

Investigator-Initiated Trial Activation: Increasing Collaboration with a Protocol Navigator

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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. Protocol complexity contributes to these delayed timelines; however, fragmented, siloed operating processes also play a role.

METHOD

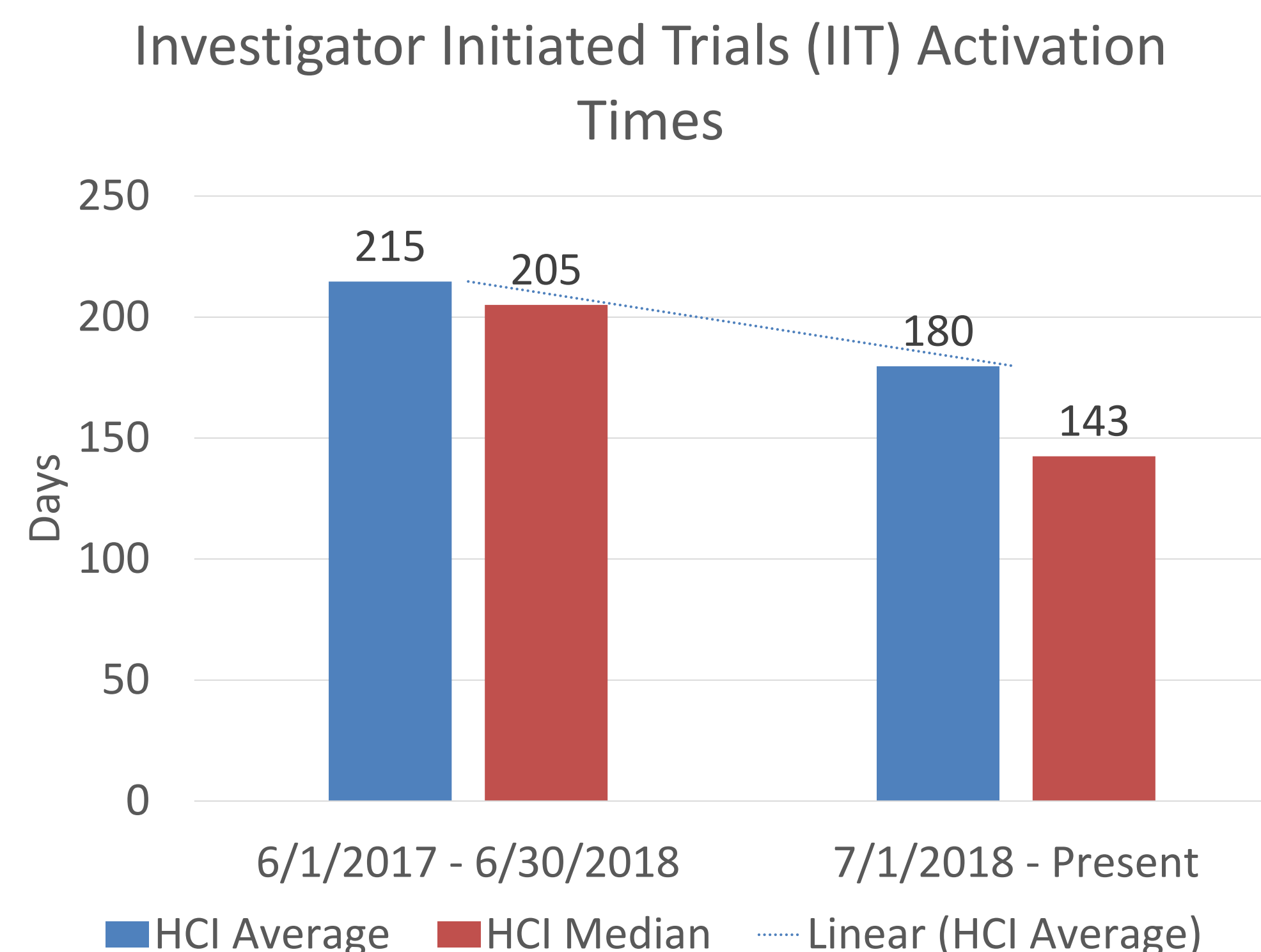
Streamline the HCI administrative processes associated with protocol development and start-up via a dedicated protocol navigator:

- Ensure approvals move forward in parallel
- Start contract/budget negotiations sooner
- Increase communication between groups (budgets, contracts, investigator, pharmaceutical companies, regulatory approvals)
- Use metrics to set milestones and track overall IIT development progress (Microsoft Project)

RESULTS

Protocol navigator resulted in these changes:

- Overall **decrease in IIT activation** timelines
- Areas where we saw the **biggest impact**:
 - PRMC submit to PRMC approval
 - IRB approval to study activation
- Facilitated **appropriate intervention** when necessary to speed up timelines
- Clinical investigator **satisfaction** with regulatory start-up process



CONCLUSIONS

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. 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.

FUTURE PLANS

- Create an investigator-initiated-trial physician handbook describing the process for activation
- Track the number of IIT protocol amendment and timelines for amendments

References

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2. Mohs, R, et al. (July 2018) Innovations in clinical trials: improving study start up (SSU). *Alzheimer's & Dementia: The Journal of the Alzheimer's Association*, Volume 14, Issue 7, P819.
3. Getz, K, et al. (May 2017) Trends in clinical trial design complexity. *Nature Reviews Drug Discovery*, Volume 16, P307.