Glossary

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A

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.

Association of the British Pharmaceutical Industry: A trade association for UK pharmaceutical companies.

Adverse Drug Reaction (ADR): Any noxious and unintended response associated with the use of a drug in humans.

Adverse Event (AE): Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment.

Advisory Group: Many research projects have an advisory group (or steering group) that 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.

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.

ARSAC (Administration of Radioactive Substances Advisory Committee): Advises the Health Departments on written applications from practitioners for certificates which will enable them to use specific radioactive medicinal products in diagnosis, therapy or research.

Arm: A group of patients receiving a particular treatment (or placebo) in a clinical trial

Audit: A systematic and independent examination of study related activities and documents, to determine whether the evaluated study-related activities were conducted, and the data were recorded, analysed and accurately reported according to the protocol, sponsor's standard operating procedures (SOP's), Good Clinical Practice (GCP), and the applicable

regulatory requirement(s).

B

BioResource: NIHR BioResource is made up of thousands of volunteers, both with and without health problems, who are willing to be approached to participate in research studies investigating the links between genes, the environment, health and disease. There are eight centres across the UK including Cambridge BioResource.

BPI (Association of the British Pharmaceutical Industry): A trade association for UK pharmaceutical companies.

Blind: This term applies to trials where a new treatment is compared against another treatment or a placebo (usually phase III trials). A trial is '**single-blind**' if either the participants or the researchers do not know which option the participants are receiving, and ' **double-blind**' if both the participants and the researchers do not know which option the participants are receiving. This makes the results of the trial more objective and therefore more reliable.

BRC: Biomedical Research Centre. These are partnerships between leading NHS organisations and universities that aim to combine facilities and expertise to boost research. The NIHR funds 20 BRCs in England, including the Cambridge BRC.

C

Caldicott Guardian: A senior person responsible for protecting the confidentiality of patient and service-user information and enabling appropriate information-sharing.

Case Report Form (CRF): A document designed to record all of the protocol required information to be reported to the sponsor for each trial subject.

Chief Investigator (CI): The investigator with overall responsibility for the research. In a multi-site study, the CI has co-ordinating responsibility for research at all sites.

Clinical trial: A written description of a study of any therapeutic, prophylactic, or diagnostic agent conduct in human subjects, in which the clinical and statistical description, presentations, and analysis are fully integrated into a single report.

Clinical Trial Authorisation (CTA): The regulatory approval for a clinical trial of an

investigational medicinal product issued by the MHRA.

Cohort: A group of individuals with some characteristics in common, e.g. a group of people born within the same period would be referred to as a birth cohort.

Competent Authority (CA): The regulatory body charged with monitoring compliance with the national statute and regulations of European Member States.

Contract Research Organisation (CRO): 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.

CTIMP: Clinical trial of an investigational medicinal product.

Contraindication: A specific circumstance when the use of a treatment could be harmful, e.g. aspirin allergy is a contraindication to taking aspirin.

Control/control group: An alternative to a new treatment that is used as a comparison. Controls are usually either an existing treatment, a placebo or no treatment.

Crossover trial: A trial that involves patients receiving one treatment for a certain amount of time then swapping to an alternative treatment for a certain amount of time.

D

Data Monitoring Committee (DMC): Group of individuals with pertinent expertise that reviews on a regular basis accumulating data from an ongoing clinical trial.

Delegation log: The purpose of this document is to provide a legal delegation of study specific principal responsibilities. Each member of study staff should sign to agree the acceptance of these, and each delegation should be signed by the Investigator.

Double-blind: See ‘blind’

E

Eligibility criteria
A description of people that can (inclusion criteria) or cannot (exclusion criteria) take part in a trial.

Eligible studies: These are studies funded externally by a qualifying charity (one that subscribes to three qualifying standards - strategic direction, open access and quality

assurance) that are eligible for support through NHS Support for Science monies.

Essential Documents: Documents that individually or collectively permit evaluation of the conduct of the study and the quality of data produced.

Ethics: Ethics is the name given to the code of practice based on a set of decent, fair and moral principles and guidelines that researchers should abide by when conducting research, in order to prevent any harm to participants. Any research that will seek to gain personal confidential information or test a new intervention or treatment on people must first get ethical approval from a Research Ethics Committee.

EUDRACT (European Clinical Trials Database): A database of all clinical trials commencing in the European Community since 1 May 2004.

European Medicines Agency (EMEA): 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.

Excess Treatment Costs: The difference between the Treatment Costs, incurred as a result of a particular piece of Research and Development, and those that would have been incurred had the patients concerned been receiving the standard alternative service. By definition, Excess Treatment Costs only arise where experimental services are being provided, or where standard care is being provided in a different way or location to routine practice.

Experts by experience: The term ‘experts by experience’ refers to service users and carers, who are experts through their experience of illness or disability and services.

F

Funder: The Institution, Body or Individual(s) providing funding for the study (unless the Sponsor already covers this role) either through grants, contracts or donations.

Focus group: A focus group is a small group of people (usually about 6-10 individuals) who have common experiences or interests, brought together to talk about a topic, usually under the guidance of a facilitator. 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.

G

Genotyping: Genotyping is the process of determining differences in an individual's genetic make-up (genotype) by examining the individual's DNA sequence using biological assays and comparing it to another individual's sequence or a reference sequence.

Good Clinical Practice (GCP): Good Clinical Practice is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects.

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. GMP is concerned with both production and quality control.

H

Hawthorne effect: This is a psychological response in which subjects change their behaviour simply because they are subjects in a study, and not because of the research treatment.

Hypothesis: A hypothesis is a proposed explanation (or theory) for an observation that could be tested with further research.

I

ICH-GCP: A standard for the design, conduct, monitoring, recording, analysis and reporting of a study that gives assurance that the reported results are accurate and credible and that the rights, integrity and confidentiality of all study participants have been protected throughout the study.

Inclusion criteria: These describe the essential conditions or attributes of people who are eligible to take part in a trial. For example, 'positive diagnosis of heart disease' would be an essential criterion for participation in a trial testing a new treatment for heart disease.

Indemnity: Compensation for damage, loss or injury.

Informed consent: The process of learning what is involved in a clinical trial and then agreeing to take part.

Investigational Medicinal Product (IMP): A pharmaceutical form of an active substance or placebo being tested or used as a reference in a CTIMP. This includes products already with

a marketing authorisation: when used or assembled (formulated or packaged) in a way different from the authorised form, when used for an unauthorised indication, or when used to gain further information about the authorised form.

Informed consent: An ongoing process that provides the subject with explanations that will help in making educated decisions about whether to begin or continue participating in a trial. Informed consent is an on going, interactive process rather than a one-time information session.

Intellectual property: The novel or previously undescribed tangible output of any intellectual activity. It has an owner, it can be bought, sold or licensed and must be adequately protected. It can include inventions, industrial processes, software, data, written work, designs and images.

Investigator Site File (ISF): 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.

Investigator's brochure: A compilation of the clinical and non-clinical data on the investigational product(s) that is relevant to the study of the investigational product(s) in human subjects.

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 is a single system for applying for the permissions and approvals required for health and social care / community care research in the UK.

J

K

L

Lay (person): 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.

Longitudinal study : A study that follows a group of patients over a period of time.

M

Medicines Assessment Research Unit (MARU): is the commercial "arm" of the R&D Directorate for NHS Grampian. The role of MARU is to liaise between sponsors and investigators in the process of negotiating contracts for commercial clinical trials and then to undertake the financial management of the trial for its duration.

Medicines and Healthcare products Regulatory Agency (MHRA): The UK government agency responsible for ensuring that medicines and medical devices work, and are acceptably safe.

Meta-analysis: A review of the results of a large number of trials on a similar subject. A meta-analysis can be a particularly powerful research tool.

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.

Monitoring: The act of overseeing the progress of a clinical trial and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, standard operating procedures (SOPs), good clinical practice (GCP), and the applicable regulatory requirement(s).

Multi-centre study: A study conducted at more than one site, by more than one investigator, but according to a single protocol.

Multi-centre trial: A trial being carried out at more than one location.

N

National Institute for Health Research (NIHR): The NIHR is funded by the Department of Health to fund health and care research and translate discoveries into practical products, treatments, devices and procedures, involving patients and the public in all their work.

National Research Ethics Service (NRES): A directorate within the National Patient Safety Agency and provides help and leadership for Research Ethics Committee's (RECs): formerly COREC (Central Office for Research Ethics Committees) in 2007.

O

Observational study: A study where the researcher is not directly controlling the experiment but instead observing behaviour or outcomes. No attempt is made to affect the outcome, e.g. no treatment is given.

P

Participant: A participant is someone who takes part in a research study or trial, contributing data that allow researchers to answer a research question. Participants may contribute data by taking a new drug, providing biological samples or answering survey questions. Sometimes participants are referred to as research "subjects".

Participatory research: This is a type of research where researchers and service users or carers are partners in a research project that addresses an issue of importance to service users or carers. Service users and carers are involved in the design and conduct of the research, and the way the findings are made available with the aim of improving people's lives and experience of care. This isn't a research method – it's an approach to research, a philosophy.

Patient Information Sheet (PIS): The PIS, in a form appropriate for the study population,

explains what the research involves and how the research study will affect the participant. It is usually accompanied by a consent form. For guidance on preparing appropriate participant information sheets see NRES website.

Peer interviews: Interviews where the participants are interviewed by people who have had a similar experience to them. 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 for their views.

Peer review: A review of a trial's results by a group of independent experts

Pharmacovigilance: The pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long term and short term side effects of medicines.

Phase 1 trial: The initial introduction of an investigational new drug into humans. Phase 1 studies are typically closely monitored and may be conducted in patients or normal volunteer subjects.

Phase 2 trial: Controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug. Phase 2 studies are typically well controlled, closely monitored, and conducted in a relatively small number of patients, usually involving no more than several hundred subjects.

Phase 2A trial: Controlled clinical studies that occur after the completion of Phase 1 studies and the first set of exposure-response studies in patients, and before beginning Phase 2B (i.e. patient dose-ranging trial) and Phase 3 clinical efficacy-safety studies.

Phase 3 trial: Studies are expanded controlled and uncontrolled trials. The are performed after preliminary evidence suggesting effectiveness of the drug has been obtained and are intended to gather the additional information about effectiveness and safety that is needed to confirm efficacy and evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labelling.

Phase 3B trial: A subcategory of a Phase 3 Trials carried out near the time of approval to elicit additional findings. These trials may be required as a condition of regulatory authority approval.

Phase 4 trial: Post marketing (Phase 4) studies to delineate additional information about the drug's risks, benefits, and optimal use that may be requested by regulatory authorities in conjunction with marketing approval.

Phase 5 trial: Post marketing surveillance is sometimes referred to as Phase 5. Research

concerned with benefits, financial costs, healthcare system usage, risks, and quality of life as well as their relation to therapeutic interventions.

Phenotyping: The full set of an individual's observable characteristics reflecting the combined influence of genetic inheritance, genetic mutations, and environmental influences. Phenotypic data can include the results of clinical tests, scans and descriptions.

Placebo: A 'dummy' treatment that resembles a medical treatment but is intended to have no physical effect on a participant. A new treatment is often compared against a placebo to get more reliable evidence about its effectiveness. Patients who receive a placebo should still also receive the best standard care.

Principal Investigator (PI): An individual who actually conducts a clinical investigation (i.e. under whose immediate direction the test article is administered or dispensed to, or used involving a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.

Prospective study: Research in which a group of participants is identified, and then studied from that point forward in time. The opposite is a retrospective study.

Protocol: A document that describes the objective(s), design, methodology, statistical consideration, and organisation of a trial.

Q

Quality Assurance (QA): All those planned and systematic actions that are established to ensure that the trial is performed and that data are generated, documented (recorded), and reported in compliance with good clinical practice (GCP) and the applicable regulatory requirement(s).

Quality Control (QC): The operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the trial related activities have been fulfilled.

Qualitative research: Qualitative research is used to explore and understand people's subjective beliefs, experiences, attitudes or motivations. It asks questions about how and why people behave or feel the way that they do. Often the term "holistic' is used, meaning that the complexities of human behaviour are preserved in the study. For example a qualitative research approach might ask questions about why people want to stop smoking (or why they don't), rather than measuring characteristics of smokers and non-smokers or enumerating the number of people who smoke. Qualitative researchers use methods like

focus groups and interviews (telephone and face-to-face interviews).

Quantitative research: In quantitative research, researchers use objective measurements to produce numerical data that can be analysed using statistical methods. 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.

R

R & D: Research and Development, which covers both ‘basic’ (pre-clinical, often cell or animal-based) research and clinical research, as well as research into improving existing treatments, service delivery and user experience.

Randomised Controlled Trial (RCT): A scientific procedure in which treatments are allocated to subjects at random, in order to eliminate bias. It is considered the most reliable form of scientific evidence because it ensures that different treatment groups are statistically equivalent.

Randomised trial: In a randomised trial, participants are allocated to receive one type of treatment or another by a random process, usually using a computer. This helps ensure the results are objective and unbiased.

Regulatory authorities: Organisations that ensure research is conducted in line with the law, e.g. such as the Human Tissue Authority, Medicines and Healthcare products Regulatory Agency.

Research Ethics Committee: Independent committees that review the ethical issues within research projects that involve people as participants or their data or tissues. Research Ethics Committees (REC) are established throughout the UK within the NHS, in particular universities as well as independent Phase 1 committees.

Research governance: A term that is first used in the UK Health Departments' Research Governance Frameworks. It is commonly used in a generic way to encompass the Research Governance Framework standards and principles, including all applicable regulatory requirements.

Research grant: A sum of money awarded to a research professional, group or institution to allow them to carry out their proposed program of research. Grants can be funded by the government or through charities and philanthropy, and may cover an entire program of

research, smaller individual projects, staff costs or equipment. Research grants are generally limited in both value and time (for example £1 million pounds over 3 years), which means that lead researchers need to continually apply for research grants so that their research can continue.

Research proposal: This is a document (or, more commonly, a set of documents) that describes a proposed or intended program of research that researchers are seeking funding for. It will 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 timescale and the cost.

Retrospective study: Research in which a group of participants is identified, and then studied from that point backward in time, usually via their medical records and interviews. The opposite is a prospective study

S

Serious Adverse Event (SAE): An untoward occurrence that results in death is life-threatening requires hospitalisation or prolongation of existing hospitalisation results in persistent or significant disability or incapacity consists of a congenital anomaly or birth defect is otherwise considered medically significant by the investigator.

Suspected Unexpected Serious Adverse Reaction (SUSAR): All suspected adverse reactions related to an investigational medicinal product (the tested investigational medicinal products and comparators) which occur in the concerned trial, and that are both unexpected and serious. For more detailed guidance please see Clinical Trials Tool Kit.

Single-blind: See 'blind'

Site Specific Assessment (SSA): An assessment performed to advise the main REC of the suitability of a site, facilities and research staff, SSA must be performed for any study with a principal investigator at each site.

Site specific information: Section of the IRAS application form which contains questions specific to an individual research site and is for assessment by the relevant local REC and is used to apply to the local research site for R&D approval.

Source data: All information in original records (and certified copies of original records) of clinical findings, observations or other activity in a clinical trial essential for the reconstruction

and evaluation of the trial. Source data are contained in source documents.

Source documents: Original documents data and records, e.g. medical records, subject files, laboratory notes and records, participants' diaries, pharmacy dispensing records, recorded data from automated instruments and x-rays.

Sponsor: An individual, organisation or group which takes responsibility for the initiation, management, and/or financing a research study.

Stakeholder: A stakeholder is anyone who has an interest in a research project. It includes the people and organisations who are actively involved, as well as the people who might be affected by the outcomes.

Standard Operating Procedures (SOPs): Detailed, written instructions to achieve uniformity of the performance of a specific function.

T

Translational research: The process of turning research findings and discoveries into practical applications that are of benefit to patients. This can include turning results from ‘basic’ research into pre-clinical studies or testing new treatments and drugs in humans.

Trial: A study of the effects of an intervention.

U

United Kingdom Clinical Research Collaboration (UKCRC): The UKCRC is a partnership of organisations working to establish the UK as a leader in clinical research, by harnessing the power of the NHS.

Unexpected adverse drug reaction: An adverse reaction, whose nature, severity, specificity, or outcome is not consistent with the term or description used in the applicable product information.

V

Vulnerable subjects: Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or note, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

W

X

Y

Z