Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Work in Progress

Streamlining Compliance: Implementing Advarra eReg for Clinical Trial Efficiency

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1. Background

Advarra eReg is an electronic regulatory binder system designed to streamline and digitize the management of regulatory documents that are essential for compliance in clinical trials. Instead of using physical binders to store and manage these documents, Advarra eReg allows research teams to store, organize, and access documents electronically thus improving efficiency, reducing the risk of human error, ensuring compliance with regulatory standards, and providing easy tracking and auditing of documents during and after the clinical trial.

In 2024 the Clinical Trials Office (CTO) Advanced Project Manager, Regulatory Manager, and Education and Quality Assurance Manager formed the CTO eReg Implementation Team, tasked with rolling out eReg to CTO staff for management of 338 clinical trials. By going digital, the CTO hopes to enhance the speed and accuracy of regulatory document management while making it easier for teams to collaborate.

2. Goals

- Create standardized templates for electronic regulatory binders based on trial sponsor type.
- Create profiles and electronic credentials for all CTO staff and physicians.
- Create a tiered system for moving studies into the eReg system based on study approval, active subjects, and monitoring status.
- Create training, guidance, and standard operating procedures (SOPs) for each step of the eReg process.

3. Solutions and Methods

- CTO eReg Implementation Team met with Indiana University (IU) Office of Clinical Research (OCR) team to build custom regulatory templates for sponsored, investigator-initiated, cooperative group, or non-interventional trials.
- Staff and physicians were given instructions for creating accounts and electronic credentials were uploaded for all staff.
- Studies were divided based on newly Scientific Review Committee (SRC)/Institutional Review Board (IRB) approved, studies with active subjects (including follow-up), and studies that continue to have monitoring visits.
- Training sessions are held monthly as project managers have studies move into one of the above categories. Lessons are divided by topics and focus on Master Delegation of Authority (MDOA), electronic signatures, organizing folders, and monitoring visits.

4. Outcomes

The CTO eReg Implementation Team started with the goal of having 100 percent of newly SRC-approved studies being built in eReg and all staff and physicians to have accounts beginning January 1, 2025. To date, 17 studies have been built in the system. All 154 CTO staff and 49 of 138 supported physicians have created accounts with linked credentials. With the support of OCR, four regulatory templates were

created to enable a customized electronic binder dependent on trial type. Training sessions, guidance documents, and SOPs are ongoing.

5. Lessons Learned and Future Directions:

- Input from various stakeholders, including system administrators, managers, subject matter experts and end users, was necessary to identify potential issues and pitfalls.
- Experimentation in the live production environment was the only true way to test some aspects of the system.
- Smaller, focused trainings targeted to specific users has been helpful in rolling out role specific aspects of the eReg platform.
- Utilizing the strategy of targeted training as new studies are opened, we plan to have eReg fully implemented by the end of 2025.

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