



## Pharmacovigilance Research Outsourcing Services

Our pharmacovigilance research outsourcing services help pharmaceutical and biotech companies maintain drug safety, detect risks early, and comply with global regulatory requirements throughout the product lifecycle.

### Our Pharmacovigilance Research Capabilities

Our pharmacovigilance experts, medical writers, and regulatory professionals use advanced safety databases, signal detection tools, and global compliance workflows to deliver robust drug safety data management.

### Types of Pharmacovigilance Research We Handle

- Adverse Event Case Processing
- Serious Adverse Event (SAE) Management
- Signal Detection and Assessment
- Risk Management Plan Development
- Periodic Safety Update Reports (PSURs)
- Development Safety Update Reports (DSURs)
- Periodic Benefit-Risk Evaluation Reports (PBRERs)
- Individual Case Safety Reports (ICSRs)
- Literature Surveillance and Screening
- Safety Database Management
- Medical Review of Safety Data
- Aggregate Safety Data Analysis
- Regulatory Submission Support
- Post-Marketing Surveillance
- Pharmacoepidemiology Studies
- Safety Signal Quantitative Analysis
- Benefit-Risk Analysis and Evaluation
- Compliance and Audit Preparation
- Safety Labeling Updates
- Regulatory Authority Query Handling
- Adverse Drug Reaction (ADR) Reporting
- Vigilance System Master File (VSMF) Preparation
- Third Party Safety Data Reconciliation

- Medical Information Call Center Support
- Social Media Monitoring for Safety Signals
- Real-World Evidence Safety Analytics
- Training and Compliance Workshops
- Cross-Functional Safety Team Collaboration
- Publication-Ready Pharmacovigilance Reports
- Custom Pharmacovigilance Research Projects

## **Key Research Outsourcing Services Offered**

- Adverse Event and SAE Case Processing
- Signal Detection and Quantitative Analysis
- Literature Surveillance and Abstracting
- Risk Management Plan Development
- Aggregate Safety Report Generation
- ICSR and E2B XML Submissions
- Post-Marketing Safety Monitoring
- Safety Data Reconciliation with CROs
- Medical Review and Narrative Writing
- Pharmacoepidemiology Data Analysis
- Safety Labeling and Updates
- Regulatory Response Support
- Compliance with GVP and ICH Guidelines
- Confidential Data Handling and NDA
- Interim Reports and Progress Updates
- Publication-Ready Safety Reports
- Stakeholder Presentation Support
- Workshops and Training for PV Teams
- Post-Project Technical Consulting
- IP and Patent Filing Support
- Grant Proposal and Manuscript Assistance
- Sample Archiving and Secure Backup
- Audit Preparation and Readiness
- Cross-Lab Data Validation and Sharing
- Collaboration with Regulatory Affairs Teams
- Long-Term PV Research Partnerships
- Custom Safety Data Visualization Dashboards
- Real-World Evidence Signal Mining
- Patient Safety Communication Support
- Social Media and Digital Safety Monitoring

## **Why Choose Us for Pharmacovigilance Research**

## Outsourcing?

Our end-to-end PV services ensure patient safety, regulatory compliance, and transparent safety data reporting, supporting your drug products from development to post-market phases.

## Industries & Sectors We Serve

- Pharmaceutical and Biotech Companies
- Generic Drug Manufacturers
- Contract Research Organizations (CROs)
- Regulatory Affairs and Compliance Firms
- Pharmacoepidemiology Research Centers
- Patient Safety and Advocacy Groups

## Customized Pharmacovigilance Solutions

We tailor safety monitoring frameworks, reporting pipelines, and regulatory documentation workflows to align with your product portfolio and market-specific compliance needs.

## Quality Assurance & Regulatory Compliance

Our workflows comply with GVP, ICH, EMA, US FDA, and global PV guidelines, ensuring robust, reproducible, and audit-ready pharmacovigilance operations.

## Case Studies & Client Success Stories

See how our outsourcing has enhanced signal detection, streamlined safety reporting, and ensured successful regulatory audits for global pharma companies. References available on request.

## How It Works: Our Research Outsourcing Process

1. **Requirement Gathering:** Define product portfolio, safety scope, and compliance targets.
2. **Proposal & Quotation:** Provide detailed plan, timelines, and cost estimates.
3. **Safety Data Collection & Analysis:** Process AE/SAE cases, conduct signal detection, and prepare reports.
4. **Reporting:** Deliver regulatory-ready submissions and stakeholder reports.
5. **Post-Project Support:** Offer audit support, training, and ongoing safety monitoring advisory.

## Frequently Asked Questions (FAQs)

**Q:** Do you handle global ICSR submissions?

**A:** Yes — we manage E2B compliant ICSR processing and global health authority submissions.

**Q:** Can you design custom risk management plans?

**A:** Absolutely — we develop RMPs aligned with product profiles and regulatory guidelines.

**Q:** How secure is patient safety data?

**A:** We guarantee strict NDAs, encrypted storage, and full compliance with GDPR and HIPAA.

## **Get Started / Request a Quote**

Contact us today to discuss your pharmacovigilance needs and receive a custom plan, timeline, and cost estimate aligned with your safety compliance goals.

## **Contact Us**

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