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Information and guidance for primary care sites on Commonly Used Research Abbreviations and Terms

Adapted from NIHR Glossary 2023 -https://www.nihr.ac.uk/about-us/glossary.htm

And GCP glossary May 2022 - https://learn.nihr.ac.uk/mod/glossary/view.php?id=2513

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ABPI	Association of the British Pharmaceutical Industry: A trade association for UK pharmaceutical companies
Abstract	A brief summary of the study and its results. It should tell you what the study tried to show, how the researchers went about it, and what they found.
AcoRD	'Attributing the costs of health and social care Research and Development'. A DHSC framework to identify, attribute and recover the various costs associated with research in the NHS. It is used to complete a SoECAT.
AE	Adverse Event: An unfavourable outcome that occurs during or after the use of a drug or other intervention, but is not necessarily caused by it.
AR/ADR	Adverse Reaction also known as Adverse Drug Reaction: Any untoward and unintended response to an investigational medicinal product related

	to any dose administered.
Advisory Group	Many research projects have an advisory group (or steering group). The group helps to develop, support, advise and monitor the project. The group often includes people who use services, carers, researchers and other health and social care professionals, who can provide relevant advice.
AHP	Allied health professional: AHPs are people who work in health care professions other than dentistry, nursing, medicine, and pharmacy. They provide a range of diagnostic, technical, therapeutic, and support services in connection with health care, for example, occupational therapists, dietitians, and podiatrists.
Amendment	A written description of a change to the protocol or supporting documents. All amendments should be submitted to HRA for ongoing HRA Approval.
Arm	Refers to a group of participants allocated to a particular treatment. In a randomised controlled trial, allocation to different arms is determined by the randomisation procedure. Many controlled trials have two arms, a group of participants assigned to an experimental intervention (sometimes called the treatment arm) and a group of participants assigned to a control (the control arm). Trials may have more than two arms.
ATMP	Advanced Therapy Medicinal Products.
Attrition	The loss of participants during the course of a study. Also called 'loss to follow up'.
Audit	An audit of health or social care involves carrying out a systematic assessment of how well that care is being delivered. Current policy and practice is compared with an agreed standard, so that any problem areas can be identified and improved. Later, the audit can be carried out again to check that the changes made have actually made a difference
Blinding or masking	The process of preventing those involved in a trial from knowing which comparison group a participant belongs to. The risk of bias is minimised when fewer people know who is receiving the experimental intervention or the control intervention. Participants, caregivers, outcome assessors, and analysts are all candidates for being blinded. Blinding of certain groups is not always possible, for example, surgeons in surgical trials.
BRC	Biomedical Research Centre: larger centre covering a number of topics with facilities and research active clinicians/academics/research nurses to run clinical projects

BRU	Biomedical Research Unit: topic-focused centre which usually combines facilities and research active clinicians/academics/research nurses to run clinical projects, e.g. respiratory BRU
C&C	Capacity and capability assessment is the method by which sites consider whether they can take on a new study. In some cases this needs to be a formal assessment and confirmation, in other cases an email is acceptable.
CA	Competent Authority: organisation approving the testing of new drugs/devices or approving the marketing licences, in the UK this is the MHRA
CI	Chief Investigator: The lead investigator with overall responsibility for the research. In a multisite study, the CI has coordinating responsibility for research at all sites. The CI may also be the PI at the site in which they work. In the case of a single-site study, the CI and the PI will normally be the same person and are referred to as PI.
CPMS	Central Portfolio Management System: a national system that will enable the NIHR CRN to capture high quality study information and produce a range of detailed reports to help manage and deliver studies.
Clinical Research	Clinical research aims to find out the causes of human illness and how it can be treated or prevented. This type of research is based on examining and observing people with different conditions and sometimes comparing them with healthy people.
CRA	Clinical Research Associate: usually a commercially employed person supporting the management of clinical studies, helps with obtaining R&D approval, site initiation, study monitoring and close out. Sometimes known as a 'monitor'
CRF	Clinical Research Facility: are purpose built facilities in NHS hospitals where researchers can deliver early-phase and complex studies. Case Report Forms: data collection tools provided by a sponsor on which the clinical data is recorded for each participant, such as weight, lab results, symptoms.
CRN	Clinical Research Network: provides the infrastructure that allows high-quality clinical research and meets the costs of using NHS staff that support research and provides specialist training so that patients can be confident that research is being delivered by trained, experienced NHS staff.

CRO	Clinical Research Organisation or Contract Research Organisation: 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
CSAG	Clinical Studies Advisory Group.
Clinical trial	An experiment to compare the effects of two or more healthcare interventions. 'Clinical trial' is an umbrella term for a variety of healthcare trial designs.
CTA	Clinical Trials Authorisation: The regulatory approval for a clinical trial of a medicinal product issued by the MHRA. Clinical Trials Agreement: contract between the legal Sponsor and the hosting research sites. Clinical Trials Administrator: person providing coordinating/secretarial support for running clinical studies.
CTIMP	Clinical Trial of an Investigational Medicinal Product.
CTU	Clinical Trials Unit: Specialist units with a specific remit to design, conduct, analyse and publish clinical trials and other well-designed studies.
Cluster randomised trial	A trial where clusters of individuals (e.g. clinics, families, geographical areas), rather than individuals themselves, are randomised to different arms.
Comparator	An investigational or marketed product (i.e. active control) or placebo, used as a reference in a clinical trial.
Confidentiality	During a research project, the researchers must put data protection measures into place, to ensure that all of the information collected about the participants is kept confidential. This means that the researchers must get the participants' written permission to look at their medical or social care records. It also means that any information that might identify the participants cannot be used or passed on to others, without first getting the participants' consent. For example, when researchers publish the results of a project, they are not allowed to include people's names. This confidentiality will only be broken in extreme circumstances: where it is essential for the person's care, treatment or safety, where it is required by a court order, for example in a criminal investigation, or where it is necessary to protect the public.

Control	A participant in the arm that acts as a comparator for one or more experimental interventions. Controls may receive placebo, no treatment, standard treatment, or an active intervention, such as a standard drug.
Control Group	The comparison group in the randomised trial. Those who are in the control group (or arm) will not receive the new medication, device or treatment that is under study, but will provide a comparison to see how the innovation compares against no treatment or a known treatment.
Controlled trial	A type of clinical trial in which observations made during the trial are compared to a standard (called the control). The control may be a group of participants in the same trial or observations from outside the trial (for example, from an earlier trial, called a “historical control”).
Data	Data is the information collected through research. It can include written information, numbers, sounds and pictures.
Data Analysis	Data analysis involves examining and processing research data, in order to answer the questions that the project is trying to address. It involves identifying patterns and drawing out the main themes and is often done with specialist computer software.
Data protection	All personal information is protected in the UK by the Data Protection Act 2018. This means that researchers have to put in all the necessary safeguards to protect the confidentiality of the information they collect about research participants. They should explain in the patient information sheet: how the participants’ data will be collected, how it will be stored securely, what it will be used for, who will have access to the data that identifies participants, how long it will be kept and how it will be disposed of securely.
DQ	Data query.
Delegation of Duties log	Document detailing who has been delegated each duty by the Principal Investigator.
DMC	A Data Monitoring Committee: a 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.
Double blind	A trial where the investigators and the subjects included in the trial (healthy volunteers or patients) do not know which interventions / treatments have been assigned.

eCRF	An electronic Case Report Form.
Efficacy	The extent to which an intervention produces a beneficial result under ideal conditions. Clinical trials that assess efficacy are sometimes called explanatory trials.
Eligibility	A clinical assessment of whether the potential participant meets the inclusion and exclusion criteria for the study as described in the protocol
Eligibility criteria	The key standards that people who want to participate in a clinical study must meet or the characteristics that they must have. These include inclusion criteria and exclusion criteria. For example, a study might only accept participants who are above or below certain ages.
EMA	The European Medicines Agency: A body of the European Union which has responsibility for the protection and promotion of public health through the evaluation and supervision of medicines for human use
Enrolment	The act of admitting a participant into a trial. Participants should be enrolled only after study personnel have confirmed that all the eligibility criteria have been met.
Equipoise	A state of uncertainty where a person believes it is equally likely that either of two treatment options is better.
Ethics	Ethics are a set of principles that guide researchers who are carrying out research with people. Ethical principles are designed to protect the safety, dignity, rights and well-being of the people taking part. They include the requirement to ask each individual to give their informed consent to take part in a research project.
Ethics Committees	The job of an ethics committee is to make sure that research carried out respects the dignity, rights, safety and well-being of the people who take part. Increasingly ethics committee approval is needed for health and social care research. Ethics committee members include researchers and health care professionals as well as members of the public.
Exclusion Criteria	Specific criteria which are defined within the study protocol that expressly exclude specific individuals from participating in a study. The reasons for considering exclusion can range from safety issues, potential difficulties in management of particular participants or the need to control variables within the study. Exclusion criteria must always be defended ethically to guard against discrimination.
ETC	Excess Treatment Cost: if the study treatment costs more than standard

	NHS care, the difference is paid for by the local clinical research network.
FDA	Food and Drug Administration: The Competent Authority in the United States, giving authorisation to conduct clinical trials and issuing marketing licences
Feasibility	The process of reviewing the protocol to determine whether or not a study can be safely and effectively delivered.
Feasibility studies	Feasibility Studies are pieces of research done before a main study in order to answer the question "Can this study be done?". They are used to estimate important parameters that are needed to design the main study.
Focus Group	A focus group is a small group of people brought together to talk. The purpose is to listen and gather information. It is a good way to find out how people feel or think about an issue, or to come up with possible solutions to problems.
Follow up	The observation over a period of time of study/trial participants to measure outcomes under investigation.
Funder	An organisation providing funding for a study (through agreements, grants or donations to an authorised member of the employing and/ or care organisation). The main funder typically has a key role in scientific quality assurance. In any case, it remains responsible for securing value for money.
GAfREC	Governance Arrangements for Research Ethics Committees
Gold standard	The method, procedure, or measurement that is widely accepted as being the best available, against which new developments should be compared.
GCP	Good Clinical Practice: GCP is an international ethical and scientific quality standard for designing, recording and reporting studies. The aim of GCP is to ensure the rights, safety and wellbeing of study participants are protected and research data is high quality
GMP	Good manufacturing practice: quality assurance standard for producing Investigational Medicinal Products (IMP).
HRA	The Health Research Authority: An NHS organisation established to protect and promote the interests of patients and the public in health research.
HRA Approval	The process for the NHS in England that brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff,

	with the independent REC opinion provided through the UK Health Departments' Research Ethics Service.
Health technology	Health Technology is an internationally recognised term that covers any method used by those working in health services to promote health, prevent and treat disease and improve rehabilitation and long-term care. "Technologies" in this context are not confined to new drugs or pieces of sophisticated equipment.
Honorary contract	Honorary contracts are required by anyone who wants to carry out research or observe people in an NHS setting, but who does not already have an employment contract or a volunteer contract with the relevant NHS Trust. The contract ensures that they are covered by NHS liability insurance, and that they are contractually bound to take proper account of the NHS duty of care.
Implementation	Implementation involves putting research findings into practice. This means using research findings to make appropriate decisions and changes to health and social care policy and practice.
Incapacitated adult	An adult unable by virtue of physical or mental incapacity to give informed consent.
Inclusion criteria	Specific criteria that are defined within the study protocol that expressly include specific individuals to participate in a study e.g. individuals within a certain age range, with a specific condition, etc.
Indemnity	Compensation for damage, loss or injury
Informed Consent	A process by which a participant 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 decision to participate.
ICF	Informed Consent Form
IRAS	Integrated Research Application System: A single, web-based system for completing applications for the permissions and approvals required for health and social care research in the UK.
Interim analysis	Analysis comparing intervention groups at any time before the formal completion of a trial, usually before recruitment is complete. Often used with stopping rules so that a trial can be stopped if participants are being put at risk unnecessarily. Timing and frequency of interim analyses should be specified in the protocol.

Intervention	The process of intervening on people, groups, entities or objects in an experimental study. In controlled trials, the word is sometimes used to describe the regimens in all comparison groups, including placebo and no-treatment arms.
Intervention group	A group of participants in a study receiving a particular health care intervention. Parallel group trials include at least two intervention groups.
Interventional trial	A clinical study in which participants are assigned to receive one or more interventions (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study protocol. Participants may receive diagnostic, therapeutic, or other types of interventions.
IB	Investigator's Brochure: A compilation of clinical and pre-clinical pharmacological/biological data relevant to the use of that IMP(s) in human subjects (one single IB for all trials using the same IMP)
IMP	Investigational Medicinal Product: an unlicensed new drug, an existing drug tested outside its licence, or existing drugs tested against each other for their efficacy/safety.
ISF	Investigator Site File: A file designed for use in organising and collating all essential documentation required to conduct a study in accordance with the principles of GCP and the applicable regulatory requirements (e.g. REC approval letter/correspondence, MHRA approval, blank CRF, staff CVs, delegation of duties log etc.)
Lay summary	A lay summary is a brief summary of a research project or a research proposal that has been written for members of the public, rather than researchers or professionals. It should be written in plain English, avoid the use of jargon and explain any technical terms that have to be included.
LCRN	Local Clinical Research Network
LIP	Local Information Pack: A consistent set of documents for study setup across England, Northern Ireland, Scotland and Wales. It contains the OID, SoECAT and delegation log as a minimum.
LoA	Letter of Access: a letter (or annexe to a letter giving NHS permission for research) to confirm responsibilities of NHS employees or staff with an honorary clinical contract with an NHS organisation. It may be used for one project or a series of projects.

LoAA	Letter of Access Assurance: This is a letter that provides confirmation to a practice that the named researcher has undergone all the relevant pre-engagement checks.
LPMS	Local Portfolio Management System: local systems which capture high quality study information and integrate with CPMS and ODP
Medical Device	Any instrument, apparatus, implement, machine, appliance, implant, software, material, or similar that can be used for: diagnosis, prevention, monitoring, treatment or alleviation of disease.
MCA	Mental Capacity Act.
mCIA	model Clinical Investigation Agreement: for medical devices, covers the running of the study, not design of prototype or design of protocol; standard template for the UK (use is not obligatory)
mCTA	model Clinical Trial Agreement: for IMP studies with commercial sponsor/CRO conducted. A list of model agreements can be found at - https://www.myresearchproject.org.uk/help/hlptemplatesfor.aspx#Contracts-Agreements
MHRA	Medicines and Healthcare products Regulatory Agency: The UK Competent Authority (CA) and licensing authority for medicines and medical devices
mNCA	model Non-Commercial Agreement: for clinical research studies; standard template for the UK (use is not obligatory)
Monitor	The person designated by the sponsor to perform site visits and conduct the monitoring process; e.g. check whether there are any deviations from the protocol and that all source data was transferred into the Case Report Forms correctly.
MRC	Medical Research Council: the main UK Government source of funds for biomedical and early stage clinical research.
Multicentre trial	A study conducted according to a single protocol but carried out at more than one site and by more than one investigator, particularly when large numbers of participants are needed.
ND	Not done (in CRFs)
NIHR	National Institute for Health Research: established by Department of Health for England in 2006 to provide the framework through which DHSC will position, manage and maintain the research, research staff and

	infrastructure of the NHS in England as a virtual national research facility
NIHR CRN	National Institute for Health Research Clinical Research Network
NK	Not known (in CRFs)
Non-CTIMP/NIMP	Any research study that is not a clinical trial of an investigational medicinal product.
Non-inferiority trial	A trial designed to determine whether the effect of a new treatment is not worse than a standard treatment by more than a pre-specified amount.
Nonsubstantial amendments	Changes to the details of a study that have no significant implications for the subjects, the conduct, the management or the scientific value of the study (sometimes referred to as administrative amendments).
Observational study	A study in which the investigators do not seek to intervene, but simply observe the course of events.
ODP	Open Data Platform: an online, open platform which provides secure access to collated study and recruitment data.
OID	Organisation Information Document: Part of the LIP, provides information to participating NHS organisations to support the setup of research and for non-interventional trials, this can be used as the agreement.
Open label	Describes a clinical trial in which blinding/masking is not used. That means that all parties involved with the trial know which participants have been assigned which interventions.
Outcome	A component of a participant's clinical and functional status after an intervention has been applied, that is used to assess the effectiveness of an intervention.
Participant	An individual who is studied in a trial, often, but not necessarily, a patient.
Patient and public involvement	Also known as PPI, involvement or public involvement. An active partnership between patients and the public and researchers in the research process, rather than the use of people as ‘subjects’ of research. Patient and public involvement in research is often defined as doing research ‘with’ or ‘by’ people who use services rather than ‘to’, ‘about’ or ‘for’ them. This includes, for example, working with research funders to prioritise research, offering advice as members of a project steering group, commenting on and developing research materials, and undertaking interviews with research participants. When using the term ‘public’ we include patients, potential patients, carers and people who use

	health and social care services as well as people from organisations that represent people who use services.
PI	Principal Investigator: The lead person at a single site designated as taking responsibility within the research team for the conduct of the study. Responsible for all aspects of the study conduct at a site
PIC	Participant Identification Centre: NHS or other organisation which only identifies participants from a database etc, but recruitment/receiving consent and study conduct are managed elsewhere
PIS	Participant or Patient Information Sheet: An information sheet given to those who have been invited to participate in a research study. The sheet is designed to provide the potential participant with sufficient information to allow that person to make an informed decision on whether or not they want to take part
Pilot studies	Pilot studies are a smaller version of the main study used to test whether the components of the main study can all work together. It is focused on the processes of the main study, for example to ensure that recruitment, randomisation, treatment, and follow-up assessments all run smoothly.
Placebo	An inactive substance or procedure administered to a participant, usually to compare its effects with those of a real drug or other intervention. Placebos are used in clinical trials to blind people to their treatment allocation. Placebos should be indistinguishable from the active intervention to ensure adequate blinding.
Preclinical study	Research using animals to find out if a drug, procedure, or treatment is likely to be useful. Preclinical studies take place before any testing in humans is done.
Primary outcome	The outcome of greatest importance.
Protocol	The protocol is the most important document in a study as it sets out what will happen in the study, why, when, how and by whom. The protocol states how scientific integrity and data quality are to be achieved in the study and helps to ensure the rights, safety and wellbeing of participants are protected
Qualitative research	Qualitative research is used to explore and understand people's beliefs, experiences, attitudes or behaviours. It asks questions about how and why. Qualitative researchers use methods like focus groups and interviews (telephone and face-to-face interviews). This research does not

	collect data in the form of numbers but might collect data in the form of interview transcripts, or notes from focus groups.
Quantitative research	In quantitative research, researchers collect data in the form of numbers. So they measure things or count things. Quantitative research might ask a question like how many people visit their GP each year, or what proportion of children have had an MMR vaccine. Quantitative researchers use methods like clinical trials.
Randomisation	The process by which participants in clinical trials are assigned by chance to separate groups that are given different treatments or other interventions. Neither the researcher nor the participant chooses which treatment or intervention the participant will receive.
Randomised controlled trial (RCT)	A randomised controlled trial is a clinical trial in which two (or more) forms of care are compared, the participants are allocated to one of the forms of care in the study, in an unbiased way.
Research Costs	Research Costs are incurred by any activities that are being undertaken to answer the research question, they are not care costs. Research Costs are paid to research sites by the central study team.
Research Governance	Research governance is a process aimed at ensuring that research is high quality, safe and ethical.
Research Methods	Research methods are the ways researchers collect and analyse information. Research methods include interviews, questionnaires, diaries, clinical trials, experiments, analysing documents or statistics, and watching people's behaviour.
Retrospective study	A study in which the outcomes have occurred before the study commenced. Case-control studies and cohort studies can be retrospective, but randomised controlled trials never are.
R&D	Research and Development: often name of Department within NHS hospitals giving permission to conduct projects on those facilities with patients/staff.
REC	Research Ethics Committee: authorised by the HRA to review study documents for research taking place in the NHS, or social services. Some REC specialise in Clinical Trials, or topics such as research in children, MCA. All Research in NHS/social services must have been reviewed by a UK REC.
Research	A system for HEI employed researchers/postgraduate students who need

Passport	to undertake their research within NHS organisations, which provides evidence of the pre-engagement checks undertaken on that person in line with NHS Employment Check Standards (among them CRB and occupational health checks)
RGF	UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research v3.3 07/11/17
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
Secondary outcome	An outcome used to evaluate additional effects of an intervention deemed as being less important than the primary outcomes.
Screening	The process of identifying eligible patients prior to approaching them to determine if they are willing to consent to participate in the study
SoECAT	Schedule of Events Cost Attribution Template:
SDV	Source Data Verification: checking the original data record, such as lab reports, patient medical notes against what was transferred onto the CRF/into a database
Site	The NHS organisation in which study activities and assessment are performed or the location(s) where trial-related activities are actually conducted.
SIV	Site initiation visit.
SLA	Service Level Agreement.
SmPC	Summary of Product Characteristics: smaller version of Investigator Brochure with details on pharmacological effects, side effects, but issued for a product that already holds a marketing licence.
SOP	Standard Operating Procedure: detailed written instructions designed to achieve uniformity of the performance of a specific function.
Source Data	Source Data is the first record of any interactions with participants and any data relating to them. The source data gathered at site is the foundation of all other activity in the study.
Sponsor	Sponsor takes responsibility for the initiation, management and financing, or arranging financing, of the study. The sponsor appoints the CI.

SSCs	Service Support Costs: the costs that arise because someone in the NHS is carrying out an activity to support the research taking place. Eg. Identifying and recruiting study participants. These costs are covered by a fund administered by the NIHR and are paid to research sites via the local clinical research network.
Substantial Amendment	An amendment to the protocol or any other study specific documentation, the terms of the REC application or the terms of the CTA application (as applicable) that is likely to affect to a significant degree the safety or physical or mental integrity of the participants or the scientific value of the trial.
SUSAR	Suspected Unexpected Serious Adverse Reaction: A Serious Adverse Reaction (SAR) which is Unexpected (i.e. its nature and severity is not consistent with the known information about that product from the Investigator's Brochure or the SmPC) and suspected, as it is not possible to be certain of causal relationship with the IMP
TMF	Trial Master File (file with essential documents held by the Chief Investigator/Sponsor organisation)
UKCRC	United Kingdom Clinical Research Collaboration
UNK	Unknown (in CRFs)