

# Glossary

## BECAUSE SHARED LANGUAGE MATTERS

*Shared definitions are an important foundation for effective communication and collaboration in the digital health field.*

First and foremost, they help to ensure that all stakeholders in the healthcare ecosystem are speaking the same language and using the same terminology. This is important because it allows regulators, industry, healthcare professionals, and others to communicate effectively with one another, which is critical for the delivery of high-quality care. It also helps to facilitate interoperability between different digital health systems and tools, which is important for enabling the exchange of health information and supporting the delivery of coordinated and high-quality healthcare.

Currently, in the digital health ecosystem, we have again seen various stakeholders using different terminologies, with myriad understanding of the digital health tools, systems, and processes. Industry stakeholders and regulators may use different terms to refer to the same concept. For example, an industry stakeholder may refer to a particular digital health product as a "mobile health app," while a regulator may refer to it as a "medical device." In such cases, it is important to ensure that there is a shared understanding of the terminology being used in order to avoid confusion and misunderstanding.

Without common foundation definitions, there is a risk of misunderstandings and errors occurring due to the use of different terminology or definitions by different parties. This leads to confusion, delays, and potentially even harm to patients if important information is not understood or acted upon correctly. Thereby, shared definitions in digital health are key to ensure that everyone is using the same terminology and understanding the same concepts. This is important because it helps to reduce confusion and improve communication between different stakeholders in the digital health field.

Terms	Definition
<b>510(k)</b>	Also known as Premarket notification, this is a premarketing submission made to the FDA to demonstrate that the device to be marketed is safe and effective by proving substantial equivalence (SE) to a legally marketed device (predicate device) that is not subject to Premarket Approval (PMA). Submitters must compare their 510(k) device to a similar legally marketed U.S. device(s).  <i>Source: <a href="#">FDA</a></i>
<b>Accelerated approval</b>	Regulatory mechanisms by which new drugs meant to treat serious, life-threatening diseases and that provide meaningful therapeutic benefit to patients over existing treatments; can be approved on the basis of adequate and well-controlled clinical trials. This establishes that the drug has an effect on a reasonably likely surrogate endpoint or, on the basis of an effect on a clinical endpoint, other than survival or

	<p>irreversible morbidity (intermediate clinical endpoint). Postmarketing confirmatory trials have been required to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. For more information, see also the chapter on Reasonably Likely Surrogate Endpoints.</p> <p><i>Source: FDA/NIH - <a href="#">Glossary - BEST (Biomarkers, EndpointS, and other Tools) Resource - NCBI Bookshelf (nih.gov)</a></i></p>
<b>Algorithm</b>	<p>(1) A finite set of well-defined rules for the solution of a problem in a finite number of steps.</p> <p>(2) Any sequence of operations for performing a specific task.</p> <p><i>Source: <a href="#">IEEE - Institute of Electrical and Electronics Engineers</a></i></p>
<b>Algorithm analysis</b>	<p>A software verification and validation (V&amp;V) task to ensure that the algorithms selected are correct, appropriate, and stable; and meet all accuracy, timing, and sizing requirements.</p> <p><i>Source: <a href="#">IEEE - Institute of Electrical and Electronics Engineers</a></i></p>
<b>Analog</b>	<p>Pertaining to data [signals] in the form of continuously variable [wave form] physical quantities; e.g. pressure, resistance, rotation, temperature, voltage. Contrast with digital.</p> <p><i>Source: <a href="#">IEEE - Institute of Electrical and Electronics Engineers</a></i></p>
<b>Analog device</b>	<p>A device that operates with variables represented by continuously measured quantities such as pressures, resistances, rotations, temperatures, and voltages.</p> <p><i>Source: <a href="#">FDA - Glossary of Computer System Software Development Terminology</a></i></p>
<b>Analytical validation</b>	<p>A process to establish that the performance characteristics of a test, tool, or instrument are acceptable in terms of its sensitivity, specificity, accuracy, precision, and other relevant performance characteristics using a specified technical protocol (which may include specimen collection, handling and storage procedures).</p> <p><i>Source: FDA/NIH - <a href="#">Glossary - BEST (Biomarkers, EndpointS, and other Tools) Resource - NCBI Bookshelf (nih.gov)</a></i></p>
<b>Application Integrity Policy (AIP)</b>	<p>The FDA's policy for the integrity of data or information submitted in an application. If it is suspected that an applicant has submitted false or misleading information, the data are thoroughly investigated. Submitting false or misleading information may result in FDA refusal to review submissions until certain requirements are met.</p> <p><i>Source: FDA - <a href="#">IDE Definitions and Acronyms</a></i></p>
<b>Breakthrough Devices Program</b>	<p>A voluntary program for certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.</p>



	<p>Source: <a href="#">FDA</a></p>
<p><b>Certificate for Device Not Exported from the United States (CDNE)</b></p>	<p>A CDNE may be issued for medical devices manufactured outside of the United States (U.S.) that are cleared, approved, granted a De Novo <b>or</b> subject of an approved humanitarian device exemption, on the market prior to May 28, 1976 <b>or</b> exempt from section 510(k) of the FD&amp;C Act, <b>but</b> are not exported from the U.S. <b>and</b> are identical to the FDA authorized device with no modifications to the technology, intended use, indications for use or labeling.</p> <p>The CDNE was created in 2020 by the FDA as an option for manufacturers of devices not exported from the U.S., who may not receive export certificates (e.g. Certificate to Foreign Government (CFG)).</p> <p>Source: <a href="#">FDA</a></p>
<p><b>Center for Devices and Radiological Health (CDRH)</b></p>	<p>CDRH assures that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products.</p> <p>Source: <a href="#">FDA Glossary for clinical trial</a></p>
<p><b>Class I Medical Device</b></p>	<p>Devices are subject to a comprehensive set of regulatory authorities called general controls that are applicable to all classes of devices. Class I devices present minimal potential for harm to the user and are often simpler in design than Class II or Class III devices.</p> <p>Source: <a href="#">FDA</a></p>
<p><b>Class II Medical Device</b></p>	<p>Devices for which general controls, by themselves, are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance. Most medical devices are considered Class II devices.</p> <p>Source: <a href="#">FDA</a></p>
<p><b>Class III Medical Device</b></p>	<p>Devices for which general controls, by themselves, are insufficient and for which there is insufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device. These devices usually sustain or support life, are implanted, or present potential unreasonable risk of illness or injury.</p> <p>Source: <a href="#">FDA</a></p>
<p><b>Classification Product Code</b></p>	<p>These are a method of internally classifying and tracking medical devices. CDRH, and a subset of CBER, regulated medical device product codes consist of a 3 letter combination which associates a device's type with a product classification designated for the application. Classification product codes, and information associated with these devices, such as names and attributes, are assigned by CDRH to support their regulation.</p> <p>Source: <a href="#">FDA</a></p>



<p><b>Classification Regulation</b></p>	<p>These are Agency-defined categories of medical devices based on intended use and technology. Each one defines the class (i.e., Class I, II, or III) for the device category, which in turn determines the regulatory requirements. Device classification regulations are codified by rule or order in 21 CFR Parts 862-892.</p> <p>Source: <a href="#">FDA</a></p>
<p><b>Clinical Utility</b></p>	<p>The conclusion that a given use of a medical product will lead to a net improvement in health outcome or provide useful information about diagnosis, treatment, management, or prevention of a disease. Clinical utility includes the range of possible benefits or risks to individuals and populations.</p> <p>Source: <a href="#">FDA/NIH - Glossary - BEST (Biomarkers, EndpointS, and other Tools) Resource - NCBI Bookshelf (nih.gov)</a></p>
<p><b>Clinical Validation</b></p>	<p>A process to establish that the test, tool, or instrument acceptably identifies, measures, or predicts the concept of interest (COI).</p> <p>Source: <a href="#">FDA/NIH - Glossary - BEST (Biomarkers, EndpointS, and other Tools) Resource - NCBI Bookshelf (nih.gov)</a></p>
<p><b>Combination Product</b></p>	<p>(1) A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity;</p> <p>(2) Two or more separate products packaged together in a single package, or as a unit, and comprised of drug and device products, device and biological products, or biological and drug products;</p> <p>(3) A drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or</p> <p>(4) Any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.</p> <p>Source: <a href="#">CFR (Code of Federal Regulations) (Title 21)</a></p>
<p><b>Companion Diagnostic</b></p>	<p>A medical device, usually an in vitro diagnostic (IVD) device, that provides information that is essential for the safe and effective use of a corresponding therapeutic product. The use of a companion diagnostic with a therapeutic product is typically stipulated in the instructions for use in the labeling of both the diagnostic device and</p>



	<p>the corresponding therapeutic product, including the labeling of any generic equivalents of the therapeutic product.</p> <p><i>Source: FDA/NIH - <a href="#">Glossary - BEST (Biomarkers, EndpointS, and other Tools) Resource - NCBI Bookshelf (nih.gov)</a></i></p>
<b>Compassionate Use</b>	<p>Expanded access, also called “compassionate use,” provides a pathway for patients to gain access to investigational drugs, biologics and medical devices for serious diseases or conditions. Investigational drugs and devices have not yet been approved by the FDA and they have not been proven to be safe and effective. Therefore, they may be effective in the treatment of a condition, or they may not. It is important to remember that the drug/biologic/medical device may have unexpected serious side effects and that patients need to consider all the possible risks when seeking access to an investigational medical product.</p> <p>To gain access to an investigational medical product outside of a clinical trial, the sponsors must decide whether to make their experimental medical product available to patients via expanded access. FDA regulations specify two groups of people eligible for expanded access:</p> <ol style="list-style-type: none"> <li>(1) Those with life-threatening diseases or conditions for which “there is a reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment”</li> <li>(2) Those with serious diseases or conditions that have a “substantial impact on day-to-day functioning”</li> </ol> <p>In most cases, patients who seek compassionate use must have exhausted all approved therapies for their condition, and be unable to enroll in a clinical trial.</p> <p><i>Source: <a href="#">FDA Glossary for clinical trial</a></i></p>
<b>Control number</b>	<p>A unique series of letters, numbers or symbols, or any combination of these, assigned to a medical device by the manufacturer and from which a history of the manufacture, packaging, labeling and distribution of a lot or batch of the device can be determined.</p> <p><i>Source: <a href="#">Canadian Food Inspection Agency (CFIA)</a></i></p>
<b>De Novo</b>	<p>The De Novo summary is intended to present an objective and balanced summary of the scientific evidence that served as the basis for the decision to grant a De Novo request.</p> <p><i>Source: <a href="#">FDA</a></i></p>
<b>Developer</b>	<p>A person, or group, that designs and/or builds and/or documents and/or configures the hardware and/or software of computerized systems.</p>



	<p>Source: <a href="#">FDA - Glossary of Computer System Software Development Terminology</a></p>
<b>Device component</b>	<p>Any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device.</p> <p>Source: <a href="#">21 CFR 820.3(c) definition for “component”</a></p>
<b>Digital health technology</b>	<p>A system that uses computing platforms, connectivity, software, and 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.</p> <p>Source: <a href="#">FDA/NIH - Glossary - BEST (Biomarkers, Endpoints, and other Tools) Resource - NCBI Bookshelf (nih.gov)</a></p>
<b>Early Feasibility Study (EFS)</b>	<p>An early feasibility study is a limited clinical investigation of a device early in development. It typically:</p> <ul style="list-style-type: none"> <li>• Enrolls a small number of subjects;</li> <li>• Is used to evaluate the device design concept with respect to initial clinical safety and device functionality; and</li> <li>• May guide device modifications.</li> </ul> <p>Source: <a href="#">FDA - IDE Definitions and Acronyms</a></p>
<b>Endpoint</b>	<p>A precisely defined variable intended to reflect an outcome of interest that is statistically analyzed to address a particular research question. A precise definition of an endpoint typically specifies the type of assessments made, the timing of those assessments, the assessment tools used, and possibly other details, as applicable, such as how multiple assessments within an individual are to be combined.</p> <p>Source: <a href="#">FDA/NIH - Glossary - BEST (Biomarkers, Endpoints, and other Tools) Resource - NCBI Bookshelf (nih.gov)</a></p>
<b>End user</b>	<p>An end user is a person who uses a product or service. Examples of end users include patients (the service used is health care) and research study participants (the service or product used is based on the research question).</p> <p>Source: <a href="#">DATAcc</a></p>
<b>Electronic submission template</b>	<p>A guided submission preparation tool for industry. An electronic submission template walks industry through the relevant contents and components for the respective premarket submission type and device to facilitate submission preparation and enhance consistency, quality, and efficiency in the premarket review process.</p> <p>Source: <a href="#">FDA</a></p>



<p><b>Equivalence</b></p>	<ul style="list-style-type: none"> <li>● Biological equivalence: “Situation where two materials or medical devices demonstrate material and contact equivalence.” [SOURCE: ISO 10993-18:2020, Annex C.2.]</li> <li>● Contact equivalence: “Situation where the intended clinical use of two materials or medical devices is sufficiently similar that the endpoints of biological evaluation identified in ISO 10993-1:2018, A.1 are identical.” [SOURCE: ISO 10993-18:2020, Annex C.2.]</li> <li>● Material equivalence: “Situation where two materials or medical devices demonstrate chemical and physical equivalence.” [SOURCE: ISO 10993-18:2020, Annex C.2.]</li> <li>● Chemical equivalence: “Situation where the chemical characteristics of two materials or medical devices are sufficiently similar, such that the composition and processing do not result in additional or different toxicological concerns.” [SOURCE: ISO 10993-18:2020, Annex C.2.]</li> <li>● Physical equivalence: “Situation where the physical characteristics of two materials or medical devices are sufficiently similar, such that the configuration, morphology, topography (per ISO/TS 10993-19) and tribology do not result in additional or different biocompatibility concerns.” [SOURCE: ISO 10993-18:2020, Annex C.2.]</li> </ul>
<p><b>eSTAR (electronic Submission Template And Resource) program</b></p>	<p>An electronic submission template built within a structured dynamic PDF that guides a user through construction of an eSubmission. The eSTAR is the only type of electronic submission template that is currently available to facilitate the preparation of eSubmissions. For simplicity, the electronic submission created with this electronic submission template is often referred to as an eSTAR. The eSTAR program is free and available for voluntary use by all medical device applicants wishing to submit 510(k)s and De Novos to CDRH. The eSTAR is not currently for use with combination products.</p> <p>Source: <a href="#">FDA</a></p>
<p><b>Expanded access</b></p>	<p>Expanded access, also called “compassionate use,” provides a pathway for patients to gain access to investigational drugs, biologics and medical devices for serious diseases or conditions. Investigational drugs and devices have not yet been approved by the FDA and they have not been proven to be safe and effective. Therefore, they may be effective in the treatment of a condition, or they may not. It is important to remember that the drug/biologic/medical device may have unexpected serious side effects and that patients need to consider all the possible risks when seeking access to an investigational medical product.</p> <p>To gain access to an investigational medical product outside of a clinical trial, the sponsors must decide whether to make their experimental medical product available to patients via expanded</p>



	<p>access. FDA regulations specify two groups of people eligible for expanded access:</p> <ol style="list-style-type: none"> <li>(1) Those with life-threatening diseases or conditions for which “there is a reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment”.</li> <li>(2) Those with serious diseases or conditions that have a “substantial impact on day-to-day functioning”</li> </ol> <p>In most cases, patients who seek compassionate use must have exhausted all approved therapies for their condition, and be unable to enroll in a clinical trial</p> <p>Source: <a href="#">FDA Glossary for clinical trial</a></p>
<p><b>Expedited access</b></p>	<p>A voluntary program for certain medical devices that demonstrate the potential to address unmet medical needs for life threatening or irreversibly debilitating diseases or conditions. Under the Expedited Access Pathway (EAP) Program, the FDA works with device sponsors to try to reduce the time and cost from development to marketing decision without changing the FDA's standards.</p> <p>Source: <a href="#">FDA/NIH - Glossary - BEST (Biomarkers, EndpointS, and other Tools) Resource - NCBI Bookshelf (nih.gov)</a></p>
<p><b>Externally communicating medical device</b></p>	<p>Medical device or medical device component that is partially or wholly located outside the body but has either direct or indirect contact with the internal body fluids and/or tissues.</p> <p>Source: <a href="#">ISO - International Organization for Standardization</a> (ISO 10993-1:2018, Clause 3.7)</p>
<p><b>FDA approved</b></p>	<p>When a FDA review is needed prior to marketing a high-risk medical device, FDA will "approve" the device after reviewing a premarket approval (PMA) application that has been submitted to FDA. To acquire approval of a device through a PMA application, the PMA applicant must provide reasonable assurance of the device’s safety and effectiveness.</p> <p>Source: <a href="#">FDA</a></p>
<p><b>FDA cleared</b></p>	<p>When a FDA review is needed prior to marketing a moderate or low risk medical device, FDA will "clear" the device after reviewing a premarket notification, otherwise known as a 510(k) (named for a section in the Food, Drug, and Cosmetic Act), that has been filed with the FDA. To acquire clearance to market a device using the 510(k) pathway, the submitter of the 510(k) must show that the medical device is "substantially equivalent" to a device that is already legally marketed for the same use.</p> <p>Source: <a href="#">FDA</a></p>





<p><b>FDA granted</b></p>	<p>When a FDA review is needed to classify novel medical devices for which general controls alone, or general and special controls, provide reasonable assurance of safety and effectiveness for the intended use, but for which there is no legally marketed predicate device. A product using the De Novo pathway must be “Granted” by FDA before they can be legally marketed in the U.S. If the De Novo is granted, it establishes a new device type, along with a new classification, regulation, necessary controls and a product code. If a De Novo is granted, the device is eligible to serve as a predicate for new medical devices, where appropriate, within the 510(k) process.</p> <p>Source: <a href="#">FDA (DiMe analysis)</a></p>
<p><b>FDA registered</b></p>	<p>Owners or operators of places of business (also called establishments or facilities) that are involved in the production and distribution of medical devices intended for use in the U.S. are required to register annually with the FDA.</p> <p>Source: <a href="#">FDA</a></p>
<p><b>Federal Register</b></p>	<p>Abbreviated to FR or sometimes Fed. Reg., is the official journal of the federal government of the U.S. that contains most routine publications and public notices of government agencies. It is a daily (except federal holidays) publication. The Federal Register is compiled by the Office of the Federal Register (within the National Archives and Records Administration) and is printed by the Government Printing Office. The final rules promulgated by a federal agency and published in the Federal Register are ultimately reorganized by topic or subject matter and codified in the Code of Federal Regulations (CFR), which is updated annually. There are no copyright restrictions on the Federal Register; as a work of the U.S. government, it is in the public domain.</p> <p>Source: <a href="#">FDA Glossary for clinical trial</a></p>
<p><b>Firmware</b></p>	<p>The combination of a hardware device; e.g., an Integrated Circuit (IC); and computer instructions and data that reside as read only software on that device. Such software cannot be modified by the computer during processing.</p> <p>Source: <a href="#">IEEE - Institute of Electrical and Electronics Engineers</a></p>
<p><b>General Control</b></p>	<p>General controls are regulatory requirements that apply to all medical devices, unless exempted by regulations. If a device is exempted from one of the general controls, such exemption is stated in the classification regulation for that device.</p> <p>Source: <a href="#">FDA/FD&amp;C Act, under sections 501, 502, 510, 516, 518, 519, and 520</a></p>
<p><b>Guidance</b></p>	<p>Describes FDA’s current thinking on a regulatory issue. Guidance is not legally binding on the public or FDA</p> <p>Source: <a href="#">FDA</a></p>



<b>Hardware</b>	Physical equipment, as opposed to programs, procedures, rules, and associated documentation. Contrast with software. <i>Source: <a href="#">ISO - International Organization for Standardization</a></i>
<b>Hazard</b>	A possible source of danger or a condition that could result in human injury. <i>Source: <a href="#">FDA</a></i>
<b>Hazard Analysis</b>	Identification of hazards and their initiating causes. <i>Source: <a href="#">FDA</a></i>
<b>Hazard Mitigation</b>	Reduction in the severity of the hazard, the likelihood of the occurrence, or both. <i>Source: <a href="#">FDA</a></i>
<b>Human Factors</b>	Human factors (HF) is the study of how people use technology. It involves the interaction of human abilities, expectations, and limitations, with work environments and system design. <i>Source: <a href="#">FDA</a></i>
<b>Humanitarian Use Device (HUD)</b>	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 U.S. per year. <i>Source: <a href="#">FDA</a></i>
<b>Humanitarian Device Exemption (HDE)</b>	A marketing application for a HUD (Section 520(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)). An HDE is exempt from the effectiveness requirements of Sections 514 and 515 of the FD&C Act and is subject to certain profit and use restrictions. <i>Source: <a href="#">FDA</a></i>
<b>Implant</b>	A device that is placed into a surgically or naturally formed cavity of the human body. A device is regarded as an implant for the purpose of this part only if it is intended to remain implanted continuously for a period of 30 days or more, unless the Commissioner determines otherwise in order to protect human health. <i>Source: <a href="#">21 CFR CFR 860.3(d)</a></i>
<b>Indication of use</b>	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. <i>Source: <a href="#">FDA</a></i>
<b>Institutional Review Board (IRB)</b>	Institutional Review Board (IRB) is a 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



	<p>protection of the rights, safety, and welfare of human subjects. The IRB should be established, operated, and function in conformance with 21 CFR 56. The term has the same meaning as "institutional review committee" in section 520(g) of the FD&amp;C Act.</p> <p><i>Source: FDA - <a href="#">IDE Definitions and Acronyms</a></i></p>
<b>Intended use</b>	<p>The general purpose of the device or its function. This includes the indications for use.</p> <p><i>Source: <a href="#">FDA</a></i></p>
<b>Invasive</b>	<p>A term applied to a device or procedure, meaning one that does not by design or intention: (1) Penetrate or pierce the skin or mucous membranes of the body, the ocular cavity, or the urethra, or (2) Enter the ear beyond the external auditory canal, the nose beyond the nares, the mouth beyond the pharynx, the anal canal beyond the rectum, or the vagina beyond the cervical os.</p> <p><i>Source: Adapted from <a href="#">CFR - Code of Federal Regulations Title 21</a></i></p>
<b>Investigation</b>	<p>Investigation is a clinical investigation or research involving one or more subjects to determine the safety and/or effectiveness of a device.</p> <p><i>Source: <a href="#">FDA</a></i></p>
<b>Investigational Device</b>	<p>Investigational device is a device, including a transitional device, that is the object of an investigation.</p> <p><i>Source: <a href="#">FDA</a></i></p>
<b>Investigational device exemption (IDE)</b>	<p>IDE refers to the regulations under 21 CFR 812. An approved IDE means that the IRB (and the FDA for significant risk devices) has approved the sponsor's study application and all the requirements under 21 CFR 812 are met.</p> <p><i>Source: <a href="#">FDA</a></i></p>
<b>Investigator</b>	<p>An individual who actually conducts a clinical investigation, i.e., under whose immediate direction the investigational device is administered, dispensed to, or used involving a subject. In the event of an investigation being conducted by a team of individuals, "investigator" refers to the responsible leader of that team.</p> <p><i>Source: <a href="#">FDA</a></i></p>
<b>Major Level of Concern</b>	<p>The Level of Concern is major if operation of the software associated with device function directly affects the patient, operator, and/or bystander so that failures or latent flaws could result in death or serious injury to the patient, operator, and/or bystander, or if it indirectly affects the patient, operator, and/or bystander (e.g., through the action of care provider) such that incorrect or delayed information could result in death or serious injury to the patient, operator, and/or bystander.</p>



	<p>Source: <a href="#">FDA</a></p>
<b>Medical Device</b>	<p>An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory which is:</p> <ul style="list-style-type: none"> <li>● Recognized in the official National Formulary, or the U.S. Pharmacopoeia, or any supplement to them;</li> <li>● 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</li> <li>● 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 any of its primary intended purposes.</li> </ul> <p>Source: <a href="#">FDA</a></p>
<b>Medical Device User Fee Amendments (MDUFA)</b>	<p>MDUFA is the law that authorizes the FDA to collect fees from device companies that register their establishments, submit applications to market devices, and make other types of device submissions.</p> <p>Source: <a href="#">Federal Registrar</a></p>
<b>Medical product development tool (MPDT)</b>	<p>Methods, materials, or measurements used to assess the effectiveness, safety, or performance of a medical product. In a regulatory context, examples of MPDTs are clinical outcome assessments (COAs), assessments of biomarkers, and non-clinical assessment methods or models.</p> <p>Source: <a href="#">FDA/NIH - Glossary - BEST (Biomarkers, EndpointS, and other Tools) Resource - NCBI Bookshelf (nih.gov)</a></p>
<b>Minimal Risk</b>	<p>Means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.</p> <p>Source: <a href="#">FDA Glossary for clinical trial</a></p>
<b>Minor Level of Concern</b>	<p>The Level of Concern is minor if failures or latent design flaws would not be expected to result in any injury to the patient, operator, and/or bystander.</p> <p>Source: <a href="#">FDA</a></p>
<b>Moderate Level of Concern</b>	<p>The Level of Concern is moderate if the operation of the software associated with device function directly affects the patient, operator, and/or bystander so that failures or latent design flaws could result in non-serious injury to the patient, operator, and/or bystander, or if it</p>



	<p>indirectly affects the patient, operator, and/or bystander (e.g., through the action of the care provider) where incorrect or delayed information could result in non-serious injury of the patient, operator, and/or bystander.</p> <p>Source: <a href="#">FDA</a></p>
<b>Monitor</b>	<p>When used as a noun, monitor is an individual designated by a sponsor or contract research organization (CRO) to oversee the progress of an investigation. The monitor may be an employee of a sponsor, or a consultant to the sponsor, or an employee of or consultant to a CRO. When used as a verb, "monitor" means to oversee an investigation.</p> <p>Source: FDA - <a href="#">IDE Definitions and Acronyms</a></p>
<b>Multiple Predicate Devices</b>	<p>Two or more predicate devices that have been provided to support an SE determination. If using multiple predicate devices to demonstrate substantial equivalence, each predicate device must have the same intended use as the new device, and any different technological characteristics between the new device and the predicate devices must not raise different questions of safety and effectiveness.</p> <p>Source: <a href="#">FDA</a></p>
<b>New Device</b>	<p>A device that is not legally marketed.</p> <p>Source: Section 201(h) of the FD&amp;C Act</p>
<b>Non-invasive</b>	<p>It is applied to a device or procedure, means one that does not by design or intention: (1) Penetrate or pierce the skin or mucous membranes of the body, the ocular cavity, or the urethra, or (2) enter the ear beyond the external auditory canal, the nose beyond the nares, the mouth beyond the pharynx, the anal canal beyond the rectum, or the vagina beyond the cervical os.</p> <p>Source: <a href="#">CFR - Code of Federal Regulations Title 21</a></p>
<b>Off-the-Shelf Software (OTS Software)</b>	<p>A generally available software component, used by a medical device manufacturer for which the manufacturer cannot claim complete software life cycle control.</p> <p>Source: <a href="#">FDA</a></p>
<b>Performance Data</b>	<p>Performance data can be any data, including non-clinical (e.g., data from engineering testing, such as fatigue, wear, corrosion, etc., biocompatibility, functional animal studies, cadaver, etc.) and/or clinical, that are provided to support the substantial equivalence of a device that is intended to be marketed.</p> <p>Source: <a href="#">FDA</a></p>
<b>Pre Amendments Device</b>	<p>Refers to devices legally marketed in the U.S. by a firm before May 28, 1976 and which have not been:</p> <ul style="list-style-type: none"> <li>• Significantly changed or modified since then; and</li> </ul>



	<ul style="list-style-type: none"> <li>For which a regulation requiring a premarket approval (PMA) application has not been published by FDA.</li> </ul> <p>Source: <a href="#">FDA</a></p>
<b>Premarket Approval Application</b>	<p>In effect, a private license granted to the applicant for marketing a particular medical device.</p> <p>Source: <a href="#">FDA</a></p>
<b>Premarket approval (PMA)</b>	<p>The FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, that are of substantial importance in preventing impairment of human health, or that present a potential, unreasonable risk of illness or injury.</p> <p>Source: <a href="#">FDA</a></p>
<b>Premarket Notification [PMN or 510(k)]</b>	<p>A PMN or 510(k) refers to the type of submission to the FDA described under 21 CFR 807 Subpart E in which the applicant must establish that their device is substantially equivalent to a legally marketed device. This type of submission is used for most Class II devices and some Class I devices.</p> <p>Source: FDA - <a href="#">IDE Definitions and Acronyms</a></p>
<b>Post Amendments Device</b>	<p>Medical devices marketed after May 28, 1976. Because medical technology has changed greatly since 1976, almost all 510(k) submissions claim substantial equivalence to a post amendment device that has been recently cleared under the 510(k) process.</p> <p>Source: <a href="#">FDA</a></p>
<b>Predicate device</b>	<p>A legally marketed device to which a new device may be compared for a determination regarding substantial equivalence because the devices have the same intended use and the same technological characteristics or different technological characteristics that do not raise different questions of safety and effectiveness.</p> <p>Source: <a href="#">FDA</a> / defined in 21 CFR 807.92(a)(3)</p>
<b>Primary predicate device</b>	<p>A predicate device with indications for use and technological characteristics that are most similar to the new device. The primary predicate should be identified within a 510(k) submission.</p> <p>Source: <a href="#">FDA</a></p>
<b>Production identifier (PI)</b>	<p>A conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device:</p> <ul style="list-style-type: none"> <li>Lot or batch number within which a device was manufactured;</li> <li>Serial number of a specific device;</li> <li>Expiration date of a specific device;</li> </ul>



	<ul style="list-style-type: none"> <li>• Date a specific device was manufactured;</li> <li>• Distinct identification code required by §1271.290(c) for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device.</li> </ul> <p>Source: <a href="#">FDA</a></p>
<b>Recall</b>	<p>A recall is when a product is removed from the market or a correction is made to the product because it is either defective or potentially harmful. Sometimes a company discovers a problem and recalls a product on its own. Other times a company recalls a product after the FDA raises concerns.</p> <p>Source: <a href="#">FDA</a></p>
<b>Reference device</b>	<p>A legally marketed device that is intended to provide scientific and/or technical information (e.g., test methodology) to help address the safety and effectiveness of a new technological characteristic. Reference devices are not predicate devices and may only be used after Decision Point 4 on the 510(k) Decision-Making Flowchart.</p> <p>Source: <a href="#">FDA</a></p>
<b>Regulatory Agency</b>	<p>A public authority or government agency responsible for exercising autonomous authority over some area of human activity in a regulatory or supervisory capacity. An independent regulatory agency is a regulatory agency that is independent from other branches or arms of the government. Regulatory agencies deal in the area of administrative law—regulation or rulemaking (codifying and enforcing rules and regulations and imposing supervision or oversight for the benefit of the public at large).</p> <p>Source: <a href="#">FDA Glossary for clinical trial</a></p>
<b>Regulatory Controls</b>	<p>The risk-based device classification system for medical devices means each device is assigned to one of three regulatory classes: Class I, Class II or Class III, based on the level of control necessary to provide reasonable assurance of its safety and effectiveness. As device class increases from Class I, to Class II to Class III, the regulatory controls also increase, with Class I devices subject to the least regulatory control, and Class III devices subject to the most stringent regulatory control.</p> <p>Source: <a href="#">FDA/Federal Food, Drug, and Cosmetic Act, section 513</a></p>
<b>Risk Analysis</b>	<p>Investigation of available information to identify hazards and to estimate risks.</p> <p>Source: <a href="#">FDA</a></p>
<b>Risk Assessment</b>	<p>Overall process comprising a risk analysis (systematic use of available information to identify hazards and to estimate the risk) and a risk</p>



	<p>evaluation (procedure based on the risk analysis to determine whether tolerable risk has been exceeded).</p> <p>Source: <a href="#">FDA</a> (FDA's <i>Biocompatibility Guidance on Use of ISO 10993-1, and ISO/IEC Guide 51:2014(E), Clauses 3.10, 3.11, and 3.12</i>)</p>
<b>Risk Controls</b>	<p>The process through which decisions are reached and implemented for reducing risks to, or maintaining risks within, specified limits.</p> <p>Source: <a href="#">FDA</a></p>
<b>Safety</b>	<p>In the regulation of medical devices, safety means that the probable benefits to health for its intended use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks.</p> <p>Source: <a href="#">FDA</a></p>
<b>Serious Injury</b>	<p>In the regulation of medical devices, safety means that the probable benefits to health for its intended use when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The use of the words “safety and effectiveness” is to remind ourselves that safety is only meaningful in the context of the benefit-risk considerations and the labeling. Serious Injury – As adopted from the Medical Device Reporting (MDR) regulation in 21 CFR 803.3(w), means an injury or illness that:</p> <ul style="list-style-type: none"> <li>● Is life threatening</li> <li>● Results in permanent impairment of a body function or permanent damage to a body structure, or</li> <li>● Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.</li> </ul> <p>Source: <a href="#">FDA</a></p>
<b>Significant risk device (SR device)</b>	<p>An investigational device that:</p> <p>(1) Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;</p> <p>(2) Is for use in supporting or sustaining human life and represents a potential for serious risk to the health, safety, or welfare of a subject;</p> <p>(3) Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or</p> <p>(4) Otherwise presents a potential for serious risk to a subject.</p> <p>Source: <a href="#">FDA</a></p>





<b>Software</b>	<p>Programs, procedures, rules, and any associated documentation pertaining to the operation of a system. Contrast with hardware.</p> <p>Source: <a href="#">ANSI - American National Standards Institute</a></p>
<b>Software characteristic</b>	<p>An inherent, possibly accidental, trait, quality, or property of software; e.g., functionality, performance, attributes, design constraints, number of states, lines or branches.</p> <p>Source: <a href="#">FDA</a></p>
<b>Software design description</b>	<p>A representation of software created to facilitate analysis, planning, implementation, and decision making. The software design description is used as a medium for communicating software design information, and may be thought of as a blueprint or model of the system.</p> <p>Source: <a href="#">FDA</a></p>
<b>Split predicate</b>	<p>Using one legally marketed device for intended use and a different legally marketed device for technological characteristics to demonstrate substantial equivalence. The use of a “split predicate” is inconsistent with the 510(k) regulatory standard.</p> <p>Source: <a href="#">FDA</a></p>
<b>Special Controls</b>	<p>Regulatory requirements for class II devices. FDA classifies into class II devices for which general controls alone are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance.</p> <p>Source: <a href="#">FDA</a></p>
<b>Sponsor</b>	<p>Manufacturer, submitter, or applicant.</p> <p>Source: <a href="#">FDA</a> (<i>FDA’s Biocompatibility Guidance on Use of ISO 10993-1</i>)</p>
<b>Sponsor - investigator</b>	<p>An individual who both initiates and actually conducts, alone or with others, a clinical investigation, i.e., under whose immediate direction the investigational device is administered, dispensed, or used. The term does not, for example, include a corporation or agency. The obligations of a sponsor-investigator include those of an investigator and those of a sponsor.</p> <p>Source: <a href="#">FDA</a></p>
<b>Subject</b>	<p>A human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or who participates as a control. A subject may be in normal health or may have a medical condition or disease.</p> <p>Source: <i>FDA - <a href="#">IDE Definitions and Acronyms</a></i></p>



<b>Total Product Life Cycle (TPLC)</b>	<p>An integrated device review, tracking, reporting and compliance scheme employed by the FDA. The TPLC approach allows the FDA to integrate all regulatory activities from device inception to obsolescence.</p> <p>Source: <a href="#">FDA</a></p>
<b>Transitional device</b>	<p>A device subject to section 520(l) of the FD&amp;C Act and which FDA previously regulated as a new drug or an antibiotic drug before May 28, 1976.</p> <p>Source: FDA - <a href="#">IDE Definitions and Acronyms</a></p>
<b>Unanticipated adverse device effect</b>	<p>Any serious adverse effect on health or safety, any life-threatening problem or death caused by, or associated with a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the application; or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.</p> <p>Source: FDA - <a href="#">IDE Definitions and Acronyms</a></p>
<b>Unique Device Identifier (UDI)</b>	<p>A mandatory, fixed portion of a Unique Device Identifier (UDI) that identifies the labeler and the specific version or model of a device.</p> <p>Source: <a href="#">FDA</a></p>
<b>User fee</b>	<p>The User Fee programs help the FDA to fulfill its mission of protecting public health and accelerating innovation in the industry.</p> <p>Source: <a href="#">FDA</a></p>
<b>Validation</b>	<p>A process to establish that the test, tool, or instrument acceptably identifies, measures, or predicts the concept of interest.</p> <p>Source: FDA/NIH - <a href="#">Glossary - BEST (Biomarkers, EndpointS, and other Tools) Resource - NCBI Bookshelf (nih.gov)</a></p>
<b>Voluntary eSTAR Program</b>	<p>A program intended to enhance the incoming quality of submissions for a wide range of medical devices by helping to ensure submitters provide quality, comprehensive data for CDRH's premarket review.</p> <p>Source: <a href="#">FDA</a></p>





## References & Resources

- [Glossary: FDA Data Dashboard | FDA](#)
- [CBER Offices & Divisions | FDA](#)
- [Glossary of Computer System Software Development Terminology \(8/95\) | FDA](#)
- [FDA Dashboards - Glossary](#)
- [Acronyms & Definitions | RAPS](#)
- [General Controls for Medical Devices | FDA](#)
- [Medical Device Glossary \(greenlight.guru\)](#)
- [IDE Definitions and Acronyms | FDA](#)
- [Glossary of Computer System Software Development Terminology \(8/95\) | FDA](#)

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