U.S. FOOD & DRUG ADMINISTRATION

## GLOSSARY FOR PATIENT ENGAGEMENT ADVISORY COMMITTEE MEETING ON PATIENT-GENERATED HEALTH DATA

| TERMS | DEFINITION |
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| **Bias** | Systematic tendency of any factors associated with the design, conduct, analysis, and interpretation of the results of clinical trials to make the estimate of a treatment effect deviate from its true value. |
| **Caregivers** | 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. |
| **CDRH Signal Management Program** | Helps to ensure consistency, efficiency, accountability, and transparency in how CDRH evaluates and addresses signals related to marketed 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; 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. |
| **Clinical Trial Clinical Investigation Clinical Study** | An investigation or research that involves one or more human subjects (participants), undertaken to assess/evaluate the safety or effectiveness of a medical device where participants are assigned to receive a specific intervention. |
| **Common data elements (CDE)** | Data elements that are common to multiple data sets across different studies. Helps improve data quality and promote data sharing. |

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| **De-identified Data** | When data has been stripped of common identifiers by removing any patient health information and the risk of re-identification is very small it is considered de-identified. |
| **Electronic health records** | An electronic version of a patient's medical history, that is maintained by the provider over time, and may include all 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, operative reports, and radiology reports. |
| **Fit-for-purpose** | The information is of sufficient quality to provide confidence in the analyses necessary to inform or support regulatory decision-making. |
| **General Data Protection Regulation (GDPR)** | Enacted on May 25, 2018 in the United Kingdom and requires that everyone responsible for using personal data follow strict rules called "data protection principles." |
| **Generalizability** | Characterized by the relevance of a study's results when applied to a larger population. |
| **Governance** | Describes the mechanisms used by an organization to ensures that its constituents follow its established processes and policies. It is the primary means of maintaining oversight and accountability. Data governance specifically refers to the management of the availability, security, usability, and integrity of data. Registry governance refers to the purpose, funding, execution, and dissemination of information. |
| **Health Insurance Portability and Accountability Act of 1996 (HIPAA)** | Regulation protecting the privacy and security of certain protected health information. |
| **Humanitarian Device Exemption (HDE)** | A marketing application similar in both form and content to a premarket approval (PMA) application but is exempt from the effectiveness requirements of a PMA and is subject to certain profit and use restrictions. |
| **Humanitarian Use Device (HUD)** | A medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year. |

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| **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. |
| **Interoperability** | The ability of computer systems or software to exchange and make use of information. |
| **Loss to Follow Up** | The act of concluding participation, prior to completion of all protocol-required elements, in a trial by an enrolled participant. |
| **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:<br>(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,<br>(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<br>(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. |
| **Medical Device Reports (MDRs)** | A report submitted to the FDA by a manufacturer, a physician, or a patient about a marketed device that may have malfunctioned and/or 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. |

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| **Medical Device Safety Action Plan** | Details how the FDA will encourage innovation to improve safety, detect safety risks earlier, and keep doctors and patients better informed. The full plan is found at the following link: https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm604500.htm. |
| **Medical Product Safety Network (MedSun)** | Adverse event reporting program launched with the goal to work collaboratively with the clinical community to identify, understand, and solve problems with the use of medical devices. |
| **Mobile Medical Apps (MMA)** | Medical devices that are mobile apps, meet the definition of a medical device and are an accessory to a regulated medical device or transform a mobile platform into a regulated medical device. |
| **Morbidity** | A complication or undesirable side effect following surgery or medical treatment. |
| **Mortality** | The number of deaths in a given time or place. |
| **National Evaluation System for health Technology (NEST)** | Intended to be an active surveillance and evaluation system that complements the passive surveillance approaches currently used by FDA to more efficiently leverage real-world evidence for medical device evaluation and regulatory decision-making. |
| **Natural Language Processing** | Development and use of computer systems and artificial intelligence to recognize and interpret natural human language. |
| **Observational clinical research** | Investigators assess health outcomes in groups of participants according to a research plan or protocol. |
| **Passive data** | Collection occurs without any patient interaction and is generally collected from sensors (such as heart rate monitors). |
| **Patient-generated health data** | Health-related data (such as health history, symptoms, biometric data, treatment history, lifestyle choices, and other information) that is created, recorded, gathered, or inferred by or from patients or their designees (which are often caregivers or those who assist them) to help address a health concern. |

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| **Patient registry** | Organized system that uses observational study methods to collect uniform data to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure that serves a predetermined scientific, clinical or policy purpose. |
| **Patient-reported outcome (PRO)** | An assessment that reflects the status of a patient's health condition that comes directly from the patient without amendment or interpretation by anyone else. |
| **Protected Health Information (PHI)** | Any information about health status, provision of healthcare, or payment for healthcare care that is created or collected by a covered entity and can be linked to a specific individual. It may include any part of a patient's medical record or health payment history. |
| **Post-approval studies (PAS)** | Studies that may be required at the time of approval of a Premarket Approval (PMA), Humanitarian Device Exemption (HDE), or product development protocol (PDP) application to help assure continued safety and effectiveness (or continued probable benefit in the case of an HDE) of the approved device. |
| **Postmarket surveillance studies** | Also referred to as "522 studies" are studies that FDA may require for a class II or class III device under Section 522 of the Food, Drug, and Cosmetic Act 21 U.S.C. § 360l in the following instances:<br>o failure of the device would be reasonably likely to have a serious adverse health consequence;<br>o expected to have significant use in pediatric populations;<br>o intended to be implanted for more than one year; or<br>o intended to be life-sustaining or life-supporting devices used outside a device user facility. |
| **Premarket application approval (PMA)** | FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. |

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| **Protocol** | A document that describes the objectives(s), design, methodology, statistical considerations, and organization of a clinical study. The protocol usually also gives the background and rationale for the study, 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. |
| **Real-world data** | The raw information about patient health status and/or delivery of health care collected from a variety of sources. |
| **Real-world evidence** | Clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of real-world data. |
| **Recalls** | A firm's removal or correction of a marketed product FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action. |
| **Safety** | Safety is relative freedom from harm. In clinical studies or in the real-world, 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. |
| **Semi-supervised learning** | Machine learning method that uses both labeled and unlabeled data for training. |
| **Sensors** | A device (not always a medical device) that detects and responds to some type of input from the physical environment including environment exposures (such as indoor smoke), location, physical activity (via accelerometry), sleep, social interactions, images, visual stimuli, glucose levels, and heart rhythms, with many more measures in development. |
| **Social Listening** | The process of learning from public conversations on the internet. Defined as mining and monitoring of user-generated and crowd-intelligence data from online conversations in blogs, medical forums, and other social networking sites to identify trends and themes of the conversation on a topic. |

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| **Signal** | Represents a new potentially causal association or a new aspect of a known association between a medical device and an adverse event or set of adverse events. |
| **Social Media** | 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), social news sites (Digg), blogging and forums, and any aspect of interactive presence which allows individuals the ability to engage in conversations with one another. |
| **Structured data** | Comprised of clearly defined data that can be easily sorted, queried, recalled, analyzed, and manipulated by machines. |
| **Subject/ Participant** | An individual who participates in a clinical trial either as a recipient of the investigational product(s) or as a control.<br><br>The term "subject" is part of the federal regulation and may be used interchangeably with participant. |
| **Supervised learning** | Machine learning approach that is trained from a set of labeled data that has been coded by humans. |
| **Underserved Population** | Populations whose voices and experiences are often not included in clinical studies. This population may include the economically disadvantaged, racial and ethnic minorities, the uninsured, rural residents, certain genders and sexual orientations, children, and the elderly. |
| **Unique Device Identifiers (UDI)** | Unique numeric or alphanumeric code that consists of two parts: a device identifier and a production identifier. Consistent use can identify and standardize the collection of medical device information in real-world databases. |
| **Unstructured data** | It is information that does not have a pre-defined data model or is not organized in pre-defined manner. It may also be human- or machine- generated, but it is not easily searchable. It includes formats like audio, video, text, and social media postings. |

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| **Unsupervised learning** | Where the machine learns the patterns in the data without any labels given by humans. |
| **Warning Letters** | Notification the FDA sends to a manufacturer for violations of regulatory significance. They give the companies an opportunity to take prompt and voluntary corrective action before it initiates an enforcement action. |
| **Web 2.0** | Evolution of the internet that allowed for improved communication and collaboration between people via social networking. |