

Implementation of Operational Feasibility Review During Study Start-up

M. Jacklin, T. Rudnitzki, M. Waggoner, J. Ranous, M. Koceja, B. George, K. Schroeder

Medical College of Wisconsin Cancer Center

1. Background

The clinical trial start-up process presents a myriad of operational challenges that require detailed planning with hospital partners and stakeholders. Since there was a lack of clarity in the process for how and when to include these partners in operational planning, this often led to inconsistency in study feasibility and operational review and ultimately negatively impacted activation timelines. A need was identified for a dedicated clinical trial operations team to develop a well-defined process for obtaining essential documents in a timely manner and involving key stakeholders (hospital partners, sponsors, PI, etc.) earlier in the start-up process.

2. Goals

- To improve feasibility review and operational planning by engaging sponsor and hospital partners early in the start-up process
- To decrease study activation timelines

3. Solutions and Methods

A dedicated clinical trial operations team, including the addition of a new program coordinator and administrative assistants, was created with the purpose of centralizing start-up activities. This team serves as a single point of contact for all parties involved in study start-up activities, including clinical research managers, regulatory, budget/contract, pharmacy, nursing, hospital compliance, and other department leaders as applicable. Having a dedicated team responsible for these activities allows for better tracking of timelines and completion of required submissions.

The first step in developing this new process was the creation of an operational feasibility committee and implementation of a review meeting to occur twice monthly. Committee members include the operations team, research managers, investigational pharmacy, nursing, and other departments as required. Once all essential documents are received by the research manager, the operations team is engaged to facilitate review of the protocol. Documents are saved to Florence eBinders electronic regulatory system for central access for partners, which drastically reduces the amount of emails and attachments to keep track of. The study is added to the agenda for the next available review meeting, and committee members are notified two weeks in advance of the meeting so they may complete a thorough operational review. Review comments are added to an operational feasibility tool, which has been developed in partnership with key stakeholders to capture all the operational planning details needed to ensure successful implementation of the protocol. Following the review meeting, outstanding questions are compiled by the operations team and sent to the necessary stakeholders to ensure there are no outstanding operational concerns at the time of final hospital compliance review and activation.

4. Outcomes

- Hospital partners are involved much earlier in the process, and in a consistent way, which leads to more effective operational planning and greater confidence in trial implementation
- Early engagement with sponsor and hospital partners ensures we have all of the required information needed for operational planning

5. Lessons Learned and Future Directions

- The implementation of an operational review meeting has been well-received by all involved, and has demonstrated value in operational planning
- An operational feasibility tool was developed to ensure that all departments receive the information that they need to plan for any study; this tool continues to evolve and now includes specific sections for treatment plan development, inpatient treatment and assessments, expected locations of care that serve to better guide compliance and billing, and additional information specific to cell therapy studies
- Currently, the operations team has grown to include an additional dedicated program coordinator, and the role of the team has expanded to include submission of studies to the hospital compliance oversight office; this is a key step in study activation and includes submission of all study documents received prior to the operational review meeting as well as the completed operational feasibility tool
- Continued engagement of the operations team and compliance office has facilitated faster review and approval of trials and ultimately will serve to lower study activation timelines