ejpmr, 2023, 10(9), 285-294

SJIF Impact Factor 6.222

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

Review Article

ISSN 2394-3211

EJPMR

A REVIEW ON THE RECENT TRENDS OF PHARMACOVIGILANCE

***Akshaykumar Meshram and [1]Pranali Kunteshwar Rabade**

*Assistant Professor, [1]Student

Maharashtra Institute of Pharmacy (B. Pharm) Chandrapur, Maharashtra, India-442605.

***Corresponding Author: Akshaykumar Meshram**

Assistant Professor Maharashtra Institute of Pharmacy (B. Pharm) Chandrapur, Maharashtra, India-442605.

Article Received on 21/07/2023 **Article Revised on 11/08/2023** **Article Accepted on 01/09/2023**

ABSTRACT

The rapid and continuous progress of medical and pharmaceutical sciences has resulted in the availability of modern medicines that can efficiently prevent, control and/or manage disease states Pharmacovigilance is such a system. The concept of pharmacovigilance is not new and its origins date back over 50 years. The thalidomide tragedy of 1961 drew attention to the importance of the assessment of the adverse effects of drugs. Between 1965 and 1970, after several meetings and resolutions, the International Drug Monitoring Program was formed by the World Health Assembly. Pharmacovigilance is defined by the World Health Organization (WHO) as "The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems". The significance of safe use of medicines, adverse drug reaction (ADR) monitoring has become an essential component to be achieved along with other health-care facilities from Pharmacovigilance Literature Screening Services. They have increased life expectancy and improved the quality of life for millions of people.

KEYWORD: Adverse drug reaction, Health care, Pharmacovigilance.

INTRODUCTION

According to WHO, Adverse drug reaction (ADR) is defined as "Any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function". An adverse drug reaction (ADR) is an unwanted, undesirable effect of a medication that occurs during usual clinical use.[1]

It is widely accepted that a drug has to go through phases of clinical trial to establish its safety and efficacy before it is marketed. However, clinical trial offers various limitations, as it excludes some population groups such as children, pregnant women, and old age population are not studied during the trials. Moreover, some other factors causing adverse drug reactions such as genetic factors, environmental factors, and drug-drug interactions may not have been studied during the clinical trial.[2]

The history routes of the word "Pharmacovigilance" are: Pharmakon (Greek word of 'drug') and vigil are (Latin word for 'to keep watch').[3]

Pharmacovigilance is not new to Asian nation and has infect been going on from 1998. When Asian nation decided to join the Uppsala centre for adverse event monitoring. It is widely accepted that a drug has to go through various phases of trial to establish its safety and efficacy before it is marketed commercially.[4]

However, the clinical trials offer various limitations, like strict criteria of inclusion and exclusion make it to be used in a very selective group of patients; special population groups like kids, pregnant lady, and maturity population are not studied during the trials; and other factor causing drug reactions such as genetic factors, environmental factors, and drug-drug interactions may not have been studied during the clinical trials.[5]

Pharmacovigilance plays a multi-modal role in promoting and improving public health. The key goals of Pharmacovigilance are

- To identify the risks associated with use of medicines by the patients.
- To participate in comparative assessment of potential beneficial and adverse effects of the drugs and help optimize the nature of use.
- To promote safe, effective and rational use of medicines.
- To promote awareness among patients and general public regarding the safe use of medicines via effective communication.

These goals are achieved only with the collaborative efforts and contributions from the key partners in the

area of Pharmacovigilance. Inputs from a variety of sources such as government, academia, pharmaceutical and medical associations, health professionals and the media will help towards achieving improved management of risks associated with the use of medicines.[6]

History of PV in India[3]

Pharmacovigilance in India started from 1986. A formal Adverse Drug Reactions (ADR) monitoring system was initiated with 12 regional centres, each covering a population of 50 million. However, no noteworthy growth was made. Afterward in 1997, India joined the World Health Organization (WHO) and Adverse Drug Reaction (ADR) scrutinizing program based at Uppsala, Sweden but got fail. Hence, after 2005 WHO supported and World Bank – funded National Pharmacovigilance Programmed (NPPV) of India was made operational.

Table 1: The sequential Pharmacovigilance developments with special reference to India.

YEAR	DEVELOPMENTS
1747	Very first known clinical trials by James Lind, proving the usefulness of lemon juice in preventing scurvy
1937	Death of more than 100 children due to toxicity of sulfanilamide.
1950	Aplastic anaemia reported due to Chloramphenicol toxicity.
1961	Worldwide tragedy due to thalidomide toxicity
1963	16th World Health congregation recognize significant to rapid action on Adverse Drug Reactions (ADRs).
1996	Global standards level clinical trials initiated in India.
1968	WHO research project for international drug monitoring on pilot scale.
1997	India attached with WHO Adverse Drug Reaction Monitoring Program.
1998	Initiation of Pharmacovigilance in India.
2002	67th National Pharmacovigilance Centre established in India.
2002-05	India launched National Pharmacovigilance Program.
2005	Accomplishment of structured clinical trials in India.
2009-10	Pharmacovigilance Program (PV. PI) started.

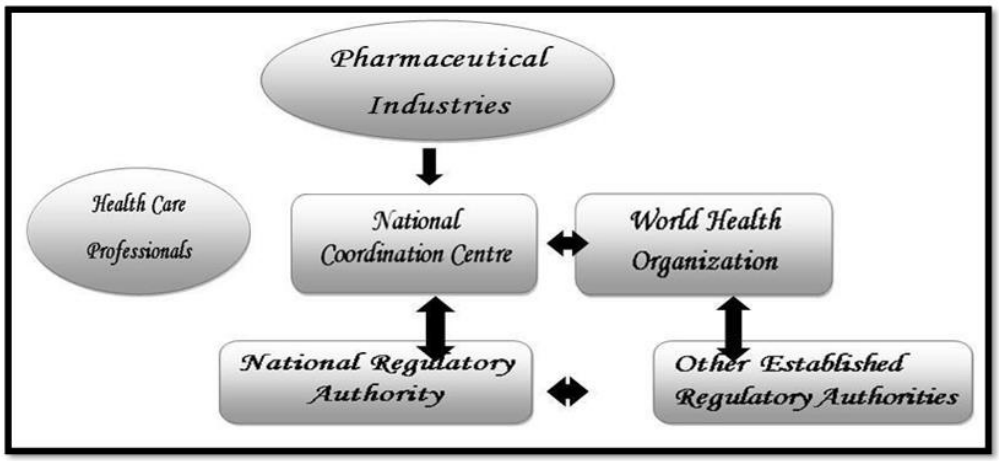

Figure 1: Diagrammatic representation of PV [18]

Definitions of Pharmacovigilance[5]

The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. It focuses on investigating and monitoring adverse drug reactions after medicinal products are licensed.

The term "Pharmacovigilance" first appeared in French in the late 1960s, when the terms "Pharmacovigilance intensive" and "Pharmacovigilance spontaneous" were contrasted.

- **Detection:** In case of clinical trial, it's the investigator or in case of post marketing trial, it's either the physician or the prescriber or the patient himself who reports the adverse event or any drug related problem.
- **Assessment:** The investigator or the health care professional (HCP) would be assessing if the adverse event or drug related problem is due to the drug or is it due to some other reason.

- **Understanding:** The reporter and safety specialist is involved in the understanding the adverse event or drug related problem.
- **Prevention:** By pro-actively reporting the adverse event or drug related problem to the regulatory authority and taking precautionary actions would help in preventing the adverse event in future.

Aim and Objectives of PV[7]

- To increase public protection from the new drugs.
- To contribute to assessment of benefit efficiency and risk of medicines
- Endorse healthy communication to the community
- To promote rational and safe use of medicines.
- Efficacy of drugs and their monitoring about adverse effects of drugs.
- Pharmacovigilance keeps way of any drastic effects of medicines.
- Improve public health and safeties in relation to the use of promote understanding, education, and clinical training in pharmacovigilance.
- Detection of severe and unexpected adverse drug reactions to the established drugs and even the minor ones to newer drugs.

Figure 2: Aims of Pharmacovigilance.

Need for Pharmacovigilance[8]

Reason 1: Humanitarian concern - Insufficient evidence of safety from clinical trials Animal experiments Phase 1-3 studies prior to marketing authorization.

Reason 2: Medicines are supposed to save lives Dying from a disease is sometimes unavoidable, dying from a medicine is unacceptable.

Reason 3: ADR-related cost to the country exceeds the cost of the medications themselves.

Reason 4: Promoting rational use of medicines and adherence.

Reason 5: Ensuring public confidence.

Reason 6: Ethics, to know of something that is harmful to another person who does not know, and not telling, is unethical.

Increasing requirement of Pharmacovigilance system. The bases of need are as follows.

1. Untrustworthiness of pre-clinical safety information.
- Well-controlled environment.
- Appropriate and precise sample size.
- Pressure from various systems to decrease time to Authorization.
2. Altering pharmaceutical marketing policies.
- Aggressive marketing.
- Launch the drug in many countries at a time.
3. Varying physicians, patients and other health professional's preferences.
- Increasing use of newer drugs.
- Increasing use of drugs to get better quality of life.
- Shift of manage to self-administered treatment.
4. Easy convenience.
- Growing conversion of prescription drugs to over the counter drugs. • Easy access to drug information on the Internet.[9]

Challenges of PV[10]

The Pharmacovigilance Programmed of India (PVPI) is an Indian government organization which identifies and responds to drug safety problems. Its activities include receiving reports of adverse drug events and taking necessary action to remedy problems.

Administration

Government has a key role in proper functioning of the programmed. In India, the government is the major stake–holder in the implementation of health care. It is

through the public sector, the programmed can reach every nook and corner of the country.

Self-Medication

Self-medication is one of the problems in our country as people are not educated about drugs and they take drugs prescribed by pharmacist without proper prescription. Advertisements by the drug companies and the readily available drug over-the-counter with available pamphlets about the dose, indication, side-effects make the patients to take their own therapeutic decisions, without assistance from doctor or pharmacist.

Health Professional

Lack of continuing medical education about Pharmacovigilance and dearth of drug information lead to underreporting of adverse drugs events. Most of the time, doctors believe that they have to report only if the adverse events have a casual relationship with the products. In our country, due to low ratio of doctor to patient, most of the events are not reported due to lack of time, low motivation, ignorance and lethargy.

Traditional Medicines

Traditional drugs are considered safe with few side effects. The processing of natural drugs are not done properly, toxic and essential ingredients are not known most of the time, they are given for long duration and there is lack of knowledge between interaction of herbal drugs with modern medicines.

Clinical Trial Monitoring

India is becoming hub for clinical trial in the 21st century. In most of the clinical trials, adverse drug reactions that happen due to the test drugs are goes unreported and not inform to the regulatory authority due to personal interest or for the fear of litigation. Thus clinical trials pose a great challenge for Pharmacovigilance programmed.

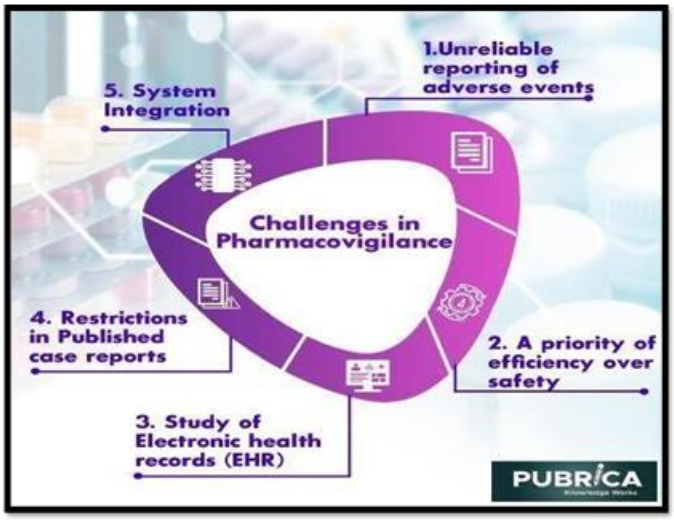

Figure 3: Challenges of Pharmacovigilance.

India Challenges of PV

India is a vast country and there is an excess of drug brands more than 6,000 licensed drug manufacturers and over 60,000 branded formulations. India is the fourth biggest producer of pharmaceuticals in the world and is also rising as a clinical trials hub. Many new drugs are being introduced in the country, so there is an immense need to improve the Pharmacovigilance system to protect the Indian population from potential harm that may be caused by some of the new drugs. In India, a pharmaceutical company holding the marketing license should ensure that they have adequate Pharmacovigilance system in place to ensure the responsibility and liability of their marketed products.

When two or more marketed products are identical in all aspects except their trade names, each pharmaceutical company holding a marketing license is obliged to meet the Pharmacovigilance obligations. This includes establishment and maintenance of appropriate Pharmacovigilance system to collect and evaluate information about suspected adverse reactions.[11]

Trends Shaping the Future of PV[13]

In an effort to continuously improve the efficacy of drugs and health outcomes for patients, the healthcare industry gradually evolves to meet changing regulations, make the most of the new technologies and communication channels, and cater to individuals and their unique needs. With the evolution of the healthcare industry comes the need to change the way, frequency or guidelines by which product safety is monitored and reported.

While Pharmacovigilance has long been a cornerstone of the healthcare industry, more thorough safety documentation and reviews for drug approvals — along with increased warnings and awareness about adverse drug reactions within the last few years — have made drug safety one of the top concerns for consumers and regulators. These safety concerns have prompted global

mandates for submitting significantly more detailed product information, as well as a push for more clinical and safety data transparency.

Understanding the trends that are shaping the future of Pharmacovigilance will help your business get a head starts on ensuring consistent performance with adherence to strict regulatory requirements.

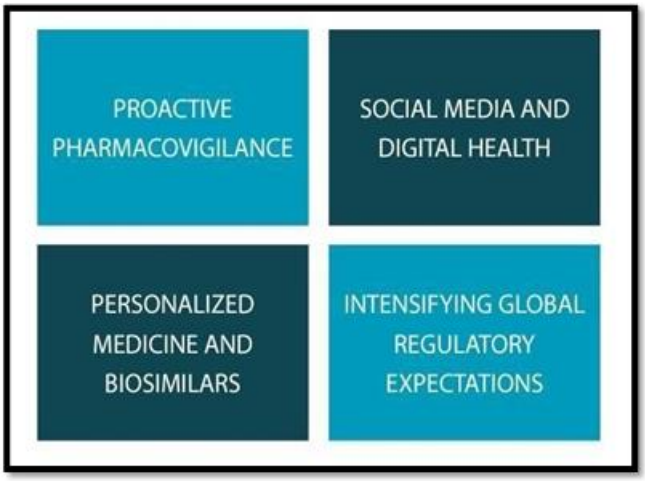

Figure 4: Trends Shaping the Future of PV.

1. Proactive Pharmacovigilance

Our reactive Pharmacovigilance system is transforming into a proactive, benefit-risk management system in order to fully adapt to modern technology and the growing need of consumers to receive immediate and reliable information through any channel. The consequences of taking a reactive approach can be disastrous – halting a clinical study, delaying drug approval, recalling a marketed drug; as well as brand damage, class action suits, and exorbitant fines. Moving forward, pharmaceutical and biotechnology companies must not only monitor for adverse events, but also proactively access and manage drug risk throughout a product's lifecycle. Developing a Pharmacovigilance risk management plan with a risk minimization action plan (Risk MAP) for high-risk products is becoming ever more essential.

2. Social Media and Digital Health

The traditional model of healthcare, with patients taking a passive role in their own health and wellbeing, is changing. A new standard of patient involvement has evolved. Social media, digital health devices, and mobile applications have made multi-channel health related interactions a part of everyday life. Social media has become an integral part of healthcare & product safety. More than 40% of consumers say that information found via social media affects the way they deal with their health.[12] Of respondents 18 to 24 years of age, 90% say they would trust medical information shared by others on their social media networks. Of adults, 47% say they are likely to share their health information on social media sites with doctors, 43% with hospitals, 38% with health insurance companies, 32% with drug companies, and 30% with other patients.

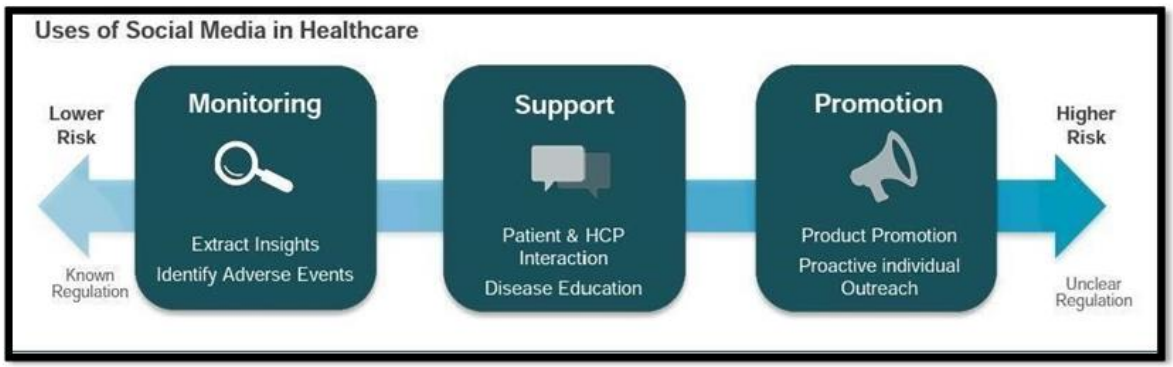

Figure 5: Social Media and Digital Health.

3. Personalized Medicine and Biosimilars

Personalized medicine will identify a patient's biological and disease characteristics, taking into account the patient's genetic, anatomical, and physiological characteristics, to tailor specific therapies for an individually optimized benefit-risk balance. It promises

to increase benefits, reduce risks, and improve the efficacy of many products for individuals. Personalized medicines will also require more complex labelling since they might only be safe and effective in particular sub-populations or might need to be administered in different doses to different sub-populations.

In cases where a therapeutic product is approved with a diagnostic device, the label of the two products must be consistent.

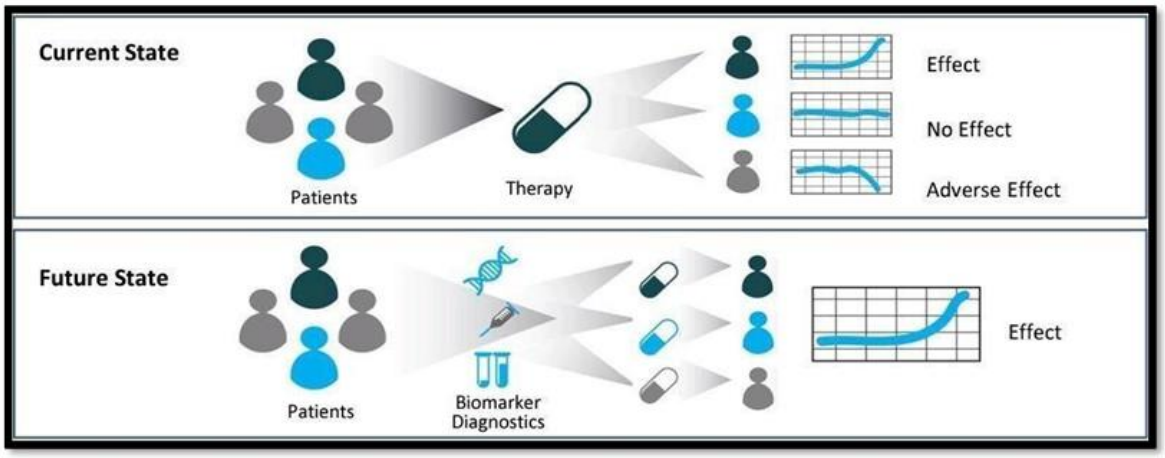

Figure 6:Personalized Medicine and Biosimilars.

4. Intensifying global regulatory expectations

The global pharmacovigilance market continually faces intensifying regulatory expectations, tougher inspection systems and an instant need for patient reporting. Organizations are more focused on introducing safer products to patients in a timely manner. Risk management plans (RMP), pharmacovigilance system master files (PSMF), periodic reports (PSUR, PBRER, PADER), product information, adverse event and adverse drug reaction reporting, drug renewals, signal management, medical literature monitoring - these are simply the basics when considering a pharmacovigilance strategy. Additionally, intensifying global regulatory expectations mean pharmaceutical companies must adapt and make risk management a center piece of global pharmacovigilance operations. The term risk management should not be thought of as mitigating only risks of adverse events, but also in terms of risks to product quality, data integrity and patient privacy. Addressing risks up front will improve risk-benefit outcomes and provides significant progress for public health.

Recent Current Trends In Pharmacovigilance[6]

The rapid and continuous progress of medical and pharmaceutical sciences has resulted in the availability of modern medicines that can efficiently prevent, control and/or manage disease states. Despite a plethora of benefits, adverse reactions to medicines are not uncommon and are associated with most newly developed drugs.

Pharmacovigilance is ingrained, and rightly so, in several areas of healthcare management of general population. The key areas where Pharmacovigilance is incorporated are, National Drug Policy: For most nations, the first step to ensure safe and rational use of medicine is the establishment of drug regulatory bodies with dedicated Pharmacovigilance programs to monitor and assess the adverse drug reactions and communicate finding to relevant stakeholders.

Drug regulation: The scope of drug regulatory authorities is beyond just the approval of manufacture and marketing of new medicines. Working in close collaboration with Pharmacovigilance programs, these regulatory authorities ensure continual safety of the drugs in public domain by conducting post-marketing surveillance and analysis of the benefits and harmful effects of the drugs in a broader population.

Moving to drive operational Efficiency

Specific re-appropriating in Pharmacovigilance is turning into a broadly utilized way to deal with adapting to the developing expenses of keeping a profoundly qualified and prepared Pharmacovigilance team in-house using.

For Manufacturers and Sponsors, a very much actualized Pharmacovigilance revaluating program brings observable advantages including:

- Reduced fixed expenses
- Increased adaptability
- Better results in the short-and long haul

These days an ever-increasing number of organizations reevaluate their Pharmacovigilance errands to accomplish better administrative consistence, more

significant, better profitability, and improved vital choices from.[14]

Information Analytics to Drive Actionable Insights
According to a clinical literature review, the successful administration of health information put away across numerous stages is imperative for away from security occasions. The developing number of Life Sciences organizations goes to cutting edge logical methods in Pharmacovigilance to look at huge and changed informational collections that contain health data.

They Endeavour to uncover new examples, obscure connections, patterns, and patient inclinations that help them guarantee patients' security all the more viably. These days, Pharmacovigilance examination gives a genuine chance to outfit information adequately, guarantee administrative consistence and drive unique experiences.

Big Data to Protect and Assimilate Huge Amount of Information
As of late novel wellsprings of actual proof and trial information in the mechanical structure, they have also opened up to Pharmacovigilance experts. In Pharmacovigilance, enormous information incorporates such sources as:

- Signal discovery
- Substantiation and approval of medication or immunization health signals online channels and web-based media.

Because of its intricacy, big information addresses both a chance and a challenge. [14]

Methods Used in Pharmacovigilance[15]
The activities undertaken in the name of PV can be roughly divided into three groups: regulatory, industry, and academia.

Regulatory Pharmacovigilance is driven by the aim to provide drugs with a positive benefit– harm profile to the public. Some of the problems related to regulatory post-marketing surveillance will be discussed in this context, followed by a description of the methods used to detect new ADRs and a discussion of the pros and cons of each method.

Spontaneous report monitoring system (SRS)
The most important and primary method for Pharmacovigilance to collect post-marketing information on the safety of drugs is SRS. It is the oldest, simplified and cost-effective method of ADR reporting. The system is structured in a way the country's health system is organized. The example is yellow card system in USA where all the patient data is available online through ADROIT (ADR online tracking system). The method involves the voluntary participation of health professionals, pharmacists, nurses and patients themselves for reporting the observations related to ADR.

All health professionals can use the report form to give all relevant data related to the drug and suspected ADR. Experts then review and evaluate the reports submitted on a case-to-case basis to check whether there is a pattern representing the possible signal. Often a single report may not be conclusive and a set of reports from independent observers is required to generate a signal.

Prescription event monitoring (PEM)
It is a state-based electronic database that works on how the prescription monitoring is organized in the country (UK). Virtually all patients are registered with a general practitioner (GP) who provides primary health care and issues prescriptions (FP10s) for the medicines considered medically necessary. The patient takes the prescription to a pharmacist who dispenses the medication and then sends the FP10 to a central Prescription Pricing Authority (PPA) which arranges the reimbursement of the pharmacist which sent it to Drug Safety Research Unit (DSRU). DSRU is, under long-standing and confidential arrangements, provided with electronic copies of all those prescriptions issued throughout England for the drugs being monitored by PEM.

These arrangements continue for a collection period adequate to allow exposure data (FP10s) to be collected for twenty to thirty thousand patients. For each of these patients the DSRU prepares a record comprising all prescriptions for the monitored drug. After this, a personalized follow-up questionnaire green form is mailed to each patient's general practitioner, usually on the first anniversary of the initial prescription, asking for information about the patient, especially any events that he or she may have experienced since beginning treatment with the drug. These green forms are then voluntarily filled up and submitted by the physicians. The advantages offered by this system are that these reports requested from physicians are on voluntary basis and nothing happens to interfere with the doctor's decision regarding which drug to prescribe for each individual patient. Thus, it is an easy and convenient method and non-interventional, observational cohort form of Pharmacovigilance. Most importantly, PEM enables the generation and testing of hypotheses regarding drug alerts or signals that may be of public health interest.

Clinical trial data insufficient to evaluate drug risk[16]
The main method currently used to gather information on a drug in the pre-marketing phase is to conduct a clinical trial. Pre-marketing clinical trials can be divided into three phases. Phase III studies are often double blind randomized controlled trials; these are considered to be the most rigorous approach to determining whether a cause–effect relationship exists between a treatment and an outcome. However, when it comes to monitoring the safety of a drug, this study design is not optimal. Due to

the limited number of patients participating, it is generally not possible to identify ADRs that occur only rarely. The relatively short duration of clinical trials makes it difficult to detect ADRs with a long latency. Another limitation of clinical trials is the population in which a drug is tested. The characteristics of the participants do not always correspond to the characteristics of the population in which it will later be used; consequently, it may be difficult to extrapolate the results obtained from clinical trials to the population at large.

Intensive monitoring[16]

In the late 1970s and early 1980s a new form of active surveillance was developed in New Zealand (the Intensive Medicines Monitoring Programmed) and the UK (Prescription Event Monitoring). These intensive monitoring systems use prescription data to identify users of a certain drug. The prescriber of the drug is asked about any adverse event occurring during the use of the drug being monitored. These data are collected and analysed for new signals. The basis of intensive monitoring is a non-interventional observational cohort, which the distinguishes it from spontaneous reporting because the former only monitors selected drugs during a certain period of time.

Database studies

In order to test a hypothesis, a study has to be performed. The study can be conducted using a variety of methods, including case–control studies and cohort studies. The limitations of these methods include power considerations and study design. In order to be able to conduct retrospective cohort and case–control studies, data which have been collected in a reliable & routine fashion needs to be available. The General Practice Research Database (GPRD) and the PHARMO Record Linkage System, which will be described in further detail in the following sections, were chosen here because they represent two different types of European databases.[16]

Clinical Trial[3]

A clinical trial could be an analysis study that tests a replacement medical treatment or a replacement Manner of mistreatment Associate in Nursing existing treatment to ascertain if it'll be higher thanks to stop and screen for Before pharmaceutical firms begin clinical test on a drug they conduct in depth pre-clinical studies.

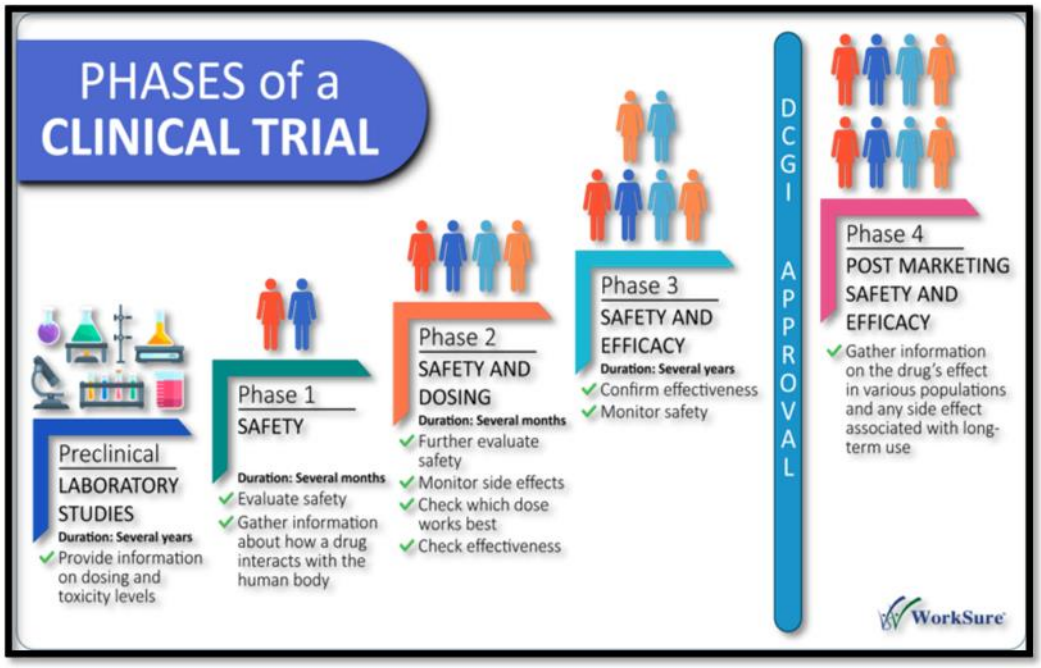

Figure 7: Phase of Clinical Trial.

Pre-clinical studies

Pre-clinical studies involve in vitro (i.e., test tube or laboratory) studies and trials on animal populations. Wide-ranging dosages of the study drug are given to the animal subjects or to an in-vitro substrate in order to obtain preliminary efficacy, toxicity and pharmacokinetic information and to assist pharmaceutical companies in deciding whether it is worthwhile to go ahead with further testing.

Clinical Studies

Phase-0

Phase zero may be a recent designation for exploratory, first-in-human trial conducted in accordance with U.S. food and Drug administration (FDA) 2006 steerage on exploratory. Distinctive options of part zero trials embrace the administration of single sub-therapeutics doses of the study drug to a little range of subjects (10-15) to collect preliminary information on the agent's pharmacological medicine (how to body processes the

drug) and Pharmacodynamics (how the drug add the body).

Phase-I

Phase I path area unit 1st stage of testing in human subject. Ordinarily a little (20-80) cluster of healthy volunteers are going to be elite. This part includes trails designed to assess the security (Pharmacovigilance) tolerability, pharmacological medicine and Pharmacodynamics of a drug. There are unit totally different styles of clinical trial trials. SAD: Single Ascending Dose studies area unit those within which tiny cluster of subjects' area unit given one dose
of the drug whereas they're ascertained and tested for a amount of your time. MAD: Multiple Ascending Dose studies area unit conducted to raise perceive the pharmacological medicine of multiple doses of drug.

Phase-II

Once the initial safety of the study drug has been confirmed in Phase I trials, Phase II trials are performed on larger groups (20-300) and are designed to assess how well the drug works, as well as to continue Phase I safety assessments in a larger group of volunteers and patients. When the development process for a new drug fails, this usually occurs during Phase II trials when the drug is discovered not to work as planned, or to have toxic effects. Phase II studies are sometimes divided into Phase IIA and Phase IIB. Phase IIA is specifically designed to assess dosing requirements (how much drug should be given), whereas Phase IIB is specifically designed to study efficacy (how well the drug works at the prescribed dose. Some trials combine Phase I and Phase II, and test both efficacy and toxicity.

Phase-III

Phase III studies are randomized controlled multi center trials on large patient groups (300– 3,000 or more depending upon the disease/medical condition studied) and are aimed at being the definitive assessment of how effective the drug is, in comparison with current 'gold standard' treatment. Because of their size and comparatively long duration.

Phase III trials are the most expensive, time-consuming and difficult trials to design and run, especially in therapies for chronic medical. Conditions. It is common practice that certain Phase III trials will continue while the regulatory submission is pending at the appropriate regulatory agency. While not required in all cases, it is typically expected that there be at least two successful Phase III trials, demonstrating a drug's safety and efficacy, in order to obtain approval from the appropriate regulatory agencies (FDA (USA), TGA (Australia), EMEA (European Union), etc.

Phase-IV

Phase IV trial is additionally called Post promoting police work Trial. Phase IV trials involves the security police work (Pharmacovigilance) and current technical support of a drug once it receives permission to sold.

Trial Table 2: Phase & Group.

Phase	Group
0	10-15
1	22-80
1A	Single Ascending Dose (SAD)
1B	Multiple Ascending Dose (MAD)
2	20-300
3	300-3000
4	Post Marketing Surveillance Trial

Future Prospects of PV

As the future prospects a robust, Pharmacovigilance system capable to detect new ADRs an, taking regulatory actions needed to protect public health. Little emphasis has been put into generating information that can assist a healthcare professional or a patient in the decision making process.

At present, the DCGI should act quickly to improve Pharmacovigilance so as to integrate Good Pharmacovigilance Practice (GPP) into the processes and procedures to help ensure regulatory compliance and enhance clinical trial safety and post marketing surveillance. An appropriately working Pharmacovigilance system is essential if medicines are to be used carefully. It will be benefit for healthcare professionals, regulatory authorities, pharmaceutical companies and the consumers. It helps pharmaceutical companies to monitor their medicines for risk.

Post-marketing Pharmacovigilance is currently a challenging and laborious process, not only industry-wide, but also for regulatory agencies.[17]

Future perspectives for, the problems & challenges facing the development of a robust PV system of India, the following proposals might be as follows:

- Build & maintain a vigorous PV system.
- Making PV reporting mandatory and introducing PV inspections.
- High-level discussions with various stakeholders.
- Creating a single country-specific ADRs reporting form to be used by all.
- Strengthen the Drug Controller General of India (DCGI) office with trained scientific and medical assessors for PV.
- Creating a clinical trial and post-marketing database for SAEs / SUSARs & ADRs for signal detection and access to all relevant data from various stakeholders.[18]

CONCLUSION

The Pharmacovigilance in India continues to grow, evolve, and improve. India is the largest producer of pharmaceuticals and now emerging as an important clinical trial hub in the world. The knowledge of drugs

Adverse Drug Reaction (ADRs) can be augmented by various means such database studies, intensive monitoring, and spontaneous reporting. Despite of recent implementation of a well-structured Pharmacovigilance program in India in accordance with the objectives and recommendations of WHO by CDSCO, desired success is still a distant dream. The health-care professionals, patients, and pharmaceutical companies should report ADRs by own selves and actively participate in the Pharmacovigilance system of the country. The health-care professionals, patients, and pharmaceutical companies should report ADRs by own selves and actively participate in the Pharmacovigilance system of the country.

A clinical trial for any new drug follows under the guidelines of ICH and GCP, clinical trial are conducted in human volunteers for confirmation of useful properties of new drug. After preclinical development, investigational new drug passes through clinical phases I, II, III and IV. These phases provide in detail explanation of pharmacokinetic, pharmacodynamic profile and side effect which may be harmful or beneficial, adverse effect and post marketing surveillance.

ACKNOWLEDGEMENT

I thank the principal of Maharashtra Institute of Pharmacy (B. Pharm), Chandrapur for their expertise and assistance throughout all aspects of study and for their help in writing the manuscript.

There is no outsource funding from any institution, NGOs, personnel.

REFERENCES

1. Gupta KB, Kumar V, Vishvkarma S, Shandily R. Isoniazid-induced alopecia. Lung India, 2011; 28: 60– 61.
2. Mann RD, Andrews EB Pharmacovigilance, John Wiley and Sons Ltd, Chichester, 2002.
3. Shuka SS, Gidwani B, Pandey R, Rao SP, Singh V, Vyas A, Importance pharmacovigilance in Indian Pharmaceutical Industry, Asian Journal of Research in Pharmaceutical Science, 2012; (2): 04-08.
4. WHO, Pharmacovigilance, ensuring the safe use of medicines, Geneva WHO, 2004.
5. www.researchgate.net/publication/345332852_Introduction_and_evaluation_of_pharmacovigilance_for_beginners.
6. Vivek S. Dave, St. John Fisher College, Wegmans School of Pharmacy, Rochester, NY 14618, USA, Tel: 585-385-5297.
7. comedjournal.com/articles/224/5-1-13-432
8. International Journal of Research Publication and Reviews, August 2022; 3(8): 476-480.
9. Int. J. Pharm. Sci. Rev. Res., May – Jun 2014; 26(2): 41
10. Misra A.K et.al Mintage journal of Pharmaceutical & Medical Sciences, 35-36
11. Sumit et al Journal of Drug Delivery & Therapeutics, 2013; 3(4): 237.
12. www.adweek.com/socialtimes/files/2012/12/social-media-healthcare.png?red=at
13. lifesciencescare.hcltech.com/wp-content/uploads/2018/12/181227_C3i-SolutionseBook_Trends-Shaping-the-Future-of-Pharmacovigilance.pdf.
14. Inácio, P., Cavaco, A., & Airaksinen, M. Current trends in Pharmacovigilance:
15. Value and gaps of patient reporting. International journal of clinical pharmacy, 2018; 40(4): 754-757.
16. https://www.researchgate.net/publication/344511909_PHARMACOVIGILANCE_AND_TECHNIQUES_FOCUS_2020
17. https://www.researchgate.net/publication/51400086_Pharmacovigilance_Methods_recent_developments_and_future_perspectives
18. https://www.thepharmajournal.com/archives/2019/vol8issue8/PartB/8-5-145-623.pdf
19. https://symbiosisonlinepublishing.com/pharmacovigilance/pharmacovigilance24.php