Accellacare

Flexible and meticulous management in an evolving environment

Accellacare Site Network boosts enrollment in COVID-19 vaccine trial

Case Study

Study description

A large pharma sponsor was conducting a Phase 2/3 randomised, placebo-controlled COVID-19 vaccine study. Facing labour and supply shortages, as well as unprecedented safety challenges due to the ongoing pandemic, the sponsor contracted Accellacare to support their staffing, enrollment, and logistics across seven US sites.

Therapeutic area

Infectious Disease and Vaccine

Phase 2/3 study

Services Used

Accellacare Site Network
FIRECREST

7 Accellacare sites contracted

Exceeded enrollment by
42%

3
Top enrolling sites

<24 hours from site activation
to first patient visit

Situation

A large pharma sponsor was studying a COVID-19 vaccine candidate in a Phase 2/3 randomised, placebo-controlled trial. Due to the ongoing pandemic, the sponsor faced a clinical development landscape that was constantly evolving as more information became available and safety recommendations were updated. To support staffing, enrollment, and logistics, the sponsor contracted seven Accellacare sites in the United States.

Challenges

Global personal protective equipment (PPE), lab supply, and labour shortages due to the ongoing pandemic added complexity to the study. Patient visits needed to be scheduled with enough time for the staff to complete additional safety and sanitation protocols between visits to avoid possible contamination, including sanitising tablets for eConsent. At the same time, sites faced staffing shortages due to possible COVID-19 exposures, mandatory quarantines, confirmed COVID-19 infections, and an overall reduced workforce.

Sites were also working to implement a new electronic source and investigator site file (ISF) system that required patient data to be entered within 24 hours of a visit. Sites that did not have the EMR were required to scan and manually upload source documents for CRAs to review remotely, which was incredibly time-consuming. Additionally, a shared investigator platform (SIP) system was put in place to streamline where all site information was stored.

Solutions

Accellacare Site Network provided the sponsor with an agile and meticulous approach to resource management and risk mitigation. Working with our sister sites, Accellacare was able to share staff that was not already working on the study, pulling resources as needed to ensure scheduling accommodated social distancing protocols and no unnecessary exposure occurred. Staff worked nights, weekends, and overtime to ensure the trial ran smoothly.

Strong communication was also critical in the study's success. ICON implemented study changes and amendments throughout the contracted Accellacare sites, assigning dedicated project managers and consistent CRAs throughout the study enrollment period. Comprehensive training was provided, and clearly organised by role, through one single platform, FIRECREST. FIRECREST also housed essential documents and any required acknowledgement of updates, acting as the central repository for the most up-to-date study information.

Additionally, Accellacare ensured all logistics needs were met, including flexibility with drug shipments that were received during off-hours, label systems for different dosages and constitutions, freezer space to keep different drugs organised, and temperature control. The team also worked diligently to schedule patient visits with drug expiration dates and social distancing measures top-of-mind. Meticulous planning and organisation upfront ensured study staff were able to manage the demand for the vaccine, scheduling for sub-studies that may be canceled, and scheduling of second dose or follow-up visits during new enrollment visits. This kept the study running smoothly and data quality high.

Outcomes

Over the course of the study, the sponsor exceeded enrollment goals by more than 42%, with more than 2,400 patients enrolled at Accellacare sites. Across all Accellacare sites, the first patient visit occurred in less than 24 hours from site activation. Additionally, three of these locations were recognised as top enrolling sites, with one site acknowledged as a top 10 enrolling site.

The overall study was able to vaccinate millions globally with a first-of-its-kind vaccine that was granted Emergency Use Authorisation (EUA) and eventually FDA approval.