

UNIT-I

BASIC TERMINOLOGIES USED IN PHARMACOVIGILANCE



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- BASIC TERMINOLOGIES USED IN PHARMACOVIGILANCE
 - Terminologies of adverse medication related events
 - Regulatory terminologies

Eudravigilance medicinal product dictionary

- **EudraVigilance:** European Union Drug Regulating Authority Pharmacovigilance
- **ATC:** Anatomical Therapeutic Chemical
- **CIOMS:** Council for International Organisations of Medical Sciences
- **EEA:** European Economic Area
- **EMA:** European Medicines Agency
- **ESTRI:** Electronic Standards for the Transfer of Regulatory Information
- **EVDAS:** Eudravigilance Data Analysis System
- **EVCTM:** Eudravigilance Eudravigilance Clinical Trial Module
- **EVPM:** Eudravigilance Post-Authorisation Modole
- **ICH:** International Conference of Harmonisation

Glossary of important terms used in Pharmacovigilance

- **Adverse Event/ Adverse Experience:** Any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this treatment.
- **Adverse Drug Reaction:** A response to a drug which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function.
- An adverse drug reaction, contrary to an adverse reaction, is characterized by the suspicion of a causal relationship between the medicine and the occurrence, i.e. judged as being at least possibly related to treatment by the reporting or a reviewing health professional.

- **Serious Adverse Event or Reaction:** A serious adverse event or reaction is any untoward medical occurrence that at any dose results in:
 - Death
 - Is life-threatening
 - Requires inpatient hospitalization or prolongation of existing hospitalization
 - Persistent or significant disability/incapacity
 - Congenital Anomaly
 - Medically important event or reaction
- To ensure no confusion or misunderstanding of the difference between the terms **‘serious’ and ‘severe’, the following note of clarification is provided:**
- The term “severe” is not synonymous with serious. In the English language, „severe“ is used to describe the intensity (severity) of a specific reaction (as in mild, moderate or severe); the reaction itself, however, may be of relatively minor medical significance (such as severe headache). Seriousness (not severity) which is based on patient/reaction outcome or action criteria serves as guide for defining regulatory reporting obligations.

- **Case Control Study:** Study that identifies a group of persons with the unintended medicine effect of interest and a suitable comparison group of people without the unintended effect. The relationship of a medicine to the medicine reaction is examined by comparing the groups exhibiting and not exhibiting the medicine reaction with regard to how frequently the medicine is present.
- **Cohort Study:** A study that identifies defined populations and follows them forward in time, examining their rates of disease. A cohort study generally identifies and compares exposed patients to unexposed patients or to patients who receive a different exposure.
- **Causality assessment:** The evaluation of the likelihood that a medicine was the causative agent of an observed adverse reaction. Causality assessment is usually made according established algorithms.

- **Clinical Trial:** A systematic study on pharmaceutical products in human subjects (including patients and other volunteers) in order to discover or verify the effects of and/or identify any adverse reaction to investigational products, and/or to study the absorption, distribution, metabolism and excretion of the products with the objective of ascertaining their efficacy and safety.
- Clinical trials are generally classified into Phases: I to IV. Phase IV trials are studies performed after marketing of the pharmaceutical product. They are carried out on the basis of the product characteristics for which the marketing authorization was granted and are normally in the form of post-marketing surveillance.

- **Drug/ Medicine:** Any substance in a pharmaceutical product that is used to modify or explore physiological systems or pathological states for the benefit of the recipient. The term drug/medicinal product is used in a wider sense to include the whole formulated and registered product, including the presentation and packaging, and the accompanying information.
- **Drug Alerts:** The action of notifying a wider audience than the initial information holder(s) of a suspected association between a drug and an adverse reaction. Note that the term is used in different contexts that can be confusing, for example, an alert may be from a manufacturer to a regulator or from a regulator to the public.
- **Dechallenge:** The withdrawal of a medicine from a patient; the point at which the continuity, reduction or disappearance of adverse effects may be observed.
- **Rechallenge:** The point at which a medicine is again given to a patient after its previous withdrawal.

- **Individual Case Safety Report (ICSR):** A document providing the most complete information related to an individual case at a certain point of time. An individual case is the information provided by a primary source to describe suspected adverse reaction(s) related to the administration of one or more medicinal products to an individual patient at a particular point of time.
- **Lack of Efficacy:** Unexpected failure of a medicine to produce the intended effect as determined by previous scientific investigation.
- **National Pharmacovigilance Centre:** A single, governmentally recognized centre (or integrated system) within a country with the clinical and scientific expertise to collect, collate, analyze and give advise on all information related to medicine safety.

- **Pharmacoepidemiology:** The study of the use and effects of medicines in large numbers of people.
- **Prescription Event Monitoring:** A system created to monitor adverse drug events in a population. Prescribers are requested to report all events, regardless of whether they are suspected adverse events, for identified patients receiving a specified medicine.
- **Record Linkage:** Method of assembling information contained in two or more records, e.g., in different sets of medical charts, and in vital records such as birth and death certificates. This makes it possible to relate significant health events that are remote from one another in time and place.

- **Side Effect:** Any unintended effect of a pharmaceutical product occurring at doses normally used in humans, which is related to the pharmacological properties of the medicine.
- **Signal:** Reported information on a possible causal relationship between an adverse reaction and a drug, the relationship being unknown or incompletely documented previously. Usually more than a single report is required to generate a signal, depending upon the seriousness of the reaction and the quality of the reaction and the quality of the information.

- **Spontaneous Reporting:** A system whereby case reports of adverse drug reactions are voluntarily submitted from health professionals and pharmaceutical manufacturers to the national regulatory authority.
- **Unexpected Adverse Reaction:** An adverse reaction, the nature or severity of which is not consistent with domestic labeling or market authorization, or expected from characteristics of the medicine.