

In today's biopharmaceutical product landscape, companies must be aware of crucial safety information about their products. Pharmacovigilance is particularly important in the first few years after launch, when knowledge of the safety profile is expanding based on exposure to a much wider range of patients than is possible during clinical trials. i3 Drug Safety is uniquely positioned to provide comprehensive pharmacovigilance services.

In addition to rapid, accurate report processing, our standard regulatory safety surveillance services can be supplemented with proactive product safety surveillance. Using our proprietary i3 Aperio® tool, and with ad hoc research programs designed by our leading epidemiologists, we are able to answer specific safety questions and help you gain a measure of certainty unattainable in any other context.

Knowledge and expertise

The i3 pharmacovigilance team is comprised of health care professionals with deep experience in both direct patient care and industry-specific pharmacovigilance services, which allows us to provide the highest-quality safety data. Working globally, i3 Drug Safety can provide integrated services to support product safety monitoring in compliance with regulatory requirements for safety surveillance in pre-approval and post-marketing settings.

Our pharmacovigilance services include:

- Collection, review, and follow-up of SAE and ADR reports
- Generation of regulatory reports, including MedWatch and CIOMS I reports, Annual Safety Reports, and PSURs
- Submission of expedited reports to regulatory authorities/competent authorities, including electronic submissions via a secure gateway to EMEA EudraVigilance
- Scientific literature review for adverse events
- Global multi-lingual call center for marketed products
- Management of standard and off-label medical inquiries from consumers and health care providers
- Option to offshore case processing services to lower cost center in Singapore

Global safety database

i3 Drug Safety uses the Adverse Reaction Information System global (ARISg™) safety database for adverse event case processing. This Oracle®-based database supports MedDRA and WHO Drug coding, is 21 CFR Part 11-compliant,

and provides an efficient and accurate workflow to facilitate processing adverse events. In addition, ARISg supports regulatory document preparation.

If you would prefer for our staff to provide case processing support using your internal safety database, we have experience using several off-the-shelf and homegrown safety database systems. Our technology team works closely with yours to establish secure connectivity; once established, i3 Drug Safety can provide case processing support by directly accessing your systems.

Signal detection and evaluation

Successful safety surveillance includes data collection and case processing, as well as ongoing review and analysis of SAE and ADR reports for signal detection and evaluation. When providing comprehensive surveillance services, our pharmacovigilance team works closely with our epidemiologists, who review the data to identify new trends or signals or to follow up on theoretical or actual safety concerns that have been previously identified.

Working together with our customers, i3 Drug Safety experts can organize and coordinate routine pharmacovigilance meetings to facilitate surveillance activities, where our level of support can range from providing tabular reports of safety data, to signal detection and analysis of safety data, to a supplementary analysis of similar events, where appropriate, using our proprietary research database of de-identified administrative and health claims data.

Find out how i3's pharmacovigilance services can support your product.

Contact us

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