The Role of Digital Monitoring in Shaping Clinical Care

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Why Wearables?
Ever-expanding options for biosignal measurement

Dunn et al. Personalized Medicine, 2018
https://pratt.duke.edu/about/news/print-in-place-electronics
https://news.mit.edu/2020/sensors-monitor-vital-signs-0423
Uses of Biomarkers

Diagnostic capabilities
- Intermediate markers of disease
- Track treatment progress

Learn new physiology
- Uncover mechanism behind phenotypes & biological function
- Putative drug targets
What is a Digital Biomarker?

Digital biomarkers are *digitally collected data* (e.g. ECG from a vital sign monitor) that are *transformed into indicators of health outcomes* (e.g. AFib)
What is a Digital Biomarker?

Target Outcomes

- Clinical measurements
- Survey data
- Illness events

\[ f\left( \text{Measurements} \right) \]

- Heart rate
- Skin Temperature
- Skin Conductance
- Accelerometry
- Location

Figure 1. Digitally collected data becomes a Digital Biomarker when a relationship can be established to a target outcome.
The Digital Biomarker Discovery Pipeline (DBDP) provides open source code, algorithms, data and resources to make discovering digital biomarkers more accessible and establish best practices for the field.
Challenges in Digital Health

- Sensor Accuracy and Validation
- Black-box Approaches
- Interoperability and Standards
- Data Deluge
- Security
- Bias & inequities
How do we evaluate Digital Biomarkers?

• What does “clinically-validated” mean?

• Biosensors and Digital Biomarkers lack a systematic, evidence-based evaluation framework.

• **Verification** and **validation** processes are critical to support a technology as *fit-for-purpose*.
  
  • Validation is divided into **analytical** and **clinical**
Modular Evaluation of Digital Measures

Evaluates and demonstrates the performance of a sensor technology within a BioMeT, and the sample-level data it generates, against a pre-specified set of criteria.

Evaluates the performance of the algorithm, and the ability of this component of the BioMeT to measure, detect, or predict physiological or behavioral metrics.

Evaluates whether a BioMeT acceptably identifies, measures, or predicts a meaningful clinical, biological, physical, functional state, or experience, in the stated context of use (which includes a specified population).

Goldsack et al. NPJ Digital Medicine, 2020
The same device can be both FDA-regulated and \textit{not} FDA regulated at the same time.

Afib detection

FDA-cleared

SpO\textsubscript{2} functionality

Not FDA-regulated

https://www.theverge.com/2020/10/7/21504023/apple-watch-ekg-blood-oxygen-fda-clearance

Duke

Bent, Dunn. \textit{JMIR mHealth & uHealth}, 2021.

Rosman et al. \textit{Cardiovasc Digit Health J}. 2020
Regulators and community stakeholders are working together to improve policy

Center for Digital Health Excellence

Network of Digital Health Experts (NoDEX)
“Living” Guidebook to the Implementation of Digital Endpoints in Clinical Trials

NOW LIVE!

The Playbook: Digital Clinical Measures

Introducing the essential industry guide for successfully developing & deploying digital clinical measures across clinical research, clinical care, and public health.

Available at playbook.dimesociety.org
Digital Clinical Measures Playbook

*The Playbook* will walk you through the foundational processes for successful remote monitoring

**Measures**
1. Determine the [meaningful aspect of health](#) (MAH)
2. Identify the [concept of interest](#) (COI)
3. Define the [digital measure](#) (e.g., outcome/endpoint)

**Technologies**
- Evaluate the [risk/benefit](#) to ensure safety and efficacy (e.g., validation (V3), utility & usability, security, data rights)

**Operations**
- Plan for the [jobs to be done](#) during deployment (e.g., purchasing, distribution, monitoring, data analysis)

Opportunities for [collaboration across industry](#) include:
- Promoting a culture of [ethics](#) to ensure equality and justice
- Setting and developing [standards](#) for digital measures
- Developing [benchmarks](#) to compare digital measures (e.g., algorithms)
- Participating in the [policy and regulatory](#) process (e.g., public comments)

Available at [playbook.dimesociety.org](playbook.dimesociety.org)
How can I learn more about the devices that are out there?

Digital Health Library
A crowd sourced collection of technologies that address your health and research needs.

https://www.gohumanfirst.com/
Wearables are revolutionizing healthcare

1. Patient empowerment
2. Precision therapies
3. Just In Time Interventions
4. Improved Access to Care
Incorporating Digital Health into Clinical Workflows: The Future of Longitudinal, Remote, and Assisted Patient Monitoring

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https://dbdp.org/amia2022
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