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The Road to Paperless: a Look Inside Our Journey to Full Implementation of Advarra's Suite of Research Systems

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1. Background

The Indiana University Melvin and Bren Simon Comprehensive Cancer Center (IUSCCC) clinical trials office (CTO) has historically operated on a system of fully paper subject research charts to supplement the electronic medical record (EMR). The CTO faces multi-faceted challenges to managing data for trials: operational staff remain hybrid after the pandemic with flexible working arrangements becoming the norm, the IUSCCC's footprint continues to expand statewide to better reach our catchment area, and the IUSCCC health partner hospital is preparing for the move to a new facility that will place staff in multiple different locations without ideal options for transporting source documents between locations.

2. Goals

- Roll out a paperless process for regulatory documents
- Roll out a paperless process for subject source documentation
- Improve data accuracy and data entry timelines

3. Solutions and Methods

- Implement Advarra eReg + eConsent
- Implement Advarra eDC + eSource
- Integrate Advarra eSource with Sponsor EDC

4. Outcomes

Advarra eReg implementation began in July 2024 and continues to date, with approximately 90% of active trials built in eReg. Physicians, external departments, and staff are now required to complete signoffs in eReg . Additionally, the CTO requires sponsors and CROs to schedule monitor visits for regulatory document retrieval. This has reduced some administrative burden on staff. Advarra eConsent is currently in pilot phase of implementation with multiple patients consented electronically. Advarra EDC is also in the pilot stage, with one protocol moving forward, and others identified.

5. Lessons Learned and Future Directions

While we are on track for eReg study build and use with IRB-approved documents, operational staff adoption of the platform is mixed due to workload, hesitation to embrace new systems, and struggles with clinician compliance. After exploring a competitive product, the CTO pivoted to Advarra's eConsent module. Although the eConsent pilot has just begun, prior experience will allow plans to expand rapidly.

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eSource is still in the planning stage, and the CTO plans to implement alongside Advarra rollout. Resource support continues to be a challenge moving forward.

Figure 1