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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**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.