

Drug Safety & Pharmacovigilance

Safety That Puts Patients First

Drug safety encompasses more than the compound, extending to each patient behind every case. Worldwide's pharmacovigilance team provides end-to-end processing of safety events reported globally, handled in a time-sensitive and regulatory-compliant way.

Sponsors can engage the team as part of a Worldwide full-service study or as a functional service through our FSP Model, Worldwide Flex, with support that runs from Phase I development through post-approval.

What We Do



Case Processing & Reporting

- End-to-end case processing for SAEs, AESIs, and other safety events
- SAE narrative development
- Medical review
- SUSAR reporting and trackaaing
- SAE reconciliation



Safety Databases

- Safety database builds in 2-4 weeks (Veeva/Argus)
- Ability to work in client or third-party safety databases
- SAE data migration, transition, and reconciliation



Data Safety Monitoring Board / Adjudication

- End-to-end support on DSMB/Adjudication
- Charter and committee management
- Independent team oversight and support of open/closed meetings
- Adjudication platform build/support



Safety Submissions

- Expedited reports direct to TGA, MHRA, EMA, and Health Canada, with other authorities via partners
- Dedicated safety submissions team and submission portal
- Global regulatory intelligence
- EudraVigilance sponsor and product registration
- Periodic and annual safety reports



Post-Approval Support

- Serious and non-serious case processing and reporting
- PSUR, annual, and quarterly reports
- Signal detection
- Global literature surveillance via EMBASE
- Registry, observational, and Phase IV studies

Proof in Practice: Safety Rescue Across Nine Studies

- 1 The challenge.** A client asked Worldwide to take over safety work from another CRO across nine protocols and two investigational products, including two Phase III studies with sites in North America, Latin America, Europe, the UK, the Middle East, and Asia-Pacific.
- 2 The transition.** The team was stood up quickly, and legacy cases were migrated out of the previous vendor's database into the client's Veeva Vault Safety System.
- 3 The scope.** Support covered SUSAR submissions to Health Canada, EMA, and MHRA, DSURs, compassionate use, named patient, and expanded access programs, plus QPPV support through a partner and PSMF development.
- 4 The outcome.** The client achieved market approval in the United States in 2021 and Europe in 2022, and Worldwide continues to provide clinical trial and post-marketed case processing and reporting.

PV Team Successes for our Sponsors

On-time Performance

- >99%** Case triage to sponsors within 1 business day
- >99%** Cases to clients per safety plan timelines
- >99%** Regulatory submissions to RAs, ECs, and investigators globally

Annual Volumes

- 12,000+** Safety cases processed
- 2,700+** Regulatory authority submissions
- 1,500+** Ethics committee submissions
- 100,000+** Site submissions
- 30+** Countries submitted to globally

Experience at a Glance

2-4 weeks	200+	93%	5
Safety database builds	Active sponsors, 20+ in an FSP portfolio	Safety team retention, last 12 months	Regions: NA, LATAM, UK, Europe, APAC

> Therapeutic Experience

Oncology, hematology, rare disease, ocular, and central nervous system (CNS) studies.

Our safety leaders also bring experience in cardiology, endocrinology, infectious disease, women's health, and pediatric indications, as well as CAR-T cell, bispecific T-cell, and macrophage engager studies.

Why Sponsors Work With Us



A named lead on every project

A lead safety specialist is assigned to each project. Case processing is not run like an assembly line, so every study and every safety event gets full attention.



Narratives that hold up

Case processing team members, including those with bedside nursing experience, produce detailed narratives that help keep the CSR accurate and complete.



A stable team

Consistent judgment across cases depends on consistent people. Our safety team retention rate has held at 93% over the last 12 months.



Fast database builds and transitions

Safety database builds (Veeva/Argus) are completed in two to four weeks, and SAE migration and transition work is an established strength.



The delivery model you choose

Engage pharmacovigilance within a Worldwide full-service study or as a standalone functional service through Worldwide Flex.

Meet the Team



Heather Kresge

BS CLS, MT (ASCP/NCA)

Vice President, Pharmacovigilance

Heather has more than 25 years of clinical research experience, from site-based study coordination to CRO roles in safety, clinical project management, medical writing, and biometrics. She provides strategic oversight for global safety, medical writing, and biometrics teams. Her experience spans Phase I-III research and post-marketing adverse event management in rare disease, pediatric, and oncology indications, along with adjudication management oversight.



Lori Medeiros

Senior Director, Pharmacovigilance

Lori brings more than 20 years of experience in clinical research, pharmacovigilance, and drug safety operations. She provides strategic leadership and global oversight for the Pharmacovigilance department, including quality governance, operational performance, and regulatory compliance, and serves as a senior escalation point for complex safety reporting. A registered nurse by background, she has experience across cardiology, oncology, women's health, infectious disease, endocrinology, rare disease, and CNS.



Lisa Dawson

Senior Director, Pharmacovigilance

Lisa is a registered nurse and pharmacovigilance leader with more than 18 years of experience in drug safety and clinical research, including 17+ years in oncology. Her safety experience spans Phase I-IV development and post-approval across CRO, biotech, and pharmaceutical organizations. She has supported the start-up and execution of CAR-T cell, bispecific T-cell, and macrophage engager studies.



Worldwide
Clinical Trials

Start a conversation.

Our pharmacovigilance team is ready to support your program, from first case to post-approval. [Contact us](#) today to learn more.