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.

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 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.

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.

Electronic Health Record (EHR)

An Electronic Health Record (EHR) is an electronic version of a patient's medical history, that is maintained by the provider over time, and may include all of the key administrative clinical data relevant to that person's care under a particular provider, including demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data and radiology reports.

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.

Intervention (Treatment)

Simply put, within the context of a clinical study, an intervention is a process or action that is the focus of the study and is believed to change the disease progression, health outcomes or product performance. Interventions include drugs, medical devices, procedures, vaccines, and other products that are either investigational or already available. Interventions can also include non-invasive approaches, such as education or modifying diet and exercise.

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.

Observational Study

Observational studies are research studies in which researchers collect information (called data) from participants or look at data that was already collected. The data may be about participants' health, habits, or environments. In observational studies, researchers do not assign participants to get an intervention.

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-Generated Health Data

Simply stated, patient-generated health data are data created, recorded or gathered by and from patients.

Patient Input

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

Patient Registry

Simply stated, patient registries are real-world databases that may be used to track patients' conditions and treatments to evaluate health outcomes and medical device safety.

Prosthesis

Simply stated, prostheses are meant to replace missing body parts or function.

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.

Real-World Data

Simply put, real-world data are information about a person's health and information about the delivery of health care routinely collected from a variety of sources. Some examples include electronic health records (EHRs), medical claims or billing data, disease or product registries, and data from devices, apps, or other technologies. Researchers can use real-world data to support many kinds of studies—such as trials with or without comparison groups, observational studies, or hybrid designs that mix methods.

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.