Practical Benefits of Defining and Implementing Structured Intake and New Study Assignment in a Centralized Startup Model

Ashley McCauley, MA, CCRP; Madeline Winkler, CCRP; Madhuri Poduri, MS; Madeleine Hibbert, CCRP
Fred Hutchinson Cancer Center, Seattle, WA
Clinical Research Support – Study Startup Team – CRSstartup@fredhutch.org

Introduction

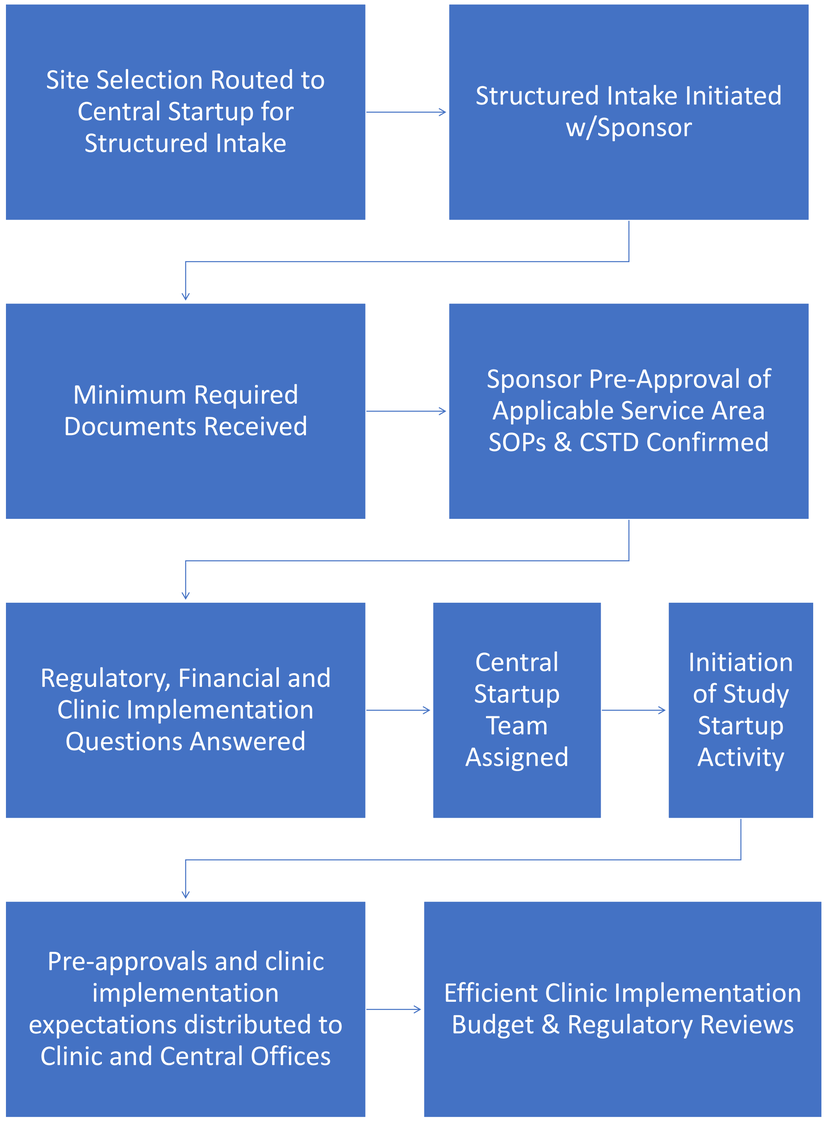
The Fred Hutchinson/University of Washington Cancer Consortium implemented a dedicated clinical trial startup team to reduce historically long startup times and to improve partnerships with industry sponsors. Startup timelines were protracted and unpredictable in part due to incomplete and inconsistent new study submissions that were managed by research group startup 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 startup process.

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

Methods

The central startup 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 startup 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 startup team and initiation of study startup activity was contingent on industry partners':
  - Readiness to furnish required sponsors documents
  - Ability to answer preliminary questions that will determine startup 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 startup team and initiation of startup activity.



Results

The structured intake process reduced median startup time to 120 calendar days and led to the improved outcomes described below.

- Frontloading key implementation questions prior to initiating startup activity enabled the centralized startup 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 startup team

Discussion

The successful implementation of a structured intake process prior to assignment and initiation of startup led to reduced median startup 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 startup team bandwidth, reduced back-and-forth with sponsors, and improved outcomes of budget negotiations.

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