

Clinical Trials Tool Kit Glossary

AE	Adverse Event
AMRC	Association of Medical Research Charities
AR	Adverse Reaction
BMJ	British Medical Journal
CA	Competent Authority
CF	Consent Form
CI	Chief Investigator
	There is some ambiguity in the Regulations as to the definition of a CI, MHRA have clarified the following:
	Chief Investigator means:
	(a) in relation to a clinical trial conducted at a single trial site, the investigator for that site
	(b) in relation to a clinical trial conducted at more than one trial site, the authorised health care professional, whether or not he is an investigator at any particular site, who takes primary responsibility for the conduct of the trial;
	That is:
	(a) a doctor,
	(b) a dentist,
	(c) a nurse,
	(d) a pharmacist
Collaborative Group	A group of clinicians collaborating in a clinical trial
Collaborator	Clinician collaborating in a clinical trial
COREC	Central Office of Research Ethics Committees
CPMP	Committee for Proprietary Medicinal Products (now known as CHMP – Committee for Medicinal Products for Human Use)
CRF	Clinical Record Form/Case Report Form
CRO	Clinical Research Organisation
CTA	Clinical Trial Authorisation
CTA*	Clinical Trial Agreement
CTC	Clinical Trial Certificate (now incorporated into the CTA)
CTD	Clinical Trial Directive
CTD*	Common Technical Document
CTX	Clinical Trials Exemption Certificate (now incorporated into the CTA)
CV	Curriculum Vitae
DDX	Doctors and Dentists Exemption Certificate (now incorporated into the CTA)
DMC	Data Monitoring Committee
DMEC	Data Monitoring and Ethics Committee
EC	European Commission
EMA	European Agency for the Evaluation of Medicinal Products
EU	European Union
EU CTD	European Union Clinical Trial Directive
EudraCT	European Clinical Trial Database
EudraVIGILANCE	European Database for Pharmacovigilance
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
IB	Investigator's Brochure
ICH	International Conference on Harmonisation
IMP	Investigational Medicinal Product
IMPD	Investigational Medicinal Product Dossier
ISRCTN	International Standard Randomised Controlled Trial Number

* Some abbreviations have more than one meaning

The Trial Managers Guide has more useful information on trials. Download a copy from www.tmn.ac.uk

Invesitgator	Clinician or nurse involved in a clinical trial
MA	Marketing Authorisation
MAH	Marketing Authorisation Holder
MHRA	Medicines and Healthcare products Regulatory Agency
MRC	Medical Research Council
MREC	Multi-centre Research Ethics Committee
MS	Member State
NHS R&D	National Health Service Research & Development
NHS REC	National Health Service Research Ethics Committee
Participant	Person participating in a clinical trial
PI	Principal Investigator at a trial site
PIS	Patient Information Sheets
Phase I	Phase I or Healthy Volunteer Studies are non-placebo controlled, small studies, and the first test of a drug in humans. <ul style="list-style-type: none"> • To establish safe/tolerable levels • To establish initial pharmacology in humans • Usually carried out on volunteers who may be paid
Phase II	Phase II studies are non-placebo controlled or randomised studies. <ul style="list-style-type: none"> • To provide evidence of activity and better evidence of safety • To define dosage and regimen • Includes participants with the disease
Phase III	Phase III studies are usually larger scale comparative, controlled trials. <ul style="list-style-type: none"> • To assess the risks and benefits • To compare benefits/side effects with those of other drugs or a placebo • Includes participants with the disease
QA	Quality Assurance
QC	Quality Control
QP	Qualified Person responsible for final despatch of trial drug
R&D	Research & Development
RCT	Randomised Controlled Trial Most clinical trials should be designed so that the results are applicable to clinical practice in the general population, e.g. Pragmatic Pragmatic <ul style="list-style-type: none"> • Assesses risks and benefits • Addresses practical questions, under 'real life' conditions • Should X or Y be recommended overall? • Broader range of issues including cost, side effects, compliance
REC	Research Ethics Committee
SAR	Serious Adverse Reaction
SAE	Serious Adverse Event
SD	Standard deviation
SDV	Source document/data verification
SmPC	Summary of Product Characteristics
SOPs	Standard Operating Procedures
Sponsor	Individual/organisation responsible for the initiation, management/financing of a clinical trial
SSA	Site Specific Assessment
SUE	Serious Unexpected Event
SUSAR	Suspected Unexpected Serious Adverse Reaction
TMG	Trial Management Group
TSC	Trial Steering Committee

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