UCSF Helen Diller Family Comprehensive Cancer Center

Creating a Clinical Research Network

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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.

CRNO Objectives

- 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. Specific goals include:

- Eliminate redundancies in study activation and operations across network sites.
- Ensure the standards and quality of research being done is uniform across network sites.
- Provide infrastructure for review and prioritization of trials, conduct of trials, compliance, and monitoring.

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CRNO Support for Network Sites

Administrative/regulatory

- Address administrative burdens such as navigation of the many electronic portals, registrations, and applications required to conduct clinical trials
- Assist local sites navigate the clinical trial process as efficiently as possible

Clinical Trial Portfolio Management

- Assist sites in selecting the most appropriate clinical trials for their patients. This consists of first examining their most common cancer types and stages, the types of trials their patients and medical providers would find exciting, and reviewing the logistical requirements of trials to ensure they can be carried out within space, equipment, and staffing constraints

Policies and Procedures

- Assist in the development of standard operating procedures (SOPs) and policies for obtaining informed consent, calendaring and scheduling, documenting/reporting treatment and toxicity, and all other data requirements
- Ensure compliance with all regulatory requirements (federal and local)
- Customize to each affiliate's electronic medical record, work flow, and staffing

Monitoring Support

- Local Data Safety Monitoring, in order to ensure compliance with mandatory reporting and data management
- Provided by a dedicated CRNO-Data Safety Auditor who supports preparation for audits and inspections
- Audits are undertaken of the research records of early patients enrolled on every clinical trials and provide feedback for improvement

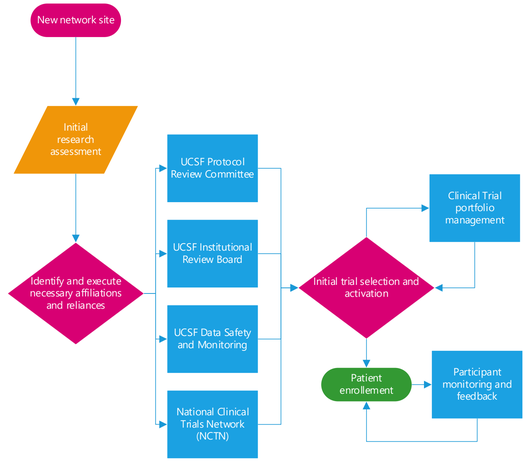
Personnel Training and Support

- Training, continuing education, certification, and mentoring of all research personnel
- Includes clinical research coordinators, pharmacists, and physicians
- Provides peer and mentoring resources to maximize job satisfaction and continuity

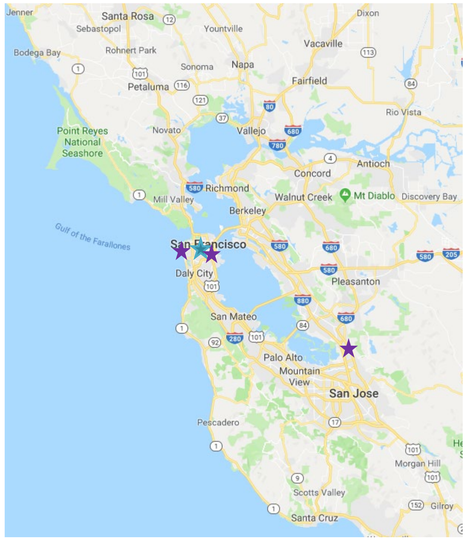
Infrastructure Support

For new research enterprises:

- Structural organization of research activities
- Developing space requirements
- Provide guidelines and infrastructure to ensure that the pharmacy meets investigational drug service requirements
- Provide guidelines and infrastructure for biologic specimen acquisition and processing



Current Network Status



Washington Hospital Healthcare System (WHHS)

WHHS partnered with UCSF to build a brand new clinical research program. This included recruitment/training of staff, IRB reliance, cooperative group affiliation, SOP creation and portfolio management.

Zuckerberg San Francisco General Hospital (ZSFG)

ZSFG is a long standing satellite site of UCSF, utilizing UCSF scientific and ethical reviews as well as monitoring and training support. CRNO is working with their clinical trial team to grow their existing program and expand access to clinical trials to more of their patients.

San Francisco Veterans Affairs Medical Center (SFVA)

SFVA is also a long standing satellite site and NCTN affiliate. The CRNO is excited to partner with them to provide training and educational opportunities, clinical trial operations support and portfolio management.

Future Directions

- 3- 5 additional network sites in planning stages
- Streamlining processes and increasing the number and complexity of clinical trials run at existing sites
- Facilitation of ongoing learning opportunities and collaboration for all involved parties