CASE STUDY

PPD Develops a Decentralized Strategy for a COVID-19 Clinical Trial

BACKGROUND

A global biotechnology organization, working on a trial intended for COVID-19 positive participants, needed a trial design that would work within the unique set of research challenges created by the pandemic.

OBJECTIVE

Conduct a Phase IIb platform trial for a novel COVID-19 treatment while respecting the limitations on travel and in-person visits imposed by various governments due to the ongoing pandemic.

CHALLENGES

- Sites had restrictions on COVID-19 positive patients entering their facilities
- The industry was looking for expedited and innovative solutions to minimize the pandemic's disruption to clinical trials

STRATEGY

The team developed a decentralized, virtual site solution supplemented by traditional brick-and-mortar sites. The strategic plan included:

- Consultancy on protocol development to optimize a decentralized clinical trial (DCT) approach and application
- Novel and remote, digital patient-recruitment strategies
- Innovative patient recruitment through enhanced use of social media
- The ability to monitor diversity and enable flexibility to pivot from traditional to virtual sites to achieve diversity goals
- Licensing technology into brick-and-mortar sites to operate in a DCT environment alongside traditional visits, resulting in a flexible digital solution with risk mitigation built in
- Designing and creating a patient trial kit with all necessary devices and equipment for trial execution – delivered directly to the patient's home

RESULTS

- The innovative operational model deployed in the study allowed for enrollment and visit challenges to be overcome with a single virtual site
- Patients completed 100% of visits in their homes
- The virtual site outperformed traditional brick-and-mortar sites with 10 times the patient recruitment
- Recruitment channels pivoted to the virtual site midstudy to increase recruitment of specific patient demographics with no timeline impact or disruption
- Site staff were protected by ensuring COVID-19 positive patients did not need to visit the site
- Geographical limitations were circumvented for over 400 patients who were recruited via the virtual site

100%
All visits were completed in the patients' homes

10 to 1
Virtual site outperformed traditional sites