

The Clinical Research Team at a Community Hospital: Essential Now and Essential After the Pandemic

By Suzanne J. Rose

Stamford Hospital, the location of our research site, is a 305-bed, Level II trauma center located in Fairfield County, the county at the epicenter of Connecticut COVID-19 cases. As of May 29, 2020, Fairfield County had 36% of the 41,303 positive cases and 31% of the 3,769 deaths in the state.¹ Our hospital expanded from one to four ICUs and added almost 100 beds to the hospital.

Like most clinical research sites, we quickly started hearing from sponsors that enrollment was on hold, anticipated site qualification and initiation visits were postponed indefinitely, and newly consented subjects were to return for re-enrollment at a future date. Study participants started cancelling visits and our enrollment numbers took a deep dive. Our site quickly went from 61 active trials with 39 actively accruing, to 27 with only therapeutic oncology trials remaining open to patient accrual. We have made remote working arrangements for six staffers, including research coordinators on days they are not seeing study participants.

Because of the increase in the number of ICUs and beds dedicated to COVID-19 patients, along with many frontline clinical personnel becoming sick from exposure, several clinical research staff members have been assisting in bedside care and joining daily ICU rounds with community physicians to help collect critical data from our most severely ill patients. We are also offering participation in our seven open COVID-19 studies, when appropriate.

We are becoming experts on COVID-19 and the various treatment options now available and under development. We work daily with sponsors, CROs and other contacts to bring in new studies, not only for our patients but also for our clinical care professionals who are either sick or have been exposed in the hospital or clinic. We are writing new protocols and working with the regulatory agencies to push new treatments forward. While we are still caring for our previously enrolled subjects, most of our patient- and subject-centered efforts have shifted to tackling this pandemic.

The above activities consume about 75% of our staff's time, leaving 25% to be put to other productive use. To that effect, we have reminded staff to keep all their studies up to date with the following actions:

- Process external and internal feasibility assessment documents.
- Review studies to see if a request to consent by phone would likely be approved by the IRB.
- Keep site monitors up to date on site status and discuss studies.
- Facilitate study remote monitoring.
- Stay in touch with active study patients.
- Prescreen patients for all studies.
- Complete all institution-required online learning modules.

We have also asked staff to fill their spare time honing or learning new skills:

- Complete all personal/competency/developmental plan goals, as possible.
- Become proficient in our CTMS and other systems by making sure all records are up to date and by watching all the training videos.
- Become proficient in eRegulatory by entering all the documentation for a clinical study not yet in the system and by reviewing training documents.

- Become proficient in our new notetaking system and start using it actively.
- Attend all inhouse virtual tumor boards, grand rounds, town hall meetings, etc.
- Apply for ACRP or SOCRA membership, train for certification, and take the certification test.

We have also asked staff to work with faculty and residents on active and potential investigator-initiated studies and to complete housekeeping chores like cleaning out and organizing email.

Ongoing studies and the above work are keeping our staff fully occupied. By getting up to speed on new technologies and catching up on work, we are staying essential now and will be well-prepared to launch into the post-COVID-19 new normal of essential clinical research.

Reference

1. Coronavirus. (n.d.). CT.gov - Connecticut's Official State Website. Retrieved May 12, 2020, from <http://portal.ct.gov/Coronavirus>.

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