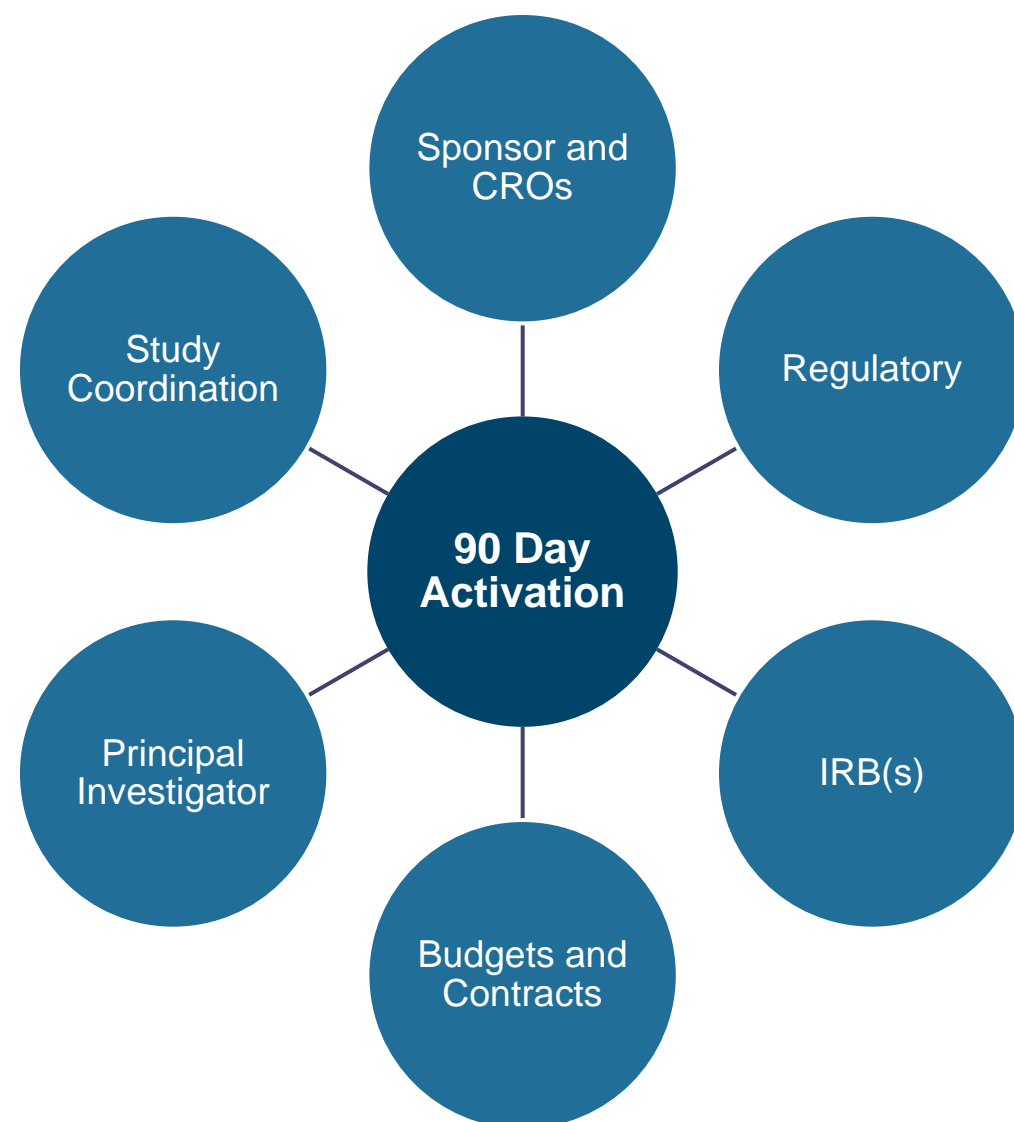


Background

Study activation within 90 calendar days has been a priority for the KCI Clinical Trials Office (CTO) since the NCI Operational Efficiency Working Group (OEWG) directive was released in the 2000s. In early 2019, a task force was established to evaluate the activation process with a goal of modifying current workflows to maintain a consistent 90 day activation median for new studies. In order to make these changes, the task force recognized the need for institutional leadership support for interdepartmental workflow changes.

Metrics and Goals

The primary goal was to decrease the activation timeline to 90 calendar days as defined by Protocol Review and Monitoring Committee (PRMC) submission to activation (open to accrual). Rate limiting steps needed to be defined and categorized by responsible department. In addition, the task force aimed to increase interdepartmental communication and collaboration.

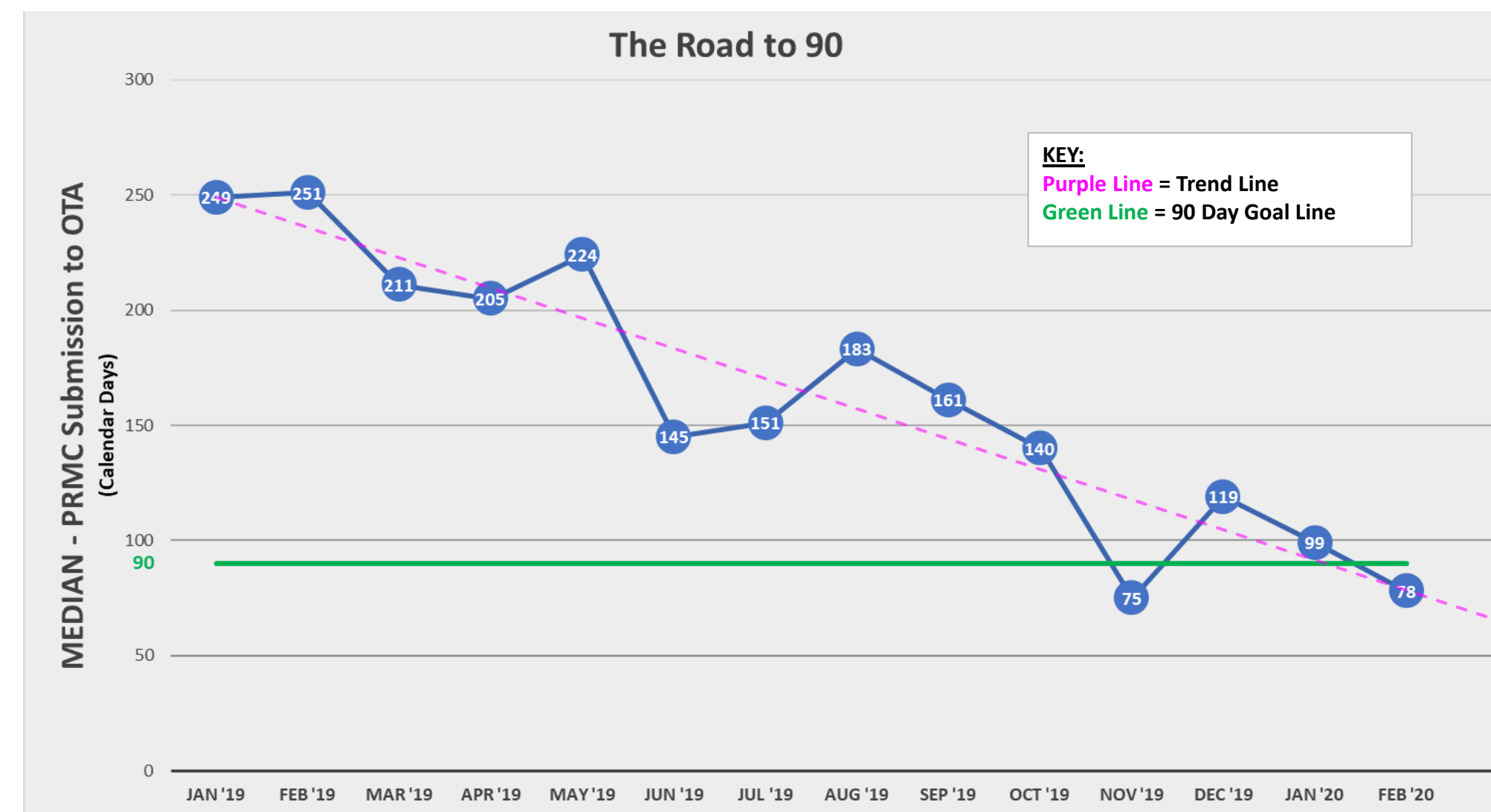


Solutions and Methods Implemented

The CTO reviewed a diverse subset of the KCI study portfolio activated in 2018. The rate limiting steps were identified, which included: receipt of required documents, consent preparation and review, IRB review, budget & contract review and Site Initiation Visit (SIV) requirements. Data related to these steps was used to develop recommendations and subsequently presented to institutional leadership. The presented recommendations were approved and introduced to the CTO as the “Road to 90” initiative in April 2019.

The following changes were implemented:

- Enforced receipt of necessary study documents prior to PRMC submission
- Consent, budget and contract study activation processes were amended
- Expanded use of OnCore® task lists across departments to track key milestones
- Addition of two activation coordinators to facilitate communication and timely completion of required steps
- Streamlined and optimized the activation of protocols throughout the KCI Network
- Increased frequency of collaborative meetings with the local IRB to communicate newly defined goals and review progress
- Developed and revised policies and procedures to support this initiative



Outcome

The changes implemented resulted in a dramatic decrease in the CTO’s monthly activation timeline. Additionally, the initiative improved internal and external communication and collaboration. The “Road to 90” initiative has been adopted as an institutional goal and continues to be supported by leadership throughout the KCI Network. A welcomed outcome that resulted from this initiative included a well-defined “Road Map” to support the activation of studies in the required timeframe. The addition of protocol activation coordinators allowed the CTO to globally track specific steps of activation using enhanced task lists within OnCore® and identify potential road blocks.



Lessons Learned and Future Direction

Optimal staffing levels and qualifications played a pivotal role in the success of the initiative. In addition, institutional leadership support was abundant since the inception of the proposed process changes. Real time task list completion allowed for accurate tracking of activation metrics. These metrics provide the CTO with a plethora of data to aid in continued efforts to improve collaboration between all involved stakeholders. The CTO established specific timelines to successfully activate trials within 90 days; however, unanticipated sponsor delays continue to impact these efforts. The CTO continues to track these trends and review the robust data accordingly for continued process improvement.