6. PHARMACOVIGILANCE :- SAFETY MONITORING IN CLINICAL TRIALS:

Pharmacovigilance is majorly known as drug safety.
It is a main integral part of clinical research. Throughout the product life cycle clinical trials safety and post marketing pharmacovigilance plays a critical role. The word pharmacovigilance is derived from two words one *Parmakon* is a Greek word which means "drug" and another *vigilare* is a Latin word which means to keep awake or to keep watch. According to WHO Pharmacovigilance (PV) is the pharmacological science relating to the detection, evaluation, understanding and prevention of adverse effects, especially long term and short-term side effects of medicine.

Aims of Pharmacovigilance:

- To improve patient care and safety.
- To contribute to assessment of benefit, harm and effectiveness of medicine.
- To identify previously unrecognized adverse effects of the drugs.
- To promote rational and safe use of medicine.
- To promote education and clinical training.
- To identify patient related risk factors of ADR such as; dose, age, gender.
- Any response to a drug which is unintended, occurs at particular doses.
- To diagnose or therapy of disease, or for the modification, of physiological function.

Pharmacovigilance helps in removal of approved and licensed products from the market because of clinical toxicity, which is caused by adverse drug reactions in the body.

Adverse Drug Reactions: ADR is a response to drug, which alters the normal physiological function of the body, factors which causes ADR includes mainly multiple drug therapy, age and gender. High index of ADRs are to be successfully diagnosed by clinicians, it is the high level of awareness about the drugs being used. Pharmacovigilance, unify all the information in all aspects of benefit risk ratio of drugs in a population.

Events that occur when a particular drug is administered are recorded in the patient's notes by drug monitoring then an adverse reaction of the drug and the activity of the drug being monitored; these studies aim to detect ADR of drugs, Reporting of ADRs after marketing must be actively encouraged and should involve all those concerned including doctors, pharmacists, nurses, patients and pharmaceutical companies.

In the process of development of a new pharmaceutical drug, there are many stages they are preclinical trials, then clinical trials this includes four phases. In this, the first three phases helps In the determination of safety efficacy and side effects of the developed drug product.

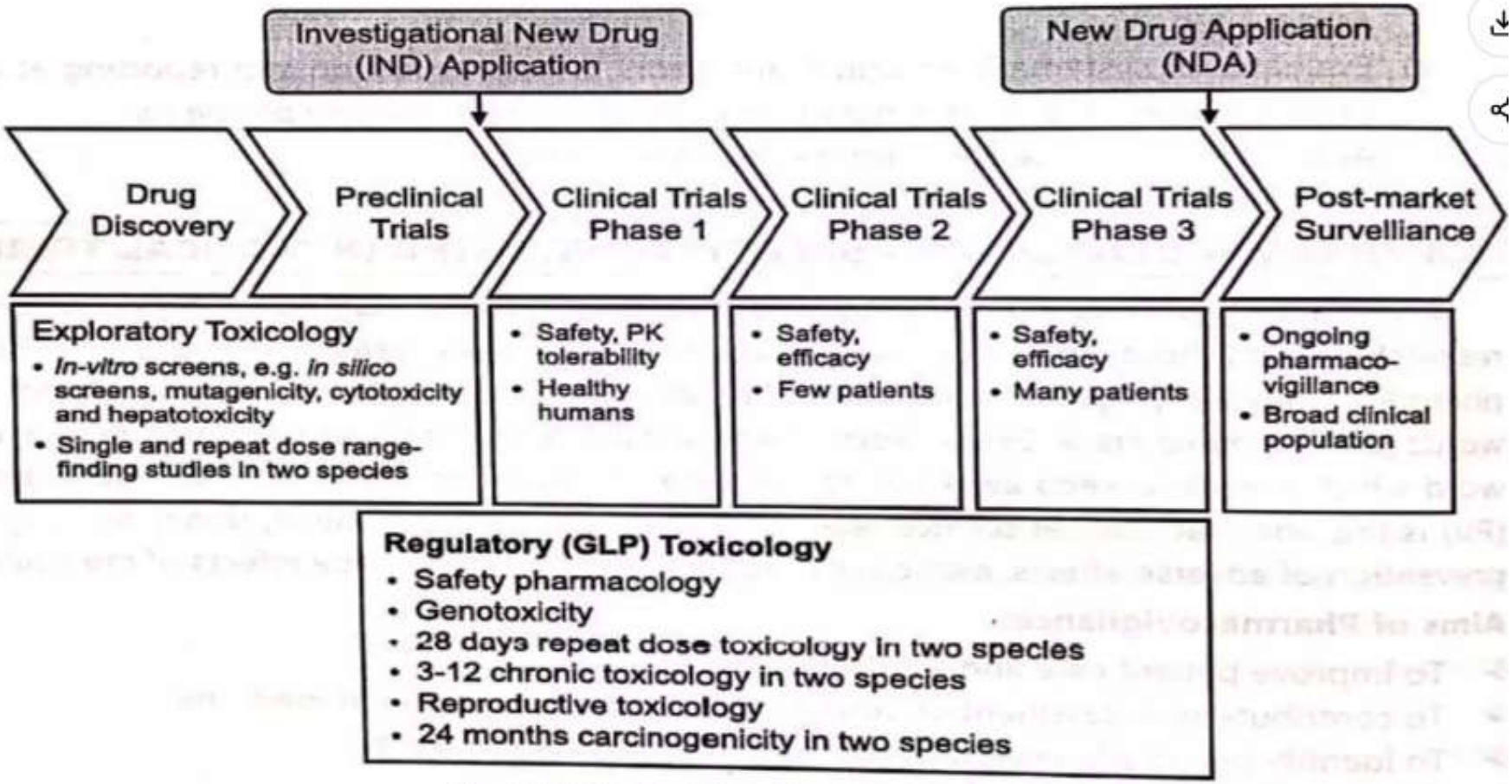

Fig. 4.4: Drug Development Process

Whereas in case of fourth phase, post marketing studies are carried out for determining; safety in patients. Thus, post marketing surveillance helps in uplifting the knowledge of pharmacovigilance.

Post Marketing Surveillance:

Pharmaceutical drug or medical device is monitored often after It has been released into the market, since drugs are approved based of clinical trials which involve relatively small number of people who do not have any other medical complications, post marketing surveillance play an important role to know the ADRs of drugs after they have released into the market.

Approaches By:

Spontaneous ADR Reporting: Doctors, health care professionals, they are provided with forms where, they can notify the suspected ADRS they detect, it helps in spontaneous reporting for all the drugs, to Pharmacovigilance department.

Prescription Event Monitoring: It involves health professionals submitting all the clinical events reported by the patient to the prescribed new drug.

Electronic Health Records: It is a computer Stored collection of health information, about one person linked by a person identifier; it represents the basis for healthcare Information system development .

Patient Registers: To bring together patient records, it is time consuming and less expensive.

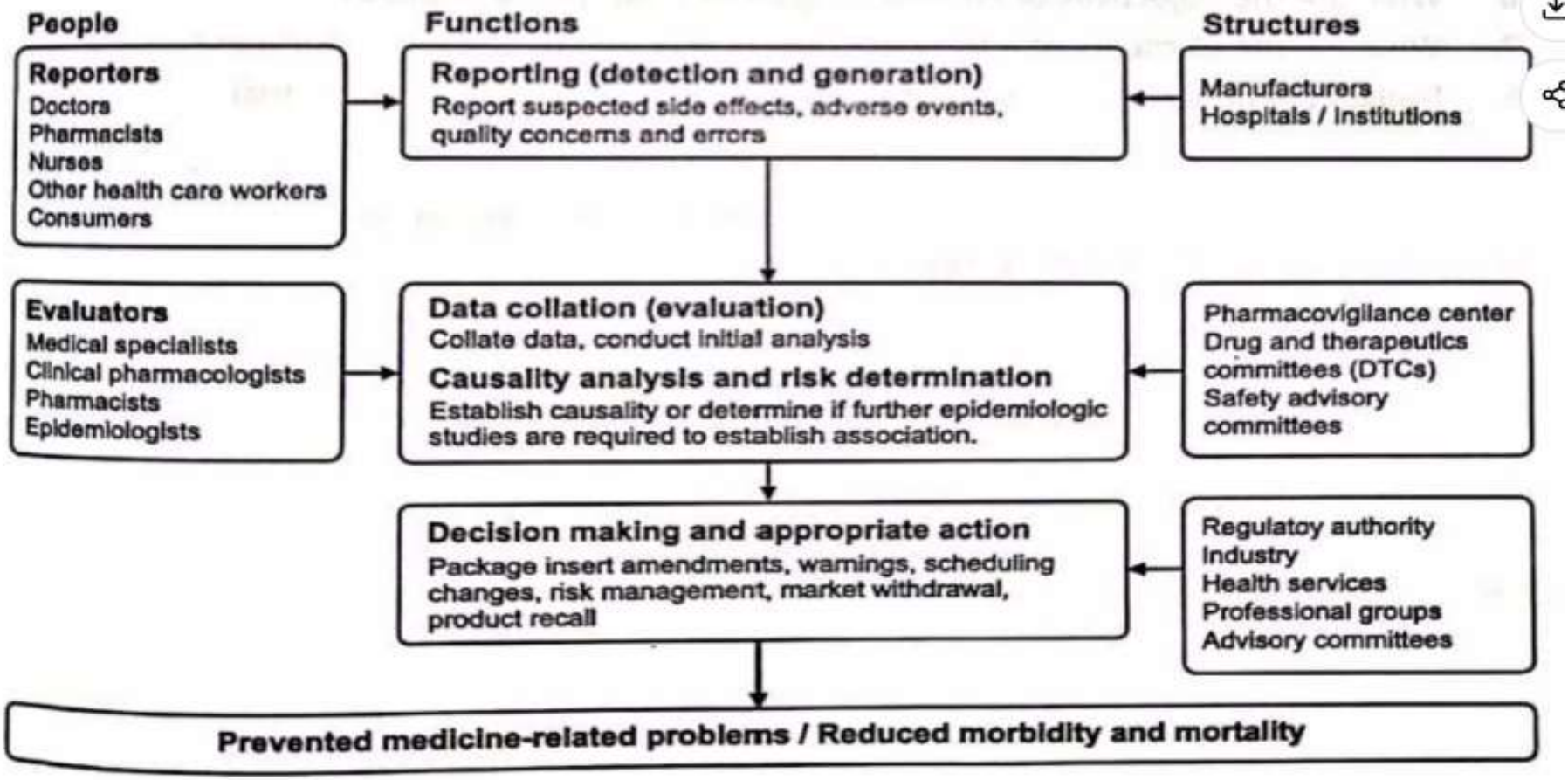

Fig. 4.5: ADRs Reporting Process

It officially starts on 23rd November 2004 at New Delhi, is under the control of CDSCO (Central Drug Standard Control Organization), Directorate general of health services, Indian Pharmacopeia commission (Ghaziabad). The program is conducting by NCC (National Coordinating Centre) to ensure that the benefits of use of medicine against the risks.

Objectives:

- To monitor ADRs.
- To create awareness among health care professionals about ADRs.
- To monitor benefit-risk profile of medicines.
- Support the CDSCO.

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