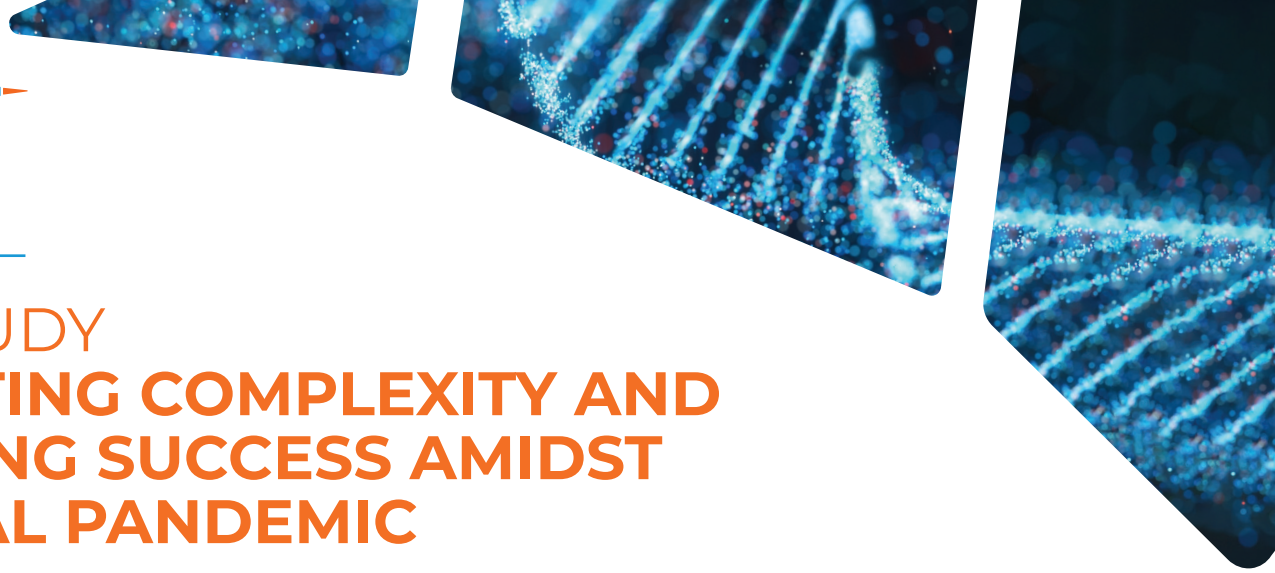
QPS
CUSTOM-BUILT RESEARCH™



CASE STUDY
NAVIGATING COMPLEXITY AND ACHIEVING SUCCESS AMIDST A GLOBAL PANDEMIC

In 2021, our team embarked on a critical Phase 1 multi-site study aimed at evaluating the safety and immunogenicity of a promising COVID-19 vaccine. This study was designed to include both young adults and older adults (over 55), who are particularly vulnerable to severe outcomes from SARS-CoV-2 infection.

STUDY OVERVIEW

Objective:
- Evaluate the safety and immunogenicity of a replication-competent chimeric virus vaccine platform developed to protect against SARS-CoV-2.

Population:
- Young adults and older adults (over 55 years).

Study Design:
- Single dose administration with domiciled observation for 7 days followed by a one-year follow-up.

CHALLENGES AND SOLUTIONS

Operational Challenges During a Pandemic:
- Our team implemented robust safety protocols to protect participants and staff, ensuring the trial's continuity and integrity.

Managing Patient Diaries:
- We utilized electronic diaries that allowed participants to record their symptoms and experiences in real-time. This approach not only streamlined data collection but also enhanced participant engagement and compliance.

Stringent Observation Period:
- We conducted a rigorous post-vaccination observation period, monitoring for any adverse events and providing immediate medical support as needed.

Evaluation of Viral Shedding:
- The study required meticulous collection and analysis of saliva, urine, and stool samples to evaluate viral shedding. Our team adhered to stringent biosafety protocols to handle and process these samples effectively.

PBMC Sampling:
- Completing PBMC sampling across multiple visits was a complex task, especially for local sites lacking the necessary capabilities. Our team not only met the enrollment expectations but also extended support to these sites by running PBMC samples on their behalf, ensuring the study's requirements were met.

OUTCOME

Despite the challenges, our site successfully met the enrollment expectations for both young and older adults. Our proactive approach and adaptability allowed us to navigate the complexities of conducting a clinical trial during a pandemic. Additionally, our collaborative efforts in running PBMC samples for local participating sites demonstrated our commitment to the study's success and the broader scientific community.