

# 3<sup>rd</sup> International Conference and Exhibition on Pharmacovigilance & Clinical Trials

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## Methods used in signal investigating: Pharmacovigilance

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A 'signal' consists of reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously. Usually more than a single report is required to generate signal, depending upon the seriousness of the event and quality of the information. Early identification of the hazards associated with drugs is the main goal of those involved in pharmacovigilance 'Signal detection', 'signal generation' or 'signaling' refers to a process that aims to find, as soon as possible, any indication of an unexpected drug safety problem which may be either new ADRs or a change of the frequency of ADRs that are already known to be associated with the drugs involved. The results of this surveillance tend to arouse suspicions and should always be followed up by in-depth investigations. Qualitative methods are based on clinical evaluation by a Research Fellow who reviews data reported by the GP for a single case or series of cases. Quantitative technique makes use of computational power to analyze the large volume of data. Different measures include ranking of incidence rates and risks within time periods, risk and/or rate ratios between time periods, and reasons for treatment withdrawal. Observations in populations (quantitative), large data sources of drug use & morbidity, case controlled studies, follow-up studies, prescription event monitoring, intensive hospital monitoring and large spontaneous reporting systems. Potential signals identified through qualitative and/or quantitative methods can be evaluated using more reliable data sources such as observational/pharmacoepidemiologic studies, additional randomized clinical studies, or mechanistic studies.

## Biography

D Varnika is pursuing Doctor of Pharmacy in JSS College of Pharmacy, affiliated to JSS University, Mysore, Karnataka.

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