Hamilton Health Sciences

EPIC Implementation: Juravinski Cancer Centre

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High Level Overview

Epic Implementation

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Epic Build Process

Epic builds are customized to the specific needs of each institution

Epic consists of distinct modules, each designed to support a specific service or core function

Epic application specialists work with frontline staff hired by institutions to build each module

Each build team focuses on their module, except for high-impact workflows, which require greater stakeholder engagement

HHS Project Odyssey

Design principles:

- One patient, one record
- On time, on budget, on scope
- Harmonize, decide, execute
- Participate, engage, and respect
- Eliminate paper records!

Early Challenges

- Epic has an established governance matrix involving 1 research and 22 clinical working groups
- Aside from the JHCC Systemic Therapy Working Group, research involvement in **clinical** working groups was minimal, with occasional touchpoints to provide information
- Priority was given to standard of care clinical processes and treatment plan builds, leaving inadequate time to plan, implement, test, refine, and standardize research requirements
- Just-in-time training limited opportunities to assess frontline staff's understanding of changes to key processes and clinical practice
- **Outcome: No opportunity to modify processes before Go-live; "must wait for optimization"**
- **Lesson Learned: Advocate for research representation on all clinical working groups to address the intersection of research and clinical care**

Treatment Plan Builds

What we learned and how we've adjusted

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BEACON hire two experienced pharmacist to build SOC and research TPs

Research TP builds start in Jan 2022

Go-live date:

June 4, 2022

Pharmacist are initially given relevant information from protocol and pharmacy manual

Once self-sufficient, they use EDGE to access information on their own

On completion, pharmacist schedule validation meeting with CTD Medical Head, Manager & Clinical Leader

Following validation, TP is moved to live system

Approximately one month before Go-live, EPIC Production system is locked down to new builds

Early Decision Points

- Recommend introducing a TP form early to help staff get acquainted with the process, encourage early adoption, and allow time for refining the form before the official Go-live
- Avoid re-inventing the wheel - network and ask other EPIC sites to share their treatment plan (TP) templates and learn what's working well and what could be improved
- Select software application, e.g., Microsoft Word or Excel, for designing form
- If using Excel, ensure format allows easy addition of columns and rows without disrupting existing content and frustrating staff
- Decide whether to include only treatment orders or all required assessments and visits

Leveraging “Groupers”

Extracted from our Standard Work document on Lab Orders:

- When possible, create an order group.
- An order group contains orders within a similar category that occur at the same time, e.g., labs such as CBC and differential & blood chemistry tests.
- Pharmacokinetic (PK) and other samples may be required at several time points during a treatment day. Each time point requires a separate order.
- Indicate the cycle number **AND** treatment day **OR** week number per the protocol schedule of assessments.
- **Note: In Epic, the pre-treatment day = day 0 of the cycle**
- Be consistent with the cycle number and treatment day or week number to ensure tests are linked to the appropriate appointment.
- List **EACH lab parameter** in an order group or as a single lab test for a specific time point.

Validation Process

- Most studies require multiple TPS, and all extracts are reviewed for accuracy and completeness
- Key stakeholders include the applicable BEACON analyst, study PI, coordinator, CT pharmacist, systemic nursing, and either the Clinical Leader or Manager
- Validation often identifies several corrections/additions to content
- Beacon analyst will complete treatment plan corrections/additions and send the final extracts and a summary of the revisions to the relevant research team members for final review
- We adopted an Attestation process that requires the PI and Study Coordinator to attest to their review and address the question “How do I know?” often asked by Regulatory Inspectors
- **I’d like to know if other sites have adopted an attestation or similar process, or if it is an unnecessary step that does not add value**

Challenges

- We went live without a TP form
- In November 2022, funding for the Pharmacist model ended, and responsibility for providing the information in a “plug and play” format shifted to the department
- Study activations fell behind as we designed the form and trained study coordinators; we were late adopters
- Proficiency of build is dependent on background of BEACON builder
- Complex protocols often take many validation meetings to finalize
- Real-world issues we faced: Single line entry of IP vs drug card, monitor not able to view start and stop times, volume hard coded impacting documentation of split syringe dose administrations, IP is not barcoded similar to SOC drugs for dispense prep requiring workaround, establishing best practice for oral agent builds, process for maintaining double-blind during dispense prep, and management of protocol amendments

Lessons Learned

- Before you begin:
  - To design an effective TP form, you need to understand build requirements, key data points, workflow, timing needs, and final documentation requirements
  - Apply this understanding to review the current process and map the future state
  - Engage key stakeholders in the defining the process and designing the form
- If possible, build a test case in the live system and pilot end-to-end drug administrations for a novel investigational product administrations, ensuring documentation is complete, accurate and meet regulatory and sponsor requirements
- Leverage SOC and IP TPs built for other studies
- Conduct regular debriefs with key stakeholders early on to identify gaps or missing information, revise accordingly, and use PDSA cycles to assess change effectiveness
- Engage the research team in communicating protocol deviations and unresolved queries as a strategy for course correction

Post Go Live

Pre-Activation to Activation

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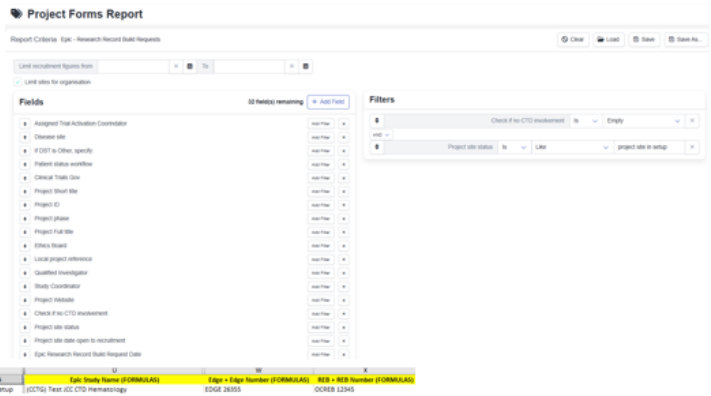
Upfront Builds in Edge and Epic

TACs create/join the study in Edge, update fields

edge

As studies are greenlit, TAC pulls a build report from Edge



TAC submit a survey to request the Epic research record build

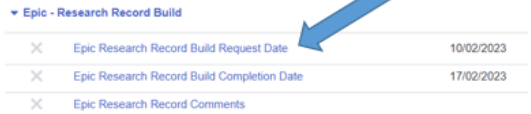
REDCap

IT builds the Epic research record, informs TAC

HITS myIT

Epic

TAC tracks build info in Edge

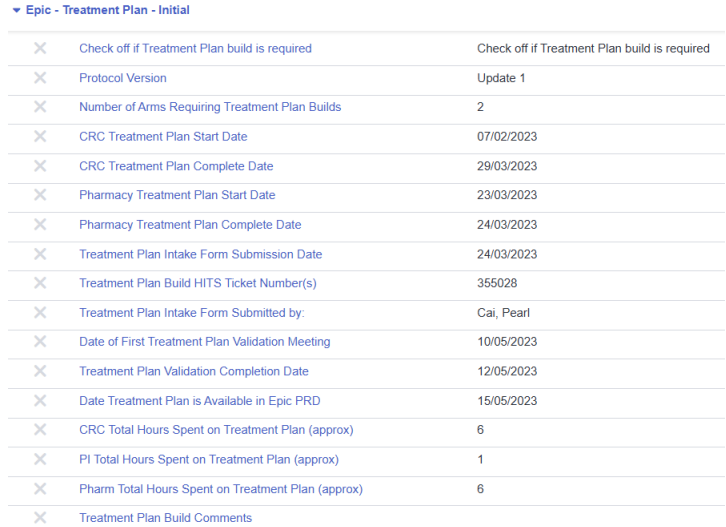


Upfront Builds in Edge and Epic

- As the TAC works on activation, the Study Coordinator is responsible for completing the research record in Epic, which involves:
  - adding Investigators and staff so they can access the study,
  - adding the initial protocol amendment approval date, and
  - creating the AE flowsheets
- In addition, the Study Coordinator will start the Epic treatment plan build process.

Creation of Initial Epic Treatment Plans

- The TAC flags in Edge if the project requires Epic treatment plan build(s).
- As Brenda mentioned, The Study Coordinator and the Clinical Trials Pharmacist work together on the Epic treatment plan intake form. They update their progress in Edge.
- Once a treatment plan is complete and validated, the Study Coordinator uploads the extract, correspondence, and PI sign off to Edge (retain original wet-ink signatures in the ISF).



Epic - Treatment Plan - Initial

Check off if Treatment Plan build is required	Check off if Treatment Plan build is required
Protocol Version	Update 1
Number of Arms Requiring Treatment Plan Builds	2
CRC Treatment Plan Start Date	07/02/2023
CRC Treatment Plan Complete Date	29/03/2023
Pharmacy Treatment Plan Start Date	23/03/2023
Pharmacy Treatment Plan Complete Date	24/03/2023
Treatment Plan Intake Form Submission Date	24/03/2023
Treatment Plan Build HITS Ticket Number(s)	355028
Treatment Plan Intake Form Submitted by:	Cai, Pearl
Date of First Treatment Plan Validation Meeting	10/05/2023
Treatment Plan Validation Completion Date	12/05/2023
Date Treatment Plan is Available in Epic PRD	15/05/2023
CRC Total Hours Spent on Treatment Plan (approx)	6
PI Total Hours Spent on Treatment Plan (approx)	1
Pharm Total Hours Spent on Treatment Plan (approx)	6
Treatment Plan Build Comments	

Post Go Live

“Site Ready” to Study Completion

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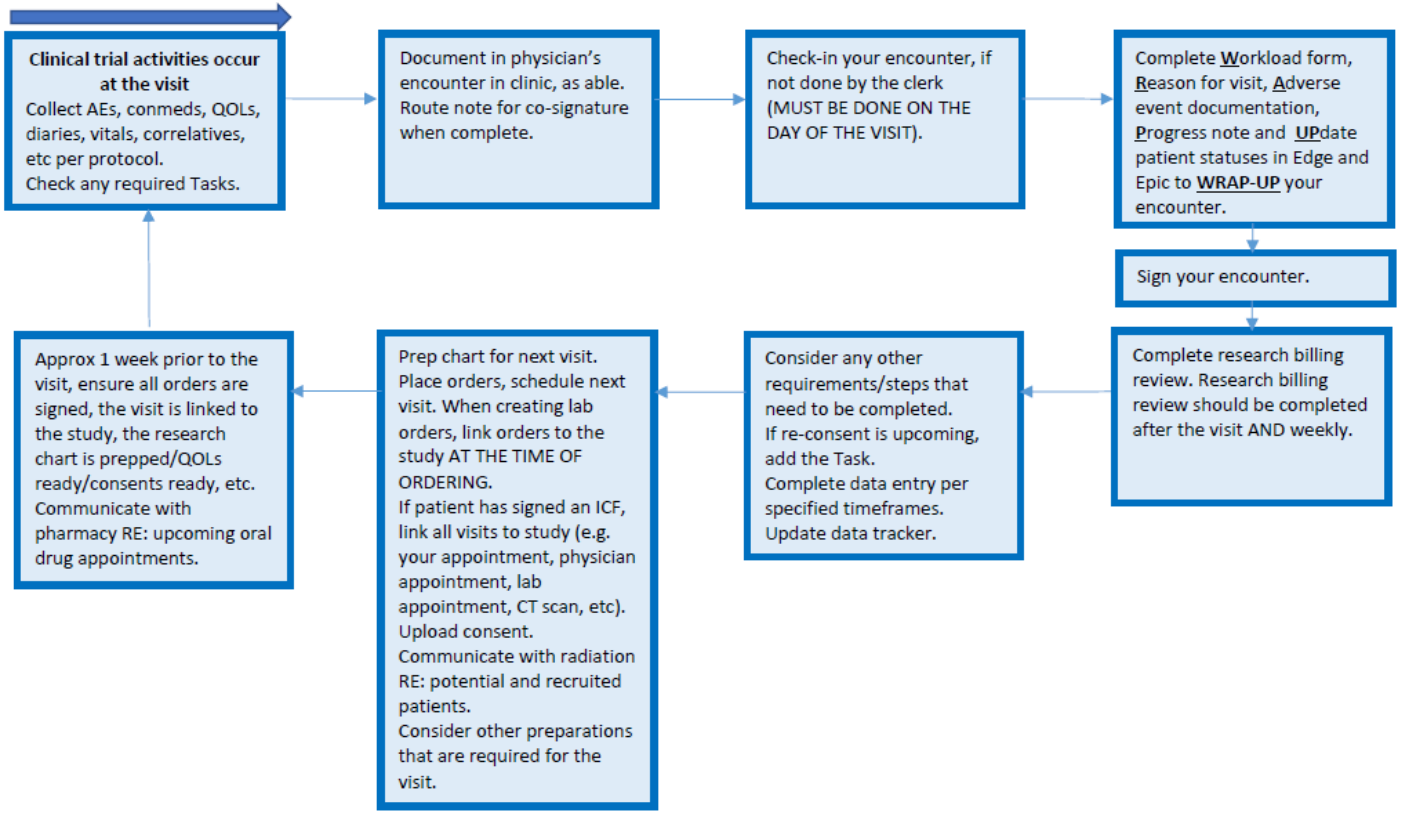
“Site Ready” to Study Completion

- Once a study receives activation and the research team is ready to recruit, the Study Coordinator informs the team and other key staff
- The Quality Specialist confirms that all required fields and documents have been completed in Edge and opens the study to recruitment in Edge and Epic

“Site Ready” to Study Completion

- The Study Coordinator is responsible for ongoing maintenance of the study, which now includes:
  - Maintenance of the Epic research record (adding/removing Investigators and staff, adding amendments, updating study arms if new arms are added, and updating the AE flowsheet if needed)
  - Working with Pharmacy to create any new treatment plans or amend existing treatment plans, working with IT to get new arms built or fixed, and tracking in Edge (Note: When an existing arm is edited, the changes need to be applied manually to all patients already on that arm, which takes time and precision)
  - Research billing review

The Flow of a Patient Visit



Research Billing Review

- Net new to our Study Coordinators.
- At Go Live, any patient in an Active status (Consented, On Treatment, On Followup) would have ALL of their charges routed to the Study Coordinator for ALL visits. Everything was “bucketed” to Bill to Study, despite the overwhelming vast majority of charges being OHIP billable.
- Changed after a year to only include visits and/or orders that are LINKED to the study, and charges are bucketed to Non-Study Charge and need to be manually changed to a study charge.
- Finance team will issue any corrections to the Study Coordinator.

Monitoring

SC sends confidentiality agreement to monitor to sign*

SC uploads signed agreement and completes account request in RedCap*

IT creates account, sends password to monitor and username to SC*

SC requests IT to link monitor to the study in Epic*

HITS myIT

SC releases Epic patient charts to monitor each visit

Epic

Monitor accesses patient charts via EpicCare Link

EpicCare Link

*only required one time per monitor per sponsor

Post Go Live

Lessons Learned

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Lessons Learned

- Need to standardize early on! Note templates, AE flowsheets, conmeds, use of certain fields in Epic, etc should ideally be standardized at a unit level.
- If your site uses Edge, create forms/fields and reports to pull and track data.
- Changing work mentality to do things in real-time. Documentation is meant to occur in clinic with the patient while it's happening.
- Extra time/work is needed.
- Institutional downtime procedures are helpful, but research-specific downtime procedures are still needed (so keep those old, paper documents and tools, just in case!)

Lessons Learned

- Get research at every single table possible! If denied, push for it. Cancer research touches practically every area of the hospital:
  - How should labs be booked if drawn in the lab vs another area? How are lab collection times entered into the system? Will this be the same with research kits?
  - If your radiologists read per RECIST, how do you get your paper measurement sheets to them in an electronic system?
  - Do primary care teams and physicians document conmeds sufficiently for research purposes?
  - How will patient phone calls be triaged to your staff if needed?
  - Will your pharmacy be able to fill clinical trials prescriptions properly?
  - How are your radiation treatments recorded, and in what system?
  - How do finances flow? How do you track bill to study items, invoiceables, milestone payments, etc? Bill to Study vs OHIP?

www.hamiltonhealthsciences.ca

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