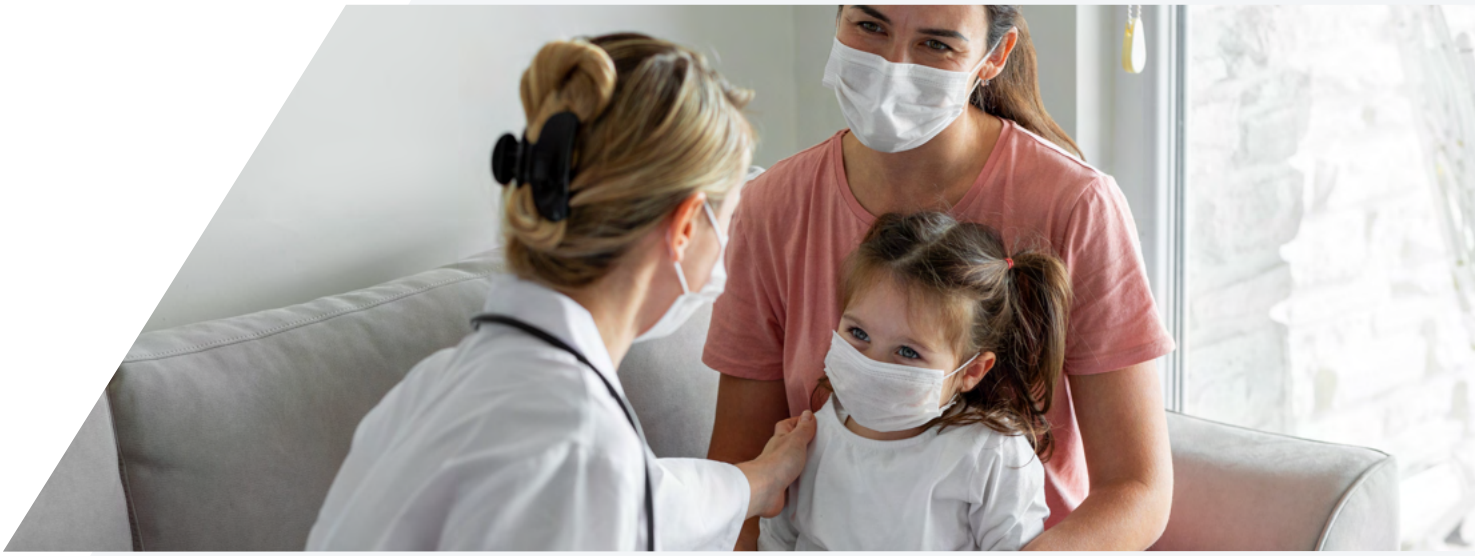
PROPHARMA GROUP®

Improving Patient Health and Safety

DECENTRALIZED VISITS IN RARE DISEASE STUDIES



Challenge

- Due to the COVID-19 pandemic, many clinical sites were forced to shut down or to function and continue to function at a reduced capacity, causing significant delays or cancellation of study visits across numerous clinical trials.
- Additionally, high-risk rare disease patients were hesitant to return to the site for fear of exposure to the Coronavirus.
- Existing challenges related to travel became even more cumbersome as patients and family members were often traveling by plane to reach their specialist. Risk of exposure as well as reduced travel options further complicated study enrollment and commitments.
- In the pediatric population, a parent or caregiver is required to participate and be present for visits, furthering the risk of exposure to the family.

Solution

- The ProPharma Group Decentralized Clinical Trial (DCT) team immediately reviewed protocols to collaborate and propose decentralized visit solutions to the Sponsor , allowing for continued and successful study milestones to be met.
- Our head of Nursing collaborated with the Sponsor team to determine and address all nursing considerations necessary for safe and successful visits and data collection. Disease-specific training was completed with each assigned clinician prior to any visit activities.
- The ProPharma Group team of trained and qualified GoClinical Clinicians were dispatched for a variety of Sponsor-approved visits that allowed business to continue as usual in an unprecedented time. These visits included safety follow ups with blood draws and ECGs.
- Our DCT team coordinated with clinicians and families to arrange for convenient and study-appropriate visits. In some cases, multiple family members were able to complete their visits within a single visit from the ProPharma Group clinician.

Results

- By including decentralized visits, the Sponsor was able to continue without major disruptions to their study timeline. It is estimated that 80% of studies that did not have DCT options were forced to put the study on hold.
- Reduced patient burden and risk of exposure to COVID-19 proved to keep patients enrolled, and therefore, reduced overall costs to the Sponsor.
- Patients continued to receive treatment or study participation with little to no disruption to their health and safety.
- Decentralized visits provided both safety from exposure to Coronavirus and the convenience of limited travel requirements for patients and their families.