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Evaluation of signal detection methods in pharmacovigilance

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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 frequentists 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 situation.

Biography

Sanjeev Miglani is an MD in internal medicine and has over 18 years of experience in the field of medicine, Pharmacovigilance and clinical research. He is the Vice President of Safety and Medical Affairs at APCER. Just before joining APCER, Sanjeev was the vice president for Pharmacovigilance and medical writing at Accenture. before joining Accenture, Sanjeev was the COO Officer and Scientific Director of CIDP Biotech. Prior to CIDP, Sanjeev was the Director of Medical Affairs at CliniRx. before CliniRx, He has worked with Ranbaxy as a senior manager in the department of medical affairs and pharmacovigilance. He has also worked as a senior resident in cardiology and medicine department in some of the prestigious hospitals of New Delhi. He is a life time member of API and a fellow of Indian Association of Clinical medicine. He has numerous publications in medical journals and books to his credit.

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