



Pharmacovigilance.

Patient safety is paramount in each and every clinical trial. The physicians, nurses and pharmacists in our global pharmacovigilance department provide safety support through all stages of our clients' clinical trials.

Services

- Safety Management Plans (SMPs)
- SAE Reporting
- Patient Narratives
- SAE Reconciliation
- Electronic SUSAR/ICSR Reporting
- Generation of Periodic Reports
- Production of Annual Safety Reports
- Medical Coding
- Medical Data Review
- 24-hour Medical Monitoring

Benefits

- 24/7 safety hotline to meet stringent timelines for regulatory compliance
- Employs industry standard Oracle Adverse Event Reporting System (AERS)
- Individualized safety management and reconciliation plans developed for each study
- Global team with local knowledge and expertise allows us to be responsive to individual country requirements

Expertise: The People

- Board certified/registered in-house physicians in key therapeutic areas
- Team fluent in the local languages, medical practices, and culture allows for effective communications with site staff
- Commitment to continuing education regarding evolving regulatory requirements

Case Study: Managing a Large Volume of SAEs

In 2004, Premier Research was contracted by a global pharmaceutical company to manage all aspects of a large seven-year 4,500 patient Phase 3b pan-European trial to study if an angiotensin II receptor blocker can prevent the onset of microalbuminuria in subjects with type 2 diabetes. One particular challenge for this study was that more than 1,000 SAEs were expected.

Premier Research provided centralized medical monitoring and safety support with reporting requirements supported by representatives in our local offices. We successfully managed the SAEs by ensuring the SAE processing was completed using a chronologically ordered template system and employing an automatic fax distribution system for SUSAR distribution. More than 1,000 SAEs for this study were processed by Premier Research.

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