**GLOSSARY FOR PATIENT ENGAGEMENT ADVISORY COMMITTEE MEETING
ON AUGMENTED REALITY AND VIRTUAL REALITY**

TERMS	DEFINITION
Angular Resolution	The smallest angle between two neighboring objects that can be seen as separate objects.
Augmented Reality (AR)	Real-world augmented experience with overlaying or mixing simulated digital imagery with the real world as seen through a camera or display, such as a smartphone or head-mounted or heads-up display (HUD). Digital imagery may be able to interact with real surroundings (often controlled by users). Sometimes referred to as mixed or merged reality.
Binocular fusion	Fusing of the images seen by the left and right eyes into a single image. This allows for depth perception.
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.
Class I Devices	Low risk devices requiring general controls to ensure safety and effectiveness.
Class II Devices	Requires general and special controls to ensure safety and effectiveness. Special controls may include guidance documents, mandatory performance standards, patient registries for implantable devices and postmarket surveillance. Requires a 510(k), unless exempted and may require clinical trials.
Class III Devices	Intended to be used in supporting or sustaining human life, or for a use which is of substantial importance in preventing impairment of human health, or that which may present a potential unreasonable risk of illness or injury, and for which insufficient information exists to determine that general controls and special controls are sufficient to provide reasonable assurance of the safety and effectiveness of a device.
Depth Perception	The ability to see the world in three dimensions to determine the distance of the object.
Display Resolution	The number of pixels that make up a display. Represented as dimensions (e.g. 1920x1080).
Extended Reality (XR)	Extended Reality (XR) encompasses all types of AR and VR.
Eye Tracking	Measuring a user's point of gaze or eye movement.
Field of View (FOV)	The angular range of the world observed by the human eye.
Fixation Point	Point in space to which the visual axes of the eyes are directed.

TERMS	DEFINITION
Frame Rate	The speed at which video is shown on a display. Usually measured in frames per second (FPS). Frame rate impacts the user's perception and may impact performance or hardware requirements.
Haptic	Refers to the sense of touch simulated by technology.
Haptic Gloves	Gloves which simulate physical touch with virtual objects and environments.
Hardware	Physical equipment, as opposed to programs, procedures, rules, and associated documentation. Contrast with software.
Head up display (HUD)	Refers to see-through display that allows a user to see both virtual content and real world simultaneously.
Head-mounted display (HMD) or Headset	A virtual or augmented reality headset that allows a user to interact in a XR environment, by often tracking the user's head, eyes, and body, and displaying images in a near eye display.
Human-Factors (Human Factors Engineering)	Human factors engineering (HFE) is the application of knowledge about human capabilities (physical, sensory, emotional, and intellectual) and limitations to the design and development of tools, devices, systems, environments, and organizations. HFE might also be called human factors, ergonomics, human engineering, usability engineering, or human–computer interaction (HCI). HFE involves the use of behavioral science and engineering methodologies in support of design and evaluation.
Immersion	Perception of being physically present in a non-physical world.
Interpupillary distance (IPD)	Distance between the center of the pupils of the eyes.
Latency (Motion-to-photon, End-to-end)	The amount of delay time between a system receiving an input and delivering an output. Latency is usually represented in milliseconds (ms). Common areas of latency associated with AR/VR include: • Motion-to-photon latency: Delay between the user or an object physically moving and the change in imagery in response on the display. • End-to-end latency: Delay between the input signal and the output signal. This can include the HMD, controller, a cloud or other network server, and other devices in the system.

TERMS	DEFINITION
Medical Device (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.
Peripheral Vision	Vision as it occurs outside the point of fixation, also called side vision.
Refresh Rate (sampling frequency)	Highest frequency with which the screen information can be changed, usually represented in hertz (Hz).
Software	Programs, procedures, rules, and any associated documentation pertaining to the operation of a system.
Software as a Medical Device (SaMD)	Software intended to be used for one or more medical purposes that perform device functions as described above without being part of a hardware medical device.
Stereotaxic Instrument	A stereotaxic instrument is a device consisting of a rigid frame with a calibrated guide mechanism for precisely positioning probes or other devices within a patient's brain, spinal cord, or other part of the nervous system.
Tracking	The determination of an object's position and orientation within three-dimensional space.
Virtual Reality (VR)	Virtual world immersive experience that may require a headset to completely replace a user's surrounding view with a simulated, immersive, and interactive virtual environment.
VR Sickness/cybersickness	Also referred to as motion sickness, VR sickness is caused by the images a user sees not aligning with the movement they feel.