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

Implementation of Advarra eRegulatory

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1. Background

In 2021, the Rogel Cancer Center's Oncology Clinical Trials Support Unit (O-CTSU) began implementation of Advarra's eRegulatory (eReg) 21 CFR Part 11-compliant application. Prior to eReg, the O-CTSU maintained an online system to electronically manage and store essential regulatory documents. eReg provided a platform that would track document owners and expiration dates, route documents for signature, maintain an electronic delegation of authority (DoA) log, provide direct access of the regulatory binder to study sponsor monitors, and allow system integration with the existing Advarra OnCore Clinical Trials Management System already utilized by the University of Michigan (U-M). O-CTSU Regulatory team members provided tremendous effort into working diligently with U-M's Health Information Technology & Services (HITS) eReg team and other applicable institutional partners to define business and regulatory requirements and standardize workflows to ensure a successful eReg launch and implementation.

2. Goals

Evaluate the effort to migrate regulatory binders and all clinical trial study team members into eReg.

3. Solutions and Methods

Using a web-based research effort tracking application (RETA), we can determine the effort spent over a standard time frame in a research specific task. Prior to the launch of eReg, a specific task was added to track the team efforts going towards eReg implementation. Efforts were tracked across three major phases:

- About 20 staff and 2 interns manually migrated study regulatory binders for over 300 trials. Completed in April 2023.
- About 5 staff uploaded organizational credentials (CAPs, CLIAs, IRB rosters, etc.) and study team credentials (about 740 individuals). Completed in February 2024.
- About 20 staff updated study teams in OnCore to match DoA logs (completed in June 2024 for 420 studies) and 2 staff began onboarding about 740 individuals to eReg accounts (ongoing work, last effort data collected October 2024).

4. Outcomes

eReg effort from October 13, 2021, to April 12, 2023, totaled 2,516 hours. In terms of 8-hour days, this equals 314 days. As there were 360 workdays available in that period (excluding only weekends and holidays), the effort needed to fully migrate all studies into eReg was approximately 87 percent of one full time equivalent (FTE).

Effort from April 12, 2023, to February 09, 2024, totaled 1,014 hours or 127 days. As there were 203 workdays in that period, the effort needed was approximately 62 percent of one FTE.

Effort from February 09, 2024, to October 22, 2024, totaled 1,151 hours or 144 days. As there were 173 workdays in that period, the effort needed was approximately 83 percent of one FTE.

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5. Learned and Future Directions

Implementation is ongoing with the expectation of additional phases including:

- Continue onboarding the remaining study team members with active eReg accounts and sign off on electronic DoA roles and tasks (75% of O-CTSU staff is complete, 25% of non-OCTSU staff is complete).
- Using the staff listed in OnCore, import study team members into eReg for each study.
- Provision external monitors / auditors direct review access in eReg (currently utilizing a workflow outside of eReg).
- Start to implement the DoA capabilities and electronic signature capabilities within eReg.