

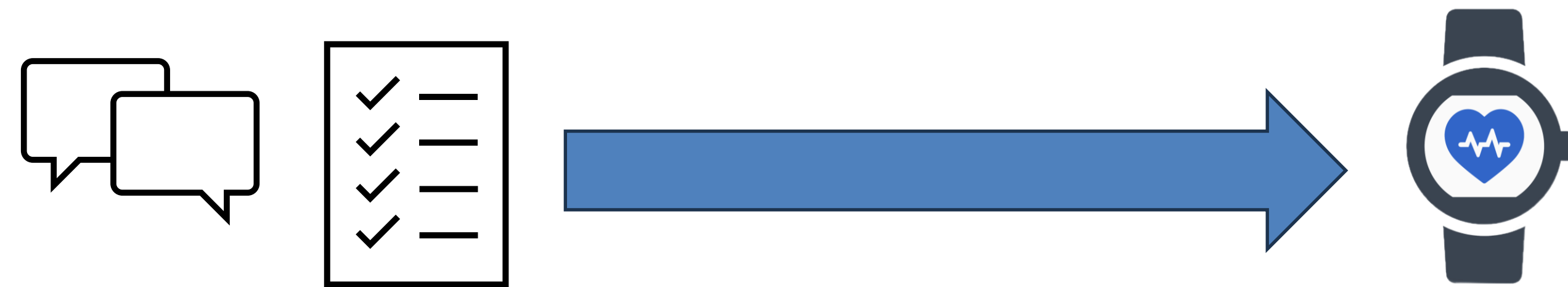
Advancing Alzheimer's Disease Research with Patient-Centric Digital Endpoints of Function

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LIMITATIONS OF CURRENT ASSESSMENTS OF FUNCTION

Current approaches to assess functioning in AD are captured episodically, burdensome to patients, and fail to capture the complex challenges that patients must navigate daily.

Digital health technologies have the potential to advance the way function is assessed in Alzheimer's Disease clinical trials

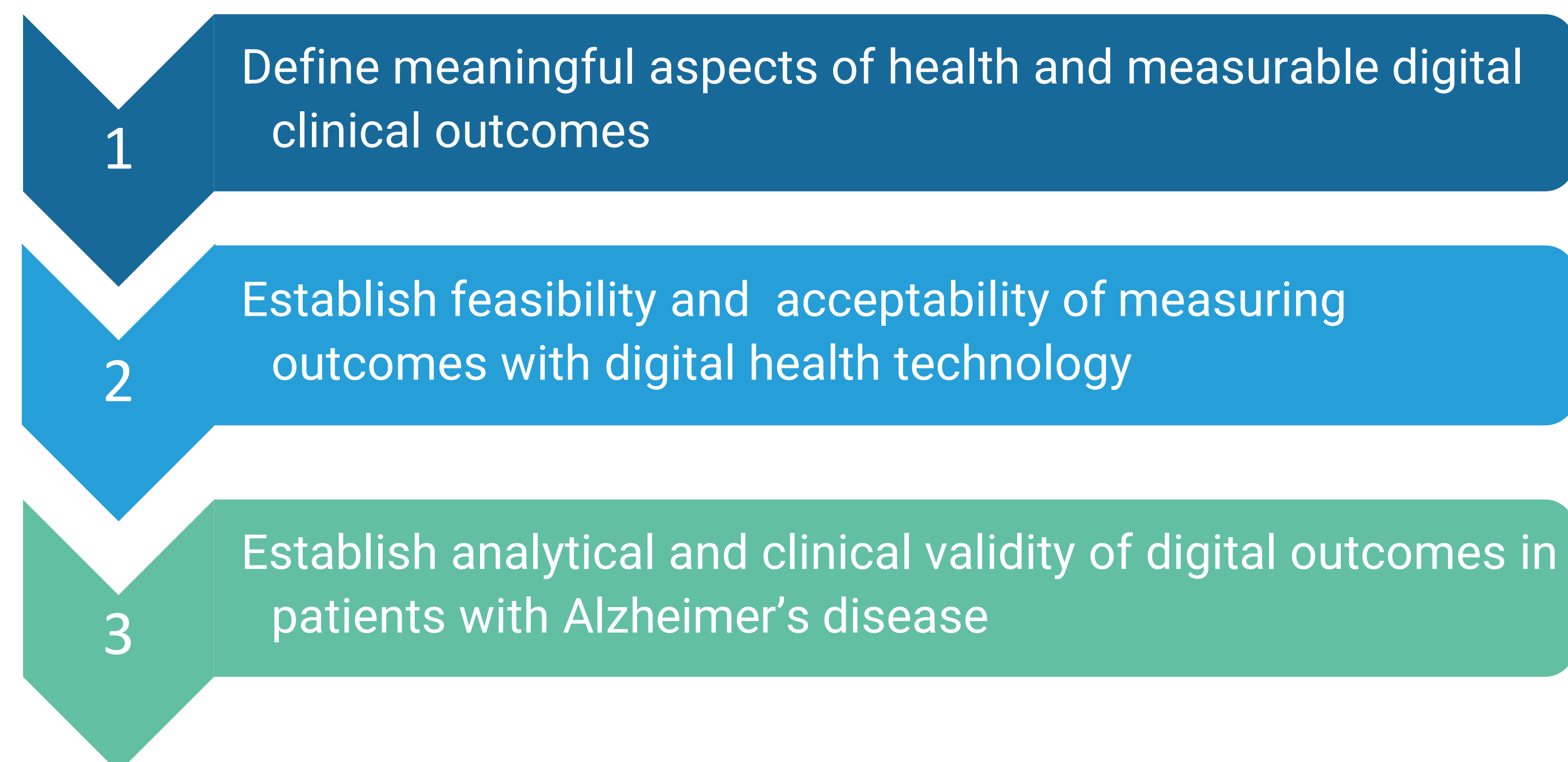


Regarding walking (or getting around in a wheelchair) in the past 4 weeks which best describes his/her optimal performance

Item from ADCS ADL inventory (Galasko et al., 1997)

Continuous assessments of physical behaviors (e.g., total steps, time in prolonged walking bouts, sedentary time) in real-world environments

DEVELOPING PATIENT-CENTRIC DIGITAL ENDPOINTS



PURPOSE OF STUDY

Understand patient perspectives on how AD impacts their daily life and function

identify the meaningful aspects of health that are measurable with low-burden wearable actigraphy sensors

METHODS

Participants: 16 older adults (≥ 65 years) with self-reported mild (n=8) and moderate (n=8) Alzheimer's disease

Study design: Individual informational interviews will be conducted using an interview guide to explore the impact of AD on daily routines, ability to function independently, and measurable concepts related to functioning.

Qualitative analysis: Transcripts will be coded using an inductive approach (ATLAS.ti 23) to identify themes reflecting patients' experiences with AD and ability to function independently.

INTERVIEW GUIDE	
Topics of Interest	Example Question(s)
Overall disease experience	Can you tell us a little bit about your experiences on a day-to-day basis? What types of activities do you do during a typical day? How does your Alzheimer's Disease impact your daily routine?
Most burdensome aspects of disease	What are two or three things in your life that have been impacted by Alzheimer's Disease that bother you <u>the most</u> ? What aspects of your life, if any, are you most worried about being impacted in the future?
Impacts of disease on independence	What activities or things, if any, are you concerned you won't be able to do independently or at all in the future?
Ideal treatment outcomes	What treatment outcomes are most important to you? If a new treatment or therapy was being tested, how do you think we could best measure [insert treatment outcome expressed as important to patient]?
Technology feasibility and receptivity	If asked, would you be willing to wear a smart watch everyday throughout a clinical trial? Why or why not?

PRELIMINARY DATA

Data collection for this study is ongoing. To date, 4 men with mild AD (75 ± 8 years [mean \pm SD]) have completed the study. Most patients are retired (n=3) and 1 reported working full time. Caregivers were present during 2 of the 4 interviews.

Because of the small sample size, formal thematic analyses were not performed.

General observations

- Primary focus on impacts of memory and forgetfulness

"It's really hard sometimes, knowing how it impacts me. I know that I have a tendency to forget things...It is tricky because you're asking me to remember things, and that's part of my problem, is remembering things."

"On a normal daily routine, I usually have to ask him to do his toiletries, to change the clothes if he's worn them more than a day or two. Just daily things, I have to remind him."

- Aspects of physical function that are most important to patients with mild AD relate to leisure time physical activities

"For me, physical functioning means skiing, means running, means calisthenics. Means all of those outdoor-type exercise activities that I do"

CONSIDERATIONS IN AD AND VALUE OF THE PATIENT VOICE

- Memory impairments in patients with AD can add unique challenges to generating qualitative data highlighting the importance of incorporating perspectives from all key stakeholder
- Patient experience data is vital to ensure that novel endpoints are patient centric and capture meaningful aspects of life that are impacted by disease and is a critical first step for therapeutic development.