

Enhancing Clinical Trial Activation: Evaluating the Role of a Trial Activation Specialist

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1. Background

To streamline the clinical trial activation process and address bottlenecks, a trial activation specialist role was piloted across two disease teams approximately one year ago. The specialist, an experienced study coordinator, served as the central point of contact for all trial activation-related communications from the coordinator's perspective. By facilitating regular meetings with critical stakeholders, including regulatory coordinators and investigational pharmacists, and systematically collecting data across all activation steps, the specialist role significantly enhanced cross-departmental communication and process transparency. This pilot suggests that a dedicated activation specialist can drive efficiencies and improve trial start-up processes in clinical research.

2. Goals

- Create a dedicated trial activation team that exclusively opens new trials from confidential disclosure agreement (CDA) to open to accrual including:
 - Study Coordinator
 - Regulatory Coordinator
 - Financial Analyst
 - Pharmacy Technician
- Accurately track data for activation timelines
- Identify bottlenecks and recurring issues
- Reduce activation timelines to under three months

3. Solutions and Methods

Since the initiation of the role, detailed activation data has been systematically collected for all studies, tracking the time required for each step, including ancillary review committees in conjunction with major activation milestones. To streamline feasibility assessments, a Site Capabilities Brochure was developed, addressing key sponsor inquiries. This resource includes a compilation of frequently asked sponsor questions, an overview of activation timelines, vendor experience, and common institutional standard operating procedures (SOPs).

The activation specialist facilitates regular meetings with key stakeholders to ensure continuous communication and process updates. Additionally, when complex processes require coordination, the specialist organizes logistics meetings with relevant parties to clarify responsibilities and align expectations, promoting efficiency and transparency in the activation process.

4. Outcomes

Although a limited number of trials have progressed from initial Scientific Review Committee (SRC) submission to open accrual since the activation specialist role was implemented, preliminary data show a 53 percent reduction in activation timelines for industry-sponsored trials and a 61 percent reduction for cooperative group trials.

Sponsors and internal stakeholders have expressed appreciation for the streamlined communication provided by a single point of contact. The activation specialist ensures prompt responses, with most

emails answered within 24 hours, and proactively follows up with sponsors and internal teams to prevent delays. Additionally, the early identification of the clinical research specialist (CRS) assigned to each new trial allows for their involvement in communications and logistics meetings, resulting in a smoother transition at hand-off and improved trial management efficiency.

5. Lessons Learned and Future Directions

Piloting the activation specialist role on only two disease teams has provided valuable insights, but the current dataset remains limited, making it difficult to determine whether observed improvements are solely due to process enhancements or other factors. By focusing exclusively on trial start-up, the activation specialist has been able to respond to emails promptly and follow up frequently, which has been well-received by sponsors and contract research organizations (CROs). However, this level of responsiveness has sometimes created unrealistic expectations for post-activation trial management once the trial transitions to the CRS.

Moving forward, expanding the activation specialist role to additional disease teams and incorporating other key roles into the activation team will help refine this model and further evaluate its long-term impact on trial start-up efficiency.