The Digital Endpoints Webinar Series

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

Hosted in partnership with:

DIGITAL MEDICINE SOCIETY

TransCelerate BIOPHARMA INC.

CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

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

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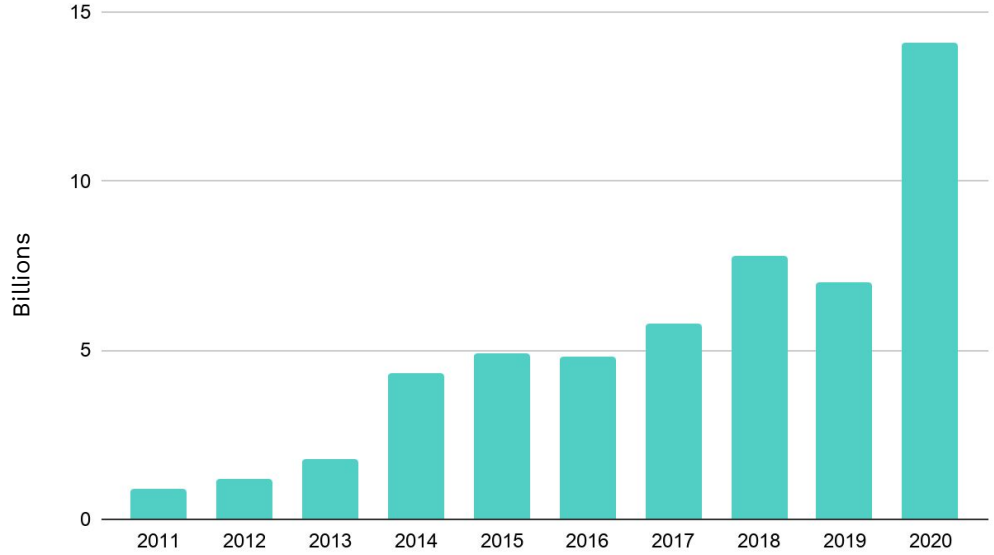
CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

Our purpose

DiMe is a the 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



	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
# deals	92	142	196	293	320	340	366	380	374	440
Avg size ($M)	$12.0	$10.6	$10.7	$13.9	$14.7	$13.5	$15.9	$21.6	$19.8	$31.9

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.

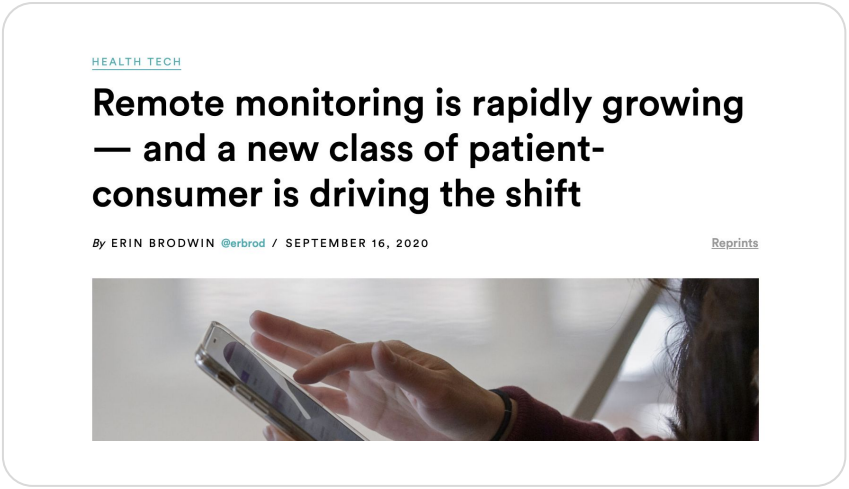
The U.S. digital health market accounted for largest share in 2018 supported by increasing prevalence of chronic diseases along with growing geriatric population in the country.

NEWS PROVIDED BY
Global Market Insights, Inc. →
Mar 06, 2019, 04:00 ET

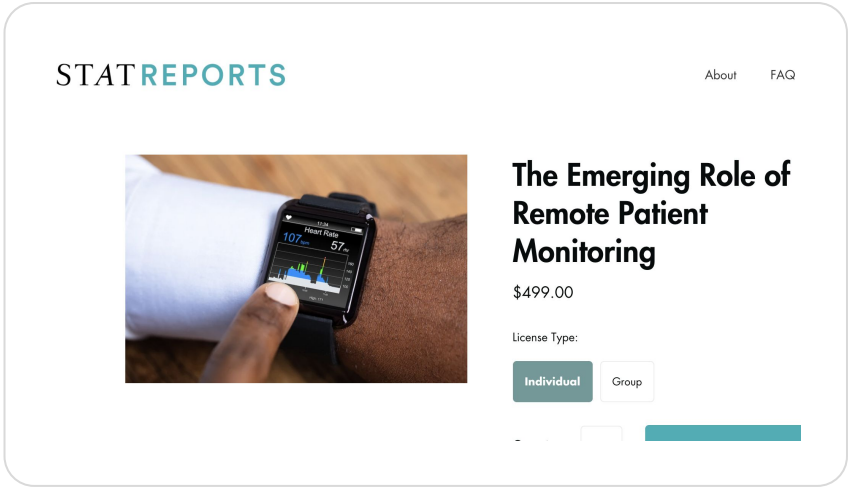
SHARE THIS ARTICLE

Source:
https://www.prnewswire.com/news-releases/worldwide-digital-health-market-to-hit-504-4-billion-by-2025-global-market-insights-inc-300807027.html

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



Source:https://www.statnews.com/2020/09/16/remote-patient-monitoring-stat-report/



Source:https://reports.statnews.com/products/the-emerging-role-of-remote-patient-monitoring?variant=32831604260967

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

amazon

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

Alphabet

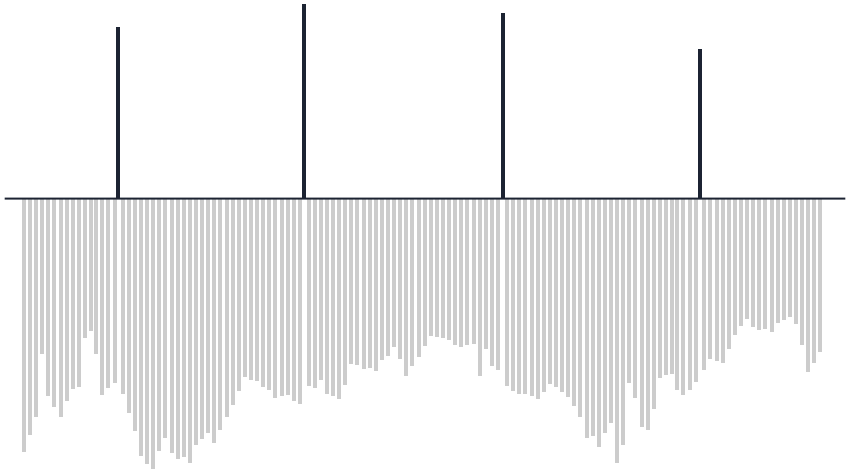
Google is on track to purchase **Fitbit Sense** includes an ECG App
Cleared by FDA Sept 11, 2020

Apple

Apple Watch 6 includes health features such as an SpO_2 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

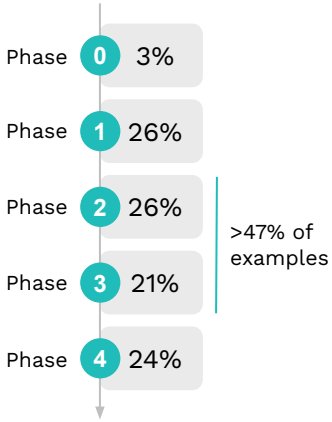
Primary, Secondary or Label Claim

Exploratory Only

Roche teva

Sponsors start digital endpoint development early

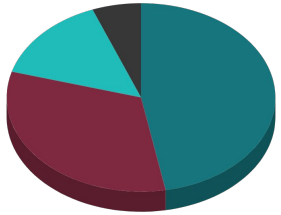
Digital Endpoints



>47% of examples

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

Investigational Product



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

Pharma trusts digital products, primary/ secondary endpoints

Endpoint Positioning

16	Primary endpoints
4	Secondary endpoints
14	Exploratory
34	**UNIQUE ENDPOINTS**

DiMe DIGITAL MEDICINE SOCIETY

Is your company's work missing? Submit it to DiMe: https://bit.ly/DiMe-Endpoints

Source: https://www.dimesociety.org/index.php/knowledge-center/library-of-digital-endpoints

STAT FIRST OPINION

Digital endpoints library can aid clinical trials for new medicines

By JEN GOLDSACK, RACHEL A. CHASSE, *and* WILLIAM A. WOOD / NOVEMBER 6, 2019

Source: https://www.statnews.com/2019/11/06/digital-endpoints-library-clinical-trials-drug-development/

62 Sponsors have collected digital endpoints

62 Sponsors have collected digital endpoints

Primary, Secondary or Label Claim

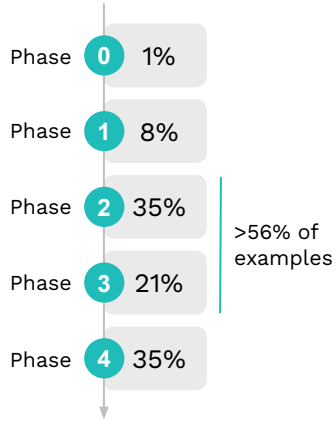
Abbott, abbvie, ABIDE THERAPEUTICS, ACTELION, ALTAVANT SCIENCES, ALKAHEST, Altec, ALTOIDA, aspen, AstraZeneca, AVAZIA, Bellerophon, BAYER, Cavion, CuraSen, dexcom, dm, Daiichi-Sankyo, Eisai, gbt, GILEAD, gsk, janssen, Insulet, Forest Laboratories, Inc., Genentech, LALLEMAND, Lilly, LMC, MEDICIS, MARREK, MERCK, NANTCELL, NOVARTIS, novo nordisk, OLATEC, ottobock., PHARMANEX, Pfizer, PrecisionBiotics, proteus, PURDUE, REGENERON, Sage Therapeutics, SANOFI, SENSIMED, SoniVie, SzeleSTIM, Takeda, ucb, VANDA, VERTEX, ViiV Healthcare, ZOLL

Exploratory Only

CORTEXYME, Roche, sunovion, sonova, teva

Sponsors start digital endpoint development early

Digital Endpoints

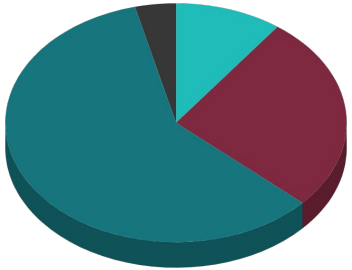


>56% of examples

*Only drug trials with reported phases are included

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

Investigational Product



Drug	60%
Device	26%
Biologic	10%
Other	4%

Pharma trusts digital products, primary/ secondary endpoints

Endpoint Positioning

62	Primary endpoints
131	Secondary endpoints
14	Exploratory
207	**UNIQUE ENDPOINTS**

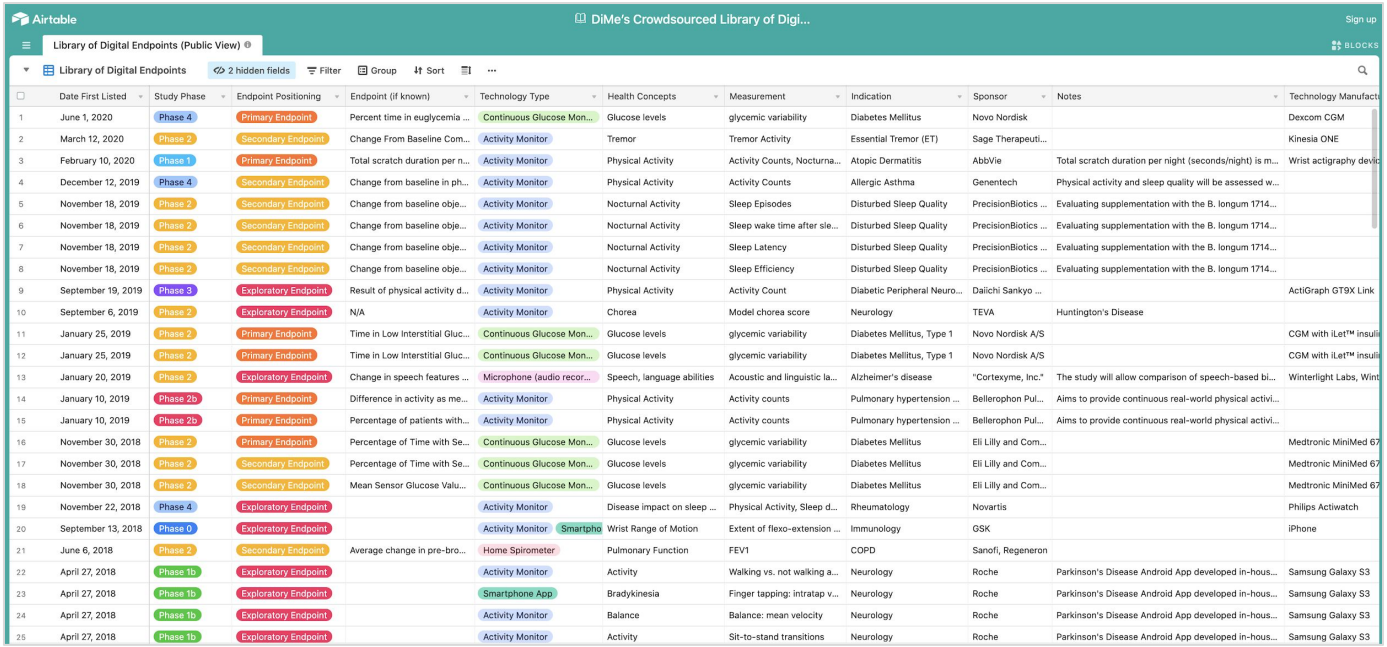
DIGITAL MEDICINE SOCIETY

Is your company's work missing? Submit it to DiMe: https://bit.ly/DiMe-Endpoints

Source: https://www.dimesociety.org/index.php/knowledge-center/library-of-digital-endpoints

Last updated June 27, 2021

DiMe's Crowdsourced Library of Digital Endpoints



	Date First Listed	Study Phase	Endpoint Positioning	Endpoint (if known)	Technology Type	Health Concepts	Measurement	Indication	Sponsor	Notes	Technology Manufact
1	June 1, 2020	Phase 4	Primary Endpoint	Percent time in euglycemia ...	Continuous Glucose Mon...	Glucose levels	glycemic variability	Diabetes Mellitus	Novo Nordisk		Dexcom CGM
2	March 12, 2020	Phase 2	Secondary Endpoint	Change From Baseline Com...	Activity Monitor	Tremor	Tremor Activity	Essential Tremor (ET)	Sage Therapeuti...		Kinesia ONE
3	February 10, 2020	Phase 1	Primary Endpoint	Total scratch duration per n...	Activity Monitor	Physical Activity	Activity Counts, Nocturna...	Atopic Dermatitis	AbbVie	Total scratch duration per night (seconds/night) is m...	Wrist actigraphy devic
4	December 12, 2019	Phase 4	Secondary Endpoint	Change from baseline in ph...	Activity Monitor	Physical Activity	Activity Counts	Allergic Asthma	Genentech	Physical activity and sleep quality will be assessed w...	
5	November 18, 2019	Phase 2	Secondary Endpoint	Change from baseline obje...	Activity Monitor	Nocturnal Activity	Sleep Episodes	Disturbed Sleep Quality	PrecisionBiotics ...	Evaluating supplementation with the B. longum 1714...	
6	November 18, 2019	Phase 2	Secondary Endpoint	Change from baseline obje...	Activity Monitor	Nocturnal Activity	Sleep wake time after sle...	Disturbed Sleep Quality	PrecisionBiotics ...	Evaluating supplementation with the B. longum 1714...	
7	November 18, 2019	Phase 2	Secondary Endpoint	Change from baseline obje...	Activity Monitor	Nocturnal Activity	Sleep Latency	Disturbed Sleep Quality	PrecisionBiotics ...	Evaluating supplementation with the B. longum 1714...	
8	November 18, 2019	Phase 2	Secondary Endpoint	Change from baseline obje...	Activity Monitor	Nocturnal Activity	Sleep Efficiency	Disturbed Sleep Quality	PrecisionBiotics ...	Evaluating supplementation with the B. longum 1714...	
9	September 19, 2019	Phase 3	Exploratory Endpoint	Result of physical activity d...	Activity Monitor	Physical Activity	Activity Count	Diabetic Peripheral Neuro...	Daiichi Sankyo ...		ActiGraph GT9X Link
10	September 6, 2019	Phase 2	Exploratory Endpoint	N/A	Activity Monitor	Chorea	Model chorea score	Neurology	TEVA	Huntington's Disease	
11	January 25, 2019	Phase 2	Primary Endpoint	Time in Low Interstitial Gluc...	Continuous Glucose Mon...	Glucose levels	glycemic variability	Diabetes Mellitus, Type 1	Novo Nordisk A/S		CGM with iLet™ insuli
12	January 25, 2019	Phase 2	Primary Endpoint	Time in Low Interstitial Gluc...	Continuous Glucose Mon...	Glucose levels	glycemic variability	Diabetes Mellitus, Type 1	Novo Nordisk A/S		CGM with iLet™ insuli
13	January 20, 2019	Phase 2	Exploratory Endpoint	Change in speech features ...	Microphone (audio recor...	Speech, language abilities	Acoustic and linguistic la...	Alzheimer's disease	"Cortexyme, Inc."	The study will allow comparison of speech-based bi...	Winterlight Labs, Wint
14	January 10, 2019	Phase 2b	Primary Endpoint	Difference in activity as me...	Activity Monitor	Physical Activity	Activity counts	Pulmonary hypertension ...	Bellerophon Pul...	Aims to provide continuous real-world physical activi...	
15	January 10, 2019	Phase 2b	Primary Endpoint	Percentage of patients with...	Activity Monitor	Physical Activity	Activity counts	Pulmonary hypertension ...	Bellerophon Pul...	Aims to provide continuous real-world physical activi...	
16	November 30, 2018	Phase 2	Primary Endpoint	Percentage of Time with Se...	Continuous Glucose Mon...	Glucose levels	glycemic variability	Diabetes Mellitus	Eli Lilly and Com...		Medtronic MiniMed 67
17	November 30, 2018	Phase 2	Secondary Endpoint	Percentage of Time with Se...	Continuous Glucose Mon...	Glucose levels	glycemic variability	Diabetes Mellitus	Eli Lilly and Com...		Medtronic MiniMed 67
18	November 30, 2018	Phase 2	Secondary Endpoint	Mean Sensor Glucose Valu...	Continuous Glucose Mon...	Glucose levels	glycemic variability	Diabetes Mellitus	Eli Lilly and Com...		Medtronic MiniMed 67
19	November 22, 2018	Phase 4	Exploratory Endpoint		Activity Monitor	Disease impact on sleep ...	Physical Activity, Sleep d...	Rheumatology	Novartis		Philips Actiwatch
20	September 13, 2018	Phase 0	Exploratory Endpoint		Activity Monitor Smartpho	Wrist Range of Motion	Extent of flexo-extension ...	Immunology	GSK		iPhone
21	June 6, 2018	Phase 2	Secondary Endpoint	Average change in pre-bro...	Home Spirometer	Pulmonary Function	FEV1	COPD	Sanofi, Regeneron		
22	April 27, 2018	Phase 1b	Exploratory Endpoint		Activity Monitor	Activity	Walking vs. not walking a...	Neurology	Roche	Parkinson's Disease Android App developed in-hous...	Samsung Galaxy S3
23	April 27, 2018	Phase 1b	Exploratory Endpoint		Smartphone App	Bradykinesia	Finger tapping: intratap v...	Neurology	Roche	Parkinson's Disease Android App developed in-hous...	Samsung Galaxy S3
24	April 27, 2018	Phase 1b	Exploratory Endpoint		Activity Monitor	Balance	Balance: mean velocity	Neurology	Roche	Parkinson's Disease Android App developed in-hous...	Samsung Galaxy S3
25	April 27, 2018	Phase 1b	Exploratory Endpoint		Activity Monitor	Activity	Sit-to-stand transitions	Neurology	Roche	Parkinson's Disease Android App developed in-hous...	Samsung Galaxy S3

Source: https://www.dimesociety.org/index.php/knowledge-center/library-of-digital-endpoints

Ensure you identify measures that matter

Digital Biomarkers

Digit Biomark 2020;4:69-77

DOI: 10.1159/000509725
Received: May 9, 2020
Accepted: June 25, 2020
Published online: September 15,2020

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Published by S. Karger AG, Basel
www.karger.com/dib

Viewpoint **Review Article**

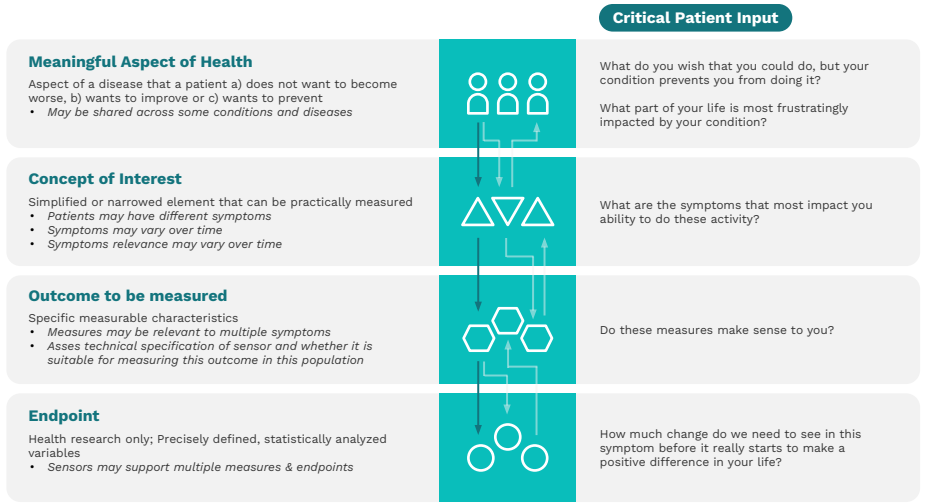
Digital Measures That Matter to Patients: A Framework to Guide the Selection and Development of Digital Measures of Health

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

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

Digit Biomark 2020;4;69-77 = DOI:10.1159/00509725



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 [36, 37, 38]

Source: https://www.karger.com/Article/Pdf/509725

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MedTech

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 Verily 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. (Verily)

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.

FDA U.S. FOOD & DRUG ADMINISTRATION

DRUG DEVELOPMENT TOOL
LETTER OF INTENT DETERMINATION
DDT COA #000142

Dinesh Puppala, MS
Verily Life Sciences
269 E Grand Ave
San Francisco, CA 94080

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 Verily 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.

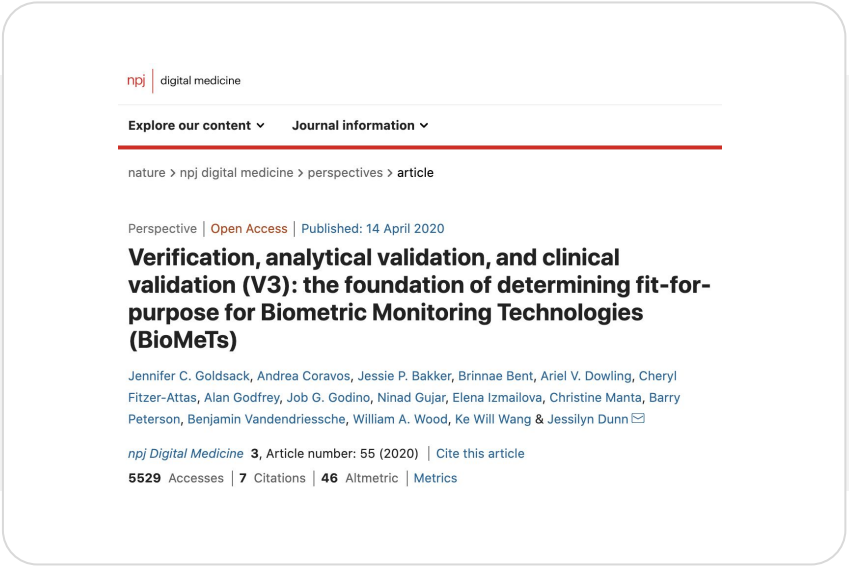
We have completed our review and decided not to accept your LOI. We have the following comments:

The Verily 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 Verily 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 Verily 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 Verily 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).

Source: https://www.fiercebiotech.com/medtech/verily-loses-fda-bid-to-add-parkinson-s-motor-function-assessment-to-clinical-research and https://www.fda.gov/media/149517/download

Evaluating digital clinical measures



npj | digital medicine

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nature › npj digital medicine › perspectives › article

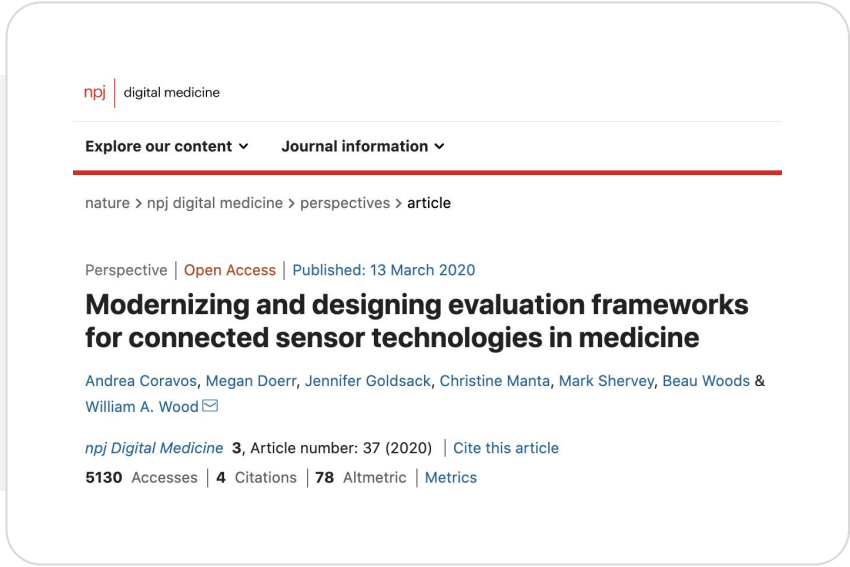
Perspective | Open Access | Published: 14 April 2020

Verification, analytical validation, and clinical validation (V3): the foundation of determining fit-for-purpose for Biometric Monitoring Technologies (BioMeTs)

Jennifer C. Goldsack, Andrea Coravos, Jessie P. Bakker, Brinnae Bent, Ariel V. Dowling, Cheryl Fitzer-Attas, Alan Godfrey, Job G. Godino, Ninad Gujar, Elena Izmailova, Christine Manta, Barry Peterson, Benjamin Vandendriessche, William A. Wood, Ke Will Wang & Jessilyn Dunn ✉

npj Digital Medicine **3**, Article number: 55 (2020) | Cite this article

5529 Accesses | **7** Citations | **46** Altmetric | Metrics



npj | digital medicine

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nature › npj digital medicine › perspectives › article

Perspective | Open Access | Published: 13 March 2020

Modernizing and designing evaluation frameworks for connected sensor technologies in medicine

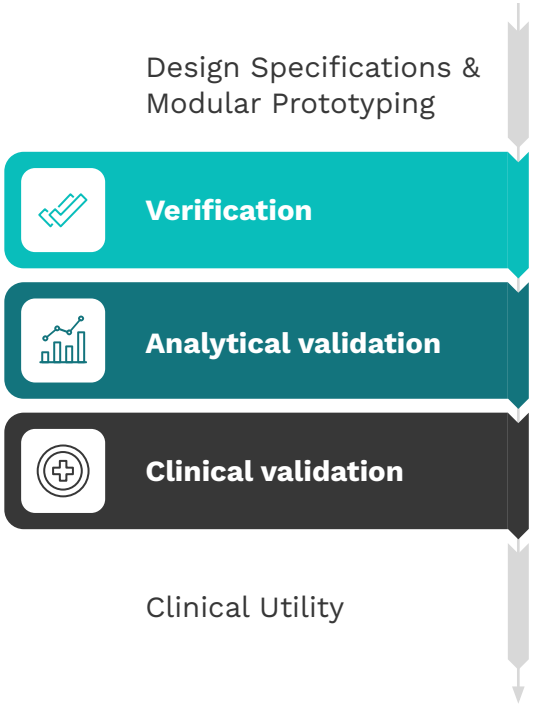
Andrea Coravos, Megan Doerr, Jennifer Goldsack, Christine Manta, Mark Shervey, Beau Woods & William A. Wood ✉

npj Digital Medicine **3**, Article number: 37 (2020) | Cite this article

5130 Accesses | **4** Citations | **78** Altmetric | Metrics

Source: https://www.nature.com/articles/s41746-020-0260-4 & https://www.nature.com/articles/s41746-020-0237-3

V3 is a modular evaluation process



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.

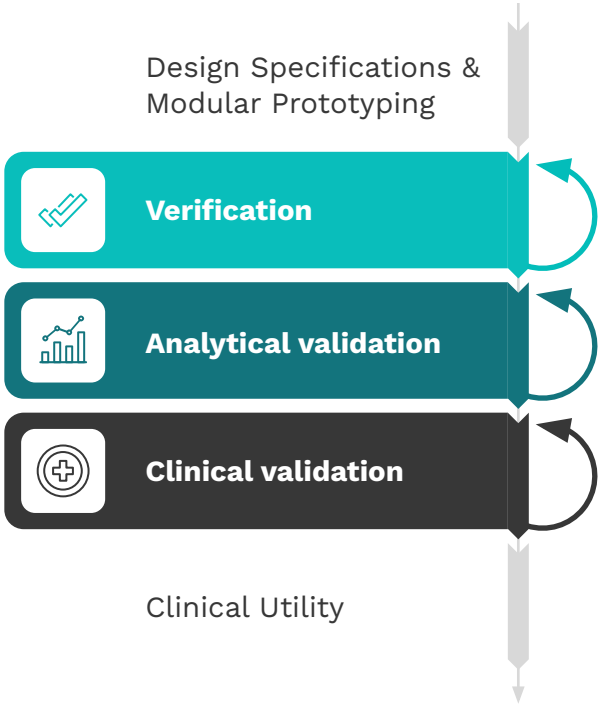
Evaluates the performance of algorithm, and the ability of this component of the **BioMeT** to measure, detect, or predict physiological or behavioral metrics

Evaluates whether a **BioMeT** acceptably identifies, 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

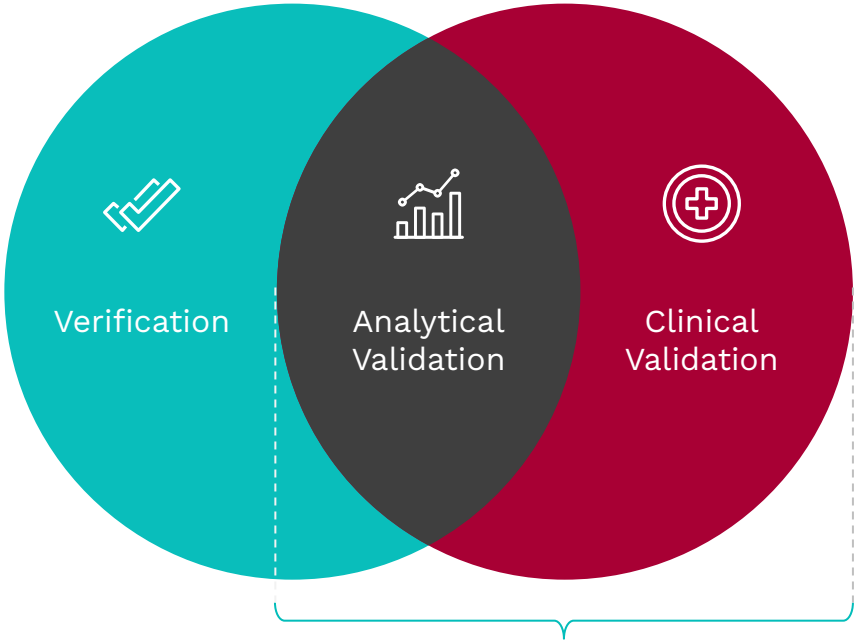
Modular evaluation of digital measures



Changes to hardware/firmware?	• Reverification, or • Documentation of back-compatibility
Changes to software that change algorithm?	• Repeat analytical validation, or • Documentation of back-compatibility
Expansion to a new patient population?	• Repeat clinical validation if analytical validation in new population is documented, or • Repeat analytical & clinical validation

Source: https://www.nature.com/articles/s41746-020-0260-4

V3 processes are typically conducted by experts across disciplines and domains



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

Adoption of the V3 framework

nature reviews drug discovery

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nature › nature reviews drug discovery › comment › article

COMMENT · 29 SEPTEMBER 2020

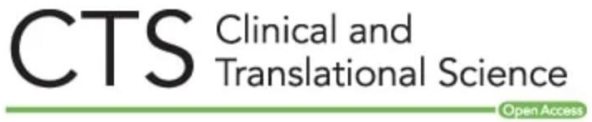
Digital health technologies in clinical trials for central nervous system drugs: an EU regulatory perspective

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 Butlen-Ducuing ✉

Source: https://www.nature.com/articles/d41573-020-00168-z

Relating the V3 framework to current approaches



Review | Open Access

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

Alan Godfrey, Benjamin Vandendriessche, Jessie P. Bakker, Cheryl Fitzer-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

Verification, Analytical Validation and Clinical Validation (V3)	Does the tool measure what it claims to measure? Is the measurement appropriate for the target population?
Security	Does the manufacturer build with safety by design? Is there a Disclosure Policy? Software Bill of Materials?
Data Rights and Governance	Who has access to the data and when? Is the privacy policy publicly accessible?
Utility and Usability	How is the tool worn? Battery life? Available technical support?
Economic Feasibility	What's the net benefit versus price? Is cost a one-time or subscription model?

Source: https://www.nature.com/articles/s41746-020-0237-3

EVIDENCE Checklist

Evaluating Connected Sensor Technologies Checklist

a DiMe Tour of Duty

Digital Biomarkers

NODE – Review Article

Digit Biomark 2021;5:127–147
DOI: 10.1159/000515835

Received: January 25, 2021
Accepted: March 10, 2021
Published online: May 18, 2021

EVIDENCE Publication Checklist for Studies Evaluating Connected Sensor Technologies: Explanation and Elaboration

Christine Manta[a, b] Nikhil Mahadevan[a, c] Jessie Bakker[a, d] Simal Ozen Irmak[e]
Elena Izmailova[a, f] Siyeon Park[g] Jiat-Ling Poon[h] Santosh Shevade[i]
Sarah Valentine[h] Benjamin Vandendriessche[j, k] Courtney Webster[l]
Jennifer C. Goldsack[a]

[a]Digital Medicine Society, Boston, MA, USA; [b]Elektra Labs, Boston, MA, USA; [c]Pfizer Inc., Cambridge, MA, USA; [d]Philips, Monroeville, PA, USA; [e]Tibi Health Inc., San Francisco, CA, USA; [f]Koneksa Health Inc., New York, NY, USA; [g]Geisinger Health System, Danville, PA, USA; [h]Eli Lilly and Company, Indianapolis, IN, USA; [i]Independent Consultant, Mumbai, India; [j]Byteflies, Antwerp, Belgium; [k]Department of Electrical, Computer and Systems Engineering, Case Western Reserve University, Cleveland, OH, USA; [l]Nymbly.work, Seattle, WA, USA

Source: https://www.dimesociety.org/tours-of-duty/evidence/

TOUR OF DUTY: Driving adoption

The Playbook: Digital Clinical Measures

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

ActiGraph · Activ insights · APhA · Big Ideas Lab · BlackThorn Therapeutics · Digital Health · COVANCE Solutions Made Real · DiMe Digital Medicine Society · elektralabs · Lilly · European Medicines Agency · evidation · FDA · Genentech · koneksa · MERCK · MYOKARDIA · Open mHealth · Pfizer · physIQ · savvy · SageBionetworks · Scripps Research · Takeda · VivoSense · Winterlight

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Google Slides

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

Source: https://www.healthcaredive.com/news/medicare-seniors-telehealth-covid-coronavirus-cms-trump/578685/ and https://c19hcc.org/telehealth/physician-survey-analysis/

TELEHEALTH | Impact Study: Physician Survey

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%).

Source: https://c19hcc.org/telehealth/physician-survey-analysis/

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

STAT FIRST OPINION

With Covid-19 halting clinical trials, wearables could be key — but data 'wild west' gets in the way

By JORDAN BRAYANOV, JEN GOLDSACK, *and* BILL BYROM / AUGUST 11, 2020

Reprints

Source: https://www.statnews.com/2020/08/11/with-covid-19-halting-clinical-trials-wearables-could-be-key-but-data-wild-west-gets-in-the-way/

Building the workforce needed for digital health

Digital Biomarkers

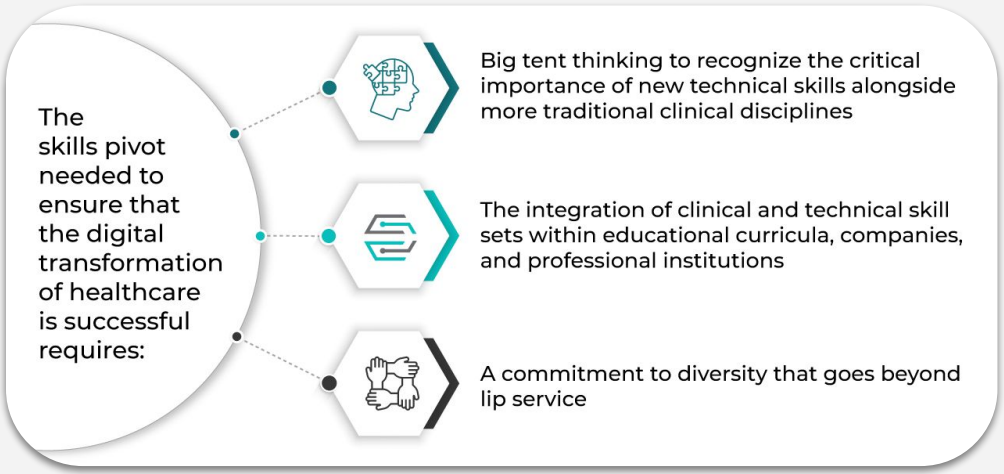
Digit Biomark 2020;4(suppl 1):136–142
DOI: 10.1159/000512382
Received: August 30, 2020
Accepted: October 16, 2020
Published online: November 26, 2020

Next Generation

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

Jennifer C. Goldsack[a] Cole A. Zanetti[b]

[a]Digital Medicine Society (DiMe), Boston, MA, USA; [b]Rocky Vista University College of Osteopathic Medicine, Parker, CO, USA



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

http://bit.ly/Join-DiMe

Source: https://www.dimesociety.org/research/

The Playbook in action: Use Case Library

The Playbook
Driving Adoption

a DIME Tour of Duty

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.

DATAcc

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:

DIGITAL MEDICINE SOCIETY

TransCelerate BIOPHARMA INC.

CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

Novel Digital Endpoints Consideration Paper Coming Soon!

Recently accepted in the Digital Biomarkers Journal

POV Paper | **Novel Digital Endpoints Consideration Paper** | Implementation Framework | PT Discussion Guide | Patient Considerations | Regulatory Landscape Tool | PT Site Feedback Questionnaire | Vendor Engagement & Vendor-Influenced Tools

NOVEL DIGITAL ENDPOINTS CONSIDERATION PAPER

Novel Digital Endpoints (NDEs) are an evolving field and have the potential to unlock many opportunities within the drug development lifecycle. The NDE Sub-team has developed an NDE opinion paper that 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. **Coming soon!**

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:

Attend the 3-Part Webinar Series with DiMe, TransCelerate and CTTI

- ✔ Part 1: Digital Endpoints Webinar hosted by DiMe
- ❑ 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)
- ❑ Part 3: CTTI hosted Webinar (date TBD in October)

Enroll in DIA Short Course

DIA Digital Technology in Clinical Trials

Date: 9am - 1pm ET on October 21st, 2021.

Speaker: Michelle Crouthamel, Jennifer Goldsack, and Lindsay Kehoe

Registration: Conference website

CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

Aug 2, 2021

CTTI Resources & Insights to Support the Use of Novel Endpoints

Lindsay Kehoe, CTTI Project Manager

CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

Multi-stakeholder,
public-private partnership
co-founded by Duke University & FDA

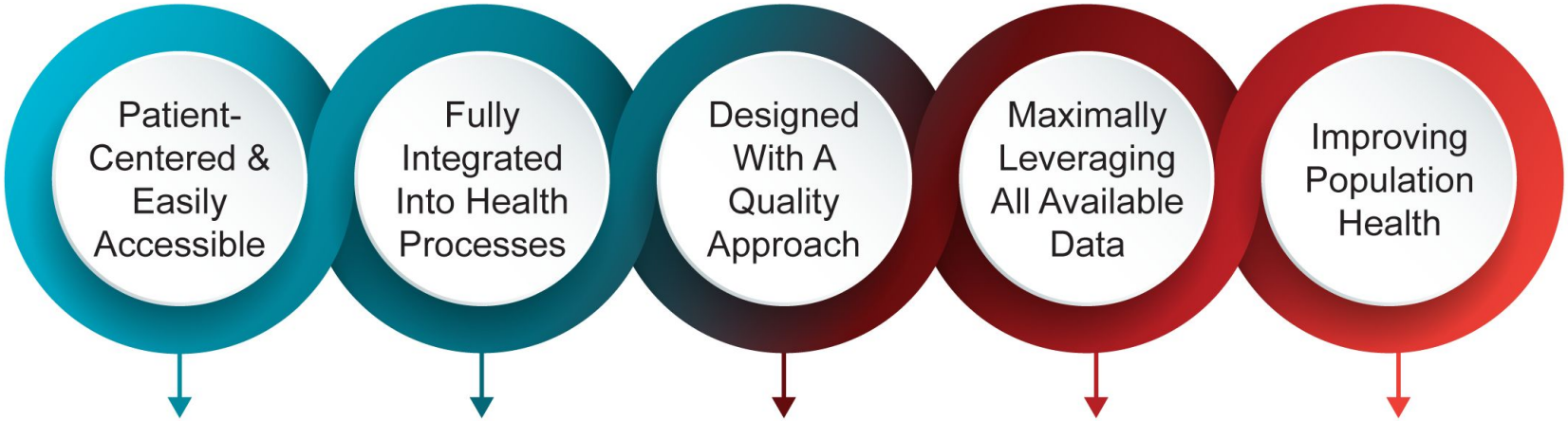
Participation of 500+ more orgs and ±80 member organizations

MISSION: To develop and drive adoption of practices that will increase the quality and efficiency of clinical trials

CTTI

TRANSFORMING TRIALS 2030

By 2030, clinical trials need to be:



A critical part of the Evidence Generating System

CTTI

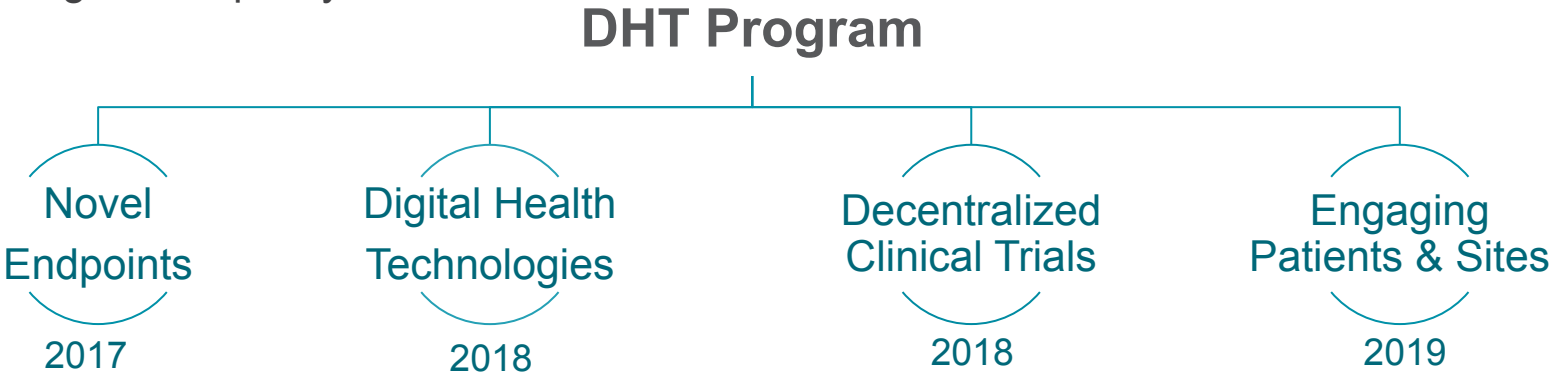
CTTI's Digital Health Trials (DHT) Program*

- **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.



Formerly CTTI's Mobile Clinical Trials (MCT) Program

CTTI

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

CTTI

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

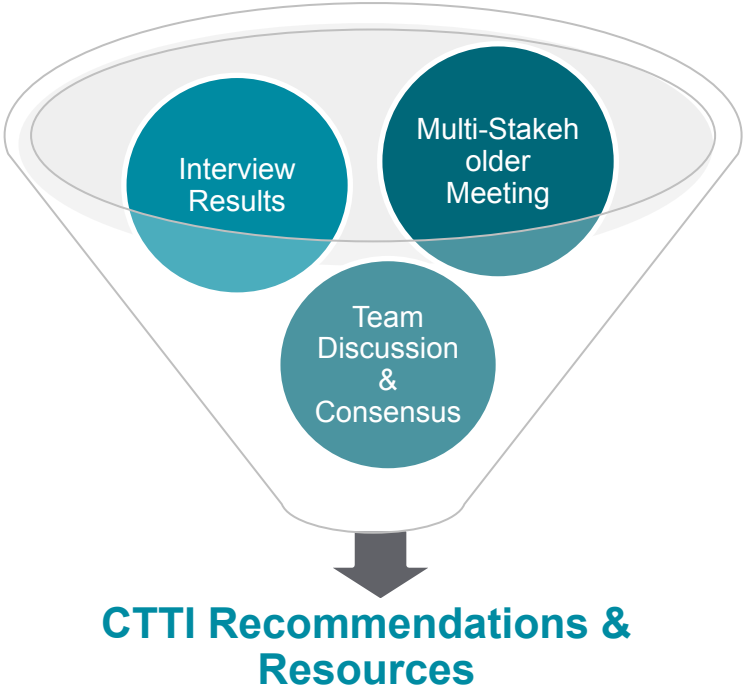
Project Scope & Deliverables

IN SCOPE

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

OUT OF SCOPE

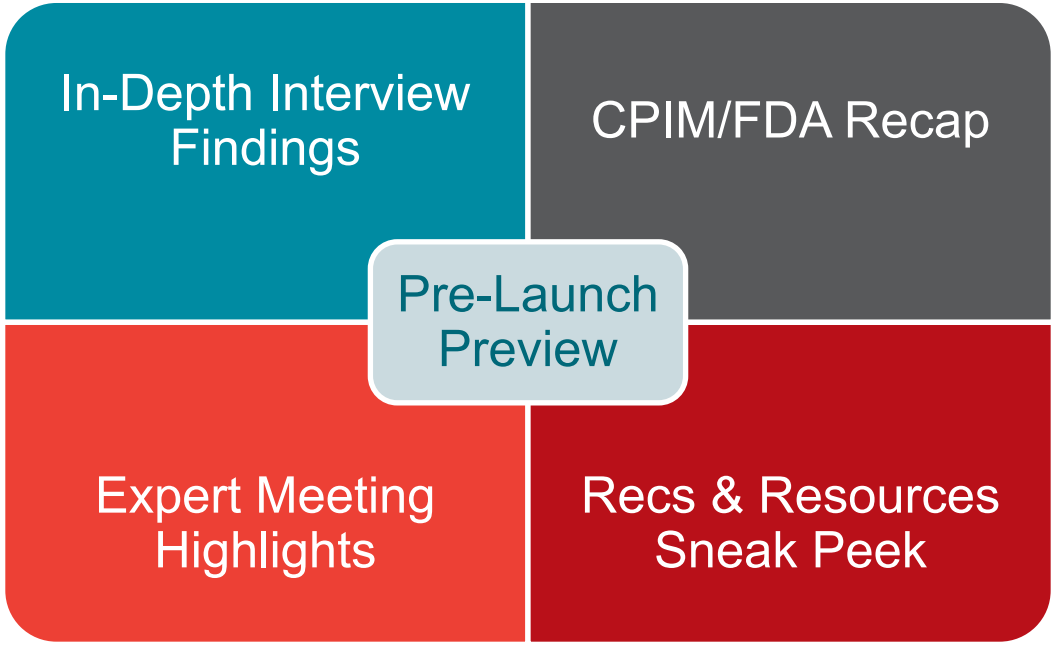
- Surveys (ePROs)
- Digital therapeutics
- Biomarkers



*Per FDA/NIH's BEST glossary, a clinical outcome describes or reflects how an individual feels, functions or survives.

CTTI

Developing Novel Digital Endpoints Webinar Series: CTTI October Webinar *(week of Oct. 4 TBD)*



Registration Link is Forthcoming – Stay Tuned!

CTTI

CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

@CTTI_Trials

Lindsay Kehoe, CTTI Project Manager

THANK YOU

www.ctti-clinicaltrials.org

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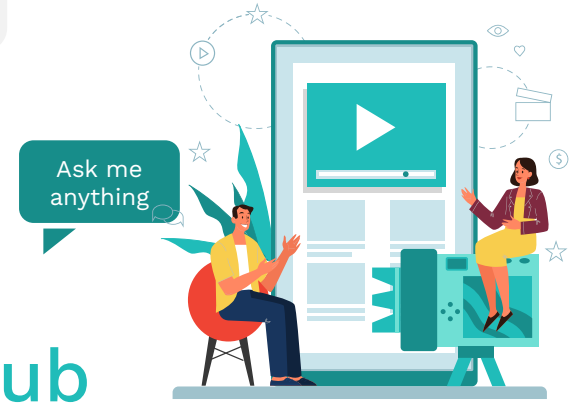

Virtual Journal club

Statistical considerations for successful digital health innovation

August 26th, 2021
1p ET

Eric Daza, DrPH, MPS

Lead statistician, digital health outcomes
Evidation Health

DIGITAL MEDICINE SOCIETY

Patient Engagement & Activation for Better Adherence Using Digital Platforms

Wednesday, September 15, 2021
12-1pm ET

Susan Baumgartner, PharmD, MBA
VP, Clinical & Regulatory Affairs
etectRx

Hima Kher, MBA
IT Senior Director
Janssen

Carlo Lopez, BSN, RN
Expert Patient, Registered Nurse
@ogcancerpatient

Edward Greeno, MD
Professor of Medicine
University of Minnesota MHealth

Kelly Brassil, PhD, RN
Director, Research & RWE
Pack Health

THANK YOU

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