Expanding Decentralized Clinical Trial Options at the UCSF Helen Diller Family Comprehensive Cancer Center

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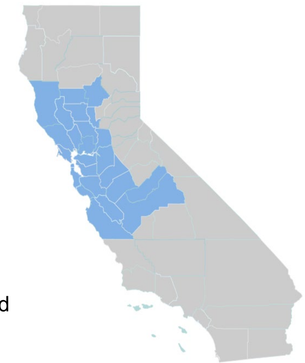
Background

Decentralized clinical trials (DCTs) offer a flexible alternative to traditional site-based clinical research, allowing participants to engage from home and/or local healthcare providers. This model enhances accessibility, efficiency, and participation by utilizing technologies such as telemedicine, wearable devices, and electronic data capture systems. These innovations also alleviate the burden on site staff by streamlining data collection processes. Federal regulatory agencies have increasingly shown support for DCT practices, with the FDA releasing guidance in Fall 2024, Conducting Trials With Decentralized Elements.

The UCSF Helen Diller Family Comprehensive Cancer Center (HDFCCC), located in San Francisco but serving 25 counties across Northern California, recognizes the challenge many patients face in accessing our main campuses. Travel to our San Francisco locations is often time-consuming, costly, and complicated by tolls, traffic, and limited parking.



By studying the DCT model, we aim to expand the number of trials incorporating decentralized elements, offering more options for patients seeking cutting edge care that will be available in locations closer to their homes and across our catchment area.

Decentralized clinical trials are not only a shift in operations, but they also represent a shift in mindset, placing the patient at the center of research by meeting them where they are, not where the trial site is.

Objectives

We aim to increase the adoption of DCTs at the HDFCCC and create a culture of acceptance around decentralized trial elements in standard clinical research practice.

To do this we will pilot selected trials at strategically chosen partner sites around the San Francisco Bay Area.

Considerations

- Use of technologies at main campus, participant home, community sites
- Data Management
- Participant uptake
- Study feasibility
- Regulatory Compliance (including billing)

Key outputs

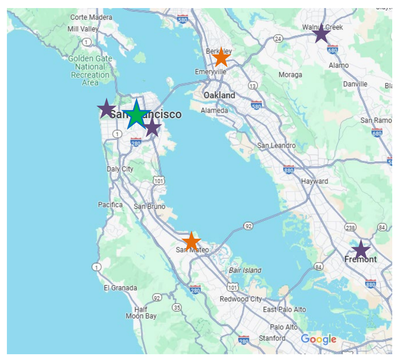
- Define the roles and responsibilities of all stakeholders involved in DCTs
- Ensure that necessary resources are available
- Train the HDFCCC Protocol Development team to collaborate with PIs in incorporating DCT elements into new Investigator Initiated Trial protocols
- Document challenges and considerations related to technology access, compliance, and data security
- Enhance patient clinical trial participation experience and improve access to trials
- Evaluate the operational feasibility and ensure that data quality maintains high standards of accuracy

DCT pilot plan using HDFCCC partner sites

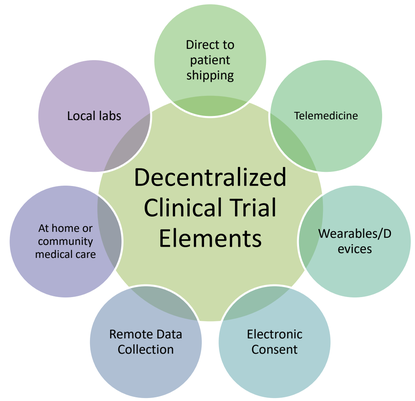
Selected HDFCCC Investigator Initiated Trials (IITs) will be used to pilot DCT elements at strategically chosen partner sites around the San Francisco Bay Area. Initially chosen trials will be hybrid, meaning they combine elements of traditional site-based trials with decentralized elements.

Staged roll out plan by trial type and location

Stage	Type of Trial	Locations
1	Observational, ancillary/correlative,	Any partner site
	Non-treatment interventional	Partner site with shared EMR
2	Phase III treatment, Phase II standard of care (SOC) drug	Partner site with shared EMR
	Investigational treatment at main site, follow up activities in the community	Any partner site
3	Phase II/III treatment with Investigational Product (IP)	Partner site with shared EMR
	Phase II SOC drug	Any partner site
4	Phase II/III treatment with SOC drug	Non-partner (other community) sites



Decentralized elements available at our Partner Sites will be included on all feasibility review forms to facilitate integration during study activation. We have partnered with our Investigational Drug Service, Regulatory Affairs, and Data Safety and Monitoring teams to ensure methods and trials selected are in line with all applicable regulations. We have also partnered with large network and federal providers to expand access to UCSF trials.



Future Directions

This model aims to provide patients with a more flexible clinical trial participation option while enabling UCSF to expand access beyond traditional geographic and socio-economic limitations. As we increase DCT activity, we envision broader participation in clinical trials, enhancing both patient care and research.

We will use the data collected during the pilot phase of the project to develop guidelines and best practices for managing DCTs at our site. Once these workflows are in place, the HDFCCC will be able to offer decentralized trial support to sponsors, allowing us to further expand clinical trial offerings throughout our catchment area.