Centralized Investigational New Drug (IND) Safety Report Management Within an eBinder System: A Pilot Program

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1. Background
Management of IND Safety Reports (safety reports) can represent a burden for study teams, from completing timely review and escalation to the principal investigator (PI), to tracking and reporting for financial invoicing. In 2022, our central regulatory team completed a pilot using our eBinder system to permit more efficient processing of safety reports.

2. Goals
1. Standardize a method of receipt for reports, limiting portal access points for study staff
2. Streamline report management workflows to allow more efficient invoice processing
3. Demonstrate increased efficiency to justify the creation of dedicated report management roles within regulatory teams

3. Solutions and Methods
Our pilot involved one disease team with 23 active industry trials. We estimated management of 500-1,000 reports annually, with an expected average billable rate to sponsor of $75 per report. For efficiency, our team requested emailed safety reports, or direct links from sponsors to access, download, and upload reports into the study eBinder instead of accessing individual sponsor portals. Within the eBinder system, the following process was followed:

- Reports were tagged as "safety report"
- Reports were reviewed according to IRB reporting criteria
- Staff sign as "acknowledged" if the report did not meet reporting criteria
- Staff sign as "reviewed" if the report met escalation criteria to the PI
- A task was assigned to the PI to determine if the report met IRB reporting criteria
- Confirmed PI review and task completion as signed "approved" by the PI

4. Outcomes
1. We were unable to completely move away from accessing sponsor portals, as 10 of the 23 trials required accessing the sponsor portal; however, we limited access to delegated regulatory coordinators only, reducing the burden to study coordinators and PIs
2. By shifting the management of reports into our eBinder system, we streamlined documentation reviews by transitioning from paper tracking systems which also permitted immediate financial reporting
3. Across the 23 trials, 2,741 reports were received, exceeding the expected volumes; the use of our eBinder system, as well as dedicated staff, enables us to support the increase in volume without additional resources

5. Lessons Learned and Future Directions

Two key lessons: we had a much higher volume of reports than predicted, straining staff resources; however, with previously planned staff increases, we balanced this work across an additional centralized resource.

One goal of the pilot was to demonstrate a level of efficiency to justify the centralization of this task across regulatory teams. With these results plus report volumes within other disease teams, we can justify centralizing this effort and removing the burden from disease teams.