

The Need for Speed: Piloting a Study Activation Committee

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1. Background

The adapting landscape, increasing complexity, and personalization of oncology clinical trials implores faster clinical trial activation. Our mission is to deliver novel treatments to acutely ill patients, and in this we cannot delay. Considering the volume of new studies submitted to our IRB, it became increasingly imperative to develop a workflow for tracking pipeline studies centrally and successfully seeing them to IRB approval.

2. Goals

- Decrease study activation timelines.
- Track review of pipeline studies and solve impediments in real time.
- Establish selection criteria for high priority studies to gain accelerated IRB approval.

3. Solutions and Methods

A Time to Activation (TTA) committee, comprised of representatives from Regulatory, Clinical Operations, and Compliance Divisions within our Department formed. The committee began by identifying the “activation” metric. Many factors contribute to a study’s activation. However, the committee implemented tracking the most all-encompassing factor: IRB approval. This was defined as the date of IRB submission through date of initial IRB approval. This key metric incorporates approvals from all required stakeholders: PRMC, Sponsor, FDA, etc.

TTA members were assigned disease teams. During weekly meetings, members provided updates for studies in IRB submission pipeline for over 30 days. This identified rate-limiting factors in real-time. These included dates of submission, review committee meetings, correspondence content, and Sponsor/CRO/PI response times. The committee outlined actions to resolve these issues, including, follow up to the study team, addressing difficult correspondence, and, in limited cases, recommendation for withdrawal from IRB review until a more optimal time.

A Rapid Activation Initiative (RAI) was born from the TTA committee to have select trials IRB approved in under 60 days, prioritizing studies of important clinical value and the Principal Investigator was a primary intellectual contributor. We met with key stakeholders (IRB, PRMC, Research Teams, and Sponsor/CRO) to gain commitment for review and communicate timelines.

4. Outcomes and Future Directions

The Time to Activation Committee successfully decreased IRB approval timelines. Overall, there was a 24% decrease in average IRB approval from 2018 to 2017 (93 days to 71 days). Industry and Investigator-Initiated Trials showed the most improvement:

Category: Trial Start Up/Closure – Work in Progress

- Investigator-Initiated studies decreased 32% (2017: 114 days, 2018: 77 days)
- Industry studies decreased 18% (2017: 96 days, 2018: 79 days)

As a result, our site was the first activated and enrolled the first patient globally for two studies.

Six RAI studies were IRB approved in 2018 with an average review of 51 days, showing a 35% decrease compared to similar non-RAI studies. The quickest RAI study was approved in 33 days (58% decrease from non-RAI average). On a recent RAI study, Columbia treated the first patient in the United States.

The National Cancer Institute (NCI) activation goal is 90 days.¹ Our Time to Activation Committee showed successful Proof of Concept that real-time tracking and commitment amongst review committees, study team, and Sponsor/CRO, results in quicker approvals. Since implementation, we have successfully decreased IRB approval timelines, ultimately accelerating patient access to novel therapies.

As we continue our initiative, we hope to review timelines for studies that took longer than average, identify additional metrics for “activation” tracking, and vet the RAI selection process.