Office of Clinical Research

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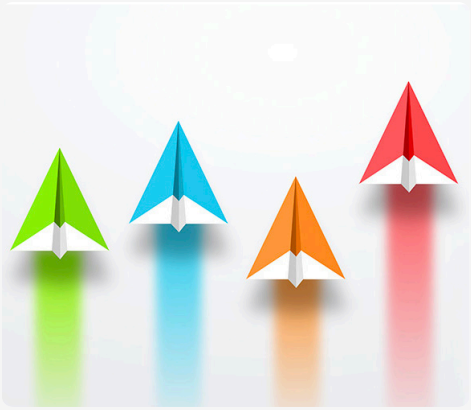

Early successes propel IU/Lilly agreement to expand clinical trials statewide

Signed in late 2025, the agreement between Indiana University and Eli Lilly and Company establishes a critical pathway for Hoosiers to Lilly's investigational medicines and leading-edge treatments.

The agreement focuses on three major strategic goals and outcomes: optimized, sustainable clinical trial infrastructure and delivery; clinical care for Alzheimer's disease designed to accelerate access to diagnostics and treatment; and workforce development for Indiana's health and life sciences.

Successes to date

- **Portfolio momentum:** Teams have achieved significant progress with activation timelines. Startup and first patient visit (FPV) have occurred ~20 to 40% faster depending on the disease state.
- **First global FPV:** The Phase II clinical trial of imlunestrant for early-stage breast cancer (JZLL) is the first IU School of Medicine clinical trial to achieve global FPV in the Lilly portfolio. This trial achieved FPV in just 68 days, far exceeding the 95-day goal for oncology studies. Global FPV was also achieved in a second breast cancer clinical trial (Pikalo 2 JSGD) aimed at slowing tumor growth. Historically from 2020-2025, activation timelines for oncology studies were more than 240 days.
- **Indiana Biobank Enrollment Support:** The Indiana Biobank team is building targeted patient-match lists for select clinical trials that have recruitment challenges.
- **IU-Lilly Study Portfolio Playbook**: To streamline and optimize progress moving forward, the school and Lilly have developed a playbook outlining end-to-end steps and best practices necessary to efficiently carry out the studies.

Next steps

With current focus on patient recruitment for the clinical trials, IU School of Medicine and IU Health teams are leveraging internal and Lilly's tools and resources to improve data management and workflows associated with patient enrollment. More proactive outreach and engagement with patients statewide is also planned.

Based on early success, IU School of Medicine is in discussions with Lilly about expanding the partnership to include more clinical trials in the future.

Advancing clinical research through a statewide ECRO model

IU Health is expanding its Enterprise Clinical Research Operations (ECRO) team to strengthen access to clinical research for patients across the state. This systemwide expansion reflects IU Health's commitment to bring innovative research opportunities closer to home, while ensuring oversight, quality and compliance across all regions.

Historically, clinical research efforts across IU Health have grown organically, resulting in variation in infrastructure, experience and processes from site to site. While many teams have delivered strong results, these differences have created barriers to scaling trials statewide and fully leveraging IU Health's collective research potential.

The expanded ECRO model addresses these challenges by providing centralized leadership, standardized operations and shared resources to support clinical research teams at IU Health facilities statewide. This includes aligning reporting structures, centralizing administrative and regulatory support, and establishing consistent expectations for training, equipment and compliance. By centralizing administrative and operational tasks within ECRO, clinical team members can scale by focusing more fully on patient enrollment, study conduct and investigator engagement.

The expansion also strengthens collaboration across regions, making it easier to identify and operationalize studies that can benefit patients in multiple communities. As new hospitals and care sites come online across Indiana, this unified approach positions IU Health to grow research access alongside clinical care.

Ultimately, expanding ECRO is about building a sustainable, coordinated ecosystem—one that supports investigators, engages partners and ensures more Hoosiers can participate in clinical research that shapes the future of patient care.

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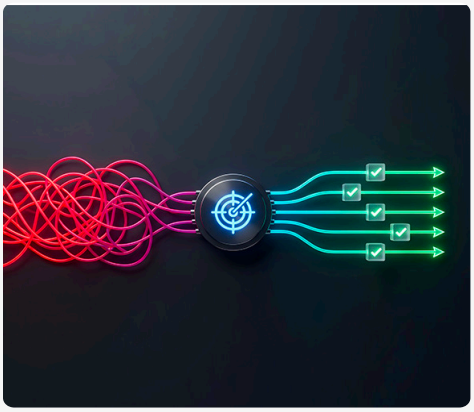


From cleanup to readiness: OnCore data optimization update

How protocol reviews and timely study updates help build a stronger foundation for Epic and enterprise reporting.

More than a month into the OnCore cleanup project, teams are reviewing and updating more than 6,000 pending and open protocols, and completed study lists are starting to roll in.

Department and division points of contacts (POCs) are currently coordinating portfolio reviews, with completed lists due to the Office of Clinical Research (OCR) by Aug. 31, 2026. Once received, the OCR and IU Health clinical research systems and Epic teams will review the information and follow up on items needing clarification. Studies with no response will be marked as inactive in OnCore and require study teams to contact the OCR for further updates. These updates matter. Up-to-date OnCore records support Epic readiness, enterprise reporting, the Integrated Portfolio Dashboard, public study listings and reliable study information for teams and partners across the enterprise.

Next steps

- **OCR review:** The OnCore and Epic teams will review submitted updates and corresponding OnCore information and may contact study teams with questions. OCR is also developing regular reports to alert POCs and study teams about data issues or discrepancies.
- **Study team ongoing responsibilities:** Study teams should continue monitoring new, pending and active protocols in a sustainable manner and make updates as study details change. Regular OnCore review helps keep study information accurate and reduces the need for large cleanup efforts later. If a study is interfaced with Cerner PowerTrials, study teams should continue monitoring the RPE (Retrieval Process for Execution) Console, which

supports the integration between OnCore and the electronic health record, for discrepancies.
- **Epic transition:** The IU Health Epic team will review OnCore information and study team spreadsheet updates to support the transition into Epic. This review is expected to continue through December 2026.

FAQs for study teams reviewing studies

What should my team review? Review study status, staff and PI information, accrual goals, enrollment data, study completion dates, and participant information for accuracy. Start with the highest-priority studies and answer the questions outlined in the spreadsheet.

IMPORTANT: What staff should be entered into OnCore? Previously, it was not required that all study staff, such as subinvestigators, be entered into OnCore; however, if a study team member needs to conduct study activities in Epic (recruitment, document adverse events, record study information, etc.), they will need to be listed as staff in OnCore so their role can be imported to Epic. People who need view access only within Epic do not need to be listed. The roles in OnCore will be assigned to the following roles in Epic:

OnCore Role	Epic Role
Principal Investigator	Principal Investigator
Co-Investigator	Other Providers
Research Coordinator	Study Coordinators
Lead Research Nurse / Research Nurse	Nurses
Lead Clinical Research Specialist / Clinical Research Specialist	Study Coordinators
Lead Data Coordinator / Data Coordinator	Research Contacts
Study Site Contact	Research Contacts
Lead Clinical Research Patient Specialist / Clinical Research Patient Specialist	Study Coordinators

What should we do if information is missing or outdated? Update OnCore with the new corrected information in coordination with OCR and POCs.

What happens after our updates are submitted? The OnCore and Epic teams will review the information and may contact study teams if clarification is needed. It is possible that a study was flagged for one group but belongs to another. In those cases, the team will reach out to the POC, alerting them of some additional studies to review.

How often should we review new, pending or active studies? Study teams should review OnCore information regularly and update it as study details change. Study status changes and participant information should be updated in real time.

What if I have questions about OnCore fields, definitions or what information should be included in an OnCore protocol?
Please refer to the guides on the OCR website and the new FAQ document, which is being updated regularly. The study listing spreadsheet also includes a workbook that defines each field and question. The latest guides and FAQs can be found on the OCR website under “OnCore” at https://ocr.iu.edu/Research-Systems/OnCore.

Keep new studies moving forward

New studies should be reviewed and updated throughout the study life cycle. Keeping status, staff, enrollment, accrual goals and key dates current helps prevent future cleanup, supports accurate reporting and keeps study information ready for enterprise-wide use.

Have questions or need help?
Join Wednesday office hours for support with portfolio review questions, OnCore updates, Cerner discrepancies or next steps. MS Teams Link for OnCore and Epic office hours call from 2 to 4 pm on Wednesdays
Meeting ID: 271 851 370 459 677
Passcode: QT6Er7gp

For OnCore portfolio review questions, contact Brenda Hudson at brlhudso@iu.edu.

For Epic readiness questions, contact clinicalresearchsupport@iuhealth.org.

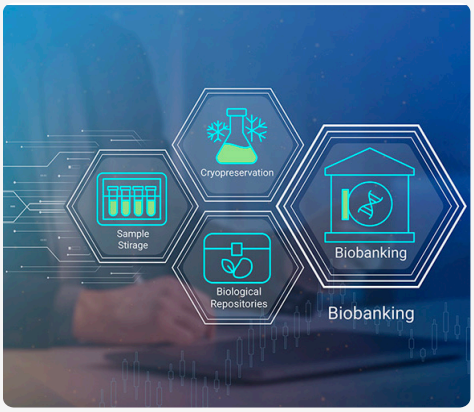
Thank you for helping keep OnCore accurate, reliable and ready for what comes next. Each update supports better reporting, smoother workflows and a stronger foundation for clinical research across the enterprise.

New hospital clinical research planning: Where we are and what's next

Planning for clinical research in the IU Health new hospital and Goodman Hall is progressing, with IU Health and IU School of Medicine working together to define the future-state model for inpatient and outpatient research, Clinical Research Center (CRC) operations, biospecimen processing, workforce needs and integration into clinical workflows. The goal is to create a flexible, patient-centered environment that supports safe, efficient and compliant research operations.

Current planning priorities include hospital-based research models, quality and compliance guidance, CRC and biospecimen design, research volume and capacity projections, Epic integration, workforce roles and training, and future-state workflows. Project pull planning sessions, in partnership between IU School of Medicine and IU Health, are helping teams clarify sequencing, dependencies, responsibilities and key milestones across these areas. (A pull planning session is a collaborative planning session in which key stakeholders work backward from a defined milestone or outcome to identify the activities, dependencies, sequencing, responsibilities and timing needed to achieve it.)

Over the coming months, work will increasingly focus on detailed transition and implementation planning, including finalizing workflows, refining clinical studies volume over a 12 to 24 months window, capacity estimates, advancing workforce and training plans, and defining how studies, patients and staff will transition into the new environment. Together, these efforts will help establish a coordinated and sustainable clinical research model that is ready to support research operations as the new hospital moves toward activation.



Indiana Biobank reaches 109,000 participants and enhances clinical trial recruitment

The Indiana Biobank continues to expand research opportunities for patients and investigators across Indiana. With more than 100,000 participants enrolled, the biobank is a growing resource for clinical and translational research.

The launch of Indiana Biobank consent at IU Health self-registration kiosks is a major milestone this year. By integrating research enrollment into routine patient registration and continuing text-based consent outreach, the Indiana Biobank is now averaging more than 3,600 new participants each month.

As enrollment has grown, so has the value of the biobank's research resources. Participant biospecimens are undergoing whole-genome sequencing and are linked to longitudinal clinical data, creating a deeply characterized dataset available to approved investigators through the Indiana Biobank Researcher Portal.

The Indiana Biobank also supports participant recall for additional sampling, data collection and research studies. Leveraging this capability, the Indiana Biobank launched a participant recall initiative in July in collaboration with Julie Clary, MD, MBA, and Benjamin Helm, PhD, MS, CGC, and the IU Health Enterprise Clinical Research Operations (ECRO) team. The initiative identifies and contacts participants who may be at increased risk for elevated lipoprotein(a) [Lp(a)], a common but underdiagnosed disorder of increasing public health importance. Participants are invited to contribute an additional sample for Lp(a) testing and receive their results. Individuals may then connect with Lp(a)-focused clinical research opportunities, including clinical trials conducted through partnerships with Eli Lilly and Company and IU Health.

By helping investigators identify and engage eligible participants more efficiently, the Indiana Biobank is reducing barriers to clinical research and expanding access to research opportunities for patients throughout Indiana.

Research nonworkers: Review these important updates

IU Health research renewal process

As part of an ongoing commitment to maintain a secure and compliant research environment, IU Health conducts an annual renewal process for all individuals involved in research. This process ensures that each person's access to necessary systems and resources remains active and that all compliance requirements are up to date.

- **Who needs to renew:** All research nonworkers (entered into IU Health systems prior to June 1, 2026) with active roles in research projects requiring electronic health records (Cerner and future Epic) access must renew. This renewal is required for both research monitors and research study team members.
- **What is required:** Refer to the email you received on Aug. 10 that includes steps to review and confirm your continued research access needs; update relevant information; and sign a new IU Health "Information Security Responsibility Statement and Data Stewardship Agreement." Contact Shannon Ryan or Deb Broach if you didn't receive an email or have questions.
- **Deadline:** Please complete the renewal process by Sunday, Aug. 30.
- **Ask:** If you no longer need access to IU Health systems, please contact clinicalresearchsupport@iuhealth.org and you will be terminated in the system. Termination will also include badge access to IU Health buildings.

New IU Health email provisioning

To further enhance security and streamline communication, IU Health is introducing new email accounts for nonworkers participating in research. These IU Health-issued email addresses will be used for IU Health-specific, research-related correspondence, notifications and access to certain IU Health systems. **Note: Research monitors will NOT receive IU Health emails.**

- **What to expect:** Refer to the email you received on Aug. 10 with instructions on how to access your new IU Health email account, along with links to resources and expectations for accessing IU Health emails routinely. Contact Shannon Ryan or Deb Broach if you didn't receive an email or have questions.

New research tool reduces data entry time by half

Indiana CTSI's new Clinical Data Interoperability Services (CDIS) tool enables research study teams to pull data from electronic health records into their REDCap study databases as soon as it becomes available.

"With CDIS, we have been able to continue our study without having to hire another person to help with data entry, and coordinators can spend their time on other things, like clinical visits, where they are needed the most," said Kiran Naqvi, a clinical research specialist at Riley Children's Health.

Learn more ⟶

Tammy Tomandl named director of Quality Assurance

Tammy Tomandl is the new director of Quality Assurance, succeeding Jennifer Marsh, who retired at the end of May. Tomandl brings more than 10 years of experience in clinical operations, quality assurance and regulated laboratory environments, with particular expertise in oncology, infectious diseases, biomarker operations and companion diagnostics. Her background includes leadership in quality management systems, regulatory compliance, audit readiness and clinical research operations across academic, biotechnology and pharmaceutical settings.

In this role, Tomandl leads the IU School of Medicine Quality Assurance organization and provides quality support to programs and operations across IU, including Cell and Gene Therapy Manufacturing, the Gene Therapy Testing Laboratory, the IU Genetics Biobank, the Laboratory Animal Resource Center, the Biospecimen Management Core and the Clinical Research Center.

Tomandl also provides strategic quality leadership for broader initiatives, including the Quality and Compliance Workstream of the IU Health Clinical Research Council and works with the Indiana Clinical and Translational Sciences Institute

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