

Glossary

Adverse Drug Reaction (ADR) – In the pre-approval clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not be established: all noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions. The phrase responses to a medicinal product means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility, i.e. the relationship between a medicinal product and an adverse event is at least a reasonable possibility, i.e. the relationship cannot be ruled out.

Regarding marketed medicinal products: a response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for modification of physiological function (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

Adverse Event (AE) – Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

Applicable Regulatory Requirement(s) – Any law(s) and regulation(s) addressing the conduct of clinical trials of investigational products

Approval (in relational to Institutional Review Boards or Independent Ethics Committees) – The affirmative decision of the IRB/IEC that clinical trial has been reviewed and may be conducted at the institution site within the constraints set forth by the IRB/IEC, the institution, GCP, and the applicable regulatory requirements.

Audit – A systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analyzed and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), GCP and the applicable regulatory requirement(s).

Audit Certificate – A declaration of confirmation by the auditor that an audit has taken place

Audit Report – A written evaluation by the sponsor's auditor of the results of the audit

Audit Trail – Documentation that allows reconstruction of the course of events.

Blinding/Masking – A procedure in which one or more parties to the trial are kept unaware of the treatment assignment(s). Single-blinding usually refers to the subject(s) being unaware, and double-blinding usually refers to the subject(s), investigator(s), monitor, and in some cases, data analyst(s) being unaware of the treatment assignment(s).

Case Report Form (CRF) – A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject.

Clinical Trial/Study – Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and /or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.

Clinical Trial/Study Report – A written description of a trial/study of any therapeutic, prophylactic, or diagnostic agent conducted in human subjects, in which the clinical and statistical description, presentations, and analyses are fully integrated into a single report (see the ICH Guideline for Structure and Content of Clinical Study Reports).

Comparator (Product) – An investigational or marketed product (i.e., active control), placebo, used as a reference in a clinical trial.

Compliance (in relation to trials) – Adherence to all the trial-related requirements, GCP requirements, and the applicable regulatory requirements.

Confidentiality – Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or a subject's identity.

Consent Form - A document explaining all relevant study information to assist the study volunteer in understanding the expectations and requirements of participation in a clinical trial. This document is presented to and signed by the study subject.

Contract – A written, dated, and signed agreement between two or more involved parties that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters. The protocol may serve as the basis of a contract.

Co-ordinating Committee – A committee that a sponsor may organize to co-ordinate the conduct of a multi-centre trial

Co-ordinating Investigator – An investigator assigned the responsibility for the coordination at different centres participating in a multicentre trial.

Contract Research Organisation (CRO) – A person or an organisation (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions.

Declaration of Helsinki - A series of guidelines adopted by the 18th World Medical Assembly in Helsinki, Finland in 1964. The Declaration addresses ethical issues for physicians conducting biomedical research involving human subjects. Recommendations include the procedures required to ensure subject safety in clinical trials, including informed consent and Ethics Committee reviews.

Direct Access – Permission to examine, analyse, verify, and reproduce any records and reports that are important to evaluation of a clinical trial. Any party (e.g., domestic and foreign regulatory authorities, sponsor’s monitors and auditors) with direct access should take all reasonable precautions within the constraints of the applicable regulatory requirement(s) to maintain the confidentiality of subjects’ identities and sponsor’s proprietary information.

Documentation – All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records, and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken.

EMA - European Medicines Agency

Essential Documentation – Documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced (see Chapter 8 – Essential Documents for the Conduct of a Clinical Trial).

Ethics Committee - See **Independent Ethics Committee (IEC)**

Good Clinical Practice (GCP) – A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

HTA - Human Tissue Authority

IMCA - Independent Mental Capacity Advocate

Independent Data-Monitoring Committee (IDMC) (data and Safety Monitoring Board, Monitoring Committee, Data Monitoring Committee) – An independent data-monitoring committee that may be established by the sponsor to assess at intervals the progress of a clinical trial, the safety data, and the critical efficacy endpoints, and to recommend to the sponsor whether to continue, modify, or stop a trial.

Impartial Witness – A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the subject.

Independent Ethics Committee (IEC) – An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving / providing favourable opinion on, the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

The legal status, composition, function, operations and regulatory requirements pertaining to Independent Ethics Committees may differ among countries, but should allow the Independent Ethics Committee to act in agreement with GCP as described in the guideline.

Informed Consent – A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.

Inspection – The act by regulatory authority(ies) of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority(ies) to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's and/or contract research organisation's (CRO's) facilities, or at other establishments deemed appropriate by the regulatory authority(ies).

Institution (medical) – Any public or private entity or agency or medical or dental facility where clinical trials are conducted

Institutional Review Board (IRB) – An independent body constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

Interim Clinical Trial/Study Report – A report of intermediate results and their evaluation based on analyses performed during the course of a trial.

Investigational Product – A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorisation when used or assembled (formulated or packaged) in a way

different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

Investigator – If trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the Principal investigator.

Investigator / Institution – An expression meaning “the investigator and/or institution, where required by the applicable regulatory requirements”.

Investigator’s Brochure – A compilation of the clinical and nonclinical data on the investigational product(s) which is relevant to the study of the investigational product (s) which is relevant to the study of the investigational product(s) in human subjects (see Chapter on Investigator’s Brochure).

Legally Acceptable Representative – An individual or juridical or other body authorised under applicable law to consent, on behalf of a prospective subject, to the subject’s participation in the clinical trial.

LPA - Lasting Power of Attorney

Monitoring – The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

Monitoring Report – A written report from the monitor to the sponsor after each site visit and/or other trial-related communication according to the sponsor’s SOPs.

Multicentre Trial – A clinical trial conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator.

Nonclinical Study – Biomedical studies not performed on human subjects.

Opinion (in relation to Independent Ethics Committee) – The judgement and/or the advice provided by an Independent Ethics Committee (IEC)

Original Medical Record – See Source Documents

Protocol – A document that describes the objective(s), design, methodology, statistical considerations, and organisation of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. Throughout the ICH-GCP Guideline the term protocol refers to protocol and protocol amendments.

Protocol Amendment – A written description of a change(s) to or formal clarification of a protocol

Quality assurance (QA) – All those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded), and reported in compliance with Good Clinical Practice (GCP) and the applicable regulatory requirement(s).

Quality Control (QC) – The operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the trial-related activities have been fulfilled.

Randomisation – The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias.

Regulatory Authorities – Bodies having the power to regulate. In the ICH-GCP guideline the expression Regulatory Authorities includes the authorities that review submitted clinical data and those that conduct inspections. These bodies are sometimes referred to as competent authorities.

Research Team - Investigator, sub investigator and clinical research coordinator involved with study.

Serious Adverse Event (SAE) or Serious Drug Reaction (Serious ADR) – Any untoward medical occurrence that at any dose:

- results in death
- is life-threatening
- requires inpatient hospitalisation or prolongation of existing hospitalisation
- results in persistence or significant disability/incapacity

or

- is a congenital anomaly/birth defect

Source Data – Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklist, pharmacy dispensing records, recorded data from automated instruments,

copies or transcriptions certified after verifications as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical department involved in the clinical trial).

Sponsor – An individual, company, institution, or organisation which takes responsibility for the initiation, management, and/or financing of a clinical trial.

Sponsor-Investigator – An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a subject. The term does not include any person other than an individual (e.g., it does not include a corporation or any agency). The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator.

Standard Operating Procedures (SOPs) – Detailed, written instructions to achieve uniformity of the performance of a specific function

Subinvestigator – Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows)

Subject/Trial Subject – An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control

Subject Identification Code – A unique identifier assigned by the investigator to each trial subject to protect the subject's identity and used in lieu of the subject's name when the investigator reports adverse events and /or other trial related data.

Trial Site – The location(s) where trial-related activities are actually conducted.

Unexpected Adverse Drug Reactions – An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g., Investigator's Brochure for an unapproved investigational product or package insert/summary of product characteristics for an approved product).

Vulnerable Subjects – Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

Well-being (of the trial subjects) – The physical and mental integrity of the subjects participating in a clinical trial