DIGITAL HEALTH

The broad scope of digital health includes categories such as mobile health (mHealth), health information technology (IT), wearable devices, telehealth and telemedicine, and personalized medicine. From mobile medical apps and software that support the clinical decisions doctors make every day to artificial intelligence and machine learning, digital technology has been driving a revolution in health care. Digital health tools have the vast potential to improve our ability to accurately diagnose and treat disease and to enhance the delivery of health care for the individual.

Digital health technologies use computing platforms, connectivity, software, and sensors for health care 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, as companion diagnostics, or as an adjunct to other medical products (devices, drugs, and biologics). They may also be used to develop or study medical products.

The Benefits of Digital Health Technologies

Digital tools are giving providers a more holistic view of patient health through access to data and giving patients more control over their health. Digital health offers real opportunities to improve medical outcomes and enhance efficiency.

These technologies can empower consumers to make better-informed decisions about their own health and provide new options for facilitating prevention, early diagnosis of life-threatening diseases, and management of chronic conditions outside of traditional health care settings. Providers and other stakeholders are using digital health technologies in their efforts to:

- Reduce inefficiencies,
- Improve access,
- Reduce costs,
- Increase quality, and
- Make medicine more personalized for patients.

Patients and consumers can use digital health technologies to better manage and track their health and wellness-related activities.The use of technologies, such as smart phones, social networks, and internet applications, is not only changing the way we communicate, but also providing innovative ways for us to monitor our health and well-being and giving us greater access to information. Together, these advancements are leading to a convergence of people, information, technology, and connectivity to improve health care and health outcomes.

The FDA's Focus in Digital Health

Many medical devices now have the ability to connect to and communicate with other devices or systems. Devices that are already FDA approved, authorized, or cleared are being updated to add digital features. New types of devices that already have these capabilities are being explored.Many stakeholders are involved in digital health activities, including patients,

health care practitioners, researchers, traditional medical device industry firms, and firms new to the FDA regulatory requirements, such as mobile application developers.

The FDA's Center for Devices and Radiological Health (CDRH) are excited about these advances and the convergence of medical devices with connectivity and consumer technology. The following are topics in the digital health field on which the FDA has been working to provide clarity using practical approaches that balance benefits and risks:

- Software as a Medical Device (SaMD)
- Artificial Intelligence and Machine Learning (AI/ML) in Software as a Medical Device
- Cybersecurity
- Device Software Functions, including Mobile Medical Applications
- Health IT
- Medical Device Data Systems
- Medical Device Interoperability
- Telemedicine
- Wireless Medical Devices

As another important step in promoting the advancement of digital health technology, CDRH has established the Digital Health Center of Excellence which seeks to empower digital health stakeholders to advance health care.

Indian policies affecting the digitization of healthcare

Type of Regulation	**Title of Regulation**	**Date Effective**	**Relevant Clauses**
Law	The Drugs and Cosmetics Act ("D&C Act")	10 April 1940	—
Law	Information Technology Act and Rules (IT Act)	9 June 2000	Section 2(w), Section 43A, Section 79
Regulations	The Clinical Establishments (Registration and Regulation) Act	9 August 2010	Section 38(1) and 38(2)

Type of Regulation	Title of Regulation	Date Effective	Relevant Clauses
Law	The Information Technology Reasonable security practices and procedures and sensitive personal data or information Rules ("Data Protection Rules")	1 April 2011	Rule 3, Rule 4(1), Rule 5(1), Rule 5(3), Rule 5(7), Rule 7
National Standards	The Information Technology (Intermediaries Guidelines) Rules ("Intermediary Guidelines")	1 April 2011	Rule 3
Law	The Medical Devices Rules ("MDR")	5 May 2017	—
Regulations	DNA Technology (Use and Application) Regulation Bill	8 July 2019	—
Regulations	Digital Personal Data Protection Bill (DPDP Bill)	18 November 2022	Clause 8

Electronic Health Record (EHR)

An **electronic health record** (**EHR**) is the systematized collection of electronically stored patient and population health information in a digital format. These records can be shared across different health care settings. Records are shared through network-connected, enterprise-wide information systems or other information networks and exchanges. For several decades, EHRs have been touted as key to increasing quality of care. EHR combines all patients' demographics into a large pool, which assists providers in the creation of "new treatments or innovation in healthcare delivery" to improve quality outcomes in healthcare. Combining multiple types of clinical data from the system's health records has helped clinicians identify and stratify chronically ill patients. EHR can also improve quality of care through the use of data and analytics to prevent hospitalizations among high-risk patients.

EHR systems are designed to store data accurately and to capture a patient's state across time. It eliminates the need to track down a patient's previous paper medical records and assists in ensuring data is up-to-date, accurate, and legible. It also allows open communication between the patient and the provider while providing "privacy and security." EHR is cost-efficient, decreases the risk of lost paperwork, and can reduce risk of data replication as there is only one modifiable file, which means the file is more likely up to date. Due to the digital information being searchable and in a single file, EMRs (electronic medical records) are more effective when extracting medical data to examine possible trends and long-term changes in a

patient. The widespread adoption of EHRs and EMRs may also facilitate population-based studies of medical records.

Patient access to electronic health records

Providing patients with information is central to patient-centered health care and has been shown to positively affect health outcomes. Providing patients access to their health records, including medical histories and test results via an EHR, is a legal right in some parts of the world.

There is evidence that patient access may help patients understand their conditions and actively involve them in their management. For example, granting people who have type 2 diabetes access to their electronic health records may help these people to reduce their blood sugar levels.

Challenges with sharing the electronic health record with patients include a risk of increased confusion or anxiety if a person does not understand or cannot contextualize the testing results. In addition, many EHRs are not designed for people of all educational levels and do not consider the needs of those with a lower level of education or those who are not fluent in the language. Accessing the EHR requires a level of proficiency with electronic devices, which adds to a disparity for those without access or for those who have a mental or physical illness that restricts their access to the electronic system.