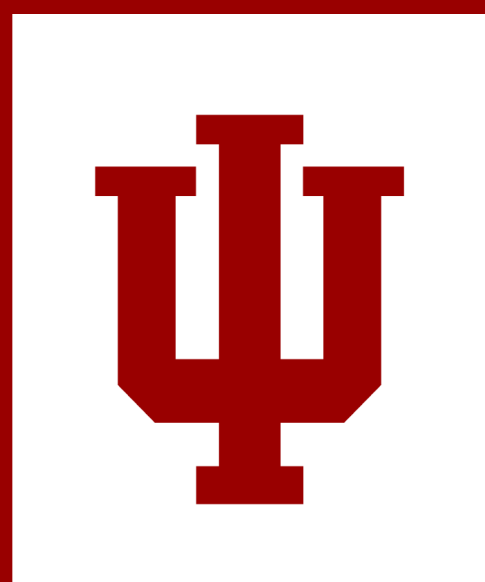


Creating a Tool for Managing and Assessing Enrollment Holds due to Safety, Risk Updates from Investigator Brochures, Dear Investigator Letters, and Package Inserts

Fyalon Kerr, CCRP; Vanessa Williams, CCRP; Amy Graf, RD, CCRC
 Indiana University Melvin and Bren Simon Comprehensive Cancer Center



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 noncompliances due to missed or delinquent updates, particularly for investigator-initiated trials. We needed a solution to ensure regulatory compliance and quality assurance.

Goals

1. Create a system for tracking new IBs, DILs, or Product Inserts
2. 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
3. Provide automated notifications/reminders to study coordinators to gather PI assessment of new risks for ICF updates
4. 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.)
5. Calculate deadlines of when amendments should be submitted to the IRB

Materials & 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.

Outcome

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.

Conclusions

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.

Protocol No.	PI	Current Status	Sponsor	Sponsor Type	Lead Site	Subjects on Treatment	Subjects on F/U	Date Received	Require consent update for new risks	Require consent update for procedures related to risk prevention	If consent update, sponsor forecast about release date	Submitted IB to SharePoint	IRB Deadline to submit new updated consent/ addendum	Date Suspension Request sent to Reg Team	Reg. Mgr. / Comp Off. Comments	Team Comments
★ CTO-IUSCCC-YYY	PI Name	OPEN TO ACCRUAL	Indiana University	Institutional		3	1	04/01/2024	N	N		Y	05/31/2024			