Explanations of medical terms and abbreviations used in clinical research

AE (Adverse Event): unwanted event

Actively checked: a study has been“ actively checked“ when a team of participants has got the new substance to be tested and a control team an established medicine. The study compares effect and digestibility of both substances.

AMG (drug law): law regulating drug use)

Audit: Systematic and independent check of study related activities and documents with investigator or drug producer.

Auftragsforschungsinstitut (Contract Research Organisation):
Organisation commissioned by drug producer to take over tasks of clinical study.

BfArM: Bundesinstitut für Arzneimittel und Medizinprodukte.
Federal institute for drugs and medical products.

Co-Investigator (second investigator): medical member of study team named by investigator to carry out essential task within clinical study.

CRF (Case Report Form): see checklist

CRO (Contract Research Organisation):
See commissioning research institute

Double-blind: A study is considered „double-blind“ if neither participant nor investigator know whether the substance to be tested or the comparitive one is being tested. Therefore, substances are made „blind“: they look and taste similar and are only marked by a bar code on the packing.

FDA (Food and Drug Administration):
US authority in charge of drugs‘ admission.

GCP (Good Clinical Practice)
International ethical and scientific standard for planning, execution, documentation and reporting on clinical studies.

GMP (Good Manufacturing Practice):
International standard for manufacturing drugs.

ICH (International Conference on Harmonisation):
The international conference on harmonisation has defined uniform guidelines of „good clinical practice“ valid in Europe, the US and Japan.

Inspection: Offical check of documents, equipment, records and quality securing systems in connection with a clinical study made by a competent authority.

Investigator: - see doctor carrying out a study

Investigator's Brochure, IB: - see doctor's brochure

Clinical investigation (clinical study): Drug testing on humans to find out about effects and/or digestibility of a drug under test or to confirm/investigate acceptance, distribution, metabolism and excretion of a drug under test aiming at securing the drug's effectiveness and/or digestibility.

LKP: Head of clinical study (according to AMG, § 40)

Monitoring: monitoring the continuation of a clinical study by a sponsor's representative (clinical monitor); among his tasks are looking after the investigator, evaluation of study results obtained and ensuring the study being carried out and documented by all people involved in accordance with ruling guidelines and laws.

NDA (New Drug Application, FDA):
Application for admittance of a new substance in the US.

Original data (Source data):
All information gathered from original records such as ECG-print outs, patients' sheets, lab print-outs etc. during a clinical study, required for comprehensive reconstruction and evaluation.

Plazebo: Ein Plazebo ist eine Behandlung ohne therapeutische Wirkung. In klinischen Studien dient die Gabe eines Plazebos an eine Kontrollgruppe dem Ausschluss einer scheinbaren Wi
Placebo: Placebo is a treatment without therapeutical effect. Giving a placebo to a control team in clinical studies serves to exclude an apparent effect. A placebo is never used for illnesses where there is an effective therapy (standard therapy).

Investigator
An investigator is a person in charge of a clinical study in a study centre. If study in a study centre is made by a team, the investigator is the head in charge (principal investigator).

Investigator's Brochure,(IB):
A summary of relevant clinical and non-clinical data on the medicine in question for studies with test medicines on humans.

Case Report Form (CRF):
Document (either on paper or electronic) stipulating the required study data according to the study minutes and reported to the principal.

Study plan (study minutes): document describing the aims, design, methods, statistical ideas and organisation of a clinical study.

Test preparation: pharmaceutical form of a substance or placebo tested in a clinical study or used as reference substance.

Study participant (patient, test person): a person participating in a clinical study.

Randomisation: random (by chance) assignment of study participants into different treatment groups.

Serious Adverse Event (SAE):
Any unwanted event which, independent of dosage, is fatal or life-threatening, requires stationery treatment or its prolongation, leads to permanent or serious handicap or invalidity or represents a congenital deformity or abnormality or defect.

Sponsor: principal of a clinical study. A person, a company, an institution or organisation taking over responsibility for planning, management and/or financing of a clinical study.

Standard Operating Procedure (SOP):
Written operating instructions ruling uniform standardized procedude when carrying out clinical studies.

Study Report:
Written summary of a clinical study showing the clinical and biometrical procedure, data gathered and evaluation.

Study minutes: see study plan

Adverse Event (AE):
Any medically unfavourable event such as abnormal lab results, symptoms or illness that appears with a study participant after a medicine has been administered and which is not necessarily causally related to treatment.