The Digital Endpoints Webinar Series

Part I: August 2nd, 2021 at 11a ET

Hosted in partnership with:
But first, housekeeping

- Please note: today’s session is being recorded
  - Slides and recording will be available on DiMe’s webinar page after the session
- To ask a question for discussion during live Q&A, please either:
  - ‘Raise your hand’ in the Reactions and moderator will unmute you to ask your question live, or
  - Type your question into the chat box
The Digital Endpoints Webinar Series

Part I: August 2nd, 2021 at 11a ET

Hosted in partnership with:
Our purpose

DiMe is a professional society for all experts committed to advancing the **safe, effective, equitable, and ethical** use of digital medicine to optimize human health.

Source: https://www.dimesociety.org/index.php/about-us-main
Digital health captured over $40B of venture investment over the last decade

Source: https://rockhealth.com/reports/2020-market-insights-report-chasing-a-new-equilibrium/
The case for digital clinical measures

Worldwide Digital Health Market to Hit $504.4 Billion by 2025: Global Market Insights, Inc.

The U.S. digital health market accounted for largest share in 2018 supported by increasing prevalence of chronic diseases along with growing geriatric population in the country.

Source:
STAT News reports that, “Health care is undergoing a monumental shift toward remote patient monitoring”


In recent months, **3 of the 5 biggest companies** in the world announced new remote monitoring products.

- **Amazon Halo** - Health & wellness band and membership  
  *Launched August 27, 2020*

- **Google** is on track to purchase **Fitbit Sense** includes an ECG App  
  *Cleared by FDA Sept 11, 2020*

- **Apple Watch 6** includes health features such as an SpO₂ monitor  
  *Launched September 15, 2020*
Remote monitoring using connected sensors offers a *more holistic view* of a person’s lived experience.

**Visible Data Points** (episodic)

Data collected from **traditional** visits to hospitals, clinics, and sites

**Invisible Data Points** (continuous)

Data collected **remotely** from everyday life

Source: “Visible vs. Invisible Data” chart designed by Evidation Health, re-worked by Elektra Labs, Playbook team analysis | playbook.dimesociety.org
12 Sponsors have collected digital endpoints

12 Sponsors have collected digital endpoints

Sponsors start digital endpoint development early

Digital endpoints are being used across drug, device, and biologic development

Pharma trusts digital products, primary/secondary endpoints

Digital endpoints are being used across drug, device, and biologic development

12 Sponsors have collected digital endpoints

12 Sponsors have collected digital endpoints

Primary, Secondary or Label Claim

Digital Endpoints

Investigational Product

Endpoint Positioning


Digital Medicine Society / DiMe’s Crowdsourced Library of Digital Endpoints

Digital endpoints are being used across drug, device, and biologic development

Exploratory Only

Drug 47%
Device 32%
Biologic 15%
Other 6%

16 Primary endpoints
4 Secondary endpoints
14 Exploratory
34 UNIQUE ENDPOINTS
Digital endpoints library can aid clinical trials for new medicines

By JEN GOLDSACK, RACHEL A. CHASSE, and WILLIAM A. WOOD / NOVEMBER 6, 2019
62 Sponsors have collected digital endpoints

62 Sponsors have collected digital endpoints

Sponsors start digital endpoint development early

Digital Endpoints

Investigational Product

Endpoint Positioning

Digital endpoints are being used across drug, device, and biologic development

Pharma trusts digital products, primary/secondary endpoints

Is your company's work missing? Submit it to DiMe:

*Only drug trials with reported phases are included


Last updated June 27, 2021
## DiMe’s Crowdsourced Library of Digital Endpoints

### Airtable

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>November 18, 2019</td>
<td>Change from baseline to p.   Activity Monitor: Activity Monitor: Physical Activity Activity Count: Activity Counts Allergic Anemia Genitourinary  Physical activity and sleep quality will be assessed.</td>
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### Source

Digital Measures That Matter to Patients: A Framework to guide the Selection and Development of Digital Measures of Health

Viewpoint

**Digital Biomarkers**

*Digit Biomark 2020;4:69-77*

**DOI:** 10.1159/000509725  
**Accepted:** June 25, 2020  
**Published online:** September 15, 2020

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**Source:** [https://www.karger.com/Article/Pdf/509725](https://www.karger.com/Article/Pdf/509725)

**Abstract**

Digital Measures That Matter to Patients: A Framework to Guide the Selection and Development of Digital Measures of Health

Christine Manta a,b  
Bray Patrick – Lake a,c  
Jenifer C, Goldsack a

a Digital Medicine Society, Boston, MA, USA; b Elektra Labs, Boston, MA, USA; c Evidation Health, Inc., San Mateo, CA, USA

<table>
<thead>
<tr>
<th>Critical Patient Input</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Meaningful Aspect of Health</strong></td>
</tr>
</tbody>
</table>
| Aspect of a disease that a patient a) does not want to become worse, b) wants to improve or c) wants to prevent  
  • May be shared across some conditions and diseases |
| What do you wish that you could do, but your condition prevents you from doing it? |
| What part of your life is most frustratingly impacted by your condition? |

<table>
<thead>
<tr>
<th>Concept of Interest</th>
</tr>
</thead>
</table>
| Simplified or narrowed element that can be practically measured  
  • Patients may have different symptoms  
  • Symptoms may vary over time  
  • Symptoms relevance may vary over time |
| What are the symptoms that most impact your ability to do these activities? |

<table>
<thead>
<tr>
<th>Outcome to be measured</th>
</tr>
</thead>
</table>
| Specific measurable characteristics  
  • Measures may be relevant to multiple symptoms  
  • Assess technical specification of sensor and whether it is suitable for measuring this outcome in this population |
| Do these measures make sense to you? |

<table>
<thead>
<tr>
<th>Endpoint</th>
</tr>
</thead>
</table>
| Health research only; Precisely defined, statistically analyzed variables  
  • Sensors may support multiple measures & endpoints |
| How much change do we need to see in this symptom before it really starts to make a positive difference in your life? |

This figure was adapted from original work by Evidation Health, with permission. This figure illustrates patient considerations that should drive digital measure selection and development, these should precede technical considerations [8]. Additional information on subsequent technical considerations are available at [34, 37, 38].

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**Table:**

<table>
<thead>
<tr>
<th>Aspect of a disease</th>
<th>Patient Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does not want to become worse</td>
<td>What do you wish that you could do, but your condition prevents you from doing it?</td>
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<tr>
<td>Wants to improve</td>
<td>What part of your life is most frustratingly impacted by your condition?</td>
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<tr>
<td>Wants to prevent</td>
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</table>
Verily loses FDA bid to add Parkinson’s assessments to clinical research smartwatch

by Andrea Park | Jun 8, 2021 1:00pm

The virtual motor exam uses the Verity Study Watch to guide wearers through eight tasks designed to measure their motor abilities in accordance with the standardized MDS-Unified Parkinson’s Disease Rating Scale (UPDRS).

Though wearable devices have proven to be incredibly helpful in monitoring a variety of health conditions—from diabetes to atrial fibrillation—the FDA is sending Verily back to the drawing board in its efforts to add a Parkinson’s disease symptom assessment to its clinical research-focused smartwatch.


Dear Mr. Puppala,

We have completed our review of the Letter of Intent (LOI) for Drug Development Tool (DDT) COA #000142 received on January 25, 2021 by the CDER Clinical Outcome Assessments (COA) Qualification Program, submitted under section 507 of the Federal Food, Drug, and Cosmetic Act.

The LOI is for the Virtual Motor Exam for Parkinson’s disease, Part III Estimator (VME Part III), as measured by the Verity Study Watch, a Digital Health Technology (DHT) – Passive Monitoring COA, proposed for the assessment of motor symptom severity in adults who have been diagnosed with Parkinson’s disease across the full range of disease progression.

We have completed our review and decided not to accept your LOI. We have the following comments:

The Verity Study Watch/VME III measures a change in digitally assessed parameters of a subset of Parkinson’s disease motor signs from the MDS-UPDRS Part III (motor examination). However, the MDS-UPDRS Part III and the VME III are limited in their capacity to evaluate meaningful aspects of concepts of interest that are relevant to the patients’ ability to function in day-to-day life. For example, a change in rigidity or finger tapping in the MDS-UPDRS Part III cannot be directly interpreted as being meaningful to patients. However, a change in speech, eating and dressing (as assessed in the MDS-UPDRS Part II) represents meaningful change in how patients function in daily life. Additionally, the Verity Study Watch/VME III is a remote assessment that provides an algorithmic representation of change in selected items of the MDS-UPDRS Part III. This raises additional concerns about the ability to interpret changes on the VME III measured by the Verity Study Watch as representing meaningful change in patients’ ability to function. For example, it is unclear how the change in the digital signature for finger tapping (as measured by the Verity Study Watch) could be interpreted as representing meaningful change in patient function.

For these reasons, when evaluating drug efficacy in Parkinson’s disease, the FDA prefers content that is more representative of daily life functioning (e.g., consistent with the MDS-UPDRS Part II or other similar instruments).

Dinesh Puppala, MS
Verily Life Sciences
269 E Grand Ave
San Francisco, CA 94080
Evaluating digital clinical measures
V3 is a modular evaluation process

- **Verification**: 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.

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

- **Clinical validation**: Evaluates whether a BioMeT acceptably identifies, measure, or predicts a meaningful clinical, biological, physical, functional state, or experience, in the states context of use (which includes a specified population).

---

**BioMeT** - Biometric Monitoring Technology

Source: [https://www.nature.com/articles/s41746-020-0260-4](https://www.nature.com/articles/s41746-020-0260-4)
Modular evaluation of digital measures

Design Specifications & Modular Prototyping

Verification

Changes to hardware/firmware?
- Reverification, or
- Documentation of back-compatibility

Analytical validation

Changes to software that change algorithm?
- Repeat analytical validation, or
- Documentation of back-compatibility

Clinical validation

Expansion to a new patient population?
- Repeat clinical validation if analytical validation in new population is documented, or
- Repeat analytical & clinical validation

Clinical Utility

Source: https://www.nature.com/articles/s41746-020-0260-4
V3 processes are typically conducted by experts across disciplines and domains.

Stage involves human subjects.

Activity performed by:
- (non-clinical) engineers
- Both engineers and clinically-trained professionals
- Clinically-trained professionals

Source: [https://www.nature.com/articles/s41746-020-0260-4](https://www.nature.com/articles/s41746-020-0260-4)
Digital health technologies in clinical trials for central nervous system drugs: an EU regulatory perspective

Digital health technologies have the potential to help address some of the challenges in the clinical development of drugs for central nervous system disorders. This article discusses strategies for the development of such tools in the context of the European regulatory environment.

Valentina Mantua, Celso Arango, Pavel Balabanov & Florence Butlin-Ducuing
Relating the V3 framework to current approaches

Fit-for-Purpose Biometric Monitoring Technologies: Leveraging the Laboratory Biomarker Experience

Alan Godfrey, Benjamin Vandendriessche, Jessie P. Bakker, Cheryl Fitz-Attas, Ninad Gujar, Matthew Hobbs, Qi Liu, Carrie A. Northcott, Virginia Parks, William A. Wood, Vadim Zipunnikov, John A. Wagner, Elena S. Izmailova... See fewer authors

First published: 08 August 2020 | https://doi.org/10.1111/cts.12865

Source: https://www.nature.com/articles/d41573-020-00168-z
V3 is the first step of a comprehensive evaluation framework for fit-for-purpose connected sensors

<table>
<thead>
<tr>
<th>Category</th>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Verification, Analytical Validation and Clinical Validation (V3)</td>
<td>Does the tool measure what it claims to measure? Is the measurement appropriate for the target population?</td>
</tr>
<tr>
<td>Security</td>
<td>Does the manufacturer build with safety by design? Is there a Disclosure Policy? Software Bill of Materials?</td>
</tr>
<tr>
<td>Data Rights and Governance</td>
<td>Who has access to the data and when? Is the privacy policy publicly accessible?</td>
</tr>
<tr>
<td>Utility and Usability</td>
<td>How is the tool worn? Battery life? Available technical support?</td>
</tr>
<tr>
<td>Economic Feasibility</td>
<td>What’s the net benefit versus price? Is cost a one-time or subscription model?</td>
</tr>
</tbody>
</table>
EVIDENCE Publication Checklist for Studies Evaluating Connected Sensor Technologies: Explanation and Elaboration

Christine Manta\textsuperscript{a,b}, Nikhil Mahadevan\textsuperscript{a,c}, Jessie Bakker\textsuperscript{a,d}, Simal Ozen Irmak\textsuperscript{e}, Elena Izmailova\textsuperscript{a,f}, Siyeon Park\textsuperscript{g}, Jiat-Ling Poon\textsuperscript{h}, Santosh Shevade\textsuperscript{l}, Sarah Valentine\textsuperscript{h}, Benjamin Vandenbergriessche\textsuperscript{l,k}, Courtney Webster\textsuperscript{l}, Jennifer C. Goldsack\textsuperscript{a}

\textsuperscript{a}Digital Medicine Society, Boston, MA, USA; \textsuperscript{b}Elekta Labs, Boston, MA, USA; \textsuperscript{c}Pfizer Inc., Cambridge, MA, USA; \textsuperscript{d}Philips, Monroeville, PA, USA; \textsuperscript{e}Tibi Health Inc., San Francisco, CA, USA; \textsuperscript{f}Konexsa Health Inc., New York, NY, USA; \textsuperscript{g}Geisinger Health System, Danville, PA, USA; \textsuperscript{h}Eli Lilly and Company, Indianapolis, IN, USA; \textsuperscript{i}Independent Consultant, Mumbai, India; \textsuperscript{j}Byteflies, Antwerp, Belgium; \textsuperscript{k}Department of Electrical, Computer and Systems Engineering, Case Western Reserve University, Cleveland, OH, USA; \textsuperscript{l}Nymblywork, Seattle, WA, USA
The Playbook: Digital Clinical Measures

Introducing the essential industry guide for successful remote monitoring across clinical research, clinical care, and public health.
TOUR OF DUTY: Driving adoption

The Playbook: Digital Clinical Measures

Introducing the essential guide for successful remote monitoring across clinical research, clinical care, and public health.

Source: Playbook team analysis | https://playbook.dimesociety.org/
During the pandemic:

Telehealth increased by nearly 1,200%

Yet only 11% of encounters used any form of remote monitoring to support care

A chasm remains between digital health innovation and implementation

The survey responses show that telehealth is positively influencing four important dimensions of care:

**CLINICAL OUTCOMES**

More than 75% of clinicians responding to the survey indicated that telehealth enabled them to provide quality care in the areas of COVID-19-related care, acute care, chronic disease management, hospital follow-up, care coordination, preventative care, and mental/behavioral health. Additionally, 60% of clinicians reported that telehealth has improved the health of their patients.

- Of those using telehealth, 80% are conducting live, interactive video visits with patients and 67.9% are doing audio-only visits.
- 68% of respondents are motivated (agree and strongly agree) to increase telehealth use in their practices. The majority would like to continue to offer telehealth for chronic disease management, medical management, care coordination, and preventative care following the pandemic.
- 11% of respondents said they were using remote patient monitoring technologies with patients in their homes; the commonly used tools include smartphones (camera), blood pressure cuffs, body weight scales, and pulse oximeters. Currently, data is usually shared verbally over the phone or via email.

**PATIENT EXPERIENCE**

More than 80% of respondents indicated that telehealth improved the timeliness of care for their patients. A similar percentage said that their patients have reacted favorably to using telehealth for care.

**COST**

Respondents indicated that telehealth decreased the costs of care for their patients (61% either agreeing or strongly agreeing) and improved the financial health of their practices (56% either agreeing or strongly agreeing).

**PROFESSIONAL SATISFACTION**

A majority of respondents indicated that telehealth has improved the satisfaction of their work (55%).

**Digital Health Measurement Collaborative Community (DATAcc)**

The Digital Medicine Society (DiMe) is launching a **collaborative community** to advance the use of digital health measurement in an **equitable** and **effective** manner in order to promote individual and public health.

DATAcc will use interdisciplinary expertise, data, and use cases to develop and demonstrate **best practices** and advance **harmonized approaches** to speed the use of **digital health measurement** to improve **health outcomes**, **health economics**, and **health equity**.

Source: [https://datacc.dimesociety.org](https://datacc.dimesociety.org)
With Covid-19 halting clinical trials, wearables could be key — but data ‘wild west’ gets in the way

By JORDAN BRAYANOVA, JEN GOLDSACK, and BILL BYROM / AUGUST 11, 2020
Building the workforce needed for digital health

Defining and Developing the Workforce Needed for Success in the Digital Era of Medicine

Jennifer C. Goldsack\textsuperscript{a} Cole A. Zanetti\textsuperscript{b}

\textsuperscript{a}Digital Medicine Society (DiMe), Boston, MA, USA; \textsuperscript{b}Rocky Vista University College of Osteopathic Medicine, Parker, CO, USA

Digital Biomarkers

Digit Biomark 2020;4(suppl 1):136–142
DOI: 10.1159/000512382
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www.karger.com/doi

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Source: https://www.karger.com/Article/FullText/512382
Who is involved with DiMe?

Individuals passionate about advancing the safe, effective, ethical, and equitable use of digital medicine products to improve lives.

We are a professional society!
Become a member today

Generates Evidence

Facilitates Collaborations

Promotes Education

Source: https://www.dimesociety.org/research/
The Playbook in action:
Use Case Library

See how organizations are using The Playbook resources to solve real-world problems within their organizations. (Updated July 27, 2021)
playbook.dimesociety.org

Want to include your use case? Submit details here.
Our Vision

To achieve the promise of digital health measurement to improve lives, for everyone.

Apply to join DATAcc today!
The Digital Endpoints Webinar Series

Part I: August 2nd, 2021 at 11a ET

Hosted in partnership with:
We are pleased to announce that the Novel Digital Endpoints Consideration Paper was accepted to a journal and will be published soon! The opinion paper and more information will be available soon on the Patient Technology Solutions Page.

The paper summarizes key considerations (complemented with a case study) on how to develop and navigate the path to Health Authority approval to use digital tools for NDE development in a clinical trial.
Interested in Novel Digital Endpoints?
The Novel Digital Endpoints team has a few options to learn more

Please feel free to share with your Head of Digital Medicine/Health, Digital Data group and Regulatory colleagues. Anyone interested in the topic can:

<table>
<thead>
<tr>
<th>Attend the 3-Part Webinar Series with DiMe, TransCelerate and CTTI</th>
</tr>
</thead>
<tbody>
<tr>
<td>✔ Part 1: Digital Endpoints Webinar hosted by DiMe</td>
</tr>
<tr>
<td>❑ Part 2: Developing a Novel Measurement of Sleep in Rheumatoid Arthritis: Study Proposal for Approach and Considerations hosted by TransCelerate (details to follow pending publication)</td>
</tr>
<tr>
<td>❑ Part 3: CTTI hosted Webinar (date TBD in October)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Enroll in DIA Short Course</th>
</tr>
</thead>
<tbody>
<tr>
<td>DIA Digital Technology in Clinical Trials</td>
</tr>
<tr>
<td>Date: 9am - 1pm ET on October 21st, 2021.</td>
</tr>
<tr>
<td>Speaker: Michelle Crouthamel, Jennifer Goldsack, and Lindsay Kehoe</td>
</tr>
<tr>
<td>Registration: <a href="#">Conference website</a></td>
</tr>
</tbody>
</table>
CTTI Resources & Insights to Support the Use of Novel Endpoints

Lindsay Kehoe, CTTI Project Manager
Multi-stakeholder, public-private partnership co-founded by Duke University & FDA

Participation of 500+ more orgs and ~80 member organizations

MISSION: To develop and drive adoption of practices that will increase the quality and efficiency of clinical trials
By 2030, clinical trials need to be:

- Patient-Centered & Easily Accessible
- Fully Integrated Into Health Processes
- Designed With A Quality Approach
- Maximally Leveraging All Available Data
- Improving Population Health

A critical part of the Evidence Generating System
PURPOSE:
Develop evidence-based recommendations that affect the widespread adoption and use of digital health technology in clinical trials for regulatory submission.

ANTICIPATED IMPACT:
Increased number of clinical trials leveraging digital health technologies. More efficient trials generating better quality information.

DHT Program

- Novel Endpoints
  - 2017

- Digital Health Technologies
  - 2018

- Decentralized Clinical Trials
  - 2018

- Engaging Patients & Sites
  - 2019

*Formerly CTTI’s Mobile Clinical Trials (MCT) Program*
CTTI’s 2017 Developing Novel Endpoints Work

• Optimizing Novel Endpoint Selection
  ▪ Focus on measures that are meaningful to patients.
  ▪ Select the technology after selecting an outcome assessment.
  ▪ Use a systematic approach to identify key novel endpoints.

• Practical Approaches to Novel Endpoint Development
  ▪ Foster collaboration among key stakeholders.
  ▪ Create technical standards for mobile technology-derived assessments.
  ▪ Engage with regulators.
  ▪ Include novel endpoints as exploratory endpoints in existing clinical trials and observational cohort studies.
  ▪ Think critically about how to optimally position novel endpoints in interventional trials.

Additional information at https://www.ctti-clinicaltrials.org/projects/novel-endpoints
NEW: Current Novel Endpoint Work Overview

• **Purpose:** Obtain reliability and acceptance of meaningful, DHT-derived novel endpoints

• **Objectives:**
  ▪ Identify gaps and barriers and solutions to achieve regulatory acceptance for a DHT-derived endpoint
  ▪ Create a glossary for DHT-derived novel endpoints
  ▪ Describe the evidence needed to achieve regulatory acceptance for a novel, DHT-derived endpoint

• **Expected Impact:** Increase the use of meaningful, DHT-derived novel endpoints as key endpoints in clinical trials for labeling claims
Project Scope & Deliverables

IN SCOPE
- Clinical Outcome Assessments (COAs)*
  - Functional outcomes
  - Passive and active monitoring
  - Technology intended for use in clinical trials

OUT OF SCOPE
- Surveys (ePROs)
- Digital therapeutics
- Biomarkers

*Per FDA/NIH’s BEST glossary, a clinical outcome describes or reflects how an individual feels, functions or survives.
Developing Novel Digital Endpoints Webinar Series: CTTI October Webinar (week of Oct. 4 TBD)

- In-Depth Interview Findings
- CPIM/FDA Recap
- Pre-Launch Preview
- Expert Meeting Highlights
- Recs & Resources Sneak Peek

Registration Link is Forthcoming – Stay Tuned!
Lindsay Kehoe, CTTI Project Manager

THANK YOU

www.ctti-clinicaltrials.org
The Digital Endpoints Webinar Series

Part I: August 2nd, 2021 at 11a ET

Hosted in partnership with:
Virtual Journal club

Statistical considerations for successful digital health innovation

August 26th, 2021
1p ET

Eric Daza, DrPH, MPS
Lead statistician, digital health outcomes
Evidation Health
Patient Engagement & Activation for Better Adherence Using Digital Platforms

Wednesday, September 15, 2021
12-1pm ET
THANK YOU