Definitions

Adverse drug reaction: Any noxious and unintended response to an unapproved medicinal product, related to any dose. The phrase "response to an unapproved medicinal product" means that a causal relationship between the product and an adverse event is at least a reasonable possibility, i.e. the relationship cannot be ruled out. (Unapproved medicinal product here includes approved products used at levels or in ways that are unapproved)

Or a noxious and unintended response to a drug that occurs at doses of marketed medical products normally used in humans for prophylaxis, diagnosis or therapy of diseases or for modification of physiological function.

Adverse device event: a clinical sign, symptom or condition that is causally related to the device implantation procedure, the presence of the device, or the performance of the device system.

Adverse event (AE): Any untoward medical occurrence in a patient or clinical trial participant administered a medicinal product and that does not necessarily have a causal relationship with this treatment.

Blood relatives: Close genetic relatives.

Clinical trial: A form of research designed to find out the effects of an intervention, including a treatment or diagnostic procedure.

Confidentiality: The obligation of people not to use private information – whether private because of its content or the context of its communication – for any purpose other than that for which it was given to them.

Conflict of interest: In the research context: where a person's individual interests or responsibilities have the potential to influence the carrying out of his or her institutional role or professional obligations in research;

or

where an institution's interests or responsibilities have the potential to influence the carrying out of its research obligations.

Consent: A person's or group's agreement, based on adequate knowledge and understanding of relevant material, to participate in research.

Data: Pieces of information. Data can be raw, cleaned, transformed, summary or metadata (data about data). It can also be research outputs and outcomes.

Databank: A systematic collection of data, whether individually identifiable, re-identifiable or non-identifiable.

Ethical/unethical: Right or morally acceptable / wrong or morally unacceptable.

Ethical review: Review of research by an HREC or other body.

Ethical review body: Body set up to carry out ethical review of human research.

Ethics: The concepts of right and wrong, justice and injustice, virtue and vice, good and bad, and activities to which these concepts apply.

Genetic material: Any source of DNA or RNA that can be tested to obtain genetic information. It includes cells (whether isolated or as part of tissues) and extracted DNA and RNA.

Harm: That which adversely affects the interests or welfare of an individual or a group. Harm includes physical harm, anxiety, pain, psychological disturbance, devaluation of personal worth and social disadvantage.

HREC: Human Research Ethics Committee.

Human tissue: The substance, structure, and texture of human organs or body parts when separated from human beings; includes blood, blood components and waste products.

Identifier: Details attached to data, such as name and/or contact information, that identify an individual. (It may remain possible to identify an individual even after all identifiers have been removed, if a code number has been assigned and there is access to the code, or if the data or tissue can be cross-linked to other data or tissue banks).

Individually identifiable data: Data from which the identity of a specific individual can reasonably be ascertained.

Integrity: Honesty and probity as qualities of character and behaviour.

Justice: Regard for the human sameness shared by all human beings, expressed in a concern for fairness or equity. Includes three aspects of justice: procedural justice, involving fair methods of making decisions and settling disputes; distributive justice, involving fair distribution of the benefits and burdens of society; and corrective justice, involving correcting wrongs and harms through compensation or retribution.

Limited disclosure: Not disclosing to research participants all of the aims and/or methods of the research.

Low risk (research): Research in which the only foreseeable risk is one of discomfort.

Monitoring (of research): The process of verifying that the conduct of research conforms to the approved proposal.

Multi-centre research: A multicentre research trial is a clinical trial conducted at more than one medical centre or clinic. Most large clinical trials, particularly Phase III trials, are conducted at several clinical research centres.

Negligible risk: Research in which there is no foreseeable risk of harm or discomfort, and any foreseeable risk is of inconvenience only.

Non-identifiable data: Data that have never been labelled with individual identifiers or from which identifiers have been permanently removed, and by means of which no specific individual can be identified. A subset of non-identifiable data are those that can be linked with other data so it can be known they are about the same date subject, although the person's identity remains unknown.

Participant (in research): Anyone who is the subject of research.

Personal information: Information by which individuals can be identified.

Placebo (in research): A substance not containing an active agent under study, administered to some participants to compare the effects of the active agent administered to other participants.

Privacy: A domain within which individuals and groups are entitled to be free from the scrutiny of others.

Protocol: A document that provides the background, rationale and objectives of the research and describes its design, methodology, organisation and the conditions under which it is to be performed and managed.

Qualitative research: Research involving the studied use of empirical materials such as case studies, personal experience, life stories, interview, observations and cultural texts.

Re-identifiable data: Data from which identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual by, for example, using the code or linking different data sets.

Research: Includes at least investigation undertaken to gain knowledge and understanding or to train researchers.

Research misconduct: Includes fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting the results of research, and failure to declare or manage a serious conflict of interest. Also includes failure to follow research proposals approved by a research ethics committee, particularly where this failure may result in unreasonable risk or harm to humans, other animals or the environment. Also includes the wilful concealment or facilitation of research misconduct by others.

Respect for human beings: Recognition that each human being has value in himself or herself.

Risk: The function of the magnitude of a harm and the probability that it will occur.

Serious adverse event: Any untoward medical occurrence that:

- results in death;

- is life-threatening (NOTE: The term "life-threatening" refers to an event/reaction in which the patient was at risk of death at the time of the event/reaction; it does not refer to an event/reaction which hypothetically might have caused death if it were more severe);
- requires inpatient hospitalisation or prolongation of existing hospitalisation;
- results in persistent or significant disability/incapacity;
- is a congenital anomaly/birth defect; or
- is a medically important event or reaction.

Serious unexpected suspected adverse reaction: A serious adverse event (see definition above) for which there is some degree of probability that the event is an adverse reaction to the administered drug, and the adverse reaction is unexpected.

Single ethical review: Single ethics review is a process whereby one Human Research Ethics Committee (HREC) provides the ethics review for a research proposal that is accepted by the other institutions participating in the multi-centre research.

Sponsor: An individual, company, institution or organisation that takes responsibility for the initiation, management, and/or financing of research.

Therapeutic (intervention): Intervention directed towards the wellbeing of the individual concerned.

Unexpected adverse drug reaction: An adverse reaction, the nature or severity of which is not consistent with the applicable scientific information (e.g. Investigator's Brochure for an unapproved investigational product or Product Information (PI) document or similar for an approved, marketed product).

Voluntary participation: Participation that is free of coercion and pressure.

References

TP G1 General information on trials

TP F1.1.1 Information to consider before entering a trial

TP F1.1.2 Questions to ask