The Evolution of IRB Submissions – Streamlining IRB Amendment Submission Workflows for Local Implementation Utilizing Oncore

Rashad Perry, BS, CCRP; Beth Scanlan, MAP, CCRP; Matthew Kovak, MS, CCRP; Aaron Holley, BS, CCRP
Cancer Clinical Trials Office, Winthrop P. Rockefeller Cancer Institute,
University of Arkansas for Medical Sciences

Background

Institutional Review Board (IRB) submissions have always been a complex challenge for the Clinical Trials Office (CTO), involving a linear IRB submission system requiring collaboration with multiple campus teams and consistent communication between sponsors and local staff. As a result, these linear workflows led to bottleneck submission timepoints, inconsistent documentation, delayed implementation, unclear re-consent communication, and audit vulnerabilities.

Goals

- Reduce regulatory implementation timelines.
- Ensure regulatory compliance by enrolling subjects according to the most current local and external IRB-approved protocols.
- Maximize synchronization between regulatory approval and operational implementation
- Create a reproducible, auditable workflow for IRB protocol amendments

Methods

With the introduction of Oncore, CTO regulatory staff were given the capability to decentralize protocol related document submissions for IRB review from their associated financial and clinical aspects.

Regulatory Specialists (RS) are now able to upload all documents associated with an amendment while simultaneously notifying and allowing financial, pharmacy and EPIC/Beacon staff to review individual aspects of the trial without delaying submissions. In doing so, the IRB can complete an initial review while financial staff finalize budget negotiations, and a final treatment plan is built.

After IRB review, the RS will complete all contingency requests and gain approval. At the time of local implementation, clinical staff are notified of the approved documentation as well as the status of the treatment plan to ensure all subjects are enrolled with the appropriate treatment plan in place.

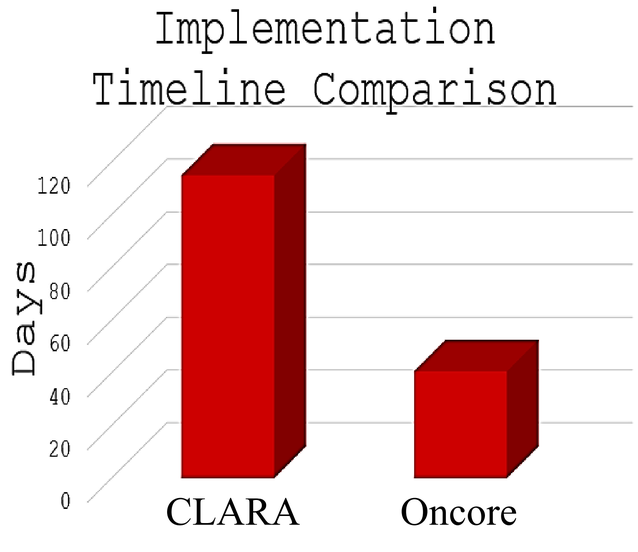
Previous Methods
- Linear system
- IRB documents, financial and clinical aspects required prior to official submission to IRB.

Decentralized Processes
- Financial revisions
- Pharmacy review
- Qualisty assurance check
- Treatment plan modification

Implemented Process
- Regulatory documents implementation shortened drastically
- Beacon treatment plan and billing updates made independently

Outcomes

- ☑ Improved clinical staff performance in treatment plan development
- ☑ Increased efficiency in implementation timelines
- ☑ Increased collaboration and understanding of clinical and regulatory logistics leading to more efficient efforts and reduced delays.



Future Directions

- Potential for dual submission capability for added regulatory and budget development flexibility
- Clarifications regarding internal trigger points leading to more effective communication
- Further workflow development to outline overall processes and automate notification system.

Contact

Rashad Perry, CCRP
Regulatory Specialist III
Cancer Clinical Trials Office
University of Arkansas for Medical Sciences
4301 West Markham, Slot 724
Little Rock, AR 72205
(501) 686-8274;
Rperry3@uams.edu