

## **Glossary**

### **Adverse Drug Reaction (ADR)**

In the preapproval 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 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 diseases or for modification of physiological function.

### **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.

### **Applicable Regulatory Requirement(s)**

Any law(s) and regulation(s) addressing the conduct of clinical trials of investigational products.

### **Approval (In relation to Institutional Review Boards)**

The affirmative decision of the IRB that the clinical trial has been reviewed and may be conducted at the institution site within the constraints set forth by the IRB, the institution, Good Clinical Practice (GCP), and the applicable regulatory requirements.

### **Approved Training in Good Clinical Practice**

Training which is approved by the National Committee for Clinical Research (NCCR). The content of the training must incorporate the curriculum as stipulated by the committee.

### **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, analysed, and accurately reported according to the protocol, sponsor’s standard operating procedures (SOPs), Good Clinical Practice (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 Exemption (CTX)**

An approval by the DCA authorising the applicant to manufacture any local product for the purpose of clinical trial.

**Clinical Trial Import Licence (CTIL)**

A license in Form 4 in the schedule of The Control of Drugs and Cosmetics Regulations of 1984, authorising the licensee to import any product for purposes of clinical trials, notwithstanding that the product is not a registered product.

**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, diagnostic agent conducted in human subjects, in which the clinical and statistical description, presentations, and analyses are fully integrated into a single report.

**Clinical scientist**

Refer to biomedical, clinical laboratory and healthcare scientist. Clinical scientists are healthcare and medical experts who support clinical staff in their work with patients.

**Comparator (Product)**

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

**Compliance (*in relation to trials*)**

Adherence to all the trial-related requirements, Good Clinical Practice (GCP) requirements, and the applicable regulatory requirements.

**Confidentiality**

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

**Conflict of Interest**

COI defines as the existence of contradictory interests in relation to any part of the study activity by an individual or institution. Example:

1. The study subject is also your patient under care
2. Researcher is also the stakeholder of the relevant institution
3. Researcher holds a supervisory or administrative post over the potential subjects that may influenced the participatory decision making.

**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.

**Coordinating Committee**

A committee that a sponsor may organise to coordinate the conduct of a multicentre trial.

**Coordinating Investigator**

An investigator assigned the responsibility for the coordination of investigators at different centres participating in a multicentre trial.

**Contract Research Organization (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.

**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.

**Drug Control Authority (DCA)**

A regulatory authority established for the purpose of regulating the Control of Drugs and Cosmetics Regulations, 1984.

**Essential Documents**

Documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced.

**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.

#### **Herbal/Animal Medicinal Products**

Plant/animal-derived materials or products with therapeutic or other human health benefits which contain either raw or processed ingredients from one or more plants/animals.

#### **Independent Data-Monitoring Committee (IDMC) (Data and Safety Monitoring Board, Monitoring Committee, Data Monitoring Committee)**

Independent data-monitoring committees 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.

#### **Independent Consultant**

A person who is not a member of JEPeM and has special skill or knowledge/expertise in a particular field.

#### **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/scientific professionals and non-medical/non-scientific members, whose responsibility 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 this 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 a 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 that may be located at the site of the trial, at the sponsor's and/or contract research organization'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 including plant/ animal-derived medicinal products 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 (off-label use), or when used to gain further information about an approved use.

**Investigator**

A person responsible for the conduct of the clinical trial at a trial site. If a 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. See also ***Sub-investigator/co-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) in human subjects.

**JEPeM-USM Members**

Refer to the 3 categories in JEPeM-USM which is main committee, sub-committee and independent reviewers.

**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.

**Minor modification**

If the modifications are minor in a sense of grammatical corrections or other minor corrections not involving the methodology, the decision of minor correction will be made with review at the secretariat/chair level

If the modifications are deemed minor but involves methodology, the revised version will be reviewed by the primary reviewer

**Major modification**

Includes major parts of methodology or major ethical issues to be addressed. Revised versions of projects with this decision will be sent to the primary reviewer and will be tabled again the full board meeting.

**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.

**National Committee for Clinical Research (NCCR)**

A committee established for the purpose of coordinating and promoting clinical research in Malaysia, chaired by the Director General of Health, Ministry of Health Malaysia.

**Non-clinical scientist**

Non-clinical are those which do not provide any type of medical treatment or testing. Some non-clinical workers do interact with patients but do not actually provide medical care.

**Non-institutional Member**

A person who is not attached/affiliated to USM.

**Nonclinical Study**

Biomedical studies not performed on human subjects.

**Opinion** (*in relation to Independent Ethics Committee/ Institutional Review Board*).

The judgement and/or the advice provided by an Independent Ethics Committee (IEC)/ Institutional Review Board (IRB).

**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.

**Protocol deviation**

A protocol deviation occurs when, without significant consequences, the activities on a study diverge from the Institutional Review Board-approved protocol, e.g., missing a visit window because the subject is traveling. Not as serious as a protocol violation.

**Protocol violation**

A divergence from the protocol that materially (a) reduces the quality or completeness of the data, (b) makes the Informed Consent Form inaccurate, or (c) impacts a subject's safety, rights, or welfare. Examples of protocol violations may include the following:

- Inadequate or delinquent informed consent
- Inclusion/exclusion criteria not met
- Unreported serious adverse events
- Improper breaking of the blind
- Use of prohibited medication
- Incorrect or missing tests
- Mishandled samples
- Multiple visits missed or outside permissible windows
- Materially inadequate record keeping
- Intentional deviation from protocol, Good Clinical Practice, or regulations by study personnel
- Subject repeated non-compliance with study requirements

**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 Malaysian Guideline for Good Clinical Practice 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 scientist**

A formal scientist or any establish discipline of sciences

**Resubmission.**

The project has major flaws and needs resubmission. These re-submitted projects will be handled as if they were new projects for initial review.

**Serious Adverse Event (SAE) or Serious Adverse 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 persistent or significant disability/incapacity, or
- is a congenital anomaly/birth defect.

**Source Data**

All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).

**Source Documents**

Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification 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 departments 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 an 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.

**Sub-investigator/co-investigator**

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 Reaction**

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, and 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.