DEPARTMENT OF OTOLARYNGOLOGY

Research Acronyms and Definitions

Acronyms

AE	Adverse Event
CBER	Center for Biologics Evaluation and Research
CCTSI	Colorado Clinical and Translational Sciences Institute
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
CFR	Code of Federal Regulation
CoI	Co- Investigator (also known as sub-Investigator)
COMIRB	Colorado Multiple Institutional Review Board
CRC	Clinical Research Coordinator
CRF	Case Report Form
CRSC	Clinical Research Support Center
CTA	Clinical Trial Agreement
CTRC	Clinical Translational Research Center
DSMB	Data Safety Monitoring Board
EDC	Electronic Data Capture
FDA	Food and Drug Administration
GCP	Good Clinical Practice
GMP	Good Manufacturing Practices
HIPAA	Health Insurance Portability and Accountability Act
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IDE	Investigational Device Exemption
IEC	Institutional Ethics Committee
IND	Investigational New Drug
IRB	Institutional Review Board
LAR	Legally Authorized Representative
N/A	Not Applicable
OGC	Office of Grants and Contracts
PI	Principal Investigator
PMA	Pre-Market Approval
PMS	Post-Market Surveillance
REDCap	Research Electronic Data Capture
SAE	Serious Adverse Event (Effect)
SAR	Suspected Adverse Reaction
SARC	Scientific Advisory Review Committee
SDV	Source Data Verify
SOP	Standard Operating Procedure
UADE	Unanticipated Adverse Device Event (Effect)
UAE	Unanticipated Adverse Event (Effect)
UCH RSS	University of Colorado Hospital Research Support Services
WIRB	Western Institutional Review Board

Definitions

Adverse Event (Effect)	Any untoward change from baseline (pre-treatment or pre-participation) condition; any intercurrent illness that occurs during the course of a clinical study after treatment with the investigational product/treatment has started, whether considered related to the investigational product/ treatment/ processes or not, or any effect that is unintended and/or unfavorable, such as a sign, a symptom, a laboratory abnormality, or a disease.
Arm	A group of study participants who receive specific treatment, or no treatment, as defined by the study protocol.
Baseline	A trial measurement taken prior to the introduction of an intervention.
Blinding	The act of providing treatment to subjects without knowing if the drug, device, or procedure is that of the one being studied.
Case Report Form	Paper or electronic document to record data for purposes of submitting research data to sponsor.
Clinical Research Coordinator (CRC)-	A trained member of the research team that assists the PI with the conduct of the study.
Data Safety Monitoring Board (DSMB)	A committee established to review clinical trial data concerning subject safety.
De-identified	All information that could potentially reveal the identity of a participant is removed from the research dataset.
Good Clinical Practice (GCP)	A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.
Health Insurance Portability and Accountability Act (HIPAA)	Enacted on April 14, 2003 to ensure protection of health information on all patients.
Informed Consent	A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is typically documented by means of a written, signed, and dated informed consent form.
Informed Consent Form (ICF)	A document that describes the study in lay terms. The Informed Consent Form is presented to the subject as part of a consent discussion prior to enrollment into the study. The Informed Consent Form must be signed by the subject (or LAR) prior to initiating any study activity.
Institutional Review Board (IRB)	The regulatory board that is responsible for the oversight of the approved clinical trial.
Lost to Follow-up	A subject who cannot be reached for purposes of follow-up or continued study visits.

Open label	A study designed to reveal which participants receive which intervention (no blinding).
Principal Investigator (PI)	The person ultimately responsible for the overall conduct of the clinical trial. The PI may delegate certain responsibilities to other members of the research team but must always maintain control of the clinical trial.
Randomization	The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias.
Screen Fail	A subject who undergoes screening procedures as defined by the protocol, but who does not meet the qualification requirements to continue with the study.
Serious Adverse Event (Effect) or Serious Adverse Reaction	An adverse event that results in death, is life-threatening, requires inpatient hospitalization (or prolonged stay), significantly incapacitates or disrupts the subject's ability to lead a normal life, results in a congenital anomaly/birth defect or if intervention is required to prevent one of the above outcomes.
Source Data Verified (SDV)	Data on a case report form (CRF) has been monitored and/or reviewed against the original source documents.
Source document	The initial place of data record.
Study ID	An alphanumeric code given to a subject in order to hide and protect the subject's name.
Sub/Co-Investigator (Sub-I/Co-I)	Any individual member of the research team designated by the PI to perform critical trial-related procedures and/or to make important trial related decisions.
Subject/Trial Subject	An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control.
Suspected Adverse Reaction	Reasonable possibility that an adverse event was caused by drug or treatment.
Unanticipated Adverse Event (Effect):	A problem not previously identified in nature, severity, or degree of incidence in the investigational plan, informed consent or application (including a supplementary plan, consent or application), or any other unanticipated serious problem associated with an investigation that relates to the rights, safety, or welfare of subjects.
Vulnerable Subjects	Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.
Well-being (of the trial subjects)	The physical and mental integrity of the subjects participating in a clinical trial.

Withdrawn	A subject that was enrolled into the study but will not complete the study.