

## **Pilot to Decrease Time-to-Activation for Investigator-Initiated Trials**

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### **1. 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 and 29 in 2022. 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, from February 2022 to February 2023, a pilot project aimed at decreasing TTA for IITs was implemented.

### **2. Goals**

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

### **3. Solutions and Methods**

The pilot included two categories: 1) new workflows (or services offered), and 2) process improvements to existing workflows.

- 1) 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
  - a. The PD team retrained on medical writing best practices through a custom-built course
  - b. 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)
- 2) Process improvements to existing workflows: Contract negotiations were initiated earlier to iron out collaboration terms before trial activation begins
  - a. Submissions were reorganized for efficiency (i.e., parallel reviews)
  - b. Study eCRFs were built in-house
  - c. Stakeholder communication was increased to improve project management and accountability

Also, two additional FTE were hired to support these efforts.

### **4. Outcomes**

The pilot demonstrated a decrease in average TTA for IITs of 75 days [average TTA for February 2021 to February 2022 = 196 days (n=5); average TTA for February 2022 to February 2023 = 121 days (n=6)]. 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).

*Category: Trial Start-up, Activation, and Protocol Development - Completed Project*

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.

#### **5. 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.