



# ABS047

## DATA MINING ALGORITHMS USED BY REGULATORY BODIES OF DIFFERENT COUNTRIES FOR SIGNAL DETECTION IN PHARMACOVIGILANCE

**A. Ashritha\***,  
A. Pramod Kumar,  
U. Krishna

JSS College of  
Pharmacy, Department  
of Pharmacy Practice,  
JSS University, Mysuru,  
India

### AIM:

To identify the methods used by regulatory bodies of different countries for signal detection through the assessment of individual case safety reports.

**METHODS:** Literature search is conducted using PubMed and manually. The search terms included data mining algorithms and signal detection.

**RESULTS:** There are quantitative and qualitative methods used by regulatory bodies for signal detection. Under the quantitative methods, disproportionality analysis involves the calculation of frequentist metrics. Some of the widely applied frequentist measures include the relative reporting ratio, proportional reporting ratio adopted by the EMA (Eudravigilance), Italian Regulatory Agency (AIFA) and in UK (MHRA) and reporting odds ratio (ROR) adopted by the Netherlands (LAREB) Pharmacovigilance Center. In addition to the frequentist approaches, more complex data mining algorithms based on Bayesian statistics were developed such as the gamma-Poisson shrinker (GPS), the multi-item gamma-Poisson shrinker (MGPS), and empirical Bayesian geometric means (EBGMs).

The GPS and MGPs methods are currently used by the FDA. Moreover, Bayesian Confidence Propagation Neural Network (BCPNN) analysis was proposed based on Bayesian logic where the relation between the prior and posterior probability was expressed as the "information component (IC)". Under the qualitative methods, case series, medical event follow ups, periodic safety records are the methods commonly used in signal detection.

**CONCLUSION:** The choice of a given DMA mostly relies on local habits, expertise and attitude and there is room for improvement in this area; DMA performance may be highly situation dependent, especially with the so called "designated medical events", for which a case-by-case analysis is mandatory. The most appropriate selection of pharmacovigilance tools needs to be tailored to each situation, being mindful of the numerous biases and confounders that may influence performance and incremental utility of DMAs.

**Keywords:** Signal Detection, Pharmacovigilance, PMS