APCER LIFE SCIENCES
Together for better health

CASE STUDY

Scaling up to address safety challenges for an oncology product

Therapeutic area: Oncology

Product type: Drugs

Geography: US

Product life cycle stage: Post-marketing

About the Client

A global US oncology-focused biotechnology company that strives to accelerate the discovery, development and commercialization of new medicines for difficult-to-treat cancers to extend and improve the quality of patients' lives.

Business Challenge

This global, US pharmaceutical company with its key innovator molecule in complex medullary thyroid cancer therapeutic area was facing challenges in maintaining quality and regulatory compliance due to:

- Backlogs of cases due to consistently increasing territories and approval in other indications.
- Unable to scale up inhouse resources to compete with volume surge leading to backlogs mounted up to 6,000 cases, and 80+ queries and pending regulatory submissions.
- Inefficient reconciliation with specialty pharmacies and different business partners leading to missing cases.

They wanted to focus largely in developing and exploring the molecule in other cancer areas and drug marketing in other countries. They needed a pharmacovigilance company to bring them into compliance for regulatory due dates and provide a designated team to provide case processing to meet their demands. They also needed a gap assessment and process improvements.

Overview - Pharmacovigilance System

Ensuring patient safety is of utmost importance for Pharma companies. However, many companies perceive the pharmacovigilance (PV) process to be a complicated area and the operation is seen as an add on financial burden due to several reasons:

- setting up of a proper compliant PV system,
- hosting the safety database,
- employing skilled PV personnel, and
- keeping up pace with the dynamic regulations.

Companies in early-stage clinical trials rely on outsourcing models to manage their clinical trials and drug safety needs. When the product enters in Phase 3, the pharma company begins to plan and prepares to market the drug.

The company needs a cohesive pharmacovigilance plan and to aggregate the safety data that will be a part of their submission(s).

There is a need for a specialized partner who is capable of helping to navigate this next stage as well as support the product as it is commercialized.

Solution

APCER life sciences as their business partner provided a robust ramp up plan for the transition of the responsibilities for all PV activities considering the increasing volume and unanticipated surges:

- activities were transferred over the period of 6 months to 1 year to dedicated skilled resources,
- handover was secured in a phase wise manner with successful achievement of pre identified goals for each milestone,
- non-serious cases were targeted first to provide training as well as clear the backlogs,
- the second phase involved taking over the processing of serious cases and follow up of pending queries,
- backlog of pending cases was cleared based on priority along with the new cases,
- within 1 month of inception all pending 90 day submissions were also accomplished,
- organizing Quality & Medical review meetings to review the quality and efficiency of the process,
- corrections in the data entry manual to further improve the quality and processes,
- SLA driven compliance with complete transparency,
- comprehensive reconciliation plan for all pharmacies and business partners.

Pending queries were completed by APCER within a month of go-live which helped further streamlining the due-diligence activities. Complicated E2B NIS case submissions were retrieved and executed in a timely manner through effective management of technical challenges, communication and co-ordination with the client. APCER's subject matter expert helped to reframe the existing SOPs, data entry database and formulated work instructions for better visibility of the process from an audit readiness perspective.

Outcome

APCER, through its thought leadership and subject matter expertise in a complicated therapeutic area such as oncology helped the innovator company to be compliant and audit-ready and enabled the company to focus on commercial activities.

Ongoing improvements include:

- Scaling up of the team to meet client's increasing PV requirements.
- Streamlining processes and conventions to continuously improve quality and productivity.
- Taking over responsibility for clinical trials and business partners cases across territories.
- Managing SDEAs with different partners resulting inefficient reconciliation and improved compliance.

APCER has become the preferred partner for processing of all types of cases (PMS, CT, Business partners) and managing allied PV activities (aggregate reporting, literature monitoring, etc.)

We enabled the client to explore new avenues in:

- other indications with new clinical trials,
- seeking new MAH approvals for new territories, and
- long-term benefit-risk product value.

Our Pharmacovigilance Capabilities

Domain Expertise: 100+ physicians, 90% healthcare professionals supporting drug safety and Pharmacovigilance.

Experience and expertise in 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: Risk management solutions provided by our experts and QPPVs are core to 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 on 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, makes us a trusted partner for PV for this pharmaceutical company.

APCER LIFE SCIENCES | Together for better health
Part of APC Group

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 27001:2013, and ISO 27701:2019 certified company.

Learn more at www.apcerls.com or contact us at one of our global offices: Americas: (+1) 609 455 1600 • Europe: (+49) 2409 725 6120 • UK: (+44) 208 326 3220 • Asia: (+91) 11 4650 0802

For Business enquiries, please email at: marketing@apcerls.com
For General enquiries, please email at: info@apcerls.com