



Pharmacovigilance: Overview and Importance

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SUMMARY:

Clinical Research refers to evaluation of an Investigational product with respect to safety and efficacy conducted on human beings. It encompasses some laboratory research on the mechanisms of human disease, translational research (in which laboratory and clinical activities are closely aligned), clinical trials of preventive and therapeutic strategies, epidemiology, behavioral research, and health services.

Pharmacovigilance is a demanding science that fall under one umbrella of Clinical Research offering great opportunities for reducing harm to patients and costs to healthcare systems. From small beginnings, with the right knowledge and skills, Pharmacovigilance can make a significant contribution to the health of the nation.

Pharmacovigilance, the word is derived from Greek word Pharmakon (drug) and Latin word Vigilare (means to keep watch). The World Health Organization (WHO) defines Pharmacovigilance as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems."

Also referred as Drug safety, is one of most essential part of clinical research that has potential to gain trust and to improve the quality of patient care. Pharmacovigilance was first born in December 1961 with the publication of case report called thalidomide disaster. The term Pharmacovigilance was in proposed mid-70s by a French group of pharmacologists and toxicologists to define the activities promoting "The assessment of the risk of side effects potentially associated with drug treatment".

No medicine is absolutely safe; there is risks/side effects associated with every medication. As defined Pharmacovigilance identifies, assesses, understands and prevents the adverse effects or any other possible drug-related problems. The need of Pharmacovigilance arises with the fact that the clinical trial studies are limited to selective restricted smaller population with a limited period under a pre-defined protocol.

The adverse event reporting for both investigational and marketed drugs involve active involvement of Healthcare professionals, Investigators, Pharmaceutical Company (sponsors), Hospitals, Consumers, Companies importing or distributing drugs to report to the drug regulatory authority in a timely fashion.



Although Pharmacovigilance starts from the clinical trial stage (Pre Marketing clinical studies) that has controlled patient population, Post Marketing Surveillance plays an integral role in the monitoring of the safety of a pharmaceutical drugs or medical device throughout the life cycle of the drug as the population is larger and diverse. Until unless the drug is there in the market the marketed product requires constant monitoring. Thus it becomes necessary to understand the importance and duty of all who are involved in Pharmacovigilance to report on ADRs for overall wellbeing of patient life.

Frances Kelsey – A medical officer in FDA in 1960s who is known Leader in Drug safety and protection of patients says:

“She will not approve until she had proof of being it safe”