

# The Need for Speed: Piloting a Study Activation Committee

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## Background

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

## 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.

## Methods

A Time to Activation (TTA) committee, comprised of representatives from Regulatory, Clinical Operations, and Compliance Divisions within our Department was formed. The committee began by identifying the “activation” metric. Many factors contribute to a study’s activation time line. The committee implemented tracking the most all-encompassing factor: IRB approval, 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 committee members were assigned disease teams to track. During weekly meetings, members provided updates for studies in IRB submission pipeline for over 30 days. This allowed for real time identification of rate-limiting factors. 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 select trials for targeted IRB approval in under 60 days. Studies of important clinical value for which the Principal Investigator was a primary intellectual contributor were prioritized. We met with key stakeholders (IRB, PRMC, Research Teams, and Sponsor/CRO) to discuss timelines and gain commitment for rapid review.

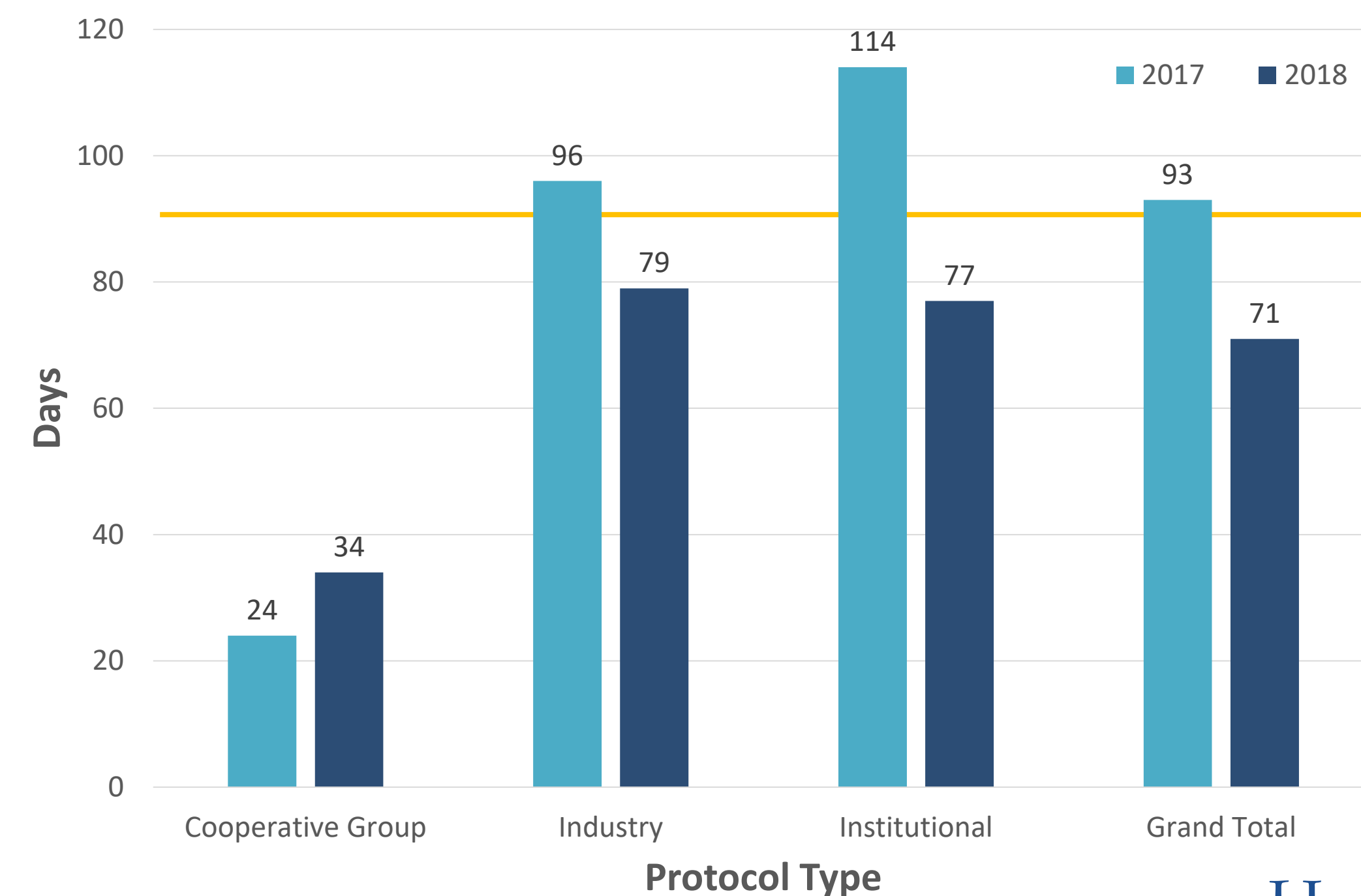
## Results

Since implementing the Time to Activation Committee, IRB approval timelines have considerably decreased. 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 :

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

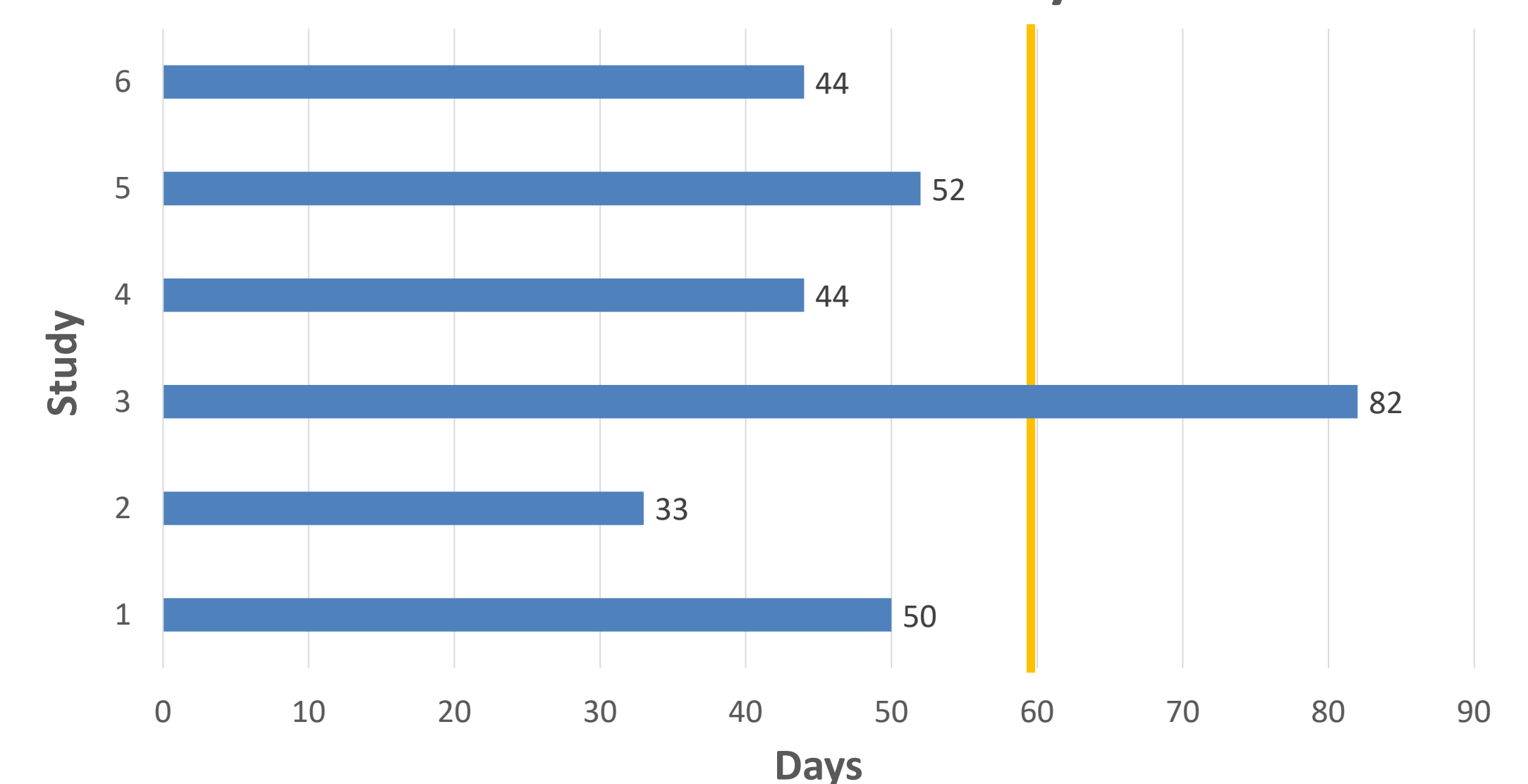
As a result, our site was the first activated and enrolled the first patient globally for two studies.

### Average Total Protocol Review in Days



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 fastest RAI study approval was 33 days, a 58% decrease from the non-RAI average. On a recent RAI study, Columbia treated the first patient in the United States.

### RAI Total Review in Days



## Future Improvements

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, thus accelerating patient access to novel therapies. Future TTA initiatives include review of timelines for studies that took longer than average, identifying additional metrics for “activation” tracking, and vetting of the RAI selection process.

#### Sources:

(1) Abrams, Jeffrey S et al. “Implementation of timeline reforms speeds initiation of National Cancer Institute-sponsored trials.” *Journal of the National Cancer Institute* vol. 105,13 (2013): 954-9. doi:10.1093/jnci/djt137