Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Completed Project

Streamlining Clinical Trial Start-Up: Reducing Time to Open and Personnel Effort Through the TIME Trial Program

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1. Background
Time to Open (TTO) clinical trials is a key metric to ensure that patients receive timely access to investigational treatment options that they might not otherwise have. Our TTO goal for industry sponsored clinical trials is within 90 days. In June 2022, we began participating in the Tempus Integrated Molecular Evaluation (TIME) Trial Program, which streamlines start-up activities to more rapidly open sponsored clinical trials at pre-qualified sites. Through our partnership with Tempus, we anticipated being able to further reduce our TTO to bring more novel therapeutic options to our patients.

2. Goals
To reduce the TTO and personnel time spent on start-up activities for sponsored clinical trials by partnering with Tempus through the TIME Trial Program

3. Solutions and Methods
The TIME Trial Program utilizes a standardized contract, rate card, feasibility process, consent form, and a central Institutional Review Board (IRB) to reduce inefficiencies in the start-up process. Rather than activating trials with the expectation that we will have a sufficient patient population to enroll, the Just-In-Time (JIT) approach allows us to first identify a patient and then rapidly activate a trial that they are eligible for based on their diagnosis and/or biomarkers, ensuring that we are bringing the most relevant trials to our portfolio.

4. Outcomes
We have activated five studies through the TIME Trial Program that averaged a TTO of 47 days. Other sponsored trials opened from the onset of our participation in the TIME Trial Program from the beginning of Q3 2022 to Q4 2024 averaged a TTO of 228 days, marking a 79.4 percent reduction in TTO for TIME versus other sponsored trials. We also saw a 28 percent reduction in personnel effort with time spent on startup for TIME trials averaging 155.95 hours (76.85 clinical and 79.1 regulatory hours) versus 216.2 hours (98.87 clinical and 117.25 regulatory hours) for other sponsored trials.

5. Lessons Learned and Future Directions
The streamlined approach of the TIME Trial Program has helped to reduce redundant processes and improve efficiency in clinical trial initiation. We have been able to more rapidly bring relevant clinical trial options to our patients and have reduced the amount of staff time spent on start-up activities. As we continue to refine our internal processes, we can apply the insights gained from this partnership to other areas, helping to optimize the activation of sponsored trials beyond the TIME Trial Program.