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Review Article

A Review On Pharmacovigilance And Its Important

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ABSTRACT

Event Monitoring Pharmacovigilance Is Know As The Activities Of Involved In The Detection Of Assessment, Understanding, And Protection Of Adverse Effects Or Any Other Drug Linked Problems….' All Drugs Have The Capacity To Cause Adverse Effects And No Drug Is Completely Safe. The Drug Safety Monitoring Is Now The Mandate Area Of Interest For Controlling Authority; Ethics Committee And Pharmaceutical/Bio-Pharmaceutical Companies. Every Drug Is Associated With Beneficial As Well As Objectionable Or Adverse Effect WHO Finally The Conclusion Describes The Major Challenges And Accomplishments For The Future Pharmacovigilance Programme. Pharmacovigilance Is Not New To India And Has Infact Been Going On From 19982. When India Decided To Join The Uppasla Centre For Adverse

INTRODUCTION

Pharmacovigilance supports safe as well as appropriate utilise the drugs by a) encouraging the detection of previously unknown ADRs and communications and increases in frequency of known ADRs, b) finding risk factors for the development of ADRs and c) estimating quantitative aspects of benefit/risk analysis and disseminating information to improve drug prescribing and regulation 1 Pharmacovigilance involves additional spontaneous reporting, as well as is more than just calculating marketed medications. It has grown from a minor component of drug control to a major activity and prolonged its scope to encompass the assistance for patient safety during clinical trials by ensuring adequate informed consent and institutional review boards (ethical committees); development of a safety profile for proper use of a new molecular entity and appropriate communication of that information to a range of relevant stakeholders; selection of the first safe dose for use in humans based on pharmacologic data found in animal studies; development of a safety profile.

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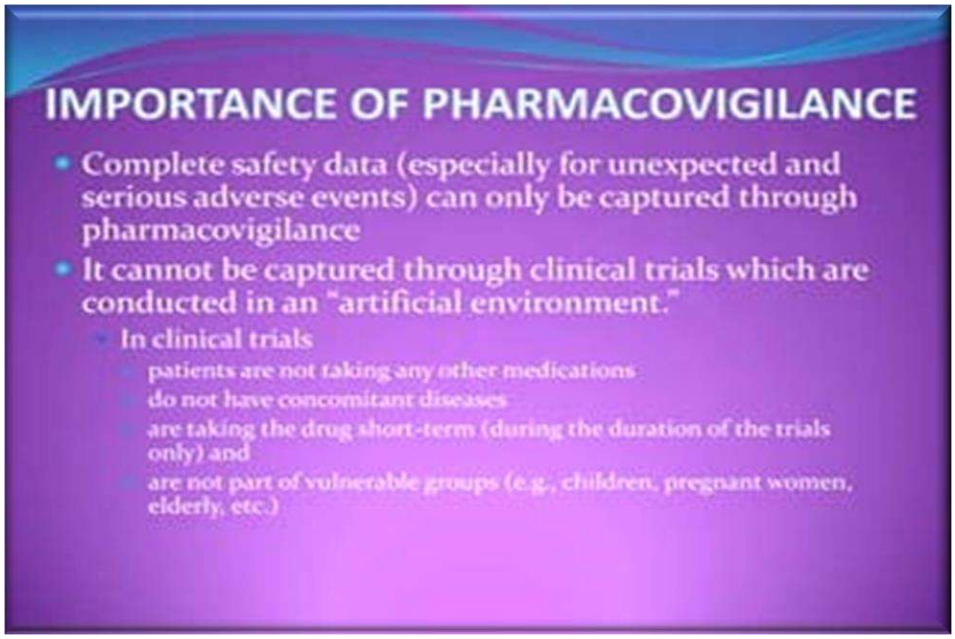
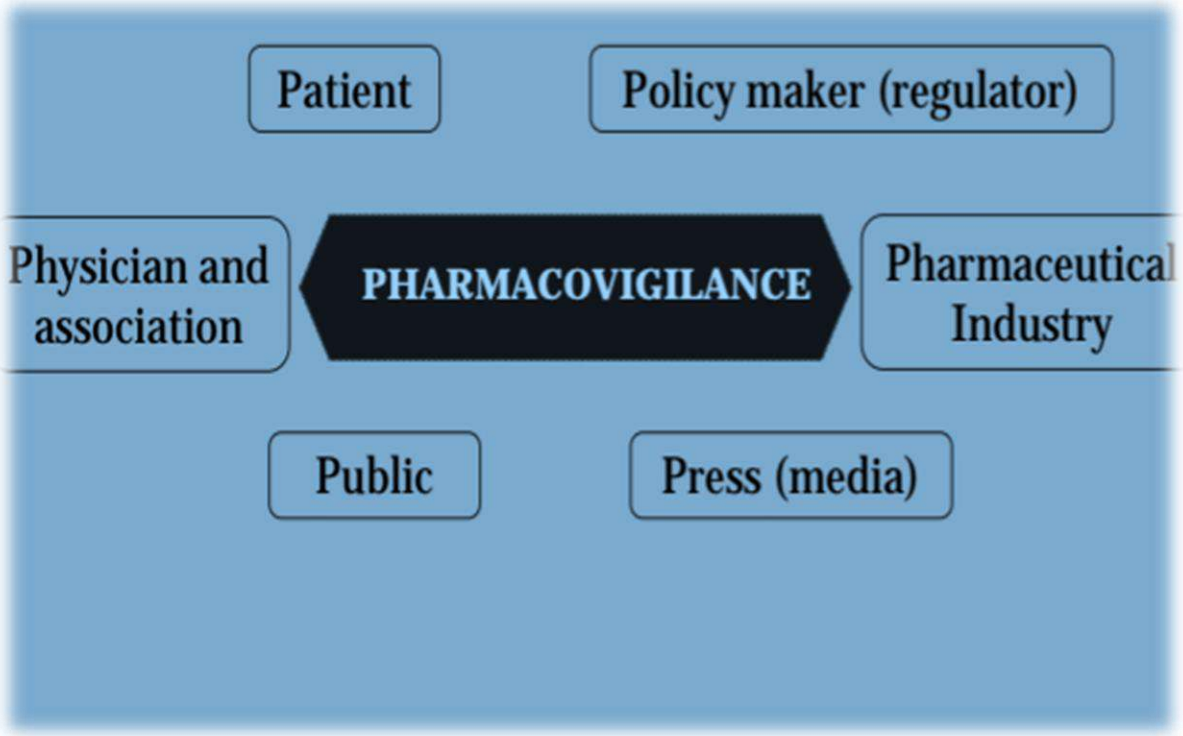
This study implicates the growth of pharmacovigilance in assessing the safety of drugs2.

Importance of pharmacovigilance:-

It is the science which deals through the complex process of the empathetic and explaining the nature of ADR befallen in a patient taking either oral or parenteral or intravenous (I.V) drugs for an sickness. The drugs being marketed worldwide underwent a whole selection of tests and also underwent clinical trials in animals and human subjects to assess the safety of the drug for a specific disease and to know the exact side effects linked with it. Still there is a major part of it goes undetected and some of the ADR are detected in post marketing investigation. It is estimated that there is significant amount of ADRs which decreases the quality of life, increase hospitalization stay and increases the humanity. A landmark study by Lazarou in 1998 described, ADRs to be the fourth to sixth leading cause of death in the US and ADRs are estimated to cause 3-7% of all hospital admissions 3



Pharmacovigilance partnership
1. Detection And Increases in Frequency
2. Early Defecation Of Unknown Safety Problems
3. Preventing Patients From Being Affected Unnecessarily [4]



Purpose the study of pharmacovigilance :-

The aim of the study is to determine the handiness of pharmacovigilance systems employed in the regulation as well as monitoring of off-label use of medicines in the dissimilar parts of the world. The recognized activities are also ascertained for whether they are implemented, in the pipeline, or just recommendations. In the process, the study also aspires to highlight the importance of PV or post- marketing observation in off-label drug use and to emphasize the growing importance and dynamism of PV.5

Roll of pharmacovigilance in new drug discovery:-

A. Preclinical trails

His includes in vitro as well as in silicon testing of the compounds to identify the best members of an series to take into the Clinical Trials. This is also where the first stages of safety assessment are undertaken way of toxicity testing in the animals. If a drug show promise in preclinical trials, a pharmaceutical company can request permission from the FDA [food and drug administration] to begin testing in the humans (known as First-in-Man or FIM trials). This is known as an Investigational New Drug (IND) application. In Europe, the European Medicines Agency (EMA) equivalent is an Investigational Medicinal Product Dossier (IMPD7

Clinical trails

PHASE

Clinical trials involving new drugs are commonly classified into five phases. Each phase of the drug approval process is treated as a separate clinical trial. The drug development process will normally proceed through phase's I–IV over many years, frequently involving a decade or longer. If the drug successfully passes through phases I, II, and III, it will usually be approved by the national regulatory authority for use in the general population Phase IV trials are performed after the newly approved drug, diagnostic or device is marketed, providing assessment about risks, benefits, or best uses.8

Pre- clinical trails

In pre-clinical trials we can selected 1000 of newly chemical compound and this compound is sending to the pre-clinical trials authority and this authority selection to important and effective ingredient of

above 1000 ingredient Now final ingredient trial with experimental animal to check the drug softy purity bioavablity and toxicology after successful trial on animals the drug approval for the clinical trail this trail conducted with the phase 0 to phase 4 9

Phase 0

Phase 0 studies use only a rare small doses of a new drug in a few people. They might test whether the drug reaches the tumour, how will drug acts as in the human body, and how cancer cells in the human body answer to the drug. People in these studies might need extra tests such as biopsies, scans, and blood samples as part of the process.

Phase 2

Phase I studies of a new drug stand usually the first that encompass people. Phase I studies are done to find the highest dose of the new treatment that can be given safely without causing plain side effects. Although the treatment has been tested in lab and animal studies, the side effects in people can't be known for sure. These studies also help to ape [resolve on the best way to give the new treatment.

Phase 3

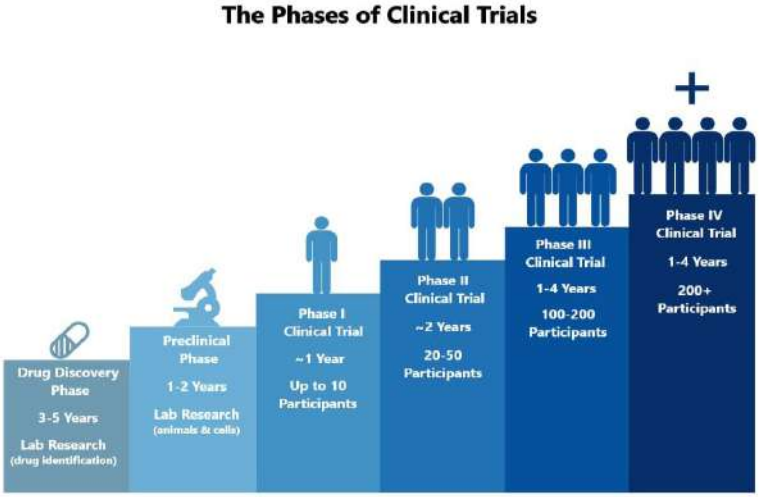
If a new treatment is found to be safe in phase I clinical trials, a phase II clinical trial is done to see if it works in certain types of cancer. The benefit the doctors look for depends on the goal of the treatment. It may mean the cancer shrinks or disappears. Or it might mean there's a long period of time where the cancer doesn't get any bigger, or there's a longer time before the cancer comes back. In some studies, the benefit may be an improved quality of life. Many clinical trials look to see if people getting the new treatment live longer than most people do without the treatment.

Submit ion of new drug FDA

In the United States, when phase III clinical trials (or sometimes phase II trials) show a new drug is more effective or safer than the current treatment, a new drug application (NDA) is submitted to the Food and Drug Administration (FDA) for approval. The FDA reviews the results from the clinical trials and other relevant information.

Phase 4

Drugs approved by the FDA are often watched over a long period of time in phase IV studies. Even after testing a new medicine on thousands of people, all the effects of the treatment may not be known. Some questions may still need to be answered. For example, a drug may get FDA approval because it was shown to reduce the risk of cancer coming back after treatment. But does this mean that those who get it are more likely to live longer? Are there rare side effects that haven't been seen yet, or side effects that only show up after a person has taken the drug for a long time? These types of questions may take many more years to answer, and are often addressed in phase IV clinical trials.10



Adverse Event Reporting

All pharmacologically effective drugs have benefits and risks. The risk may be insignificant or may be acceptable in relation to the drug's therapeutic action. Continuous monitoring of the safety of a drug throughout the duration of its use helps to ensure that its risks and benefits remain acceptable. AstraZeneca is committed to protecting the safety of patients who receive our products.uspected Adverse Events to11

CONCLUSION

The ultimate goal of pharmacovigilance is to accurately characterize and optimize the benefit/risk ratio of a health product throughout its life cycle 12

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