Alphanumeric

MAKE YOUR MARK!

Pharmacovigilance Services

Pharmacovigilance (PV), is the scientific study of the detection, assessment, understanding, and prevention of adverse effects with pharmaceutical products. Pharmacovigilance encompasses all aspects of drug safety, from the initial phases of development through licensure and post-marketing surveillance. Because PV is a global science, it requires an alphanumeric classification system to maintain consistency across languages. In addition to being crucial for patient safety, Pharmacovigilance is also essential for developing an understanding of how drugs work in real-world settings. As such, our Pharmacovigilance services offerings are designed to support all stages of PV, from strategy deployment to signal management. Whether you need help generating SOPs or preparing for an audit, we have the experience and expertise to support your Pharmacovigilance efforts. Contact us today to learn more about our Pharmacovigilance services.

– Our Services Include –

SOP Generation, Project Management, & Strategy Deployment Service

- Lead/author creation of procedures, policies, job descriptions, etc.
- Assist clients to successfully grow from start-up to mid size and beyond
- Conduct gap assessments, evaluate strategies and/or provide insights, etc.
- Project manage creation of reports

Auditing, Inspection Prep, & Quality Monitoring

- Perform GCP and PV Audits and Mock Inspections to help clients meet regulatory obligations
- Implement QC checklists, in-quality reviews, create quality monitoring plans

Aggregate Reports & Risk Management Plans

- Authoring Risk Management Plans and aggregate reports such as...
  - Drug Safety Update Reports (DSURs)
  - Periodic Benefit Risk Evaluation Reports (PBRERS)
  - Investigational New Drug (IND) Annual Reports

Clinical Services

SAE reconciliations, Tracking of submissions to HAs and sites/Ethics Committees/IRBs

- Coordinate and carry out safety activities in clinical trials. For example: Monthly Reconciliations of safety reports across different clinical Contract Research Organizations (CROs). These essential activities demonstrate compliance and adequately sponsor oversight by Safety and Clinical Operations plus are burdensome (require dedicated staff).

Regulatory Intelligence Monitoring

- Collect and analyze HA websites for PV Regulatory information
- Incorporate other tools such as Cortellisand Tairus for PV regulatory information
- Provide impact assessment
- Periodically monitor and update the tracking of this information

Signal Management

- Conduct signal detection activities, author/draft responses to Health Authorities on specific ad hoc safety requests

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