

## Epidemiology

**When it comes to drug safety and epidemiology, you want real insights, not just information. i3 Drug Safety's epidemiology experts are recognized for their scientific rigor and integrity. They have appeared before the FDA, EMEA, and scores of professional congresses, and their publications on drug safety, including key product studies and research into methods, place them at the forefront of epidemiologic design and practice. i3 Drug Safety research leaders have served as key advisors to sponsors, regulators, and payers on how to best meet a product's safety information needs, and they stand ready to provide you with the best in reliability, clarity, data quality, and technical expertise.**

### **Unmatched data**

Our proprietary research database of de-identified health care and administrative data links patient, physician, and treatment attributes on millions of geographically diverse individuals in the U.S. Laboratory findings and consumer data supplement a core structure built on health insurance claims representing several aspects of health services.

### **Proactive safety, no surprises**

Our drug safety experts work in tandem with clients to develop proactive information plans, then leverage our rich data assets to create large patient follow-up programs that meet the post-marketing regulatory requirements for safety surveillance and physician compliance to label. Results of these programs are then used to guide best-practice decisions on marketed and planned products.

When ad hoc research is required to answer specific safety questions, we can use our existing data to conduct both prospective and retrospective studies, and can also design prospective studies requiring *de novo* data collection.

### **Natural history of disease research**

Novel compounds may find their first use in a previously untreated or poorly understood affliction. i3 Drug Safety's epidemiology team helps clients avoid confusing drug effects with uncommon but predictable outcomes of disease, and works to pinpoint the diseases where an unmet need exists. We quantify disease burden and evolution and profile the patients when a breakthrough drug finds its market.

### **Clinical epidemiology research**

The ability to analyze rich diagnostic, therapeutic, and procedural information provides the i3 epidemiology group with a distinctive opportunity to conduct large clinical epidemiology investigations. Whether the question is to elucidate the clinical course of rare diseases, to determine the best therapy in disease subgroups, or to delineate risk factors for particular medical conditions, we are poised to make a significant impact in understanding the patients who will ultimately use your products.

**Pregnancy**

With a unique ability to link mother and baby profiles in our representative, population-based dataset, we can examine the relations between drugs dispensed to the mother and conditions identified in the offspring.

**Pharmacogenetics**

Pharmacogenetic studies play an important role in the drug lifecycle. They can help companies discover new drugs or valid diagnostics, achieve favorable clinical trial results through the targeted recruitment of patients more likely to respond, and identify patient subgroups most likely to experience certain serious adverse effects to manage risk. i3 Drug Safety's pharmacogenetic services include:

- Consulting to incorporate biomarker information into clinical trials
- Real-life data on drug efficacy stratified by age, sex, ethnicity, or race
- Study design and scientific support
- Access to patients with rare outcomes
- Statistical analysis including data mining

Find out what i3's drug safety expertise can do for your product.

**Contact us**

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