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

FAST-TRACK PILOT PROGRAM

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1. Background

Efficient clinical trial activation is crucial for timely patient access to innovative therapies and maintaining a competitive research environment. However, activation timelines are often prolonged due to regulatory approvals, budget and contract negotiations, and administrative bottlenecks. To address these challenges, the Fast-Track Pilot Program was initiated to streamline activation for select studies while ensuring compliance and quality standards.

2. Goals

The Fast-Track initiative aims to activate clinical trials within 60-90 days from Protocol Review and Monitoring Committee (PRMC) submission. This is achieved through optimized workflows, parallel processing, streamlined communication tools, and enhanced stakeholder coordination. By identifying and mitigating common delays, the program accelerates the transition from site selection to patient enrollment.

3. Solutions and Methods

A pre-submission checklist ensures all regulatory documents and templates (e.g., final protocol, budget, contract templates, study manuals) are available in advance. Study teams must submit a complete regulatory packet before requesting Fast-Track review.

A scoring tool prioritizes studies based on alignment with Cancer Center goals. When multiple investigators apply for limited Fast-Track slots, the score sheet informs decision-making.

A dedicated Fast-Track team oversees and prioritizes activation. This includes enhanced internal stakeholder collaboration by engaging PRMC, Sponsored Programs Administration (SPA), Pharmacy, IRB, and other stakeholders to address protocol and budget-related questions early. Meeting timelines for PRMC submission and IRB review are established during this time.

Enhanced sponsor collaboration was established to set clear expectations for expedited document exchanges, reviews, and approvals. Sponsors must assure that there are no planned protocol amendments and commit to activation timelines, ensuring alignment with Fast-Track requirements.

A mechanism for milestone-based monitoring tracks key activation points to identify bottlenecks and drive continuous process improvements.

4. Outcomes

Since implementation, seven (including six industry-sponsored) studies have completed the Fast-Track process, achieving a median activation time of 84 calendar days, an improvement from the previous median of 147 calendar days in 2023 (and compared to 181 for industry-sponsored studies). This has positioned UTSW as the first site activated and first to enroll patients in several studies, significantly enhancing patient access to life-saving treatments.

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5. Learned and Future Directions

Active engagement from both the Contract Research Organization (CRO) and the funding sponsor is critical for timely activation. Delays have occurred when one party commits to Fast-Track without the other's awareness. To prevent setbacks, both must adhere to established timelines for informed consent form (ICF) and budget review. For investigator-initiated studies, FDA IND/IDE applications should be completed and approved before Fast-Track submission to avoid unnecessary delays. Additionally, Site Initiation Visits (SIVs) should be scheduled at least two weeks before the activation goal date to mitigate sponsor-related delays post-SIV.

Moving forward, the Study Fast-Track Activation Team will continue to expand with additional dedicated resources to increase volume and oversight. The program will aim to activate two Fast-Track studies per month, with one slot reserved for a Phase 1 study to accelerate early-phase research. This strategic approach will enhance efficiency, optimize resource allocation, and further streamline activation timelines, ensuring the continued advancement of high-priority clinical trials.

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