Case Study

PROPHARMA GROUP™

A Rare Disease Biopharmaceutical Company Sponsoring a Global Phase III Clinical Trial

Background

After developing a favorable impression of ProPharma Group's post-market pharmacovigilance services, our client who specializes in rare diseases identified the benefits of having their clinical and postmarketing PV services with the same global safety provider and of housing the entirety of their safety data, including clinical trials, within one global safety database.

The recognized benefits include: consistent case processing of clinical and postmarketing cases; access to specific case information from one source; ease of access to information for analysis of similar events; audit preparedness; and simplified regulatory report development. With a working relationship already established between ProPharma Group and our client, we were confident that we could provide the same high quality and responsive service across the continuum of the safety spectrum from pre-market clinical safety to post-market pharmacovigilance.

The Challenge

Each patient who enrolls in a clinical trial is extremely valuable to the body of research and his or her experience with the product requires specialized attention, especially in the development of orphan products for rare diseases. For this reason, our client sought a safety provider able to provide high-touch services with the ability to attend to their specific requests, while still being able to provide a scalable service model as their clinical program progressed from Phase I through Phase III studies. Also important to our client in selecting a safety service provider, was our availability and responsiveness, which were identified as essential factors to their overall customer satisfaction.

When an adverse event report is received, it must not only be processed as outlined in the safety management plan, it must also be evaluated thoroughly to ensure all aspects of the event and product use are reviewed and addressed. Case narratives need to be succinct yet detailed with the necessary information to convey the relevant details of the cases.

Attention to timelines and submission requirements to global regulatory authorities is paramount.

The Solution

As an industry leader in Individual Case Safety Report (ICSR) processing, ProPharma Group was able to easily respond to this request. Working in concert with the client, we developed the safety management plan and safety reporting forms to meet specific details of the clinical trial. Case notification lists were regularly maintained to ensure all designated team members are notified in a timely manner. Upon initial case receipt, clinical safety specialists were available to meet ad hoc with the medical monitor and other team members to discuss case specifics and the development of the regulatory report. Cases were actively processed from receipt to closure, addressing all relevant details to ensure a thoroughly vetted case while meeting deadlines for global regulatory submission.

The ProPharma Group team was proactive and worked to anticipate the needs of the client's rare disease clinical program. In doing so, potential issues were addressed early and resolved quickly. We were responsive to the requests of the client with focused attention. In providing a dedicated team, knowledgeable about the product, protocol, and special-handling requirements for their cases, our client has been highly complementary of ProPharma Group as both a pre-market clinical safety and post-market pharmacovigilance service provider.

Need a trusted parter for pre-market clinical safety services? Contact ProPharma Group today.

Contact Us