NHS
National Institute for Health Research

Commonly Used Research Abbreviations and Terms

ABPI	Association of the British Pharmaceutical Industry: A trade association for UK pharmaceutical companies
AE	Adverse Event
Amendment	A written description of a change to the protocol or supporting documents. All amendments should be submitted to HRA for ongoing HRA Approval.
AMRC	Association of Medical Research Charities
AR	Adverse Reaction (also known as ADR)
ARSAC	Administration of Radioactive Substances Advisory Committee: Research studies wishing to administer radioactive medicinal products to human subjects need to obtain ARSAC approval before NHS R&D approval
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 SARs that have occurred in subjects on that study in the past year
ATMP	Advanced Therapy Medicinal Products
BRC	Biomedical Research Centre: larger centre covering a number of topcs with facilities and research active clinicians/academics/research nurses to run clinical projects
BRU	Biomedical Research Unit: topic-focused centre which usually combines facilities and research active clinicians/academics/research nurses to run clinical projects, e.g. respiratory BRU
CA	Competent Authority: organisation approving the testing of new drugs/devices or approving the marketing licences, in the UK this is the MHRA
CC	Coordinating Centre
CCF	NIHR Central Commissioning Facility. The CCF manages the following research funding programmes.
CF	Consent Form (also ICF, Informed Consent Form)
CFR	Code of Federal Regulations (US)
CI (i)	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.
CI (ii)	Coordinating investigator
CPMS	Central Portfolio Management System: a national system that will enable the NIHR CRN to capture high quality study information and produce a range of detailed reports to help manage and deliver studies. CPMS will replace the Portfolio Database, Industry Application Gateway and interim Industry Tracker
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
CRF (i)	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 (ii)	Clinical Research Facility: hospital-like facility with consulting rooms, standard patient beds, ward medical equipment, research nurses supporting only research
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
CSAG	Clinical Studies Advisory Group
CSG	Clinical Studies Group
CSP	Coordinated System for gaining NHS Permissions (no longer in use, see HRA Approval)

CTA (i)	Clinical Trials Administrator: person providing coordinating/secretarial support for running clinical studies
CTA (ii)	Clinical Trials Agreement: contract between the legal Sponsor and the hosting research sites
CTA (iii)	Clinical Trials Associate (similar to CRA): person involved in the management of a study from initiation, through conduct/monitoring to close-out
CTA (iv)	Clinical Trials Authorisation: The regulatory approval for a clinical trial of a medicinal product issued by the MHRA
CTAAC	Clinical Trials Advisory and Awards Committee
CTIMP	Clinical Trial of an Investigational Medicinal Product
CTU	Clinical Trials Unit: Design and manage CTIMPs, sometimes in specialist clinical areas, such as Cancer, or types of trial, such as RCTs
Delegation of Duties log	Document detailing who has been delegated each duty by the Principal Investigator.
DH	Department of Health (for England)
DPA	Data Protection Act
DQ	Data query
DSMB	Data and Safety Monitoring Board: An independent committee composed of clinical research experts and community representatives that reviews data whilst a clinical trial is in progress to ensure that participants are not being exposed to undue risk
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
ECMC	Experimental Cancer Medicine Centre
eCRF	An electronic CRF
Eligibility	A clinical assessment of whether the potential participant meets the inclusion and exclusion criteria for the study as described in the protocol
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
EPAP	European Patient Ambassador Programme
eTMF	An electronically stored TMF
EU	European Union
EudraCT	European Clinical Trials Database: A database of all clinical trails in Europe, held since 1994 in accordance with EU directive 2001/20/EC
FDA	Food and Drug Administration: the Competent Authority in the United States, giving authorisation to conduct clinical trials and issuing marketing licences
Feasibility	The process of reviewing the protocol to determine whether or not a study can be safely and effectively delivered
GAfREC	Governance Arrangements for Research Ethics Committees
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
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
GMP	Good Manufacturing Practice: quality assurance standard for producing IMP, medicinal products
GTAC	Gene Therapy Advisory Committee: the ethics committee for clinical studies using genetically modified products; usually no REC approval required
HEI	Higher Education Institution
HFEA	Human Fertilisation and Embryological Authority
HRA	Health Research Authority

HRA Approval	The process for the NHS in England that brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent REC opinion provided through the UK Health Departments' Research Ethics Service. 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.
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
IB	Investigator's Brochure: A compilation of clinical and pre-clinical pharmacological/biological data relevant to the use of that IMP(s) in human subjects (one single IB for all trials using the same IMP)
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
IMP	Investigational Medicinal Product: an unlicensed new drug, an existing drug tested outside its licence, or existing drugs tested against each other for their efficacy/safety. The MHRA provide advice to help you decide if your product is an investigational medicinal product (IMP).
Indemnity	Compensation for damage, loss or injury
Investigator	Researcher conducting the (clinical) study, those researchers leading the team are referred to as CI or PI
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)
IRB	Independent Review Boards: US equivalent of authorised REC
IRMER	Ionising Radiation Medical Exposure Regulations: part of NHS R&D approval, usually done by the local hospital experts
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.)
ISRCTN	International Standard Randomised Control Trial Number: A simple numeric system for the identification of randomised controlled clinical trials worldwide. Allows the identification of trials and provides a unique number that can be used to track all publications and reports resulting from each trial.
LCRN	Local Clinical Research Network
LPMS	Local Portfolio Management System: local systems which capture high quality study information and integrate with CPMS
MCA	Mental Capacity Act
mCIA	model Clinical Investigation Agreement: for medical devices, covers the running of the study, not design of prototype or design of protocol; standard template for the UK (use is not obligatory)
mCTA	model Clinical Trial Agreement: for IMP studies with commercial sponsor/CRO conducted; standard template for the UK (use is not obligatory)
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
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

mNCA	model Non-Commercial Agreement: for clinical research studies; standard template for the UK (use is not obligatory)
Monitor	The person designated by the sponsor to perform site visits and conduct the monitoring process; eg check whether there are any deviations from the protocol and that all source data was transferred into the Case Report Forms correctly
MRC	Medical Research Council
Multi Centre Study	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
ND	Not done (in CRFs)
NHS	National Health Service
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	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
NIHR CRN	National Institute for Health Research Clinical Research Network
NIMP (or non-IMP)	Non-Investigational Medicinal Product: product used alongside IMP but not directly under investigation in the research study, e.g. a challenge agent
NK	Not known (in CRFs)
NOCRI	National Office for Clinical Research Infrastructure
Non-substantial amendments	Changes to the details of a study that have no significant implications for the subjects, the conduct, the management or the scientific value of the study (sometimes referred to as administrative amendments).
NRES	National Research Ethics Service: umbrella organisation responsible for all REC across the UK (replaced COREC in 2007)
ODP	Open Data Platform: an online, open platform which provides secure access to collated study and recruitment data
PI	Principal Investigator: The lead person at a single site designated as taking responsibility within the research team for the conduct of the study
PIC	Participant Identification Centre: NHS or other organisation which only identifies participants from a database etc, but recruitment/receiving consent and study conduct are managed elsewhere
PIS	Participant or Patient Information Sheet: An information leaflet given to those who have been invited to participate in a research study. The sheet is designed to provide the potential participant with sufficient information to allow that person to make an informed decision on whether or not they want to take part
PPIE (or PPI)	Patient and Public Involvement and Engagement
QA	Quality Assurance
QC	Quality Control
QLQ	Quality of Life Questionnaire
R&D	Research and Development: often name of Department within NHS hospitals giving permission to conduct projects on those facilities with patients/staff
RCT	Randomised Controlled Trial: A randomised controlled trial (RCT) is a clinical study in which two (or more) forms of care are compared; the participants are allocated to one of the forms of care in the study, in an unbiased way
RDS	Research Design Service: organisation with a number of experts who can help write the protocol/documents for NIHR grant applications
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

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)
RfPB	Research for Patient Benefit: NIHR research funding stream
RGF	Research Governance Framework: DH guidance for the conduct of research within the NHS in England (use 2nd edition, 2005)
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
Screening	The process of identifying eligible patients prior to approaching them to determine if they are willing to consent to participate 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
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)
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
SIV	Site initiation visit
SLA	Service Level Agreement
SMO	Site Management Organisation
SmPC	Summary of Product Characteristics: smaller version of Investigator Brochure with details on pharmacological effects, side effects, but issued for a product that already holds a marketing licence
SOP	Standard Operating Procedure: detailed written instructions designed to achieve uniformity of the performance of a specific function
Substantial Amendment	An amendment to the protocol or any other study specific documentation, the terms of the REC application or the terms of the CTA application (as applicable) that is likely to affect to a significant degree the safety or physical or mental integrity of the participants or the scientific value of the trial.
SUSAR	Suspected Unexpected Serious Adverse Reaction: A Serious Adverse Reaction (SAR) which is Unexpected (i.e. its nature and severity is not consistent with the known information about that product from the Investigator's Brochure or the SmPC) and suspected, as it is not possible to be certain of causal relationship with the IMP
TMF	Trial Master File (file with essential documents held by the Chief Investigator/Sponsor organisation)
UKCRC	United Kingdom Clinical Research Collaboration
WHO	World Health Organisation
WMA	World Medical Association