FIFARMA

Pharmacovigilance Glossary

A

Adverse Event (AE): Any adverse medical event in a patient or clinical research subject administered a pharmaceutical product that does not necessarily have to have a causal relationship with this treatment.

Adverse drug reactions (ADRs): Pre-approval clinical experience with a new drug or use, noxious and unintended responses to a drug at any dose.

Adverse event in marketed products: A response to a drug that is noxious and unintended and that occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease or for the modification of physiological function.

Alert or signal: Information reported on a possible causal relationship between an adverse event and a drug, when this relationship was previously unknown or incompletely documented.

B

Backward compatibility: It is the ability to map ICG E2B(R3) to the previous version E2B(R2), ensuring that data integrity is maintained and that constraints are described and supported by the E2B community.

Benefit-risk ratio: It reflects the relationship between the benefit and the risk presented by the use of a drug. It serves to express a judgment on the role of the drug in medical practice based on data on its efficacy and safety.

C

Case Studies and Controls: Epidemiological studies of observational type, since no intervention is performed but the occurrence of events is "observed", and analytical since they allow the formulation of a hypothesis in relation to the evaluation of the association between two or more variables, having also a contrast group called in this case "Control". The presence of an event is given by identifying persons or patients with the presence of the event and comparing them with a group of similar characteristics, but without the presence of the event.

Causality: The result of the analysis of the imputability and the individual assessment of the relationship between the administration of a drug and the occurrence of an adverse reaction, makes it possible to determine a causality category.

Cohort studies: Cohort studies (CE) are longitudinal, observational and analytical studies, in which the cohort(s) refers to a group of people, and the cohort(s) is (are) a group of people who share a previously defined characteristic; and who are followed over time. They provide information regarding pathogenesis, particularly, they facilitate the understanding of how multiple factors acting over time may determine the etiology, natural history and clinical course of a disease or event of interest (EI); allowing to study the dynamic nature of various risk factors (RF) over time, for the occurrence of a disease or EI, for descriptive purposes, or for the purpose of testing hypotheses related to the disease or EI.

Combined Therapies: The use of two or more therapies and especially medications to treat a disease or condition.

Compatibility: Different systems that can work together or exchange data are supported, in terms of ICH E2B, it refers to different pharmacovigilance (PV) systems (protocols, languages) that interact to support the electronic exchange of pharmacovigilance data based on ICH E2B(R2) and E2B(R3) and applicable message specifications.

Compatibility with later versions: It is the ability to map data from the E2B(R2) guideline of February 2001 to the new version, i.e. E2B(R3), maintaining the integrity of the data that the E2B community describes and fully supports with the limitations (loss of data during conversion).

Consumer: A consumer is defined as a person who is not a health care professional, such as a patient, an attorney, a friend or family member of a patient.

Cross-sectional study: Data collected in a patient population at a single point in time (time interval) independent of exposure or disease status.

D

Drug Utilization Studies (DUS): They describe how a drug is marketed, prescribed and used in a population and how these factors influence clinical, social and economic outcomes.

Drug holder, registrant or applicant: Natural or legal person who is the owner of the pharmaceutical product and in whose name the sanitary registration is issued.

G

Good pharmacovigilance practices: A set of standards or recommendations designed to guarantee the authenticity and quality of the data collected for the evaluation of the risks associated with medicinal products at any given time; the confidentiality of information on the identity of the persons who have presented or reported adverse reactions; and the use of uniform criteria in the evaluation of reports and in the generation of warning signals.

Harmonization: Consensus-building process on requirements and procedures for the registration of pharmaceutical products and other regulatory matters involving regulatory authorities and the pharmaceutical industry.

Health professional: Health care professional is defined as a medically qualified person, such as a physician, dentist, pharmacist, nurse, coroner or as specified by local regulations.

Known adverse reactions: These are reactions described in the scientific literature.

Medication: Chemical entities, biotechnology-derived products and vaccines.

Multicenter studies: Controlled clinical study performed in different hospitals under a single management and a unified protocol, with the objective of determining the effectiveness or not of what is being tested.

O

Orphan drugs: Drugs that would not be developed by the pharmaceutical industry for economic reasons but respond to public health needs.

Other significant adverse effects: These are marked hematological and laboratory abnormalities and any adverse events that led to intervention, including discontinuation of drug treatment, dose reduction or significant additional concomitant therapy.

Owners of the terminology list: Organizations that are able to obtain, create and have significant control over the content, access and distribution of Terminology Lists.

P

Partial suspension: It includes several actions (discontinuation of repeated dose studies, continuation of single dose study, discontinuation of trials in the indication, continuation in another and /the discontinuation of a particular dosing regimen in a trial, but the continuation of another dose).

Patent Holder: Natural or juridical person in whose favor an invention patent was granted in Costa Rica, in accordance with the regulations in force on the matter.

Patient Safety: A set of structural elements, processes, instruments and methodologies to minimize the risk of suffering an adverse event in the health care process and/or to mitigate its consequences.

Periodic safety report: It is a summary of the updated global information on the safety of a pharmaceutical specialty, made by the holder of the registration or manufacturer.

Pharmacovigilance (FV): Science and activities related to the detection, evaluation, understanding and prevention of adverse effects or any other drug-related problems." This definition encompasses the use of pharmacoepidemiological studies.

Pharmacovigilance database: A computerized system that allows the recording of reports of suspected adverse reactions, once evaluated and coded, and the generation of alerts or signals.

Potential medication errors: Recognition of circumstances that may lead to a medication error and may or may not involve a patient.

Potentially Lethal: Event in which the patient is at risk of death at the time of the event.

Regulatory Authority: A Regulatory Authority, or drug regulatory body, establishes and maintains the rules, laws and policies necessary to ensure that drugs (including pharmaceuticals, vaccines and other biological products) are safe, effective and meet the quality specifications offered. Its functions include registration and authorization for commercialization, licensing, market surveillance and control, pharmacovigilance, clinical trial control, inspection of manufacturing practices, laboratory testing, batch release, surveillance and monitoring of product safety in the market.

Response to a drug: Causal relationship between a drug and an adverse event.

S

Security incident: An event or circumstance that has caused or could have caused unnecessary harm to a patient.

Sentinel Sites: These are population groups selected for their degree of representativeness of an area. The population to be included is a stratified sample of communities and is surveyed periodically to obtain information.

Serious Adverse Event: Experience or reaction, any adverse medical event that, at any dose results in: death, is life threatening, requires hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, congenital anomaly/ birth defect.

Signatory: Person who signs or who has that right (signatory of a document).

Spontaneous notification: Adverse drug reaction information obtained through voluntary reporting by health professionals, hospitals and centers.

Sponsor: The individual, company, institution, or organization responsible for initiating, administering, controlling, or financing a clinical trial. This function may be performed by a corporation or agency external to the institution or by the investigator or the hospital institution.

Spontaneous notification system: A method of pharmacovigilance based on the reporting, collection and evaluation of reports of suspected adverse reactions by a health professional; includes the harmful clinical consequences of drug dependence, abuse and misuse.

Standard operating procedures: Detailed written instructions to achieve uniformity in the performance of a specific activity. They are the basis for internal and external audits.

Technovigilance: A set of methods and observations that make it possible to detect adverse incidents during the use of a medical device that may cause harm to the patient, the operator or his environment.

Terminology list manager: The person responsible for managing the Terminology List in an organization in terms of integrated and consistent definitions, structures, calculations, derivations, etc.

Terminology list governance group: A group of individuals (or a hierarchy of groups) that normally represents a cross-section of stakeholder groups. Together, they define a set of rules in the form of policies, standards, requirements, guidelines or data definitions.

Uppsala Monitoring Center (UMC): Uppsala International Drug Monitoring Center, part of the WHO.

Unexpected adverse drug reaction: It is an adverse reaction whose nature or severity is not consistent with the corresponding product information according to the labeling.

Unexpected Serious Reactions (ADR): These are those that are neither fatal nor life-threatening. An AMR whose nature, severity, specificity or outcome is not consistent with the term or description used in the local/regional product labeling (e.g., package insert or summary of product characteristics) should be considered unexpected.

Yellow card: Form where suspected adverse reactions are recorded.