

Pharmacovigilance management for Multinational Pharma/Biotech Industry



Client introduction

The Client is a well-known manufacturer of medicines since last many decades and is one of the largest pharmaceutical manufacturers of India. The company has its global presence in various nations and is actively involved in research in different segments and anticipating market expansion. Not only this, the company has its segment of pharmaceutical molecules from medicinal products, vaccines, veterinary products to biosimilars sailing across the globe.

Operational requirement for global pharmacovigilance

Ensuring pharmacovigilance compliance at global scale is indeed a pivotal task as we need to assure that the standard practices (both, company and regulatory) are followed without any deviation in timelines or quality being downgraded. There is a requirement to address this concern for all Major MNCs having operational foot in varied regions and different time zones to avail product safety and patient safety.

Requirement for global PV compliance

The client wanted to monitor global PV activities with basic requirements of:

- Restricted (country-specific) access to remote user
- User should not be able to view safety/PV data of other countries in database
- Centralized access control - Only global user to have access to whole safety database with a rationale to monitor global PV activities for overall company portfolio
- Workflow management - One of the PV team users to have access to all ICSRs and non-expedited cases in database for central medical review

Addressing global safety data management

PvNET database very well addressed this client concern and was able to provide a convenient alternate to assure global PV monitoring and tracking in following areas:

- User specific access and controls
- Site-specific viewing and editing of safety datasets
- Successfully establishing a link between global and local users
- Ensuring data confidentiality between regions
- Using same database for different configurations

The robust PvNET safety database is flexible enough to incorporate requirements of client to manage product safety profile for a large-scale manufacturer, manufacturing and marketing medicinal products worldwide.

Contact Us

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