



VA



U.S. Department
of Veterans Affairs

The Playbook: **Digital Healthcare**

Glossary



Glossary

AI/ ML Artificial Intelligence and Machine Learning (AI/ML) are human-like capabilities of mathematical algorithms processed by computers. It refers to software applications that, using advanced statistical methodologies, can learn patterns and derive insights from seemingly complex datasets	Algorithmic Bias When human biases are integrated into algorithms. Algorithmic bias can skew the accuracy and impact of an algorithm. Bias baked into an algorithm, whether intentionally or not, will replicate when the algorithm is used and can have the effect of amplifying human bias	Biomarker A defined characteristic that is measured as an indicator of normal biological processes, pathogenic processes, or biological responses to an exposure or intervention, including therapeutic interventions. It may include molecular, histologic, radiographic, or physiologic characteristics. It is not a measure of how an individual feels, functions, or survives.	Broadband Adoption Traditionally defined as residential subscribership to high-speed Internet access, but now as daily access to the Internet: <ul style="list-style-type: none">- at speeds, quality and capacity necessary to accomplish common tasks,- with the digital skills necessary to participate online, and- on a personal device and secure convenient network.
Broadband Broadband equity is achieved when all people and communities are able to access and use affordable, high-speed, reliable internet that meets their long-term needs.	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 Care Describes activities that occur between a patient and a healthcare provider. Primary purpose historically has been to address health problems with recent shifts towards preventative care and maintaining wellness	Clinical Outcome A measurable characteristic that describes or reflects how an individual feels, functions or survives

Glossary

Clinical Research <p>Describes activities that occur during a study or investigation. Primary purpose is to develop a better understanding of factors influencing health and illness in people; Clinical trials for drug development are a subset of clinical research</p>	Combination product <p>Product composed of any combination of a drug and device; a biological product and a device; a drug and a biological product; or a drug, device and a biological product. An example would include continuous glucose monitoring (CGM).</p>	Connected implantables <p>Implanted medical devices, digitally connected to transmit regular data (i.e. insulin pumps).</p>	Connected Sensor Technology <p>Technology products that process data captured by mobile sensors using algorithms to generate measures of behavioral and/or physiological function</p>
Clinical Utility <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.</p>	Intended use <p>The specific clinical circumstance or purpose for which a medical product or test is being developed. In the regulatory context, “intended use” refers to the objective intent of the persons legally responsible for the labeling of medical products.</p>	Data Rights <p>The rights of individuals and organisations to access and control certain data. These are not absolute rights and the needs of individuals (including privacy), organisations and society at large need to be balanced.</p>	Digital Clinical Measure <p>Health outcomes, or measurable characteristics of their health and/or condition that are collected digitally with a sensor or survey</p>

Glossary

Digital Divide <p>The gap between those who have affordable access, skills, and support to effectively engage online and those who do not. It prevents equal participation and opportunity in all parts of life, disproportionately affecting people of color, Indigenous peoples, households with low incomes, people with disabilities, people in rural areas, and older adults.</p>	Digital Equity <p>Condition in which all individuals and communities have the information technology capacity needed for full participation in our society, democracy and economy</p>	Digital Health <p>Use of technology and electronic communications tools, services and processes to deliver healthcare services or to facilitate better health. Incorporates a broad array of technologies including: telemedicine, remote monitoring, AI-enabled solutions, apps, trackers and digital therapeutics.</p>	Digital Health literacy <p>Ability to seek, find, understand and appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem.</p>
Digital Health Measurements <p>Digital health measurement uses digital technologies to collect clinical and other forms of health data from individuals outside of traditional clinical settings during activities of daily living.</p>	Digital Health Technologies <p>Electronic tools, systems, devices and resources that generate, store and process data in health care and include mobile health, wearable devices, telehealth, telemedicine, electronic health records, patient portals.</p>	Digital Inclusions <p>Refers to activities necessary to ensure all individuals and communities have access to and use of Information and Communication Technologies (ICTs). This includes 5 elements: 1) affordable, robust broadband internet service; 2) internet-enabled devices that meet the needs of the user; 3) access to digital literacy training; 4) quality technical support; and 5) applications and online content design</p>	Digital Inclusion Ecosystem <p>A combination of programs and policies that meet a geographic community's unique and diverse needs. Coordinating entities work together in an ecosystem to address all aspects of the digital divide, including affordable broadband, devices, and skills.</p>

Glossary

Digital Intervention Products <p>Digital intervention products include digital therapeutics and connected implantables (e.g., an insulin pump).</p>	Digital Literacy <p>The ability to use information and communication technologies (ICTs) to find, evaluate, create, and communicate information, requiring both cognitive and technical skills.</p>	Digital Measurement Products <p>Technologies that process data captured by mobile sensors using algorithms to generate measures of behavioral and/or physiological function. AKA ‘connected sensor technology’ Include digital biomarkers, e-clinical outcome assessments and digital tools that measure adherence and safety</p>	Digital Measurement System <p>The sensor, algorithms, data science platforms and person/patient data platforms that are required for remote monitoring</p>
Digital Medicine <p>Describes a field, concerned with the use of digital technologies as tools for measurement, and intervention in the service of human health</p>	Digital Navigators <p>Trusted guides who assist community members in internet adoption and the use of computing devices. Services include ongoing assistance with affordable internet access, device acquisition, technical skills, and application support.</p>	Digital Sensing Product <p>Technology products that capture data using mobile sensors, then process these data using algorithms to generate measures of behavioral and/or physiological function.</p>	Digital Specimen <p>Any personal data collected digitally. This could include medical records, sensor data, race, education level, social media post, and bill payments that may or may not be covered by HIPAA</p>

Glossary

Digital Wellness Products Describes products that consumers use to measure characteristics that might influence their personal well-being, such as physical activity and sleep	Electronic Health Record (EHR) Electronic platforms that contain individual health records for patients. Generally maintained by health care providers, health care organizations, and health care institutions and are used to deliver care. Can be used to integrate real-time electronic health care information from medical devices and multiple health care providers involved in care of patients.	Endpoint Events or outcomes that can be measured objectively to determine whether the intervention being studied is beneficial	Fit-for-purpose In the context of use of a Digital Health Technology (DHT) in a clinical investigation, a conclusion that the level of validation associated with a DHT is sufficient to support its context of use.
Health Disparity Particular type of health difference that is closely linked with social or economic disadvantage. They adversely affect groups of people who have systematically experienced greater social or economic obstacles to health based on their racial or ethnic group, religion, socioeconomic status, gender, mental health, cognitive, sensory, or physical disability, sexual orientation, geographic location, or characteristics historically linked to discrimination or exclusion.	Health Economics The study of the allocation of resources within the health economy to optimize productivity and outcomes.	Health Equity Health equity means that everyone has a fair and just opportunity to be as healthy as possible. This requires removing obstacles to health such as poverty, discrimination, and their consequences, including powerlessness and lack of access to good jobs with fair pay, quality education and housing, safe environments, and health care.	Health Inequities The unfair and avoidable differences in health status seen within and between populations.

Glossary

Health Literacy <p>The degree to which individuals have the capacity to obtain, process and understand basic health information needed to make appropriate health decisions.</p>	Internet of Bodies (IoB) <p>A network of smart technologies attached to and/or inside human bodies</p>	Internet of Medical Things (IoMT) <p>An amalgamation of medical devices and applications that can connect to healthcare information technology systems using networking technologies.</p>	Internet of Things (IoT) <p>A network of smart technologies attached to and/or inside things</p>
Interoperability <p>The ability of different information systems, devices and applications to access, exchange, integrate and use data in a coordinated manner, within and across organizational, regional and national boundaries, to provide timely and seamless portability of information and optimize the health of individuals and populations globally</p>	Sensor <p>A transducer that converts a physical, biological, or chemical parameter into an electrical signal; for example, temperature, pressure, flow, or vibration sensor. A sensor is typically hardware.</p>	Software as a Medical Device (SaMD) <p>Software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device</p>	Software Bill of Materials (SBOM) <p>Analogous to an ingredients list on food packaging. A nested inventory listing all the components in a given piece of software.</p>

Glossary

Usability	Utility	User Experience	Virtual First Care (V1C)
<p>How easy and pleasant the features of a digital medicine product are to use for the intended users Usability is often considered alongside utility, and lower usability may be acceptable when utility is high</p>	<p>Does a digital product have the features that users need? Utility evaluates a product's usefulness, profitability, and benefits to a specific population</p>	<p>The overall experience of a person using a product such as a website or computer application, especially in terms of how easy or pleasing it is to use.</p>	<p>Virtual first care is medical care for individuals or a community accessed through digital interactions where possible, guided by a clinician, and integrated into a person's everyday life.</p>

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