Technology and Centralization in Early Study Startup Activities

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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).

METRICS/GOALS

- Centralize sponsor communications.
- Homogenize early study startup portion of our study lifecycle.
- Reduce burden of new-study work on PMs.
- Solidify ownership of the early study startup process.

METHODS

- July 2020, we hired this new position.
- AA assumed the early startup 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 for tracking trials.
- Tools and templates for early study startup were created.
- After all disease groups were incorporated into the workflow, the AA assumed responsibility over new CDA requests.

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OUTCOMES

- AA manages and routes all new study inquires allowing for consistency in early review process across groups (Figure 2, process outline).
- 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 startup.
- Visual aids related to startup milestones increase sponsors' understanding of our startup process.
- Templates were created (EMR/Source Data, Contact Information) reducing the number of sponsor forms that need to be completed during startup.
- Virtual tour website created, allowing our PSVs to remain remote, reducing the burden of holding PSVs.
- 25% increase in trials activated in 2021 (v. 2020) (Figure 1).

Figure 1

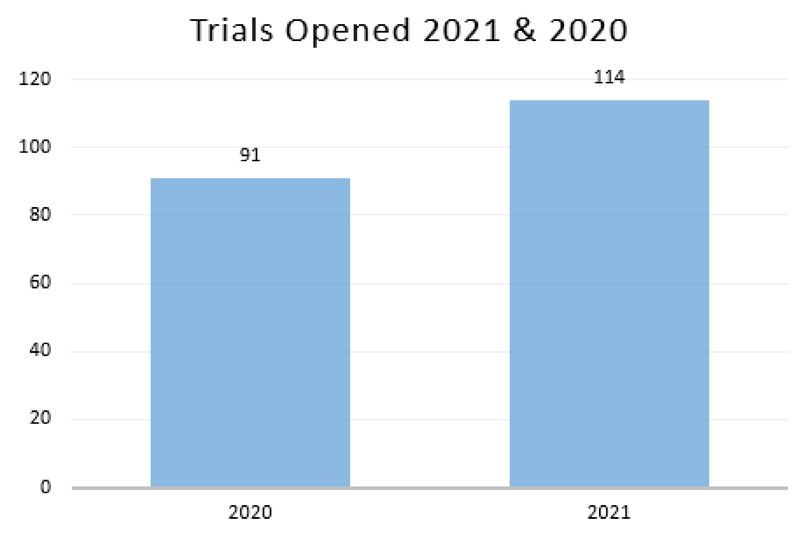
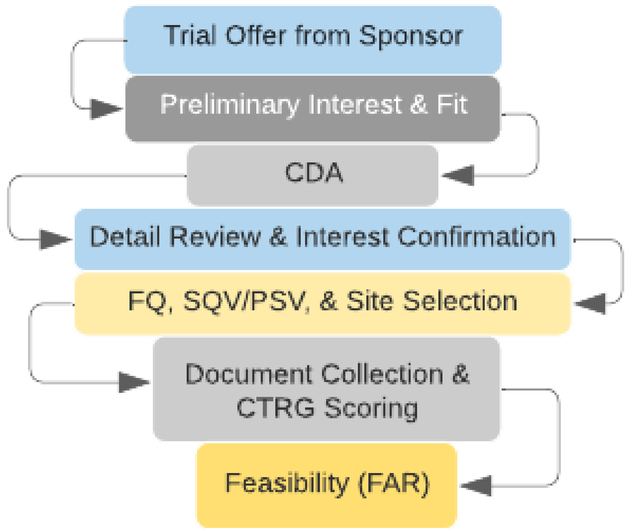


Figure 2



LESSONS & FUTURE PLANS

The volume of incoming trials would make this position nearly impossible without the effective use of technology. Additionally, having the AA assume all tasks related to early study startup 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.

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