Clinical and Post-
Marketing Safety Services
Case Study

Top 20 Pharmaceutical Innovator Raises Standards and Reduces Costs with Support from APCER Life Sciences

The Challenge

A top 20 global pharmaceutical company with hundreds of trials and marketed products worldwide realized that its distributed model for clinical and post-marketing safety was yielding inconsistent narratives and medical assessments. The company initiated a project to move from multiple CROs and regional case processing units in Asia, Europe, and North America to a single worldwide center of excellence.

The goal of the global safety leadership team was to improve signal detection and benefit-risk management across all products by raising data quality and causality assessment standards. The team also wanted to eliminate backlogs of literature and other non-serious cases, along with the processes that enabled backlogs to form.

The Solution

The pharmaceutical innovator understood that partnering with a specialized service provider was the only way to accomplish its goals and reduce costs at the same time. APCER Life Sciences came highly recommended at the executive level based on the high quality of work delivered at other large pharmaceutical companies, and the firm stood ready with an experienced team of physicians and healthcare professionals to raise the bar in clinical and postmarketing safety operations.

The APCER pharmacovigilance centers in Asia, Europe and the US facilitated the transition of a variety of safety-related activities, including:

- Processing of individual case safety reports (ICSRs)
- Submission of ICSRs to US and European regulatory authorities
- Safety data exchange with marketing authorization partners
- Case processing of investigator-sponsored studies in Asian countries
- Query management
- Literature cases from a backlog of articles
- Safety data migration from newly acquired companies
- Training of company and CRO staff
- QPPV support

The Results

APCER Life Sciences continues to meet both the predictable and the unanticipated requirements at this dynamic company with a model that blends traditional offshore outsourcing with onsite staff augmentation under a single management structure.

Metrics within drug safety operations are monitored closely, and APCER continues to raise the bar while managing assignments of increasing volume and complexity in both clinical and post-marketing settings.

The high quality and consistency of case narratives and assessments is providing the company's experts in signal detection and health outcomes research with reliable real-world data needed to demonstrate the safety and value of its products.

By partnering with APCER Life Sciences, the safety leadership team has been able to:

- Maximize quality and compliance while reducing costs by 30-40%
- Stabilize safety operations and transition to a global center of excellence
- Eliminate backlogs

APCER Life Sciences is helping this Top 20 global pharmaceutical company realize its goals for growth and leadership in the industry, including:

- Absorbing business acquisitions and partnerships efficiently while remaining compliant
- Building safety profiles that facilitate longer-term benefit-risk and product-value assessments
- Listening and responding to the patient voice through every channel

Together for better health

APCER Life Sciences is committed to improving health in partnership with its clients. We bring together safety, medical, regulatory, and technology resources to ensure that patients receive the safest, most effective therapies possible.

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