

# IRB FAST TRACK: EXPRESS REVIEW OF INDUSTRY INITIATED STUDIES

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NYU SoM IRB was seeking a way to improve submission to approval times. In 2016, metrics indicated the turnaround time for full board submissions took approximately 67 calendar days from the time of submission to approval. Industry-initiated studies are typically more complete with some minor issues that impact approval time. we wanted to test a process change that would impact the approval times for these studies.

As a result of our review, we evaluated the internal processes that include a pre-review of studies to be reviewed at a fully convened IRB meeting. An innovative new approach was developed to increase efficiency that would allow for a quicker review of full board studies – this approach was termed “fast track”.

## THE CHALLENGE

**The Pilot**  
The IRB Fast Track Pilot Program was implemented in 2017. The program consisted of a specifically designed training program for regulatory support teams at the NYU Langone Laura and Isaac Perlmutter Cancer Center.

- The Process**  
Research study teams:
- held biweekly and quarterly meetings with IRB operations to review progress
  - continuously trained their regulatory support staff based on feedback obtained from the IRB
  - developed internal process of ensuring their PI carried out their regulatory responsibilities
  - communicated with the sponsor to obtain required information and request changes prior to IRB submission.
  - conducted a modified IRB pre-review using a custom checklist

- IRB Operations:
- designed customized checklist
  - developed and carried out an orientation and training program regarding the IRB-preview process prior to pilot implementation
  - evaluated ongoing pilot program for issues and created custom interim training to address them
  - collected and analyzed metric data for all fast track submissions
  - created detailed feedback reports that were then shared with the research study teams

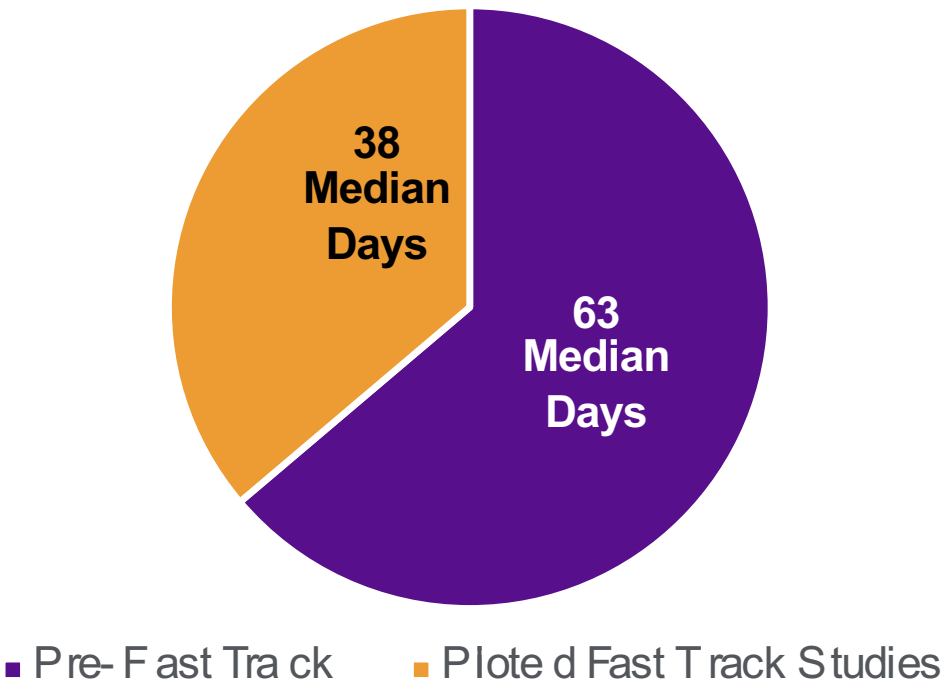
## THE SOLUTION

**Program Assessment**  
One year post pilot implementation, metrics indicated a 40% decrease in median rate of approval for studies submitted via the Fast Track Pilot Program. The success of the program led to full scale implementation across the institution for all new industry-initiated studies. Most studies were approved with directed changes pending response.

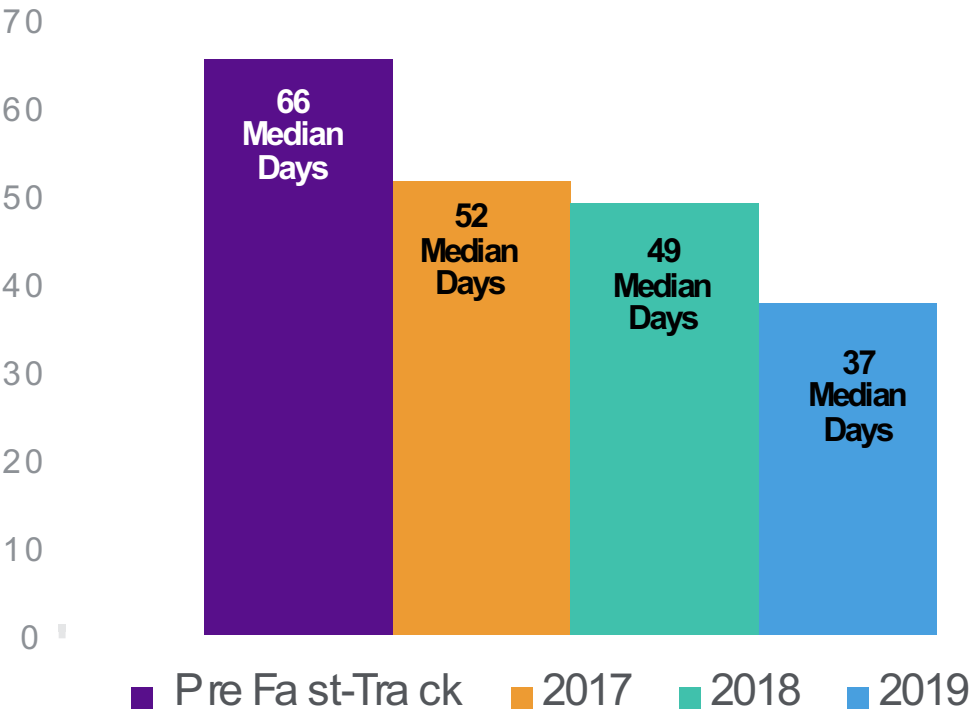
**Results**  
There has been a 45% decrease in submission to approval times from 67 calendar days (median) in 2016 to 37 calendar days (median) in 2019.

## RESULTS & ANALYSIS

Turnaround Time Comparison Chart for Standard vs. Piloted Fast Track Submissions



Turnaround Time Comparison Chart (All New Full Board Submissions)



**Conclusion**  
Implementation of the fast track method for industry-initiated trials is an effective way to reduce IRB metrics without compromising quality of the submissions for IRB review. Overall median approval times can be greatly impacted and researchers can rely on the local IRB for a competitive review time for their new human subjects research.

- Remaining Challenges**  
Research Study Teams
- The time spent awaiting sponsor’s edits would sometimes negate the efforts of the IRB operations team and the research staff working to process studies quickly
  - Regulatory support staff expertise varies greatly across study teams within the institution

- IRB Operations
- The fast track program is currently inclusive of only those new submissions applications that meet the definition of “industry-initiated”. No other submission types have been evaluated at this time.
  - Additional internal initiatives were implemented in conjunction with the fast track program that may also have contributed to the decline in overall turnaround time.

**Future Goals**  
Moving forward, we are looking for ways to improve and expand the program to include other submission types and possibly PI-initiated new studies. Next steps include surveying the research community for feedback regarding their overall satisfaction with the program.

## THE CONCLUSION