Category: Trial Start-up and Activation – Work in Progress

Technology and Centralization in Early Study Start-up Activities

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1. Background

Creating a successful and balanced clinical trial portfolio is a multifaceted process that begins with managing incoming new study opportunities. At Huntsman Cancer Institute (HCI) our clinical trials office (CTO) received > 400 new study invitations in 2021. In order to maintain and improve the quality of the invitations—as well as our relationships with sponsor partners—tracking early in the study lifecycle, maintaining streamlined processes, and communicating with sponsors is essential. Managing new study invitations and the process afterwards had been additional work for our trial disease group program managers (PM). In order to better prioritize this important aspect of a trial, we created the new position of trial activation administrator (AA).

2. Goals

The goals of the position: centralize sponsor communications, homogenize early study start-up portion of our study lifecycle, reduce burden of new-study work on the PMs, and solidify ownership of the early study start-up process.

3. Solutions and Methods

In July 2020, we hired this new position. The AA assumed the early start-up work of one disease group at a time, progressively incorporating all groups. An Access database with specific database views for our disease teams was designed and built by the AA for tracking trials, who also helped create tools and templates for early study start-up. After all disease groups were incorporated into the workflow, the AA assumed responsibility over new CDA requests.

4. Outcomes

- AA manages and routes all new study inquires allowing for consistency in review process across groups; this has created a high level of efficiency for start-up activities and reduced resources expended across PMs
- AA interfaces with all incoming trial sponsors which removes the need for PMs to answer sponsor questions and status inquiries
- Automated front-end reports for each team allow our PMs to stay informed in real time about studies' statuses without being actively involved in all steps
- Semi-automated charts/reports run from database information allow our leadership to keep informed about the distribution and number trials in start-up
- Visual aids related to start-up milestones increase sponsors' understanding of our start-up process
- Templates were created (EMR/source data, contact information) reducing the number of sponsor forms that need to be completed during start-up
- Virtual tour website created, allowing our PSVs to remain remote, reducing the burden of holding PSVs
- Observed 25 percent increase in trials activated in 2021 (v. 2020)

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5. Lessons Learned and Future Directions

The volume of incoming trials would make this position nearly impossible without effective use of technology. Additionally, having the AA assume all tasks related to early study start-up was not entirely feasible due to the number of meetings that the AA needed to attend. As PMs already were attending these meetings, we divided the work and minimized overlap between the PMs and AA. Also, our increased new trial volume has highlighted a need for better trial vetting strategies at an early stage. Going forward, we hope to create more user tools for communicating information to teams and sponsors. In addition, we hope to use technology and tools/templates to automate or improve the workflow of additional parts of this process.