

GLOSSARY

COMMERCIAL CONTRACT RESEARCH: Commercial contract research is that where a company has developed a protocol and is approaching one or more investigators to collect data to support the study. All research costs should be covered by the company who would normally be the sponsor.

COMMERCIAL COLLABORATIVE RESEARCH: Commercial collaborative research is that where the local investigator has developed the protocol and approached a commercial company to provide funding, or where a company has approached an investigator with an idea for a study and the protocol is developed in collaboration.

COMPREHENSIVE RESEARCH NETWORK (CRN): The NIHR Comprehensive Research Network (CRN) was created as part of the government's research and development strategy, "Best Research for Best Health" to provide a world-class infrastructure for clinical trials in all areas of disease and clinical need within the NHS. For more information see, <http://www.ukcrn.org.uk/networks/comprehensive>

COMPREHENSIVE LOCAL RESEARCH NETWORKS (CLRN)s: 25 CLRN)s have been established covering the whole of England. CLRN)s are the primary vehicle for providing infrastructure to support study involvement. They will encourage participation in the range of high quality clinical studies in the UKCRN portfolio and will provide a coordinated and efficient infrastructure of research personnel and facilities to support recruitment. A map of the CLRN)s is available at <http://www.ukcrn.org.uk/index/networks/comprehensive/map.html>

DEMENTIAS AND NEURODEGENERATIVE DISEASES RESEARCH NETWORK (DeNDRoN): The Dementias and Neurodegenerative Diseases Research Network supports research in the field of dementia and neurodegenerative, covering major diseases including Alzheimer's, motor neurone disease, Parkinson's and Huntington's disease. Seven Local Research Networks support work in this area. <http://www.dendron.org.uk>

DIABETES RESEARCH NETWORK (DRN): The primary goal of the Diabetes Research Network is to achieve benefits for people with diabetes, or those at risk of developing diabetes, through excellence in clinical research. Eight Local Research Networks support work in this area. See, www.ukdrn.org

EU DIRECTIVE FOR CLINICAL TRIALS: The final version of this was published in the *Official Journal of the European Communities* on 1 May 2001. The UK Regulations were implemented on 1 May 2004. In the UK the requirements of this Directive are implemented with the UK Medicines for Human Use Regulations 2004. The Directive covers the conduct of all clinical trials in the EU on human subjects involving medicinal products (as defined in Article 1 of Directive 65/65/EEC). See <http://medicines.mhra.gov.uk/ourwork/licensingmeds/types/clintrialdir.htm>

EUDRACT: (THE EUROPEAN CLINICAL TRIALS DATABASE): EUDRACT is designed to be a register of all clinical trials in the Community, information on the content, commencement and termination of the clinical trials and on inspections. See http://pharmacos.eudra.org/F2/pharmacos/docs/Doc2003/april/cp-guidance-eudract_230403.pdf (Note: This database is not publicly available)

EUDRAVIGILANCE: EudraVigilance is the European data-processing network and database management system for the exchange, processing and evaluation of

Individual Case Safety Reports (ICSRs) related to medicinal products authorised in the European Economic Area (EEA). See <http://www.eudravigilance.org/>

EXPERIMENTAL MEDICINE (EM): Experimental medicine is defined as an investigation in human beings to identify the cause of disease and to test the validity and importance of new discoveries or treatments.

GMP (GOOD MANUFACTURING PRACTICE): GMP refers to principles and specifications for good manufacturing of medicinal products that are set by the Federal Therapeutic Goods Administration (FTGA), in accordance with international standards (known as Codes of GMP). These are the standards manufacturers must comply with to provide safe and reliable products for consumers.

HUMAN TISSUE AUTHORITY (HTA): The Human Tissue Authority has replaced the Retained Organs Commission. The Authority has oversight of the use of human tissue for a widely drafted series of purposes including anatomical examination, education and training relating to human health and research, research and transplantation. As such it will subsume HM Inspectorate of Anatomy and ULTRA. Any person carrying out any of the activities specified in the act must be licensed and there are strict guidelines and procedures governing the use of tissue to be used for donation or research purposes. For more information about the Human Tissue Act and the HTA download the relevant reports from <http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsLibrary/fs/en> or visit <http://www.hta.gov.uk>

ICH-GOOD CLINICAL PRACTICE (GCP): International Conference on Harmonization 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. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that clinical trial data are credible. See <http://www.emea.eu.int/pdfs/human/ich/013595en.pdf>

INVESTIGATIONAL MEDICINAL PRODUCT: An Investigational Medicinal Product is an active substance or placebo being tested or used as a reference in a clinical trial. It includes licensed medicinal products that are being used either off licence, within the licence but where the study involves assessing the efficacy and/or safety of the product, or assembled (formulated or packaged) in a way different from the form of the product authorised under the authorisation. See <http://medicines.mhra.gov.uk/ourwork/licensingmeds/types/clintrialdir.htm>

INVOLVE: (Formerly Consumers in NHS Research). Involve aims to ensure that consumer involvement in R&D in the NHS, Public Health and Social Care improves the way that research is prioritised, commissioned, undertaken and disseminated. See <http://www.invo.org.uk/>.

MEDICINE FOR CHILDREN RESEARCH NETWORK (MCRN): The MCRN aims to facilitate the development of medicines that are both safe and effective in the treatment of children. Six Local Research Networks in England support this work. <http://www.mcrn.org.uk>

MEDICINES FOR HUMAN USE (CLINICAL TRIALS) REGULATIONS 2004: The UK Statutory Instrument, which implement the requirements of EU Directive

2001/20/EC for Clinical Trials. It came into force on 1 May 2004. See <http://www.hmsa.gov.uk/si/si2004/20041031.htm>

MENTAL HEALTH RESEARCH NETWORK (MHRN): The UK MHRN is a network designed to provide a research infrastructure. The network supports vital large-scale research which will help to raise the standard of mental health and social care research throughout England. <http://www.ukmhrn.info>

NHS R&D FORUM: The NHS Research and Development Forum is an organisation for individuals and departments involved in the management and planning of R&D activities and in conducting R&D in health and social care. The purpose of the Forum is to improve the environment for research within organisations delivering health and social care by encouraging high standards and providing support and communication networks. The Forum is an inclusive organisation open to all involved in R&D, including directors, managers, administrators, consumers and researchers themselves. The activities of the Forum encompass research across the full range of health and social care including community and primary care, secondary and tertiary care, public health and social services. See <http://www.rdforum.nhs.uk/>

NHS RESEARCH GOVERNANCE FRAMEWORK: The NHS Research Governance Framework (RGF) defines the broad principles of good research governance and is key to ensuring that health and social care research is conducted to high scientific and ethical standards. The publication of the research governance framework is the first stage in a continuing process for promoting improvements in health and social care research across the board. It will help to enhance the contribution of research to the partnership between services and science. It sets standards, details the responsibilities of the key people involved in research, outlines the delivery systems and describes local and national monitoring systems. The RGF “came into force” on 1 April 2004 but is not actually legislation. See <http://www.dh.gov.ukPolicyAndGuidance/ResearchAndDevelopment/ResearchAndDevelopmentAZ/ResearchGovernance/fs/en>

NHSC (NATIONAL HORIZON SCANNING CENTRE): The National Horizon Scanning Centre (NHSC) aims to provide advance notice to the Department of Health in England and Wales of selected key new and emerging health technologies (including changing applications and uses of existing technologies) that might require urgent evaluation, consideration of clinical and cost impact or modification of clinical guidance. See <http://www.publichealth.bham.ac.uk/horizon/>

NATIONAL INSTITUTE FOR HEALTH RESEARCH (NIHR): The National Institute for Health Research provides a key mechanism through which the Department of Health will deliver the new R&D strategy set out in 'Best Research for Best Health'. The R&D strategy outlines the direction that NHS research will take to build a vibrant and world-class research environment in England. <http://www.nihr.ac.uk>

NRES (NATIONAL RESEARCH ETHICS SERVICE): The National Research Ethics Service (NRES) is a directorate within the National Patient Safety Agency and provides help and leadership for Research Ethics Committees by co-ordinating the development of operational and infrastructure arrangements in support of their work. Further details at: <http://www.nres.npsa.nhs.uk/recs/index.htm>

ONCORE UK (NATIONAL CANCER TISSUE RESOURCE): NTRAC led work on behalf of the NCRI to develop proposals for a National Cancer Tissue Resource (NCTR). The NCTR will facilitate research that advances cancer therapeutics and

diagnostics from the laboratory to the clinic and will ultimately provide benefit for UK citizens. This initiative is an important development for cancer research and depends upon the willingness of surgical patients to engage with researchers to combat cancer by donating surplus surgical samples to the national resource. See <http://www.ntrac.org.uk/Initiatives/NCTR/NCTR.aspx>

ORPHAN DRUGS/STUDIES: An orphan drug is any drug developed under the 1983 U.S. Orphan Drug Act, which concerns drugs for rare diseases such as those affecting less than 200,000 people in the US. This has been adopted as a subclause of the FDA. Developing a drug for these small groups would be financially unsound. Therefore, development of drugs for such diseases is rewarded by tax reductions and a monopoly for that drug for a limited time (7 years). See <http://www.fda.gov/orphan/index.htm>

PHARMACOKINETICS: The study of the absorption, distribution, metabolism and elimination of drugs.

PHARMACODYNAMICS: The Study of the biochemical and physiological effects of drugs and the mechanisms of drug action.

PHARMACOGENETICS: The study of how people respond differently to drugs due to their genetic makeup, in terms of both how well the drug will work and what side effects the person might suffer.

PHARMACOVIGILANCE: Pharmacovigilance is defined as watchfulness in guarding against danger from drugs or providing for safety of drugs. It can also be a dedicated department whose role is to monitor toxicity and safety of drugs both in the developmental phase and post marketing. A joint MRC/DoH workstream on pharmacovigilance aims to develop workable operating procedures for the publicly funded research community for reporting, monitoring and managing adverse reactions and events that will satisfy the requirements of the Medicines for Human Use (Clinical Trials) Regulations. It is also envisaged that the group will review and make a statement of good practice of use of existing pharmacovigilance systems including Data Monitoring Committees, Drug Information Services and ADR Monitoring Centres. The group will also produce a draft capacity building plan to achieve the requirement for the operating procedures. See <http://www.ncchta.org/eudirective/pharmaco.asp>

PHASE I CLINICAL TRIALS: In Phase I trials researchers test an experimental drug or treatment in a small group of people (20-80) for the first time to evaluate safety, determine a safe dose range and identify side effects.

PHASE II CLINICAL TRIALS: In Phase II trials the experimental study drug or treatment is given to a larger group of people (100-300) to see if it is effective and to further evaluate its safety.

PHASE III CLINICAL TRIALS: In phase III trials, the experimental drug or treatment is given to large groups of people (100s or 1000s) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and to collect information that will allow the experimental drug or treatments to be used safely. A phase III trial can provide enough information for a new treatment or procedure to be used as the new 'standard treatment'.

PHASE IV CLINICAL TRIALS: In phase IV trials, often referred to as post marketing studies as they occur once a drug has been licensed for use, provide further information on side effects, safety and longer term risks and benefits.

PRIMARY CARE RESEARCH NETWORK (PCRN): The PCRN works closely with the UKCRN topic-specific Clinical Research Networks to support research in primary care. It has as a central objective, the development of the evidence base to inform the prevention, diagnosis, treatment and management of illness and disease in primary care. <http://www.ukcrn.org.uk/index/networks/primarycare.html>

SERVICE SUPPORT COSTS: Service Support Costs are one of three categories into which the costs of externally funded non-commercial R&D can be divided (the other two are R&D Costs and Treatment Costs). These costs are the *additional* patient care costs associated with the research, which would end once the R&D activity in question had stopped, even if the same patient care service continued to be provided. For more information see <http://www.dh.gov.uk/Home/fs/en>

SPONSOR: The concept of a “Sponsor” for a clinical trial was introduced by the EU Clinical Trials Directive (2001/20/EC) and was adopted into the Department of Health’s Research Governance Framework for Health and Social Care for all clinical research. The definition of Sponsor for trials of investigational medicinal products (IMPs) is the individual, organisation or group of organisations/individuals that take responsibility for the initiation, management and financing (or arranging financing) for the study. Sponsors of trials involving IMPs have specific legal responsibilities as specified in the EU Clinical Trials Directive and the UK’s Medicines for Human Use (Clinical Trials) Regulations 2004. For all other studies, (i.e. research that falls within the scope of the Research Governance Framework but that is not a trial of an IMP), the definition of sponsor is the individual, organisation or group of organisations/individuals that takes the lead in confirming that there are proper arrangements in place for the initiation, management, monitoring and financing of a study. There is more information about the responsibilities of Sponsor on the Department of Health website: <http://www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment/ResearchAndDevelopmentAZ/ResearchGovernance/fs/en>

STROKE RESEARCH NETWORK (SRN): The aim of the SRN is to facilitate stroke research by bringing about focused, effective investment to enhance NHS research infrastructure for stroke. Eight Local Research Networks in England support this work. <http://www.uksrn.ac.uk>

SUSAR (SUSPECTED UNEXPECTED SERIOUS ADVERSE REACTION): All adverse events that are suspected to be related to an investigational medicinal product and that are both unexpected and serious are considered to be SUSARs. For more information see <http://eudract.emea.eu.int/docs/Detailed%20guidance%20SUSAR.pdf>

UKCRC (UNITED KINGDOM CLINICAL RESEARCH COLLABORATION): The UK Clinical Research Collaboration (UKCRC) is a partnership of organisations working to establish the UK as a world leader in clinical research, by harnessing the power of the NHS. Its aim is to re-engineer the environment in which clinical research is conducted in the UK, to benefit the public and patients by improving national health and increasing national wealth. UKCRN forms part of the UK Clinical Research Collaboration See <http://www.ukcrc.org>

UKCRN (UNITED KINGDOM CLINICAL RESEARCH NETWORK): The UKCRN aims to improve the speed, quality and integration of research with the ultimate aim of improving patient care. The network will initially cover the existing NHS networks in cancer and mental health and new ones in the priority areas of medicines for children. <http://www.ukcrn.org.uk>

UKCRN PORTFOLIO STUDY: A UKCRN Portfolio study is any clinical study which is supported or funded by a UKCRC partner. Future trials funded or supported by these organisations will also become part of the Portfolio. In addition to UKCRC partner-funded trials, it is recognised that there are a number of other well-designed local, national and international “non-UKCRC trials” that have the potential to be part of the UKCRN Portfolio (thus enabling access to UKCRN infrastructure). The UKCRN has established a process for the approval of non-UKCRC partner trials for the inclusion in the UKCRN portfolio. View the UKCRN portfolio at <http://www.ukcrn.org.uk/index/clinical/portfolio.html>