Category: Clinical Trial Operations – Completed Project

Clinical Trial Office Response to COVID-19 at an Academic Comprehensive Cancer Center

E. Bentlyewski, F. Brogan, R. Shelton, J. Jurcic, A. Lassman

Herbert Irving Comprehensive Cancer Center, Columbia University Irving Medical Center

1. Background
The COVID-19 pandemic challenged our department to adapt existing workflows to maintain high quality cancer care and clinical trial compliance. Limited patient access to campus altered the way trial procedures were conducted. Clinical research staff, including research nurses, were redeployed to other departments within the institution. Limited hospital bed availability due to COVID-19 proved difficult for our cancer clinical trial patients.

2. Goals
To evaluate practice alterations in response to the COVID-19 pandemic, including redeployment of research staff, decreasing research activities, utilizing telehealth, shipping oral study agents, and coordinating inpatient admissions for patients actively on trial who require hospitalization.

3. Solutions and Methods
Our department has staff of 25 research nurses and research nurse practitioners who work primarily in assigned disease-based teams and assume all clinical care for patients on study. One-third of the nursing staff were redeployed to other clinical departments. In response, remaining nurses filled these gaps in coverage. This was possible because of standardization of policies and procedures throughout our department.

Many of our patients travel from out of state for clinical trial and had difficulties coming to New York. For these patients, we performed remote telehealth visits where feasible. If possible, we performed laboratory and other assessments locally and shipped oral study drugs directly to patients. This involved careful coordination to ensure investigational product stability and maintain patient safety.

Cancer center leadership recognized the continued need to provide excellent cancer care and access to clinical trials during the pandemic while mitigating risk. To reconcile these competing needs, we carefully decreased our study activities while maintaining care of active patients and still offering patients access to trials with potential therapeutic benefit. Enrollment to trials was paused with a review process implemented to request exceptions for accrual of new patients to existing studies. No exception requests were denied.

4. Outcomes
Standardized workflows aided in cross coverage between disease team research nurses and research coordinators.

Obtaining local laboratory and imaging assessments, use of telehealth and direct shipment of oral study agents to patients helped keep maintain protocol adherence and mitigate COVID-19 exposure risk. Careful ramp-down of research activities prioritized studies with potential therapeutic benefit. This allowed us to adhere to university research restrictions and maintain patient access to clinical trials with potential benefit.

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5. Lessons Learned and Future Directions

The pandemic experience demonstrated that clinical trials offices must remain nimble to adapt to large-scale disruptions. Standardized workflows, training, and competencies allowed the continued conduct of clinical trials while many staff members were redeployed to departments. The use of telehealth and local assessments was beneficial and can be applied more widely to allow patient-centered care closer to their home.