

Research & Reviews: Journal of Pharmacology and Toxicological Studies

Role of Pharmacovigilance in Health Care Industry

Nagashree Kotturi* and Phani KumarKotturi

Department of Clinical Research, Nizam's institute of medical sciences, Hyderabad, India

Commentary

Received date: 13/04/2015

Accepted date: 14/04/2015

Published date: 20/04/2015

*For Correspondence

Nagashree K, Department of Clinical research, Nizam's institute of medical sciences, Hyderabad, India;

E-mail: nagashreekotturi@yahoo.com

Keywords: Pharmacovigilance, Safety, Efficacy, Adverse drug reaction, Signal detection, Post marketing surveillance.

ABSTRACT

Pharmacovigilance (or drug safety surveillance) is a branch of science which deals with adverse reactions of pharmaceutical products enclosing collection, detection, monitoring, assessment and prevention of adverse reaction of pharmaceutical products. It is one of the crucial steps in drug development process, which ensures safety of newly developed pharmaceutical product. This study is conducted before post marketing surveillance, which helps in assessing the risk benefit ratio of new pharmaceutical product. Thus the formulation gets approval from FDA for further processing.

Adverse drug reactions includes

- (a) Serious drug reaction
- (b) Unexpected drug reaction

Objectives of Pharmacovigilance

- detection of risk factors ^[1,2]
- early identification of unknown safety problems
- quantifying the probability of risk
- Measurement of effectiveness

Novel drug discovery is time consuming and expensive process, which also requires a strict vigilance to ensure safety and efficacy of the drug. Pharmacovigilance plays a crucial role in drug development process. The safety of pharmaceutical product may not be distinct, post effects of drug when used in combination of other drugs are generally unknown and safety concerned in different groups can be different as in young children, elderly patient, pregnant women.

Pharmacovigilance plays a pivotal role at different stages of drug discovery development process, which involves submission of reported adverse drug reactions observed during clinical trials to respective drug regulatory agencies ^[3-4].

Signal Detection in Pharmacovigilance

Signals can be evolved from post marketing data or other sources, such as preclinical data and events associated with other products of same pharmacologic class. After signal identification, it should be further subjected to assessment in order to identify potential safety risk ^[5-10].

Signals detected through four different methods: spontaneous reporting, published case reports, cohort studies and post-marketing clinical trials.

Spontaneous reporting

Identifying and reporting clinical findings of suspected adverse drug reactions with a marketed drug is termed as spontaneous or voluntary reporting.

Published case reports

Case reports with suspected ADRs which are published in medical journals is one way to alert others of possible drug hazards.

Cohort studies

Companies may organize sponsor prospective or non-interventional cohort studies in order to resolve the queries rose after marketing the drugs.

Post-marketing clinical trials

Large randomized Clinical trials with wide entry criteria can be useful in detecting the safety and efficacy of marketed products.

Reporting of safety signals

With the detection of safety signals, sponsors would be responsible in submitting all the available safety information to regulatory authority, starting from preclinical findings to the current findings.

Regulatory authority will make the own assessment of available data considering the following: seriousness of event with respect to disease being treated, magnitude of the signal, biologic plausibility, consistency of findings with the available data sources, availability of other therapies and potential to mitigate the safety signal in the population through various risk management strategies.

Role of Pharmacovigilance in Monitoring Safety Signals

Safety signals can be detected prior to product marketing approval or after the drug has been marketed. Scheme for pharmacovigilance depends on several factors (scientific and logistical) which includes: type of the signal, whether it occurs commonly or rarely, the nature of the population(s) at risk, whether the product is prescribed to a broad range of patients or in selected populations only and whether the product is dispensed at all pharmacies or via restricted distribution systems only.

The proposed pharmacovigilance scheme includes

It involves submitting adverse event reports in an expedited manner (i.e. as 15 day reports) or at more frequent, pre-specified intervals (Eg. quarterly rather than annually).

It involves active surveillance to identify adverse events, which may not be observed or identified in passive surveillance.

Need for Pharmacovigilance

Pharmacovigilance ^[11,12] is an important part of clinical research ranging from drug discovery to post marketing surveillance. With requirement to patient safety, prior identification of adverse drug reactions are utmost required. Pharmacovigilance ^[13-17] involves evaluating the information provided by health care providers , pharmaceutical companies and patients in order to diagnose the risk and benefits involved with respect to particular drug.

Pharmacovigilance is a very crucial part of drug discovery and development process, which requires careful monitoring of drug at every phase including pharmacovigilance inspection, reporting of ADR, periodic safety report, post-authorization safety studies ^[18-21]. Establishing good pharmacovigilance is foremost required in order to understand the drug safety issues during drug development process, thus patients can be provided with safe and effective innovative drugs.

With the developing trends in health care industry, information technology (IT) has transformed the world health care and clinical medicine, to meet their standards, thus improving the safety, efficacy of drugs, and reducing the costs. Booming of IT into clinical safety practice creates a strong platform, to establish pharmacovigilance ^[22] systems for safety signal detection. Thus, it brought a significant change in conducting clinical research practice of medicines and medical safety monitoring. For an fruitful pharmacovigilance system to be effective, all the stakeholders need to be keen enough throughout the lifecycle of a drug in the market. Thus pharmacovigilance is very critical step involved in drug development process, which ensures new innovative drug meets the regulatory compliance, thus enhancing the clinical trials safety and post marketing surveillance.

REFERENCES

1. Gamal Osman Elhassan. Pharmacovigilance: Clinical Perspectives towards Patient Safety. J Pharmacovigil. 2005; 3: 2.
2. Vivek S. Dave. Current Trends in Pharmacovigilance. J Pharmacovigil. 2012; 1: 108.

3. Prashansa Agrawal. Drug Discovery and Development: An Insight into Pharmacovigilance. *J Pharmacovigil.*2014; 2: 2.
4. Preda A . Pharmacovigilance in the New Millennium: Challenges, Opportunities and New Directions. *J Pharmacovigilance.* 2013; 1: e106.
5. Fabrizio De Ponti. Global Perspectives in Pharmacovigilance. *J Pharmacovigil.* 2013; 1: e108.
6. Darren R Flower. Pharmacovigilance, Drug Repositioning, and Virtual Screening *J Pharmacovigilance.* 2012; 1: e103
7. Vishwani Persaud-Sharma ,Shu-Feng Zhou. Incorporation of New Technologies into Global Pharmacovigilance. *J Pharmacovigilance.* 2012; 1: e102.
8. Vijay Kumar. Challenges and Future Consideration for Pharmacovigilance . *J Pharmacovigilance.* 2013; 1: 102.
9. Atsuko Shibata, Manfred Hauben. Pharmacovigilance, Signal Detection and Signal Intelligence Overview . ISIF. 2011.
10. Lekha Saha. Role of Pharmacovigilance in Drug Development. *Enliven: Pharmacovigil Drug Saf.* 2014; 1: e002.
11. L S Simon. Pharmacovigilance: towards a better understanding of the benefit to risk ratio. *Ann Rheum Dis.* 2002; 61: ii88-ii89.
12. L. Härmark, A. C. van Grootheest. Pharmacovigilance: methods, recent developments and future perspectives. *Eur J Clin Pharmacol.*2008; 64: 743-752.
13. Ankur Rohilla, et al. Pharmacovigilance: Needs and Objectives. *J Adv Pharm Edu Res.* 2012; 2: 1-5.
14. Avani Patel, et al. Pharmacovigilance: A Review. *International Journal of Pharmaceutical & Biological Archives.* 2011; 2: 1569-1574.
15. Arora Rashmi et al. Pharmacovigilance a better for tomorrow. *Irjp.* 2011; 2: 43-46.
16. Babita Ravindra Alhat. PHARMACOVIGILANCE: AN OVERVIEW. *IJRPC.* 2011; 1: 7.
17. Rahul Dogra et al.Detection, Assessment, Understanding and Prevention of Adverse Effects: Pharmacovigilance: A Review. *Int. J Pharm Sci Rev Res* 2013; 20: 71-86.
18. J C C Talbot and B S Nilsson. Pharmacovigilance in the pharmaceutical industry. *Br J Clin Pharmacol.* 1998; 45: 427 –431.
19. Guideline on good pharmacovigilance practices (GVP) (2011) – Module IX.
20. WHO (2004) Pharmacovigilance: ensuring the safe use of medicines, Geneva.
21. WHO (1995) Safety monitoring of medicinal products. : Guidelines for good Clinical Practice (GCP) for trials on pharmaceutical products, Geneva.
22. Klepper MJ. The periodic safety update report as a pharmacovigilance tool. *Drug Safety.* 2004; 27: 569-578.