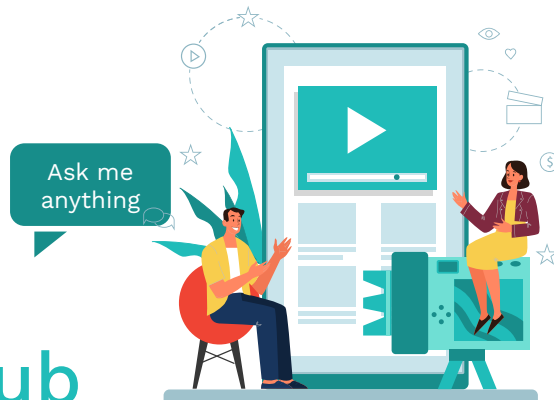


Virtual Journal club



Digital health technology derived measures: Biomarkers or clinical outcome assessments?

Thursday, August 24, 2023 11:00am ET



Elena Izmailova
CSO
Koneksa Health



Charmaine Demanuele
Executive Director, AI/ML
Digital and Quantitative
Sciences
Pfizer



Jessie Bakker
VP; Digital Measures &
Diagnostics
DiMe
Moderator

But first, housekeeping


- Please note: today's session is being recorded
- To ask a question for discussion during Q&A, please:
 - Raise your virtual-hand; the moderator will ask you to unmute yourself
 - Type your question into the chat box
- Slides and recording will be available after today's session

Why This Topic?



MINI REVIEW |  Open Access | 

Digital health technology derived measures: Biomarkers or clinical outcome assessments?

Elena S. Izmailova  Charmaine Demanuele, Marie McCarthy

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Definitions

Biomarker

- Indicator of normal biological processes, pathogenic processes, or biological responses to an exposure or intervention, including therapeutic interventions.
- May include molecular, histologic, radiographic, or physiologic characteristics.
- Not a measure of how an individual feels, functions, or survives.



Digital Health Technologies

- Uses computing platforms, connectivity, software, and sensors for healthcare and related uses.
- Wide range of uses, from applications in general wellness to applications as a medical device.
- Technologies intended for use as a medical product, in a medical product, or as an adjunct to other medical products
- May be used to develop or study medical products



Clinical Outcome Assessment

Describes or reflects how an individual

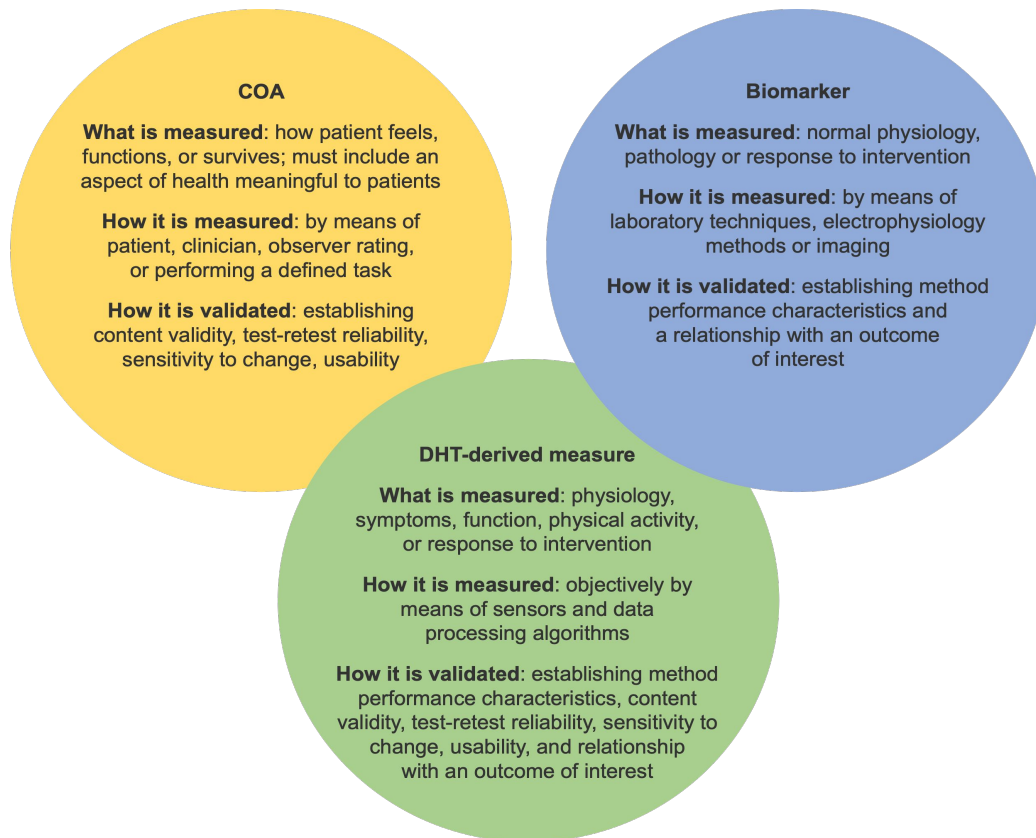
- Feels
- Functions
- Survives

Can be made through report by:

- Clinician
- Patient
- Non-clinician observer
- Performance-based assessment



Biomarker or Clinical Outcome Assessment?



What Is Confusing?



DHT-derived measures can be classified as either biomarkers or COAs

Biomarkers: blood oxygen saturation by pulse oximetry
COAs: instrumented 6-minute walk test



Example: Reduction in mobility in congestive heart failure predictive of mortality

Biomarker supporting surrogate endpoint
OR
COA assessing patient capacity



Digital measures are sometimes categorized as COAs BUT may not be feasible to establish meaningfulness to patients

Analogy: Other imaging and blood-based biomarkers are used to support surrogate endpoints and yet carry little meaning to patients



Uncertainty for drug developers on regulatory strategy

Uncertain requirements for evidentiary submission packages
Validation studies for biomarker vs COA differs



Terminology varies across geography

Challenging for global studies
Digital mobility outcome measures considered as biomarkers by EMA but COAs for FDA

Examples

➤ Finger tapping in Parkinson's disease

- Measuring variability of finger tapping to assess bradykinesia in Parkinson's disease
 - **Biomarker:** measuring variability of finger tapping to assess bradykinesia in Parkinson's disease
 - **COA:** tasking a study participant to complete a structured finger tapping exercise on the smartphone to assess hand function

➤ Nocturnal scratch in patients with clinician diagnosed atopic dermatitis

- **Biomarker:**
 - Digital biomarker measuring the change in selected disease component - scratching - as a response to therapeutic intervention
 - Used as pharmacodynamics endpoint, baseline screening tool, patient phenotyping, pathophysiology evaluation, etc.
- **COA:**
 - A digital health technology (DHT) clinical outcome assessment (COA)
 - Used as an efficacy endpoint in drug development clinical trials of new medical products, supporting label claims of new treatments

Call for Action

- ❑ **Recognize unique opportunities offered by DHTs in drug development and identify the differences of DHT-derived measures that will require adjusting existing definitions.**
- ❑ **Create definitions for DHT-derived tools and derived measures with specific examples of how these tools can be leveraged in drug development.**
- ❑ **Define specific requirements for evidentiary criteria to declare DHT-based tools to be fit for purpose according to defined categories.**



Q&A



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*Virtual First Care
V1C Initiative*

Navigating Reimbursement for Virtual First Care (V1C)

Wednesday, September 6, 2023 | 12pm-1pm ET



Abby Sugg | *Moderator*
Program Lead
Digital Medicine Society (DiMe)



Dr. Zeke Silva
Radiologist & Chair of the American
Medical Association Speciality
Relative Value Scale Update
Committee (RUC)
American Medical Association



Lucia Savage
Chief Privacy and Regulatory Officer
Omada Health



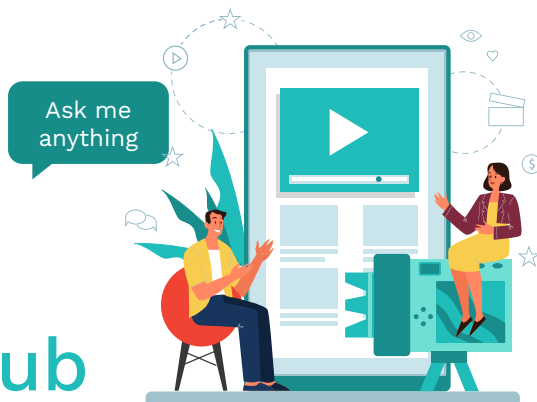
Dr. Ryan Vega
Physician in Residence
Digital Medicine Society (DiMe)



Don Jones
IMPACT Co-founder & Chair of
Cardiff Ocean Group
Digital Medicine Society (DiMe)

DiME

Virtual Journal Club



Nocturnal scratch: A study bringing patient input into development of novel digital measures

September 20, 2023, 11 am ET



Keith Meadows, PhD
Expert Researcher, Founder & CEO
Health Outcomes Insights



Stefan Avey, PhD
Principal Data Scientist
Janssen



Katelyn Keyloun, PharmD, MS
Associate Director, Patient Centered
Outcomes Research
AbbVie



Carrie Northcott, PhD
Senior Director, Digital Sciences &
Translational Imaging
Pfizer



Sylvain Zorman, PhD
Director of Digital Health Sciences
ActiGraph



Lucy Cesnakova, MS
Program Lead
DiMe



THANK YOU



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