Category: Trial Start-up and Activation – Completed Project

Practical Benefits of Defining and Implementing Structured Intake and New Study Assignment in a Centralized Start-up Model

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1. Background

The Fred Hutchinson/University of Washington Cancer Consortium implemented a dedicated clinical trial start-up team to reduce historically long start-up times and to improve partnerships with industry sponsors. Start-up timelines were protracted and unpredictable in part due to incomplete and inconsistent new study submissions that were managed by research group start-up teams. Minimum submission requirements were defined for Consortium reviews but variability across sponsor documents and study team vetting of sponsor documents led to downstream delays in the start-up process.

2. Goals

The primary goal of the central start-up team was to achieve reduced start-up times from a median of 204 to 100 calendar days by implementing a comprehensive intake and study assignment process.

3. Solutions and Methods

The central start-up team initiated gatekeeping for new studies using a structured intake process with defined minimum requirements and a robust set of intake questions. The intake process set clear expectations with industry partners and frontloaded a comprehensive package to the assigned central start-up staff.

- The structured intake process included:
  - Collection of minimum required documents
  - Sponsor enrollment projections
  - Relevant regulatory, financial, and clinic implementation questions
  - Site-required pre-approvals
- Assignment to the central start-up team and initiation of study start-up activity was contingent on industry partners':
  - Readiness to furnish required sponsors documents
  - Ability to answer preliminary questions that will determine start-up workflow, implementation requirements, and expectations
  - Acceptance of non-negotiable site fees and standard operating procedures
- Completion of the structured intake process resulted in assignment to the central start-up team and initiation of start-up activity

4. Outcomes

The structured intake process reduced median start-up time to a median of 120 calendar days and led to the improved outcomes described below.

- Frontloading key implementation questions prior to initiating start-up activity enabled the centralized start-up team to fulfill regulatory requirements, inform clinic implementation, negotiate and finalize budgets and contracts, secure third-party accesses and site-trainings, coordinate site initiation visits (SIVs), and complete site activations with greater precision and efficiency

- Pre-approval of product/device compatibility with non-negotiable site standard operating procedures, devices, and equipment reduced late-discovery feasibility issues and expense to site and industry partners
- Structured intake managed by dedicated site contact increased transparency and continuity with industry partners
- Status and outcomes of structured intake informed study selection and portfolio prioritization with investigators and research groups
- Utilization of structured intake to gatekeep study assignments allowed for workload planning and equitable distribution to the central start-up team

5. Lessons Learned and Future Directions

The successful implementation of a structured intake process prior to assignment and initiation of start-up led to reduced median start-up time by ensuring needed information and materials were frontloaded and available to the site staff, service areas, and other central offices in advance. The process also increased central start-up team bandwidth, reduced back-and-forth with sponsors, and improved outcomes of budget negotiations.

Central start-up budget and regulatory specialists continue to evaluate other internal start-up processes and opportunities for efficiency gains, including but not limited to budget development and negotiation; negotiation of consent language, essential regulatory documents, and eReg platform utilization.