Empowering Study Teams to Improve Clinical Trial Activation Timelines

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Background

In 2016, the Yale School of Medicine and Yale Cancer Center (YCC) identified clinical trial activation timelines as a strategic improvement opportunity to:

- advance medical care and research,
- enhance Yale's position as a competitive Medical School and Comprehensive Cancer Center, and
- expand patient access to clinical trials within the Yale Medicine network.

An initial activation analysis included input from more than 100 stakeholders, which resulted in the identification of 43 areas for improvement and the creation of an internal Protocol Activation (PAct) Team. A pilot of all YCC trials opened since December 2017 has utilized newly established processes and metric tracking (over 130 protocols to-date).

Goals

- **Empower research teams to improve start-up timelines in order to consistently achieve clinical trial activation within 90 calendar days from Protocol Review Committee (PRC) submission.**
- **Optimize 13 individual activation sub-processes**
  - Establish tasks that start and end each sub-process
  - Identify co-dependencies with other sub-processes
  - Review actual and target durations for each sub-process
- **Decrease overall time to activation (TTA), to achieve current target timelines (Table 1)**

Table 1: Target calendar days from PRC submission to open to accrual

Master Contract Agreement; External IRB	55
Master Contract Agreement; Internal IRB	60
Existing Contract Agreement; External IRB	75
Existing Contract Agreement; Internal IRB	75
New Contract Agreement; External IRB	130
New Contract Agreement; Internal IRB	130
Cooperative Group/NCI; CIRB	55

Methods

Sub-process workflows translated into **OnCore Activation Task Lists (Table 2)**

→ Track completed tasks and achieved milestones

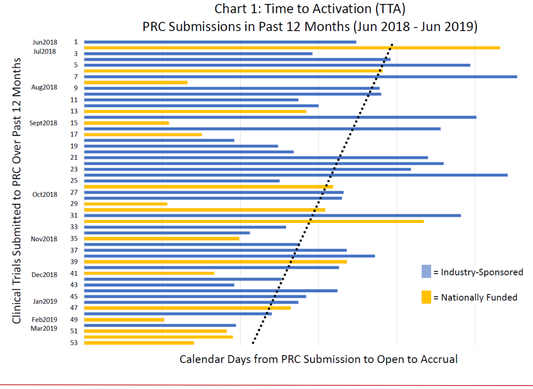
→ Feed into custom protocol activation dashboards

Table 2: OnCore Activation Task Lists [Number of Tasks]

Study Decision [5]	Internal IRB [5]
Feasibility [10]	Internal IRB Contingencies [4]
Consent Form [4]	Internal IRB Deferred [5]
OnCore Build [36]	External IRB [3]
Beacon Build [9]	CIRB [5]
Protocol Review Committee (PRC) [6]	Negotiate Contract (Master/Existing/New) [3]
Radiation Safety Committee [6]	Execute Contract (Master/Existing/New) [3]
Institutional Biosafety Committee [4]	Budget [7]
Human Research Protection Program [3]	Business Office [3]
	Activation [20]

Monitoring of the **overall time to activation (TTA)** for each protocol (Chart 1)

→ Decrease in median TTA seen for trials submitted to PRC June 2018 through June 2019



Outcomes

- Creation of an internal Protocol Activation (PAct) Team
- Implementation of 19+ new activation task lists in OnCore
- Development of data field definitions for over 100 task fields
- Concurrent PRC and HRPP submissions for industry sponsored and authored protocols
- Regular meetings with sub-process owners, regulatory managers, and disease-aligned study teams to ensure a bidirectional flow of information

There has been a notable decrease in activation timelines since the initiation of the YCC Pilot with the PAct Team. Metrics show that between 2017 and 2018, the overall clinical trial activation timelines decreased by 19 calendar days. As of June 2019, the TTA median for protocols submitted to PRC in 2019 is 96 calendar days.

Future Direction

- Continue working with sub-process owners and disease teams to identify and address additional areas for improvement
- Continue attending oncology research team meetings to present metrics and identify bottlenecks for pending trials in real time
- Currently finalizing a number of **additional process improvements**, based on stakeholder feedback:
  - Implementing Centralized Medicare Coverage Analysis
  - Streamlining submission processes to ancillary committees
  - Optimizing treatment plans in Epic Beacon
  - Tracking of IND submissions associated with investigator-initiated trials
  - Expanding access to dashboards and enhance metric reporting

The Protocol Activation (PAct) project is an ongoing endeavor which continues to evolve based on the data trends. As the project matures, the data will more fully demonstrate the impacts on study activation timelines

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