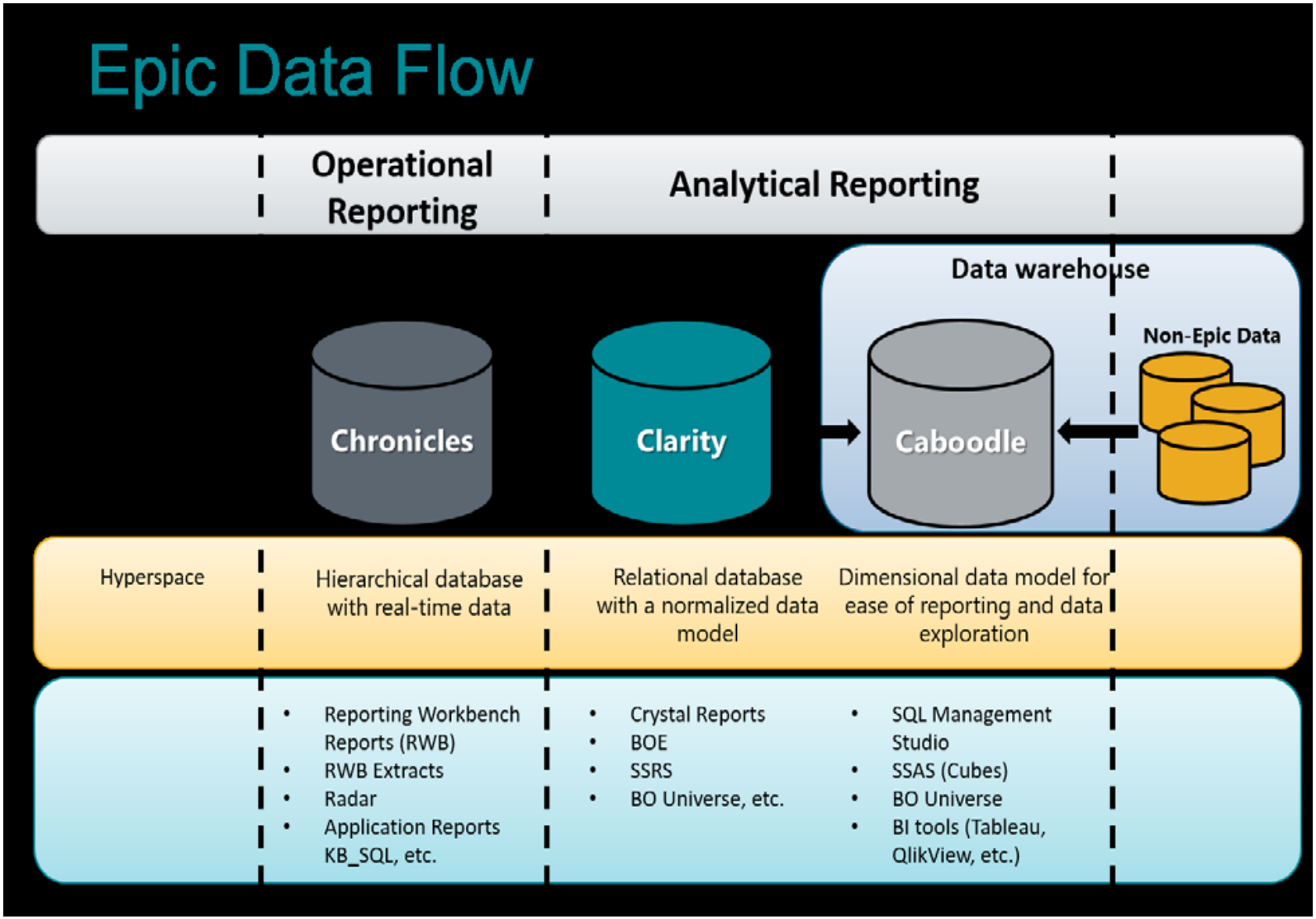
Inpatient Admitting/Consulting	O & G
Ambulatory	Oncology – Medical, Pediatric & Radiation
Surgery	Pathology – Anatomical, Clinical & Hemo
Anaesthesia	Pediatrics
Emergency	Addiction & Mental Health
Cardiology	Radiology
Critical Care – Adult, PICU & NICU	Rural Medicine
Lumens	Medical Learner
Consult Only (Wave 4)	Medical Outpatient Unit Prescriber

EACH track will be compromised of THREE training modules:

- Basic: 6-12 weeks before go-live; basic skills/functionality
- Personalization: 1-4 weeks before go-live; specialized skills/specialty workflows
- Optimization: 4-6 weeks post go-live; increased proficiency (the spot where detailed Cogito analytic/reporting training will be provided)

Overview of Research Education in Training

- Recognizing a Research Patient - Basic Lesson
  - Participants in class will be shown the research icon within the patient's chart.
  - They will be shown how to access information related to the study such as the name of the study, a brief description and the name of the Principal Investigator.
  - Orders associated with the study are clearly identified within the chart, participants will be taught how to identify them.
- After Class Workbook Exercises
  - Recognizing a Research Patient and identifying pertinent research study information
  - How to Associate Orders with Research Studies – Recommended for Investigators
- Learning Home Dashboard
  - Research Quick Start Guide – access the Research Coordinator Learning Home Dashboard


Epic Data Flow
Operational Reporting
Analytical Reporting
Data warehouse
Chronicles
Clarity
Caboodle
Non-Epic Data
Hyperspace
Hierarchical database with real-time data
Relational database with a normalized data model
Dimensional data model for ease of reporting and data exploration
Reporting Workbench Reports (RWB)
RWB Extracts
Radar
Application Reports KB_SQL, etc.
Crystal Reports
BOE
SSRS
BO Universe, etc.
SQL Management Studio
SSAS (Cubes)
BO Universe
BI tools (Tableau, QlikView, etc.)

Understanding Inquiry-Support Tools

	Radar	SlicerDicer	Workbench	Metrics
Real-time source	✓		✓	✓
Abstracted source	✓	✓		✓
Refresh rate	Hourly	Daily	Real-time	Daily
Large query OK	✓	✓		✓
Drill-down details	✓	✓	✓	
Chart/activity links	✓	✓	✓	✓
Export to Excel		✓	✓	
Mobility (Canto iPad)			✓	✓

Understanding Inquiry-Support Tools

Radar Dashboards

Create dashboards that combine real-time data or other SQL sources to deliver report results and data visualizations to your users.

SlicerDicer On-Demand Analytics

Explore and interact with large datasets using a data-first tool with an intuitive interface.

Reporting Workbench Real-Time Reports

Access real-time data with a flexible and embedded reporting engine to generate worklists that are directly actionable.

Metrics

Track summarized data using standard and custom KPIs and metrics across clinical and financial outcomes within your organization. Supports benchmarking against your peers, forecasting, and SMS notification.

In-System Information – *Study Management Reports*

Type	Purpose	Example
Radar Dashboards	- Visualize real-time and analytical data from Epic and non-Epic sources - Integrated into workflows - Summarize data via charts and graphs	Research Reporting Home: a “home page” for coordinators to access tools for billing review, release to external monitors, research links, and patients in pre-consent status awaiting follow-up
Reporting Workbench	- Real-time actionable data - Integrated into Hyperspace and workflows - Ad-hoc self-service reporting - Take action and make data driven decisions like jumping to patients chart - Export data	Find Patients Associated with My Research Studies: for research staff to keep track of patients who are involved with any study the user is involved in Find Upcoming Appointments for Patients on My Studies Find Research Adverse Events for Follow-Up: coordinators can review adverse events that have been documented for patients enrolled in their studies

Research and Connect Care

June 2021

Do not distribute

Alberta Health Services

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What is SlicerDicer?

- SlicerDicer is a self-service reporting tool that provides users with intuitive and customizable data exploration abilities.
- Using SlicerDicer, users can find the data they need to investigate a hunch, and then refine their searches on the fly to better understand the data they work with.
- Right in Hyperspace, they can examine trends, drill down to line-level details, and jump to related records to follow up.

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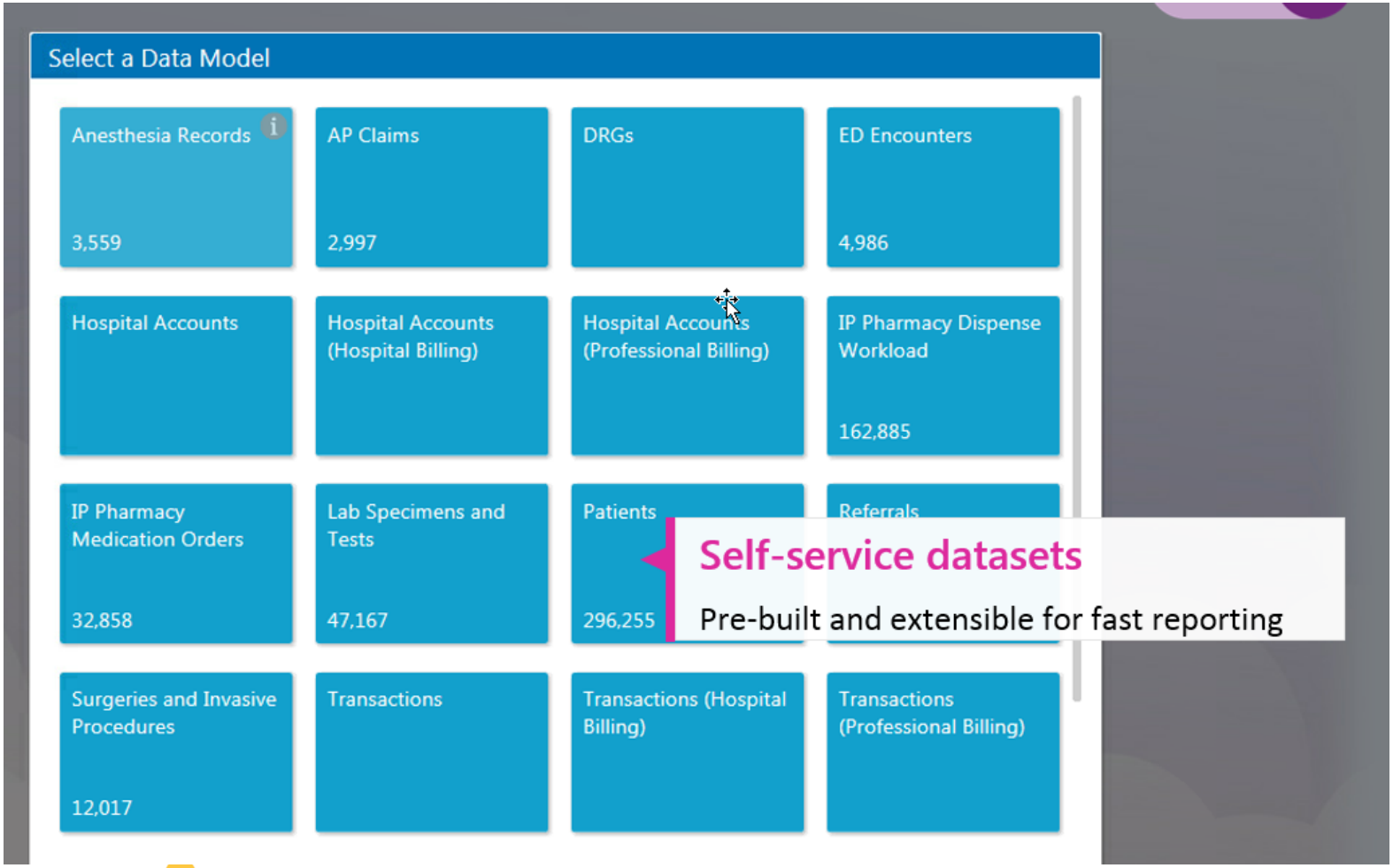

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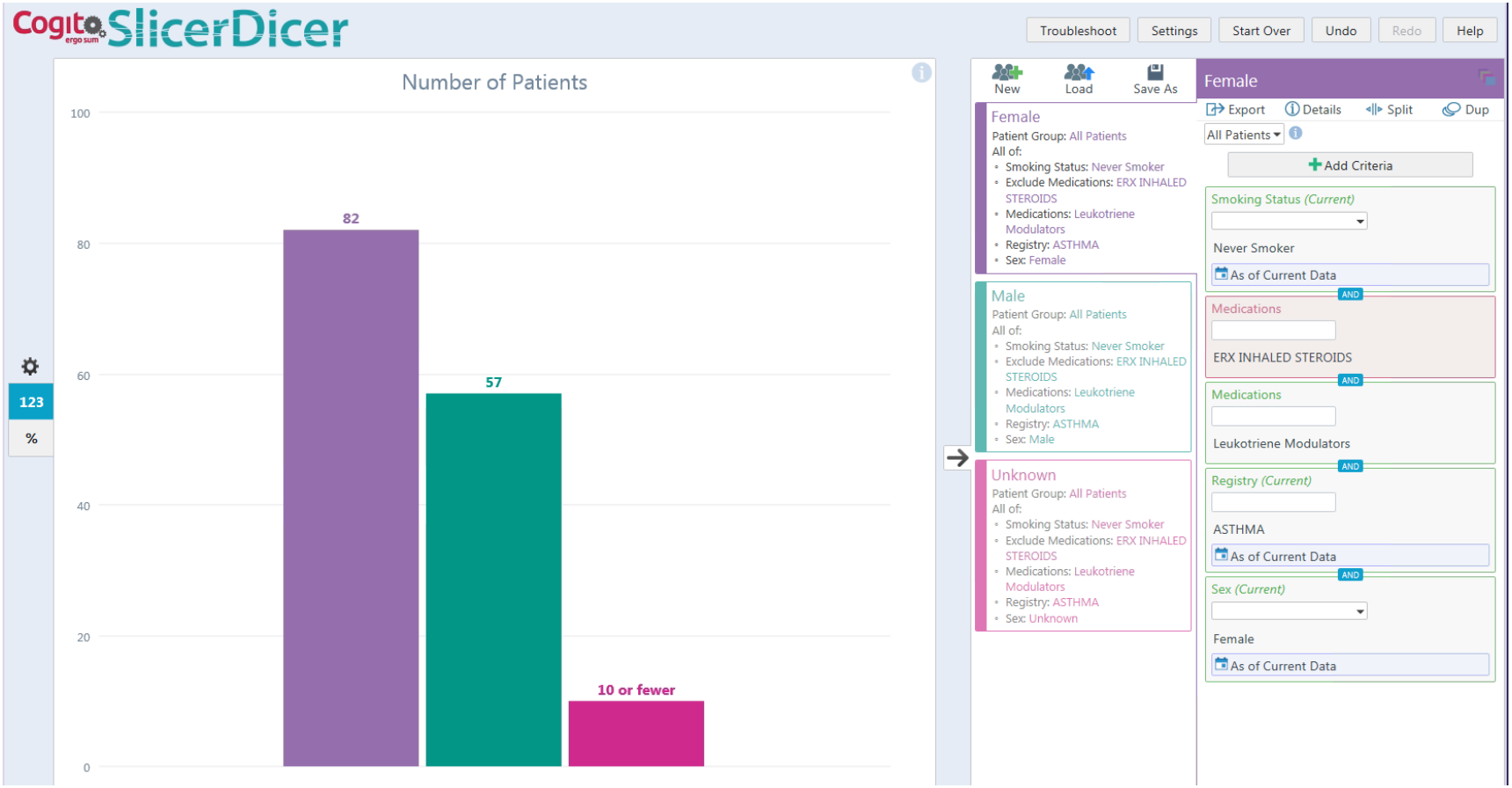

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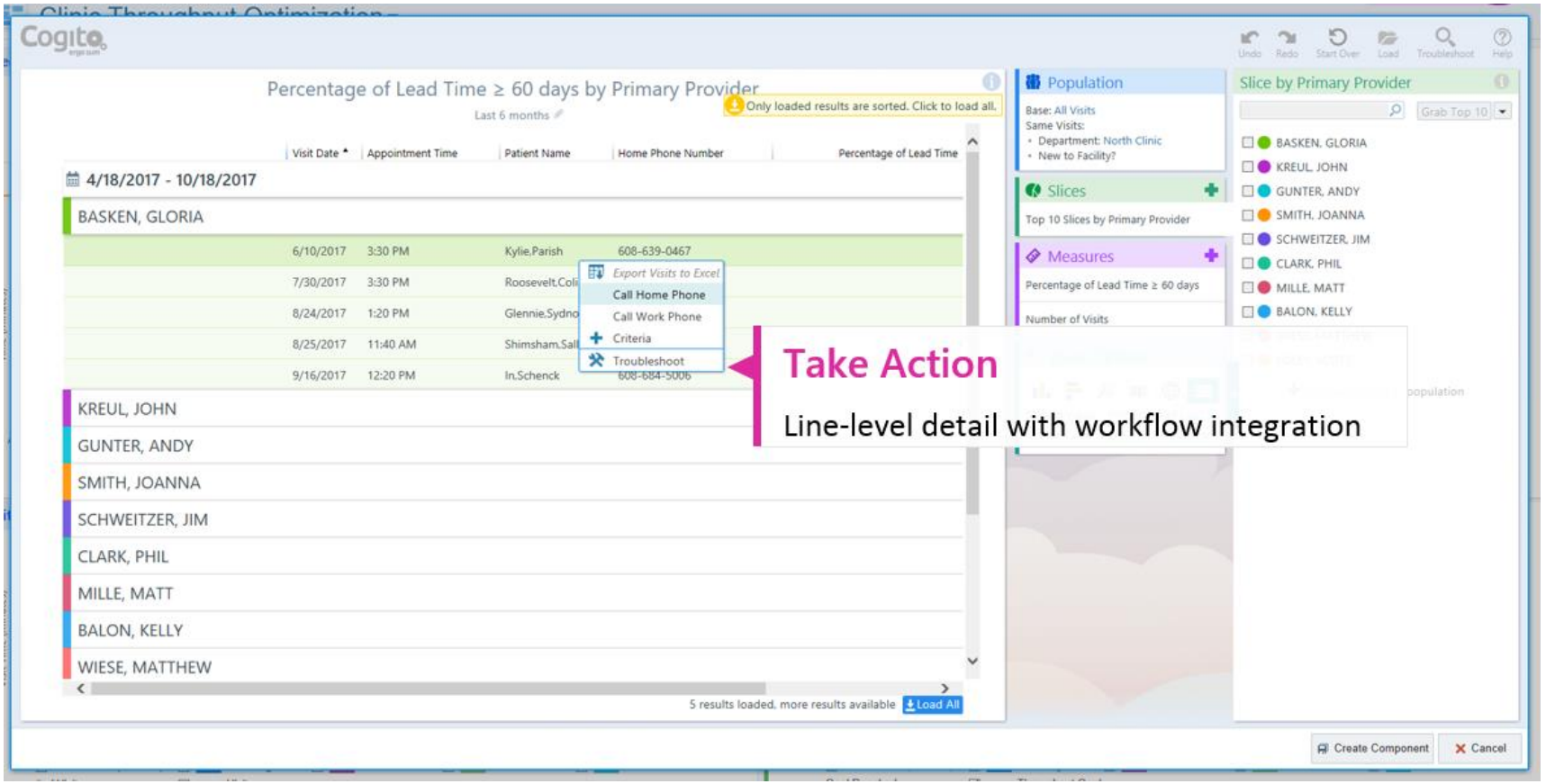

Important Resources

- CC_Research_Assumptions for Launch.pdf (ahsnet.ca)
- CC Research_Wave 4 Research Coordinator Checklist_07May2021.pdf (ahsnet.ca)
- A Day in the Life of a Research Study Coordinator (ahsnet.ca)
- CC Research_Wave 4 Training Requirements and Sequencing_May2021
- Connect Care Glossary (albertahealthservices.ca)
- Super User Training to Support CMIO (albertahealthservices.ca)

Finding Help/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).

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 ‘Clinical Area’, select ‘Research’.

Remember: Research is care!!

Question and Answer Period

- **QUESTION #1:** If an individual acts as co-investigator on a study, what kind of role would they be assigned?
  - Answer: Based on whether you are a clinical or a non-clinical co-investigator, you get the same role assignment as a principal investigator. This is based on the completion of the role selector tool as per the following hyperlink: IT Access for Research - CC_Role_Selector_Tool (ahsnet.ca)

- **QUESTION #2:** For clinical staff who are interested in doing the full day Research Staff ILT, how do we get access to sign up for the full day Research Investigator Module?
  - Answer: Please ensure that all relevant staff members are included on OR added to the REB application as a member of the research team. Reach out to cc.research@ahs.ca for signing up for the Research Staff ILT.

Question and Answer Period

- **QUESTION #3:** If a study is purely observational and therefore, does not include any interventions, what kind of access will be provided and how does it differ from what has been the process in the past? Once ethics approves the study, how long does it take to get approvals? This has been the rate-limiting step in research - getting that last institutional/ AHS approval.
  - Answer: If a study does not include care-related elements but has data extraction requirements, (i.e. – chart reviews), this study is not, by default, in-scope for a Connect Care research record. Research teams with observational studies can choose to 'opt-in' to creating a research record and access to in-system reporting and patient management tools. To request this opt-in, the Health System Access (HSA) team has a series of forms for completion, on their webpage that will help assess and determine specific needs. If a request to access data has been included as part of a REB submission, the HSA team will pick that up and allocate access as appropriate. For more information and to access the forms please visit: Provincial Health System Access - Home (ahsnet.ca) or email research.administration@ahs.ca.

Question and Answer Period

- **QUESTION #4:** If an individual supports both inpatient admitting and pediatrics, what training track should be followed?
  - Answer: Pediatrics is a mirror of inpatient and admitting, therefore, an individual would be required to complete training for pediatrics.

- **QUESTION #5:** In relation to rehabilitation research, what is the ability for PT, OT, SPL, Audiology, and Recreational Therapy to report on activities associated with their research therapy?
  - Answer: Galaxy web (part of Epic) has a metrics catalogue that will allow an individual to look up what is available in the foundation system. Use the Epic user web portal as per the following hyperlink: Epic UserWeb Sign In. All users with AHS credentials can apply for access to the user web.
    - There is also an analytics catalogue available in Connect Care, once access has been granted and training is completed.
    - There is also a data and analytics catalogue available on SharePoint: Analytics Definition Library - Home (ahsnet.ca)

Question and Answer Period

- **QUESTION #6:** Is it a future goal for Connect Care to push data directly in other platforms such as REDCap or eCRF? Also, what is the timeline for this functionality and/or who should be contacted for more information on this?
  - Answer: Currently, there is work underway to build an interface between Connect Care and REDCap. The AHS instance of REDCap is only to be used for non-REB approved projects and QI initiatives. Following the PIA revisions later in November 2021, REB-approved studies will be able to request access to this functionality sometime next year, in 2022.

- **QUESTION #7:** For end users working on a Mac device, is there help available to ensure that access to the eLearnings is not an issue?
  - Answer: For any IT related issues please contact the AHS helpdesk for support @ 1-877-311-4300 or to access web chart and email support click on the following link: Alberta Health Services - IT Support.
  - Alternatively, please click on→ Mac User Tips for MLL if you use a Mac device to access eLearning. It is recommended to use a Chrome browser as other browsers tend to cause technical issues.

Question and Answer Period

- **QUESTION #8:** Who decides what metrics are available as a self-serve option for QI projects for the purpose of generating reports to extract applicable and appropriate data? Is there a vetting system that decides if individuals can use whatever data?
  - Answer: Area Councils (i.e. – research, neurosciences, etc.), are the primary decision-making bodies associated with the Connect Care implementation project team that make the decisions regarding the dashboard content of each of the specialty areas. Those area councils approve the metrics related to foundational builds via the EPIC system or AHS custom builds. Stakeholders would include medical leads, front-end users and clinicians. Availability of data is directly related to an individual end user's security and role/access template.

Question and Answer Period

- **QUESTION #9:** For those individuals that work within a tissue bank setting and therefore are required to correlate patient information to samples collected, is there a way to connect with someone who can help establish a process that will reflect that workflow? Also, can information be downloaded or would end users need to access information on a real time basis?
  - Answer: If end users currently have access to an existing system to gather this info (i.e. – SCM, eClinician, etc.), then they will be applying for read only access within Connect Care. There is not an expectation this should have already been completed; however, this activity typically occurs right before launch or based on the readiness of research teams. It is recommended that any research team who has not been contacted by September 2021, reach out to their research advisor from the Health System Access team to ensure they have the appropriate access.

Question and Answer Period

- **QUESTION #10:** What is the content of the '*Research Staff Instructor Led Training*' course? Does it include similar content that is part of the '*Physician Builder* Analytics' training course in Epic catalogue?
  - Answer: Content is different between the two training courses.
    - Physician Builder Analytics (CLN171) from the EPIC catalogue is aimed at physicians who are involved in creating or importing reporting tools and dashboards for clinicians.
    - Research Staff Instructor Led Training: This course covers research workflows performed within Connect Care. You learn how to associate patients, orders, and encounters to studies. In addition, this course covers, updating research records, releasing information to study monitors, documenting adverse events, managing study tasks, reviewing research charges, and tracking study amendments.

Question and Answer Period

- **QUESTION #11:** What is the process to follow for physicians who have a clinical role with a new clinical project and think the research would be suitable for Connect Care?
  - Answer: After REB approval; submit a study intake questionnaire. The HSA (Health System Access) team will use this information to determine eligibility for Connect Care and role provisioning. HSA Study intake questionnaire: PRA Team Resources - PRA Questionnaire (ahsnet.ca)

- **ADDITIONAL RESOURCES of Interest:**

  Connect Care In-system Reporting Resources (albertahealthservices.ca)

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**