Office of Clinical Research

May 2026

New clinical study dashboard standardizes reporting

Launched on May 4, the new integrated **Clinical Study Portfolio Metrics and Key Performance Indicators** dashboard now serves as the single authoritative source for operational and performance metrics across clinical study research activities at IU School of Medicine and IU Health.

The integrated tool consolidates fragmented reporting into one standardized, reliable and automated dashboard that supports consistent decision-making, oversight and enterprise-level reporting. The dashboard received an

overwhelmingly positive response from clinical research leaders and select study teams who were asked to review and evaluate the tool prior to deployment.

The primary data input for the dashboard is OnCore, IU School of Medicine's Clinical Research Management System of record for clinical research studies. Review *Integrated Dashboard Logic* for background and core design principles.

For questions about the dashboard, please email the OnCore team at *oncore@iu.edu*.

OCR data optimization project update: OnCore 'quality assurance' review

The Office of Clinical Research (OCR) Data Optimization Project focuses on keeping study information in OnCore—the IU and IU Health Clinical Research Management System (CRMS)—accurate and up to date. This is important because OnCore data feeds other systems and reports, including Cerner/Epic, the Clinical Study Portfolio Metrics and Key Performance Indicators dashboard, and the All IN for Health study listings.

This effort is being conducted in partnership with departments, the IU Simon Comprehensive Cancer Center, and IU Health to ensure accurate data and communications in preparation for IU Health's Epic go-live.

What does this mean for study teams?

- *All* studies in OnCore are subject to review.
- The status of your protocol must be updated in OnCore as soon as you are notified a change has occurred.
- All participant registrations must be added and participant statuses updated within 48 hours of their occurrence.
- Summary Accrual must be updated each month, so numbers are reflected accurately on

reports. Per IU Health policy, individual subject registration is required when patients have signed written informed consent.
- Review OnCore accrual goals and study duration at least quarterly (monthly is preferred) and update as needed. The Epic team will need the Anticipated Study End Date updated. Only studies with an end date of 06/01/2027 or later will be moved into Epic.
- All data required in the *OnCore minimum footprint documents* should be reviewed monthly by the study teams to ensure accurate reporting and visibility across connected systems.

All study teams are asked to review and confirm their study status, accrual numbers and other required information in OnCore for accuracy and completeness.

Why is this data initiative happening now?

OnCore data quality is foundational to Dashboard metrics and KPI data accuracy and is essential for robust oversight of clinical research at IU and IU Health. Current discrepancies between OnCore and Cerner should be reviewed and addressed to prevent these issues from transitioning to Epic. Prioritizing OnCore maintenance now will help avoid future problems. The release of the new Integrated Study Portfolio Dashboard also enhances transparency and will facilitate informed decisions regarding clinical research initiatives.

What is under review?

We have expanded our review of studies in OnCore beyond just “Zero Accruing Studies” to all studies. The OCR (working with IU Health IS and the IUSCCC) will contact study teams to confirm or update most pending and all active OnCore protocols. This is based on their current OnCore status and length of time in that status. Accrual numbers will be reviewed based on time from last reported enrollment. Studies will be flagged using the criteria below:

OnCore Protocol Status	Flagged Eligibility Criteria	OnCore Outcome/Notification
New	6+ months in single status	Study updated to *Abandoned*
On Hold	6+ months in single status	Study team notified
SRC Approval	6+ months in single status	Study team notified
IRB Initial Approval	6+ months in single status	Internal notification
Account Signoff	6+ months in single status	Study team notified
OCR Signoff	6+ months in single status	Study team notified
Research Unit Signoff	6+ months in single status	Internal notification
***Any study not Open to Accrual in **12+ months** will also be flagged and study team notified.*		
Open to Accrual • *Non-Cancer Center* • *Cancer Center*	• No accrual updates for 12+ mths • Refer to PRMS Bylaws	• Study team notified; response noted in OnCore; “Closed to Accrual” if no response • Refer to PRMS Bylaws
Closed to Accrual	5+ years in a single status	Study team notified
Suspended	6+ months in single status	Study team notified

Studies will be evaluated regularly. Studies that are Open to Accrual can be moved to a Suspended status upon request if enrollment is stalled. The study can then be reactivated once enrollment efforts resume.

For Epic readiness, department and division leadership will receive a spreadsheet of studies with IU Health study sites for review. Departments and/or Divisions need to designate a single point ofcontact to be responsible for monitoring and managing their respective study portfolios, addressing zero accruing and other neglected protocols, and resolving the issues in a timely manner on an ongoing basis.

The goal is to have OnCore study data in an accurate and complete state by October 2026, with a process in place to maintain this quality in a durable manner. This is a foundational element of the Epic transition for clinical research studies.

Kuali Protocols (KP) IRB status monitoring

KP IRB Status	Action	OnCore Status Update
Closed in KP IRB	Study team notified to respond and/or update OnCore study status. If there is no response or update, OnCore team will update status.	IRB Study Closure
Expired in KP IRB (6 months from KP expiration date)	OnCore team updates; No study team notification	• *Active Protocol* → IRB Study Closure • *Pending Protocol* → Abandoned

Study statuses in OnCore can be reactivated should studies be closed or abandoned in the system prematurely.

Why this matters

OnCore data accuracy and completeness plays a critical role in the Clinical Study Portfolio Metrics and Key Performance Indicators dashboard, and the future linkage between OnCore and Epic for clinical studies. Accurate and timely data entry in OnCore is essential for ensuring adequate study resource availability, reliable reporting, operational decision-making, and enterprise oversight of clinical research.

The OCR and Epic team would like to thank all study teams who have helped in this effort thus far and in our future outreach. We greatly appreciate your hard work and time dedicated to helping us achieve an accurate and complete enterprise system.

Questions? Contact Brenda Hudson at *brlhudso@iu.edu*. For Epic readiness questions, contact *clinicalresearchsupport@iuhealth.org*.

Clinical trials with Eli Lilly focused on enrollment

As part of the *agreement with Eli Lilly and Company*, the group of activated clinical trials is focused on optimizing patient enrollment statewide. The first cohort of trials includes Phase 2 and Phase 3 trials targeting diseases such as Crohn's disease, ulcerative colitis, malignant afferent loop obstruction, peripheral arterial disease, breast cancer, urothelial cancer, and major depressive disorder.

Understanding your role in Epic Orderset readiness

As we approach the Epic implementation on May 1, 2027, the Epic Research Implementation team must prepare and plan for the build of research ordersets.

Today, most research oncology treatment plans and adult inpatient research ordersets have been built in Cerner. It is suspected, however, that many research studies (including outpatient) have multiple orders per visit, investigational medication administrations or established day/event-based care being conducted on IU Health subjects/patients that do not have established ordersets in Cerner.

With the implementation of Epic and the associated new research features and functionalities, it is vital that these orders are entered and documented in Epic for clinical care and patient safety communication and research revenue accountability.

All studies teams are asked to complete the following research orders request survey for all current active interventional studies. Deadline: Aug. 14, 2026.

Epic Research Orderset Request Survey

Due to timing and resource availability during this Epic implementation timeline, if a request has not been submitted by Aug. 14, 2026, there is no guarantee that a research orderset for your current active study will be built by the May 1, 2027, go-live.

The following will drive scope and order tool decision-making.

Scope: Study-specific ordering tool build will be in scope for studies that meet all the following criteria:

- Patient target accrual is > 10
- > 5 orders are expected per visit
- All studies with an investigational medication will have a unique medication orderable linked to IRB available in Epic.
- For studies that don't meet the above criteria, study teams may use standalone orders, shared user order panels, or the blank treatment plan template to streamline order entry.

What tools will be used? For studies that meet the criteria above, the ordering tool(s) used will be dependent on the study protocol and setting.

- For studies involving recurring treatment that is:
    - Day/cycle based and contain chemotherapy: Treatment Plans
    - Interval based: Therapy plans
- For studies involving non-recurring treatment that occurs:
    - Inpatient or peri-op: Order sets
    - Outpatient: SmartSets
- Studies with complex needs spanning multiple settings may use a combination of the tools outlined above.

If you have any questions or need more information, please contact *EpicResearchGenomicsTeam@iuhealth.org*.

Frequently asked questions

1. What if I have already submitted a Cerner orderset build request for my research study or have an orderset already built in Cerner?
   Response: *Please continue to complete the Epic Research Orderset Request survey to ensure we are accurately tracking your future Epic build.*

2. What if I know I have a research study with in-scope orders that will be approved after the Aug. 14 request submission deadline and will be open to accrual before May 1, 2027?
   Response: *In addition to following the current Cerner processes, please continue to complete this Epic Research Orderset Request survey to ensure we are accurately tracking your future Epic build.*

Epic Super User recruitment: Join the team

Be a leader in research system transformation

The OCR is thrilled to announce the official launch of the Epic Super User Recruitment Program. We are seeking enthusiastic representatives from all divisions, departments and research groups, with a special focus on those who are actively involved in research study records—particularly individuals working on interventional research with informed consent, as well as those currently documenting and proposing orders in Cerner.

This call is especially relevant for research coordinators and research nurses who will be using Epic, but we welcome all interested staff engaged in clinical research activities to apply. Your expertise and insights are essential for ensuring a smooth and successful implementation across our research enterprise.

How to Apply

- Complete the *REDCap application form* by June 12, 2026.

Selected Super Users will be finalized in July to ensure diverse representation and will be asked to accept the program expectations outlined below.

What is a Super User?

A Super User is an expert within a specific department, clinical area or subject matter who supports colleagues during the adoption of new systems. Super Users are invaluable during end-user training and go-live, as they combine in-depth knowledge of Epic with experience in Cerner systems and workflows.

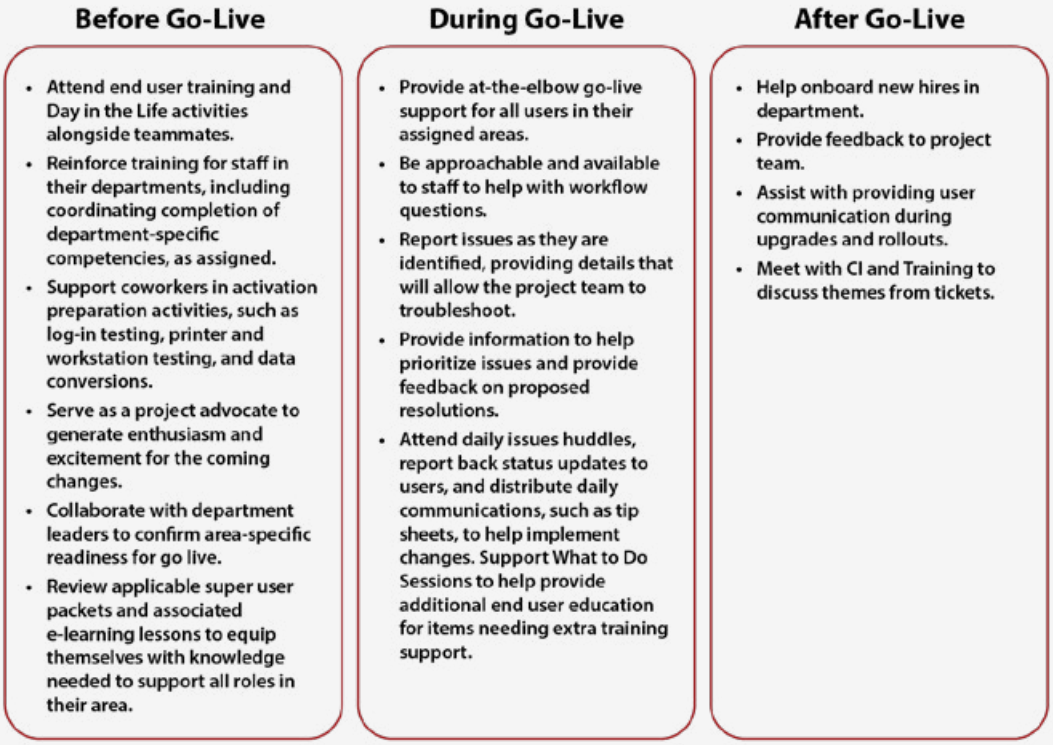
Benefits of being a Super User

- Early access to Epic training
- Opportunity to shape the future system build and enhancements
- Help onboard new team members to departmental EMR standards
- Be the first to experience quarterly updates and changes in the EMR system

Super User preparation timeline

- Introductory meeting: 1–2 hours (November 2026)
- Monthly Super User Basics sessions: 1 hour/month (November 2026–April 2027)
- Epic Super User Training Path: Complete required courses
- Role-Based End User Training: January–February 2027
- Asynchronous Super User Course: 1–3 hours (January–February 2027)
- Support End User Training Sessions: February–April 2027
- Participate in Day-in-the-Life Activities: February–April 2027

What are the expectations of a Super User?



Questions?

If you have any questions or need more information, please contact *clinicalresearchsupport@iuhealth.org*.

Don’t miss this unique opportunity to lead and support your colleagues during this exciting transition. We look forward to your applications and your continued dedication to advancing research excellence.

Coming in June: OCR Community Call & summer activation workflow updates

Continually optimizing clinical study processes in support of the clinical research community is a high priority for the Office of Clinical Research (OCR). Beginning Aug. 1, the OCR, in partnership with IU School of Medicine and IU Health teams, will implement new capabilities and enhancements to the clinical study activation process. A high-level overview will be shared during the June OCR Community Call, with additional communication, training and support resources to follow in June and July.

Why are the updates needed?

These updates will improve coordination and cohesiveness across activation steps by:

- Providing increased transparency and better visibility into the status of where studies are in the activation process.
- Reducing delays caused by incomplete submissions.
- Eliminating redundant data inputs and forms.
- Minimizing duplicate requests for information.

In addition, communication will improve between participating review groups to help studies move through the activation process more efficiently.

What's staying the same?

The OCR will continue to partner with investigators and study teams throughout the activation process, and existing regulatory and compliance requirements will remain in place. IRB approval and other required study reviews will still be necessary before activation.

What's changing?

- **Revised OCR intake form:** Study teams will be asked to provide more complete information and supporting documents up front before studies are entered into OnCore.
- **Improved coordination across review groups:** Information submitted through OCR intake may also be shared with participating ancillary groups to reduce duplicate submissions and avoid repeated requests for the same information. For example, separate Clinical Research Center (CRC) submissions will no longer be required for applicable studies.
- **Greater visibility into study progress:** When implementation is complete, study teams will be able to track activation progress and key milestones through the OCR Study Activation Tracker.
- **Additional support for billing review studies:** For studies requiring OCR Financial Compliance review, start-up meetings, assigned Activation Project Managers, and earlier coverage analysis review will help support study start-up planning and coordination.

What to expect during the Community Call

- A preview of what's changing and why
- Key dates, workflow expectations and where to find updates
- How to prepare ahead of the Aug. 1 transition
- Where to direct questions and access future training resources

Following the Community Call, the OCR will share additional written guidance and training opportunities throughout June and July.

Plan to attend

Researchers, coordinators, business managers and collaborators are encouraged to attend the June OCR Community Call to learn more about the upcoming activation workflow updates and how to prepare for the transition.

OCR Community Call: Thursday, June 4, 2-3 pm

Register for the June OCR Community Call

Quality and Compliance Workstream launches post-activation readiness survey

To support ongoing efforts to optimize clinical research operations across IU Health and the IU School of Medicine, the Quality and Compliance Workstream has developed a REDCap survey. The survey is designed to better understand post-activation readiness for pharmaceutical-sponsored studies.

Specifically, this survey, launched as a pilot initiative, focuses on the time from a study being open to accrual (in OnCore) to the first patient screening visit. The survey takes about 8 to 10 minutes to complete. Participation is voluntary and anonymous.

Workstream Feedback Survey

The survey is intended for clinical research teams involved in post-activation study activities, including Principal Investigators (PIs), Study Coordinators, Clinical Research Nurses, Clinical Research Managers, Project Managers, and Clinical Research Specialists. Recipients are encouraged to complete the survey, as their feedback is valuable in helping identify opportunities for improvement.

This effort builds on the *OCR Clinical Research Roadmap* introduced in the spring 2025 Community Call to guide clinical research from pre-activation to study activation.

Insights from the survey will:

- Identify barriers and pain points that may follow study activation.
- Inform development of post-activation study activities.
- Support alignment with the Eli Lilly and IU/IU Health Enterprise Initiative guidebooks.

The Quality and Compliance Workstream also requests continued feedback on the OCR Roadmap.

Provide feedback about Roadmap →

Denney named director of OCR financial operations; Brims promoted

Effective March 1, Kelly Denney has been appointed as director of financial operations for the Office of Clinical Research (OCR). In this role, Denney provides strategic oversight of the financial compliance (coverage analysis) program, while expanding her focus to broader clinical research financial operations, including clinical trial budgeting, financial strategy, and clinical operations optimization initiatives across the research enterprise. Denney continues to report to Carmel Egan, PhD, OCR director.

As part of this transition, Lauren Brims has been promoted to assistant director of financial compliance. In this role, Brims leads day-to-day operations of the financial compliance program, serves as the primary point of contact for coverage analysis and research billing education, and contributes to OCR and enterprise-wide projects and initiatives that support clinical research operations.

Indiana CTSI
410 W. 10th Street Ste. 1000
Indianapolis, IN 46202