*Category: Clinical Trial Operations – Completed Project*

**Solutions for Clinical Research Continuity During the COVID-19 Pandemic**

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**1. Background**

At the beginning of the COVID-19 pandemic, clinical trial sites were forced to create new and innovative strategies to ensure continued compliance with study milestones. On March 17, 2020, all research staff at Sylvester Comprehensive Cancer Center (SCCC) clinical research services (CRS) began working remotely. The CRS quickly transitioned with the addition of twice weekly virtual meetings for each site disease group (SDG) to ensure the continuity of communication flow and patient care. SCCC and the University of Miami system adapted quickly with innovations to counter challenges posed by the pandemic, including shipment of oral medications, monitoring of staff safety and well-being, development of remote informed consent procedures, travel limitations, interruption of treatment, and transition to telehealth.

**2. Goals**

The goal of our team was continuity of care within clinical research. We had many subjects in the middle of treatment, and many that come from the local area as well as Latin America to obtain care.

**3. Solutions and Methods**

Disruption caused by the pandemic highlighted the importance of adaptation and flexibility in designing patient- and sponsor-friendly approaches in establishing sustainable trials, including COVID mitigation plans that were approved by the institutional review board (IRB). At the start of the pandemic, SCCC had approximately 275 active patients in clinical trials, with approximately 89 percent transitioned to telehealth visits to ensure continuity of care. Required lab monitoring was conducted through laboratories near patient homes to reduce exposure risk. Radiologic testing continued as required per protocol. Patients on oral drug regimens (112 subjects over 47 trials) received medication shipped to their homes per FDA, NCI, and sponsor-specific guidelines, reaching multiple countries including the United States, Russia, Brazil, and Argentina. A standard operating procedure (SOP) was implemented for conducting remote informed consent via videocall to limit subject onsite visits and quality of life (QoL) surveys were also performed remotely via standard mail.

With the support of our clinical research leadership, SCCC never fully closed enrollment during the pandemic and was able to continue enrolling and treating our subjects on clinical trials.

**4. Outcomes**

Promising advances that emerged include:

- Creating sponsor newsletter to address blanket study mitigations
- Establishing and communicating new in-home patient visit procedures
- Transitioning clinical trial activity to homecare models
- Creating managed access programs for medication pre-approval
- Accelerating cost effective therapies through the sharing and analysis of real time data

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**5. Lessons Learned and Future Directions**

The pandemic has illustrated the need to have a complete remote environment with regards to clinical trial data. This has allowed us to continue our implementation of having research source documents uploaded to a separate section of the electronic medical record so that all data is housed for access remotely. We are also working with our research data group to ensure that we continue to develop our clinical trials management system to meet the needs for remote access.