APCER LIFE SCIENCES
Together for better health

CASE STUDY

Successful Project Transition Through Proactive Planning and Flawless Execution for Aggressive Go-Live for a Leading Biotech Company

Therapeutic area: Infectious Diseases, Immuno-Oncology, and Rare Diseases

Product type: Vaccine

Geography: United States

Product life cycle stage: Post-marketing and Clinical Trials

About the Client

A leading innovative biotechnology company that focuses on the discovery and development of vaccines (both prophylactic and therapeutic) with wide range of therapeutic areas: Infectious diseases, immuno-oncology, rare diseases, cardiovascular diseases, and autoimmune diseases.

Business Challenge

Our client, a global biotechnology company, planned to transition its postmarketing case intake activities. They had a very aggressive go-live aim and targeted to complete the transition within a significantly reduced time frame. Some other challenges besides the aggressive timeline were the ask for defined experienced resource pool, need of expedited resource mobilization with effective training and mentoring of large team within a short time frame.

Overview - Pharmacovigilance system

A robust pharmacovigilance (PV) system is a vital need for pharmaceutical companies intending to market their products globally as patient safety is of utmost importance. Therefore, setting up a compliant PV system with experienced PV personnel to tackle high number of adverse event reports has become a priority for pharmaceutical industries, especially when the company is further expanding with multiple products in their pipeline. In the dynamic world of pharmacovigilance, successful project transitions play a pivotal role in ensuring that a project is delivered on time and within the planned budget. In this case study, we will delve into the journey of a client's project transition where the project had a stringent deadline for a go-live and will analyze how a proactive hiring, rapid resource ramp-up, effective governance, and meticulous project management made the transition a resounding success.

Solution

To meet aggressive timelines for project transition, APCER utilized planning, effective resource allocation, and effective project management methodologies.

Meticulous Planning and Strategic implementation: Developed a comprehensive plan in alignment with the client's requirements.

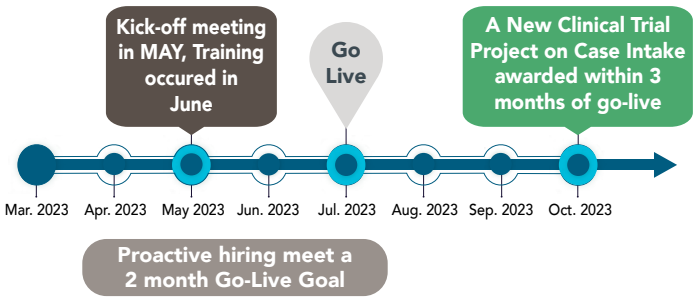
Proactive Hiring and Rapid Resource Ramp-Up with Internal Movement of Resources: To manage the case volumes, APCER hired a large workforce in a proactive manner. Internal resources were leveraged in addition to external hiring.

Robust Project Monitoring and Reporting System: Real-time project monitoring and reporting systems were implemented to track progress, identify delays and adjust plans.

Effective Communication with Client and Internal Stakeholders: A dedicated project manager ensured effective communication and continuous engagement

Effective Risk Management and Benchmarking Best Practice: A proactive risk-management strategy was implemented to identify, assess, and mitigate risks. As part of the continuous benchmarking process, the team adopted proven methods and processes to enhance efficiency

Outcomes



- APCER ensured seamless Transition and Successful On-Time Go-Live.
- Despite the rapid resource ramp-up, the team ensured high-quality work and compliance to contractual timelines for turnaround of deliverables.
- The client expressed immense satisfaction with the engagement. A proactive approach to hiring and resource ramp-up demonstrated APCER's commitment to the project success.
- Aggressive go-live helped the client and APCER save on costs that would have accrued from a more extended project timeline.
- Helped build trust and enhanced scope of expansion for APCER with supporting client's clinical trial case intake services.

Our Pharmacovigilance Capabilities

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

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: Risk-management solution provided by our experts and QPPVs is 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 a 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 exceed 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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