Divya B et al., J Pharmacovigilance 2014, 2:5
http://dx.doi.org/10.4172/2329-6887.S1.014

OMICS Group Conferences
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3rd International Conference and Exhibition on
Pharmacovigilance & Clinical Trials
October 27-29, 2014 Hyderabad International Convention Centre, India

Signal detection in Pharmacovigilance

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WHO defines safety signal as, "reported information in a possible causal relationship between an adverse event and a drug, the relation being unknown or incompletely documented previously." The strength of a safety signal is determined by several factors of the adverse effect. These include frequency, nature, duration and presence of documented rechallenge/dechallenge information of the adverse effect. The detection of these signals is usually done by pharmaceutical companies, regulatory agencies or government agencies like the WHO. Signal detection is an important tool in pharmacovigilance. It can either be quantitative or qualitative. The traditional, case by case assessment of reports constitute the qualitative method. The automated signal detection programs quantitatively compare the combinations of drugs and their adverse effects against the background of a database and use statistical parameters for signal detection. The quantitative methods help analysing large amounts of data in a shorter time span. Hence the use of these advanced signal detection technologies in the clinical trial processes allows the researchers to perform close-to-real-time data analysis and reduces time in interchange of information between researchers, clinicians and statisticians.

Biography

Divya B has completed M.B.B.S from Dr. N.T.R University of Health Sciences, and now pursuing post graduate course in M.D Pharmacology in S.S Institute Of Medical Sciences And Research Center. She is currently working on a research project titled 'prescription pattern of drugs in upper respiratory tract infections and their cost analysis'.

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