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Statistical Methods in Pharmacovigilance

After pharmaceutical products are approved by a governing health organization, regulatory bodies have a difficult time with post-market surveillance. Spontaneous reporting systems (SRS) are data collection methods that rely on the individual consumers to report, either directly or indirectly through a health professional, any adverse drug reactions (ADRs) they are experiencing. This data can then be collected by the governing health body and expressed in the form of a large dimensional contingency table which will be screened for 'signals', or when observed interactions appear higher than expected under the hypothesis of independence. This field of study is known as pharmacovigilance.

A number of methods for assessing signals in pharmacovigilance exist and are currently being implemented. The Proportional Reporting Ratio (PRR) and Reporting Odds Ratio (ROR) are two of the more commonly used Frequentist methods and the Bayesian Confidence Propagation Neural Network (BCPNN) and the Empirical Bayes Geometric Mean (EBGM) are two commonly used Bayesian methods. I will summarize the mechanics of these methodologies and briefly discuss some of their properties. Finally, I will go over some of the issues surrounding comparing the methods using Monte Carlo simulation.