Clinical Safety
Case Study

Innovative Biotechnology Company Relies on APCER Life Sciences to Manage Complex Safety Reporting in Oncology Trials

The Challenge

A biotechnology company dedicated to enhancing the body's immune response to cancer cells was advancing its lead oncology product through the clinical development process.

Since the drug was being tested as a third-line treatment in conjunction with anti-tumor monoclonal antibodies for colon, lung and hematologic cancers, the studies generated complex serious adverse event (SAE) reports that required a more experienced safety team with deeper medical knowledge than the company's contract research organization (CRO) could provide.

The Solution

The biotechnology company evaluated several drug safety specialty firms and found APCER Life Sciences to have a high ratio of safety-trained physicians experienced with SAE cases in oncology trials. With operations and expertise on three continents, a unified set of procedures, and a global technology platform, APCER was able to provide clinical safety program management worldwide.

APCER developed a transition plan that provided a clean cutover to its hosted safety database and regulatory reporting systems, taking responsibility for:

- Receiving SAEs from clinical sites in the US and EU
- Assessing SAEs for seriousness and causality and informing the biotechnology company of all reportable events
- Drafting MedWatch and CIOMS forms, as well as queries
- Notifying investigators, institutional review boards (IRBs), and ethics committees of suspected unexpected serious adverse reactions (SUSARs)
- Submitting reports to all European regulatory authorities
- Migrating and reconciling SAE cases from the clinical data management system to the APCER-hosted safety database
- Authoring the annual Developmental Safety Update Report (DSUR)

The Results

With APCER as its compliance partner, the biotechnology company is advancing its clinical studies and is more confident than ever in its product's potential to be included in every treatment regimen containing a cancer-targeted antibody.

APCER Life Sciences provided this innovative company with:

- Deep medical knowledge and extensive safety experience to parse through the complexity of SAEs associated with a third-line cancer treatment
- A comprehensive system of skilled people, global processes, supportive technology, and project governance to ensure efficient, proficient regulatory compliance
- The ability to document the long-term safety profile of its oncology drug across global studies

Together for Safer Therapies

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.

Learn more at **www.apcerls.com**, or contact us at one of our global offices

Americas
(+1) 609 455 1600
americas@apcerls.com

Europe
(+44) 208 326 3220
europe@apcerls.com

Asia
(+91) 11 4650 0802
asia@apcerls.com

APCER LIFE SCIENCES