RESEARCH CENTERS COLLABORATIVE NETWORK

The Role of Digital Monitoring in Shaping Clinical Care

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RCCN Workshop: mHealth and Digital Health Approaches to Research in Aging

November 2, 2022

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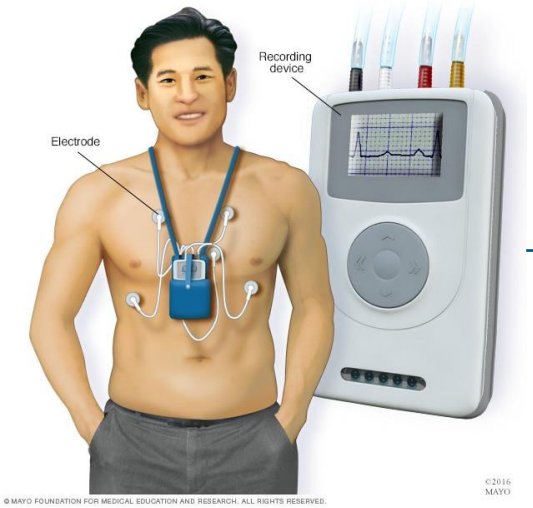
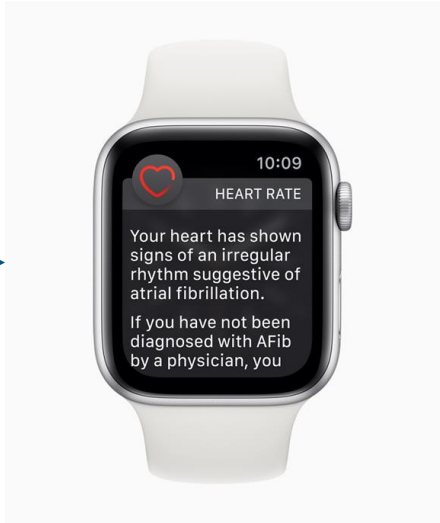
Why Wearables?





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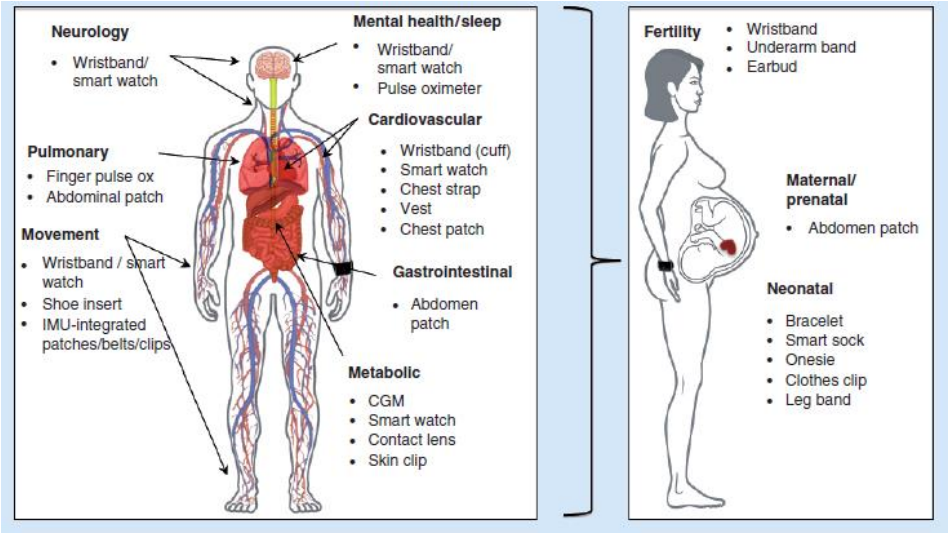
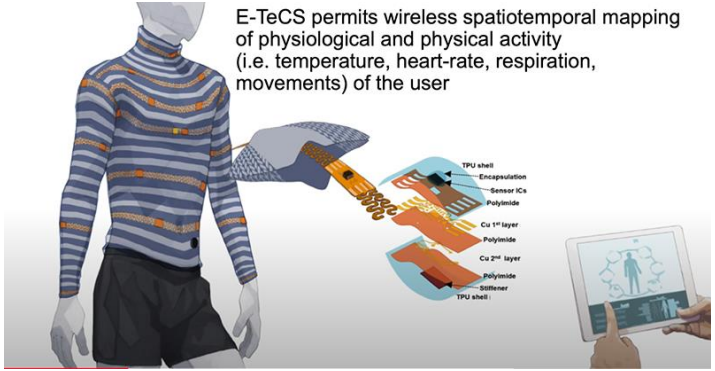
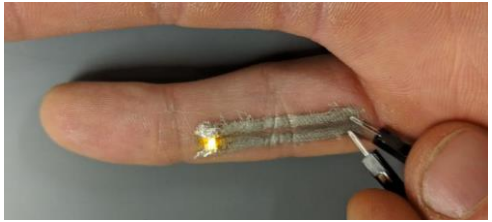
Ever-expanding options for biosignal measurement







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)

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What is a Digital Biomarker?

Target Outcomes $= f(\text{Measurements})$

- Clinical measurements
- Survey data
- Illness events

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

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.

DBDP.org

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Bent et al. JCTS, 2020.

Challenges in Digital Health

Sensor Accuracy and Validation

Black-box Approaches

Interoperability and Standards

Data Deluge

Security

Bias & inequities

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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**

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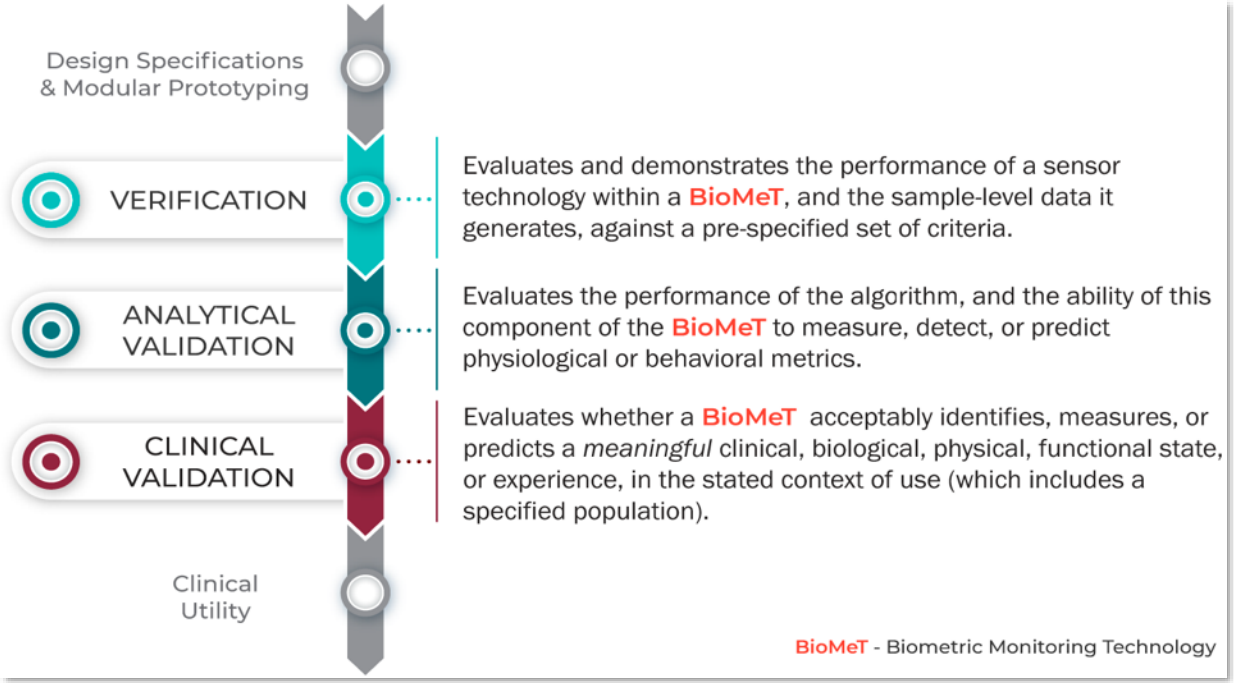
Goldsack et al. NPJ Digital Medicine, 2020

Modular Evaluation of Digital Measures



Goldsack et al. NPJ Digital Medicine, 2020

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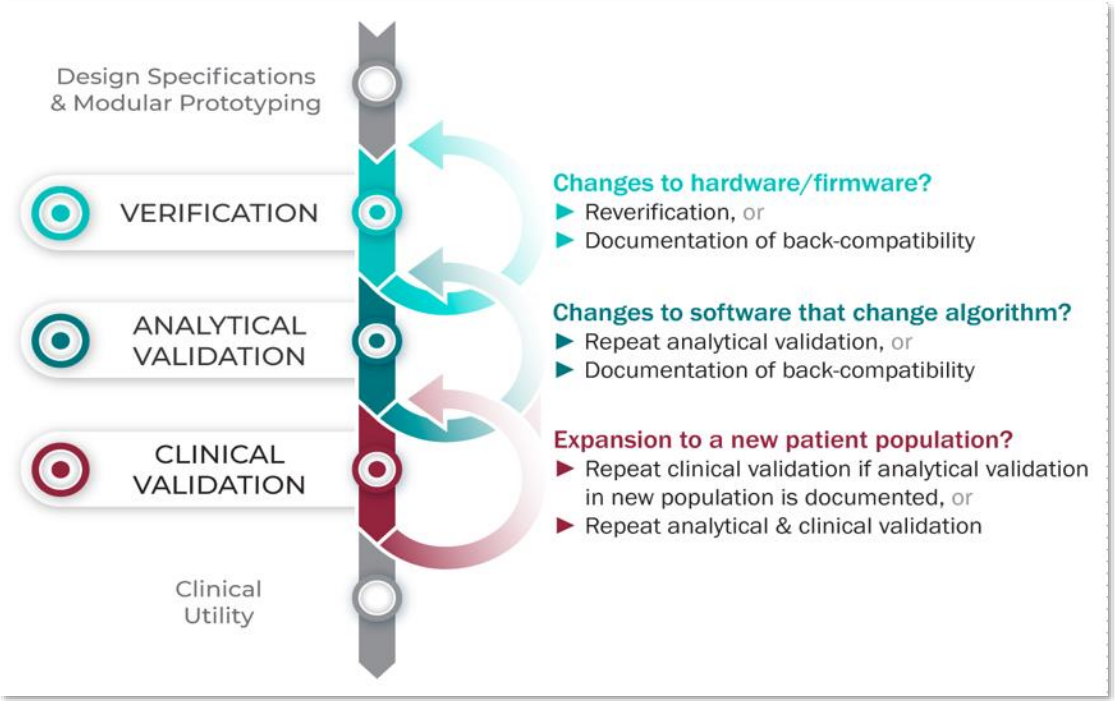
DiME

Modular Evaluation of Digital Measures



Goldsack et al. NPJ Digital Medicine, 2020

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DiME

The same device can be both FDA-regulated and *not* FDA regulated at the same time

Afib detection
FDA-cleared

SpO_2 functionality
Not FDA-regulated

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

Bent, Dunn. *JMIR mHealth & uHealth*, 2021.
Rosman et al. *Cardiovasc Digit Health J*. 2020

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Regulators and community stakeholders are working together to improve policy

Center for Digital Health Excellence

Network of Digital Health Experts (NoDEX)

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“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

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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)

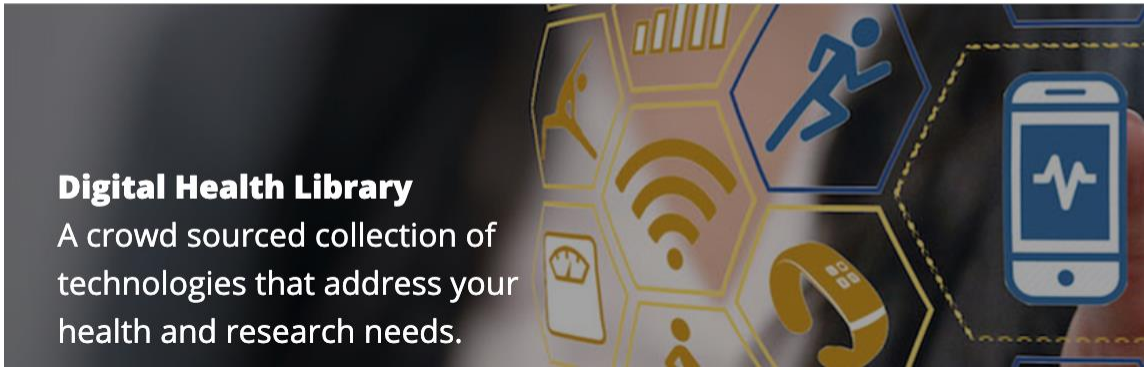
Opportunities for **collaboration across industry** include:

- Promoting a culture of **ethics** to ensure equality and justice
- Developing **benchmarks** to compare digital measures (e.g., algorithms)
- Setting and developing **standards** for digital measures
- Participating in the **policy and regulatory** process (e.g. public comments)

Available at playbook.dimesociety.org

How can I learn more about the devices that are out there?

Scripps Research
Translational Institute



HumanFirst Atlas

https://www.gohumanfirst.com/

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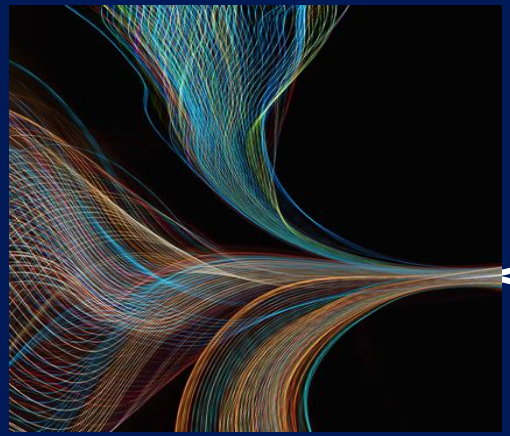
Wearables are revolutionizing healthcare



1. Patient empowerment
2. Precision therapies
3. Just In Time Interventions
4. Improved Access to Care

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AMIA
INFORMATICS PROFESSIONALS. LEADING THE WAY.

AMIA 2022 Annual Symposium

Incorporating Digital Health into Clinical Workflows:
The Future of Longitudinal, Remote, and Assisted Patient Monitoring

Md Mobashir Hasan Shandhi, PhD, Brinnae Bent, PhD, Simona Carini, MA, William Ed Hammond, PhD, Ryan J. Shaw, PhD, Ida Sim, MD, PhD, Jessilyn P. Dunn, PhD

November 5, 2022

https://dbdp.org/amia2022

Duke Open mHealth dbdp EXTEND UCSF Big Ideas Lab

Big Ideas Lab

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dbdp Digital Biomarker Discovery Pipeline