Disclaimer

• The opinions and views expressed are my own and do not represent those of my current or former employers

• Any mention of companies or products does not represent an endorsement
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• Physician-scientist
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Vital signs and health parameters digital health technologies can directly provide patients with

<table>
<thead>
<tr>
<th>Parameter/data it provides</th>
<th>Name of the service(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>One channel ECG</td>
<td>Kardia*</td>
</tr>
<tr>
<td>One channel ECG, oxygen saturation, body temperature, heart rate</td>
<td>Viatom Checkme Pro*</td>
</tr>
<tr>
<td>Multi-channel ECG</td>
<td>ECG Dongle</td>
</tr>
<tr>
<td>Daily physical activities, heart rate</td>
<td>Fitbit, Garmin, Polar</td>
</tr>
<tr>
<td>Genetic risks for certain medical conditions</td>
<td>23andMe, Futura Genetics</td>
</tr>
<tr>
<td>Microbiome</td>
<td>uBiome</td>
</tr>
<tr>
<td>Cardiac and lung sounds</td>
<td>EKO*, CliniCloud</td>
</tr>
<tr>
<td>Sleep quality</td>
<td>Live by EarlySense, Viatom O₂, Beddit</td>
</tr>
<tr>
<td>Stress</td>
<td>PIP</td>
</tr>
<tr>
<td>EEG</td>
<td>MindWave, Muse</td>
</tr>
<tr>
<td>Muscle activity</td>
<td>Gymwatch</td>
</tr>
<tr>
<td>Blood glucose</td>
<td>Medtronic*</td>
</tr>
</tbody>
</table>

*, indicates if the device is approved by the Food and Drug Administration (FDA).

What is Digital Health?

• 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 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.

FDA’s Focus in Digital Health

- These are digital health topics 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

FDA’s Digital Health Center of Excellence

• **Our goal:** Empower stakeholders to advance health care by fostering responsible and high-quality digital health innovation.

• **Our objectives:**
  
  • **To connect and build partnerships** to accelerate digital health advancements.
  
  • **To share knowledge** to increase awareness and understanding, drive synergy, and advance best practices.

  • **To innovate regulatory approaches** to provide efficient and least burdensome oversight while meeting the FDA standards for safe and effective products

[Link to FDA Digital Health Center](https://www.fda.gov/medical-devices/digital-health-center-excellence)
Digital Health Stakeholders

- The same individuals that practice traditional medicine
- Patients are the stakeholders at the center of digital medicine
- Critically important role of caregivers
- Clinical care providers
- Physician-scientists
- Healthcare researchers
- Regulators and payers
- Ethicists

- Developers of traditional, non-software medical products (biopharma and medical device companies)
- Experts in the emerging field of digital therapeutics
- Data scientists
- Cyber-security experts
- Engineers (hardware and software)
- Funders

Benefits of Digital Health Technologies

- Opportunity to improve medical access and outcomes, reduce inefficiencies and costs, increase quality and make medicine more personalized for patients
- Providers have a more holistic view of patient health through access to data
- Patients have more control over their health
- Patients and consumers can better manage and track their health and wellness
- 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

Digital Health Results in a Cultural Transformation

The differences between traditional and modern healthcare following the digital health transformation

<table>
<thead>
<tr>
<th>Traditional medicine</th>
<th>Modern medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Point-of-care is the clinic or lab</td>
<td>Point-of-care is the patient</td>
</tr>
<tr>
<td>Based on populations</td>
<td>Based on the individual</td>
</tr>
<tr>
<td>Hierarchy</td>
<td>Partnership</td>
</tr>
<tr>
<td>Prescriptions and orders</td>
<td>Collaboration</td>
</tr>
<tr>
<td>Data owned by institutions</td>
<td>Data owned and shared by the patient</td>
</tr>
<tr>
<td>Individual experience dominates</td>
<td>Limitless data analyses</td>
</tr>
<tr>
<td>Physicians as authority</td>
<td>Physicians as guides</td>
</tr>
<tr>
<td>Ivory tower</td>
<td>Social media</td>
</tr>
<tr>
<td>Expensive</td>
<td>Costs driven down by Moore's law</td>
</tr>
</tbody>
</table>

Comparison of traditional and digital health based medical practices


FAU CMBB Lecture Series – Spring 2021
Raul Perez-Olle, MD, PhD
Unprecedented Ethical Considerations & Challenges

• Misinterpreted information can lead to dangerous medical decisions if medical professionals are not involved as expert partners in the process.

• With devices that make data accessible to both stakeholders and patients, unauthorized third parties might acquire sensitive information about patients’ health.

• Laws, such as the Genetic Non-Discrimination Act in the United States, are expected to defend patients from their employers and/or insurers gathering data from their direct-to-consumer genetic testing results.

• Need more emphasis on validation of health sensors, other digital health devices and smartphone applications to provide quality, reliable information to users.

• Digital health literacy has a wider aspect than the notion of classic health literacy, as it adds the requirement to be technically literate.

Digital Health, Medicine or Therapeutics?

• **Digital Health** is a broad category that encompasses **Digital Medicine**, which in turn includes **Digital Therapeutics**

• Products in these categories make different levels of claims and therefore have different levels of risk

• Thus they have varying requirements:
  - Clinical evidence
  - Regulatory oversight

Collaborative Risk-Based Framework

• Help end users discern between products of different risk and corresponding levels of necessary evidence and regulatory oversight

• The Digital Medicine Society (DiMe) is a Massachusetts non-profit and professional society for individuals from all backgrounds working to advance digital medicine to optimize human health

• The Digital Therapeutics Alliance (DTA) is a non-profit trade association with the mission of broadening the understanding and integration of clinically-evaluated digital therapeutics into healthcare to improve clinical and health economic outcomes

• HealthXL is the market intelligence platform and expert community for digital health

• NODE.Health is a 501(c)(3) non-profit organization dedicated to education, validation and dissemination of evidence based digital medicine

## Digital Health vs. Digital Medicine vs. Digital Therapeutics

<table>
<thead>
<tr>
<th></th>
<th>Digital Health</th>
<th>Digital Medicine</th>
<th>Digital Therapeutics</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>Digital health includes technologies, platforms, and systems that engage</td>
<td>Digital medicine includes evidence-based software and/or hardware products that</td>
<td>Digital therapeutic (DTx) products deliver evidence-based therapeutic interventions to</td>
</tr>
<tr>
<td></td>
<td>consumers for lifestyle, wellness, and health-related purposes: capture,</td>
<td>measure and/or intervene in the service of health.¹</td>
<td>prevent, manage, or treat a medical disorder or disease.²</td>
</tr>
<tr>
<td></td>
<td>store or transmit health data; and/or support life science and clinical</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>operations.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Clinical Evidence</strong></td>
<td>Typically do not require clinical evidence.</td>
<td>Clinical evidence is required for all digital medicine products.</td>
<td>Clinical evidence and real world outcomes are required for all DTx products.</td>
</tr>
<tr>
<td><strong>Regulatory Oversight</strong></td>
<td>These products do not meet the regulatory</td>
<td>Requirements for regulatory oversight vary.</td>
<td>DTx products must be reviewed and cleared or certified by regulatory bodies as</td>
</tr>
<tr>
<td></td>
<td>definition of a medical device² and do not require regulatory oversight.</td>
<td>Digital medicine products that are classified as medical devices require</td>
<td>required to support product claims of risk, efficacy, and intended use.</td>
</tr>
</tbody>
</table>

² [https://www.dtxalliance.org/dtxproducts/](https://www.dtxalliance.org/dtxproducts/)
³ It is important to check with local regulatory requirements in each jurisdiction the product is manufactured, registered, or used in.

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## Product Examples

### Digital Health
- Data & information capture, storage, and display
  - User-facing technologies
  - Health Information Technology (HIT)\(^1\)
  - Consumer health information
  - Data & information transmission
    - Telehealth
    - Decision support software\(^*\)
    - Enterprise support
    - Clinical care administration & management tools

### Digital Medicine
- Measurement products
  - Digital diagnostics
  - Digital biomarkers
  - Electronic clinical outcome assessments
  - Remote patient monitoring
  - Decision support software\(^*\)
- Measurement & intervention products
  - Digital companion\(^2\)
  - Digital products that both 1) measure and intervene, and 2) do not require human intervention to serve primary purpose

### Digital Therapeutics
- Software that delivers a therapeutic intervention
  - Medical claims include:
    - Treat a disease
    - Digital therapeutics that deliver a medical intervention to treat a disease.
    - Manage a disease
    - Digital therapeutics that deliver a medical intervention to manage a disease.
    - Improve a health function
    - Digital therapeutics that deliver a medical intervention to improve a health function and/or prevent a disease.

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*See full categorization chart for details

\(^1\) In the United States, ONC-certified EHR functions are not devices according to the FD&C Act, as amended by 21st Century Cures Act

\(^2\) Note: 1) integration of the digital tool with an existing drug or biologic requires a label change for the drug or biologic, and 2) regulatory requirements may recognize digital tools coupled with a drug or biologic as a combination product

About Rock Health

• The first venture fund dedicated to digital health
• It defines digital health as the intersection of healthcare and technology
  ▪ They track venture funding only for technology-enabled health-related companies, focused on:
    o Administration of healthcare
    o Delivery of healthcare
    o Process of bringing breakthrough new healthcare products to market (R&D and commercialization)

https://rockhealth.com/
Digital Health VC Funding Beat Records 2020

- There were more deals closed and digital health companies raised more per deal

Adoption of Digital Health Tools

- The 2020 survey data suggest that consumers more than ever expect technology to be an integral part of their healthcare experience.
- With a national pandemic and stay-at-home orders, consumer adoption rates grew significantly from 2019 to 2020 (approx. 10%) across live video telemedicine, wearable ownership, and digital health metric tracking.
- The rate of change in adoption differed by technology and by subgroup.
- Telemedicine adoption (across all mediums—video, text, phone, etc.), for example, remained highest among subgroups which were (in prior years) already the likeliest adopters.

Willingness to Share Health Data

- Consumer willingness to share their health data depends on whom they are sharing it with.
- Most willing to share their health data with their doctor (72%), health insurer (53%), and family (52%).
- Respondents’ comfort in sharing COVID-19 data followed that of health data generally.

[Image of chart showing willingness to share health data]

Making Recent Digital Health Gains Last

• Growth in digital health adoption had stalled before COVID-19

- Global pandemic greatly accelerated adoption of virtual health, but will it persist?
  - Virtual healthcare services became a necessity
  - Unprecedented opportunity for healthcare providers and payers to permanently shift the default care model to virtual services for many medical needs
  - From forced to voluntary digital health adoption

- Amid the pandemic, consumers with nowhere else to turn were forced to lower their expectations for the quality of digital health experiences
- There are several factors that could drive or stall post-pandemic progress


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Raul Perez-Olle, MD, PhD
Digital Health and the Future of Medicine 20
Providers Need to Enable Digital Health

- Consumers look to providers for motivation to manage their health
  - 23% of healthcare consumers say reliable and secure digital tools that help them to understand their health habits would motivate them to take a more active role in managing their health
  - 55% said “trusted healthcare professionals” would motivate them to take a more active role in managing their health
  - Only 11% said that their healthcare providers recommended use of digital tools for patient health management
- Doctors are key to promoting digital engagement and awareness

Lackluster Digital Options Can Taint the Overall Patient Experience

- 52% of consumers who have a primary care physician agreed that a bad digital experience with a provider ruins the entire experience with the provider, compared to 42% of those without a PCP.

Concerns About Privacy/Security will Resurface

- Need for social distancing and lack of other options for medical consultations outweighed privacy and security fears, but these issues did not disappear.

- Trust in doctors to keep their digital health information secure dropped (89% in 2019 vs. 83% in 2020).

- Similar observation regarding trust in tech companies (55% consumers do not trust them).

Trust in hospitals and doctors to keep digital healthcare information secure is high, but drops significantly for tech companies and government:

- 84% Hospitals I visit
- 83% My doctor(s) or other healthcare providers
- 82% My pharmacy
- 80% Labs that process my medical tests
- 75% My health insurance company
- 74% Urgent care or walk-in retail clinics I visit
- 63% Non-medical staff at my doctor’s or healthcare provider’s office
- 45% Tech companies
- 38% Government

Q: Overall, how much do you trust each of the following people or organizations to keep your digital healthcare information (including electronic medical records and other information) secure? “Very much” and “Some” responses.

Making Recent Digital Health Gains Last

• Consumers are interested in comprehensive virtual care:
  ▪ Before the pandemic urgency drove adoption, consumers already showed strong interest in a wide variety of virtual health services
  ▪ Younger generations even prefer virtual over in-person care in some cases, when given the choice

• Consumers want a variety of virtual health services:
  ▪ Many healthcare consumers would choose virtual for basic care services, and even for specialty care
  ▪ 62% of consumers would choose virtual for health and wellness advisories
  ▪ 57% of consumers are open to remote monitoring of ongoing health issues through at-home devices

• Virtual care from new and traditional providers:
  ▪ 54% of healthcare consumers are open to receiving virtual healthcare services from their traditional providers
  ▪ Also willing to receive virtual care from technology or social media companies such as Google and Microsoft (27%), retail brands such as Best Buy, Walmart and Amazon (25%) and medical startups (21%)

The Future of Healthcare

A New World Order will Emerge

• Digitally-enabled business models will shift the balance of power within sectors and across the industry’s value chain

• Healthcare incumbents (providers, payers, pharmacies, pharma, medical device, healthcare IT, and channel players like PBMs) will also face different kinds of competition from disruptors:
  ▪ Startups
  ▪ Big tech
  ▪ Big box retailers (Amazon, Apple, Walmart, Best Buy, and Walgreens)

Platform Wars are Raging

• The question is not if but when platforms will win dominance in healthcare
• Data generated by digitally-enabled healthcare platforms open opportunities to improve outcomes, lower costs, and build truly consumer-centric patient experiences:
  ▪ Care Management platforms go deep in a specific condition(s)
  ▪ Convenience care platforms provide one-stop access to treatment and medication for a range of common conditions
  ▪ Unified virtual care platforms pull together primary care telemedicine with condition management
  ▪ Omnichannel retail health platforms such as Best Buy, CVS, and Walgreens leverage their retail expertise to provide a set of primary care, diagnostics, testing, and remote monitoring services
  ▪ Integrated digital and physical care platforms combine telemedicine with brick and mortar providers, such as Ochsner’s partnership with Hims
  ▪ Tech infrastructure platforms such as AWS, Google Cloud, Salesforce, and Microsoft Azure that healthcare companies plug into to support information management and virtual care

https://rockhealth.com/reports/digital-healths-platform-wars-are-heating-up/
The Science of Medicine is Going Digital

• Last decade was about the digitization of existing processes, and this will be the decade of digital transformation in the science of medicine
  ▪ Drug discovery
  ▪ Decentralized clinical trials
  ▪ Real world evidence
  ▪ Digital therapeutics

• For patients this trend means access to better therapeutics sooner and at lower cost

• For current owners of therapy pipelines it means entirely new asset classes, capabilities, IP strategies, and worldviews reflecting the agility to compete in a digital landscape

Patient Experience will Become Table Stakes*

- Rock Health’s 2019 Consumer Adoption Survey:
  - 76% of US consumers went online to learn about their health and care
  - 64% searched for provider reviews online
  - 60% brought information they found online into conversations with their providers

- Organizations that embrace the full measure of how consumers are shopping, and reshape themselves in the form of how patients want to receive care, will earn trust and business

- Patient access to the healthcare system itself will be personalized in the future

* “Table stakes” are the minimum offering it takes to be considered a player in the market (https://brandmarketingblog.com/articles/branding-definitions/table-stakes-business/)

Digital will be the Great Equalizer

• Individuals want and deserve healthcare that addresses their individual needs

• Digital technology has the potential to deliver more personalized health experiences than the brick and mortar world has previously allowed

• The “worried well” (young, wealthy, and healthy consumers) have been the beachhead market for many digital health companies

• More recently digital health companies have emerged to meet previously untapped demand from underserved populations

The End of “Digital Health” is Near

- You don’t hear anyone talking about “internet companies” anymore. These days every company has a website, but they compete on differentiators such as consumer experience or brand trust. Despite its customary lag in all things digital, healthcare is now catching up with the rest of the economy. The future of healthcare is digitally enabled, and leaders in that future will act early with purpose, agility, and investment in innovation. Ten years from now there will be no such thing as digital health, because all healthcare will be digitally enabled.

Thank you!

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