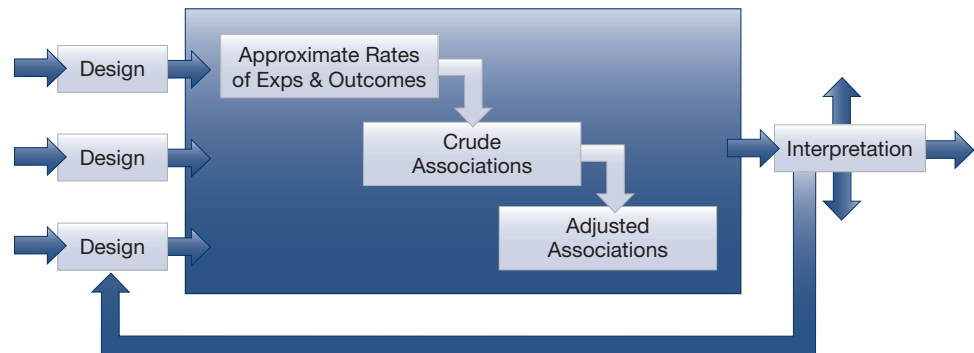




Database Analytics Automation: Proactive Signal Detection, Strengthening & Refinement

Bridge the gap between signal detection and signal adjudication and confirmation with United BioSource Corporation's (UBC) suite of Database Analytics Automation tools. Current methods of signal validation and refinement require labor intensive, time consuming and costly analyses. Our automated, user-friendly, analytical tools offer scalable, cost-effective, transparent and reproducible results quickly to help you decide accurately and reliably whether additional studies may be required and how they should be designed. Our expert analysis, backed by our knowledge and cutting-edge tools, drives informed and reliable results quickly. The results enable the user to evaluate and prioritize potential signals in several minutes to a few hours.



Signal 1: Product + Outcome = Known drug-related adverse events (AEs) (agranulocytosis, Stevens-Johnson, hepatic failure)
Signal 2: Product + Outcome = Possible mechanism of action or toxicity, minimal existing data
Signal 3: Product + Outcome = Common medical condition that may be part of disease process

Proactively manage risks and uncertainties in signal detection, strengthening and refinement.

Our comprehensive signal detection, strengthening and refinement suite of tools helps you

- Leverage multiple data sources for comprehensive review
- Reduce the time and resources needed to evaluate data
- Triage signals more confidently in less time
- Identify signals requiring further study and lessen the potential for exposure
- Reduce channel bias quickly
- Gain insight from experts in Risk Management

Overcome Challenges with UBC's Database Analytics Automation Suite

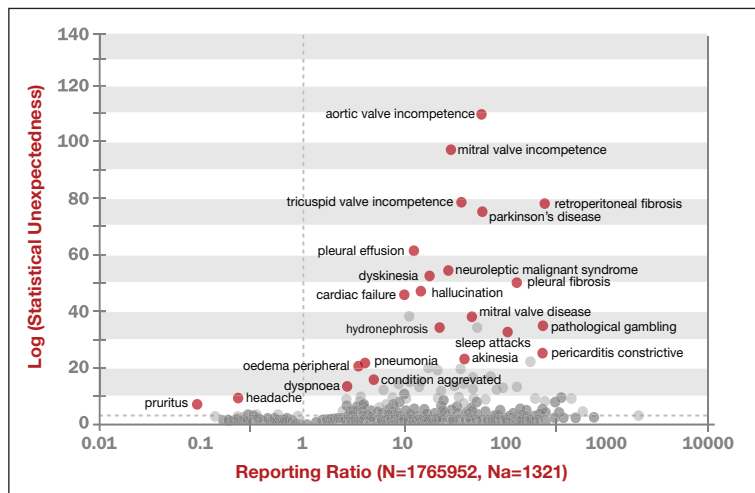
A knowledge gap between detection and adjudication exists. Clinical trials are often too small and homogenous to ascertain the full scope of safety adverse event (SAE) potential with less than a few thousand people. Protocols are too precise and safety profiles are not defined until they are used in the real world. Proactive identification of safety signals can create reluctance, however, regulatory affairs agencies are increasingly mandating proactive signal detection.

With broader evidence, you can

- Look at comparator, disease and class of drugs
- Generate savings (faster, less resources, less expensive)
- Reduce channel bias
- Make sentinel and signal refinement scalable and sustainable
- Close the gap between case processing and prospective studies
- Better understand the outcome, then manage the risk

Results in Seconds, Not Weeks

Investigate and manage potential safety signals in adverse event data for investigation of AERS and other spontaneous reporting databases with CLÆRITY[®], UBC's intuitive, web-based software.



Detect and investigate signals

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 Map
mitral valve incompetence	92	4584	2.7623e+001	98.2255	2	Signal of Interest	<input type="checkbox"/> PV Map
tricuspid valve incompetence	20	2786	3.4210e+001	80.3238	3	Signal of Interest	<input type="checkbox"/> PV Map
parkinson's disease	32	1386	5.5995e+001	77.6160	4	Indication Confounding	<input type="checkbox"/> PV Map
retroperitoneal fibrosis	32	239	2.2218e+002	77.5156	5	Already on Label	<input type="checkbox"/> PV Map

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:
Decision Code:

Signal Groups: 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

Uncover safety signals in adverse event data with this software for investigation of AERS and other spontaneous reporting databases.

CLÆRITY[®] enables you to

- Access real-time results in an easy-to-understand, compelling visual format
- Create a collaborative environment for signal investigation and management
- Rapidly classify signals of interest
- Track and monitor selected signals over time and assess trending
- Document actions and decisions
- Generate summary status of detailed signal history reports
- Use complementary data mining technologies (PVmaps[™], PRR, MGPS) for full coverage

CLÆRITY[®] answers your critical safety and epidemiology questions

- What are the significant signals for a drug, class or group?
- Is 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?
- Should this event be studied retrospectively or prospectively?

Robust, Transparent, Interactive and Fast

Rapidly investigate and understand any observational database with SAEFETYWORKS®, UBC’s web-based, easy-to-use software.

Save time, resources and reduce costs

- Execute an unlimited number of safety studies across multiple databases in hours
- Facilitate savings in database access, governance and infrastructure
- Eliminate the need for custom programming code and associated support

Standardized approaches for reproducible results

- Unlock valuable information buried within the complexities of observational data quickly and easily
- Identify and analyze potential safety risks and benefits faster and more reliably
- Better understand drug uses, benefits and effects

Robust and transparent analytic methodology

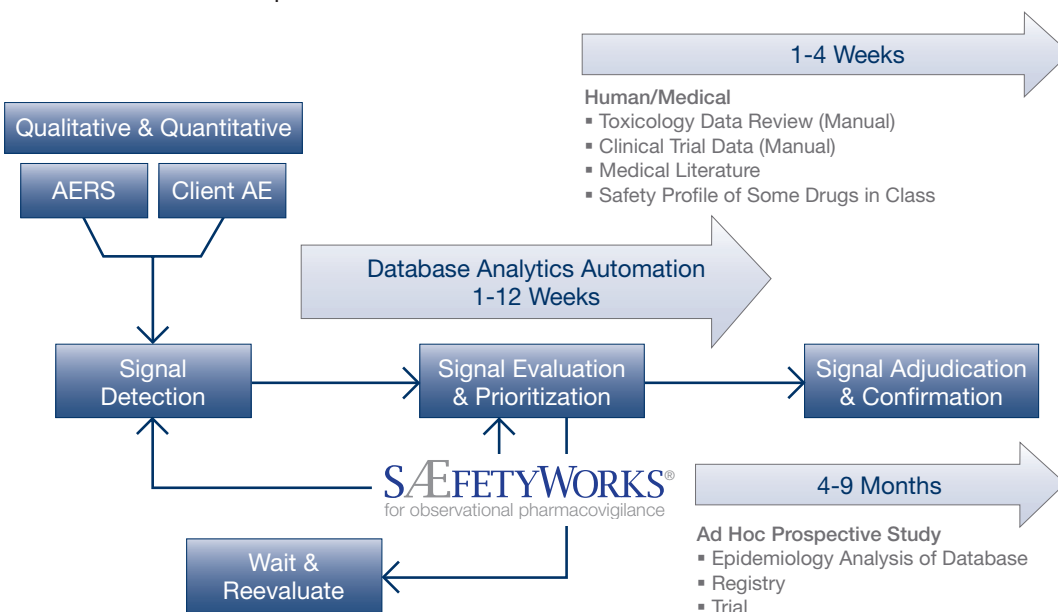
- Real-world context for a given cohort (e.g., most common concomitant medications, most common co-morbid conditions)
- Comparison among rates of drug-condition pairs to identify potential signals
- Uses traditional epidemiology methods and statistics
 - Control for multiple confounders and bias
 - Systematic evaluation of the strength of potential signals
- Analyze multiple databases with a single protocol and analysis definition

Industry accepted vocabularies

Drug Explorer, Condition Explorer and Procedure Explorer facilitate standardization of queries and cohort selection:

- MedDRA and ICD-9 for conditions
- SNOMED-CT and NDC for drugs
- CPT and HCPCS for procedures

Especially for drug safety scientists and epidemiologists, this web-based software detects and evaluates signals in any observational database.





Investigate and manage potential safety signals in adverse event data for investigation of AERS and other spontaneous reporting databases with the intuitive, web-based CLÆRITY[®].



Especially for drug safety scientists and epidemiologists, web-based SÆFETYWORKS[®] detects and evaluates signals in any observational database saving time, resources and reducing costs.



Track and manage safety concerns in accordance with EMA guidance on risk management. The web-based PVPLAN[™] enables information sharing among geographically-dispersed teams across the product development life cycle.



Get comparative effectiveness data on demand for product differentiation and brand management. CEWORKS[™] delivers the information you need at every stage of the product life cycle to facilitate messaging and respond to evolving market conditions.

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UBC is a global medical and scientific affairs organization that partners with life science companies to develop and commercialize their products. For more information, call us in the U.S. at +1 866 458 1096, in the E.U. at +44 (0) 20 8834 0100, or email us at evidence@unitedbiosource.com.