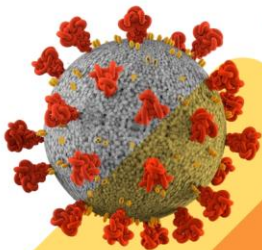




CASE STUDY:

MEETING MI & PV OBLIGATIONS FOR A COVID-19 VACCINE

PARTNERING FOR **MULTI-COUNTRY COMPLIANCE**



OVERVIEW:

Lambda Therapeutic Research partnered with a leading COVID-19 vaccine manufacturer to establish their Medical Information (MI) and Pharmacovigilance (PV) obligations for a multi-country vaccine launch.

Immediate challenges anticipated included and were not limited to the uncertainty of the anticipated volume and availability of skilled resources during the Pandemic.

Discover how Lambda implemented effective solutions and completed the project successfully.



COMPLEXITIES & CHALLENGES:

- There was a substantial increase in the volume of MI and PV obligations due to the launch of a COVID-19 vaccine pan India and globally.
- Varied regulatory requirements across the globe and ensuring compliance seamlessly.
- The monitoring of safety data reported from multiple sources added complexity to the PV obligations.
- Hiring skilled resources in large numbers was a significant challenge, especially given the impact of the pandemic on the workforce.



EXECUTION:

- Established a **24x7 call center** for MI & AE reporting to educate and provide correct information to consumers and healthcare professionals (HCPs).
- Recruited and planned necessary **skilled resources** to provide PV services.
- Expedited **training** to onboard resources quickly for the project.
- Ensured **proper resource management** by calculating the requirement of extended working hours for contingencies.
- Regularly assessed each resource before and after onboarding based on **quality and compliance** parameters.
- Successfully managed **over 10,000 calls and ICSRs** in the database in less than a quarter.

OUTCOME:

- The **successful completion** of the project became a **significant milestone** for the sponsor.
- The project was executed with **excellent Service Level Agreements (SLAs)** and adherence to **regulatory compliance**, ensuring high-quality work.
- Lambda's adherence to all necessary requirements and standards was reflected in the **successful** completion of subsequent **inspections and audits**.
- As a result of the successful collaboration, Lambda is now the **preferred partner** for the sponsor's future PV obligations.

Ensuring safety & compliance worldwide with team of 150+ PV Professionals



UK-HQ
(UK QPPV & MI Services)

POLAND
(EU QPPV, LRP & MI Services)

INDIA
(PV Delivery & MI Services)

CANADA
(MI Services)

Unlock seamless collaboration with Lambda's expert team and gain access to a comprehensive range of cutting-edge drug safety and pharmacovigilance services.

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