Weston Area Health Trust Research and Development Department

Glossary of terms

V1 – 08/03/2013

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

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

An Adverse Event (AE) can there for be any unfavourable and unintended sign (including an abnormal laboratory finding, symptom, or disease temporally associated with the use of medicinal (investigational) product whether or not related to the medicinal (investigational) product.

**Adverse Incident (AI):** Any event or circumstance that could or did lead to harm, loss or damage.

**Adverse Reaction (AR):** Any untoward or unintended medical occurrence in a subject to an investigational medicinal product (IMP) which is related to any dose administered to that subject.

All Adverse Reactions judged either by the reporting investigator or the sponsor as having a reasonable causal relationship to an IMP (there is evidence or argument to suggest a causal relationship) qualify as an AR.

**Amendment:** A written description of a change or formal clarification.

**ARSAC:** The Administration of Radioactive Substances Advisory Committee. A Department of Health committee established to advise Health Ministers on applications for Certificates to administer Radioactive Medicinal Products to human subjects.

**Annual Safety Report (ASR):** For studies involving the use of an Investigational Medicinal Product, this is the annual report which must be submitted to the MHRA detailing all SUSARs and SAEs that have occurred in subjects on that study in the past year.

**CLRN:** Comprehensive Local Research Network

**CSP**: National Institute for Health Research (NIHR) Coordinated System for gaining NHS Permission

**CTIMP**: Clinical trial of an investigational medicinal product

**Case Report Form (CRF):** A printed, optical or electronic document designed to record all of the protocol required information to be reported for each study subject.

**Chief Investigator (CI):** The investigator with overall responsibility for the research. In a multi-site study, the CI has co-ordinating responsibility for research at all sites. The CI may also be the PI at UBHT. In the case of a single-site study, the CI and the PI will normally be the same person.

Clinical Trials Authorisation (CTA): The regulatory approval for a clinical trial of a medicinal product issued by the MHRA. It replaces the previous CTX, DDX.

**COREC:** Central Office for Research Ethics Committees (now defunct and replaced by National Research Ethics Service).

**Data and Safety Monitoring Board** **(DSMB):** 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.

**EMEA:** 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.

**Essential Documents:** Those documents required in order for a research study to be conducted in accordance with (ICH) GCP guidelines, the Research Governance Framework and the Medicines for Human Use (Clinical Trials) Regulations 2004. A table of all essential documents required can be found in the R&E department document ‘Investigator Site File Template’.

EudraCT number: A unique reference number given to each clinical trial for which at least one study site is located in the European Community. The number must be included on all Clinical Trial Authorisation (CTA) applications, REC applications and other documents relating to the trial (e.g. SUSAR reports).

EudraCT: European Clinical Trials Database. A database of all clinical trials commencing in the European Community from May 1st 2004. Established in accordance with the Medicines for Human use (Clinical Trials) Regulations 2004.

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

**GCP:** A standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of research studies that provides assurance that the data and results reported are accurate and credible and that the rights, integrity, confidentiality and well-being of all study participants are protected.

**GTAC**: Gene Therapy Advisory Committee

**HFEA**: Human Fertilisation and Embryology Authority

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

**IRAS:** Integrated Research Application System, the online application system used to apply for most permissions and approvals for research in health and social care in the UK.

**Indemnity**: Compensation for damage, loss or injury

Informed Consent Form (ICF): A form signed and dated by a study participant which voluntarily confirms their willingness to participate in a study after having been informed of all aspects of the study relevant to the their decision to take part.

Informed Consent: A process by which a subject voluntarily confirms his or her willingness to participate in a particular study, after having been informed of all aspects of the study that are relevant to the subject’s decision to participate.

**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 a medicinal product which has a marketing authorisation but is, for the purposes of the trial being used or assembled (formulated or packaged) in a way different from the approved form or being used for an unapproved indication or when used to gain further information about an approved use.

**Investigator Site File (ISF):** A file designed for use in organising and collating all essential documentation required to conduct a study in accordance with the principles of GCP and the applicable regulatory requirements.

Investigators Brochure: A compilation of clinical and non-clinical data on the Investigational Medicinal Product (IMP)(s) relevant to the study of the use of that IMP(s) in human subjects.

**International Standard Randomised Control Trial Number (ISRCTN):** 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.

ISRCTN Register: (International Standard Randomised Controlled Trial Number) A register of all Randomised Controlled Trials (RCTs) which have an ISRCTN number

LREC: Local Research Ethics Committee.

**Main Research Ethics Committee:** An operational term used to denote the ethics committee undertaking ethical review of a multi-site study where site-specific assessments will be made by other RECs. The main REC may be an LREC or an MREC.

Medicines and Healthcare products Regulatory Agency (MHRA): The competent authority for medical devices and licensing authority for Pharmaceuticals in the UK. It replaced the Medical Devices Agency (MDA) and the Medicines Control Agency (MCA) in April 2003.

**Minor 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). Examples may be as follows:

* Correction of typographical errors in the protocol or other study documentation
* Amended contact details for the sponsor or project staff
* Changes in funding arrangements
* Appointment of new support staff
* Changes in the documentation used to record study data
* Changes in the logistical arrangements for transporting or storing samples

**Monitor:** The person designated by the sponsor to perform site visits and conduct the monitoring process.

**Monitoring:** The act of overseeing the progress of study and of ensuring that it is being conducted, recorded and reported in accordance with the protocol, good clinical practice (GCP) and the applicable regulatory requirements.

**MREC:** Multi-Centre Research Ethics Committee

**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.

**NIGB**: National Information Governance Board for Health and Social Care - incorporates the functions of the former Patient Information Advisory Group.

NIHR: National Institute for Health Research

PIAG: Patient Information Advisory Group was established to provide advice on issues of national significance involving the use of patient data. PIAG was replaced by the National Information Governance Board for Health and Social Care (NIGB) and was formally wound up on 31 December 2008.

Patient Information Sheet (PIS): An information sheet 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.

**Point of Contact (PoC):** (In relation to monitoring) The person designated by the CI/PI as being the primary point of contact between the study site and the Research and Effectiveness Department

**Principal Investigator (PI):** The person at a single site designated as taking responsibility within the research team for the conduct of the study.

**Protocol:** A document that describes the objective(s), design, methodology, statistical considerations and organisation of a study. The protocol also usually gives the background and rationale for the study.

**R&D Study file:** The study specific file stored in the Research and Development Office, created at study registration and used to store all study specific documentation.

**REC:** Research Ethics Committee

**Research Governance Framework For Health and Social Care (RGF):** The Department of Health guidance on ensuring that health and social care research is conducted to high scientific and ethical standards. Defines the broad principles of good research governance.

**Research staff:** Staff involved in the conduct of the study

Randomised Controlled Trial (RCT): 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.

SAE (Serious Adverse Event): Any untoward medical occurrence in study subject that at any dose:

* Results in Death
* Is life threatening
* Requires or prolongs inpatient hospitalization
* Results in significant or persistent disability / incapacity
* Is a congenital abnormality / birth defect

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

**SSI form:** Site Specific Information form.

**Site:** The location at which study activities and assessments are performed.

**SmPC:** Summary of Product Characteristics.

**Source Data:** All information in original records (and certified copies of original records) of clinical findings, observations or other activities in a clinical trial essential for the reconstruction and evaluation of the trial. Source data are contained in source documents.

**Source Documents:** Original documents data and records, e.g. Medical records, subject files, laboratory notes & records, participants’ diaries, pharmacy dispensing records, recorded data from automated instruments & x-rays.

Sponsor: The Institution, Body or Individual(s) responsible for the initiation, management and financing of a study (unless this role is already covered by the Funder)

**Standard Operating Procedure (SOP):** Detailed written instructions designed to achieve uniformity of the performance of a specific function.

**Substantial Amendment:** A substantial amendment can be defined as 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:

* the safety or physical or mental integrity of the subjects of the trial;
* the scientific value of the trial;
* the conduct or management of the trial; or
* the quality or safety of any investigational medicinal product used in the trial.

Other changes to the particulars of a study that qualify as substantial amendments include:

* A change of sponsor(s)
* Appointment of a new Chief Investigator and
* Extension of the research beyond the planned closing date for recruitment

A substantial amendment may not be made to a research study without the favourable opinion from the REC that gave a favourable opinion for the study (the main REC) and as applicable the MHRA. The only exceptions to this rule are:

* The Inclusion of a new research site or
* The Appointment of a new PI at an individual site

Both of these qualify as substantial amendments but as they require further SSA and approval from the main REC there is no requirement for notice of amendment to the main REC. These changes do still however need to be notified to the MHRA (as applicable).

**SUSAR** **(Suspected Unexpected Serious Adverse Reaction):** An Adverse Reaction which is **Serious**, i.e. it

* Results in death
* Is life threatening
* Requires inpatient hospitalization or prolongation of existing inpatient hospitalization
* Results in persistent/significant disability or incapacity or
* Is a congenital birth defect or anomaly

Is **Unexpected**, I.e. its nature and severity is not consistent with the known information about that product, and

Is **Suspected**, i.e. it is suspected to have a causal relationship with the IMP in question.

**Unexpected Adverse Reaction:** An Adverse Reaction, the nature and severity of which is not consistent with the information about the medicinal product in question set out:

* In the case of a product with a marketing authorization, in the summary of product characteristics for that product,
* In the case of any other investigational medicinal product, in the investigator's brochure relating to the trial in question