CASE STUDY

PPD leverages key digital and operational capabilities to rescue and decentralize a study in a matter of days

BACKGROUND AND CHALLENGE

A dermatology study was successfully underway in Italy that required several primary end points to be collected via in-person clinic visits. Following the impact of COVID-19, stringent controls were implemented by the Italian government to restrict the movement of people that directly resulted in the risk of five patients being unable to attend a planned visits – and therefore, the inability to collect primary end point data from these visits.

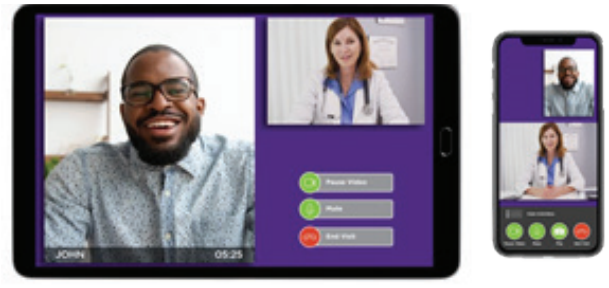
SOLUTION

Strategy

The Italian Ministry of Health (MOH) released guidance that supported rapid adaptation of the approved study protocol and the subsequent amendment process, facilitating the continuation of the patient visits. Our digital trial team was continuously monitoring the situation and via their consultancy group were to implement a technology solution that would allow the primary end points to be collected as planned. Over the next week, our digital and operational experts collaborated to develop a successful strategy for the customer.

Technology

PPD's digital trial group implemented a TeleVisit solution, powered by Medable, that enabled our teams to quickly deploy to the site. This included:



1. A TeleVisit lite module

A visual communication tool used to facilitate investigator and patient interaction, developed specifically in response to COVID-19.

2. Consent to support the application of the TeleVisit

Ensures compliance for the TeleVisit to proceed.

Rapid Implementation

Consulting

Together with our internal clinical operational teams, we assessed the possibilities and feasibility of digital applications, including remote solutions to ensure visits continue as planned. In addition, we aligned on training, supporting documentation and regular discussions with the Principal Investigator (PI) and client on next steps.

Device deployment

Utilizing our network, we identified supplies and created contingency plans for materials, including local Italian suppliers' availability.

Site readiness

Our teams provided support through training for the site, patient and study team as well as documentation for application. In tandem, we developed a TeleVisit performance feedback questionnaire for all Principal Investigators (PIs) to gather feedback on application.

Regulatory and data privacy, compliance

Our in-house regulatory experts were highly involved in the strategy that aligned with the new, unprecedented Ministry of Health (MOH) guidance for accelerated deployment and application. In addition, the data privacy team worked together to review guidance for novel consent development to support application of the TeleVisit solution.

OUTCOME

Despite tight deadlines, our digital trial team pushed through and deployed a visual communication tool that allowed all of the patient assessments to continue as planned.

This strategy not only provided a 21 CFR Part 11 compliant digital solution for the customer, but also created a way for the investigator to better connect with the patient and assess their safety and efficacy. As a global team, we ensured patient safety and primary end point collection was maintained.

INTERESTED IN LEARNING MORE?

Contact us today: godigital@ppdi.com