Trusted Services. Built on Science.

Sciformix Corporation is a global scientific process organization (SPO) that partners with life science companies to develop, launch and sustain medical products that aim to improve the quality of healthcare worldwide. We collaborate with our clients through the entire product development lifecycle to provide a full range of services from study design to post-marketing surveillance and commercialization support.

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Safety and Risk Management
Scignal Plus: Taking the Noise Out of Signal Detection
Emergence of Signal Detection

The area of safety signal detection has come into focus over the past few years and is growing in importance. It is well accepted that statistical methods of signal detection can flag certain drug-event combinations for in-depth analysis from a medical perspective, potentially leading to confirmation of evidence and identification of a signal. It is recognized that the quality of the data on which these methods are applied has to substantially improve. However, the methods also have inherent limitations and are used primarily as a screening tool. Hence new and improved statistical methods are being developed.

As a premier provider of end-to-end safety and risk management services, Sciformix has seen growing interest from all healthcare segments in quantitative methods of signal detection, across product categories and across both innovator and generic companies. We are developing new and innovative tools and services to improve the quality and performance of signal detection for our clients.

Introducing Scignal Plus

Scignal Plus provides superior, efficient signal detection by incorporating computational algorithms for a new method and previously known methods of signal detection. It has several distinct and important advantages over other products that are available in the market. Scignal Plus is a browser-based tool which employs a user-friendly interface for navigation, graphical depiction and drill-down analysis of signal data.

Previously available statistical methods, both frequentist and Bayesian, are primarily data mining tools for analyzing post-marketing safety databases. They focus on identifying drug-event combinations with disproportionately high frequencies and are subject to high false discovery rates. Inadequacies of these methods have been known to users.

Scignal Plus includes all commonly used statistical methods of signal detection and the new Likelihood Ratio Test-based (LRT) method. The tool can be used on data from US FDA Adverse Event Reporting System (AERS), any other publicly available database, company’s safety database, clinical trial safety database or a combination of these.

The LRT method for signal detection, proposed by a group of statisticians from the FDA, has been demonstrated to be superior to available methods with respect to power, sensitivity and false discovery rates while controlling the type 1 error rate.1

LRT method and Scignal Plus work effectively with small and large data sets, including clinical trial and spontaneous safety data, and can be customized based on the analyses and the comparisons of interest.

In the following example we illustrate Scignal Plus capabilities by using raw US FDA AERS data to understand the safety profile of the drug Citalopram.

Key Functionality

- The new LRT method and all commonly used statistical signal detection methods are available: Proportional Reporting Ratio (PRR), Reporting Odds Ratio (ROR), Information Component (IC) and Empirical Bayes Geometric Mean (EBGM)
- Applicable to any safety data: clinical trial and post-marketing data, internal company data and data available in the public domain
- Ability to query the data by drug or by AE
- Visual summary of data based on available covariates, analysis by subgroup and comparative displays
- Tabular and graphical displays of the signals
- Computation of signals relative to a defined class of products

In the above screenshots the data are selected and extracted based on query type, time period, drug name etc., the event frequencies are summarized both in a table and in a doughnut and then the frequencies are also summarized in bar charts by selected covariates, in this case, age-group and gender.
Key Differentiators

- Only product that incorporates all major signal detection methods, including the clearly superior LRT method
- Only product available to apply all signaling methods on clinical trial as well as spontaneous adverse event data, and with publicly available data such as US FDA AERS or WHO VIGIBASE or data made available by any other regulatory agency
- Allows customization along several dimensions, such as databases to be used, covariates to be used, subgroups to be analyzed etc.

Benefits

A variety of home-grown and commercially available signal detection tools are used by organizations, with varied pros and cons. Scignal Plus is the only solution on the market which can be your one-stop-shop for all signal detection methods. Given that these methods are used for exploratory purposes and that some of the commonly used methods have high false discovery rates, it is very important to use the new LRT method which has low false discovery rates and also easily compare its results with those of the previously available methods. Scignal Plus provides robust and reliable analysis of adverse event data from clinical trials as well as from spontaneous post-marketing adverse event data.

Sciformix has been delivering signal detection services to global healthcare companies, and the new signal detection solution is an integral part of our comprehensive Safety and Risk Management portfolio. We constantly seek to improve our people, process and technology capabilities to deliver consistent, reliable and superior quality results to our clients. This solution is another example of how Sciformix is creating value and enabling better client outcomes.