Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Work in Progress

Refining IRB Submissions: Reducing Returns and Accelerating Approval Timelines

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1. Background
From January to April 2023, the regulatory team experienced an average of 3 returns per Institutional Review Board (IRB) Initial Application submission, resulting in an extended timeline of 70 days from submission to full IRB approval. These delays significantly impacted our ability to meet the 90-day site activation goal.

2. Goals
Improve the quality of IRB Initial Applications. One or less return during initial review and decrease time to approval.

3. Solutions and Methods
Addressing the quality of IRB applications required a significant effort from our regulatory management team. We conducted a review of previous submissions to identify reoccurring issues, including incorrect document uploads, informed consent form (ICF) edits, missing ancillary approvals, insufficient IND letters and not addressing all IRB stipulations.

To mitigate these issues, we implemented a second check system from May 2023 to December 2023, where all initial submissions and responses were reviewed by a supervisor before submitting. This process ensured accuracy and compliance, reducing the likelihood of returns.

In 2024, we consolidated the identified trends/barriers, updated guidance documents and provided ongoing education to the team. We phased the second check system out in January 2024, except for specific cases: new Research Coordinators (1st/2nd application) and Research Coordinators who have not submitted an initial application in 6+ months.

4. Outcomes
From May 2023 to December 2023, with the second check implemented, we cut our returns from 3 to 1.5 returns per submission and cut our submission to approval time from 70 days to 41 days.

For 2024, without the second check but with enhanced guidance, our average returns were 2 (1.9) returns per initial application and stayed steady at 41 days from submission to approval.

5. Lessons Learned and Future Directions
We learned that many of the errors we saw on initial applications were consistent across all disease teams. While our interventions have led to measurable progress, there is still work to be done to further reduce returns and time to approval.

Future direction- continue to improve our IRB approval time by focusing on the quality of our submissions, so we can achieve our goal of 1 or less IRB return within 21 days. In 2024 20 percent of our submissions had only 1 return and 9 percent of our submissions were approved within 21 days. We will continue to track our progress throughout 2025 and look for opportunities for efficiencies.