Category: Clinical Trial Operations (Trial Startup, Regulatory, Finance, Data Management, IITs) – Work in Progress

Expediting Start-up Timelines by Dedicating a Start-up Specific Project Manager for Early-Phase Research

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1. Background

The urgency for expedited study activation in Early Phase clinical trials is vital due to competitive slot allocation. Participating in Phase I research provides patients with novel treatments in settings where no approved options exist and gives them a sense of purpose in advancing cancer care for future generations. The diverse patient population at Sidney Kimmel Comprehensive Cancer Center at Jefferson (SKCCC) enhances the scientific value of research by ensuring representation of underserved groups. SKCCC Clinical Trials Office (CTO) Leadership identified competing priorities in the clinical Project Management role as one of the key drivers of extended study start-up timelines. SKCCC CTO leveraged these challenges by creating a study start-up (SSU) focused Project Manager (PM). This role ensures that trials aligned with our catchment area are prioritized for activation, reducing institutional burden while maximizing clinical impact.

2. Goals

- Create a start-up specific Project Management position.
- Develop collaborative interdepartmental relationships and improve study start-up processes to expedite time to activation.
- Reduce Early Phase Research study activation timelines to less than 90 days.

3. Solutions and Methods

SKCCC implemented a dedicated SSU PM focused exclusively on the Early Phase Research Operations (EPRO) team. This role facilitates interdepartmental collaboration through targeted meetings with Regulatory, Budgets, Contracts, and collaborators to resolve bottlenecks. Key methodologies include shadowing the Investigational Drug Service (IDS) to understand pharmacy resources and requirements and addressing concerns from nursing and clinical teams. The SSU PM serves as the sponsor liaison to streamline communication, track milestones, and reduce time to study activation. This position prioritizes preparation and response for institutional committee reviews, ensuring stakeholders' concerns are addressed. Activation metrics are tracked through Posit to compare real-time pipeline metrics with historical data.

4. Outcomes

A comparative analysis of studies submitted to the Protocol Feasibility Committee (PFC) between October–December 2024 and 2025 demonstrates the impact of the specialized SSU unit. The total median time from Multidisciplinary Disease Group approval to Site Initiation Visit (SIV) decreased from 190 days to 87 days, representing a 54 percent reduction. By significantly lessening these timelines, the

institution reduced the administrative resource burden and expanded the portfolio of treatment options. Furthermore, this specialization allowed clinical PMs to focus on study maintenance and patient-centered care and facilitated quicker availability of novel trials for patients. While these descriptive data points show marked improvements in efficiency and institutional health, formal statistical analysis will not be performed until additional data is available.

5. Lessons Learned and Future Directions

Innovation in the SSU process requires proactive engagement with key stakeholders. Open channels of communication lessen misinterpretation and accelerate troubleshooting during trial activation. Progress should never be assumed, and frequent updates must occur to maintain activation momentum.

Future efforts will focus on developing standardized processes to further streamline activation through integrated collaboration with sponsors and internally across clinical, regulatory, financial, pharmacy, and nursing teams. As the EPRO team grows, the SSU PM is integral in expediting activation timelines to accelerate clinical trial availability for the SKCCC patient population.