

i3 Drug Safety's comprehensive risk management services include consulting on the development of risk management plans (RMPs), proactive identification and investigation of predicted or emerging risks, and design and execution of studies to assess post-market real-world risk and the effectiveness of risk minimization initiatives.

Our clients include marketing authorization holders, applicants, and regulators. We help our clients plan and implement risk management strategies for soon-to-be-launched products, assess risks for both newly launched or more established products, and evaluate the effectiveness of risk minimization activities. We are dedicated to assisting our clients with proactive safety surveillance, and our world-class scientists are supported by industry-leading technology specifically designed to facilitate comprehensive risk management systems.

Data, expertise, and proactive tools for monitoring safety

The best risk management strategies involve continual monitoring of risk-benefit throughout the product lifecycle, so that key findings about product safety can be identified and addressed as early as possible. i3 Drug Safety scientists help organizations develop and implement a comprehensive risk management approach, utilizing risk management services and tools that include:

RISK MANAGEMENT PLAN DEVELOPMENT AND

CONSULTATION: A good RMP addresses product-specific issues based on pharmacological principles as well as the most current data available; the best RMPs also describe proactive surveillance approaches that will be utilized to identify and investigate emerging safety concerns. In supporting overall RMP development, i3 Drug Safety's scientists add particular value to these sections:

- Characterization of background information through comprehensive literature review, supplemented by results

from automated health care databases when the literature is not sufficient

- Planning and support for additional pharmacovigilance activities when routine pharmacovigilance will not be sufficient, including use of i3's proactive safety monitoring tools
- Consultation on appropriate risk minimization approaches should such activities be required, including strategies to evaluate their effectiveness

i3 STORK (Systematic Tracking of Real Kids) is i3's automated pregnancy surveillance system that links mothers and babies to determine maternal exposures, then prospectively relates these exposures to pregnancy outcomes. With more than 100,000 deliveries each year, i3 STORK allows clients to proactively monitor pregnancy outcomes to ascertain risks associated with drug exposure during pregnancy at a fraction of the cost associated with a more traditional pregnancy registry approach.

i3 RAPID CYCLE SURVEILLANCE facilitates early identification and assessment of targeted safety issues of concern. By capturing medical claims in a large insured population in near-real time, this system helps our clients monitor the frequency of targeted safety issues. Through the automated filtering of health care encounters on a daily basis, results are available with a lag time of often only days from the patient encounter with a health care provider that generated the claim.

i3 APERIO® is a first-in-class signal detection and assessment tool that provides i3's clients with the ability to proactively identify safety signals, and to comparatively assess potential signals against similar products or in unexposed patients derived from the same source population. Using i3 Aperio, our clients can also monitor the use of marketed products in accordance with product labeling, and can evaluate the effectiveness of several risk minimization approaches.

PHARMACOEPIDEMIOLOGY STUDIES: When a safety signal requires more thorough investigation, i3 Drug Safety's scientists lead the industry in designing and executing studies in multiple data sources that conform to regulatory standards and enable rigorous assessment of medical products. The

results are routinely submitted to regulatory agencies worldwide and published in high-impact peer-reviewed journals. The same scientific expertise has been applied to evaluate the effectiveness of risk minimization activities.

Find out how i3 Drug Safety's risk management services can support your product.

Contact us

kelly.warren@i3global.com

www.i3global.com