CONNECT CARE RESEARCH: Including Research Studies with your Site Launch

Participation in Research studies is part of the patient’s care journey!

When research affects patient care, it must be included in the health record. This is vital for ensuring the safety of our patients participating in research studies. With the implementation of Connect Care, study teams (physicians, coordinators and research nurses) will perform workflows in the Clinical Information System (CIS). Research-specific workflows include:

- Scheduling research-related visit encounters to the clinical calendar
- Orders for research-related tests, procedures and medications
- Documenting research activities and study enrollments in the patient chart

This is a significant change for research, clinical and service teams.

- **For the first time in AHS, Research teams will have an active role in maintaining the electronic health record.** Individuals who did not previously have access to the patient chart, including university-employed research coordinators, will have access and responsibility for keeping the patient record up to date (as it relates to research). Training in all research workflows will be research role-specific. Access will be assessed and research end users will be assigned an appropriate user role.

- **Clinical teams will have easy access to research information that may affect patient care decisions.** By clicking on the research icon available on the patient storyboard, users will have access to the research study name, a brief description and the name of the Principal Investigator responsible for that study.

- **Health service departments will be required to receive, process, result and invoice research-related orders in Connect Care.** Entering and managing research orders in-system will partially or completely replace paper requisitions. This represents a key workflow change for our pharmacy, lab, DI, ECG, and diagnostics departments supporting research.

Not all research studies will be included in Connect Care; a study is included in Connect Care when it meets at least one of the following criteria:

- Interventional drug trials and device studies
- Survey-based or observational studies where:
  - Research-specific visits are occurring in AHS clinical spaces, the use of recruitment tools are requested, or if there is any research-study specific order entry or documentation
  - Release of information to outside study monitors is required
  - Research teams require notifications of ED arrivals or admissions
  - Pharm/lab/DI/ECG will be invoicing the study for services rendered in support of research

How will we know from the patient chart if a patient is involved in a research study?

To enhance patient safety and support clinical decisions, all patients actively enrolled in research studies will be identifiable by the presence of the research icon on their storyboard. Clinically relevant details of studies will be available to the clinician using this icon.
Preparing Clinical Operations Staff

Clinical staff, especially in acute settings, may not be accustomed to seeing research orders in-system. The research icon is visible in several areas of the patient chart and is intended to create awareness that activities such as visit encounters, lab tests, medications, procedures, notes, etc., are associated with a research study. It is important to understand the significance of the research icon in order to avoid inadvertently canceling research orders, labs, and/or appointments.

What can you do?
Include information about research as part of your site readiness meetings, specifically how it affects your team’s workflows. Questions that clinical operations staff can ask include:
- **HOW** are research visit encounters being scheduled currently and **WHO** will help researchers book their visits in-system moving forward (i.e. in the ambulatory setting **WHO** will be scheduling in the clinic calendar)?
  - NOTE: Individuals that will be scheduling and booking research visit encounters will receive additional training to support this functionality. It is important to also consider **WHAT** a research only visit is and **HOW** it will transition from being done on paper to now being done in-system as all documentation in-system requires an encounter
- Is the research icon present on the multi-provider schedule?
- Are all the clinical users aware that research orders, medications and other documentation will be visible in the patient chart?

Preparing Health Service Departments

Now that Research is part of Connect Care, Health Service Departments will be required to receive, process, result and invoice research-related orders. Like any change, the implementation of these workflows may raise some questions.

What can you do?
Identify service areas or departments and users providing in-kind or cost-recovered services in support of research (i.e. pharmacy, lab, DI, ECG, diagnostics). Ensure that they are:
1. Aware of how to receive, process, result and invoice for research-related orders
2. Familiar with tools that support research-related orders, (reports, work queues or other system functions) in order to identify those orders and act on them according to established protocols
3. Assigned the appropriate sub-roles to view research-related reports (i.e. billing, invoicing).
4. Knowledgeable about how to integrate CC research-related orders with other legacy systems and processes
5. Identifying research studies requesting services from their department and know how to reach out to research teams or Connect Care support to avoid delays/issues at or after launch

Operational questions that service departments should be able to answer in advance of launch include:
- What can my team expect to see when research orders come in? Who will receive/process/result/bill?
- Will it be apparent in our work queues/task lists if orders are research or Standard of Care?
- What will happen when research orders come in? What happens to paper requisitions for locally resulted research tests? Research kits?
- What research-related roles (reporting) should service area staff apply for to be ready for launch?
- Where in their training support materials can they find information to help when they have questions?
  - When researchers do not follow the new process, how will I communicate this to them? How will we correct the error and prevent it from happening again?

We are here for you

You are not alone! The Connect Care Support Team for Research is dedicated to support all sites and users implementing the Connect Care – Research Module. Please do not hesitate to reach out with questions at cc.research@ahs.ca.