Case Study

COVID -19 Clinical Trial

Type of study

A Randomized, Double-Blind, Placebo Controlled, Trial To Evaluate The Efficacy And Safety Of A New Therapy For Post-Exposure Prophylaxis Of COVID-19 And Other Viral Respiratory Illnesses (VRI)

Phase: 3

Key Achievements

- Successful and accurate study step-up in less than 2 weeks versus the standard 8 weeks
- Sourcing materials in-house for shipment on time despite current logistical challenges
- Building and shipping kits to site within client's expectation window
- Ability to quickly adapt to changes made and cource the new required supplies

Study Details

Patients Screened: ~1600

Patients Enrolled: ~ 1400

Sites: ~ 30

Regions-Countries: North America

Services Provided:

- Safety testing: hematology, biochemistry, and urinalysis
- RT-PCR through GenMark ePlex® Respiratory Pathogen Panel
- Hologic SARS-CoV-2 (Panther Fusion® System) for COVID-19 testing
- COVID-19 testing in stool samples
- Sample management: drug susceptibility testing and blood samples for PK

Timeline

Challenges

Due to the Covid-19 outbreak, a flexible and quick approach was required for every aspect of the trial. New assays needed to be developed despite stability and testing information not being complete. Protocol changes were introduced during study set-up, due to new FDA requirements. Shipments needed to be turned around quickly upon sponsor's "Go" decision. Multiple lastminute changes occurred.

Successes

Contingency planning and our flexibility to execute quickly and communicate effectively allowed us to meet the timelines. While the trial was conducted in North America, our global team provided support around the clock. Risk identification and challenge mitigation proved helpful as the team and Sponsor were well-prepared when the risks became real. We were able to ship everything within the short time frame provided.

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