

...E NOS PRURITUS VOMITING DIZZINESS (EXC VERTIGO) ...LLAISE DIARRHOEA
...IA WEIGHT DECREASED HYPOTENSION MYALGIA DEATH ABDOMINAL PAIN NOS
...T INCREASED CEREBROVASCULAR ACCIDENT DERMATITIS NOS PHARMACEUTICAL
...LAIN T UNCOVER SAFETY SIGNALS PAIN NOS DIARRHOEA FROM THROMBOCYTOP
...EMA IN ADVERSE EVENT DATA NOS PERIPH UNITED BIOSOURCE CORPORATION ST
...H COUGH ANXIETY WITH CLÆRITY DEPRESSION PAIN HAEMOGLOBIN DECREASED
...UTE BLOOD GLUCOSE INCREASED ALANINE AMINOTRANSFERASE INCREASED AS
...TRANSFERASE INCREASED PALPITATIONS RASH SYNCOPE FEELING ABNORMAL I
...AL SYNDROME HYPOAESTHESIA NEUTROPENIA CARDIAC ARREST ABDOMINAL PAIN
...D PRESSURE INCREASED BLOOD CREATININE INCREASED SOMNOLENCE ANOREXIA
...RIDUBNESS TREMOR RHABDOMYOLYSIS CONVULSION HYPERTENSION ALOPECIA
...SIONAL STATE CONVULSIONS NOS DRUG EXPOSURE DURING PREGNANCY WEAKN
...REMITY VISION BLURRED SEDATION ANXIETY NEC DRUG EFFECT DECREASED HE
...ASED COMPLETED SUICIDE DRUG INTERACTION NOS CARDIAC FAILURE CONGESTI

CLÆRITY*

for safety signal investigation

CLÆRITY is a part of United BioSource Corporation's safety and risk management product and services suite.

CLÆRITY is easy-to-use, web-based software for investigation and management of potential safety signals in adverse event data:

To learn more visit www.unitedbiosource.com.

- * Detect and investigate potential safety signals
- * Manage and monitor signals of interest over time
- * Document and track outstanding actions
- * Use complementary data mining technologies (PVmaps®, PRR, MGPS) for full coverage

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* For Investigation Of AERS and Other Spontaneous Reporting Databases

From United BioSource Corporation

Web-based application generates results in real time

Visual format is easy-to-understand and compelling

Collaborative environment for signal investigation and management

Detect and investigate signals:

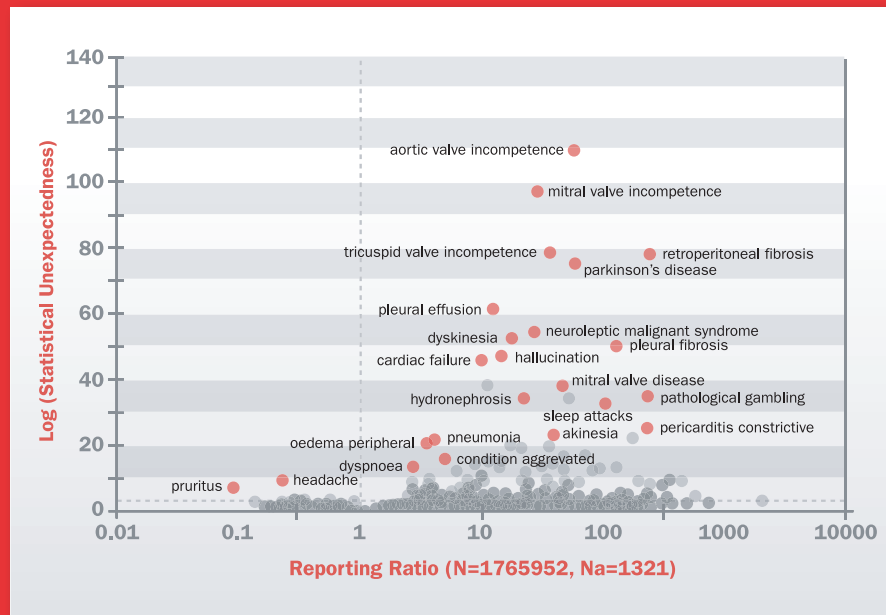
- ✦ What are the significant signals for a drug, class or group?
- ✦ Is the signal strength changing over time?
- ✦ Is the signal part of a bystander effect or a drug-drug interaction?
- ✦ How do safety profiles of similar drugs compare?

Manage and monitor signal investigation workflow:

- ✦ Classify signals of interest
- ✦ Track and monitor selected signals over time
- ✦ Document actions and decisions
- ✦ Generate summary status and detailed signal history reports

For use with AERS and Other Spontaneous Reporting Databases.

✦ **Detect and investigate signals**



✦ **SEE RESULTS IN SECONDS, NOT HOURS**

✦ **Manage and monitor signal investigation workflow**

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Adverse Event	Safety Reports	Events in AERS	Reporting Ratio	Statistical Unexpectedness	Rank (SU)	Classification Code	Notes
aortic valve incompetence	81	2072	5.3227e+001	108.3768	1	Signal of Interest	<input type="checkbox"/> PV Plan
mitral valve incompetence	93	4584	2.7623e+001	98.2255	2	Signal of Interest	<input type="checkbox"/> PV Plan
tricuspid valve incompetence	20	2786	3.4210e+001	80.3238	3	Signal of Interest	<input type="checkbox"/> PV Plan
parkinson's disease	57	1386	5.5995e+001	77.6150	4	Indication Confounding	<input type="checkbox"/> PV Plan
retroperitoneal fibrosis	29	239	2.2218e+002	77.5156	5	Already on Label	<input type="checkbox"/> PV Plan

AERS Release: 2007Q3

Drug: Drug A
Event: Aortic Valve Incompetence
SOC: Cardiac Disorders
HLGT: Cardiac Valve Disorders
HLT: Aortic Valve Disorders
Serious? Yes **Designated Medical Event?** Yes **Labeled?** No

Signal Classification: Signal of Interest
Decision Code: Quarterly Monitoring

Signal Groups: (New)
 1. Mitral Valve Incompetence, Tricuspid Valve Incompetence, Mitral Valve Disease
 Not a member of a Signal Group

Notes / Justification
 2007Q3 Ongoing epidemiology study, scheduled completion 11/2008