Transforming Alzheimer's Disease and Related Dementia Research: New Core Digital Clinical Measures

WEBINAR

Thursday, November 14

11 am - 12 pm ET

RECORDINGS POSTED HERE

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Digital Health Measurement Collaborative Community

by DiME

ALZHEIMER'S DISEASE
& RELATED DEMENTIAS

Digital Measures Development

Agenda

- **Welcome and background of project**

- Opening remarks

- Fireside chat: Supporting patients and care partners with Digital Measures of ADRD

- Overview of research conducted, core measures & resources

- Panel discussion - Why digital measurement makes a clinical difference

- Panel Discussion - The use of technology in ADRD clinical research

- Panel discussion - The importance of the out of lab ADRD assessment

- Closing remarks

But first, housekeeping

⇨ **Today's session is being recorded.**

- Slides and recording will be available on <u>DiMe's webinar page</u> after the session

⇨ **Type your question** into the chat box for discussion during live Q&A.

⇨ **Participants are not permitted to transcribe this webinar**. Violators will be removed from the session

DiMe convenes stakeholders to take action to fix the problems in our complex field

HEALTHCARE

TECHNOLOGY

OUR MISSION:

To advance the safe, effective, and equitable use of digital approaches to **redefine healthcare** and **improve lives**

OUR VISION:

Better health powered by digital innovation

ALZHEIMER'S DISEASE & RELATED DEMENTIAS

Digital Measures Development

Identifying Patient Specified Digital Measures in Alzheimer's Disease and Related Dementias

Project Partners
- abbvie
- Alzheimer's Drug Discovery Foundation
- Biogen
- BOSTON UNIVERSITY
- Cognito Therapeutics
- Eisai
- Lilly
- LUCA
- MERCK
- OREGON HEALTH & SCIENCE UNIVERSITY (OHSU)

Digital Solutions Collaborators
- altoida
- Aural Analytics
- BioSensics
- CAMBRIDGE COGNITION
- Cogniant
- Cogstate
- Cumulus
- ki elements
- koneksa
- MEDIDATA
- LINUS HEALTH
- SageBionetworks
- vivosense
- WINTERLIGHT

Also funded by Roche

ALZHEIMER'S DISEASE
& RELATED DEMENTIAS

Digital Measures Development

*We conducted **worldwide** primary and secondary research across the whole ADRD spectrum*

A systematic literature review

2,020 Articles recovered from the literature screened down to **24**

10 Symptom Groups
6 Impact Groups

An international study

1007 Participants with clinical diagnosis

6 Countries, **14** sites

Patient, Care Partner and Physician perspective

A library of available technology

84 different technologies

125 pieces of evidence

All used by **A Delphi Panel of 20 Experts** over **3 rounds** of review

SYMPTOMS

Cognitive

Communication & language

- Difficulty following conversation
- Trouble finding words
- Reduced speech content
- Reduced talking bouts
- Question repetition

Memory & forgetting

- Trouble remembering names
- Forgetting meals
- Forgetting object placement
- Object misplacement
- Short-term memory formation
- Trouble remembering destinations & directions
- Long-term memory abolition

Concentration & clear thinking

- Confusion

Planning and organizing

- Problems organizing daily life

Orientation/awareness of day/time/people

- Thinking the present is the past
- Looking for people who are gone

Neuropsychiatric & Behavioral

Sleep behavior & disturbance

- Sleeping during the day
- Nightmares
- Tiredness due to lack of sleep
- Sleeping more
- Waking in the night
- Change in sleep routine
- Not being able to get to sleep

Neuropsychiatric

- Anger & aggression
- Agitation
- Apathy
- Mood change
- Frustration
- Depression
- General anxiety

Behavioral

- Wandering

Physical

Physical symptoms

- Decline in physical strength
- Swallowing
- Weight loss

Physical functioning

- Unsteadiness & falls
- Stiffness & slowness
- Worsening gait
- Reduced mobility

IMPACTS

Activities of daily living

- Cleaning
- Cooking
- Nutrition & appetite
- Danger related to forgetting
- Forgetting how to conduct specific tasks
- Loss of driving ability
- Remembering to take medication on time

Independence

- Independence in choosing to do activities
- Reliance on others
- Organizing daily life
- Toileting
- Self hygiene
- Dressing
- Loss of travel independence

Emotional

- Anxiety about disease progression
- Anxiety about reliance on others
- Anxiety about moving to care situations
- Feelings of being a burden
- Sadness about condition

Social/leisure/relationship

- Loneliness
- Withdrawing from conversation
- Less interest in hobbies
- Increasing isolation from friends & family
- Reduced interest in social situations
- Withdrawing from social groups due to impact of cognition issues
- Arguing

Work

- Initial reduced ability to work
- Having to stop work
- Not accepting mistakes at work

Carepartner

- Loneliness
- Change in/loss of relationship
- Reduced/lack of free time
- Carepartner sleep disruption
- Impact on carepartner's capacity to work

Our mixed methods study showed alignment between people with ADRD, their care partners and physicians

The study presented areas from the systematic review and asked participants which aspects they would like to see improve and not worsen

- Performing activities of daily life
- Living life independently
- Communication

- Performing activities of daily life
- Emotions
- Communication

- Essential bodily function
- Living life independently
- Communication

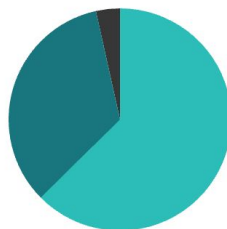*"I hope she remembers where her things are."*

"The words would come easily and I wouldn't have to get out of awkward situations."

"I worry when I can't sleep I lie down and can't sleep, I get worried I often wake up at night."

"If my mobility were to worsen, I may become a further fall risk, and I wouldn't be able to enjoy all of the rooms of my home. I would simply sit on the couch and wait for my bedtime."

Snapshot of **ALZHEIMER'S DISEASE** & RELATED DEMENTIAS

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by **DiME**

84 Identified technologies

125 Pieces of evidence... *so far. It's still growing!*

Technology types

63% ambient or non-wearable

34% wearables

3% both

Using V3⁺

Verification: **1** technology

Usability validation: **13** technologies

Analytical validation: **57** technologies

Clinical validation: **83** technologies

Top 3
Health concept areas

- **Neurocognition**
- **Physical activity**
- **Sleep**

Top 3
Technology form factors

- **Smartphone/tablet**
- **Strap/brace**
- **Watch or wristband**

Top 3
Locations for wearables
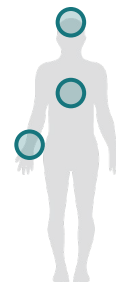
- Wrist
- Chest/torso/waist/trunk
- Head/scalp

Delphi Panel

We conducted 1:1 interviews with our ADRD partner experts using the generated evidence

Partners had to select and justify areas of measurement based on:

- Maturity for digital measurement

- Explainability of the measure and its importance

- Patient and care partner relevance

- Clinical relevance relevance

- ADRD spectrum coverage

ALZHEIMER'S DISEASE
& RELATED DEMENTIAS

Digital Measures Development

Visuospatial Memory
Remembering where things are

Expressive Communication
Speech fluency and word finding
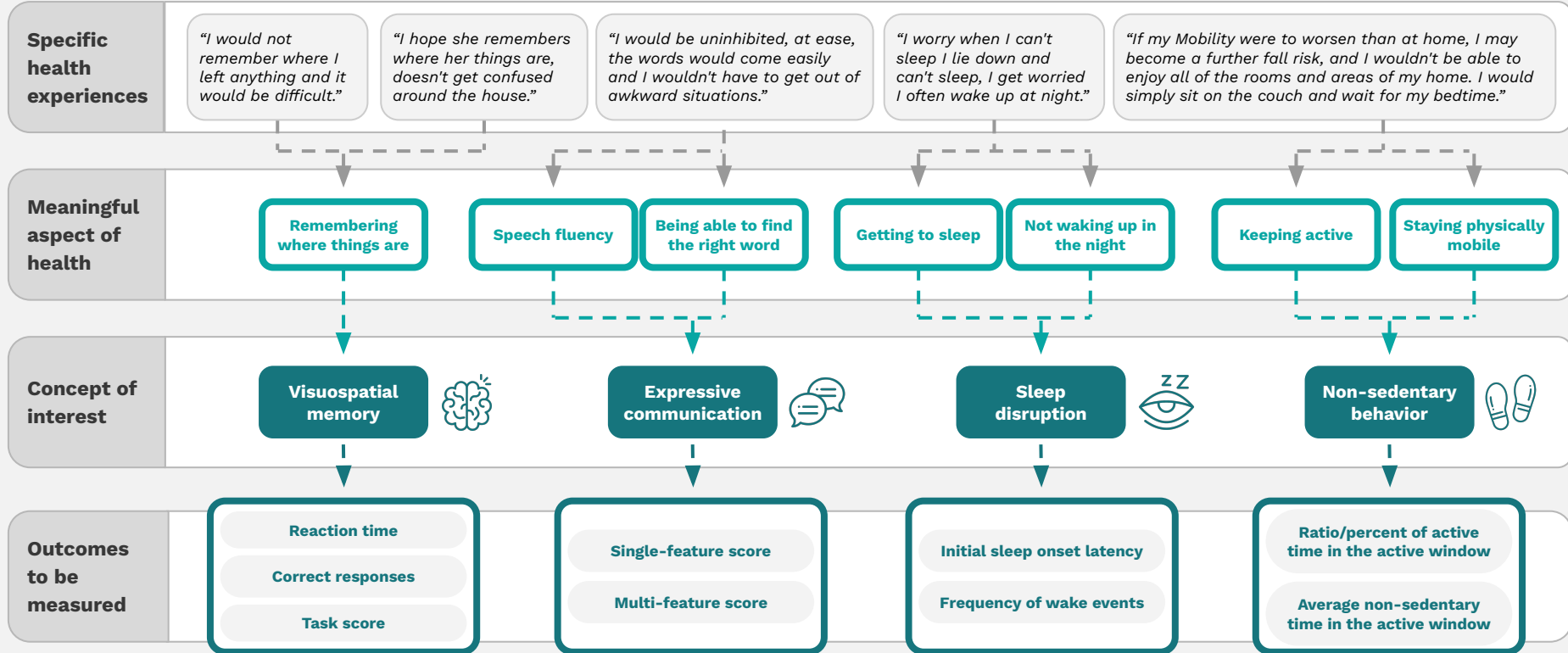
Sleep Disturbance
Getting to sleep and staying asleep

Non-sedentary Behaviour
Keeping active, staying mobile

Core Digital Measures of ADRD conceptual model

Specific health experiences

"I would not remember where I left anything and it would be difficult."

"I hope she remembers where her things are, doesn't get confused around the house."

"I would be uninhibited, at ease, the words would come easily and I wouldn't have to get out of awkward situations."

"I worry when I can't sleep I lie down and can't sleep, I get worried I often wake up at night."

"If my Mobility were to worsen than at home, I may become a further fall risk, and I wouldn't be able to enjoy all of the rooms and areas of my home. I would simply sit on the couch and wait for my bedtime."

Meaningful aspect of health

Remembering where things are

Speech fluency

Being able to find the right word

Getting to sleep

Not waking up in the night

Keeping active

Staying physically mobile

Concept of interest

Visuospatial memory

Expressive communication

Sleep disruption

Non-sedentary behavior

Outcomes to be measured

Reaction time

Correct responses

Task score

Single-feature score

Multi-feature score

Initial sleep onset latency

Frequency of wake events

Ratio/percent of active time in the active window

Average non-sedentary time in the active window

Examples of measurement approaches

Augmented reality (AR)-based place and find, visuospatial paired associate learning

Picture description task, structured word finding

Actigraphy-based sleep measurement, at-home electroencephalogram (EEG)

Actigraphy-based activity measurement

ALZHEIMER'S DISEASE & RELATED DEMENTIAS

Digital Measures Development

We have developed resources to help you implement the core measures in your work

Select and Evidence

Use the library of digital measurement product to find evidence for digital health technologies available today

Interrogate and Support

Access our mixed methods study data and re-analyse it to your specific needs

Plan and Report

Download our discussion guides, conceptual model and template text to help you describe the background and implementation of the core measures in your work

Transforming Alzheimer's Disease and Related Dementia Research: New Core Digital Clinical Measures

Fireside chat
Supporting patients and care partners with Digital Measures of ADRD

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Colleen Llasca
Care Partner

Isaac O'Neal
Care Partner

Transforming Alzheimer's Disease and Related Dementia Research: New Core Digital Clinical Measures

Panel discussion - Why digital measurement makes a clinical difference

Alexandra König
Head of Clinical Research
ki:elements

Ann Marie Hake
Executive Director
Eli Lilly and Company

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Panel discussion - The importance of the out of lab ADRD assessment

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Brian Murphy
Chief Scientific Founder
Cumulus Neuroscience Ltd

Christopher James Edgar
Executive Scientific Advisor
Cogstate

Emmanuel Streel
Sr. Medical Affairs Director
Altoida, Inc.

Ricardo Sainz Fuertes
Global Director Digital Health Solutions
Eisai

Transforming Alzheimer's Disease and Related Dementia Research: New Core Digital Clinical Measures

Panel discussion - The use of technology in ADRD clinical research

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Anindita Saha
Associate Director for Strategic Initiatives, Digital Health Center of Excellence
FDA

Alexandra S. Atkins
Senior Director, Clinical Research, Neurodegeneration
Eli Lilly and Company

New resources launch on December 10!

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Validating
Novel Digital
Clinical Measures

Join us to learn more about the framework and simulation toolkit and how they can support your work in validating and developing novel digital clinical measures.

Free DiMe webinar
Tuesday
December 10
11 a.m. ET
Scan to register

PEDIATRIC RARE DISEASE

Digital Measures Development

Join us defining a core digital measures set for **pediatric rare disease** to accelerate research and transform care

Driving Market Access *for*
Diabetes Management

Unlocking market access for diabetes management with sensor-based health data solutions

Join us

Transforming Alzheimer's Disease and Related Dementia Research: New Core Digital Clinical Measures

Closing remarks

Jennifer Goldsack
CEO
Digital Medicine Society (DiMe)

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