# Purpose

This document is downloadable and printable version of the Glossary of Terms. It contains all abbreviations and definitions used by the Clinical Research Compliance Team and within the University of Birmingham clinical research quality management system. This document is only valid for 14 days and may be subject to amendment at any time. For the latest version refer to: [birmingham.ac.uk/crct](https://www.birmingham.ac.uk/crct).

# Abbreviations and definitions

| Term | Description |
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| Advanced Therapies Facility (ATF) | Three synergetic units at the University of Birmingham with the prime objective of facilitating high quality translational research; the Human Biomaterials Resource Centre (HBRC), the Cell Therapy Suite (CTS) and the Microbiome Treatment Centre (MTC).  |
| Advanced therapy investigational medicinal product (ATIMP) | Advanced therapy investigational medicinal products (ATIMPs) are ATMPs that are tested or used in a clinical trial. |
| Advanced therapy medicinal product (ATMP) | Advanced therapy medicinal products (ATMPs) are medicinal products that are prepared industrially or manufactured by a method involving an industrial process. ATMPs fall into three categories: gene therapies, somatic cell therapies and tissue engineered products. |
| Adverse device effect (ADE) | An adverse event related to the use of an investigational medical device. This includes any adverse event resulting from insufficiencies or inadequacies in the instructions for use, the deployment, the implantation, the installation, the operation, or any malfunction of the investigational medical device. This includes any event that is a result of a use error or intentional abnormal use of the investigational medical device. |
| Adverse event (AE) | Any untoward medical occurrence in a participant or clinical research participant administered a medicinal product and which does not necessarily have a causal relationship with this treatment.Comment: An Adverse Event can therefore be any unfavourable and unintended sign (including abnormal laboratory findings), symptom or disease temporally associated with the use of a medicinal product, whether or not related to the medicinal product.For studies and trials sponsored by UoB it is an event, which results in or may result in harm or damage to the interests the Researcher, the research participants, the University (including its reputation), society, the environment or a failure to maintain appropriate standards of animal welfare. |
| AER  | Application for ethical review |
| Adverse reaction (AR) | For clinical trials of an investigational medicinal product(s), all untoward and unintended responses to an investigational medicinal product related to any dose administered. |
| Analyst | The person(s) that perform the analysis or evaluation of the clinical trial samples. |
| Analytical manager  | A named individual who oversees the analysis or evaluation of clinical trial samples and takes responsibility for the conduct and reporting of the work. |
| Analytical plan | A written plan which will include the purpose of the analysis and the methodology that will be used to perform the analysis. Also described as a “work instruction” or “analytical protocol” in the Reflection paper for laboratories that perform the analyses or evaluation of clinical trial samples (2012), European Medical Agency. It is expected that this role will be assigned to the Principal Investigator of the laboratory and that they will in turn delegate some of the responsibilities to other members of the laboratory team. |
| APR | Annual progress report |
| Archive system | A collection of documents detailing the content, location, transfer details and review outcomes of archived documents pertaining to a clinical trial. |
| Archiving | Long-term storage of (study/trial) materials, where those materials are not required to be kept in an active format. The storage environment must be deemed suitably secure environment for the required retention period, with risks around security, location, size, environment and pests having been considered. For CTIMPs, the long-term storage of the materials is under the control of an archivist and in an archive fit for the purpose of the specific trial.  |
| Archivist | The person who defines and maintains an archive index recording all essential documents that have been entered into the archive, and who approves, tracks and retrieves documents on loan from the archive. |
| Administration of Radioactive Substances Advisory Committee (ARSAC) | Clinical research involving the administration of radioactive substances must be approved by the ARSAC. |
| Assay | An investigative procedure in a laboratory, for qualitatively assessing or quantitatively measuring the presence, amount, or functional activity of a target entity (for example, a hormone, gene or metabolite). |
| Assay validation | Assay validation is a documented process that demonstrates that an assay is suitable for its intended purpose. |
| Audit | A systematic and independent examination of both project-specific activities and their related documentation. An audit is used to determine whether the activities that have been evaluated were carried out in accordance with the project’s protocol, the sponsor's SOPs, GCP, GCP in the Laboratory, HTA research licensing standards, GMP and any other applicable regulatory requirement(s). An audit will also assess whether the clinical research data were appropriately recorded, analysed and accurately reported. |
| Audit manager | The person responsible for setting up and executing the audit programme. This role may be taken on by a Quality Assurance (QA) Manager. |
| Audit plan | An audit plan describes the aims and objectives of the audit, the scope, the resources required, the audit methodology, the audit sites and timing of the audit. The audit plan also describes how the audit will be reported. |
| Audit programme | A description of the specific audit(s) planned for a specific time frame, which is agreed upon by the relevant oversight committee.  |
| Audit report | A written evaluation by the auditor of the results of the audit. |
| Authorised health professional | An authorised health professional is defined as a doctor, dentist, nurse or pharmacist. |
| Blinding | Blinding is the process that keeps one or more parties involved in a clinical research project (for example, the sponsor, the investigator team, and/or the participant) unaware of what treatment arm participants have been randomised to. In relation to an investigational medicinal product, blinding is the deliberate disguising of the identity of the product in accordance with the instructions of the sponsor. |
| Branded product | The brand name is the name given to a medicine by the pharmaceutical company that makes it. This is also called the "proprietary name". |
| BRC | Biomedical Research Centre |
| Confidentiality Advisory Group (CAG) | The Confidentiality Advisory Group (CAG) is an independent body which provides expert advice on the use of confidential patient information. |
| Calibration | A process undertaken to determine or check the range and accuracy of a piece of equipment. |
| Case report form (CRF) | A printed or electronic document designed to record all of the protocol required information to be reported to the sponsor on each participant.  |
| Chief investigator (CI) | The person who takes overall responsibility for the design, conduct and reporting of a study if it is at one site; or if the study involves researchers at more than one site, the person who takes primary responsibility for the design, conduct and reporting of the study, whether or not that person is an investigator at any particular site. Note that for CTIMPs the chief investigator must be an authorised health professional.  |
| Clinical research  | Any health-related research on humans. |
| Clinical Research Compliance Team (CRCT) | The Clinical Research Compliance Team (CRCT) forms part of the College of Medical and Dental Sciences Research and Knowledge Transfer Office, and is responsible for developing an infrastructure for researchers involved in clinical research. In addition, the team takes on responsibilities relating to Sponsor oversight such as audits and quality checks. |
| Clinical research laboratory manager | Referred to as ‘laboratory manager’ in the Reflection paper for laboratories that perform the analyses or evaluation of clinical trial samples (2012), European Medical Agency. The individual(s) having the authority and formal responsibility for the organisation and functioning of a laboratory in which work that forms part of a clinical trial is conducted. |
| Clinical sample kit | The necessary components required to collect clinical samples prior to their analysis or evaluation in a laboratory. |
| Clinical study  | Any health-related research study on humans. This includes:* Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
* Study involving qualitative methods only
* Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
* Study limited to working with data (specific project only).
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| Clinical trial | For clinical trials of an investigational medicinal product(s):Any investigation in human participants intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal product(s) and/or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal product(s) with the object of ascertaining its (their) safety and/or efficacy. See also ‘Clinical Trial of an investigational medicinal product (CTIMP)’.For all other clinical trials:Prospective biomedical research on human participants that are conducted to allow safety (or more specifically, information about adverse drug reactions and adverse effects of other treatments) and efficacy data to be collected for health interventions. Examples include devices, surgery and radiotherapy trials. |
| Clinical trial authorisation (CTA) | The regulatory approval for a clinical trial of an investigational medicinal product, issued by the MHRA. |
| Clinical trial of an investigational medicinal product (CTIMP) | Any investigation in human participants intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal product(s) and/or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal product(s) with the object of ascertaining its (their) safety and/or efficacy. |
| Clinical trial task delegation log | A UoB document that defines all clinical trials tasks and how these are delegated between CI and CTU. |
| Clinical Trials Oversight Committee (CTOC) | The Clinical Trials Oversight Committee (CTOC) is responsible for overseeing the activities undertaken by UoB in its role as a sponsor, co-sponsor, host institution or partner with other organisations for clinical research. This includes clinical trials of investigational medicinal products (CTIMPs), trials conducted through the UoB’s Clinical Trials Units (CTUs), any clinical research where a UoB research ethics committee has stipulated that the research must be conducted to the principles of GCP. The CTOC reports directly to both the pro-vice chancellor and the Head of College of Medical and Dental Sciences (MDS) through the MDS Research & Knowledge Transfer (R&KT) Executive Committee, and the Pro-Vice Chancellor for R&KT through the UoB Research Governance, Ethics and Integrity Committee (RGEIC). |
| Clinical Trials Unit (CTU) | A specialist unit which has been set up with a specific remit to design, conduct, analyse and publish clinical trials and other well-designed studies. The University of Birmingham has two UKCRC fully registered Clinical Trials Units; the Cancer Research UK Clinical Trials Unit (CRCTU) and the Birmingham Clinical Trials Unit (BCTU).  |
| Closed project | Research project where any project closure procedures have been completed and where all outstanding action points have been completed. |
| Closed site | A site where any site closure procedures have been completed and where all outstanding action points have been completed. |
| Closed trial | A trial where any trial closure procedures have been completed and where all outstanding action points have been completed.  |
| Code break | Also known as breaking the blind, a mechanism that permits the rapid identification of the intervention/treatment received by a participant in the case of a medical emergency, pre-specified protocol indication or safety reporting requirement but does not permit undetectable breaks of the blinding. |
| Competent authority (CA) | A body with authority to act on behalf of the government of the EU Member State to perform a designated function; in the case of clinical trials, to ensure that requirements of the Clinical Trials Directive are transposed into national law and applied. The Medicines and Healthcare products Regulatory Agency (MHRA) is the ‘competent authority’ UK.  |
| Compliance reviewee | The individual/team or organisation in receipt of the compliance review. |
| Compliance reviewer | An appropriately-trained individual, and where applicable competent to perform audits, monitoring visits and/or SSVs, whose qualifications should be documented. They conduct the compliance review. |
| Computerised system validation | The process of documenting that a computer system meets a set of defined system requirements. |
| Conclusion of a project | The point in time where all project closure procedures have been completed, including final analysis. |
| Consolidated Standards of Reporting Trials (CONSORT) | Encompasses various initiatives developed by the CONSORT Group to alleviate the problems arising from inadequate reporting of randomised controlled trials. The main product of CONSORT is the CONSORT Statement, which is an evidence-based, minimum set of recommendations for reporting randomised trials. |
| Coordinating centre | A term commonly used to refer to the team responsible for the overall management of the trial and their physical location. A coordinating centre may be based in a Clinical Trials Unit and may also be referred to as a Trials Office. There may be more coordinating centres involved in a trial, e.g. for international trials the international and national coordinating centre, and for trials managed regionally the central and local coordinating centre.  |
| Corrective and preventive action (CAPA) plan | A plan produced by the compliance reviewee detailing the actions to be taken following a compliance review, in order to correct any issues found and to prevent those issues from reoccurring. |
| Critical data item | Information that is essential for the successful analysis of the primary and key secondary endpoints of a clinical trial. |
| CTU hosted study/trial | A study for which the CTU undertakes some individual tasks related to the conduct of the study/trial, but for which the CTU has not been delegated the overall task of managing the entire study/trial on behalf of the Sponsor. Examples, though not exhaustive, would be acting as or supporting the investigator site, and/or undertaking one or more individual tasks such as Monitoring, Pharmacovigilance, IMP Supply, Data Management and Statistics. Where the CTU undertakes such specific tasks, the CTU is responsible for ensuring those tasks are conducted as expected and in line with the relevant QMS. Where all or the majority of the functions listed above are being carried out, it may be appropriate to regard the study/trial as CTU managed. |
| CTU managed study/trial | A study/trial for which the overall study management or the majority of study/trial management duties has been delegated to the CTU on behalf of a sponsor. Examples include all or most of the activities of Registration, Site Initiation, Monitoring, IMP supply, Pharmacovigilance, Data Management and Statistical Analysis. |
| CTU manager | Those staff members within a CTU who take on line management responsibilities for their staff, e.g. Team Leaders, Team Managers, and Senior Trial Coordinators. |
| CTU member | Any member of staff who is either line managed within the CTU, or who has been invited by the Director of the CTU to join the CTU (e.g. as member of the executive committee), under the understanding that in the case of any issues or non-compliance, the Director has a right of sanction. |
| CTU mentorship | Clinical Trials Unit (CTU) mentorship is defined as an informal and professional relationship between an independent chief investigator and/or their research team and one of the two UKCRN registered UoB CTUs, whereby there is an informal transmission of clinical trial experience, knowledge, skills, information and perspective imparted from the UoB CTU to the independent chief investigator and/or their research team. The UoB CTU will not act in a supervisory capacity and the ultimate responsibility for the conduct of a trial will lie with the independent chief investigator. Where CTU mentorship is agreed upon, this will be documented. Where the UoB CTU feels their mentoring provision is ignored, leaving the Sponsor open to risks, they may choose to discuss this directly with the Sponsor. |
| CWoW | Combined Ways of Working, now known as the combined review process. |
| Data | Facts, figures and statistics collected together for reference or analysis. |
| Data clarification | A data clarification is a query generated by the sponsor and sent to, and is completed by, the investigator site (or if applicable the participant) as part of the data validation process. |
| Data clarification form (DCF) | A document used to formally record a data clarification.  |
| Data collection forms | All forms used to collect data for the trial dataset. This may include CRF, DCF, Quality of Life (QoL) questionnaires, health economic measures, participant diaries and/or correspondence with the site. |
| Data entry quality check (DEQC) | A quality check performed on the data entered into the trial dataset (database) to ensure that the data entered is accurate.  |
| Data management | The administrative process by which trial data are acquired, processed, cleaned for analysis (verified), stored, and protected to ensure that the trial results are accurate and collected in accordance with the protocol and Good Clinical Practice. |
| Data monitoring committee (DMC) | An independent group of experts appointed by the sponsor, who provide independent assessment of the safety, scientific validity and integrity of the clinical research.  |
| Data snapshot | A copy of a dataset as it exists at one particular point in time. Also known as a frozen dataset.  |
| Decontamination | The removal of microbes or non-biological contaminants. |
| Device deficiency | Inadequacy of an investigational medical device related to its identity, quality, durability, reliability, safety or performance. This may include malfunctions, use error, or inadequacy in the information supplied by the manufacturer. |
| DEXA scan | Dual-energy X-ray absorptiometry scan. |
| DH | Department of Health. |
| DRTB | Dental Research Tissue Bank. |
| Development safety update report (DSUR) | A common standard for periodic reporting of drugs under development. In the EU, it replaces the annual safety report for CTIMPs. |
| eCRF | Electronic case report form. See ‘case report form (CRF)’ |
| Editorial amendment (EA) | An amendment to an existing document that does not affect the substantive content of the document, e.g. updating links, style, or grammar, or where reference will be made to the latest SOP. |
| EEA | European Economic Area. |
| Effective date | Effective date is the date a document was authorised to go live. |
| Employee training record  | Record of any training sessions that relate to previous and current functions and that are relevant for the current post. |
| End of trial | The end of trial definition is trial-specific. In most cases, it will be the date of the last visit of the last participant or the completion of any follow-up monitoring and data collection described in the protocol. |
| Essential documents | Essential Documents are those documents which individually and collectively permit evaluation of the conduct of a trial or study and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor and monitor with standards of Good Clinical Practice and with all applicable regulatory requirements. |
| Ethics registration number (ERN) | An internal number assigned to a project following completion of a UoB Ethical Review of Research Self-Assessment Form. |
| European Union Drug Regulating Authorities Clinical Trials Register (EudraCT) | European database for all interventional clinical trials on medicinal products authorized in the EEA and outside the EU/EEA if they are part of a Paediatric Investigation Plan from 1 May 2004 onwards. Protocol and results information on interventional clinical trials are made publicly available through the European Union Clinical Trials Register since September 2011. |
| Existing study | For the purposes of UoB sponsor oversight, a study that has a minimum provisional sponsor approval. |
| External archive facility | An off-site archive facility that is used to archive materials that are expected to be no longer used, e.g. the TMF after a trial is closed and the final report is generated. |
| Final analysis | An analysis of project data performed on the final cohort of participants with follow-up as defined by the protocol and statistical analysis plan. |
| Frozen dataset | See ‘Data snapshot’. |
| Generic product | The generic or scientific name of a drug product is the term given to the active ingredient in the medicine that is decided by an expert committee and is understood internationally. This is also called the "non-proprietary name". |
| Good Clinical Practice (GCP) | A set of internationally recognised ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical research that involve the participation of human volunteers. |
| Good Distribution Practice (GDP) | A code of standards ensuring that medicines are consistently stored, transported and handled under suitable conditions throughout the distribution network.  |
| Good Laboratory Practice (GLP) | A recognised standard for laboratories that conduct testing of medicines during their development.  |
| Good Manufacturing Practice (GMP) | A recognised standard for pharmaceutical manufacturing, processing, packing, release and holding ensuring medicinal products are consistently produced and controlled.  |
| Good Pharmacovigilance Practices (GPvP) | The minimum standard for monitoring the safety of medicines on sale to the public in the EU. Also known as ‘GVP’.  |
| GP | General Practitioner. |
| GxP | General abbreviation for Good Practice standards. |
| Hard-coding | Programming term, whereby a variable’s value (i.e. a data point) in the dataset is changed directly within the database tables (e.g. by using an ‘if-then’ function). |
| Healthcare professional | An authorised health professional, or a qualified and registered (or alike) [Allied Health Profession](https://www.england.nhs.uk/ahp/role/) such as a physiotherapist, dietitian or radiographer.  |
| Healthy volunteer | An individual who has either no known significant health problems or does not suffer any significant health problems relevant to the proposed research  |
| HRA | Health Research Authority |
| HRA approval | The process for the NHS in England that comprises a review by an NHS Research Ethics Committee (REC) (where required) as well as an assessment of regulatory compliance and related matters undertaken by dedicated HRA staff. In England, it replaces the need for local checks of legal compliance and related matters by each participating NHS organisation. |
| HTA | Human Tissue Authority |
| Human biomaterial  | For clinical trials: samples taken from a human being to be analysed for the purposes of that clinical trial. This may include both HTA ‘relevant’ and ‘non-relevant’ material. For clinical studies: samples of human tissue obtained for analysis. |
| Human Biomaterials Resource Centre (HBRC) | An ethically approved, HTA licensed human sample biorepository at the University of Birmingham offering sample collection, processing, storage and analytical service.  |
| Human tissue | Any and all constituent part/s of the human body formed by cells. |
| Human Tissue Oversight Committee (HTOC) | The Human Tissue Oversight Committee (HTOC) is responsible for overseeing all activities surrounding the use of human tissue at UoB. The HTOC provides support for quality assurance and risk management process in relation to activities carried out under the HTA licences held by UoB. The HTOC is also responsible for overseeing Good Clinical Practice (GCP) compliance in laboratories undertaking the analyses of clinical trial samples at UoB. The HTOC reports to the Pro-Vice Chancellor for Research & Knowledge Transfer through the UoB Research Governance, Ethics and Integrity Committee (RGEIC).  |
| ICH GCP | International Council on Harmonisation: Guidelines for Good Clinical Practice (ICH GCP). This is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve human participants. See also ‘International Council on Harmonisation (ICH)’. |
| International Council on Harmonisation (ICH) | International Council on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; commonly referred to as ‘International Council on Harmonisation’. |
| International Organisation for Standardisation (ISO) | Commercially developed international standards for quality, in a variety of different areas, developed to create industry-wide consensus.  |
| Independent chief investigator | For the purpose of the UoB QMS, either a principal investigator for single-centre studies, or a chief investigator for multicentre studies who manages their study(s) outside a UoB CTU. |
| Informed consent form (ICF) | A form which is used to document the voluntary confirmation of a participant’s willingness to take part in a trial after having been informed of all aspects of the trial that are relevant to their decision. The form must be signed and dated.  |
| Inspection | The act by a regulatory authority(ies) of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority(ies) 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 organization’s (CRO’s) facilities, or at other establishments deemed appropriate by the regulatory authority(ies). |
| Integrated Research Application System (IRAS) | A single system for applying for the permissions and approvals for health, social and community care research in the UK. |
| Interactive voice response system (IVRS) | A phone technology that allows a computer to detect voice and touch tones using a normal phone call. IVRS can respond with pre-recorded information to further direct callers on how to proceed with regards to a clinical research project. |
| Interactive web response system (IWRS) | A Web technology that is designed to give adequate information for users to manage clinical research projects. |
| Investigational medicinal product (IMP) | A pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products already with a marketing authorisation but used or assembled (formulated or packaged) in a way different from the authorised form, or when used for an unauthorised indication, or when used to gain further information about the authorised form. |
| Investigator 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 participant.  |
| Investigator managed study | A study for which the overall study management is under the responsibility of an independent chief investigator. Specific tasks may be delegated to a member of his/her team or to a CTU. |
| Ionising Radiation (Medical Exposure) Regulations (IRMER) | Under the IRMER Research Ethics Committee (REC) approval is required where participants are to be exposed to ionising radiation as part of their involvement in medical or biomedical, diagnostic or therapeutic, research. Also see ‘Administration of Radioactive Substances Advisory Committee (ARSAC)’. |
| ISF | Investigator Site File. Also see ‘Site File’. |
| ITM | Institute of Translational Medicine. |
| Laboratory | A facility that conducts manipulation, analysis or evaluation of samples collected as part of a clinical trial; such analysis or evaluation may include the generation of pharmacokinetic or pharmacodynamic data, safety data, primary efficacy data, histopathology data or data used to support any other stated primary, secondary and exploratory end point. |
| Laboratory academic lead (LAL) | At the University of Birmingham the LAL takes on the responsibility of the ‘Lab Manager’ and the ‘Analytical Manager’ as described in the Reflection paper for laboratories that perform the analyses or evaluation of clinical trial samples (2012), European Medical Agency. It is expected that this role will be assigned to the Principal Investigator of the laboratory and that they will in turn delegate some of the duties to other members of the laboratory team. |
| Laboratory adverse events | A laboratory adverse event refers to any event which may compromise participant safety, sample or data integrity. Examples include security breaches, equipment failure or calibration failure, analytical failures, or the production of aberrant or out of range results. |
| Laboratory manual | A document containing work instructions/assay plan to ensure trial specific sample analyses are GCP compliant. |
| Laboratory master file (LMF)  | A file containing evidence of a documented approach to GCP compliance on the laboratory. |
| LES | College of Life and Environmental Sciences at the University of Birmingham. |
| Local QMS | A Quality Management System used by a research team or unit. |
| Manager | A person within the UoB who takes on line management responsibilities. This is typically an academic related or support staff function. |
| Manufacturing and importing authorisation for investigational medicinal products (MIA(IMP)) | Authorisation to manufacture, assemble and/or import investigational medicinal products for human use. Authorisation is granted by the MHRA. See also 'Qualified Person (QP)'. |
| Marketing authorisation (MA) | A product licence given before a medicine can be placed on the market by a medicines regulator (i.e. MHRA) which is required by law. |
| Marketing authorisation holder (MAH) | A company or other legal entity that has been granted a marketing authorisation in one, several or all EU Member States.  |
| MDS | College of Medical and Dental Sciences at the University of Birmingham. |
| Medicines and Healthcare Products Regulatory Agency (MHRA) | The UK government agency responsible for ensuring that medicines and medical devices work and are acceptably safe. See also ‘Competent Authority’. |
| Microbiological and pyrogen tested (MPT) | A quality standard for preparing biochemical products for research applications. Products are tested at tested in the bulk form for the presence of microbial or pyrogens. Tests may include checks for S. aureus, P. aeruginosa, E. coli, Salmonella sp., aerobic bacteria, yeast and mould and for bacterial endotoxins. |
| Monitoring | The act of overseeing the progress of a clinical research project to ensure that it is conducted, recorded and reported in accordance with the protocol, written procedures, Good Clinical Practice and the applicable regulatory requirements. |
| Monitoring plan | A plan that describes the aims, objectives, scope and strategy of the on-site monitoring for a trial. |
| MRC | Medical Research Council. |
| mNCA | UK model agreement for non-commercial research. |
| Monitoring visit report (MVR) | A written report submitted by the monitor to the sponsor after each monitoring visit. The report will include the date of the visit, site details, name of the monitor, and name of the PI and/or other individuals contacted. The report will include a summary of what the monitor reviewed, and the monitor’s statement concerning the significant findings/facts, deviations and deficiencies, conclusions, actions taken or to be taken and/or actions recommended to secure compliance. The report contains evidence of Sponsor review. |
| National Institute for Health Research (NIHR) | The National Institute for Health Research (NIHR) is a UK government agency. It is the nation's largest funder of health and care research and provides the people, facilities and technology that enables research to thrive. The NIHR works in partnership with the NHS, universities, local government, other research funders, patients and the public. |
| Non-commercial clinical trial | In accordance with Directive 2001/20/EC, a non-commercial clinical trial is defined as a trial:* Conducted by a non-commercial organisation, with no industry sponsor, that is not part of the development program for a marketing authorisation of a medicinal product; or,
* If potentially leading to a marketing application, where the holder of the intellectual property/patent is a not-for-profit organisation.
 |
| Non-CTIMP | Any clinical trial which is not a CTIMP. See also ‘Clinical trial’. |
| NRES | National Research Ethics Service. |
| Non-investigational medicinal product (NIMP) | Medicinal products supplied to participants in a trial, used in accordance with the protocol, which do not fall under the definition of IMPs in Directive 2001/20/ECExamples include:Medicinal products used to minimise anticipated adverse reactions e.g. corticosteroids and/or antihistamines (NIMP) treatment given to reduce the risk of expected adverse reactions before the administration of a new anti-neoplastic agent (IMP).Medicinal products used as rescue medication e.g. opioid pain relief treatment (NIMP) given as a rescue medication when administration of a new IMP painkiller (IMP) is found not to give adequate pain reliefMedicinal products used as challenge agents e.g. a skin prick test (NIMP) used to identify participants with allergic responses for the inclusion/exclusion criteria for a clinical trial.Medicines used to assess primary end-points in the clinical trial e.g. PET radiopharmaceuticals (NIMP) administered to a clinical trial population to measure organ function before and after the participant has been given an IMP whose effects in this organ are the primary end-point.Concomitant medicinal products systematically prescribed to study participants e.g. Anti-cancer treatment (NIMP) in the trial of a new anti-sickness drug (IMP), where the objective of the trial is to assess the anti-sickness effect of the new drug by testing the new drug against the gold standard anti-sickness drug (NIMP) in participants treated with the same anti-cancer treatment (NIMP).Background treatment administered to each participant in a trial e.g. Adjuvant chemotherapy (NIMP) given to all participants in the development of a new indication for a licensed medicine (IMP).Detailed and useful examples of NIMPs can be found in the European Commission ‘Definition of Investigational Medicinal Products (IMPs). Definition of Non Investigational Medicinal Products’. |
| OID | Organisation information document. |
| On-site monitoring | The act of overseeing the progress of a clinical trial by visiting the trial site, and of ensuring that it is conducted and recorded in accordance with the protocol, Standard Operating Guidelines (SOP’s), Good Clinical Practice (GCP) and the applicable regulatory requirement(s).  |
| Outcome measure(s) | The specific measure(s) used to assess whether the research objectives have been met. |
| Participant | An individual who participates in a clinical research project. This may involve being the target of observation for research, a recipient of an investigational product(s) or as a control. |
| Participant information sheet (PIS) | The Participant Information Sheet describes in lay (clear and easy) language a research project, explaining its purposes and methods, and outlining the risks and benefits of participation. Information sheets are also referred to as ‘Patient Information Sheet’. |
| pCRF | Paper case report form. See ‘case report form (CRF)’.  |
| PDR | Performance and Development Review. |
| Peer review | The evaluation of research by fellow scientist, academics and/or professionals to assess its suitability. |
| Personal protective equipment (PPE) | Equipment that will protect the user against health or safety risks at work e.g., in the laboratory. Personal protective equipment includes gloves, respirators, eye protectors, helmets, harnesses and other items of personal clothing. See also UoB Safety Services for guidance on Personal Protective Equipment.  |
| Policies | Policies are developed to describe the UoB’s approach to areas that are regulated; they explain why the UoB has its procedures. Where regulatory requirements are not explicitly prescriptive (e.g. they do not detail an implementation method), a policy may be developed to specify the way in which the UoB will meet the requirements. A policy may also be developed when the UoB’s position on an issue or area is still undetermined, but that issue or area would normally be documented within the UoB QMS. |
| Principal investigator (PI) | An individual responsible for the conduct of the research at a research site. There should be one PI for each research site. In the case of a single-site research project, the chief investigator and the PI will normally be the same person. See also 'Chief investigator (CI)' and 'UoB principal investigator'. |
| Projects mailbox | Central mailbox stored on the University of Birmingham’s email system. Used as a central email address and storage facility for all emails relating to the project. Access to the mailbox is allocated to specified staff members as required. |
| Project management group | The group normally includes those individuals responsible for the day-to-day management of the clinical research project, such as the chief investigator, study/trial co-ordinator, statistician, and monitor. The role of the group is to monitor all aspects of the conduct and progress of the project, ensure that the protocol is adhered to, and to take appropriate action to safeguard both the participants and the quality of the clinical research itself. For clinical trials, also known as a trial management group (TMG).  |
| Project steering committee | The role of the committee is to provide the overall supervision of the clinical research project. Ideally, it should include members who are independent of the investigators, their employing organisations and sponsors. The committee should monitor the project’s progress and conduct and advise on scientific credibility. For clinical trials, also known as a trial steering committee (TSC). |
| Public | The general public includes carers, relatives of patients and service users and healthy volunteers. |
| Public engagement | Working in collaboration with patients, service users or the public to disseminate information and knowledge about research, for example, science festivals, open days and media coverage. |
| Public involvement | Public involvement in research refers to the public being involved in the research process so that the work, or elements of it, is done with or by the public and not 'to', 'about' or 'for' them.Public involvement does not refer to taking part in research as a research participant. |
| PQS | Pharmaceutical quality system. |
| QMS management plan | The plan to develop, maintain and review the quality management system. |
| QMS manager | The individual responsible for developing and maintaining a QMS. The individual may also have another job title/role. |
| Qualified person (QP) | The qualified person is responsible for certifying that each batch of IMP has been manufactured and checked in compliance with the requirements of EU GMP, the product specification file and the CTA. |
| Quality assurance (QA) | All the planned and systematic actions that are established for a research project’s compliance. They ensure that the research project is conducted in compliance with GCP and the applicable regulatory requirements. They also ensure that any data generated, documented/recorded, and reported is also compliant with relevant regulatory requirements/legislation. |
| Quality control (QC) | The operational techniques and activities undertaken within the quality assurance system, to verify that the requirements for quality of the project-related activities have been fulfilled. |
| Quality control documents (QCDs) | Quality Control Documents can be instructions, forms, templates or checklists. They are developed to share best practices, promote standardisation to guarantee quality standards are maintained and reduce resources otherwise needed to develop similar documents. Unless indicated otherwise in the relevant SOP, QCDs are not mandatory and are designed to be an optional aid. |
| Quality management system (QMS) | A quality management system (QMS) is a system that includes procedures and policies to describe how certain tasks should be performed. It encapsulate any standards and/or regulatory requirements that may apply to those tasks. By adhering to the Quality Management System, the user and the UoB will be assured that applicable regulations are adhered to. |
| R&KT Office  | Research and Knowledge Transfer Office located in each College at the University of Birmingham. First point of contact for advice and assistance with all research-related issues. |
| Randomisation | The process of assigning participants to intervention/treatment or control groups in order to reduce bias. |
| Randomisation code | A unique number or code that is linked via a randomisation list to the intervention/treatment. |
| Randomisation schedule | A list of intervention groups, randomly ordered, used to assign sequentially enrolled participants to intervention groups. Also termed the "randomisation list". |
| Reference safety information (RSI) | Term used within EC Detailed Guidance (CT3) June 2011, meaning the applicable product information which is used to determine the expectedness of an Adverse Reaction. This information is normally obtained from within the Summary of Product Characteristics or Investigator Brochure; when referring to the Investigator Brochure the relevant section must be defined. It may be a separate document in its own right. It must be defined at the start of a trial. |
| Relevant material | As defined by the Human Tissue Act: material, other than gametes, which consists of or includes human cells, does not include embryos outside the human body, or hair and nail from the body of a living person. |
| Reportable issue | Either a deviation from the Laboratory’s documented policies, work instructions, clinical trial protocol, contract or any comparable documents or equipment failures (for example, refrigerators, freezers or centrifuges), which may compromise the integrity of the sample or the quality of the data.  |
| Research ethics committee (REC) | An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human participants involved in clinical research and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favourable opinion on, the protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the participants. |
| Research Ethics, Governance & Integrity team (REGI) | Research Ethics, Governance & Integrity team (REGI) facilitates the University’s research ethics and governance processes for all staff and postgraduate student research projects. See also 'Research Governance Team (RGT)' and 'Research ethics team'.  |
| Research ethics team | That part of the Research Governance and Ethics Team whose primary activity is the management of the University’s research ethics review processes. |
| Research facilitator | The research facilitator acts as the central contact point in project development, initiation and conduct. The research facilitator liaises with relevant contacts e.g. Finance Office, peer review and any other internal or external bodies which may be able to assist. Research facilitators work closely with Head of School to ensure compliance with the UoB Code of Practice for research and other regulations especially with regard to more junior researchers or those working outside of a Clinical Trials Unit. Different Colleges may use different job titles for the same role. |
| Research Governance, Ethics and Integrity Committee (RGEIC) | A University of Birmingham committee providing senior management oversight of research activities within the University, and establish and implement research related policies within the University, with referral to the University Executive Board where necessary. |
| Research Governance Team (RGT) | The Research Governance Team is part of the Research Governance and Ethics Team and is responsible for Sponsorship decisions and confirmation of Sponsorship on behalf of the UoB, signing-off any applications for approval/authorisation as Sponsor representative, issuing trial specific template Site Agreements, and for maintaining Sponsor oversight. |
| Research support partner | The Research Support Partner is responsible for ensuring research in the College is supported by providing the first point of contact, both internally and externally, for advice and assistance with all research-related issues, by providing up to date information regarding research funding and by providing an essential interface with relevant corporate services. Different Colleges may use different job titles for the same role. |
| RG number | Research Governance number; the unique identifier that the Research Governance Team will assign to any project put forward for UoB Sponsorship. May also be known as the Sponsor number.  |
| RG&ET | Research Governance and Ethics Team, consisting of the Research Governance Team and the Research Ethics Team. |
| Self-assessment form (SAF) | UoB Ethical Review of Research Self-Assessment Form. |
| Self-evident correction | A correction to the CRF that can be made by the sponsor without the requirement for a referral of a data clarification to the investigator. |
| Serious adverse device effect (SADE) | Adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event. |
| Serious adverse event (SAE) | Any untoward medical occurrence or effect that at any dose:* results in death
* is life threatening\*
* requires hospitalisation or prolongation of existing inpatients’ hospitalisation
* results in persistent or significant disability or incapacity
* is a congenital anomaly/birth defect
* or is otherwise considered medically significant by the Investigator\*\*.

Comments: The term severe is often used to describe the intensity (severity) of a specific event. This is not the same as serious, which is based on participants/event outcome or action criteria.\* Life threatening in the definition of an SAE refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event that hypothetically might have caused death if it were more severe.\*\* Medical judgment should be exercised in deciding whether an AE is serious in other situations. Important AEs that are not immediately life threatening or do not result in death or hospitalisation but may jeopardise the participant or may require intervention to prevent one of the other outcomes listed in the definition above, should be considered serious. |
| Serious adverse reaction (SAR) | For CTIMPs, an adverse reaction which also meets the definition of a serious adverse event. |
| Serious breach | A 'serious breach' is a breach that is likely to affect to a significant degree: the safety or physical or mental integrity of the participants; or the scientific value of the trial. |
| Site | A hospital, health centre, surgery or other establishment or facility in the UK at or from which the research is being conducted on participants. |
| Site file | The site file contains all essential documents held by principal investigator(s) conducting a trial which individually and collectively permit the evaluation of the conduct of a trial and the quality of the data produced. Also known as the Investigator Site File (ISF). |
| Source data verification (SDV) | The process of checking the accuracy and completeness of case report for (CRF) entries against the source data contained in source documents. |
| Sponsor | Individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a clinical study. |
| Sponsor number | The unique identifier that the Research Governance Team will assign to any project put forward for UoB Sponsorship. May also be known as the RG number. |
| Sponsor support visit (SSV) | A visit to the investigators and their teams by the CRCT where the UoB is the sponsor or provides institutional oversight for the clinical research project. The SSV involves discussions with the research team and a review of the project, including key processes and documents such as participant consent and enrolment, collection and processing of study data and tissue sample management, as applicable. The SSV allows best practice to be shared between research teams, as well as providing feedback in areas of work that need further attention to ensure full adherence to applicable regulations and standards.  |
| Standard operating procedures (SOP) | A SOP is a set of detailed written instructions designed to encourage best practice and help users standardise the performance of a specific functions. It define tasks, allocates responsibilities, details processes, indicates documents and templates to be used and cross-reference to other work instructions, guidance or policy documents. SOPs provide standards against which the UoB may be audited or inspected. |
| Statistical advisor | A qualified statistician or experienced researcher who may contribute to some, but not all, aspects of the clinical research design and analysis, but takes responsibility for the statistical aspects of the tasks they perform. |
| Statistical analysis plan (SAP) | Pre-specified statistical methodology documented for the trial, either in the protocol and/or in a separate document. |
| Statistician | A qualified statistician who contributes to the design, analysis and interpretation throughout the clinical research life cycle and takes responsibility for the statistical aspects of the project. The statistician may be unblinded to the allocation and evolving results whilst performing interim analyses but will not disclose these to the rest of the research team. There may be a senior statistician supervising a more junior statistician. |
| Study/trial master file (S/TMF) | The study/trial master file consists of essential documents kept at the sponsor (or delegate) site, which enables both the conduct of a clinical study/trial and the quality of the data produced to be evaluated. The filing system can be in the form of a single file or a number of files as deemed most appropriate. |
| Study/trial system | The study/trial system describes the software and database used to store and manage clinical research data used for the analysis of outcome measures as defined in the protocol. This may include databases containing data, contact databases and data tracking systems. |
| Summary of product characteristics (SmPC) | Summary of product characteristics (SmPC) describes the properties and conditions for use of a particular medicinal product, and is the basis of information for health professionals on how to use the medicinal product safely and effectively. It includes the composition, pharmaceutical form and strength, approved indications, side effects, warnings and precautions for use, shelf life, storage conditions and the name of the marketing authorisation holder. |
| Suspected unexpected serious adverse reaction (SUSAR) | For CTIMPs, a Serious Adverse Reaction that is unexpected i.e. the nature, or severity of the event is not consistent with the applicable product information. A SUSAR should meet the definition of an Adverse Reaction, an Unexpected Adverse Reaction and a Serious Adverse Reaction. |
| System administrator | A person who is responsible for the upkeep, reliable operation and control of access of a computer system. |
| System testing | The process of ensuring that the software/system and database meets the requirements outlined in the URS. |
| System validation | The process of ensuring that a program operates on clean, correct and useful data through documented design, build and testing. For more information in the appropriate levels of testing please refer to the MHRA Good Clinical Practice Guide, section 14.5.2. |
| Trial data set (database) | (Personal) trial (relational) database, Excel spread sheet, Word documents etc. used to store trial data for the purposes of analysis. |
| Trial management group (TMG) | See ‘Project Management Group’. |
| Trial master file (TMF) | See ‘Study/Trial Master File (S/TMF)’. |
| Trial statistician | See ‘Statistician’. |
| Trial steering committee (TSC) | See ‘Project Management Group’. |
| Trial team | Chief investigator (CI) and their team of individuals taking on CI duties relating to the trial management. Individuals may include co-investigator, trial coordinator, trial administrator and/or data manager. |
| Trials office | A term commonly used to refer to the team responsible for the overall management of the trial, and their physical location. A trials office may be based in a Clinical Trials Unit, and may also be referred to as coordinating centre. |
| UK Clinical Research Collaboration (UKCRC) | The UKCRC brings together the NHS, research funders, industry, regulatory bodies, Royal Colleges, patient groups and academia in a UK-wide environmental that facilitates and promotes high quality clinical research for the benefit of patients. |
| UK Clinical Research Network (UKCRN) | Clinical research networks established in each of the four UK nations funded by the UK Health Departments. |
| Unanticipated serious adverse device effect (USADE) | Serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report. Note: Anticipated SADE (ASADE) is an effect which by its nature, incidence, severity or outcome has been previously identified in the risk analysis report. |
| Unblinding | The disclosure of the identity of blinded intervention/treatment. |
| Unexpected adverse reaction (UAR) | For CTIMPs, an adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g. investigator's brochure for an unauthorised investigational product or summary of product characteristics for an authorised product). |
| Unexpected and related event | For non-CTIMPs, an event which meets the definition of both an Unexpected Event and a Related Event. |
| Unexpected event | For non-CTIMPs, the type of event that is not listed in the protocol as an expected occurrence. |
| UoB | University of Birmingham. |
| UoB lead | The UoB lead is a (senior) person in the UoB who takes responsibility for the conduct and delivery of those parts of the study which are either carried out at or managed/overseen by the UoB. Normally this would be an academic researcher, but in some cases it may be a senior member of a UKCRC registered UoB CTU. |
| UoB principal investigator | The primary researcher in a research, who takes responsibility for the conduct and delivery of those parts of the research which are either carried out at or managed/overseen by the UoB.Note the term ‘principal investigator’ is also used in clinical research but has a different meaning.  |
| UoB sponsored study | A study for which the University of Birmingham acts as a sponsor or co-sponsor. These studies may be either CTU managed, or Investigator managed. |
| User requirement specification (URS) | A document that contains the requirements for the trial system. |
| Validation | The process of ensuring that a program operates on clean, correct, and useful data through documented design, build and testing. For more information in the appropriate levels of testing please refer to the MHRA Good Clinical Practice Guide, section 14.5.2. |
| Vendor  | Various types of external providers to whom a sponsor may delegate their functions to e.g. contract research organisations, laboratories, consultants, freelancers/ contractors etc. They exclude research collaborators and clinical research sites. |
| Version number | For the purposes of the UoB QMS, the version number format is based on the principle that whole numbers are used for finalised versions, and draft versions use decimal points. For example, the initial draft would have version number 0.1 and each subsequent draft will result in a changed version number (i.e. 0.2, 0.3 etcetera). Typically, the draft version number changes following an update and again at the time the updated draft is circulated for review. The first finalised version will have version number 1.0 and each draft update thereafter will have version number 1.1, 1.2. Any future finalised versions will have version numbers 2.0, 3.0 etc.  |
| West Midlands Research Training Collaborative (WMRTC) | The WMRTC aims to provide a forum whereby collaborating organisations can share best practice, pool learning resources and promote local initiatives in partnership with the Network. It aims to complement the activities of other research and training structures in the West Midlands. |