UCSF Helen Diller Family Comprehensive Cancer Center

Pilot to Decrease Time-To-Activation for Investigator-Initiated Trials

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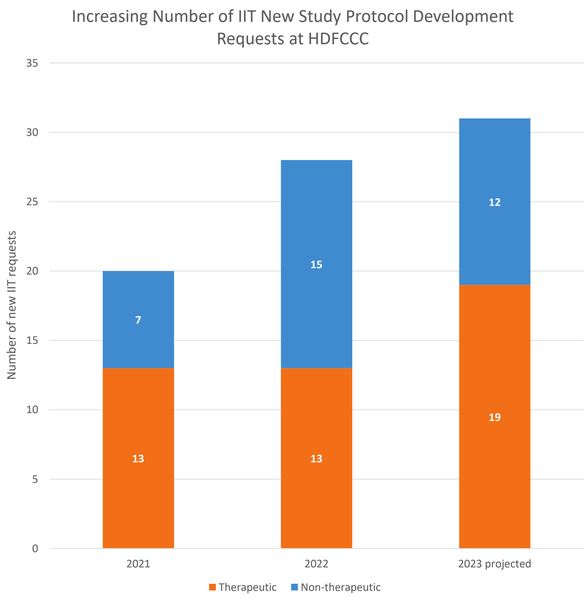
Background

The Helen Diller Family Comprehensive Cancer Center (HDFCCC) at the University of California San Francisco (UCSF) has an increasing number of investigator-initiated trials (IITs): 20 requests for new IITs in 2021, 28 in 2022, and a projected 31 in 2023.

At UCSF, IITs are developed by the Protocol Development (PD) team. Keeping time-to-activation (TTA) as brief as possible while producing quality clinical trial protocols is a central goal of the PD team. Therefore, beginning February 2022, a pilot project was launched with the aim of decreasing TTA for IITs.

Goals

The pilot project aimed to determine the most effective ways to decrease TTA while not compromising protocol quality.



Solutions and Methods

The pilot included two categories:

- new workflows (or services offered)
- process improvements to existing workflows

New Workflows

- To ensure the quality of protocols and ancillary documents and decrease potential slowdowns during reviews, the PD team began working with the PI earlier in the protocol development process, at the initial study concept phase.
- The PD team also re-trained on medical writing best practices through a custom-built course.
- To improve version control and decrease back-and-forth communications between PD and study teams, the PD team became responsible for all protocol-related submissions (PRMC, IRB, FDA).

Solutions and Methods (cont'd)

Process Improvements

- Contract negotiations were initiated earlier to iron out collaboration terms before trial activation begins.
- Submissions were reorganized for efficiency (i.e., parallel reviews).
- Study eCRFs were built in-house.
- Stakeholder communication was increased to improve project management and accountability.

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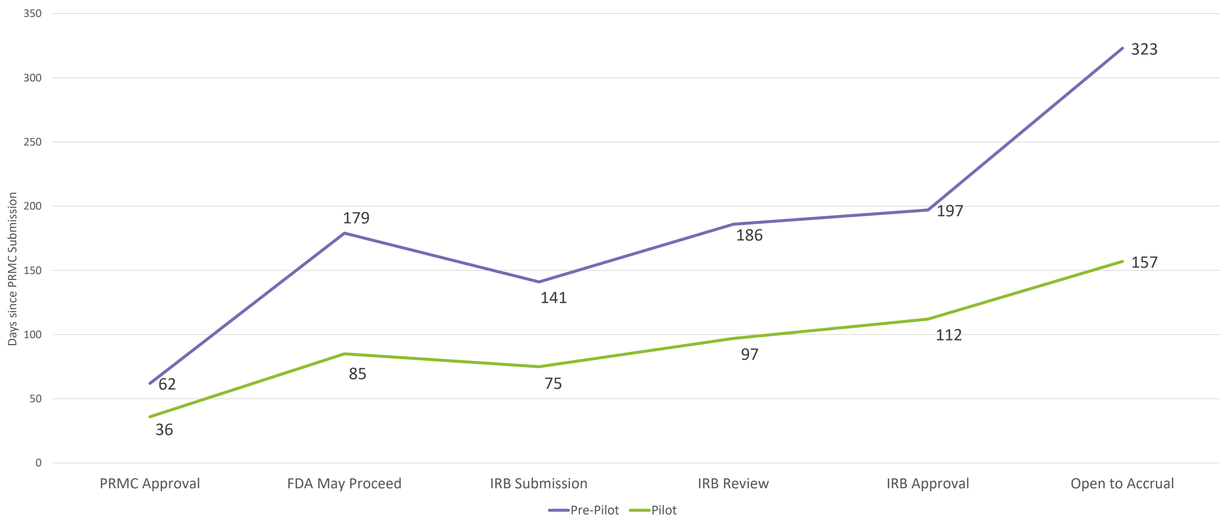
- Two additional FTE were hired to support these efforts.

Pre-Pilot vs. Pilot Time-to-Activation Milestones



Outcomes

The pilot demonstrated a 51% decrease in average TTA for IITs of 165 days [average pre-pilot TTA = 323 days (n=20); average pilot TTA = 157 days (n=9)].

Having PIs attend their IRB reviews allowed for more direct communication and decreased timelines, saving an average of 41 days during the IRB review process (average IRB review length when PI did not attend = 84 days; average IRB review length when PI attended = 43 days).

Stronger relationships with improved communications were developed with the UCSF clinical trial activation teams outside the HDFCCC.

Workflow changes improved efficiencies by allowing for more parallel processing.

Increased FTE for the PD team allowed for better faculty support in the IIT process.

Lessons Learned and Future Directions

- The pilot has successfully reduced the TTA for IITs and enhanced the support available to HDFCCC investigators who wish to run their own trials.
- The PD team, UCSF IRB, budgeting, and contracting departments have worked closely together to significantly decrease the amount of back and forth at each activation stage.
- The PD team will continue operating under the new set of workflows.
- In addition, the lessons learned from this pilot will be used to streamline trial activation in industry and cooperative group trials.
- While successful, the pilot highlighted that this work is resource-intensive, so ways to scale effectively are still being sought.