WORLDWIDE CLINICAL TRIALS

A PHARMACOVIGILANCE FACT SHEET

PATIENT SAFETY, SPONSOR SECURITY

PHARMACOVIGILANCE AT WORLDWIDE CLINICAL TRIALS

Worldwide Clinical Trials is a midsize, full-service CRO that was initiated in 1986. We have offered pharmacovigilance services since 2008 with a team of safety experts located in North America, South America, Europe and Asia-Pacific. In addition to safety experts, the team includes dedicated PV physicians located in North America and Europe. The global nature of the Worldwide PV team allows us to stay fully apprised of regional regulatory developments. Led by executives with more than 20 years of PV experience, we work alongside you to deliver solutions designed to your unique needs.

FLEXIBILITY ON A GLOBAL SCALE

Your pharmacovigilance plan is the lifeblood of your ongoing work in therapeutic development. When you need support to manage your patient safety data, choose a partner you can trust to handle that continuous flow effectively and consistently. With a global presence and a hands-on approach, Worldwide Clinical Trials marries the capacity of a larger CRO with the accessibility of a smaller organization. We are innovative, we are global, and we are accessible.

> *"I believe the cornerstone of pharmacovigilance is being able to be a partner with our sponsors where we are just as dedicated and passionate about the success of their compound as they are. Without a solid safety profile, life-changing therapies are not able to be provided to those patients who desperately need them. I'm extremely proud of Worldwide's PV team; not only can we be a dedicated partner, handling global case processing, receipt, and, in particular, global regulatory submissions to RA/EC/IRB and sites but also do this with quality and compliance where our KPIs are all more than 98%!"*

Heather Kresge, MT (ASCP)
Executive Director, Pharmacovigilance

KEY PERFORMANCE INDICATORS

You are accountable to your patients. We are accountable to you.

How can you be certain that your PV solution is doing what you need it to do? Meeting regulatory requirements is just the beginning. You need to be sure the PV systems you have in place are running efficiently and continuously, so you know you are always audit-ready. Worldwide's KPIs are the foundation of our reputation and the basis for your trust in us as your partner.

OUR KPI METRICS

WORLDWIDE'S PHARMACOVIGILANCE CAPABILITIES

Adverse Event (AE/ SAE) Case Processing

- Clinical trial and post marketing
- Intake – case receipt
- Triage – case assessment
- Data entry into safety database
- Safety database hosting
- Narrative writing
- Case quality review
- Medical review
- Sponsor notification

Global Safety Database

- Argus
- CIOMS/MedWatch
- Validated report generation
- Comprehensive global metrics

Global Regulatory Submissions

- Periodic safety update reports (PSUR)
- Periodic adverse drug experience reports (PADER)
- Investigators
- Ethics committees/IRBs (local and central)
- Regulatory agencies
- EudraVigilance
- Product and sponsor EU registration
- Annual and periodic safety submissions
- Local support
- SafetyVigilance Submissions Portal

Development Safety Update Report (DSUR)

- Generation of report, including writing and analysis
- Submission per global regulatory requirements

Functional Service Provider (FSP)

- Safety stand-alone service
- Collaboration with multiple CROs
- Centralization of all safety services

Risk Management

- Risk management log
- Quality issue tracking and trending

Additional Support

- Data and Safety Monitoring Board (DSMB)
- Adjudication
- Regulatory guidance

FLEXIBLE SERVICE SOLUTIONS

MANAGE THE FLOW OF YOUR PATIENT SAFETY DATA.

Patient safety data is a continuously flowing resource, both during a clinical trial and after your product has entered the market. You need to be able to manage that data flow to safeguard the welfare of those who use your therapies. Particularly where adverse events and drug reactions are concerned, you have a responsibility to ensure such information is received, processed, reported, and communicated appropriately, and in a timely manner.

WHAT IS YOUR PV STATUS?

- Are your in-house capabilities managing the flow of patient safety data related to your products?
- Are you experiencing bottlenecks at certain stages of your workflow and unsure how to create a more efficient process?
- Do you need a full-service solution to manage the entire process from case receipt and triage to report writing and regulatory submission?

WHY CHOOSE WORLDWIDE?

Worldwide Clinical Trials provides the flexibility and hands-on attention of a smaller organization but has a global capacity and technological capabilities that rival much larger CROs. Here are a few of the features that make Worldwide Clinical Trials a perfect fit for pharmacovigilance.

Global Capacity

Our pharmacovigilance team handles global case processing, receipt, and submission to regional and global regulatory authorities, ethics committees, and institutional review boards at all levels. We have experts on the ground in the United States, the United Kingdom, Brazil, and South Korea who are fully engaged with local regulatory authorities and can support your global pharmacovigilance obligations. Worldwide utilizes a global state of the art Safety Database, Argus, which centralizes all safety data globally for your compound.

Automated Data Processing

Our safety submissions portal, powered by SafetyVigilance, provides speedy, efficient, and cost-effective management of safety submissions to sites, ECs and regulatory agencies. Providing a central repository for data, we can automate distribution of safety letters based on country-specific regulatory parameters and detailed compliance for acknowledgements. The system enables robust tracking and compliance, while reducing the workload for clinical sites.

PV Regulatory Intelligence

A key pharmacovigilance requirement is to ensure compliance with regulatory timelines globally. Ensuring your safety submissions are on time and compliant is our focus. With a dedicated PV regulatory intelligence database, our PV team can immediately provide regulatory requirements for all countries globally down to the investigator, EC/IRB and regulatory authority level. The Worldwide PV team knows the expectations and key requirements and is able to submit to all countries directly.

Accessible Experts

We see our sponsor clients as full partners. When you work with Worldwide, you are assigned a dedicated safety lead who is familiar with your compound's safety profile and will work side-by-side with your organization. Unlike larger CROs, we are not inhibited by a large bureaucracy; instead, we give you direct and meaningful engagement at every level of our company.

Footnote:

The Median Cost of Bringing a Drug to Market is $985 Million, According to New Study | BioSpace