

Case Study

When a Safety Vendor Transition Puts Your Program at Risk

How Worldwide transitioned a global pharmacovigilance program, migrated the legacy safety data, and kept submissions compliant across 6 regions.

If your safety vendor is not performing, you are facing more than a contract change. Legacy cases must move into your system intact, expedited and periodic reporting cannot lapse in any market, and a multi-region program leaves no room for a gap in compliance. You need a partner who can take over a live program, stabilize it, and carry it through approval and beyond.



The Sponsor's Challenge

A pharmaceutical client needed pharmacovigilance services for 2 investigational medicinal products across 9 clinical trials, plus multiple compassionate use protocols, named patient programs, and expanded access programs. It was a transition; safety cases had to be transferred out of the previous vendor's database and into the client's Veeva Vault Safety System, without disrupting an active global study.



Worldwide's Solutions

- **Took over a live program.** The safety team stepped in as the transition vendor and migrated legacy cases from the prior vendor's database into the client's Veeva Vault Safety System.
- **Covered the full global footprint.** Support spanned 9 protocols, including 2 Phase III studies with sites in North America, Latin America, Europe, the United Kingdom, the Middle East, and Asia-Pacific, including South Korea.
- **Kept regulatory reporting compliant.** SUSAR and DSUR submissions were made to Health Canada, the EMA via EudraVigilance, and the MHRA.
- **Solved the local entity problem.** The team worked with the client's clinical and regulatory vendors in other countries to facilitate local SUSAR submissions where a local entity was required to submit.
- **Built the E.U. compliance infrastructure.** Worldwide and its partners provided QPPV support and developed the pharmacovigilance system master file required by the EMA.



Outcome

US & EU	9 Protocols	Trial to Market
Market approval achieved with Worldwide's support	Supported across 6 regions and multiple programs	Ongoing clinical trial and post-market case processing

What began as a rescue became a long-term partnership. The client moved from a failing vendor transition to market approval in the United States and Europe, with Worldwide continuing to deliver pharmacovigilance services, including clinical trial and post-market case processing and reporting.

Let's talk about how our personalized approach, therapeutic expertise, and global resources make us a strong partner for your drug development program.

Contact Us