Drug Safety & Pharmacovigilance

Through a combination of technology and deep-rooted expertise, Allucent offers transformative, efficiency-driven pharmacovigilance (PV) solutions to our partners, across clinical, expanded access, and the entire post-marketing lifecycle.

Clinical Pharmacovigilance Solutions

Allucent provides flexible end-to-end global solutions that streamline clinical safety operations at the study or portfolio level. By leveraging the latest technology advancements in combination with deep expertise, we enhance pharmacovigilance efficiency, providing high quality, complete safety oversight.

Safety Planning & Strategy Development

- Safety management planning
- Risk management strategies

Global Safety Database Management

- Direct sponsor access
- Database set-up and validation
- Seamless data migration from all sources

Case Management

- Case intake and triage
- Data entry and coding
- Medical review
- Narrative writing

Regulatory Reporting & Intelligence

- Global regulatory intelligence
- Preparation and submission of expedited reports to regulatory agencies, ethics committees/institutional review boards, and investigators
- Eudra Vigilance and xEVMPD registration and management

Aggregate Reports

- Preparation of Development Safety Update Reports (DSURs)
- Authoring and medical review
- Submission to regulatory agencies, ethics committees, and sites

Safety Monitoring & Risk Management Planning

- Continuous safety monitoring
- Literature monitoring
- Trend analysis
- Therapeutic area medical expertise
- Risk Management Plan development

Safety Committee Coordination

- Formation and management of safety committees, e.g. Data Safety Monitoring Boards, Data Monitoring Committees, and Safety Review Committees

Audits & Inspections

- Audit conduct and reporting
- Audit and inspection preparation and training

Consulting Services

- PV system set-up and optimization
- Compliance and best-practice consulting
- Quality Management System development
- Strategic advice, e.g. PV strategy, global regulatory requirements

Post-Marketing Pharmacovigilance Solutions

Allucent's global, post-marketing solutions combine integrated expertise across pharmacovigilance (PV), medical, regulatory, and clinical, with technology-driven efficiencies.

PV Planning & Strategy Development

- PV planning and strategy
- Risk assessment and mitigation strategies

PV System Set-up & Management

- Establishment of full post-marketing PV systems
- Management and oversight of PV systems
- Transfer of PV systems and safety data

Global Safety Database Management

- Direct sponsor access
- Database set-up and validation
- Seamless data migration from all sources

Adverse Event Management

- Medical information call center
- Case intake and triage
- Data entry and coding
- Medical review
- Narrative writing
- Literature monitoring

Regulatory Reporting & Intelligence

- Global regulatory intelligence
- Preparation and submission of expedited reports to regulatory agencies and partners
- Eudra Vigilance and xEVMPD registration and management

Aggregate Safety Reports

- Periodic Benefit-Risk Evaluation Reports (PBRER)/Periodic Safety Update Reports and Periodic Adverse Drug Experience Reports (PADERs) development, including medical review

Safety Surveillance & Risk Management

- Signal detection and analysis
- Risk Management Plan development and maintenance
- Risk management strategies and implementation of risk minimization measures
- Benefit-risk assessments
- Safety Review Committee management
- Safety Communication (e.g. DHPC, educational materials, patient alert cards)

Qualified Person Responsible for PV & PV System Master File

- EU and local QPPV in all countries required; 24/7 availability
- Creation and maintenance of Pharmacovigilance System Master File

Audits & Inspections

- Audit strategy development and tactical planning
- Audit conduct and reporting
- Audit and inspection preparation and training

SDEA/PVA Management

- Global SDEA/PVA template creation
- SDEA/PVA maintenance

Consulting Services

- PV system set-up and optimization
- Compliance and best-practice consulting
- Quality Management System development
- SOP gap analysis
- Strategic advice, e.g. PV strategy, global regulatory requirements
- Expanded access and compassionate use program