Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Completed Project

Enhancing Efficiency with a Comprehensive Site Information Packet

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1. Background
In 2023, our team dedicated over 1,600 hours to pre-site activities, such as completing feasibility questionnaires. These forms contain redundant site-specific information, requiring significant effort and time from the team. Some questions were outside our ability to answer or did not directly impact our capacity to accrue patients. This inefficiency highlights an opportunity to streamline the process to reduce redundancy and refocus valuable time on tasks that more effectively support trial activation and patient care.

2. Goals
Create efficiency by eliminating redundant work on sponsor feasibility questionnaires.

3. Solutions and Methods
In 2023, we initiated the development of a comprehensive site information packet to address the redundancy and inefficiencies of sponsor feasibility questionnaires. Using our existing sponsor questionnaire and reviewing recent sponsor feasibility forms, we created a packet that consolidated frequently asked questions about our site, along with a source packet detailing where to locate specific information. Additionally, we conducted a total overhaul to our sponsor questionnaire focusing on key information required for regulatory submissions.

We implemented a streamlined process: when considering a study, we send sponsors a standard email with both the information packet and our questionnaire. This standard communication outlines our policy of not filling out feasibility questionnaires, aiming to expedite site selection and activation. If sponsors have additional questions not addressed in our packet, we request they return these via email. We also clarify that we do not provide specific patient population numbers, as these figures do not impact our ability to enroll patients. Instead, we offer broad disease category numbers and an anticipated enrollment (when requested).

4. Outcomes
In 2024, we saw a 40.5 percent reduction in time spent on pre-pending activities by our research coordinators. Overall, this approach was well-received by our pharmaceutical sponsors and CROs. We have reduced time spent on questionnaires and allowed our team to focus on tasks that directly support trial activation.

5. Lessons Learned and Future Directions
This change in process has ultimately been a positive one for our teams. We will continue to monitor time spent on pre-pending activities and evaluate our information packet and questionnaire quarterly for improvements/updates. We hope to continue to see a decrease in time spent on pre-pending activities.