Category: Clinical Trial Operations – Work in Progress

Navigating Oncology Clinical Trials in the Era of COVID-19 – A CRC Perspective

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1. Background

When COVID-19 was declared a pandemic on March 11, 2020, who would have known the road that lay ahead? Emergency meetings among leadership were called and the clinical trials office (CTO) prepared for all possible scenarios while keeping in mind the best interest of patients and staff.

2. Goals

Our CTO had to immediately pivot our processes to conduct business remotely, with limited in-person contact. At the same time, working with oncology patients, we knew that our trials could not be put on hold. Goals included:

1. Providing staff the tools needed to work remotely
2. Developing alternate workflows for clinical trials operations
3. Revising policies for virtual environment

3. Solutions and Methods

Technology became the backbone of our CTO. Effective almost immediately, the majority of the CTO staff were instructed to work remotely. Only a limited number of staff had supplied laptops which could connect to the university's intranet. Equipment, internet availability, etc., had to be assessed for all staff. Employees worked closely with IT to ensure virtual connectivity. Meetings became virtual, and regular "check-ins" were scheduled to assess morale and employees' ability to manage workload. Clinical research coordinators (CRC), research nurses, specimen technicians, and management continued a presence on campus, as some tasks could only be done on site.

Subjects' treatment on clinical trials and recruitment never stopped during the pandemic. Patient safety was the CTO's first priority. Staff learned how to accommodate ever-changing visitor policies, COVID-19 guidelines, and protocol deviations directly related to the pandemic. A new standard operating procedure (SOP) was created for alternate methods of consent, which detailed consent when meeting face-to-face was not an option. This SOP included fax, email, and mail options, while also incorporating phone or video chat. In-person contact with patients required special personal protective equipment. Introduction of COVID-19 vaccines created new hurdles as investigators worked to ensure patient safety was maintained and study participation interruptions were minimal. Communication with sponsors was integral to ensure subject safety and quality data.

Routine monitoring and audit visits were moved to virtual, with the hospital restricting all visitors. This was an easy transition for CTO, as we already had electronic regulatory binders in use and most (if not all) of the source documents were in a patient's electronic medical record.

4. Outcomes

The CTO continued to operate throughout the pandemic, with minimal disruption in subject treatment. Staff was able to communicate effectively and work as a team to ensure that our participants came first. Now that staff are back on campus 100 percent, we are beginning to expand and restructure our teams to help increase the number of therapeutic clinical trials, with the aim of increasing therapeutic enrollments.

5. Lessons Learned and Future Directions

We learned a lot during the pandemic, which tested every aspect of the CTO. Flexibility and acceptance of change became something our office can easily handle. We survived, and we are on the road to thriving. We have integrated technology in our workflow by conducting meetings virtually and allowing staff flexibility to work virtually. Telehealth and alternate methods of consent are still being utilized.