MOORE BARLOW
LIFE SCIENCES GLOSSARY

June 2020 Edition

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Introduction

It is common for international and UK Life Science companies to use specific medical terms and acronyms. For those in this industry some terms are second nature, but for others they are not and so can create confusion! We have produced a glossary of terms in order to help navigate some of the most commonly used terms.

We hope that this new edition of our Life Sciences glossary is of use and welcome suggestions for additions at any time.

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1st June 2020

GLOSSARY

ADME
Used in pharmacology and means absorption, distribution, metabolism and excretion which describes the disposition of a pharmaceutical compound within a living thing.

Adverse Drug Reaction or **ADR**
In clinical trials: all adverse or unusual noxious and unintended responses to a medicinal product related to any dose or doses so that a causal relationship between a medicinal product and an adverse reaction is at least a reasonable possibility so that the relationship cannot be ruled out.
Regarding marketed medicinal products: a response to a drug which is noxious and unintended and which occurs at usual doses normally used for therapy of diseases, for modification of physiological function or diagnosis.

Adverse Event or **AE**
Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product. An 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 (or investigational) product, whether or not related to the medicinal (or investigational) product.

Amendment to the Protocol
See the definition of Protocol Amendment.

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

API
Active pharmaceutical ingredient

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, 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, analysed and accurately reported according to the protocol, sponsor's standard operating procedures, Good Clinical Practice, 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.

BID or **b.i.d.**
Means twice a day (*Latin: bis indie*) as in the dosage of a medicine.

bio courier
Means a compound, metal (i.e. gold) or thing which acts within the human body as a delivery method for APIs, also used to describe drug delivery technology generally.

BLA
Used in the United States and means a biologics license application, as defined by the FDA, submitted after an IND has been approved.

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 (also **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.

CAP
Means centrally authorised products (i.e. in the EU).

CDA
Means clinical data architecture, an international standard for the exchange of clinical data and documents often electronically held.

Clinical Trial/Clinical 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).

CTA
Clinical trial authorisation.

CHMP
Means the committee for medicinal products for human use.

CMC
Means chemistry, manufacturing and controls: being an early and important part of drug development examining its chemical safety as well as suitability for use as capsules, tablets or other forms of prescription.

CoA
Means certificate of analysis.

COMP
Means the committee for orphan medicinal products.

Comparator (Product)
An investigational or marketed product (such as an active control), or a placebo, used as a point of reference in a clinical trial.

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

Confidentiality Provisions
Prevention of disclosure, to other than authorized individuals, of a pharma company's or person's proprietary information or of a subject's identity. See also the definition of NDA.

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 organize 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 or **CRO**
A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions.

CTA
Means a clinical trial application.

CTR
Means clinical trial regulations in particular the EU Clinical Trials Regulation (EU 536/2014).

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.

DNA
Is deoxyribonucleic acid a molecule structured in a double helix carrying genetic instructions for the operation of all forms of life. As with RNA it is a nucleic acid.

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.

ECHA
Means the European Chemicals Agency (see the definition of REACH).

EMA
Means the European (EU) Medicines Agency being the medical regulator for all EU States.

EMRN
Means the EU medicines regulatory network.

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

FDA
Means the United States Food and Drug Administration.

FHD
Means first human dose in a clinical trial of drugs.

FIM
Means first in man, being the first use in humans of a new drug in a relevant clinical trial (see also the definition of FHD).

Field
Means the description or definition of the proposed treatment, prevention, diagnosis or palliation regarding a human condition or dis-order which is relevant to a particular agreement.

GCP or Good Clinical Practice (or **cGMP current Good Manufacturing Practices**)
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. GMP is the equivalent standard for the manufacturing equivalent.

Gene
Is a region of DNA that encodes function.

Gene Editing
A type of genetic engineering in which DNA is modified or deleted in the genome of a living thing.

Gene Expression
The process by which information from a gene is used in the synthesis of a functional gene product, often being proteins.

Genome
Is a living thing's set of DNA (i.e. all of its genes).

IDMC or **Independent Data Monitoring Committee**
In relation to 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.

IEC or **Independent Ethics Committee**
An independent body which can be a review board or a committee, institutional, regional, national, or supranational). Normally constituted of medical professionals and non-medical members, whose responsibility it is to ensure instigation of GCP and consequently the protection of the rights, safety and well-being of human subjects involved in a trial. Further, 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 to act in agreement with GCP.

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.

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 and 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
Commonly a university or college but can include any public or private entity or agency or medical facility where research or clinical trials are conducted.

Institutional Review Board or **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.

IMD
Means an investigational medical device.

IND
Means investigational new drug and usually refers to the FDA's programme whereby a pharma company can obtain approval to commence human clinical trials before marketing application has been approved but can also apply to other countries (including EU) which have similar procedures.

Investigational Medical Product or **IMP** (also **IMPD** for dossier)
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 authorization 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
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 the definition of Subinvestigator).

In vitro
Means in an artificial environment such as a test tube, in order for samples to be tested or trialled.

In vitro diagnostics
Testing of in vitro samples

In vivo
Means performed or taking place in a living thing (for testing/clinical trials).

In vivo diagnostic
Is a testing procedure carried out in the human body in order to identify a disease or condition.

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.

IPA means an individual project addendum.

Legally Acceptable Representative (or **LAR**)
An individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the clinical trial.

MIA or Manufacturer's Licence
A licence to lawfully manufacture medical products.
Marketing Authorisation Holder (also **MAHs**)
Usually a reference to EU central system authority but can also mean authorisation by MHRA.

messenger RNA (or **mRNA**)
Means a family of RNA molecules that convey genetic information from DNA to the ribosome where they specify the amino acid sequence of the protein products of gene expression.

MHRA
Means Medicines and Healthcare products Regulatory Agency being the medical regulator in the UK.

microRNA or **miRNA**
A small non-coding RNA molecule found in plants, animals and some viruses which functions in RNA silencing and post-transcriptional regulation of gene expression.

MSDs
Material safety data sheet, (see also the definition of SDS).

MTD
Means the maximum tolerate dose of a drug or medicine.

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.

NCE
Means a new chemical entity arising out of drug discovery (see also definition of NME).

NDA
Means a new drug application. (This acronym can also be mistaken for Non-Disclosure Agreement.)

NIBSC
Means national Institute for Biological Standards and Control.

NICE
Means the (UK) National Centre for (Clinical) Health and Care Excellence.

NIH
Means the National Institutes of Health in the USA.

NME
Means a new molecular entity arising out of a drug discovery (see also the definition of NCE).

Nonclinical Study
Biomedical studies not performed on human subjects.

OCABR
Means official Control Authority Batch Release.

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

Original Medical Record
Means records in relation to a clinical trial (see also the definition of Source Documents).

Orphan Drug
Means a drug used to combat rare diseases.

OOS or **Out of Specification**
Means analytical results that do not comply with pre-determined acceptance criteria.

OOT or **Out of Trend**
Means analytical results that do not follow the expected trend. The result is not necessarily Out of Specification but is not the expected data point.

Pharmacovigilance or **PV** (also **PhV**)
The practice of monitoring the safety and/or effects of medical drugs after they have been licenced for use particularly to identify and evaluate previously unreported adverse reactions.

PASS
Post authorisation safety study.

PBMC
Means peripheral blood mononuclear cells.

PoC
Means, in relation to clinical testing, (at) point of care which is testing done outside of a laboratory and perhaps at the bedside of a patient or testing of a patient remotely. Sometimes this acronym is used in medicine to describe naturally occurring physical material such as *products of conception* (being human tissue).

PRAC
Means pharmacovigilance risk assessment committee.

Protocol
The document that describes the overall objective(s), design, methodology, statistical considerations, and general organization of a medical trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other referenced documents. Throughout the ICH GCP Guidelines, the term Protocol refers to protocol and also any protocol amendments.

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

PSF
Means a product specification file.

PSDS
Product safety data sheet (see SDS).

PSMF
Means the Pharmacovigilance System Master File (see PV above)

PSURs
Means periodic safety update reports.

QP or **Qualified Person**
In respect of the right to manufacture products in the UK or directly imported into the UK.

QPPV
Means the qualified person for pharmacovigilance who is responsible for maintaining an entity's PV system.

QA or **Quality Assurance**
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 and the applicable regulatory requirement(s). Also **QA** can mean the agreement (quality agreement) between parties setting out responsibilities regarding services performance including cGMP.

QC or **Quality Control**
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.

Q.D. or **q.d.**
Means daily dose (*Latin: quaque die*), also sometimes used historically is the acronym OD which in fact is a mis-spelling of QD. In each case, it is used in the dosage of medicine.

QPR
Used in Pharmacovigilance requirements, often refers to a Quality Problem Report.

Randomization
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.

REACH
Is an EU regulation concerning the registration, evaluation, authorisation and restriction of chemicals in order to protect human health in relation to which the EU agency ECHA has been established (*see EU No1907/2006*).

Regulatory Authorities
Bodies having the power to regulate. In the ICH GCP guidelines 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.

RNA
Means ribonucleic acid being a polymeric molecule important in coding, decoding, regulation and expression of (human) genes. RNA and DNA are both nucleic acids being essential for all forms of life.

RNA interference (or **RNAi**)
Means a process where RNA molecules inhibit gene expression or translation by neutralizing targeted mRNA molecules.

RP-I
Means a responsible Person for Import.

SAD
Means a single ascending dose of a drug/medicine.

Safety Data Sheets or **SDS**
SDS are key documents in the safe supply, handling and use of chemicals for medical use. They should help to ensure that those who use chemicals in the workplace do so safely without risk of harm to users or the environment. SDSs are required by the REACH Regulation. They list health and safety information on chemicals and chemical compounds and their use (also MSDS and PSDS).

SAE or **Serious Adverse Event** or **Serious ADR** or **Serious Adverse Drug Reaction**
Any untoward medical occurrence that at any dose of a drug:

- results in death,
- is life-threatening,
- requires inpatient hospitalization or prolongation of existing hospitalization,
- results in persistent or significant disability/incapacity,

or creates a congenital anomaly/birth defect
(see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

siRNA (also **Small interfering RNA** and sometimes **silencing RNA**)
Is a class of double stranded RNA molecules operating within the RNA interference pathway.

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 (such as hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data, clinical subject files, and records kept at a pharmacy, laboratory and also at medico-technical departments involved in any clinical trial).

SPC or **Supplementary Protection Certificate**
Extends patent protection for medicinal products.

Sponsor
An individual, company, institution, or organization 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.
SOPs or **Standard Operating Procedures**
Detailed, written instructions to achieve uniformity of the performance of a specific function: can also mean sponsor's standard operating procedures.

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). See also Investigator.

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) (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

Vulnerable Subjects
Generally falls into two parts:

(a) Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation of benefits associated with participation (or of a retaliatory response from third party groups in case of refusal to participate). Third party groups include medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel or employees of the pharmaceutical industry; and

(b) 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 (when used in clinical trials)
The physical and mental integrity of the subjects participating in a clinical trial.