Category: Clinical Trial Operations (Trial Start-up, Regulatory, Finance, Data Management, IITs) – Idea

Establishing an IIT Committee to Streamline Oncology Investigator-Initiated Trials

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1. Background

Investigator-Initiated Trials (IITs) are a vital component of oncological research, providing clinicians with opportunities to explore innovative hypotheses and improve patient care. Recognizing the complexity of these trials, our Clinical Trials Office (CTO) identified the need to strengthen collaboration and ensure that all appropriate stakeholders are engaged early in the process.

2. Goals

Establish a dedicated IIT Committee aimed at creating a more efficient and standardized process for IIT development and infrastructure support. The Committee's objectives include:

1. Implementing standardized templates to streamline protocol development.
2. Reducing startup timelines to accelerate trial activation.
3. Ensuring the trial is ready for Food and Drug Administration (FDA) and CSRC submission.
4. Engaging the Principal Investigator (PI) with the budgeting team at the earliest stages of project planning.
5. Supporting PIs at any stage of protocol development by connecting them with essential resources, including statisticians, protocol writers, regulatory officers, multi-site coordination teams, and laboratory staff.

3. Solutions and Methods

The IIT Committee consists of a diverse group of experts, including experienced IIT principal investigators, biostatisticians, financial advisors, regulatory officers, laboratory staff, a multicenter coordination team, and a protocol implementation team. Any PI planning a therapeutic oncology IIT must submit their protocol to the IIT Committee for review before FDA submission, following the workflow outlined in Figure 1.

The process will begin when the PI completes the IIT Committee intake form and answers questions to clarify protocol development needs. Based on these responses, the IIT Committee coordinator determines whether the PI will follow Path 1 or Path 2. If protocol development support is required, the PI enters Path 1, and the coordinator connects them with committee members who can assist. If the protocol is fully developed, the PI enters Path 2, and the coordinator distributes the protocol to committee members for review and confirmation of FDA readiness.

Final review is to be conducted by physician members of the IIT Committee using a standardized checklist to ensure all essential elements are present. Physician reviewers will be assigned on a weekly rotating on-call schedule once the protocol is confirmed to be ready for review (Path 2). After review, the coordinator will issue either a "Progress to FDA" letter, allowing the PI to proceed with FDA submission, or a "Protocol Development Feedback" letter, requiring further refinement before submission.

The IIT Committee will meet monthly to address pending trials and resolve issues that may delay protocol readiness for FDA submission.

Once fully operational, the Committee's effectiveness will be evaluated using Time to Trial (TTT) as a key performance metric. Additionally, qualitative feedback will be collected from PIs to determine whether Committee involvement contributed to a more streamlined and supportive process. These insights will inform ongoing refinements to the Committee's structure and services.

4. Outcomes
N/A

5. Lessons Learned and Future Directions
By establishing an IIT Committee, we aim to transform the current IIT landscape into a more responsive and efficient system that empowers oncology researchers. Through standardized processes and robust infrastructure support, the Committee will help ensure that IIT protocols are financially viable and operationally ready—ultimately accelerating the pace of innovation in cancer research.