Glossary of Terms

This glossary provides definitions of key terms used in this course. Content is structured for accessibility and screen reader compatibility.

Blood Sugar (Blood Glucose)

Blood glucose is a sugar that your body uses as a source of energy. Unless you have diabetes, your body regulates the amount of glucose in your blood.

Body Mass Index (BMI)

Body Mass Index (BMI) is a calculated measure of a person's body weight (in kilograms) divided by the square of their height (in meters). BMI = weight (kg) / height (m)2. Although BMI does not directly measure body fat, BMI is moderately to strongly associated with other measures that capture the amount, location, and distribution of body fat.

Caregiver

A person who helps a patient with daily activities, health care, or any other activities that the patient is unable to perform himself/herself due to illness or disability, and who understands the patient's health-related needs. This person may or may not have decision-making authority for the patient and is not the patient's healthcare provider.

Clinical Study

A clinical study involves research using human volunteers (also called participants) that is intended to add to medical knowledge. There are two main types of clinical studies: clinical trials (also called interventional studies) and observational studies (also called non-interventional studies).

Clinical Study (Research) Coordinator (CRC)

Simply stated, a Clinical Research Coordinator (CRC), manages and conducts the day-to-day activities of a clinical trial. In general, the CRC makes sure that the clinical study follows procedures and regulatory, clinical and Institutional Review Board (IRB) requirements.

Clinical Trial

The Clinical Data Interchange Standards Consortium (CDISC) defines a clinical trial as a type of clinical study. It is a research investigation involving human subjects that is designed to answer specific questions about the safety and efficacy of a biomedical intervention (drug, treatment, device) or new ways of using a known drug, treatment, or device). NOTE: NIH Office of Science Policy further specifies that a clinical trial is a type of research study that prospectively assigns subjects to interventions, and the EU clinical trial regulations set forth 3 specific conditions, any one of which qualifies a study as a clinical trial. These conditions include applying diagnostic or monitoring procedures not used in normal clinical practice to subjects.

Continuous Glucose Monitor (CGM)

A continuous glucose monitor is a device that automatically estimates your blood glucose level, also called blood sugar, throughout the day and night.

Continuous Positive Airway Pressure (CPAP) Machine

Simply stated, a Continuous Positive Airway Pressure (CPAP) machine is a device you use every night when you sleep. It blows air at a gentle but steady pressure into your nose, or nose and mouth. That extra air helps keep your breathing passages open while you sleep, so they don’t collapse or get blocked.

Data

Simply stated, data are facts or pieces of information you collect about a patient and sometimes their caregiver, like things you see or measure. In medical studies or patient registries, the investigators often collect numbers (quantitative data) like height or test results, and words or descriptions (qualitative data) like how a patient feels or their story.

Deep Brain Stimulation (DBS)

Deep brain stimulation (DBS) is a type of treatment for symptoms of some movement disorders, including dystonia, essential tremor, and Parkinson's disease (PD). DBS uses a surgically implanted, battery-operated device to send electrical signals to areas in the brain that control movement. The signals from DBS control (regulate) the nerve signals that cause movement disorder symptoms. It is a safe and effective treatment for many movement disorders that are not responding to medication.

Diabetes

Diabetes is a disease that happens when the level of glucose in your blood (blood sugar) is too high. Insulin is a hormone made by the pancreas that helps move sugar out of your blood and into your cells for energy. If you have diabetes, your body doesn't make or use insulin well. Symptoms of diabetes include increased thirst and urination, increased hunger, fatigue, blurred vision, sores that do not heal, unexplained weight loss, numbness or tingling in the feet or hands.

Health (Clinical) Outcome

Simply stated, a clinical outcome is a way to show or measure how a person feels, how well they can do things, or how long they live because of a treatment or disease.

Inclusion Criteria

Simply stated, inclusion criteria are the traits or qualities a person must have to join a study. These are things like age, health condition, where they live, or other important clinical or demographic features. For example, a study might say participants must be between 18 and 65 years old, have been diagnosed with a certain disease, and live within a certain city to be eligible.

Lived Experience

Lived experience refers to “representation and understanding of an individual’s human experiences, choices, and options and how those factors influence one’s perception of knowledge” based on one’s own life.

Medical Device

An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: (A) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (C) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o).

Medical Device Life Cycle

Simply stated, the medical device lifecycle refers to all stages of a device's life from device development through when it's available for use.

Obstructive Sleep Apnea

Apnea is defined as a pause in breathing for at least 10 seconds. Obstructive sleep apnea, also called OSA, causes you to stop breathing in your sleep for several seconds, up to many times an hour. People diagnosed with OSA have at least five breathing pauses an hour and can have many more.

Parkinson's Disease

Parkinson's disease is a progressive movement disorder of the nervous system. It causes nerve cells (neurons) in parts of the brain to weaken, become damaged, and die, leading to symptoms that include problems with movement, tremor, stiffness, and impaired balance. As symptoms progress, people with Parkinson's disease (PD) may have difficulty walking, talking, or completing other simple tasks.

Patient

A patient is an individual with or at risk of a specific disease or health condition, whether or not they currently receive any therapy to prevent or treat that disease/condition. A patient is the individual who directly experiences the benefits and harms associated with medical products.

Patient Advisor

Simply stated, patient advisors refer to individuals who have experience living with a disease or condition, and can serve in an advisory or consultative capacity to improve clinical study design and conduct. They are not study participants, caregivers, or healthcare professionals involved in prescribing or recommending a medical product.

Patient Input

Patient input is information that captures patients' experiences, perspectives, needs, and priorities.

Patient-Reported Outcome (PRO)

Simply stated, patient-reported outcomes (PROs) are the things a patient says about their own health without anyone else interpreting it. These outcomes are measured using tools like questionnaires, rating scales, or diaries.

Quality of Life

Simply put, an individual's perception of their life which may be influenced by their physical health, psychological state, level of independence, social relationships, personal beliefs, and their relationships to key features of the environment.

Regulatory

Simply stated, "regulatory" describes the laws, regulations, policies and decisions of a government agency, such as FDA. For example, FDA regulatory actions ensure that medical devices are safe and effective, and that products emitting electronic radiation are safe.

Researcher

Generally, a researcher is an individual who follows a systematic process of gathering and analyzing information to contribute to general knowledge.

Safe and Effective

Simply stated, safe and effective means that devices meet specifications and requirements for safety and performance.

Sensor

Generally, sensors are devices that detect physical, chemical, and biological signals and provide a way for those signals to be measured and recorded.

Study Protocol

A study protocol is the general design of a clinical study.

Study Team Member – Engineer

Generally, an engineer on a medical device clinical study team plays an important technical role in ensuring the device functions properly throughout the study and that all technical parts are properly managed.

Study Team Member – Physician

Generally, the role of a physician on a medical device clinical study team has many different sides. Key responsibilities include: medical expertise and oversight, protocol development and adherence, safety monitoring, patient care interaction, data interpretation, regulatory compliance, training and education, communication, and ethical considerations.

Study Team Member – Principal Investigator (PI)

A principal investigator (who is often a doctor) leads the clinical research team and, along with the other members of the research team, regularly monitors study participants' health to determine the study's safety and effectiveness.

Study Team Member – Research Nurse

Generally, clinical research nurses are clinical staff nurses with a central focus on care of research patients.

Study Team Member – Statistician

Generally, a statistician on a medical device study team ensures the clinical research, including clinical trials, are conducted with quality, transparency, reproducibility and integrity. They play an important role in clinical trials research across all stages of design, delivery, analysis and reporting.

Usability (Human Factors Engineering)

The application of knowledge about human behavior, abilities, limitations, and other characteristics of medical device users to the design of medical devices including mechanical and software driven user interfaces, systems, tasks, user documentation, and user training to enhance and demonstrate safe and effective use. Human factors engineering and usability engineering can be considered to be synonymous.