EU Clinical Trials Register

Disclaimer: *The explanations are provided for the benefit of public users of the system and to enhance general understanding of terms used. They are not intended as the regulatory definitions and should not be used or substituted for the regulatory definitions and guidelines.*

Glossary of Terms used in EU Clinical Trials Register

Term	Explanation
a	
Active Substance	An active substance (AS), is the substance in a medicinal product that is biologically active
Active substance of biotechnological origin	A product that contains an active substance of biological or biotechnological origin
Active substance of chemical origin	A product that contains an active substance of chemical origin
Adolescents (12-17 years)	Subjects are aged 12 to less than 18 years.
Adults (18-64 years)	Subjects are aged 18 to 64 years.
Advanced Therapy IMP (ATIMP)	Advance Therapy Investigational Medicinal Products are medicinal products involving cell or gene therapy or tissue engineering.
Adverse Event	Any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment. *Ref: DIRECTIVE 2001/20/EC*
ATC	Anatomic, therapeutic, chemical. International system for classification of medicines maintained by World Health Organisation.
b	
Bioequivalence study	Bioequivalence is a term in pharmacokinetics used to assess the expected in vivo biological equivalence of two preparations of a Medicinal Product.
Biotechnology	Biotechnology is the application of biological organisms, systems or process to manufacturing of pharmaceuticals.
c	
CAS number	Chemical Abstract Services (CAS) are unique numerical identifiers for chemical elements, compounds, polymers, biological sequences, mixtures and alloys. A service of the American Chemical Society that indexes and compiles abstracts of worldwide chemical literature called Chemical Abstracts.
CAT classification	Procedural advice on the provision of scientific recommendation on CAT (classification of advanced therapy medicinal products).

Glossary of Terms used in EU Clinical Trials Register	
Term	**Explanation**
CE mark	European conformity Marking: A mandatory European marking for products falling under one of the New Approach Directives (including medical devices, but excluding cosmetics, chemicals, pharmaceuticals, foodstuffs) to indicate conformity with the health and safety requirements set out in European Directive.
Classification code (MedDRA)	An eight digit unique numeric code assigned to a MedDRA term. The code is non-expressive and is intended to fulfil a data field in various electronic submission types.
Clinical Trial (CT)	Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal product(s) and/or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal product(s) with the object of ascertaining its (their) safety and/or efficacy. *Ref: DIRECTIVE 2001/20/EC*
Combination ATIMP	An ATIMP (Advanced Therapy Investigational Medicinal Product) involving a medical device.
Comparator	An investigational or marketed product (i.e. active control) or placebo, used as a reference in a clinical trial.
Competent Authority (CA)/ National Competent Authority (NCA) Also referred as National Medicine Regulatory Authorities	A regulatory agency in an EU Member State or for medical devices, a Competent Authority is the organization with the authority to act on behalf of the government of a Member State to ensure that all medical devices meet the essential requirements laid down in the Directives prior to marketing authorisation.
Concentration unit	The unit of measurement used for the concentration of the active substance.
Controlled	In a controlled trial, the tested product is compared to a reference treatment. The reference treatment can be, for example, a placebo, a product known to be effective, a surgical procedure, or a different dose of the same product.
Countries in which trial sites are planned	Country(s) where clinical trials are planned to be conducted.
Country which granted the Marketing Authorisation	Name of the country where the holder was granted the Marketing Authorisation of the actual IMP to be used in the clinical trial in the member state concerned by the application.
Cross over	Comparison of two (or more) treatments in which patients are switched to the alternative treatment after a specified period of

Glossary of Terms used in EU Clinical Trials Register	
Term	**Explanation**
	time.
Current sponsor code	The current code in use by the sponsor for an active substance.
d	
Data Monitoring Committee	A Data Monitoring Committee is a group of independent experts external to a study assessing the progress, safety data and, if needed critical efficacy endpoints of a clinical study.
Date of Competent Authority Decision	This is the date on which the National Competent Authority Decision was made on clinical trial.
Date of Ethics Committee Opinion	This is the date on which the Independent Ethics Committee Opinion was given on clinical trial.
Date of the global end of the trial	This is the date on which the trial is ended in all countries.
Description of the IMP	The physical description of the product (e.g. white tablet, solution).
Diagnosis	1. the determination of the nature of a case of disease. 2. the art of distinguishing one disease from another.
Dose response	The dose-response describes the change in effect caused by differing doses to a Medicinal Product after a certain exposure time. This may apply to individuals, or to populations.
Double blind	A trial where the investigators and the subjects included in the trial (healthy volunteers or patients) don't know which treatment is given.
e	
EEA	European Economic Area.
Efficacy	A measure of whether the medicinal product has its intended effect.
Elderly (>=65 years)	Subjects are aged 65 years or more.
EMA	European Medicines Agency.
EMA Decision number of PIP	European Medicines Agency's decision number for the Paediatric Investigation Plan (PIP).
Emergency situation	Situation where urgent care is needed for the patient and this involves enrolment in the trial (for example: head injury).
Ethics Committee (EC)	Independent reviewing body that considers and approves/disapproves biomedical research involving human subjects. Ethics Committee approval is required for each clinical

Glossary of Terms used in EU Clinical Trials Register	
Term	**Explanation**
	study protocol and Principal Investigator prior to study initiation.
EU	European Union.
EudraCT	EudraCT (European Union Drug Regulating Authorities Clinical Trials) is the European Clinical Trials Database of all interventional clinical trials of medicinal products commencing in the European Union from 1 May 2004 onwards. The EudraCT database has been established in accordance with Directive 2001/20/EC.
EudraCT Number	When registered, each trial is issued with a unique EudraCT number, which identifies the protocol and trial throughout its lifespan.
EV Product Code	Marketed Product's EudraVigilance Number.
EV Substance Code	Active Substance's EudraVigilance Substance Code.
Extractive medicinal product	A medicinal product derived from human tissue such as blood or plasma.
f	
First human administration	Conducting the first dose in human phase I clinical trial.
Full title of the trial	The title as specified in the study protocol and other documents submitted as part of the Clinical Trial Application.
Functional name of contact point	The point of contact for further information on the trial (e.g. “Clinical Trial Information Desk”).
g	
Gene therapy medical product	Product aimed at the transfer of a prophylactic, diagnostic or therapeutic gene to human and its subsequent expression in vivo.
GMO	A genetically modified organism (GMO) or genetically engineered organism (GEO) is an organism whose genetic material has been altered using genetic engineering techniques.
h	
Healthy volunteers	Clinical trial includes subjects in good health.
Herbal medicinal product	Any medicinal product exclusively containing as active ingredients one or more herbal substances or preparations. Adapted from Dir 83/2001.
Homeopathic medicinal product	Homeopathic medicinal products are medicinal products based on a dilute solution of raw material from the plant, animal or mineral kingdoms.

Glossary of Terms used in EU Clinical Trials Register	
Term	**Explanation**
Human pharmacology (Phase I)	Human pharmacology (Phase I) trials are the first stage of testing in human subjects, generally comprising a small group of healthy volunteers. This phase includes trials designed to assess the safety (pharmacovigilance), tolerability, pharmacokinetics, and pharmacodynamics of a drug.
i	
IEC Opinion of amendment	Independent Ethics Committee opinion.
Immunological medicinal product	Any medicinal product consisting of vaccines, toxins, serums or allergen products used to produce an immunological response.
IMP	(Investigational Medicinal Product) A pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products already with a marketing authorisation but used or assembled in a different way from the authorised form, or when used for an unauthorised indication, or when used to gain further information about the authorised form.
IMP to be used in the trial has a marketing authorisation	Investigational Medicinal Product has a Marketing Authorisation in the Member State concerned by this application.
Interventional trial	An interventional trial sets up to discover or verify the effects of one or more investigational medicinal product(s) (IMP), to ascertain its (their) safety and/or efficacy. The assignment of the patient to a particular therapeutic strategy is decided in advance by a trial protocol. The way the IMP(s) are used, and the way the patients are selected for the trial and followed up are not as per current practice, and the data from the trial are systematically analysed.
In the whole clinical trial	Details of the planned number of subjects in the entire world to be included.
In Utero	Subjects are unborn infants, still in the womb.
Investigator	A doctor or a person following a profession agreed in the Member State for investigations because of the scientific background and the experience in patient care it requires. The investigator is responsible for the conduct of a clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the leader responsible for the team and may be called the principal investigator.
In Vivo	Within the living body (animal/man). A phenomenon that occurs in real life, as opposed to in the laboratory ("in vitro").
Infants and toddlers (28 days-23	Subjects are aged 28 days to less than 2 years.

Glossary of Terms used in EU Clinical Trials Register	
Term	**Explanation**
months)	
INN - Proposed INN	The International Non-proprietary name for an active substance.
ISRCTN number	International Standard Randomised Controlled Trial Number is used for the identification of clinical trials worldwide. The randomly generated, eight-digit ISRCTN is unique to a registered trial at current controlled trials, thereby ensuring that the trial can be simply and unambiguously tracked throughout its lifecycle from initial protocol to results publication.
IVRS	Interactive Voice Response System: commonly used for randomisation of treatment and controlling the shipment of stock of product.
j	
k	
l	
Legal Representative of Sponsor	An individual, company, institution, or organisation authorised to act on behalf of the sponsor of a clinical trial. Must be based in the EU or the EEA, which includes Iceland, Norway, and Liechtenstein.
m	
Main objective of the trial	A description of the main objectives of the trial.
Marketing Authorisation	The approval granted by the Regulatory Authority to market a specific product in a particular country.
MAH	Marketing Authorisation Holder.
Marketing Authorisation Holder (MAH)	The company named on the Marketing Authorisation for a specific product in a particular country.
MedDRA Classification	MedDRA (Medical Dictionary for Regulatory Activities) - is a medical terminology used to classify adverse event information associated with the use of biopharmaceuticals and other medical products (e.g., medical devices and vaccines).
MedDRA Level	Key to MedDRA hierarchical levels (highest to lowest) SOC (System Organ Class) HLGT (High Level Group Term) HLT (High Level Term) PT (Preferred Term) LLT (Lowest Level Term).
Medical condition in easily understood language	A description of the medical condition being studied in non-medical language.

Glossary of Terms used in EU Clinical Trials Register	
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Medical condition(s) investigated	Description of intended indication for the product under development.
Multiple Member States	This is where the trial will be conducted in more than one Member State of the European Economic Area.
Multiple sites in the Member State concerned	A trial is conducted in multiple sites in the concerned Member State.
Multinational trial	A multinational research trial is a clinical trial conducted in more than one country at the same time.
n	
Name of organisation	Name of individual, company, institution or organisation which takes responsibility for the initiation, management and/or financing of the clinical trial.
Name or abbreviated title of the trial	A shortened title or description of the clinical trial.
Newborns (0-27 days)	Subjects are newborn babies from birth to less than 28 days of age.
Number of sites anticipated in Member State concerned	This is number of sites in the Member State concerned where the trial will take place.
Number of sites anticipated in the EEA	Number of investigator sites in the European Economic Area where the trial is planned to take place.
Number of sites anticipated outside of the EEA	Number of investigator sites outside the European Economic Area where the trial is planned to take place.
Number of treatment arms in the trial	Any of the treatment groups in a randomized trial. Most randomized trials have two "arms," but some have three "arms," or even more.
Nursing women	Clinical trial includes women subjects who are breastfeeding.
o	
Objective of the trial	The goal intended to be attained by the Clinical Trial.
Open Trial	A Trial where the investigators and the subjects know which treatment is actually given.
Orphan drug	An orphan drug is a pharmaceutical agent that has been developed specifically to treat a rare medical condition, the condition itself being referred to as an orphan disease. A drug for the treatment of a rare disease (affecting fewer than 200,000 people in the US or fewer than 5 in every 10,000 individuals in the EU) or for a disease not likely to generate sufficient profit to justify Research and

Glossary of Terms used in EU Clinical Trials Register	
Term	**Explanation**
	Development costs.
Orphan drug designation number	Designation of orphan drug status to drugs that are in the process of development for the treatment of rare diseases.
Other descriptive name	Any other descriptive name for an active substance.
p	
Parallel group	A trial in which two or more treatments are evaluated concurrently in separate groups of patients.
Paediatric Investigation Plan (PIP)	Document upon which the development and authorisation of medicinal products for the paediatric population is based. It is presented by an applicant early during the development of a product to the EMA Paediatric Committee in order to agree a paediatric development plan.
Patients	Clinical Trial includes subjects, who are currently patients, and can also include healthy volunteers.
Pharmaceutical form	A dosage form is the physical form of a dose of medication, such as a capsule or injection. The route of administration is dependent on the dosage.
Pharmacodynamic	Pharmacodynamics is the exploration of what the Medicinal Product does to the body.
Pharmacoeconomic	Pharmacoeconomics refers to the scientific discipline that compares the value of one pharmaceutical drug or drug therapy to another.
Pharmacogenetic	Pharmacogenetics is generally regarded as the study or clinical trial of genetic variation that gives rise to differing response to drugs.
Pharmacogenomic	Pharmacogenomics is the broader application of genomic technologies to new drug discovery and further characterization of older drugs.
Pharmacokinetic	Pharmacokinetics is the exploration of what the body does to a Medicinal Product.
Phase I	Phase I is the first stage of a clinical trial. It is to ensure a treatment is safe for people to take, rather than to try to treat a condition. These trials are very small, (typically around 30 people), and usually involve healthy volunteers or sometimes patients. Ref: *http://www.mssociety.org.uk*

Glossary of Terms used in EU Clinical Trials Register

Term	Explanation
Phase II	The second phase in clinical trials aims to investigate the safety and effectiveness of a potential therapy. Usually between 100 and 300 people will be enlisted to take part with the aim of determining whether the treatment will be safe and effective to treat a condition.
Phase III	If previous trials have indicated a treatment is safe and that it also shows promise in being able to treat a condition, phase III clinical trials begin. These involve large numbers of participants usually from several hundred to several thousand subjects, and are often spread between different hospitals and countries. If these trials show that a drug is safe and effective, the manufacturers can apply for a drug license.
Phase IV	Post marketing studies to delineate additional information including the drug's risks, benefits, and optimal use. These studies are designed to monitor effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.
PIP	Paediatric Investigation Plan.
PIP Addressee/Addressee of PIP Decision	The PIP Addressee is the name given to the legal entity that has received the Agency's decision on a Paediatric Investigation Plan (PIP).
Placebo	A placebo is a control substance (a dummy treatment) that is given to people taking part in a clinical trial. It allows researchers to test for the 'placebo effect'. This is a psychological response where people feel better even though the substance they are taking has no effect. By comparing people's responses to the placebo and to the drug being tested, researchers can tell whether the drug is having any real benefit.
Planned number of subjects	The number of subjects planned to be enrolled for a Clinical Trial.
Post Trial Treatment	Plans for treatment or care after the subject has ended the participation in the trial, if not already provided in the protocol.
Plasma derived medicinal product	A medicinal product derived from human blood or human plasma.
Preterm newborn infants	Subjects are not more than 37 weeks from their conception.
Primary end point(s)	The main result that is measured at the end of a study to see if a given treatment worked (e.g., the number of deaths or the difference in survival between the treatment group and the control group). What the primary endpoint will be is decided before the study begins.

Glossary of Terms used in EU Clinical Trials Register	
Term	**Explanation**
Principal exclusion criteria	Reasons for exclusion of subjects from the clinical trial from among the exclusion criteria described in the protocol.
Principal inclusion criteria	Reasons for the inclusion of subjects in the clinical trial.
Product code	This is a code designated by the sponsor who represents the name routinely used by the sponsor to identify the product in the Clinical Trial documentation.
Product name	In the absence of trade name this is the name routinely used by a sponsor to identify the IMP in the Clinical Trial Documentation.
Prophylaxis	Medical or public health measure taken whose purpose is to prevent, rather than treat or cure a disease. Primary prophylaxis is generally intended to prevent the development of a disease, while secondary prophylaxis is intended to prevent the disease, once contracted by a patient, from worsening.
Proposed date of start of recruitment	The anticipated start date for the recruitment of subjects (patients) for a Clinical Trial.
Protocol	A document that describes the objective(s), design, methodology, statistical considerations and organisation of a trial. The term protocol refers to the protocol, successive versions of the protocol and protocol amendments.
q	
r	
Radiopharmaceutical medicinal product	A radioactive pharmaceutical, nuclide, or other chemical used for diagnostic or therapeutic purposes.
Randomised	A trial in which subjects are randomly assigned to one of the treatment arms.
Rare disease	A rare disease concerns a restricted number of patients in the general population and shows evidence of gravity (because it is life-threatening, invalidating or serious and chronic). The limit accepted in Europe is 5 people in 10,000 affected by the disease.
Recombinant	A cell or organism in which genetic recombination has occurred.
Routes of administration	A route of administration in pharmacology and toxicology is the path by which a drug, fluid, poison, or other substance is brought into contact with the body.
RSS	Really Simple Syndication. RSS is a family of web feed formats used to publish frequently updated works—such as blog entries,

Glossary of Terms used in EU Clinical Trials Register	
Term	**Explanation**
	news headlines, audio, and video—in a standardised format.
s	
Safety	The potential of a drug to be endured. Also known as 'Tolerability'.
Scope of the trial	A definition of the general outline of what the clinical trial will investigate.
Secondary end point(s)	Results that are measured at the end of a study, in addition to the main result (primary endpoint) to see if a given treatment worked. Secondary endpoints can explore other aspects of the treatment.
Secondary objectives of the trial	A description of the secondary objectives of the trial as defined by secondary end points.
Single blind	A trial where the subjects (healthy volunteers or patients) included in the trial doesn't know which treatment they are given but the investigator does.
Single site in the Member State concerned	A trial is conducted in a single centre (clinical trial site) in the EU Country concerned by the application.
Somatic cell therapy medicinal product	Means the use of autologous (emanating from the patient himself), allogeneic (coming from another human being) or xenogeneic (coming from animals) somatic living cells, the biological characteristics of which have been substantially altered as a result of their manipulation to obtain a therapeutic, diagnostic or preventive effect.
Source(s) of Monetary or Material Support for the clinical trial	Organisation or Pharmaceutical company providing monetary or material support for the conduct of the trial.
Specific paediatric formulation	Formulation specifically developed for paediatric use.
Specific vulnerable populations	Clinical trial includes subjects (healthy volunteers or patients), who are considered to be part of a population at risk.
Sponsor	An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial.
Sponsor Country	Country name of the organisation or individual who is providing the finance or resources for the clinical trial.
Sponsor's protocol code number	Unique Identifier number for the Protocol e.g. Trial acronym and Year (MAG 98).
Start Date	The date upon which the clinical trial commenced.
Status of the sponsor	Indication of whether the sponsor is commercial or non-

Glossary of Terms used in EU Clinical Trials Register	
Term	**Explanation**
	commercial.
Study	Clinical Trial.
Subject	A person participating in a trial - the subject may be a patient or a healthy volunteer.
Subjects incapable of giving consent personally	Subjects who are incapable of giving consent personally to be enrolled in the trial. For example: minors or mentally impaired subjects.
Summary of Product Characteristics (SmPC)	This is the product information document which is made available to all prescribing physicians in the EU for marketed products.
SUSAR	Suspected Unexpected Serious Adverse Reactions.
t	
Tissue Engineered Product	A product that contains or consists of engineered cells or tissues, is presented as having properties for, or is used in or administered to human beings with a view to regenerating, repairing or replacing a human tissue.
Title of the trial for lay people	Title of the clinical trial in non-technical terms, suitable for comprehension by individuals without medical/pharmaceutical training.
Trade name	Name of the MA holder of the actual IMP used in the member state concerned by the application.
Trial being conducted both within and outside the EEA	Trial being conducted both within and outside the European Economic Area.
Trial being conducted completely outside of the EEA	Trial being conducted outside the European Economic Area.
Trial contains a sub-study	A sub-study, or ancillary study, is a study performed on a sub-group of the subjects included in the clinical trial. For example, a pharmacokinetics or pharmacogenetics sub-study may include a sample of the patients participating in the clinical trial.
Trial has a placebo	The clinical trial using placebo - A dummy medicine containing no active ingredients; an inert treatment;
Trial is part of a PIP	A study is part of a Paediatric Investigation Plan.
Trial Phase	The trial phase (Phase I, II, III or IV).
u	
US NCT number	ClinicalTrials.gov registry number. NCT numbers are 8 digits, ascending and correlated with registration date.

Glossary of Terms used in EU Clinical Trials Register	
Term	**Explanation**
v	
Version (MedDRA)	The version of MedDRA terminology used.
w	
WHO (UTN)	World Health Organisation Universal Trial Number. The UTN is a number, obtained by the trial's sponsor or principal investigator and is used for the identification of clinical trials worldwide.
Women of childbearing potential not using contraception	Clinical trial includes female subjects who have the potential to give birth and are not using contraception.
Women of child-bearing potential using contraception	Clinical trial includes female subjects who have the potential to give birth and are using contraception.
x	
y	
z	