Glossary of terms used in clinical trials

Adverse event (AE)	Any untoward medical occurrence in a subject to whom a medicinal product has been administered, including occurrences which are not necessarily caused by or related to that product
Adverse reaction (AR)	Any untoward and unintended response in a subject to an investigational medicinal product which is related to any dose administered
AE	See adverse event
AR	See adverse reaction
Blinding	The process through which one or more parties to a clinical trial are unaware of the treatment assignments. In a single-blinded study, usually the subjects are unaware of the treatment assignments. In a double-blinded study, both the subjects and the investigators are unaware of the treatment assignments. Also, in a double-blinded study, the monitors and sometimes the data analysts are unaware. "Blinded" studies are conducted to prevent the unintentional biases that can affect subject data when treatment assignments are known.
CI	Chief investigator
Clinical Research Associate (CRA)	Person employed by the study sponsor or CRO to monitor a clinical study at all participating sites.
Clinical Trial	Any investigation in human subjects intended to determine the clinical pharmacological, pharmacokinetic, and/or other pharmacodynamic effects of an investigational agent, and/or to identify any adverse reactions to an investigational agent to assess the agent's safety and efficacy.
Clinical trial authorisation (CTA)	The authorisation issued by the MHRA in the case of a clinical trial of an investigational medicinal product (CTIMP). No CTIMP can commence in the UK without the issue of both a CTA and a favourable ethical approval.
Control Group	A comparison group of study subjects who are not treated with the investigational agent. The subjects in this group may receive no therapy, a different therapy, or a placebo.
Cross over trial	Each subject receives both treatments being compared or the treatment and the control.
CTA	Clinical trial authorisation
CTIMP	Clinical trial of an investigational medicinal product
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.

Dose-ranging study	A clinical trial in which two or more doses of an agent (such as a drug) are tested against each other to determine which dose works best and is least harmful.
Double dummy	A technique for retaining the blind when administering supplies in a clinical trial when the two treatments cannot be made identical. Supplies are prepared for treatment A (active and indistinguishable placebo) and treatment B (active and indistinguishable placebo) and subject take two sets of treatment either A (active) and B (placebo) or A (placebo) and B (active)
Double-Blind	The design of a study in which neither the investigator nor the subject knows which medication (or placebo) the subject is receiving.
Efficacy	A product's ability to produce beneficial effects on the duration or course of a disease. Efficacy is measured by evaluating the clinical and statistical results of clinical tests.
Eligibility criteria	Summary criteria for participant selection; includes Inclusion and Exclusion criteria.
EMEA	European Agency for Evaluation of Medicinal Products
Empirical	Based on experimental data, not on a theory.
Equivalence trial	Aim to show that the effect of different trials differ by no more than a specific amount (the equivalence margin). Equivalence trials are appropriate when a new treatment offers some advantages over an existing treatment (less cost, greater safety, improved convenience or freedom of choice for the patient), in addition to the expected equal therapeutic effectiveness.
eSMS	External Scientific and Medical Service (of the MTU)
Ethics Committee	An independent group of both medical and non-medical professionals who are responsible for verifying the integrity of a study and ensuring the safety, integrity, and human rights of the study participants.
Exclusion Criteria	Refers to the characteristics that would prevent a subject from participating in a clinical trial, as outlined in the study protocol.
GCP	See Good clinical practice
Good clinical practice (GCP)	An international quality standard for designing, conducting, recording and reporting trials that involve participation of human subjects
Health Care Professional	A doctor, dentist, nurse, pharmacist or registered ophthalmic optician or other officially registered health professional.
Healthy volunteer	A healthy person who participates in a clinical trial and receives no direct health benefit from it.
IB	see Investigator's brochure
ICH	International Conference on Harmonisation
IMP	Investigational medicinal product

Inclusion Criteria	A list of criteria that must be met by all study subjects.
Informed Consent	The voluntary verification of a patient's willingness to participate in a clinical trial, along with the documentation thereof. This verification is requested only after complete, objective information has been given about the trial, including an explanation of the study's objectives, potential benefits, risks and inconveniences, alternative therapies available, and of the subject's rights and responsibilities in accordance with the current revision of the Declaration of Helsinki.
Investigator	A medical professional, usually a physician but may also be a nurse, pharmacist or other health care professional, under whose direction an investigational drug is administered or dispensed. A principal investigator is responsible for the overall conduct of the clinical trial at his/her site.
Investigator's brochure (IB)	A compilation of the clinical and non-clinical data on the investigational product(s) which is relevant to the study of the product(s) in humans.
Longitudinal Study	A study conducted over a long period of time.
Masked Treatment Allocation Schedules	Listings with details of subject's treatment allocation covered either by a scratch-off or peel-off covering
Match-pair design	A type of parallel trial design in which investigators identify pairs of subjects who are 'identical' with respect to relevant factors (e.g. age, weight) and then randomised then so one receives Treatment A and the other Treatment B.
Megatrial	A massive clinical trial that tests the advantages of a marginally effective experimental drug by enrolling 10,000 or more subjects.
MHRA	Medicines and Healthcare products Regulatory Agency
Multicentre trial	A clinical trial conducted according to a single protocol at more than one site and carried out by more than one investigator
Non-inferiority trial	These aim to show that an experimental treatment is not worse than an active control by more than the specified margin (called the equivalence margin).
Off-label use	A drug prescribed for conditions other than those approved by the MHRA
Open trial	see Open-Label Study
Open-Label Study	A study in which all parties, (patient, physician and study coordinator) are informed of the drug and dose being administered. In an open-label study, none of the participants are given placebos. These are usually conducted with Phase I & II studies.
Patient card	A card, supplied to the trial subject by the Sponsor, providing information required in an emergency situation, for example; the trial number, trial title, product name/number, Sponsor name/address/telephone number and emergency contact details for Investigator

Phase I trial	Phase I or Healthy Volunteers studies are non-placebo controlled, small studies, and the first test of a drug in humans. • To establish safe/tolerable levels • To establish initial pharacology in humans • Usually carried out on volunteers who may be paid
Phase II trial	Phase II studies are non-placebo controlled or randomised studies. • To provide evidence of activity and better evidence of safety • To define dosage and regimen • Includes participants with the disease
Phase III trial	Phase III studies are usually larger scale comparitive, controlled trials. • To assess the risks and benefits • To compare benefits/side effects with those of other drugs or a placebo • Includes participants with the disease
Phase IV trial	Post-marketing studies to delineate addition information including the drug's risks, benefits and optimal use.
Pivotal Study	Usually a phase III study which presents the data that the regulatory authority uses to decide whether or not to approve a drug. A pivotal study will generally be well-controlled, randomised, of adequate size, and whenever possible, double-blind.
Placebo	An inactive substance designed to resemble the drug being tested. It is used as a control to rule out any psychological effects testing may present. Most well-designed studies include a control group which is unwittingly taking a placebo.
Placebo controlled study	A method of investigation of drugs in which an inactive substance (the placebo) is given to one group of participants, while the drug being tested is given to another group. The results obtained in the two groups are then compared to see if the investigational treatment is more effective in treating the condition.
Placebo effect	A physical or emotional change, occurring after a substance is taken or administered, that is not the result of any special property of the substance. The change may be beneficial, reflecting the expectations of the participant and, often, the expectations of the person giving the substance.
Pre-Clinical Testing	Before a drug may be tested on humans, pre-clinical studies must be conducted either *in vitro* but usually *in vivo* on animals to determine that the drug is safe.
QA	Quality assurance
QC	Quality control
Quality Assurance	Systems and procedures designed to ensure that a study is being performed in compliance with Good Clinical Practice (GCP) guidelines and that the data being generated is accurate.
Randomisation	Study participants are usually assigned to groups in such a way that each participant has an equal chance of being assigned to each treatment (or control) group. Since randomisation ensures that no specific criteria are used to assign any patients to a particular group, all the groups will be equally comparable.

Randomised controlled trial	A trial where subjects are randomly allocated to a treatment group or to a control group (who do not receive the drug under investigation)
RCT	See Randomised controlled trial
REC	Research Ethics Committee
Recruitment	Act of enrolling subjects with the proper inclusion criteria.
Regulatory Affairs	In clinical trials, the department or function that is responsible for ensuring compliance with government regulations and interacts with the regulatory agencies. Each drug sponsor has a regulatory affairs department that manages the entire drug approval process.
Risk-Benefit Ratio	Risk to individual subject vs. potential benefits. Also called Risk-Benefit Analysis.
RUS	Read, understand, sign
SAE	see Serious Adverse Event
SAR	see Serious Adverse Reaction
Serious	For an AE, AR or UAR that at any dose • Results in death • Is life-threatening (at the time of the event) • Requires hospitalisation or prolongation of existing hospitalisation • Results in persistent or significant disability or incapacity • Consists of a congenital anomaly or birth defect
Serious Adverse Event (SAE)	Any untoward medical occurrence in a subject to whom a medicinal product has been administered that results in death or is life threatening or requires hospitalisation or prolongation of existing hospitalisation or results in persistent or significant disability or incapacity or is a congenital anomaly or birth defect including occurrences which are not necessarily caused by or related to that product.
Serious Adverse Reaction (SAR)	Any untoward medical occurrence in a subject to whom a medicinal product has been administered that results in death or is life threatening or requires hospitalisation or prolongation of existing hospitalisation or results in persistent or significant disability or incapacity or is a congenital anomaly or birth defect which is related to any dose administered.
Single-blind trial	The investigator knows the details of the treatment but the subject does not.
SmPC	Summary of Product Characteristics
SOP	Standard operating procedure
Source Documentation	Location where information is first recorded including original documents, data and records.
SPC	Summary of Product Characteristics

Sponsor	An individual, company institution or organisation responsible for a clinical trial and to which eSMS is providing a contracted service
SSAR	Suspected serious adverse reaction
Standard Treatment	The currently accepted treatment or intervention considered to be effective in the treatment of a specific disease or condition.
Statistical significance	The probability that an event or difference occurred by chance alone. In clinical trials, the level of statistical significance depends on the number of participants studied and the observations made, as well as the magnitude of differences observed.
Study List	A table listing study documentation currently held for studies covered by service agreements
Study Protocol	A document that describes the objective(s), design and organisation of a trial
Subject	An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control. Also referred to as the patient.
Superiority trial	A trial in which the superiority of a treatment can be demonstrated.
SUSAR	See Suspected Unexpected Serious Adverse Reaction.
Suspected Unexpected Serious Adverse Reaction (SUSAR)	All suspected adverse reactions related to an investigational medicinal product that are both unexpected and serious. Fatal or life threatening SUSARs must be reported to the MHRA within 7 days and follow-up information within an additional 8 days. All other SUSARs must be reported within 15 days.
Trial subject	An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control. Also referred to as the patient
Triple-blind trial	Various meanings. Commonly the subject, investigator and person administering the treatment are blinded to what is being given. Or it may mean the subject, investigator and statistician analysing the data are blinded.
Unblinding	This involves revealing the treatment allocation of a particular subject. This usually occurs at the end of a trial but may occur due to other circumstance e.g. in an emergency situation. A subject that has been unblinded before the end of a trial will be removed from the trial and all their data will not be used in the subsequent analysis.
Unexpected adverse reaction (UAR)	Any adverse reaction, the nature or severity of which is not consistent with the applicable product information (Investigator Brochure / Summary of Product Characteristics)