Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Work in Progress

Clinical Trial Operation Turbo Speed - Progress & Opportunities to Decrease Study Start-up Timelines

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1. Background
Efficient start-up in clinical trials is critical to execution, innovation, and patient care. Survey results of 61 U.S. cancer centers in 2018 reported a median trial activation timeline of 167 days with a range of up to 327 days. In short, study timeline activation is a complex and broad problem. In 2020 the University of Minnesota Masonic Cancer Center Clinical Trials Office (CTO) started an interdisciplinary process improvement initiative to improve study start-up timelines.

2. Goals
The current study evaluated ongoing efforts to improve start-up timelines to identify successes and opportunities for further enhancements.

3. Solutions and Methods
New project management software has been implemented and continuously evolves to adapt to meeting timeline goals. Specific fast-track study start-up benchmarks were established, and designated study start-up clinical teams were formed. Best practices, opportunities for collaborative change, and metrics to evaluate success were investigated. Data was exported from OnCore Clinical Trial Management Software (CTMS) and analyzed in Excel.

4. Outcomes
Median study start-up times decreased by over 100 days from 2022 to 2024. In 2022, the average overall start-up time was 376 (+/- 43) days, which decreased to 250 (+/-21) days in 2024. When holds were included in the timeline, where delays caused by external factors were removed, start-up was reduced from 308 (+/-34) days in 2022 to 123 (+/-9) days in 2024. Both changes in timeline length were significant (Actual timeline, 2022-2024, $t(35)$ $p<.005$, hold timeline, 2021-2024, $t(35)$ $p<0.001$, independent samples, one-tailed t-test). Follow-up analysis investigated contributing factors to this result, such as comparing start-up length for studies opened on a fast-track (90 day) compared to standard (120 day) timeline. The gains in improved timeline efficiency translated to enhanced clinical performance, as overall patient accruals increased by 20 percent from 300-260. Additionally, the number of days from open to accrual to first patient consented decreased from 2022 to 2023, suggesting further gains in clinical performance.

5. Lessons Learned and Future Directions
Systems-level strategic planning data-driven tools, like Smartsheet, are critical in facilitating interdisciplinary cooperation. Best practices in efficient workplace behaviors will continue to be developed and evaluated to further improve clinical trial start-up timelines.

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Figure

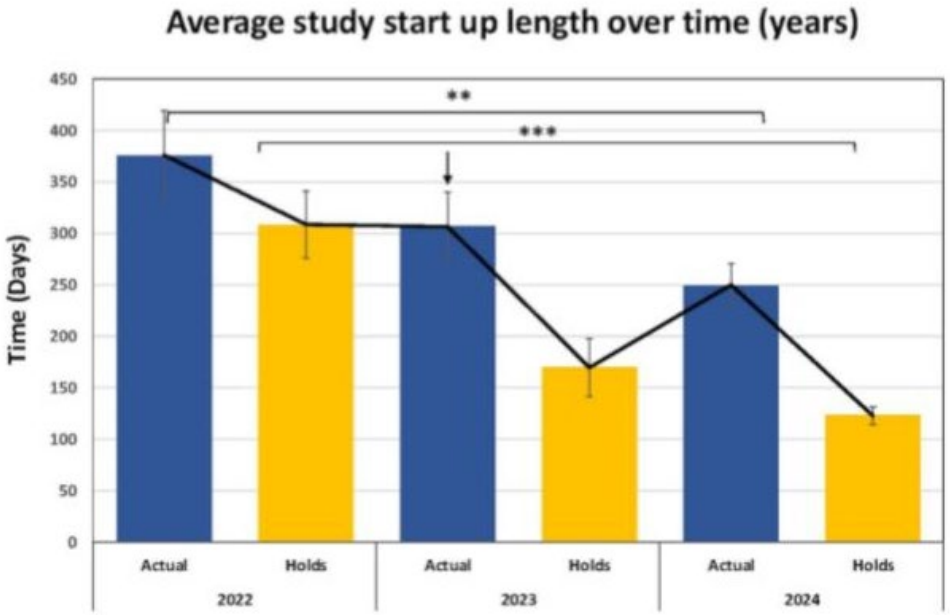

Fig. 1. Comparison of actual start up time line, with timeline that implements holds (doesn't include delays outside the control of the cancer center, i.e sponsor initiated or budget and contracting).
Error bars = SE, Arrow marks implementation of SmartSheet
2022 vs 2024 (Actual) ** P<.005
2022 vs 2024 (Holds) *** P= <.001 (1e-10)