



GLOSSARY FOR PATIENT ENGAGEMENT ADVISORY COMMITTEE MEETING ON ADVANCING HEALTH EQUITY IN MEDICAL DEVICES

TERM	DEFINITION
Caregiver Carepartner	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. Source: PEAC 2017 Glossary
CDRH	Center for Devices and Radiological Health (CDRH) has the responsibility for protecting and promoting the public health through the authorization of safe and effective medical devices. Source: PEAC 2017 Glossary
Clinical Investigation	A clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a device. For the purposes of the PEAC meeting, the terms study, clinical study, clinical trial, and investigation are used interchangeably. Source: 21 CFR 812.3(h)
Device User Interface	All points of interaction between the user and the device, including all elements of the device with which the user interacts. Source: PEAC 2020 Executive Summary
Digital Health Technologies (DHTs)	A system that uses computing platforms, connectivity, software, and/or sensors for healthcare and related uses. These technologies span a wide range of uses, from applications in general wellness to applications as a medical device. They include technologies intended for use as a medical product, in a medical product, or as an adjunct to other medical products (devices, drugs, and biologics). They may also be used to develop or study medical products. Source: Digital Health Technologies Draft Guidance
Digital Literacy (in relation to health literacy)	The ability to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem. Source: WHO
Diversity	The practice of including the many communities, identities, races, ethnicities, backgrounds, abilities, cultures, and beliefs of a society, including underserved communities. Source: HHS DEIA Strategic Plan
Generalizability	Characterized by the relevance of a study's results when applied to a larger population. Source: PEAC 2018 Glossary



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Health Care Provider (HCP)	A licensed or non-licensed healthcare professional with proficient skill and experience with the use of the medical device so that they can aid or train care recipients and caregivers to use and maintain the medical device. Source: Home Use Device Webpage
Health Disparities	Differences in health outcomes and their determinants among segments of the population as defined by social, demographic, environmental, or geographic category. Source: HHS Action Plan to Reudce Racial and Ethnic Health Disparities
Health Equity	Attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes. Source: CMS
Health Literacy	Degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions. Source: PEAC 2019 Glossary
Home-Use Medical Device	A medical device intended for use in any type of location outside of a professional healthcare facility, including a person’s home, outdoors, workplaces, schools, vehicles, emergency shelters, and independent living retirement homes. Source: Home Use Device Webpage
Human-Factors (Human Factors Engineering)	Human factors engineering (HFE) is the application of knowledge about human capabilities (physical, sensory, emotional, and cognitive) and limitations to the design and development of tools, devices, systems, environments, and organizations to optimize performance and safety and user satisfaction within human work/systems interactions. 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. Source: Applying Human Factors and Usability Engineering to Medical Devices Guidance
Labeling	All labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article ¹ at any time while a device is held for sale after shipment or delivery for shipment in interstate commerce. Source: Device Labeling Webpage



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Medical Device (Device)	<p>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.</p> <p>Source: Food, Drug & Cosmetic Act</p>
Medical Technologies	<p>For the purposes of the PEAC meeting, medical technology encompasses a broader scope of products that includes medical devices and other technologies which may not be subject to regulation by CDRH.</p>
Social Media	<p>Internet-based tools that allow groups or individuals to generate content and engage in peer-to-peer sharing and discussing opinions, insights, experiences, and perspectives with each other. It is based on user participation and user-generated content. They include social networking sites (LinkedIn, Facebook, Twitter), social bookmarking sites (Pinterest, Reddit), blogging and forums, and any aspect of interactive presence which allows individuals the ability to engage in virtual conversations with one another.</p> <p>Source: PEAC 2019 Glossary</p>
Subject/Participant	<p>An individual who participates in a clinical trial either as a recipient of the investigational product(s) or as a control.</p> <p>The term “subject” is part of the federal regulation and may be used interchangeably with participant.</p> <p>Source: PEAC 2019 Glossary</p>
Underserved Population	<p>Populations who include consumers who share one or more of the following characteristics: receive fewer health care services, encounter barriers to accessing primary health care services (e.g., economic, cultural, and/or linguistic), have a lack of familiarity with the health care delivery system, or face a shortage of readily available providers.</p> <p>Source: HHS Guidance Serving Vulnerable and Underserved Populations</p>