Category: Clinical Trial Operations – Work in Progress

Transitioning to Remote Monitoring Visits at the Helen Diller Family Comprehensive Cancer Center

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1. Background

As of March 16, 2020, the city and county of San Francisco implemented a shelter-in-place order that required our study teams to quickly begin working remotely. As a result, many of our monitoring visits were cancelled or postponed. Due to the need of ongoing monitoring, many study teams were overwhelmed with requests to manually scan in source documents to share with study monitors and/or unable to share electronic source documents with sponsors in a secure fashion.

2. Goals

Our primary goal was to develop a workflow that allowed study monitors secure access to our electronic source documents so that we could continue to safely treat and enroll patients onto our clinical trials. Due to limited staffing on site, we also needed to identify a solution that effectively utilized our clinical research coordinators' (CRCs) time on campus preparing for monitoring visits.

3. Solutions and Methods

We worked with our IT and legal team to establish a workflow and participation agreement that allowed monitors access to our study patients' electronic medical record using MD Links. While establishing our workflow and sponsor level agreements, we reached out to multiple cancer centers to understand their workflows, lessons learned, and best practices. We then piloted our workflow with two of our main study sponsors. After successful visits, we then expanded to the entire cancer center. As of December 2020, this workflow was implemented across all research at UCSF.

4. Outcomes

During 2020, we conducted over 592 monitor visits remotely. This represents over 60 percent of our yearly monitoring visits and over 30 of our clinical trials sponsors.

5. Lessons Learned

We are focusing on standardizing our workflows and working with our IT team to fully use our EMR to its capacity for research purposes.