conferenceseries.com

J Clin Trial 2017, 7:4 (Suppl)
DOI: 10.4172/2167-0870-C1-017

Comparison of signal detection methods in pharmacovigilance

Sanjeev Miglani
APCER Life Sciences, India

The pharmaceutical companies collect the adverse events (AE) data from varied sources, and this collected data need to be analyzed for the safety surveillance. Spontaneous reporting (SR) adverse event system databases, large clinical projects and health records databases contain data that may be valuable for timely detection of potential risks associated with drugs, devices, and vaccines. All of the data sources include many different AEs and many medical products, so that any approach designed to identify critical signals of potential harm must have adequate specificity to protect against false alarms yet provide acceptable sensitivity for detecting issues that really need further investigation. The algorithms may seek to identify potential drug-event associations without any prior specifications, to identify events associated with a particular product or set of products, or to identify products associated with a particular event or set of events. A whole range of statistical methods have been applied for data mining and signal detection in pharmacovigilance. Primarily there are frequentist as well as Bayesian approaches to SD. This session will provide guidance to various approaches for signal detection. This session will provide recommendations for using data from post marketing spontaneous adverse event reporting databases to provide insight into safety signals and offer guidance regarding appropriate methods like frequentist and Bayesian approaches to use in various situations.

sanjeev.miglani@apcerls.com