Pharmacovigilance

Services

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 different types of safety 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 Cortellis and 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