Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Ariennir gan **Lywodraeth Cymru**
Funded by **Welsh Government**

Health and Care Research Wales Jargon Buster

A

ABPI	Association of the British Pharmaceutical Industry : A trade association for UK pharmaceutical companies
Abstract	This is a brief summary of a research study and its results. It should tell you why the study was done, how the researchers went about it and what they found.
ACFs	Academic Clinical Fellowships
Action Research	Action research is used to bring about improvement or practical change. A group of people who know about a problem work together to develop an idea about how it might be resolved. They then go and test this idea. The people who take part in the testing provide feedback on their experiences. They may also identify further actions that need to be researched and tested. This cycle of developing solutions and testing them is repeated until the problem has been solved
Adverse event (AE)	An unfavourable outcome that occurs during or after the use of a drug or other intervention, but is not necessarily caused by it.
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.
AHPs	Allied Health Professionals
Allocation Concealment	A technique used to prevent selection bias by concealing the allocation sequence from those assigning participants to intervention groups, until the moment of assignment. Allocation concealment prevents researchers from (unconsciously or otherwise) influencing which participants are assigned to a given intervention group.
Amendment	A written description of a change or formal clarification. Substantial amendments (See below under 'Substantial Amendment') to protocol, participant information/consent require REC, R&D, MHRA approval, Non-substantial amendments should be 'notified' to REC, R&D, MHRA
AMRC	Association of Medical Research Charities
AMS	Academy of Medical Sciences
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.
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.

ARSAC	Administration of Radioactive Substances Advisory Committee: A Department of Health committee established to advise Health Ministers on applications for Certificates to administer Radioactive Medicinal Products to human subjects
ASR	Annual Safety Report: For studies involving the use of an Investigational Medicinal Product, this is the annual report which must be submitted to the MHRA detailing all SUSARs and SAEs that have occurred in subjects on that study in the past year
ATIMP	Advanced Therapy Investigational Medicinal Products. Means an ATMP as defined in Article 2(1) of Regulation 1394/2007 which is tested or used in a clinical trial (in accordance with Article 2(d) of Directive 2001/20/EC).
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.

B

Basic Research	Basic research aims to improve knowledge and understanding, rather than finding a solution to a practical problem. It usually involves work in a laboratory – for example to find a gene linked to a disease or to understand how cancer cells grow. This kind of research can sometimes provide clues as to which avenues to explore to develop new treatments.
BIA	Bio Industry Association
Bias	A systematic error or deviation in results or inferences from the truth. In studies of the effects of health care, the main types of bias arise from systematic differences in the groups that are compared (selection bias), the care that is provided, exposure to other factors apart from the intervention of interest (performance bias), withdrawals or exclusions of people entered into a study (attrition bias) or how outcomes are assessed (detection bias). Reviews of studies may also be affected by reporting bias, where a biased subset of all the relevant data is available.
Blinding	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.
Blog	A website or web page that contains information or promotes discussion and consists of discrete entries (also called posts) written over a period of time. The most recent post usually appears first.
BP	Blood pressure
BRCs	Biomedical Research Centres: larger centre covering a number of topics with facilities and research active clinicians/academics/research nurses to run clinical projects
BRUs	Biomedical Research Units: topic-focused centre which usually combines facilities and research active clinicians/academics/research nurses to run clinical projects, e.g. respiratory BRU

C

CAT	Clinical Academic Training Programme
CI	Chief Investigator: The lead investigator with overall responsibility for the research. In a multi-site 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.
CF/ICF Consent form	Consent Form (also ICF, Informed Consent Form)
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. It can also involve research on samples of blood or other tissues, or tests such as scans or X-rays. Clinical researchers will also sometimes analyse the information in patient records, or the data from health and lifestyle surveys.
Clinical Trial Notification Scheme	For certain 'Type A' trials notification of the trial to the MHRA is possible. Type A trials are those involving medicinal products licensed in any EU Member State if: • they relate to the licensed range of indications, dosage and form; or • they involve off-label use (such as in paediatrics and oncology, etc) if this off-label use is established practice and supported by sufficient published evidence and/or guidelines. See the MHRA website for further information.
Clinical Trials Regulations	A term used to describe The Medicines for Human Use (Clinical Trials) Regulations (SI 2004 1031) and its amendments.
Closed Facebook group	When a Facebook group is closed, only those who have been invited into a group can see the content and information shared within it. Others will still be able to see that the group exists and who its members are, but they will not be able to see any posts or information within the closed group unless they are invited. Only the creator of the group and anyone they make an administrator has the power to invite someone to a group. For more information see http://facebook.about.com/od/ PagesGroups/ss/Everything-You-Need-To-Know-AboutFacebook-Groups.htm
Cluster randomised trial	A trial where clusters of individuals (e.g. clinics, families, geographical areas), rather than individuals themselves, are randomised to different arms.
Co-sponsor	Where two or more organisations share a significant interest in a study, they may elect to act as co-sponsors.
Cochrane collaboration	The Cochrane Collaboration is an international, non-profit, independent organisation. It ensures that up-to-date and accurate information about the effects of healthcare interventions is readily available worldwide. It produces and disseminates systematic reviews of healthcare interventions, and promotes the search for evidence in the form of clinical trials and other studies on the effects of interventions.
Cohort study	An observational study in which a defined group of people (the cohort) is followed over time. The outcomes of people in subsets of this cohort are compared, to examine people who were exposed or not exposed (or exposed at different levels) to a particular intervention or other factor of interest. A prospective cohort study assembles participants and follows them into the future. A retrospective (or historical) cohort study identifies subjects from past records and follows them from the time of those records to the present.
Collaboration	Collaboration involves active, on-going partnership with members of the public in the research process. For example, members of the public might take part in an **advisory group** for a research project, or collaborate with researchers to design, undertake and/or **disseminate** the results of a research project.

Commissioned calls	Calls for proposals based on pre-defined research questions developed to respond to the information needs of decision-makers (typically, but not exclusively, within the NHS).
Commissioned workstreams	Commissioned workstreams start with the information needs of decision makers typically, but not exclusively, within the NHS. These are refined and prioritised by experts in the field, and commissioning briefs are then advertised. Applications are assessed for compliance with the commissioning brief, scientific quality, feasibility and value for money.
Commissioner	A commissioner is the person (or organisation) who asks for a piece of research to be carried out.
Commissioning	Commissioning usually involves: • identifying funding for a piece of research • preparing a **research brief** • advertising the research topic • selecting a shortlist of researchers who apply to undertake the research • arranging for proposals to be **peer reviewed** • making a decision about which researchers are going to be awarded the funding • agreeing a contract.
Commissioning board	A commissioning board is a group of people who oversee the **commissioning** process. It is made up of research funders, researchers, health and/or social care professionals and often includes people who use services and carers.
Commissioning brief	A detailed description of a question to be answered by new research. In responding to a commissioning brief, researchers outline what studies they would undertake to obtain the information required.
Comparator	An investigational or marketed product (i.e. active control) or placebo, used as a reference in a clinical trial.
CA Competent Authority	Each member state in the European Economic Area has appointed a competent authority to perform certain functions required by Directive (2001/20/EC). The MHRA (the UK's licensing authority established under the Medicines Act 1968) is the competent authority in the UK.
Confidence Interval	A measure of the uncertainty around the main finding of a statistical analysis. Wider intervals indicate lower precision and narrow intervals indicate greater precision.
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.
Confounder	A factor that is associated with both an intervention and the outcome of interest. For example, if people in the experimental group of a controlled trial are younger than those in the control group, it will be difficult to decide whether a lower risk of death in one group is due to the intervention or the difference in age. Age is then said to be a confounder, or a confounding variable. Randomisation is used to minimise imbalances in confounding variables between experimental and control groups. Confounding is a major concern in non-randomised trials.

Consultation	Consultation involves asking members of the public for their views about research, and then using those views to inform decision-making. This consultation can be about any aspect of the research process – from identifying topics for research, through to thinking about the implications of the research findings. Having a better understanding of people's views should lead to better decisions.
Consumer	The term consumer is used to refer collectively to: • people who use services • carers • organisations representing consumers' interests • members of the public who are the potential recipients of services • groups asking for research to promote good health or because they believe they have been exposed to potentially harmful circumstances, products or services.
Contamination	The unintended application of the intervention being evaluated to people in the control group; or unintended failure to apply the intervention to people assigned to the intervention group.
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/Arm	The groups being compared in the randomised trial. Also referred to as "study groups", "treatment groups", "the arms" of a trial, or by individual terms such as treatment and control groups.
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 observations from a group of participants in the same trial or observations from outside the trial (for example, from an earlier trial, called a "historical control").
Cost-effectiveness	A measure addressing the cost implications of achieving health benefits. To facilitate comparisons, health benefits can be quantified in terms of 'QALYs' (Quality-Adjusted Life Years), which incorporate both extra life achieved and improvements in quality of life. Knowing the cost associated with each QALY gained can help decision-makers assess whether the introduction of a treatment or service should be recommended.
CQC	Care Quality Commission
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
CRN	Clinical Research Network
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
CRF Case Report Form	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
CRF	Clinical Research Facility: hospital-like facility with consulting rooms, standard patient beds, ward medical equipment, research nurses supporting only research
CSAG	Clinical Studies Advisory Group
CSG	Clinical Studies Group
CTA	Clinical Trials Administrator: person providing coordinating/secretarial support for running clinical studies
CTA	Clinical Trials Agreement: contract between the legal Sponsor and the hosting research sites
CTA	Clinical Trials Authorisation: The regulatory approval for a clinical trial of a medicinal product issued by the MHRA

CT Toolkit	Clinical Trials Toolkit
CTAAC	Clinical Trials Advisory and Awards Committee
CTIMP	Clinical Trial of an Investigational Medicinal Product
CTD	Clinical Trials Directive
CTR	Clinical Trials Regulation
CTU	Clinical Trials Unit: Design and manage CTIMPs, sometimes in specialist clinical areas, such as Cancer, or types of trial, such as RCTs
CV	Curriculum Vitae

D

Data	Data is the information collected through research. It can include written information, numbers, sounds and pictures. It is usually stored on computer, so

	that it can be analysed, interpreted and then communicated to others, for example in reports, graphs or diagrams.
Data Monitoring Committee (DMC) (also known as DMEC, IDMC, DSMB and ISMC)	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.
DPA	Data Protection Act
DQ	Data query
Delegation log	Document detailing who has been delegated each duty by the Principal Investigator.
Dementia TRC	Dementia Translational Research Collaboration
DeNDroN	Dementias and Neurodegenerative Diseases Research Network
DH	Department of Health (for England)
Diagnostic test	This is a definition that has been agreed by the EME, PHR, HTA, RfPB and i4i programmes. A diagnostic test is an indicator or predictor of an illness state. As such, the term needs to be interpreted broadly as it includes diagnostic tests, screening, tests to stage disease, treatment monitoring, and estimate prognosis estimation. There are a number of types of diagnostic study that will be considered by the NIHR: • The first of these is the development of a new test or instrument and/or the broad assessment of its reliability and validity. These might range from questionnaires that identify mental states to molecular assays. Test development and/or testing for psychometric properties or analytic validity, as it is called in the ACCE framework, are only supported to the extent that the test technology is well-developed and forms part of a clear pathway into further research which directly promotes patient benefit • Diagnostic accuracy studies examine the clinical validity of a test, i.e. whether the changes in the measure reflect changes in disease state or risk, and usually assess a new test against a gold-standard or reference one. Such studies are likely to report sensitivity and specificity, positive and negative predictive values and Receiver Operating Characteristic (ROC) curve in a defined population • Diagnostic utility studies examine the value of a diagnostic test in improving patient outcomes and are often designed as trials and powered on relevant clinical endpoints. Economic outcomes may also be important.
DIPEx	Database of Individual Patient Experience – the DIPEx website has a range of open source videos of real patient experiences http://www.healthtalk.org/
Dissemination	Dissemination involves communicating the findings of a research project to a wide range of people who might find it useful. This can be done through: • producing reports (often these are made available on the Internet) • publishing articles in **journals** or newsletters • issuing press releases • giving talks at conferences. It is also important to feedback the findings of research to research **participants**.
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.
DRFs	Doctoral Research Fellowships
DRN	Diabetes Research Network
DSUR	Development Safety Update Report: In addition to the expedited reporting required for SUSARs, Sponsors are required to submit a safety report (DSUR) to

	the MHRA and Research Ethics Committee, once a year throughout the clinical trial or on request

E

Economic analysis (economic evaluation)	Comparison of the relationship between costs and outcomes of alternative healthcare interventions.
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
EM	Experimental Medicine
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
Emancipatory research	With emancipatory research, people who use services, rather than professional researchers, have control of the whole research process. They plan and undertake the research, and interpret the findings. The main aim is always to empower people and improve people's lives. 'Professional' researchers may be brought in as advisers or have specified roles within the project.
Empowerment	This is the process by which people who use services equip themselves with the knowledge, skills and resources they need to be able to take control over decisions and resources. It often involves people building confidence in their own strengths and abilities. It does not always mean people take control over all decisions or all resources.
Engagement	Where information and knowledge about research is provided and disseminated, for example science festivals, open days, media coverage.
ENRICH	Enabling Research in Care Homes
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. Formal enrolment must occur before randomised assignment.
EudraCT	European Clinical Trials Database: A database of all clinical trials in Europe, held since 1994 in accordance with EU directive 2001/20/EC
Epidemiology	The study of population and community health, not just individuals.
Equipoise	A state of uncertainty where a person believes it is equally likely that either of two treatment options is better.
Essential Documents (EDs)	The essential documents relating to a clinical trial are those which enable both the conduct of the clinical trial and the quality of the data produced to be evaluated; and show whether the trial is, or has been, conducted in accordance with the applicable regulatory requirements.
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.
EU Clinical Trials Register	The website providing the public with information held in the EU clinical trial database, EudraCT. It provides the public with information on clinical trials which have been authorised in the EEA and also those which are part of a PIP (Paediatric Investigation Plan). It gives users the ability to search for information on any paediatric clinical trial and any adult clinical trial recorded in EudraCT.

EudraVigilance Clinical Trials Module (EVCTM)	Part of the EudraVigilance data processing network and management system to facilitate the electronic reporting of Suspected Unexpected Serious Adverse Reactions (SUSARs) as required by Directive 2001/20/EC.
European Commission (EC)	The European Commission is the executive body of the European Union, responsible for proposing legislation, implementing decisions, and day-to-day running of the EU.
Evaluation	This involves assessing whether an **intervention** (for example a treatment, service, project, or programme) is achieving its aims. A project can be evaluated as it goes along or right at the end. An evaluation can measure how well the project is being carried out as well as its impact. The results of evaluations can help with decision-making and planning.
Evaluative research	Evaluative research seeks to assess or judge in some way, providing useful information about something which cannot be gleaned by mere observation or investigation of relationships.
Evidence base	An evidence base is a collection of all the research **data** currently available about a health or social care topic, such as how well a treatment or a service works. This evidence is used by health and social care professionals to make decisions about the services that they provide and what care or treatment to offer people who use services.
Evidence synthesis	Evidence synthesis involves the development of techniques to combine multiple sources of quantitative and qualitative data to derive best evidence for use in healthcare.
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.
eCRF	An electronic CRF
eTMF	An electronically stored TMF

F

Factorial design	A trial design used to assess the individual contribution of treatments given in combination, as well as any interactive effect they may have. In a trial using a 2×2 factorial design, participants are allocated to one of four possible combinations. This type of study is usually carried out in circumstances where no interaction is likely.
Feasibility	The process of reviewing the protocol to determine whether or not a study can be safely and effectively delivered
FAQ	Frequently Asked Questions
Fast-track	A streamlined system used in some NETS programmes under exceptional circumstances to speed up the assessment of proposals.
Feasibility	This is a definition that has been agreed by the EME, PHR, HTA and RfPB programmes. 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. For instance: • standard deviation of the outcome measure, which is needed in some cases to estimate sample size; • willingness of participants to be randomised; • willingness of clinicians to recruit participants; • number of eligible patients, carers or other appropriate participants • characteristics of the proposed outcome measure and in some cases feasibility studies might involve designing a suitable outcome measure; • follow-up rates, response rates to questionnaires, adherence/compliance rates, ICCs in cluster trials, etc. • availability of data needed or the usefulness and limitations of a particular database • time needed to collect and analyse data
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	A process of periodic contact with participants enrolled in the trial for the purpose of administering the assigned intervention(s), modifying the course of intervention(s), observing the effects of the intervention(s), or for data collection.
FP	Fellowships Programme
Full and appropriate funding	Full and appropriate funding is provided because no upper limit is placed on the amount of funding granted for a project. Subject to availability of funds, if the question is important enough and the science requires it, we will fund it. For University based projects, we will fund up to 80 per cent of the Full Economic Cost (FEC) of the research, and 100 per cent of the direct costs for NHS Trust based projects. Other organisations are welcome to apply to our programmes and should discuss costing with us.
Funder	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.
Funding committee	A group of experts who consider grant applications and reviewer reports to decide whether to recommend funding.

G

GLP	Good Laboratory Practice: standard for laboratories involved in pre-clinical analyses (e.g. animal, in vitro); does not apply to Laboratories analysing samples from clinical trials involving humans
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 (GMP) is that part of quality assurance which ensures that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorisation (MA) or product specification.
Generalisation	The extent to which the findings of a clinical trial can be reliably extrapolated from the subjects who participated in the trial to a broader patient population and a broader range of clinical settings.
Gold standard	The method, procedure, or measurement that is widely accepted as being the best available, against which new developments should be compared.
GTAC	Gene Therapy Advisory Committee: the ethics committee for clinical studies using genetically modified products; usually no REC approval required

H

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.
HEI	Higher Education Institution
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.
HRA	Health Research Authority
HRC	Honorary Research Contract
HSE	Health and Safety Executive
HTA	Human Tissue Act or Human Tissue Authority
HTA	Health Technology Assessment – one of the NIHR research funding streams
HRA/Health Care Research Wales 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. It replaces the need for local checks of legal compliance and related matters by each participating organisation in England. This allows participating organisations to focus their resources on assessing, arranging and confirming their capacity and capability to deliver the study.
Hypothesis	In a trial, a statement relating to the possible different effect of the interventions on an outcome. The null hypothesis of no such effect is amenable to explicit statistical evaluation by a hypothesis test, which generates a P value

IAT	Integrated Academic Training Programme
ICF	Informed Consent Form
ICH-GCP	International Conference on Harmonisation (Europe, USA, Japan): Defined standards for the terminology, design, conduct, monitoring, recording, analysis and reporting of a study. Section E6 of ICH defines principles of Good Clinical Practice (referred to as ICH-GCP)
IDMC	Independent Data Monitoring Committee
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.
IMP	Investigational Medicinal Product: an unlicensed new drug, or an existing drug tested outside its licence, or existing drugs tested against each other for their efficacy/safety.
Incapacitated Adult	An adult unable by virtue of physical or mental incapacity to give informed consent.
Inclusion Criteria	Specific criteria which 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	Insurance or indemnity includes provision for meeting losses or liabilities— a) under a scheme established under— i) section 21 of the National Health Service and Community Care Act 1990 (schemes for meeting losses and liabilities etc. of certain health service bodies in England and Wales)(**d**), ii) section 85B of the National Health Service (Scotland) Act 1978 (schemes for meeting losses and liabilities etc. of certain health service bodies in Scotland)(**e**), or iii) Article 24 of the Health and Personal Social Services (Northern Ireland) Order 1991(schemes for meeting losses and liabilities etc. of certain health service bodies in Northern Ireland)(**f**), or b) in accordance with guidance issued by— i) the Secretary of State, ii) the Scottish Ministers, iii) the National Assembly for Wales, or iv) the Department for Health, Social Services and Public Safety, As to the arrangements to be adopted by health service bodies for meeting the costs arising from clinical negligence (known as NHS Indemnity).
Informed Consent (IC)	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. For CTIMPs: A person gives informed consent to take part only if his/her decision: a) is given freely after that person is informed of the nature, significance, implications and risks of the trial; and b) either— i) is evidenced in writing, dated and signed, or otherwise marked, by that person so as to indicate his consent, or ii) if the person is unable to sign or to mark a document so as to indicate his consent, is given orally in the presence of at least one witness and recorded in writing.
Inspection	The act by a competent authority of conducting an official review of documents, facilities, records, quality assurance arrangements, and any other resources that are deemed by the competent authority 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 organisation's facilities, or at other establishments which the competent authority sees fit to inspect. In the UK, the MHRA's Good Clinical Practice (GCP) Inspectorate is part of the Inspection, Standards and Enforcement Division of the MHRA.
Intellectual Property (IP)	IP can be described as the novel or previously undescribed tangible output of any intellectual activity. It has an owner and can be bought, sold or licensed and must be adequately protected. It can include inventions, industrial processes, software, data, written works, designs and images.
Interactive website	A website that encourages people to interact with it, rather than just offering information or selling products. For example it might invite contributions (e.g. stories, photos, films), comments and blogs; hold online events and discussions; and include open or closed discussion forums.
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.
Internal Agreements	An agreement between an organisation and relevant internal parties. Examples include: 1. Agreements, memoranda or documentation between a ' R&D Office' and clinical and non-clinical support services in order to facilitate engagement and internal authorisation from named support service leads. 2. Agreements between a Principal Investigator / Chief Investigator and support service or stakeholders within an organisation. 3. Agreements between the organisation and relevant party for resources who require an honorary research contract or letter of access. These agreements may be in the form of a standardised document or email format.
International Committee of Medical Journal Editors (ICMJE)	The ICMJE is a group of general medical journal editors whose participants meet annually and fund their work on the Uniform Requirements for Manuscripts
International Conference on Harmonisation (ICH)	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use is a joint initiative involving both regulators and research-based industry focusing on the technical requirements for medicinal products containing new drugs to establish common standards for clinical trials.
International Standard Randomised Controlled Trial Number (ISRCTN)	A simple numeric system for the unique identification of randomised controlled trials worldwide. The randomly generated number is unique to a registered trial, thereby ensuring that the trial can be simply and unambiguously tracked throughout its lifecycle. The ISRCTN Register also accepts registration of other forms of studies designed to assess the efficacy of health-care interventions.
Intervention	An intervention is something that aims to make a change and is tested through research. For example, giving a drug, providing a counselling service, improving the environment or giving people information and training are all described as interventions.
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.
Interview	In research, an interview is a conversation between two or more people, where a researcher asks questions to obtain information from the person (or people)

	being interviewed. Interviews can be carried out in person (face-to-face) or over the phone
Investigational Medicinal Product Dossier (IMPD)	The IMPD includes summaries of information related to the quality, manufacture and control of any IMP (including reference product and placebo), and data from non-clinical and clinical studies.
Investigator	Researcher conducting the (clinical) study, those researchers leading the team are referred to as CI or PI
Investigator's Brochure (IB)	A document containing a summary of the clinical and non-clinical data relating to an investigational medicinal product which are relevant to the study of the product in human subjects. Guidance on when an Investigator's Brochure is required can be accessed from the Trial Supplies station.
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.)
INVOLVE	INVOLVE is a national advisory group that supports greater public involvement in NHS, public health and social care research. INVOLVE is funded by and part of the National Institute of Health Research (NIHR).
Involvement	Involvement in research refers to active involvement between people who use services, carers and researchers, rather than the use of people as participants in research (or as research 'subjects'). Many people describe involvement as doing research with or by people who use services rather than to, about or for them.
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. The various applications can be printed or submitted for this single system (includes REC, R&D, MHRA, GTAC, NIGB, ARSAC)
IRMER	Ionising Radiation Medical Exposure Regulations: part of NHS R&D approval, usually done by the local hospital experts
IS	Information Systems Programme
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.)

J

JLA	James Lind Alliance
Joint Sponsor	Where two or more organisations share a significant interest in a study, they may elect to act as joint-sponsors.
Journal	A journal is a regular publication in which researchers formally report the results of their research to people who share a similar interest or experience. Each journal usually specialises in one particular topic area. **The British Medical Journal** (BMJ), **British Journal of Social Work** and **The Lancet** are examples of journals.

K

KMFs	Research Knowledge Mobilisation Fellowships
Knowledge Mobilisation	Getting the right information to the right people in the right format at the right time, so as to influence decision-making. Knowledge Mobilisation includes dissemination, knowledge transfer and knowledge translation.
Knowledge Transfer	https://www.healthandcareresearch.gov.wales/knowledge-transfer/

L

Lay	The term 'lay' means non-professional. In research, it refers to the people who are neither academic researchers nor health or social care professionals.
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.
Legal Representative (in relation to informed consent of vulnerable subjects in CTIMPs)	A person who gives written informed consent on behalf of a vulnerable subject in a CTIMP as defined in Schedule 1, Part 1 (2) of The Medicines for Human Use (Clinical Trials) Regulations, as amended.
Letters of Access	Letters of access enable NHS employees or staff with an honorary clinical contract (e.g. clinical academics) with one NHS organisation to conduct research in another NHS organisation.

M

Marketing Authorisation (MA)	A medicinal product may only be placed on the market in the European Economic Area (EEA) when a marketing authorisation has been issued by the competent authority of a Member State (or EEA country) for its own territory (national authorisation) or when an authorisation has been granted in accordance with Regulation (EC) No 726/2004 for the entire Community (a Community authorisation).
Marketing Authorisation Holder (MAH)	The entity that has been granted a Marketing Authorisation. Marketing Authorisation Holders must be established within the EEA.
MCRN	Medicines for Children Research Network
Medical Device	Any instrument, apparatus, implement, machine, appliance, implant, software, material, or other similar or related article a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of 1. diagnosis, prevention, monitoring, treatment or alleviation of disease, 2. diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury, 3. investigation, replacement, modification, or support of the anatomy or of a physiological process, 4. supporting or sustaining life, 5. control of conception, 6. disinfection of medical devices, and b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means. **Medicines and Healthcare Products Regulatory**
Members of the public (or public)	INVOLVE uses this term to cover: • patients and potential patients • people who use health and social care services • informal (unpaid) carers • parents/guardians • disabled people • members of the public who are potential recipients of health promotion programmes, public health programmes, and social service interventions • groups asking for research because they believe they have been exposed to potentially harmful substances or products (for example pesticides or asbestos) • organisations that represent people who use services. Other organisations have different definitions of this term.
MCA	Mental Capacity Act (2005) Provides a statutory framework to empower and protect vulnerable people who are not able to make their own decisions. It makes it clear who can take decisions, in which situations, and how they should go about this. The research provisions of the Mental Capacity Act 2005 do not apply to the conduct of CTIMPs.
mCTA	model Clinical Trial Agreement: for IMP studies with commercial sponsor/CRO conducted; standard template for the UK (use is not obligatory)
mNCA	model Non-Commercial Agreement: for clinical research studies; standard template for the UK (use is not obligatory)
Mentor	A mentor is a person willing to share their experience, knowledge and wisdom to help, guide and support someone who is less experienced. Mentors act as friends, teachers and advisers. A person who is newly involved in research can ask for a mentor to help them adjust to their new role.
Meta-analysis	Combining data from multiple independent studies. May be undertaken in evidence syntheses.

MfHU (CT)	Medicines for Human Use (Clinical Trials) Regulations: SI 2004:1031 and subsequent amendments 2006:1928, 2006:2984 ,2008:941, 2009:1164 and 2010:1882 are the UK Statutory Instruments translating EU directives 2001/20/EC and 2005/28/EC into UK law, laying down the legal requirements for conducting CTIMPs in the UK
Methodology	The term methodology describes how research is done – so it will cover how information is collected and analysed as well as why a particular method has been chosen
MHRA	Medicines and Healthcare products Regulatory Agency: The UK Competent Authority (CA) and licensing authority for medicines and medical devices. It replaced both the Medical Devices Agency (MDA) and the Medicines Control Agency (MCA) in April 2003
Minor	In relation to a CTIMP, defined in 'The Medicines for Human Use (Clinical Trials) Regulations' as a person under the age of 16.
Monitor	The person designated by the sponsor to perform site visits and conduct the monitoring process; eg check whether there are any deviations from the protocol and that all source data was transferred into the Case Report Forms correctly
Monitoring	Maintaining contact with funded projects to ensure they progress satisfactorily and deliver meaningful results.
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.
Monitoring research	Monitoring research involves keeping up to date with the progress of a research project. This will include ensuring that the researchers are carrying out their research according to their **research proposal** or **protocol**, that the research is keeping to time and budget and that the research is being conducted ethically.
Morbidity	Illness or harm
Mortality	Death
MRC	Medical Research Council
MRC-NIHR NPC	MRC-NIHR National Phenome Centre
MRP	Methodology Research Programme
Multicentre/site	A study conducted according to a single protocol but carried out at more than one site and by more than one investigator; one CI oversees several local PIs

N

NCRN	National Cancer Research Network

Needs-led	We are needs-led because we assess the important questions and the priority they should be answered in. We actively ensure that our programmes meet the needs of decision makers. We ensure that we are needs-led throughout the funding pipeline, by actively assessing need and priority for all funding streams.
NHS Permission	NHS Permission for research (formerly known as R&D Approval) confirms that appropriate checks have been made and that clinical negligence will be covered by NHS indemnity schemes or by independent contractors' professional indemnity insurance during the course of the research. In addition, where the staff of an NHS organisation were responsible for designing the study, NHS permission confirms that indemnity is provided for harm arising from the design of the study. NHS permission for research ensures that: a) The organisation is aware of the potential impact of the research in terms of risks and resources. b) The organisation has made the necessary arrangements to support the activity. c) All the activities for which the organisation is responsible are compliant with the law. d) The organisation accepts vicarious liability for the activities of staff for which it is responsible.
NHS R & D Office	The responsible person / team acting on behalf of the organisation in matters relating to R&D management. The NHS R&D Office may delegate some of its functions to other parties. NB. Where a trial is run without NHS involvement, the term NHS R&D office may often be replaced with the term 'sponsor's office'.
NHS Research	NHS research is research carried out in the NHS or funded by the NHS. This includes research that takes place in local hospitals or GP surgeries, and larger studies commissioned by the NHS at a national level, for example: • a study based in a GP surgery looking at people's experience of long-term chronic pain • a **randomised controlled trial** to look at the best treatment for people with bowel cancer.
NICE	National Institute for health and Clinical Excellence: develop evidence-based guidelines on the most effective ways to diagnose, treat and prevent disease and ill health
NIHR CRN	National Institute for Health Research Clinical Research Network
NIHR	National Institute for Health Research: established by Department of Health for England in 2006 to provide the framework through which DH will position, manage and maintain the research, research staff and infrastructure of the NHS in England as a virtual national research facility
NIMP	Non-Investigational Medicinal Product: product used alongside IMP but not directly under investigation in the research study, e.g. a challenge agent
Non Interventional Trial	A study of one or more medicinal products which have a marketing authorisation, where the following conditions are met: a) The products are prescribed in the usual manner in accordance with the terms of that authorisation b) The assignment of any patient involved in the study to a particular therapeutic strategy is not decided in advance by a protocol but falls within current practice c) The decision to prescribe a particular medicinal product is clearly separated from the decision to include the patient in the study d) No diagnostic or monitoring procedures are applied to the patients included in the study, other than those which are ordinarily applied in the course of the particular therapeutic strategy in question, and

	e) Epidemiological methods are to be used for the analysis of the data arising from the study.
Non-CTIMP	Trials that do not involve an Investigational Medicinal Product (IMP) as defined by the MHRA, and therefore do not fall within the scope of the Medicines for Human Use (Clinical Trials) Regulations 2004.
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.
NRES	National Research Ethics Service: umbrella organisation responsible for all REC across the UK (replaced COREC in 2007)

O

Observational study	A study in which the investigators do not seek to intervene, but simply observe the course of events. There is a greater risk of selection bias than in experimental studies.
ODP	Open Data Platform: an online, open platform which provides secure access to collated study and recruitment data
Open label	Describes a clinical trial in which 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.
Outcome measures	Outcome measures are measurements of the effects of a treatment or service. They might include physical measurements – for example measuring blood pressure, or psychological measurements – for example measuring people's sense of well-being. So if someone takes part in research, they may be asked questions, or they may be asked to have extra tests to assess how well the treatment or service has worked.
Output	Published results from a research project. NETS projects often generate papers that are published in the scientific literature. Full details of NETS projects and their results are published in special reports or journals. Some projects generate briefing papers or other outputs for particular audiences.

P

Participant	A participant is someone who takes part in a research project. Sometimes research participants are referred to as research 'subjects'.
PIS/PIL **Patient information sheet** **Patient information leaflet**	Researchers must provide a patient information leaflet to everyone they invite to take part in a research study, to ensure people can make an informed decision about this. The leaflet explains what taking part will involve and should include details about: • why the research is being done, how long it will last, and what methods will be used • the possible risks and benefits • what taking part will practically involve, for example extra visits to a hospital or a researcher coming to interview someone at home • what **interventions** are being tested, or what topics an interview will cover • how the researchers will keep participants' information confidential • what compensation is available to people if they are harmed as a result of taking part in the research • who to contact for further information • how the results will be shared with others.
Participatory research	This is a type of research where researchers and people who use services or carers are partners in a research project. The research addresses an issue of importance to service users or carers, who are involved in the design and conduct of the research, and the way the findings are made available. The aim of the research is to improve people's lives. This isn't a research method – it's an approach to research, a philosophy.
Patient and 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 would include, for example, involvement in the choice of research topics, assisting in the design, advising on the research project or in carrying out the research.
PCF	Patient/Participant Consent Form
Peer interviewing	Peer interviewing is where people are interviewed by others who have a similar experience to them – their peers. For example, in a project to find out about children's experiences of after school care, children with experience of using after school care may act as peer interviewers, asking other children about their experience. Some researchers believe that this kind of interviewing enables people to talk more freely about their experience.
Peer review	A reviewing process for checking the quality and importance of reports of research. An article submitted for publication in a peer-reviewed journal is reviewed by other experts in the area.
Perspectives/user perspectives	A user perspective is often what people with experience of using health or social services are asked to bring when they get involved in research. They are asked to provide ideas, comments and suggestions based on the unique insight they have from their knowledge and experience of life with a health condition. They cannot be representative of everyone who uses a particular service, but they can offer their own perspective, and often that of other people.
Pharmacovigilance (PV)	The science relating to the detection, assessment, understanding and prevention of the adverse effects of medicines.
PROSPERO	Database of Prospectively Registered Systematic Reviews
Protocol/research protocol	A protocol is the plan for a piece of research. It usually research protocol includes information about: • what question the research is asking and its importance/relevance • the background and context of the research, including what other research

	has been done before • how many people will be involved • who can take part • the research method • what will happen to the results and how they will be publicised. A protocol describes in great detail what the researchers will do during the research. Usually, it cannot be changed without going back to a research **ethics committee** for approval.
Public health research	Public health is concerned with promoting good health, preventing disease and protecting people from hazards, rather than treating illnesses. It covers topics like the control of infectious diseases, vaccinations, and helping people to adopt healthy lifestyles. Public health research involves finding out new knowledge (or testing out existing ideas) to do with public health – so it might address questions about: • the best ways to help people stop smoking • how Bird Flu spreads.

Q

QA	Quality Assurance
QC	Quality Control
QOL/QLQ	Quality of Life Questionnaire
Qualified person (QP)	All manufacturing activities will need to be conducted in a unit which has an IMP manufacturing authorisation with a named Qualified Person (QP). This person ensures that an investigation medicinal product (IMP) batch is only released if there is documentation to confirm compliance with Good manufacturing Practice (or equivalent).
Qualitative analysis	Detailed subjective evaluation, used to capture views of individuals' and groups.
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 research might ask questions about why people want to stop smoking. It won't ask how many people have tried to stop smoking. It does not collect **data** in the form of numbers. Qualitative researchers use methods like **focus groups** and interviews (telephone and face-to-face interviews).
Quantitative analysis	Numerical evaluation of an intervention.
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, or whether a new drug lowers blood pressure more than the drugs that are usually used. Quantitative researchers use methods like surveys and clinical trials.
Questionnaire	A questionnaire is a prepared set of written questions used to obtain information from research participants. Questionnaires can be completed on paper, using a computer or with an interviewer.

R

R & D	Research and Development: often name of Department within NHS hospitals giving permission to conduct projects on those facilities with patients/staff
Randomisation	There are two components to randomisation: the generation of a random sequence, and its implementation, ideally in a way so that those entering participants into a study are not aware of the sequence (concealment of allocation).
Randomised controlled trial (RCT)	A controlled trial compares two groups of people: an experimental group who receive the new treatment and a control group, who receive the usual treatment or a placebo. The control group allows the researchers to see whether the treatment they are testing is any more or less effective than the usual or standard treatment. In a randomised controlled trial, the decision about which group a person joins is random (that is based on chance). A computer will decide rather than the researcher or the participant. Randomisation ensures that the two groups are as similar as possible, except for the treatment they receive. This is important because it means that the researcher can be sure that any differences between the groups are only due to the treatment.
RDS	Research Design Services
REC	Research Ethics Committee: authorised by NRES 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. See NRES website for more detail and other types of research http://www.nres.npsa.nhs.uk/ All Research in NHS/social services must have been reviewed by a UK REC
RfPB	Research for Patient Benefit: NIHR research funding stream
RfPPB	Research for Patient and Public Benefit, Health and Care Research Wales funding stream
Reporting/publication bias	A bias caused by only a subset of all the relevant data being available. The publication of research can depend on the nature and direction of the study results. Studies in which an intervention is not found to be effective are sometimes not published. Because of this, systematic reviews that fail to include unpublished studies may overestimate the true effect of an intervention. In addition, a published report might present a biased set of results.
Representative	As a representative, you are expected to speak on behalf of a larger group of people. If you've been asked to get involved in research as a representative of a particular group, you may want to think about how you can be confident that you are representing a wider range of people's views, rather than just offering your own **perspective**.
Research	The term research means different things to different people, but is essentially about finding out new knowledge that could lead to changes to treatments, policies or care. The definition used by the Department of Health is: "The attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods."
Research brief	Research commissioners write a research brief. The brief describes why they want to commission a piece of research, what questions the research should address and sometimes how the research should be carried out. It might include information about when the research needs to be completed and how much money is available. Researchers then write a **research proposal** that explains how they will address the research brief.
Research governance	Research governance is a process aimed at ensuring that research is high quality, safe and ethical. The Department of Health has a **UK Policy Framework**

	for Health and Social Care Research, which everyone involved in research within the NHS or social services must follow.
Research grant	Research grants are given to enable researchers to carry out a particular piece of research. They might amount to millions of pounds for a major study about genetics for example, or a few hundred pounds for a local study about people's experience of using a particular service. Usually, in order to get research grants, researchers have to write a **research proposal** and receive a positive **peer review**.
Research methods or techniques	Research methods are the ways researchers collect and analyse information. So research methods include interviews, questionnaires, diaries, clinical trials, experiments, analysing documents or **statistics**, and watching people's behaviour.
Research passport	A system for HEI employed researchers/postgraduate students who need 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)
Research partner	The term research partner is used to describe people who get actively involved in research, to the extent that they are seen by their 'professional' colleagues as a partner, rather than someone who might be consulted occasionally. Partnership suggests that researchers and service users/carers have a relationship that involves mutual respect and equality.
Research proposal	This is usually an application form or set of papers that researchers have to complete to say what research they want to do and how they want to do it. It will also cover the aim of the research, what the research questions are, who will be involved (both as **participants** and in carrying out the research), the time-scale and the cost.
Researcher	Researchers are the people who do the research. They may do research for a living, and be based in a university, hospital or other institution, and/or they may be a service user or carer.
Researcher-led proposals	Open calls for researchers to apply for funding for their own topics and questions. These applications are prioritised in terms of NHS or other information need in a process similar to that of the commissioned workstreams. Applications are assessed for scientific quality, feasibility and value for money.
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.
Reviewer	An individual with specific knowledge, experience and skills in a field of practice who undertakes an independent review of a grant application, commissioning brief or document for publication. The comments made by this independent 'external reviewer' are used to inform the funding decision or the preparation of a written document.
Risk Adaptation	See MRC/DH/MHRA Joint Project: The Risk-adapted Approaches to the Management of Clinical Trials of Investigational Medicinal Products (PDF, 247 KB) and the MHRA website for further information.

S

Sample size	The number of participants in the trial. The intended sample size is the number of participants planned to be included in the trial, usually determined using a statistical power calculation. The sample size should be adequate to provide a high probability of detecting as significant an effect size of a given magnitude if such an effect actually exists. The achieved sample size is the number of participants enrolled, treated or analysed in the study.
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
Secondary outcome	An outcome used to evaluate additional effects of an intervention deemed as being less important than the primary outcomes.
Secondary research	A review of individual studies (each of which is called a primary study). A systematic review is a secondary study.
Serious Adverse Event (SAE) or Serious Adverse Reaction (SAR)	Any adverse event or adverse reaction that results in death, is life-threatening*, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect. Comment: Medical judgement should be exercised in deciding whether an adverse event/reaction should be classified as serious in other situations. Important adverse events/reactions that are not immediately life-threatening or do not result in death or hospitalisation, but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above, should also be considered serious. * Life-threatening in the definition of a serious adverse event or serious adverse reaction refers to an event in which the subject was at risk of death at the time of the event. It does not refer to an event which hypothetically might have caused death if it were more severe.
Serious Breach of GCP or Protocol	A "serious breach" is a breach which is likely to effect to a significant degree: a) the safety or physical or mental integrity of the subjects of the trial; or b) the scientific value of the trial.
Screening	The process of identifying eligible patients prior to approaching them to determine if they are willing to consent to participate in the study
Service user or user	A service user is someone who uses or has used health and/or social care services because of illness or disability. Some people do not like this term because they feel it has negative connotations.
Setting	The research setting is the environment in which research is carried out. This could be a laboratory or a 'real' setting, such as the subject's working environment if you are conducting research into people's working lives.
Site	The NHS organisation in which study activities and assessment are performed or the location(s) where trial-related activities are actually conducted. Each site/Trust needs to give R&D approval
Single Technology Appraisal (STA)	A review of evidence on one specific treatment, usually carried out for policy customers such as NICE.
Skype	A messaging service which enables users to communicate with people by voice, video and instant messaging over the internet.
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
Social care research	Social care refers to a range of services provided across different settings, usually in the community. These include: • home care, day care and residential care for older people • residential care and fostering for children

	• support for parents of disabled children • supporting mental health service users, physically disabled people and people with learning difficulties • support for carers Social care research involves finding out new knowledge (or testing out existing ideas) to do with social care – so social care research might address questions about: • people's experience of using different home care services • the best ways to train new foster parents.
Social media	Interaction among people within virtual communities and networks, for example blogs, Facebook and Twitter.
Social networking service	A platform to build social networks among people who share interests, activities or connections. Twitter and Facebook are examples of social networking services.
SOP	Standard Operating Procedure: detailed written instructions designed to achieve uniformity of the performance of a specific function
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 data may be in hard copy or electronic format.
Source Documents	Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial).
SIV	Site initiation visit
Specificity	In screening/diagnostic tests this is a measure of a test's ability to correctly identify people who do not have the disease.
Sponsor	The individual, or organisation (or group of individuals or organisations) that takes on responsibility for confirming that there are proper arrangements in place to initiate, manage and monitor, and finance a study. Responsibilities are defined by the Research Governance Frameworks and by the Clinical Trials Regulations. For CTIMPs, the sponsor (or their legal representative) must be named on the Clinical Trial Authorisation. The sponsor may delegate functions as necessary to comply with the Clinical Trials Regulations, for example to the Chief Investigator or Clinical Trials Unit. The sponsor is responsible for posting clinical trial summary results in EudraCT within six or twelve months following the end of the trial, depending on the type of trial.
SI (i)	Statutory Instruments: document which defines UK law in on a specific topic, e.g. how to manage a clinical trial
SI (ii)	Sub-Investigator (as in ICH-GCP, ICH does not use the term Co-investigator)
Statistical Analysis Plan	A statistical analysis plan is a document that contains a more technical and detailed elaboration of the principal features of the analysis described in the protocol, and includes detailed procedures for executing the statistical analysis of the primary and secondary variables and other data.
Statistically significant	A result that is unlikely to have happened by chance.
Statistics and statistical analysis	Statistics are a set of numbers (**quantitative data**) obtained through research. For example, the average age of a group of people, or the number of people using a service. Statistical analysis uses a set of mathematical rules to analyse **quantitative data**. It can help researchers decide what data means. For example, statistical

	analysis can assess whether any difference seen between two groups of people (for example between the groups of people in a clinical trial) is likely to be a reliable finding or simply due to chance.
Substantial Amendment	A change to the terms of the approval given by either: • the competent authority (MHRA in the UK) or the research ethics committee or; • a change to the protocol or any other document submitted with the applications, which significantly affects one of the following: • the safety or physical or mental integrity of study participants • the conduct or management of the study • the scientific value of the study • the quality or safety of any investigational medicinal product used in the study.
Sub-group analysis	An analysis in which the intervention effect is evaluated in a defined subset of the participants in a trial, or in complementary subsets, such as sex or age.
Subject	An individual who participates in a clinical trial as either a recipient of the investigational medicinal product or a control. The preferred term for the HRA, NRES and many key trials stakeholders is 'Participant' but the term 'Subject' is referenced in law for CTIMPs. See also Participant.
Suspected Unexpected Serious Adverse Reactions (SUSAR)	An adverse reaction that is both unexpected (not consistent with the applicable product information) and also meets the definition of a Serious Adverse Event/Reaction.
Systematic review	Systematic reviews aim to bring together the results of all studies addressing a particular research question that have been carried out around the world. They provide a comprehensive and unbiased summary of the research. For example, one clinical trial may not give a clear answer about the effectiveness of a treatment. This might be because the difference between the treatments being tested was very small, or because only a small number of people took part in the trial. So systematic reviews are used to bring the results of a number of similar trials together, to piece together and assess the quality of all of the evidence. Combining the results from a number of trials may give a clearer picture.
Systematic Reviews Programme	The SR Programme comprises four different entities whose core business is creating evidence synthesis, systematic reviews,training or supporting the creation of research. These are the: UK Cochrane Review Groups, UK Cochrane Centre, Centre for Reviews and Dissemination, and Technology Assessment Review Teams.

T

TARs	Technology Assessment Reviews
Themed call	A call for proposals in a particular area of medicine or health (e.g. obesity, dementia).
Topic identification	Activities carried out to identify suitable topics for research. These activities provide a way for individuals and groups to propose areas where good evidence is lacking or unanswered questions exist.
Toxicity	The degree to which a medicine is poisonous. How much of a medicine can be taken before it has a toxic effect.
Treatment	The process of intervening with the aim of enhancing health or life expectancy. Sometimes, and particularly in statistical texts, the word is used to cover all comparison groups, including placebo and no treatment arms of a controlled trial and even interventions designed to prevent bad outcomes in healthy people, rather than cure ill people.
TRFs	Transitional Research Fellowships
Trial Management Group (TMG)	The Trial Management Group normally includes those individuals responsible for the day-to-day management of the trial, such as the Chief Investigator, statistician, trial manager, research nurse, data manager. The role of the group is to monitor all aspects of the conduct and progress of the trial, ensure that the protocol is adhered to and take appropriate action to safeguard participants and the quality of the trial itself.
Trial Master File (TMF)/Trial Site File (TSF)	The Trial Master File contains all essential documents held by the sponsor/Chief Investigator which individually and collectively permits the evaluation of the conduct of a trial and the quality of the data produced.
Trial Site	A hospital, health centre, surgery or other establishment or facility in the UK at or from which a CTIMP, or any part of a CTIMP, is conducted.
Trial Steering Committee (TSC)	The role of the Trial Steering Committee (TSC) is to provide the overall supervision of the trial. Ideally, the TSC should include members who are independent of the investigators, their employing organisations, funders and sponsors. The TSC should monitor trial progress and conduct and advise on scientific credibility. The TSC will consider and act, as appropriate, upon the recommendations of the Data Monitoring Committee (DMC) or equivalent and ultimately carries the responsibility for deciding whether a trial needs to be stopped on grounds of safety or efficacy.
TRPs	Translational Research Partnerships
Twitter	A social networking service that allows users to exchange public messages of 280 characters or less, known as tweets.
Type A Trial	Trials involving medicinal products licensed in any EU Member State if: • they relate to the licensed range of indications, dosage and form; or • they involve off-label use (such as in paediatrics and in oncology etc.) if this off-label use is established practice and supported by sufficient published evidence and/or guidelines.

U

UKCC	UK Cochrane Centre
UK CRGs	UK Cochrane Review Groups
UKCTG	UK Clinical Trials Gateway
Urgent Safety Measure (USM)	An appropriate measure required to be taken in order to protect the subjects of a clinical trial against any immediate hazard to their health or safety. Please refer to the Urgent Safety Measures station for more information.
User controlled research/user led research	User controlled research is research that is actively controlled, directed and managed by **service users** and their service user organisations. Service users decide on the issues and questions to be looked at, as well as the way the research is designed, planned and written up. The service users will run the research **advisory or steering group** and may also decide to carry out the research. Some service users make no distinction between the term user controlled and user led research, others feel that user led research has a different, vaguer meaning. They see user led research as research which is meant to be led and shaped by service users but is not necessarily controlled by them. Control in user led research in this case will rest with some other group of non-service users who also have an interest in the research, such as the **commissioners** of the research, the **researchers** or people who provide services.

V

Valid Research Application	A complete NIHR research application that has been received by the NHS provider following its submission via IRAS that enables regulatory reviews by other agencies (including but not limited to Research Ethics Committee and MHRA approval) to be conducted in parallel with the work on NHS permission by the contractor

W

WHO	World Health Organisation
WMA	World Medical Association