



The company of specialists.

www.i3global.com

Pharmacovigilance

Leading integrated or standalone services that support product safety

In today's biopharmaceutical product landscape, companies must be aware of crucial safety information regarding their portfolio. Pharmacovigilance is important at every stage of a product's lifecycle, from preclinical studies to the first few years after launch, when knowledge of the safety profile expands based on exposure to a much wider range of patients than is possible during clinical trials. i3 provides comprehensive pharmacovigilance services to help you address these concerns with confidence.

Expansive knowledge and proven expertise

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

Our pharmacovigilance services include:

- Receipt, data entry, follow-up, and medical review of SAE and ADR reports
- Production of regulatory reports, including MedWatch and CIOMS I reports, annual safety reports, FDA periodic reports, and PSURs
- Submission of expedited reports to regulatory authorities/competent authorities, including electronic submissions via a secure gateway to EMA EudraVigilance
- Scientific literature review for adverse events
- Global multi-lingual call center services for marketed products
- Management of standard and non-standard/off-label medical inquiries from consumers and health care providers
- Option to utilize lower-cost case processing services at our location in India

Global safety database

i3 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 and regulatory document preparation, is 21 CFR Part 11-compliant, and provides an efficient and accurate workflow to facilitate the processing of adverse events.

i3 also has experience using several commercial and sponsor-developed safety database systems. If needed, our technology team can work closely with yours to establish secure connectivity and provide case processing support by directly accessing your systems.

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

Contact us

specialists@i3global.com

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