PROPHARMA GROUP®

Improving Patient Health and Safety

CASE STUDY

Initiating Enrollment within 6 Days: Data Safety Monitoring Board (DSMB) Expediates Protocol Reviews to Meet Deadline for Accelerated COVID-19 Treatment Studies

Dedicated project oversight pays off with two concurrent COVID-19 treatment studies initiated and ready for Subject enrollment in less than one week.

In May 2020 as FDA released new guidelines to accelerate the development of novel COVID-19 therapeutics and vaccines, our Clinical Services experts were asked to provide independent DSMB and Medical Monitoring resources for not just one, but two concurrent COVID-19 treatment studies scheduled to enroll Subjects in less than one week. The Sponsor was granted an Emergency Use Authorization making expedited support critical for success. ProPharma Group's clinical expertise and rapid responsiveness facilitated the Sponsor's success of this milestone.

> "Our standardized practices and collaborative team of clinical experts allowed us to expedite our support by executing several parallel tasks to make this request happen and meet the enrollment deadline for both studies in under a week!

James Meckstroth
Principal Compliance Consultant

Challenge

An existing client received agency Emergency Use Authorization to sponsor two parallel COVID-19 treatment studies, but to accomplish this, they urgently needed independent and non-biased Data Safety Monitoring Board (DSMB) physicians to oversee each study as well as an experienced Medical Monitoring physician resource.

Under normal circumstances this is a routine request, where our physicians, statisticians, and administrative specialists provide oversight, coordination, and management of study safety aspects as regular activities. However, typically several weeks or even months are allowed to assemble and coordinate the safety activities for each study. **This instance of supporting two studies with less than one week's time to prepare was a formidable challenge.**

The pandemic added additional challenges such as issues of non-adherence to the protocol and the need for more frequent interventions due to patient safety concerns. The DSMB and Medical Monitoring person had to take these additional requirements into consideration while evaluating the reported data.

Solution

With just six days to complete the project we reacted quickly, and in less than 24 hours assembled a team that included a Medical Monitor, Statistician, and four DSMB team members.

As with all our clinical services projects, a dedicated Clinical Services project administrator was immediately assigned to serve as the lead point person between the client and the project members. A project kickoff meeting was held the same day that the DSMB was assembled to ensure that no time was wasted. Frequent and open communication was relayed to manage and oversee the internal and external commitments necessary to execute the project quickly and effectively.

The Clinical Services project administrator implemented project management tools to list and prioritize each of the action items to ensure that nothing was overlooked. For speed and consistency, ProPharma Group maintains well-established templates that facilitated the creation of the essential documents, such as confidentiality agreements, conflict of interest statements (or lack thereof), DSMB charters, and safety management plans. We also employed and hosted web-based meetings that allowed for efficient meeting and training collaboration throughout the process.

Results

The dedicated administrative oversight by ProPharma Group allowed time for the client to focus on finalizing the study protocols and ensured that they were ready to be initiated at the investigator sites.

As a result of thorough planning and commitment to completing the necessary actions, **both of the COVID-19 treatment studies were initiated and ready for Subject enrollment on time within a week**, **as requested, just six days after ProPharma Group received the initial request.**

The client was very appreciative of the full-service support throughout the process. Likewise, ProPharma Group is proud to partner and support our client with such a critical project, focused on improving the health and safety of patients with this new novel treatment.

This is just one example of how we partner with clients to help them achieve success.

ProPharma Group's DSMB, medical monitoring, and physician teams provide the expertise your clinical study needs to meet requirements and timelines to keep your study moving forward.

Improving Patient Health and Safety. **At Every Step.**

The ProPharma Group Advantage

Regulatory Affairs

- Drugs, Biologics, and Medical Devices
- FDA and EMA Expertise
- Full Lifecycle Support

Life Science Consulting

- 1200+ Team of Professionals
- Global Scale and Reach
- Service Excellence

Pharmacovigilance

- QPPV and LPPV Services
- Single-Source Provider
- 24/7 Multilingual Services

Medical Information

- Bilingual Native-Speaking Specialists
- Global MI Partner
- Support at Every Level

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