

Faster insights about a product’s safety profile can lead to faster actions. i3 Aperio® is a first-in-class safety surveillance tool that leverages i3 Drug Safety’s epidemiological expertise and one of the largest post-launch sample populations to date—our proprietary health care database, which contains the health care experiences of millions of individuals—so that users can monitor the safety of new medical products quickly and effectively.

### FDA Amendment Act (FDAAA)— Changing the approach to pharmacovigilance

FDAAA is increasing post-approval requirements for risk assessment and mitigation strategies. i3 Aperio is an important tool in meeting these new challenges. i3 Drug Safety scientists can tailor i3 Aperio to meet your regulatory needs, complementing other strategies in your drug's pharmacovigilance program.

### i3 Aperio—What is it?

- Specialized *large-scale registry* mining a proprietary database containing de-identified integrated medical and pharmacy claims data on *more than 25 million individuals*
- Wide variety of standard tables for New Molecular Entities (NMEs) and selected comparators, updated quarterly (*see examples of current pairs and tables*)
- Standard follow-up for up to 12 quarterly cohort pairs over three years with one-year follow-up for each drug pair cohort
- De-identified patient data at aggregate and drill-down levels
- Data integrated and linked across:
  - administrative and demographic information
  - pharmacy data from an open formulary environment
  - health care encounters across a variety of treatment settings
  - laboratory test results
  - socioeconomic factors

At the click of a mouse, the user receives this critical data linked, reported, and analyzed with descriptive statistics.

### Customized to meet your needs

Custom pairs can be created when there is interest in a drug or comparators that differ from the available i3 Aperio pairs. Other custom work includes the creation of multiple comparators, capability for stratified analysis using filters, specialized reports with targeted outcomes or client-defined outcomes, and extended accrual/follow-up periods designed to meet regulatory requirements.

### Examples of Standard Drug Pairs

Azilect / Carbidopa / Levodopa	Pristiq / Cymbalta
Byetta / Metformin / Glyburide	Ranexa / Nitrates
Bystolic / Carvedilol	Rozerem / Ambien
Invega / Risperdol	Symlin / Insulin
Januvia / Metformin / Glyburide	Tekturna / Diovan
Orencia / Enbrel	Vyvanse / Adderall XR

### Examples of Tables Comparing Drug Pairs

BASELINE	POST-DRUG INITIATION
Demographic Characteristics	Diagnosis Outcomes
Procedures	Therapeutic Drug Class Outcomes
Diagnoses	User-Defined Outcomes
Prescriber Characteristics	Health Care Utilization Periods 1-3 months 4-6 months 7-9 months 10-12 months

### Real-world data, real-world benefits

By accelerating the acquisition of real-world information on new prescription drugs, i3 Aperio can help researchers rapidly assess signals that could indicate a drug’s potential safety issues in near-real time. i3 Aperio can play an important role in a company’s Risk Evaluation & Management Strategies (REMS) or risk management programs. Data produced by i3 Aperio can be used for:

- SIGNAL DETECTION AND SURVEILLANCE
  - tracking new or existing drugs’ safety profiles in a natural environment
  - putting safety signals into a comparative context (*see table below for example*)
- COMPLIANCE
  - monitoring to determine whether a drug is being prescribed according to labeling recommendations
  - assessing changes in prescribing behavior following label updates
- OFF-LABEL USE
  - offering insight into real-life utilization of your drug
- COMPARATIVE EFFECTIVENESS
  - providing initial look at potential outcomes/costs following new drug initiation compared with those in a matched group of users of a similar drug

i3 Aperio has also proven to be a cost-effective option for safety surveillance in comparison with conducting prospective ad hoc research. And, for many marketed products, i3 Aperio provides sufficient sample size for the quantitative evaluation of infrequent events. Access to a single pair or multiple pairs is available.

In conclusion, i3 Aperio offers a complementary approach to the status quo, enabling researchers to evaluate the validity of the signal as well as collect spontaneous reports and assess signal strength as new reports accumulate. These and other features distinguish i3 Aperio as a decidedly proactive tool for drug safety evaluation.

Find out how i3 Aperio can speed your drug safety insights.

#### Contact us

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### Safety Surveillance of Byetta/Metformin-Glyburide (Matched by Propensity Score)

Outcomes	Matched Initiators				95% Confidence Interval				Unmatched Initiators	
	Byetta (N=28,100)		Metformin-Glyburide (N=28,100)						Byetta (N=282)	
	N	%	N	%	Relative Risk	Low	High	Score	N	%
Inpatient: 577.0 Acute Pancreatitis	35	0.1	36	0.1	1.0	0.6	1.6	0	2	0.7

This table contains the results comparing the number of inpatient acute pancreatitis diagnoses during follow-up for patients initiating Byetta versus Metformin-Glyburide. There is no indication that risk varies between the two diabetic therapies.