

Creating a Clinical Research Network

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1. Background

The Helen Diller Family Comprehensive Cancer Center (HDFCCC) at the University of California San Francisco (UCSF) is located in the San Francisco Bay Area – a large urban area in which travel can be challenging and time consuming. Community oncologists deliver much of the cancer care in the area, but cancer advances can take years to be adopted in the community setting and these clinical groups and community hospitals typically don't have the resources or expertise to conduct clinical trials on their own. In order to increase access to innovative care through oncology clinical trials in the community setting, UCSF created the Clinical Research Network Office (CRNO) in 2017.

2. Goals

- The primary objective of UCSF's CRNO is to help develop, streamline, and improve clinical research opportunities at regional affiliate sites. Together with our partners, our goal is to provide local access to innovative clinical trials for every patient, by removing the need for patients to travel to UCSF or other facilities.
- Eliminate redundancies in study activation and operations across network sites.
- Ensure the standards and quality of research being done is uniform across network sites.

3. Solutions and Methods

The network is currently comprised of two local hospitals in San Francisco proper, and three community hospitals located in the surrounding area. Affiliate sites can sign a UCSFIRB reliance agreement and utilize the UCSF IRB. The CRNO provides oversight and regular monitoring from the HDFCCC Data and Safety Monitoring Committee (DSMC). Training programs are provided for all study staff including research coordinators, pharmacy, regulatory, and investigators. Investigators and staff at affiliate sites have access to HDFCCC disease specific clinical research working groups (termed "site committees") where they can be involved in preliminary discussions around study design and feasibility, to ensure the trials can be implemented at their sites. Site committees also review all safety events, and community oncologists that enroll patients on clinical trials are expected to participate in these reviews. Affiliate sites can participate in tumor boards and educational talks/conferences offered at the HDFCCC. The CRNO facilitates clinical trial portfolio management at the affiliate sites in order to leverage existing patient populations and identify/ fill in gaps in offerings at UCSF (i.e. frontline therapies).

4. Outcomes and Future Directions

The network is in its early stages, but to date has built positive interactions between UCSF and our affiliate sites. We have been able to enhance the research programs at the two local hospitals as well as build a new clinical research program from scratch at one of our affiliate sites. The CRNO developed a process for how trials are offered to affiliates, metrics they must meet to open new types of trials and how the affiliate sites will be monitored to ensure compliance and patient safety. We have expanded

Category: Clinical Research Operations – Work in Progress

UCSF's HDFCCC training program to be applicable to affiliate sites. Affiliate participation in site committees and tumor boards has increased. We will continue to build the CRNO by adding more network sites as well as streamlining processes and increasing the amount and complexity of clinical trials run at already existing sites.