

i3 Drug Safety provides data and services to meet regulatory requirements around drug safety and support risk management programs for drugs, devices, and biologics throughout the product development and commercialization lifecycle. Beginning with integrated safety surveillance and risk assessment in clinical development, and continuing through post-approval pharmacovigilance and pharmacoepidemiology, we apply scientific rigor, innovative methods, and industry-leading expertise to help establish a safer health care experience for all.

Our services include:

- Epidemiology, specializing in advanced pharmacoepidemiologic studies for marketed products and supporting a full spectrum of epidemiology services that include observational study design and analysis
- Integrated global pharmacovigilance services in both pre- and post-marketing settings, including signal detection and evaluation, and implementation of risk management and risk minimization action plans
- i3 Aperio[®], our signal detection and evaluation tool designed to enhance safety surveillance for marketed products

Leading expertise

i3 Drug Safety can provide experience, evidence, and credibility for some of your most demanding product safety support needs. Staffed by leaders in epidemiologic design and practice, our scientists have spoken at the FDA, EMEA, and scores of professional congresses and published in top medical and drug safety journals. Our experience, which includes key product studies, places us at the forefront of research and methodology, enabling us to provide our clients with the best in reliability, clarity, data quality, and methodologic expertise.

Pharmacovigilance

i3 Drug Safety provides global services to support product safety monitoring in compliance with regulatory requirements.

Our services include pre- and post-approval adverse event case management, submission of individual and aggregate safety reports to regulatory agencies, and post-market medical information and literature review.

The pharmacovigilance team is comprised of health care professionals experienced in direct patient care settings and in sensitive regulatory functions. Case coordinators work closely with drug safety physicians for optimal SAE case review, trend analysis, and signal detection and assessment, while core teams working on global systems emphasize timely receipt and follow-up of events.

GLOBAL SAFETY DATABASE

i3 Drug Safety uses the Adverse Reaction Information System global (ARISg[™]) safety database to track, enter, and report adverse event cases and produce aggregate safety reports. Our experienced team can easily adapt to a customer's internal safety database.

SIGNAL DETECTION AND ASSESSMENT

i3 Drug Safety's comprehensive pharmacovigilance services are complemented by claims data mining to identify trends or signals to provide a comprehensive safety surveillance service. When unanticipated safety signals occur, we leverage data from both our i3 Aperio tool and our proprietary de-identified claims-based research database to provide a unique and rapid signal evaluation service.

i3 Aperio®

i3 Aperio is an innovative and proactive tool for signal detection and assessment that allows customers to review health care data on real-world prescription drug use. The tool puts safety signals into a comparative context of risk and permits the exploration of new patterns. i3 Aperio data and surveillance features integrate well into advanced risk management programs.

i3 Aperio also provides insight into compliance labeling such as use in contraindicated conditions and co-dispensing of contraindicated drugs. In addition, by providing baseline and follow-up laboratory test results, and by profiling prescribing physicians, i3 Aperio can help users deepen their understanding of monitored drugs.

Epidemiology and Risk Management

Our access to a vast proprietary database of de-identified health care data and administrative data allows for the accrual and follow-up of patient cohorts supplemented by information from medical records, laboratory results, consumer data, and ad hoc surveys—resources that permit the rapid construction of retrospective studies. We also routinely utilize other administrative data sources as required.

i3 Drug Safety's research into the natural history of disease helps quantify disease burden, understand disease outcomes, and pinpoint unmet needs. Our i3 STORK birth registry links mother and baby claims to examine the relations between drugs dispensed to the mother and conditions identified in the offspring.

We have expertise in pharmacogenetics with experience in complex study design, rare phenotype identification, and sophisticated data mining and pattern recognition. Our pharmacogenetics approach works to maximize risk-benefit; as the factors that predict better patient outcomes can be more precisely identified, overall risks can be minimized.

Find out how i3's expert drug safety services can support your product.

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