Category: Investigator Initiated Trials – Work in Progress

Investigator Initiated Trial Activation: Increasing Collaboration with a Protocol Navigator

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1. Background

The challenges of timely writing, activation, and implementation of quality therapeutic oncology based investigator-initiated trials (IITs) has become a growing issue at Huntsman Cancer Institute (HCI) and nationally. Recent studies show activation of clinical trials is no faster today than 20 years ago.[1-2] Protocol complexity contributes to these delayed timelines; however, fragmented, siloed operating processes also play a role[1-3].

At HCI, all new interventional treatment IITs go through a multistep institutional review process involving numerous groups (concept review, budgets, contracts, feasibility, scientific review, FDA, and more) before Institutional Review Board (IRB) submission. The review process involves many departments which have varying priorities, both within and outside HCI. As a result, the average time from protocol receipt by the CTO to trial activation was 215 days in 2017. The slow timelines were negatively affecting the quality of our research. New drug combinations were being approved sooner than we could activate institutional trials.

As a National Cancer Institute (NCI) Designated Comprehensive Cancer Center, enhancing clinical research by initiating and implementing scientifically relevant IITs is a strategic priority integral to our mission.

2. Goals

Our goal was to streamline the HCI administrative processes associated with protocol development to facilitate timely activation of IITs, while maintaining compliance with good clinical practice guidelines and federal regulations. In review of our data, we identified areas of the trial startup process where increased collaborations and coordination could decrease timelines. We reviewed the recent 2017 National Comprehensive Cancer Network (NCCN) benchmarking survey, and identified a set of activation goals based on historical data and internal expectations.

3. Solutions and Methods

We developed a protocol navigator position to work closely with departments and teams with the slowest timelines (for example, budgets, contracts, investigator engagement, regulatory approvals). This person would provide project management support and facilitate start-up activities for therapeutic oncology-based IITs. A protocol navigator was hired in June 2018. This position uses metrics to set milestones and track overall IIT development progress. The protocol navigator ensures the various areas of the start-up approval process move forward in parallel. If delays occur in one area—for example, contracts, the protocol navigator can show investigators how this delay affects the bottom line for protocol activation. The increased communication with study teams facilitates appropriate intervention when necessary to speed up timelines.

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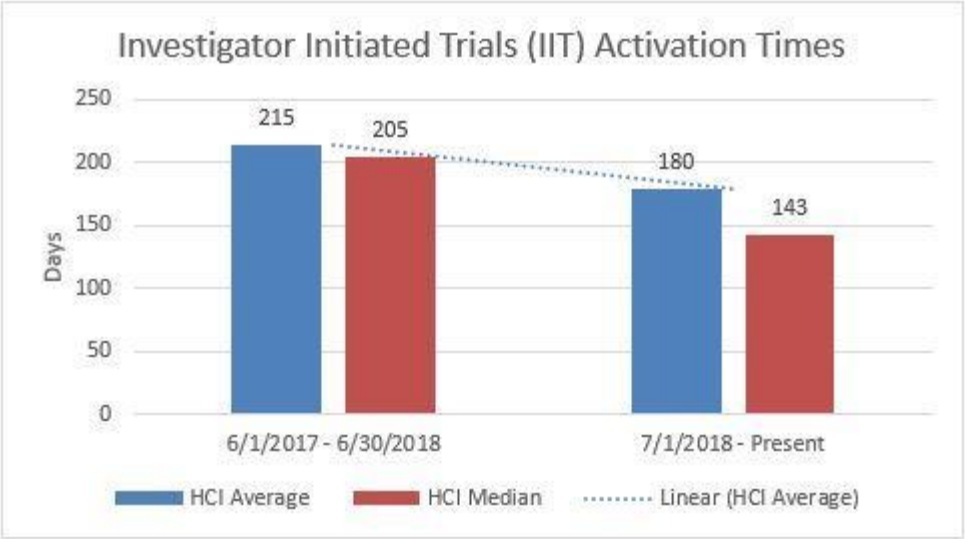
4. Outcomes and Future Directions



We have not yet gathered enough data to show whether the protocol navigator efforts have yielded statistically significant change. However, anecdotal review of HCI IIT activation timelines shows a reduction in the time for study start-ups. With continued collaboration and communication, we believe these times will continue to decrease.

Although we have seen a decrease in our protocol activation timelines, we have noticed an increase in the number of protocol amendments. Our future efforts will be geared towards continuing to improve IIT protocol activation timelines, while taking steps to improve the quality of the initial protocol.

Full references available

1. Watters, Julie, (November 2017) Transforming the activation of clinical trials.
2. Mohs, Richard, (July 2018) Innovations in clinical trials.
3. Getz, Kenneth, (May 2017) Trends in clinical trial design complexity.