Implementation of Advarra eReg

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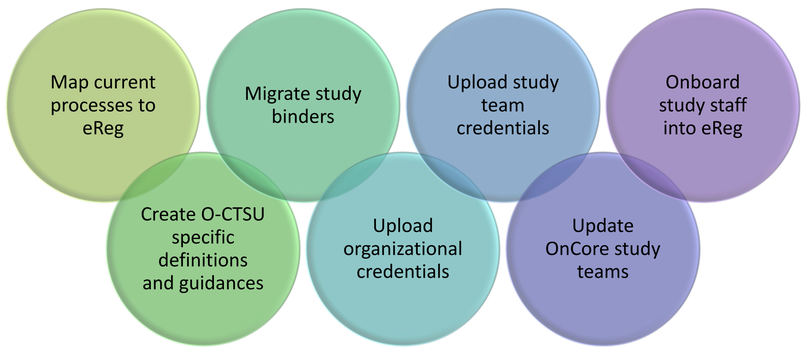
Background

In 2021, the University of Michigan 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 collaborated 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. O-CTSU Regulatory team members also utilized working groups to create processes and guidance documents specific to O-CTSU workflows.

With various functionalities available in eReg, we narrowed the initial scope of eReg implementation to initially focus on:

- Migrating study binders into the eReg system
- Uploading organizational credentials (CAPs, CLIAs, IRB rosters, etc.)
- Uploading study team credentials (CVs, licenses, training certificates, etc.)
- Onboarding applicable staff into eReg (account creation, activation, signing off on tasks for DoA logs, etc.)



Goal

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

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. This phase was completed in April 2023.
- About 5 staff uploaded organizational credentials and study team credentials (about 740 individuals). This phase was completed in February 2024.
- About 20 staff updated study teams in OnCore to match DoA logs. This phase was completed in June 2024 for 420 studies.
- About 2 staff began onboarding around 740 individuals to eReg accounts. This phase is ongoing, with the last effort data collected in October 2024.

Outcomes

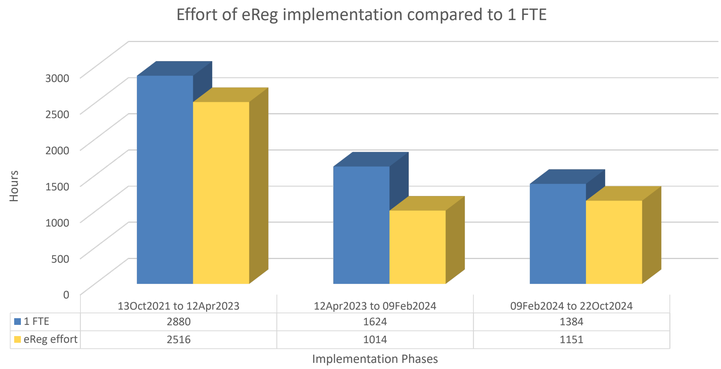
Effort to implement eReg can be divided into 3 general phases. While there was an overlap in tasks between these phases, the phases generally correspond to 1) implementation preparation (processes, guidances, etc.) and study binder migration; 2) uploading organizational and study team credentials; and 3) updating OnCore and onboarding staff into eReg.

Phase 1: eReg effort from 13Oct2021 to 12Apr2023 totaled 2516 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 prepare for migration and to fully migrate all studies into eReg was approximately 87% of 1 FTE.

Phase 2: effort from 12Apr2023 to 09Feb2024 totaled 1014 hours or 127 days. As there were 203 workdays in that period, the effort needed was approximately 62% of 1 FTE.

Phase 3: effort from 09Feb2024 to 22Oct2024 totaled 1151 hours or 144 days. As there were 173 workdays in that period, the effort needed was approximately 83% of 1 FTE.

Outcomes Cont.



Discussion

While there are many benefits to using a single program to streamline various procedures (such as study binder management, credential filing, delegation logs, and monitoring), it does take dedicated work up front to transition to a new process. It is not simply a 1:1 migration from one application to another. It took many hours of working out how our old processes map to the new eReg application, devising definitions for work (e.g., what to use for standardized dates, etc.), followed by the actual implementation. Furthermore, we found that some steps were interconnected hence the decision focus implementation on individual functions instead of trying to implement all aspects at once.

We also made the decision to migrate a study's entire history into eReg. In other words, we did not pick a date and only use eReg for future filings. Rather, for studies migrating into eReg, we transferred the entire study binder and related credentials into eReg to have one central regulatory binder source. While this did increase the upfront effort in terms of migrating study binders and credentials into eReg, it streamlines and simplifies the regulatory filing processes for the remainder of an individual study's life cycle.

Future Directions

In the future, we expect to implement additional aspects of eReg including:

- Continue onboarding the remaining study team members with active eReg accounts and sign off on electronic DoA roles and tasks (approximately 75% of O-CTSU staff is complete, 25% of non-OCTSU staff is complete).
- Using the staff listed in OnCore (completed in a prior phase), 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.

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