



## Case Study Biometrics

# SIGNAL IDENTIFICATION

## Client Situation

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Based on certain feedback received from the QP PV on an immunosuppressive agent about a few defined risks, a mid-sized pharmaceutical company decided to put in place a formal process for safety monitoring and signal identification. This had to include review of case listings classified using the MedDRA hierarchy, review of literature to identify unexpected events that may be rare adverse reactions, identification of cases requiring additional review or analysis and an appropriate method for evaluation of a case series.

## Sciformix Solution

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Based on monthly review of company cases and generation of line listing (that includes literature cases processed during the month), Sciformix identifies relevant cases that are first analyzed in detail by a senior pharmacovigilance physician. Relevant cumulative data, for the desired drug-event combinations, are also extracted from public databases like FDAAERS. All data are extracted into SAS datasets. The data are medically reviewed and the results are classified by MedDRA hierarchy. Sciformix has validated in-house algorithms to compute signal strength using all the commonly used statistical measures of signal detection. For this client, we proposed to calculate the following 3 measures – Proportional Reporting Ratio (PRR), Information Component (IC) and Empirical Bayes Geometric Mean (EBGM). Thresholds of these measures, that suggest a need for further investigation, have been agreed with the client. In addition, supporting data are collected from review of literature reports for the same class of compounds, regulatory alerts, reports from special purpose registries, poison control centers etc. Thorough medical analysis is performed to evaluate the signal and propose additional measures, e.g. label updates, broader literature review, epidemiological studies, etc.

## Outcome

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The client has been getting monthly analysis based on both quantitative and qualitative signal identification approaches. Our statisticians and clinical epidemiologists work up the epidemiological characteristics of a drug safety signal once detected. Signals are analyzed to determine causality and potential public health concerns. These reports are reviewed by the QP and any further investigation that is suggested is performed by Sciformix.

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We partner with our clients through the entire drug development cycle, to provide a full range of services from study design to post marketing services.

Our expertise lies in using scientific rigor to synthesize knowledge from the deluge of available information and using it, along with our understanding of the regulations, to help our clients make the right decision at the right time.

For more information on how Sciformix Biometrics service can benefit your enterprise contact us at

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