

Digital Health and Clinical Trials

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Table of Contents

1. Digital Health brief details
2. Regulatory Focus on Digital Health
3. Why Digital Health is beneficial to clinical trials
4. 4 Key Digital Health technologies that are transforming clinical trials
5. Future of digital technologies in clinical trials
6. Emerging Market and ongoing business across the world.
7. References

Digital Health brief details

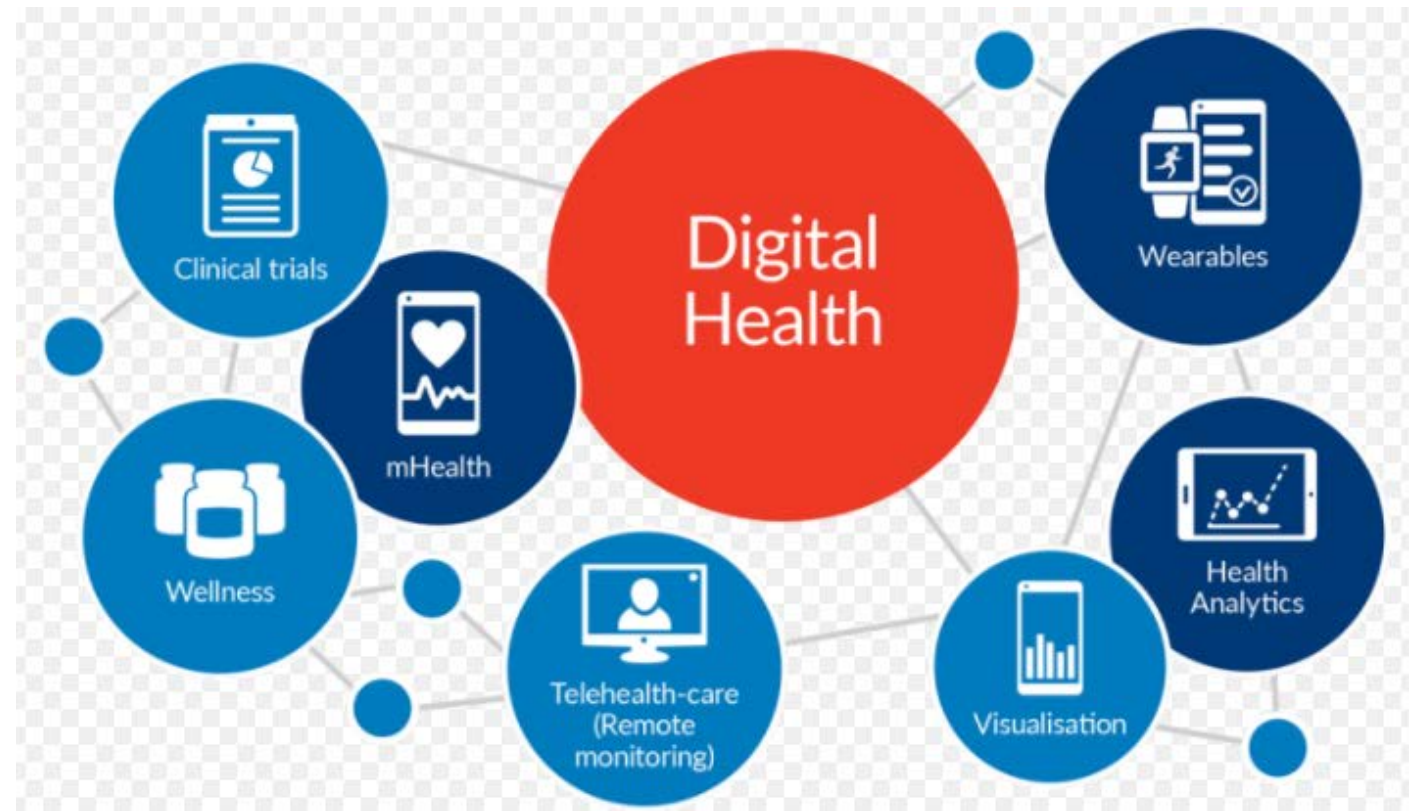
What is Digital Health?

- ✓ **Digital health** is the convergence of the digital and genomic revolutions with health, healthcare, living and society.
- ✓ The discipline involves the use of information and communication technologies which includes both hardware and software solutions and services, including telemedicine, web-based analysis, email, mobile phones and applications, text messages, and clinic or remote monitoring sensors etc., to help address the health problems and challenges faced by patients.
- ✓ Digital health is a multi-disciplinary domain which involves many stakeholders, including clinicians, researchers and scientists with a wide range of expertise in healthcare, engineering, social, sciences, public health, health economics and management.

Digital Health brief details

How it empowers and helps?

- ✓ As we are seeing and experiencing, digital health is **empowering** us to better track, manage, and improve our own and our family's health, live better, more productive lives, and improve society.
- ✓ It helps to reduce inefficiencies in healthcare delivery, improve access, reduce costs, increase quality and make medicine more personalize and precise.



Regulatory Focus on Digital Health

Why is the FDA focusing on 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 or cleared are being updated to add digital features. New types of devices that already have these capabilities are being explored and many stakeholders are involved in digital health activities.
- ✓ Many medical devices now have the ability to connect to and communicate with other devices or systems. Regulatory is excited about these advances and the convergence of medical devices with connectivity and consumer technology.



Regulatory Focus on Digital Health

What is the FDA focusing on Digital Health?

- ✓ 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:
 - Wireless Medical Devices
 - Mobile medical apps
 - Health IT
 - Telemedicine
 - Medical Device Data Systems
 - Medical device Interoperability
 - Software as a Medical Device (SaMD)
 - General Wellness
 - Cybersecurity

Regulatory Focus on Digital Health

How is FDA advancing Digital Health?

- ✓ CDRH has established the Digital Health Program which seeks to better protect and promote public health and provide continued regulatory clarity by:
 - Fostering collaborations and enhancing outreach to digital health customers, and
 - Developing and implementing regulatory strategies and policies for digital health technologies.



Digital Health and Clinical Trials

Why Digital health is beneficial to clinical trials?

The emergence of new digital health technologies will hopefully add value to the overall discovery process of new drugs which takes enormous amount of time and resources in order to generate good evidence to prove that they are safe and that it works.

- ✓ Time is always the essence.
- ✓ Digital health for clinical trials have a direct correlation with increased convenience and decreased costs.
- ✓ Researchers are continuously looking for new solution to help improve patient's well-being and ultimate aim is to save lives.

Digital Health and Clinical Trials

4 key digital health technologies that are transforming clinical trials

- ✓ For clinical trials, the road to results is often long and tedious – not to mention costly and resource intensive.
- ✓ Four digital health technologies are now poised to enhance and streamline the clinical trial process. Whether enabling more comprehensive monitoring, increasing the frequency of data collection, or growing the pool of potential participants, digital tools can help researchers reduce costs while improving efficiency and outcomes

1. Wearable fitness devices
2. Clinical devices
3. Sensors
4. Applications





Digital Health and Clinical Trials

4 key digital health technologies that are transforming clinical trials

1. Wearable fitness devices

“Wearables” are small electronic devices that are light enough to be worn or carried. Through sophisticated technology (multi-axis accelerometers), they monitor things like steps, active minutes, heart rate, sleep and so on. In the near future, they will also provide measures and insights for stress levels and blood pressure.

There are two types of wearables found in clinical trials – consumer-grade and clinical-grade

- ✓ Tech companies such as Google, Samsung and Apple are creating wearable devices that patients wear, and allow data to be captured in real time and then used in clinical trial research. e.g. remote cardiac monitoring services. Google for example, recently unveiled a new wearable that can measure a wearer’s pulse, heartbeat rhythm, skin temperature as well as light exposure and noise levels.
- ✓ Wearable devices would provide additional amounts of reliable and interpretable data which could lead to precision medicine.



Digital Health and Clinical Trials

4 key digital health technologies that are transforming clinical trials

2. Clinical Devices

Clinical devices collect data and are used to diagnosis diseases or monitor conditions. Common examples include blood pressure cuffs, glucose meters, sleep devices, spirometers and weight scales. Clinical devices are widely accepted by regulators because they are able to provide accurate and defensible information – most devices are Class II and follow the FDA 510(k) pathway.

In recent years, digital technologies have emerged that build on the functionality of well-established clinical devices, resulting in tools that retain the ability to gather regulatory-grade data but are more convenient.



Digital Health and Clinical Trials

4 key digital health technologies that are transforming clinical trials

3. Sensors

Sensors detect and measure physical properties and record or respond to the input. Although sensors are found in wearable devices, they also play a larger role in health technology. In fact, sensors are currently being used to measure a variety of physical properties that were previously difficult or impossible to track.

e.g. smart medication bottles, which tells researchers if a patient took medication and when that occurred, allowing them to better understand a patients' adherence to treatment protocols. This can more accurately highlight whether variations in test results stem from lack of compliance by the test subject.



Digital Health and Clinical Trials

4 key digital health technologies that are transforming clinical trials

4. Applications

Designed to run on mobile devices, such as smartphones and tablets, software applications are helping patients better manage their health by tracking a plethora of factors, including heart rate, sleep, fertility, physical activity, weight and even certain disease symptoms.

There are two ways in which researchers use mobile applications in clinical trials.

- ✓ First, pharma companies are leveraging companion apps, which are designed to be paired with medications.
- ✓ Second, sponsors and CRO are using mobile applications to recruit trial participants and monitor them remotely.

Digital Health and Clinical Trials

Future of digital technology in clinical trials

✓ The Digital technology vision 5 trends that proves winning in the digital age pivots on people.

1. Automation
2. Work force
3. Platform Economy
4. Predictable disruptions
5. Secured Digital platform

Digital Health and Clinical Trials

Emerging markets, ongoing business and future across the world

- ✓ Investment trends in digital health are shifting from consumer wellness applications to clinically driven solutions that drive better health outcomes at lower costs.
- ✓ This next wave of financing focuses on encouraging consumers and patients to change health-related behaviors, underscoring the greater opportunities for companies with solutions that create value for payers, providers, employers and consumers.

Reference:- Digital Health report

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Digital Health and Clinical Trials

Useful links and References

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Information for further communication

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