Category: Quality Assurance and Remote Monitoring and Auditing – Completed project

Creating a Tool for Managing and Assessing Enrollment Holds Due to Safety, Risk Updates From Investigator Brochures, Dear Investigator Letters, and Package Inserts

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1. Background

Through collaboration and correspondence with IUSCCC CTO, OHRP, and Indiana University HRPP Director, a SOP was implemented for assessing investigator drug brochures (IBs), Dear Investigator Letters (DIL), and Package Inserts for safety/risk updates and enrollment holds in accordance with federal regulations. Additionally, Indiana University has an internal policy stating failure to submit amendments which update risks, benefits, or procedures to the IRB within 60 days of receipt is considered reportable. Prior to 2022, the Clinical Trials Office (CTO) did not have a method for tracking newly released IBs, DILs, or Package Inserts that could result in risk updates or enrollment holds to active studies within the CTO to ensure regulatory compliance. Tracking and follow up with the sponsor was left to the study coordinator. Industry partners for investigator-initiated trials were not as timely with safety updates and the updates are shared a number of ways making it difficult to standardize the process. This resulted in several non-compliances due to missed or delinquent updates, particularly for investigator-initiated trials. We needed a solution to ensure regulatory compliance and quality assurance.

2. Goals

- Create a system for tracking new IBs, DILs, or Product Inserts
- Create a system of double-checks to link new IB/DIL/PI submissions to all investigator-initiated studies containing the same investigational product to avoid missing critical updates
- Provide automated notifications/reminders to study coordinators to gather PI assessment of new risks for ICF updates
- Formalize a process to permit a centralized review of progress on a given safety document and whether PI assessments were documented, and appropriate action carried out (e.g. informed consent revisions, site suspension, etc.)
- Calculate deadlines of when amendments should be submitted to the IRB

3. Solutions and Methods

- IT Development created an online portal to allow study coordinators to upload new risk-containing documents for review and assessment of informed consent updates.
- Link the portal to the IUSCCC CTO CTMS so investigator-initiated studies utilizing identical investigational products can be evaluated as soon as the first notification is released
- Create a CC-Wide SOP and Guidance Document to clearly outline the procedure for assessing risk updates and submission into the IB Portal

4. Outcomes

- The IB Portal has been active since early 2022, serving as both an electronic bookshelf and a project management console to ensure multiple teams and leaders are aware of progress around safety updates, PI assessment, and IRB submissions, as appropriate
- Documentation of PI and study team review and assessment of new IBs, DILs, and Package Inserts for study file

- Reportable events due to missing 60 -day deadline have declined

5. Lessons Learned and Future Directions

We learned that dissemination of information and corresponding documents varies depending on sponsor and CRO. However, once we learn of new safety information, we have a responsibility to share updates with our patients in a timely manner. We recognized with the volume of clinical trials that we conduct (some with the same investigational product), it was necessary to create a system of evaluation within the organization with built-in reminders and notifications to help staff stay on track.