Category: Clinical Trial Operations – Work in Progress

Executing a Healthy Volunteer Study During COVID-19 Pandemic

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1. Background

During the COVID-19 pandemic, City of Hope (COH), like other institutions, implemented and enforced visitor restrictions, including employees, both at main campus and community sites. Additionally, many patient visits were conducted via telemedicine. These restrictions dramatically decreased the number of healthy individuals accessing COH, learning about and potentially participating in healthy volunteer studies. This significantly impacted our Phase I COVID vaccine healthy volunteer study. Study participants were managed separately in a section of our clinical research unit (CRU) on evenings and weekends. Unfortunately, physician availability on evenings and weekends visits was limited. While consenting was completed remotely, all other study visits (12) required in-person assessments. The limited availability of space and physicians caused accrual delays. To meet the enrollment goal and move into Phase II, the study team needed to increase visibility, study access, and safely manage study participants and COH patients.

2. Goals

To achieve accrual goals, the study needed to be conducted outside COH main campus and was not originally operationalized for the community setting. The study requires nurses to complete multiple procedures and exams at each visit. We needed an innovative solution to execute the trial in the COH community with trained staff while also limiting the people accessing the clinic.

3. Solutions and Methods

We decided to use the COH bloodmobile unit, park it at select COH community sites, and complete study procedures in the unit, limiting the participants entering the community clinic. We hired an experienced per diem research nurse practitioner to provide study support. We selected a site with research-trained physicians for injection visits requiring MD observation post-administration. We worked closely with pharmacy and developed a clinic schedule for all injection visits to occur on Saturdays allowing use of clinic space during their closed hours. All other study visits were scheduled and conducted in the mobile unit on weekdays.

4. Outcomes

To enroll the maximum daily number of patients, based upon research lab draw requirements, we scheduled two rounds of participant enrollment visits. We did not move forward with the fist start date schedule due to limited number of participants wanting the specific community location. The second community site enrollment was scheduled for April/May.

5. Lessons Learned

After identifying the community site, we engaged marketing, updated study flyers, and established a number for participants to call with staff answering that could outline the community site schedule and

track participants interested in the community site. Additionally, we simplified complex and slow patient enrollment processes. Updating flyers and institutional review board approval took time, giving us under two weeks of community advertising. Unfortunately, the timing limited our ability to consent enough participants for our first community site scheduled start day. The FDA emergency use-approved vaccines also reduced interest. It is unclear if a second scheduled community start date will be necessary as we are able to enroll participants more quickly, and the expanded marketing increased interested participants. However, we now have a plan to implement healthy participant studies at community sites, even with limited space access, including the Phase II portion of this study.