GLOSSARY OF TERMS ON CLINICAL TRIALS FOR PATIENT ENGAGEMENT ADVISORY COMMITTEE MEETING

TERM	DEFINITION
Assent	A child's affirmative agreement to participate in a clinical investigation. Assent must be sought in addition to the consent of a legally authorized representative or surrogate when the individual is sufficiently cognitively capable of understanding the nature of his or her participation in a research study.
Attrition	A reduction in the number of participants in a clinical trial over the course of the trial.
Blinding/ Masking	One or more parties of the clinical trial are kept unaware of the treatment assignment. Patients, investigators, and health care providers may all be blinded to the treatment a patient is receiving.
Care Partner	A person helping to care for a loved one who is unable to manage day-to-day life alone due to an illness. This role includes helping with daily needs, managing the household, and supervising health care.
CDRH	Center for Devices and Radiological Health (CDRH) has the responsibility for protecting and promoting the public health through the approval of safe and effective medical devices.
Clinical Benefit	A therapeutic intervention may be said to confer clinical benefit if it prolongs life, improves function, and/or improves the way a patient feels.
Clinical Significance	Change in a subject's clinical condition regarded as important whether or not due to the test intervention.
Clinical Trial **Clinical Investigation** **Clinical Study**	An investigation or research that involves one or more human subjects, undertaken to assess/evaluate the safety or effectiveness of a medical device.
Compliance (in relation to clinical trials)	Adherence to all the trial-related requirements, good clinical practice (GCP) requirements, and the applicable regulatory requirements.
Confidentiality	Prevention of disclosure to others than authorized individuals of a sponsor's proprietary information or of a subject's identity.
Informed Consent Form	Informed consent is 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 documented by means of a written, signed and dated informed consent form.
Data Monitoring Committee (DMC)	An independent committee that may be established by the sponsor to assess, at intervals, the progress of a clinical investigation, the safety data, or the critical performance endpoints and make recommendations to the sponsor whether to continue, modify, or stop an investigation.

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Endpoint	Principal indicator(s) used for assessing the primary question (i.e., hypothesis) of a clinical trial. A variable that pertains to the efficacy or safety evaluations of a trial. An endpoint is more specific as compared to an outcome since it relate to the planned objective of the study.
Enrollment	The process of registering or entering a patient into a clinical trial. Once a patient has been enrolled, the participant would then follow the clinical trial protocol. Clinical investigations are designed to enroll a set number of participants to increase the likelihood of answering the trial questions.
Health Care Provider (HCP)	One who directly or indirectly administers interventions that are designed to improve the physical or emotional status of patients. A person otherwise authorized or permitted by law to administer healthcare in the ordinary course of business or practice of a profession, including a healthcare facility.
Hypothesis	A testable statement regarding the investigational medical device safety or performance (effectiveness) that is used to design the clinical trial and that can be accepted or rejected based on the results of the clinical trial and statistical calculations.
Inclusion/ Exclusion Criteria	The medical or other guidelines that determines whether a person may or may not be allowed to enter a clinical trial. These criteria are based on such factors as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. The criteria are not used to reject people personally, but to identify appropriate participants for the trial and keep them safe. Also known as *Eligibility or Enrollment Criteria*
Institutional Review Board (IRB)	Any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects. Also known as Ethics Committee (EC).
Indication for Use (IFU)	A general description of the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended.
Intervention	The diagnostic or therapeutic device, biologic, and/or drug under investigation in a clinical trial that is believed to have an effect on outcomes of interest in a study.
Investigator	A person responsible for the conduct of the clinical trial at the trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the Principal

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	Investigator (PI).
Labeling	All text, tables, and figures in labeling as described in regulations for a specific product.
Legally Authorized Representative (LAR)	Individual who is authorized under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the clinical trial.
Lost to Follow Up	The act of concluding participation, prior to completion of all protocol-required elements, in a trial by an enrolled subject.
Medical Device Report (MDR)	A report submitted to the FDA by a manufacturer, a physician, or a patient about a marketed device that may have caused or contributed to a death or serious injury. A report can be submitted at the following link: https://www.fda.gov/medicaldevices/safety/reportaproblem/default.htm
Medical Device	An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part, or accessory, which is – (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) 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 (3) 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).
Multicenter Trial	A clinical trial conducted according to a single protocol but at more than one site, and, therefore, carried out by more than one investigator.
Outcome	Events or experiences that clinicians or investigators examining the impact of an intervention or exposure measure because they believe such events or experiences may be influenced by the research intervention or exposure. Outcome is more general than endpoint in that it does not necessarily relate to a planned objective of the study.
Patient	Person under a physician's care for a particular disease or condition. When talking about engagement, patient refers inclusively to people who receive health care services; family members, friends, and other care partners; and any consumers of health care.
Patient Engagement	Involves meaningful involvement of patients throughout the clinical trial cycle from the initial design to the

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	implementation of the trial and the dissemination of the study results. The goal is to have clinical trials more patient-centric and relevant to patient values leading to improved clinical trials and a greater intake by patients and providers when making treatment decisions.
Patient Engagement Advisory Committee (PEAC)	This advisory committee is a forum for the voice of patients and will be asked to advise on complex issues related to medical devices and their impact on patients. The goal of PEAC is to better understand and integrate patient perspectives into our oversight, to improve communications with patients about benefits, risks, and clinical outcomes related to medical devices, and to identify new approaches, unforeseen risks or barriers, and unintended consequences from the use of medical devices.
Patient Preference	Patient perspectives include information relating to patients' experiences with a disease or condition and its management. This may be useful for better understanding the disease or condition and its impact on patients, identifying outcomes most important to patients, and understanding benefit-risk tradeoffs for treatment. Patient preference information is a specific type of patient perspective. It is the assessment of the desirability or acceptability to patients of specified choices among clinical outcomes or some other attribute that differs between potential medical interventions. https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM446680.pdf
Patient-Reported Outcome (PRO)	An outcome based on a report that comes directly from the patient about the status of a patient's health condition without amendment or interpretation of the patient's response by a clinician or anyone else.. Symptoms or other unobservable concepts known only to the patient can only be measured by PRO measures. PROs can also assess the patient perspective on functioning or activities that may also be observable by others. https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM446680.pdf
Pediatric	CDRH defines pediatric patients as individuals who are younger than 22 years.
Protocol	A document that describes the objectives(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. A protocol amendment is a written description of a change(s) to or a formal change of a protocol.

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Randomization	The process of assigning trial subjects to investigational treatment or control groups (may use a comparator) using an element of chance to determine the assignments in order to reduce bias.
Randomized Controlled Trial (RCT)	A study in which randomization is used to assign patients to treatments. The purpose of the randomized controlled trial is to: (1) to guard against any use of judgment or systematic arrangements leading to one treatment getting preferential assignment; i.e., to avoid bias; (2) to provide a basis for the standard methods of statistical analysis such as significance tests.
Recruitment	Active efforts by investigators to identify subjects who may be suitable for enrollment into a clinical trial. Subjects are selected on the basis of the protocol's inclusion and exclusion criteria during the clinical trial recruitment period. The number of subjects that must be recruited for enrollment into a study and meet the requirements of the protocol. In multicenter studies, each investigator has a recruitment target or defined number of subjects to be enrolled.
Retention	Activities by the clinical trial team to encourage and support a subject to remain enrolled and participate in the clinical trial.
Safety	Safety is relative freedom from harm. In clinical trials, this refers to an absence of harmful side effects resulting from use of the product and may be assessed by laboratory testing of biological samples, special tests and procedures, psychiatric evaluation, and/or physical examination of subjects.
Screening (of subjects)	A process of active evaluation of potential participants for enrollment in a trial. After a patient is recruited, screening occurs during the enrollment period to see if they meet the inclusion and exclusion criteria. If they meet the criteria, the subject is eligible to enroll in the trial.
Sponsor	An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial.
Statistical Analysis Plan	A document detailing the methods of all planned analyses of the clinical study data.

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Subject/ Participant	An individual who participates in a clinical trial either as a recipient of the investigational product(s) or as a control. The term "subject" is part of the federal regulation and may be used interchangeably with participant.
Termination	Discontinuance, by sponsor or by withdrawal of IRB or FDA approval, of a clinical trial before completion. This termination can be at a site or the entire study.
Underserved Population	Populations where their voices and needs are often unintentionally overlooked. This population includes the economically disadvantaged, racial and ethnic minorities, the uninsured, rural residents, children and the elderly.