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Development Standards and Regulations in HealthTech

From substantial cost reductions to improved patient care and monitoring, or smoother communication and data management, tech solutions are increasingly present in healthcare.

The use of tech-based solutions has been demonstrated to:

- Streamline organizational and administrative efficiency and productivity
- Provide flexible, interactive, accurate, and portable tech-based solutions
- Bridge the distance and reliability gap between patients and healthcare professionals
- Improve patient outcomes

Even though digital health represents the crossover between technology and healthcare, **it is not free from controversy**, especially when it comes to aspects such as:

- **Equity**
- **Security**
- **Data privacy**

The use of software in healthcare is a game-changing alternative

During the past two years, the COVID-19 pandemic turned digital health – and more specifically telehealth - into the backbone of medical services. Since visiting a hospital significantly increased the risk of infections (for both patients and caregivers), tech-based solutions made it possible for physicians to

Among the solutions, we can highlight:

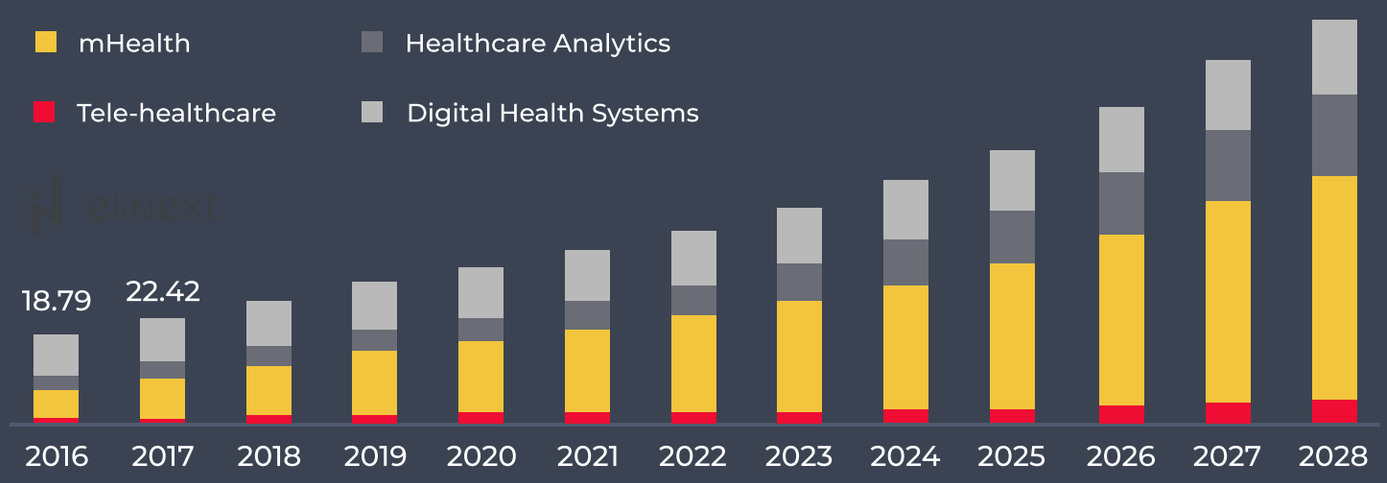
- Remote monitoring devices (e.g. IoMT, mobile apps, or wearables)
- Telemedicine software for communication provide accurate diagnosis and subsequent treatment without the necessity to have the patient visit the healthcare facility.

- Medical data management and storage software

Telehealth is not only helping to reduce the risk of infections but it also allows patients from underserviced areas or patients struggling with mobility issues to gain easier access to medical services.

The report published by **Grand View Research** clearly shows that, in 2020, the global digital health market had a value **of $96.5 billion**. According to the same report, from 2021 to 2028, the annual growth rate (CAGR) is expected to be 15.1%.

The U.S. digital health market size, by technology, 2016 - 2028 (USD billion)



Some of the most notable technological alternatives that are currently reshaping the healthcare ecosystem are:

- Robot-assisted surgery
- ML and AI algorithms for improved patient care, prevention, faster and more accurate diagnosis and decision-making, or facilitated clinical trials and drug design
- Complex analytics for enhanced organizational and management purposes
- Real-time communication platforms
- Instant access to digital health records
- Processes and tasks automation
- Personalized health apps for self-monitoring, self-education, and prevention

The impressive market growth was undoubtedly fuelled by the Covid-19 pandemic and led to an unprecedented software demand for:

- Medical devices
- mHealth apps
- Telehealth and health IT systems
- Clinical decision support
- Wearables and fitness trackers

According to Grand View Research, a study conducted in 2020 by SSCG Media Group demonstrates that the pandemic practically forced healthcare practitioners to start using telemedicine.

COVID19 digital health market impact 11.9%increase in revenue:

Pandemic Impact	Post COVID Outlook
The digital health market grew at a rate of 11% from 2019 to 2020.	In 2021 the market will witness a growth of 14.2% from 2020, owing to increasing demand and rising adoption of digital healtch solutions.
The rising adoption of telehealth services during pandemics is increasing the safety of both healthcare providers and patients, as it eliminates in-person appointments.	Consumer shift towards value-based care and rise in demand for efficient management of organizational workflows in healthcare organizations.
According to the study conducted by SSCG Media Group, in March 2020, 53% of the healthcare practitioners were using telemedecine owing to the restrictions imposed on account	The rise number of strategies undertaken by key players including mergers and acquisitions, and product developments will help sustain the growth trajectory of this

of the pandemic.

market.

Whereupon, the future of healthcare will more than likely be based on concepts such as:

- Precision
- Prediction
- Immediacy
- Streamlined communication
- Personalized approaches

It almost goes without saying that digital tools already are – and will continue to be - the fuel that feeds change and progress

Regulatory standards meant to guarantee quality and safety

We live in the era of sensitive data and cyber-crime. And data mishandling keeps being a matter of concern for patients, healthcare professionals, software providers, and governments alike. Consequently, the need for authorities such as FDA or the EU Commission to control software medical devices has led to the establishment of a set of standards and regulations meant to cover crucial aspects such as risk and quality management, software lifecycle, data protection, or software development lifecycle.

These are some of the main legal problems and standards medical software must address:

- Intellectual rights and patentability
- Data protection
- Quality control

Risk management

Usability and accessibility control

Even though we are talking about internationally recurrent issues, each country has its own regulations and standards when it comes to digital technology, medical devices, or personal data treatment.

If you are a medical software developer and you intend to target a specific market, make sure to check all the regulations in place.

Regulatory requirements and standards in the EU market

Before we take a look at the main European regulatory systems, it is important to make a clear distinction between the **two main types of software** that are currently used in healthcare:

Software for general purposes

(for instance, software used to store and manage patient data).

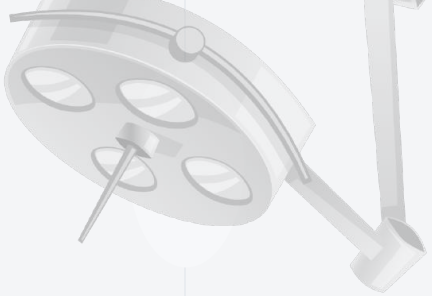
Special software

used, for example, for diagnosis, monitoring, or prediction, thus qualifying as either IVD (i.e. In vitro diagnostic medical device) or MD (i.e. Medical Device). Under European regulations, this latter type of software is referred to as Medical Device Software (MDSW).

In Europe, **MDCG 2019-11** defines MDSW as:

Medical Device Software (MDSW) is software that is intended to be used, alone or in combination, for a purpose as specified in the definition of a “medical device” in the medical devices regulation or in vitro diagnostic medical devices regulation.

In order for the software to be considered a medical device, manufacturers should make sure that their product not only qualifies as an MD or IVD but also identify the class of their MDSW and comply with the specific requirements in the **EU Regulation 2017/745 (MDR)** or the **EU Regulation 2017/746 (IVDR).**



Decision steps to assist qualification of Medical Device Software (MDSW)

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Is your software a Medical Device Software?

1 Is the product a 'Software' according to the definition of MDCG 2019-11?

- YES → **2**
- NO → **NOT COVERED BY MDCG 2019-11**

2 Is the software an 'MDR Annex XVI device', an 'Accessory' for a medical device according to Art. 2(2) of the MDR or IVDR or 'software driving or influencing the use of a (hardware) medical device'?

- YES → **1**
- NO → **3**

3 Is the software performing an action on data different from storage, archival, communication or simple search?

- YES → **4**
- NO → **1**

4 Is the action for the benefit of invidual patients?

- YES → **5**
- NO → **1**

5 Is the software a Medical Device Software (MDSW) according to the definition of MDCG 2019-11?

- YES → **COVERED BY THE MEDICAL DEVICES REGULATIONS***
- NO → **1**

NOT COVERED BY THE MEDICAL DEVICES REGULATIONS*

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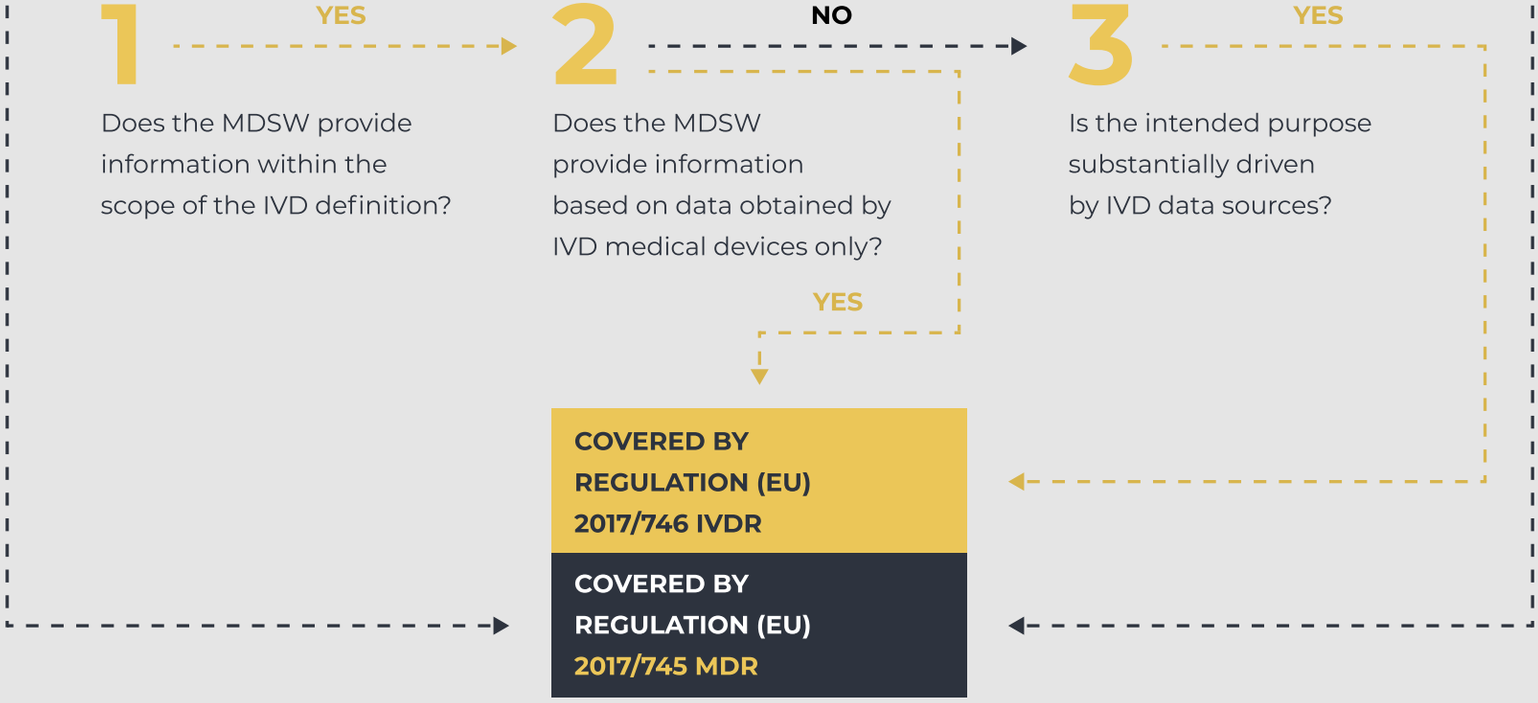
Is your MDSW an In Vitro Diagnostic Medical Device Software (IVD MDSW) or a Medical Device Software (MD MDSW)

NO

NO



If you intend to target the European medical software field, make sure to take a closer look at the following standards:

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Medical devices

- **ISO 13485**
  Quality management system
- **IEC 62366**
  Application of usability engineering to medical devices

Health informatics

- **ISO TS 25238**
  Classification of safety risks from health software
- **ISO 14971**
  Application of risk management to medical devices

Medical device software

- **IEC 62304**
  Software life cycle processes

Regulatory requirements and standards in the U.S. market

In the U.S., the regulatory system is set by the FDA (alongside other key regulators such as the FCC or the ONC) and covers areas such as patient care, HIPPA privacy and security rules, or OSHA. Healthcare software developers who wish to target the U.S. market must make sure to comply with two major regulatory systems: FDA and HIPAA.

Data security in healthcare has become a major global concern. Among the most common Protected Health Information (PHI) violations we can highlight deficient in place protection and unauthorized disclosure of patient records, disclosing PHI to third parties, or patients unable to access their records.

To obtain the HIPAA Compliance Certificate, as amended by the HITECH Act, software developers need not only to protect patients' medical records but also **sensitive personal information** such as:

- Phone and numbers
- Names, addresses, dates
- Account, certificate, and health plan numbers
- Device and vehicle identifiers and serial numbers
- Internet protocol addresses, URLs, and website links
- Full face photographic images and biometric identities

This is a quick guide toward the development of HIPAA compliant software:

Acess Control

- Define roles and responsibilities
- Allocate access to data according to roles

Session Time Handling

- Define session times for users
- Automatically logout if system is not being used

Data Protection and Encryption

- Protect data using encryption techniques

Secure Authentication

- Multi-factor authentication
- Strong password requirements

Protect Data

- Encrypted communication

Data Backup

- Data reliable storage service

FDA distinguishes between two device software functions:

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1

SaMD

(Software as a Medical Device)

SaMD can be defined as medical software designed to perform one or several medical functions by itself, without the need for hardware.

For example, software qualifies as SaMD if:

- it is used to determine a patient's drug dose according to the patient's data

In this case, the risks are connected to patients.

2

SiMD

(Software in a Medical Device)

SiMD is the software designed to power the mechanics of medical devices or processes the data these medical devices produce.

For example, software qualifies as SiMD if:

- it is used to operate a pacemaker or an X-Ray machine

In the case of SiMDs, risks are related to device hardware.

Before introducing a SaMD product in the U.S., software developers need to apply for clearance with the FDA and must ensure compliance not only with **Title 21 of the Code of Federal Regulations** (more specifically with 21 CFR Part 11, Electronic Records, Electronic Signatures and 21 CFR Part 820 Quality System Regulation) but also **with internationally accepted standards such as:**

- **ISO 14971:2019**
  Application of risk management to medical devices
- **ISO 13485**
  Quality Management System (QMS)
- **IEC 62304**
  Software life cycle processes

In order to ensure transparency and prevent fraud and abuse, medical devices must comply with a series of laws and regulations that includes the **Anti-Kickback Statute, the Stark Law, and the False Claims Act.**

Wrap up

Digital health is a relatively new concept that has been substantially redesigning the healthcare ecosystem over the past few years.

Given the continued growth of tech-based medical solutions, the regulatory system is still adapting as national and international regulatory entities strive to keep up with innovation.

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