DATA MANAGEMENT & ANALYTICS

PHARMACOVIGILANCE AND POSTMARKET SURVEILLANCE

HIGH-QUALITY, TIMELY, AND RELIABLE SURVEILLANCE OF SAFETY DATA

OUR EXPERIENCE PROVIDING PHARMACOVIGILANCE AND POSTMARKET SURVEILLANCE SERVICES

15+ years

15+ therapeutic areas

PHASE I TO 4, BIOEQUIVALENCE, AND BIOAVAILABILITY STUDIES

2+ DECADES

of experience implementing industry-leading pharmacovigilance platforms

ENHANCE YOUR SAFETY SURVEILLANCE WITH COST-EFFECTIVE, TRUSTWORTHY, GLOBAL RESOURCES.

Increased development of advanced therapeutics and vaccines as well as greater use of accelerated approval pathways require closer surveillance for safety concerns. The associated increase in workload can be challenging to meet with in-house teams. With Veranex Pharmacovigilance and Postmarket Surveillance services, your studies benefit from:

- A team of 40+ safety experts with experience across geographies, therapeutic areas, and the clinical trial lifecycle
- A robust safety system that includes notifications for new serious adverse events (SAEs)
- Industry-leading tracking and visualization tools that can be customized to your study's needs
- Close collaboration with your teams

AS A GLOBAL COMPANY WITH MULTINATIONAL STRATEGIC LOCATIONS IN THE UNITED STATES, EUROPE, AND INDIA, WE PROVIDE REGULATORY EXPERTISE ACROSS GLOBAL MARKETS.

Veranex

Transforming Your MedTech Innovation

We provide a comprehensive set of Pharmacovigilance and Postmarket Surveillance services.

Safety management plan (SMP)

- Custom creation and templates for internal and external safety communication
- Support for implementation and coordination
- Comprehensive safety protocols for each study activity
- Definition of roles and responsibilities for entire safety management process
- Organization of an efficient workflow

SAE collection and reporting

- Definition of SAE procedures for each study
- SAE collection, evaluation, causality assessments, and reporting
- Formation of E2B transport file for SAE integrations from the EDC system
- Safety database entry
- Signal detection
- Clinical and postmarketing case processing
- Medical accuracy evaluation
- CRF-compliant coding
- Reporting, including aggregate reports and all applicable reports for drugs, biologics, and devices
- Screening of the literature
- Qualified Person Responsible For Pharmacovigilance (QPPV) services
- Global PV audits

Safety database

- Safety database hosting and data maintenance
- Creation of safety database independent from the clinical trial database
- Custom database setup (Argus, ArisG, Sceptre, AB Cube) per the study protocol
- Recording and organization of all data received by the safety department
- Reconciliation of safety data with clinical adverse event data
- Collaboration with our data management team or client's data management team

Overall medical monitoring

- Support from trained regulatory specialists
- On-site medical support for project staff
- Evaluation of patient eligibility and waiver
- MedDRA and WHODrug event coding
- Assessment and resolution of protocol breaches

GAIN CLEAR INSIGHT INTO YOUR STUDY'S DATA.

Our Pharmacovigilance and Postmarket Surveillance services are available project-by project, or you can integrate with our other service offerings within the Veranex clinical data ecosystem for a complete view into your study's data:

- EDC Builds
- Clinical Data Management
- Statistical Programming and Biostatistics
- Medical Writing and Regulatory Publishing
- Data Aggregation and Visualization