

Maximizing efficiency in managing the trial activation pipeline: activating high-priority trials in a timely manner



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Background

- Time-to-activation is complex. Success of clinical trials hinges on the ability to open trials quickly. Studies that take too long to open can close without any patients accrued, thereby wasting activation and coordination resources.
- The speed with which trials can be activated often hinges on the volume of studies in the protocol development pipeline.
- In Q1 of 2022, HDFCCC investigators were on track to submit 152 interventional studies to Protocol Review and Monitoring Committee (PRMC), substantially higher than the annual average of 120 studies activated over the previous three years.

Goals & Methods

- We sought to normalize the number of studies entering the protocol development pipeline to be more reflective of the yearly average.
- We sought to identify and participate only in industry studies for which robust accrual was likely, in order to successfully manage our overall trial activation pipeline.
- We implemented a one-year pilot with two phases focused on the prioritization of trials in our activation pipeline.

Phase 1 – Low Priority Trials

Disease-oriented clinical research working groups were asked to remove lower priority Industry sponsored studies from the pipeline, including:

- Studies that were likely to be closed or near to closing at the time of projected UCSF activation
- Studies where UCSF was likely to have a limited number of available accrual slots based on the study design or number of centers involved.

Phase 2 – High Priority Trials

- Prioritization of investigator-initiated trials (IITs), NCTN trials, trials where an early-stage career faculty was the PI, and industry studies with UCSF leadership.
- Each disease oriented clinical research group was asked to adhere to a specific number of PRMC submission slots for industry studies over the course of a 1-year period.
- There were no restrictions on the number of NCTN trial and IIT submissions.
- A small number of additional slots for higher priority industry sponsored studies were allocated by a peer-review committee, through an application process.
- These measures were applied only to trials being submitted to the PRMC; open trials were not affected.

Results

Phase 1 – Low Priority Trials

- 10% of industry trials were abandoned during the activation process.

Phase 2 – High Priority Trials

- 16% fewer studies were submitted to PRMC.
- By the 1-year period, only 57.5% of assigned PRMC submission slots were used.
- 6 additional slots were awarded for high priority studies or new faculty members
- At the end of the second phase, a similar number of studies as in prior years were activated.
- The time to activation decreased by 11% over the same time-period in the year prior.

Faculty Survey

We sent a survey to HDFCCC investigators, including program leaders at the mid-point and end of the 1-year phase 2 initiative. Although the response rate was small (N=16), faculty were ambivalent regarding the initiatives ability to accurately prioritize trials (38% agreed; 43% disagreed; 19% unsure).

56% of respondents indicated that the initiatives fostered a sense of pressure and competition amongst investigators for the allocated slots.

Conclusions and Future Directions

This pilot was successful in reducing the number of submissions to PRMC and allowed resources to be focused on high-priority trials.

However, the process added stress to faculty and program leaders.

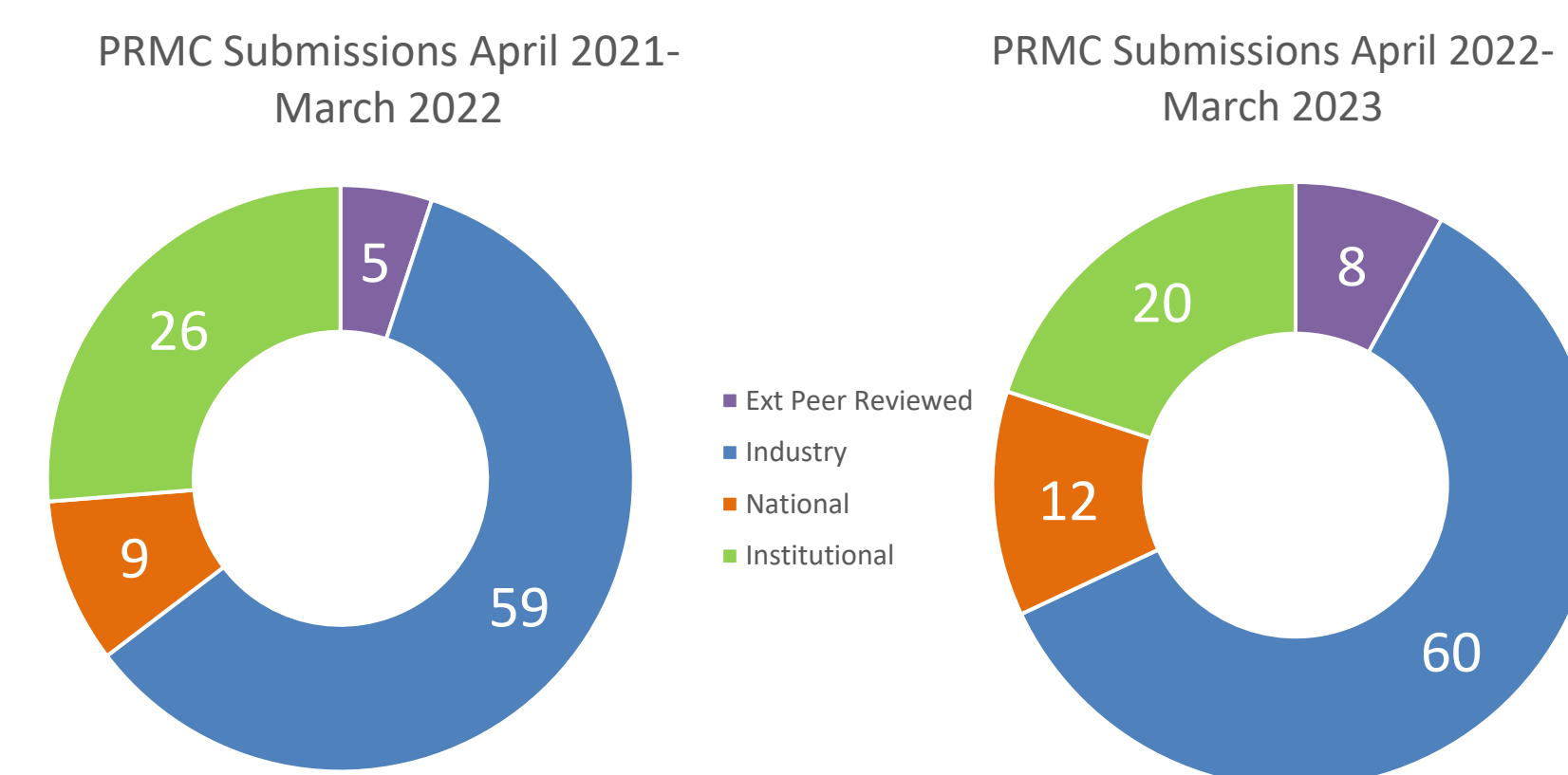
Discussions of industry-sponsored trials at disease oriented clinical research groups now include the likelihood of long-term success of a trial, including the ability to open before national accrual goals are met, and the ability to meet accrual targets.

Future Analysis

Adequately prioritizing trials that are entering the activation pipeline is expected to have downstream effects on the ability of study teams to adequately accrue and operationalize these trials. As we monitor the impacts of the prioritization program, we will:

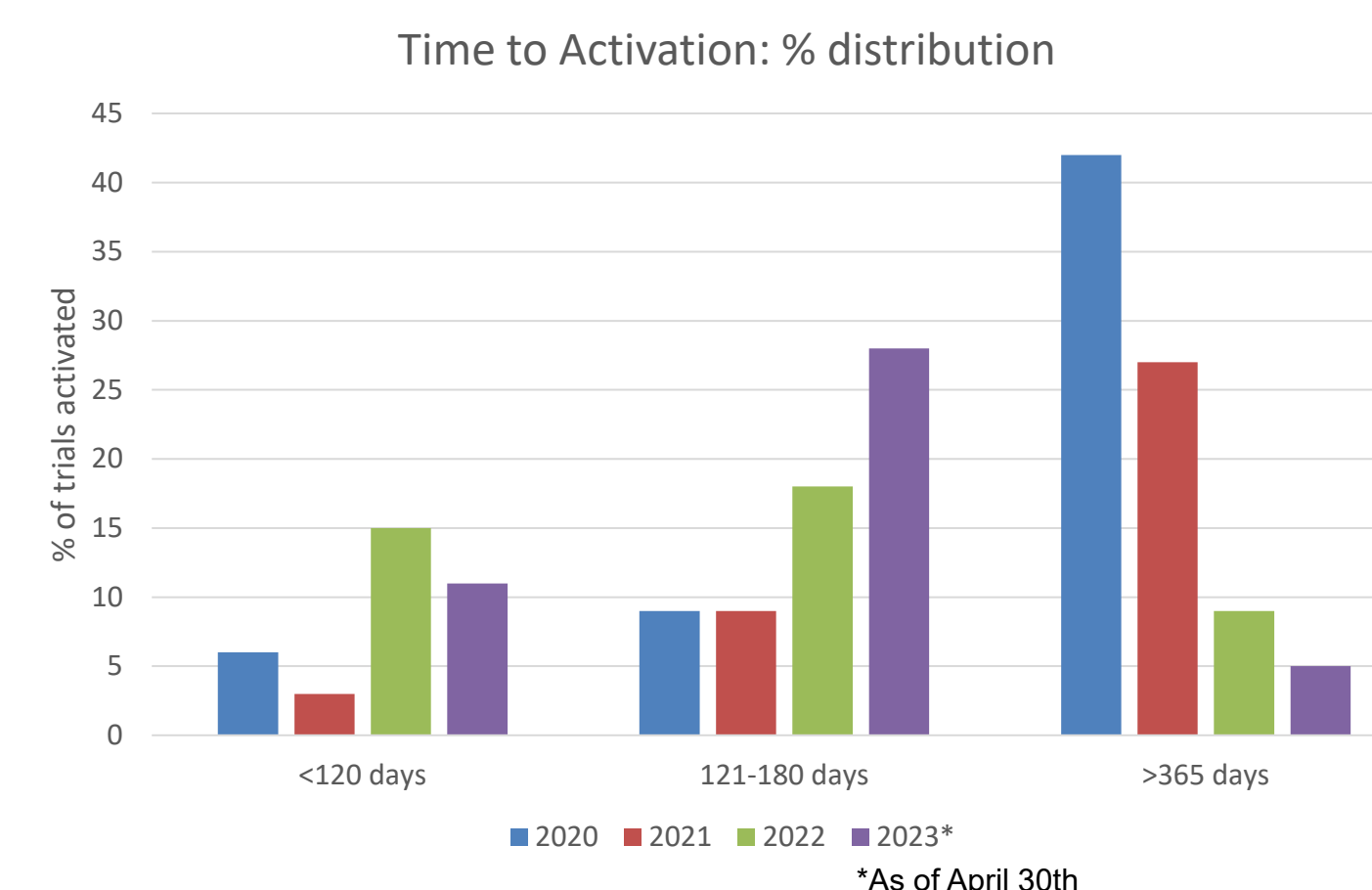
- Determine if the number of studies closed with zero accruals decreased, and if there was an ongoing impact on time to activation.
- Evaluate the impact on the relative accruals to IIT, NCTN and industry trials.
- Consider the impact on ancillary services at UCSF.

Impact



PRMC submissions portfolio

The percentage of industry and externally peer reviewed trials submitted to remained relatively the same during phase 2 (as compared with the previous 12-month period). NCTN study submissions increased by 33%, where as institutional trials decreased by 23%



Time-to-Activation

- 39% of trials opened in less than 6 months in 2023 (YTD) vs. 12% in 2021
- 5% of trials opened in >1 year in 2023 (YTD) vs. 27% in 2021