



PPD Quickly Deploys Direct-to-patient (DTP) Strategy and Hybrid Trial Model for Patients to Safely Continue Receiving Care

BACKGROUND AND CHALLENGE

An ongoing anemia study with thousands of patients enrolled at hundreds of sites around the world was at risk of delays due to the COVID-19 pandemic. With a complex protocol that included cold chain comparator and controlled ambient investigational medicinal product (IMP), there was a need to rapidly adapt and provide a solution so dosing patients could continue and that travel to clinical sites would not be a requirement during this time. Knowing the clock was ticking, the global biopharma company reached out to PPD for an immediate strategy to protect patient safety and study continuity while preventing additional risk to patients.

SOLUTION



ADAPTING PROTOCOL FOR MAXIMUM FLEXIBILITY

PPD's medical monitor and clinical team discussed the client's original study need for a third-party lab to collect and process hemoglobin tests. Our teams helped to review, adapt and optimize study requirements by removing this testing step and reconstructing the protocol to allow for a more rapid response to patient need.



DTP IMPLEMENTATION

Early in the pandemic, PPD proactively established a global process with our preferred partner to enable DTP services for all PPD-managed studies.

Equipped with a proven process, our experts were able to quickly provide the client an implementation plan that included a recommended volume of DTP shipments of IMP (requiring temperature control of 2°C to 8°C and 15°C to 25°C). Per the study protocol, these DTP shipments had a tight turnaround time of three to five days for collection with same-day or next-day delivery, depending on location.

A project-specific shipping process was set up for the study with forecasts of need provided to the vendor. Simultaneously, the forecast was provided to our preferred DTP partner to allow for preparation of the relevant materials in country. Our global clinical supplies and project delivery team members continued to closely monitor shipments and volume against projections, developing reporting and informing future forecasts.



TELEMEDICINE OPTIONS IN LIEU OF PHYSICAL SITE VISITS

With the expertise and guidance of PPD's digital and decentralized solutions group, in-clinic visits were conducted with patients via telemedicine provisions from their respective, local investigator sites.

THE RESULTS

As part of this study, PPD has successfully completed **over 100 DTP time and temperature sensitive shipments** for the client across Asia, Europe, North America and Latin America. With protocol continuity in place, these **patients have been able to continue to receive treatment** despite closures and travel restrictions. As a result, **patients have not missed treatment** or had to leave the study due to inability to access resources. With a well-structured DTP supply chain established, **the client did not experience a significant surge in trial cost** due to savvy investments made into digital and virtual options.

SOLUTION *continued*



CONTINUOUS REGULATORY MONITORING

Our regulatory team has routinely monitored guidance issued from each country it's specific direction on DTP logistics.



TRAINING

Our teams worked with sites to ensure patient consent was collected. Training was provided to the project clinical team on how to complete the forms to ensure that the local CRAs could enable the sites to work efficiently with our vendor.



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