

Review Week: Promoting Cross-Functional Collaboration During Study Start-up

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1. Background

The process for clinical trial start-up is complex and involves efforts of many different teams within the Clinical Trials Office (CTO). Previous attempts to convene a single, extended duration meeting at the beginning of the start-up process fell short. The previous method resulted in lack of preparedness and inadequate discussion and protocol understanding, which led to scheduling delays and lack of communication regarding follow-up responsibility. A streamlined process was necessary to shorten the study activation timeline while allowing for cross-functional collaboration across all disciplines of the study team.

2. Goals

- Decrease study start-up time
- Streamline development of the clinical treatment plan and billing procedures
- Efficiently negotiate the budget based on required clinical treatment plan
- Maximize cross-functional collaboration across study teams and study sponsor/Contract Research Organization (CRO)

3. Solutions and Methods

The CTO implemented a process to include the addition of a Review Week during the early stages of the study start-up process. The Regulatory Specialist (RS) assigned to the study is responsible for uploading pertinent documents into a shared file prior to the week. The RS is responsible for scheduling and leading the Review Week, taking minutes, and corresponding with the sponsor/CRO and principal investigator regarding issues that require attention. Attendees include staff from finance, coverage, and clinical teams within the CTO as well as a representative from the research pharmacy. The week consists of daily, virtual meetings that provide opportunity for study staff to review the budget build and discuss aspects of the protocol and treatment plan. During the 30-minute meetings, the teams review the protocol for clinical, financial, and regulatory questions. Internal clinical workflows and processes are discussed and assessed to minimize logistical issues as compared to current standard of care practices. Daily meetings provide opportunity to correspond with the sponsor/CRO to resolve questions that arise and report back later in the week with resolutions. The RS distributes minutes daily including an outline of questions and topics to be resolved during the week.

4. Outcomes

Implementation of the Review Week has aided in increasing collaborative work across different teams within the CTO. Feedback indicates that staff views the Review Week as a vital and productive step in study start-up. More time is given to in-depth discussions of the study treatment plan and order set builds which allows for quicker clinical review, Beacon validation, and EMR activation. The CTO has seen increased efficiency and staff engagement, resulting in decreased study start-up timelines. After implementation of the Review Week, there has been a decrease in the time to activation by an average of 22 days, while simultaneously more than doubling the number of studies activated yearly. Although other changes occurred during the same time period, much of the improvement can be attributed to implementation of the Review Week.

5. Lessons Learned and Future Directions

Future directions for improving the concept of the Review Week include:

- Designating a start-up specific team
- Developing lists/templates to be used by different teams during the week to make sure common, critical questions are answered in advance
- Developing a checklist for the RS incorporating topics that are generally addressed