APCER LIFE SCIENCES
Together for better health

CASE STUDY

Safety First: Scaling Up Oncology Solutions with Seamless Transition

Therapeutic area: Oncology

Product type: Drug

Geography: The United States of America

Product life cycle stage: Clinical phases I, II, III, and IV

Overview

Ensuring patient safety is of the utmost importance for pharmaceutical companies. However, many companies perceive the pharmacovigilance (PV) process to be a niche area that requires a high and dedicated skill set. Furthermore, the operation is seen as an additional financial burden for several reasons, including:

- Setting up a compliant PV system
- Hosting a safety database
- Employing skilled PV personnel
- Keeping pace with the dynamic regulations

In the initial phases of clinical trials, companies often rely upon outsourcing models to manage their clinical trials and ensure drug safety. As clinical trials progress to phase III, pharmaceutical companies start planning and preparing how to market/launch the drug.

A cohesive PV plan to aggregate safety data will be a part of submission(s) related to drug safety. This PV plan should be designed in a way that it integrates seamlessly with the company's overall drug development and commercialization strategies.

There is also a need for a specialized partner who navigates this next stage as well as supports the product as it is commercialized. The partner can assist with developing and implementing a cohesive PV plan, aggregating and analyzing safety data, ensuring compliance, and supporting post-market surveillance.

Such collaboration allows pharmaceutical companies to concentrate on their core mission—developing and delivering safe and effective therapies to patients.

About the Client

A US oncology-focused biotechnology company with a global footprint with a portfolio of innovative products for cancer treatment that strives to accelerate the discovery and development of new medicines for difficult-to-treat cancers to extend and improve the quality of patients' lives.

Business Challenge

A US-based global biotechnology company, specializing in oncology, with its key innovator molecules in oncology (indications: renal cell carcinoma [RCC], hepatic cell carcinoma [HCC], and solid tumors) has been utilizing APCER services for post-marketing case processing since 2018.

The company encountered several challenges in maintaining quality and regulatory and business partner compliance for clinical trial cases due to:

- an addition of a new molecule, an ongoing clinical trial for a new indication of an already approved molecule, and an increase in collaborative trials with business partners;
- difficulty in scaling up inhouse resources to manage the surge in volume, leading to backlogs mounted up to 2,000 cases' versions (non-reportable cases);
- prioritizing reportable cases, which resulted in a backlog of non-reportable cases; and
- struggling to meet regulatory/partner submission deadlines given the stringent submission timeline.

Therefore, the client reached out to APCER for support in maintaining clinical trial cases, ensuring regulatory and partner submission compliance with the highest level of quality, so that the innovator company can focus on its business goal of clinical development and safety data analysis.

Solution

The APCER team implemented a multi-faced approach involving operational scaling, effective resource allocation, and effective project management methodologies to mitigate the surge in volume while maintaining quality and compliance. Consequently, the following steps were taken:

1. **Seamless Transition and Ramp-up Plan:**
    1.1. A **robust ramp-up plan** was prepared in consultation with the operations and project management teams, which outlined transition milestones and activities to ensure a smooth transition of the responsibilities considering unanticipated surges in cases.
    1.2. A **clear agreement** was established o**n case processing timelines** for reportable and non-reportable cases to meet regulatory and partner compliance and without keeping any backlog of cases.
2. **Onboarding and Training:**
    2.1. **Onboarding of resources** was done as per the agreed **project plan** over a period of 6 months.
    2.2. **Identification and reallocation of the existing experienced resource** from post marketing case processing (same client) to clinical trial case processing was done.
    2.3. **Quick cross-training** was provided to the existing team, with a target to complete a significant number of non-reportable backlog cases.
    2.4. **Parallel training for newly identified** and onboarded resources for clinical trial reportable cases along with backfilling of post-marketing cases was conducted.
3. **Robust Project Monitoring and Client Collaboration:**
    3.1. During the initial 3 months, **regular progress reviews** were conducted through weekly calls. This was followed by bi-weekly calls, fostering close collaboration with the client to address issues and align on the project plan.
    3.2. A phase-wise handover of clinical trial cases was conducted with a successful achievement of pre-identified goals for each milestone.

Outcome

Timely backlog clearance

Along with the **rapid ramp-up** of resources, the team ensured high-quality work and completed the backlog of non-reportable cases in 3 months as agreed.

Active client involvement enabled the alignment of project strategies with successful outcomes, meeting client expectations.

Meeting client expectations

Accomplished key milestones

Continuous **monitoring** of the project plan and status reports kept stakeholders informed and ensured that the milestones were met efficiently.

100% compliance to regulatory and partner submission reinforced client oversight for quality and compliance.

Quality and Compliance

Enhanced client trust

A client diligent approach ensured swift clearance of the backlog of clinical trial cases, within an optimal timeline, further strengthening the client's trust in the team's ability to handle increasing workloads.

APCER, through its thought leadership and subject matter expertise, helped the innovator company to be more **regulatory compliant and audit-ready**, thereby reducing the risk of any future audit/inspection findings.

APCER's Pharmacovigilance Capabilities

Domain Expertise

100+ physicians, >90% healthcare professionals supporting drug safety and PV.

Experience and Expertise

Different product types including drugs, vaccines, biologics, biosimilars, cell and gene therapy products/advanced therapy medicinal products, medical devices, and combination products.

Risk Management Expertise

The risk management solution provided by our experts and QPPVs is the core of our governance model and project oversight.

Efficient Project Management

Our unique "two-in-a-box model" deploys a Client Partner and Delivery Head to ensure timely execution of deliverables and inculcate strong governance to monitor compliance at each stage through the life of the project.

Proactive Approach

Service-level adherence (SLA) and quality deliverables, coupled with strategic alignment to provide business value, make us a trusted partner for PV for pharmaceutical companies.

High-Quality Deliverables

Our quality consistently exceeds client expectations.

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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.

We are an ISO 9001:2015, ISO 27001:2022, and ISO 27701:2019 certified company.

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