







# Non-sedentary behavior discussion guide



# Keeping active, staying mobile

This discussion guide is written to support you in the development and use of the core digital measures of ADRD, while presenting the importance and benefits of employing these measures in research and practice. It also offers considerations that should be assessed when employing a measure in different contexts.

# Patient and care partner relevance

- Staying active was mentioned by patients and care partners as important. The qualitative data associated with the free text responses in the global mixed methods survey showed that worsening of mobility would severely impact the lives of both the person with ADRD and the care partner.
- In the quantitative and qualitative responses to the survey, being unable to get up and get around was flagged as important. As such, the percentage of time spent active was selected as a measure to capture the decline in mobility.
  - The amount of non-sedentary behavior that occurs in the most active window is one measure, but average sitting time or sitting frequency in this window can also be examined where this is measurable by the technology employed.
- Sitting frequency may be an interesting measure in this population, but could be difficult to measure with wrist-worn accelerometers It may be able to be estimated through smartphones and other equipment.
- When selecting technology to measure the mobility of patients, it is important to consider the sensor placement (wrist, back, waist, etc.). Depending on the stage of ADRD, patients may not be comfortable using wearable technology. Ambient sensors can be a potential alternative in this population. See V3+ resources to help determine usability of technology.

#### Use in clinical research as a clinical outcomes assessment endpoint measure

- Other measures may also be important in this area. For example, number of
  walking bouts and postural sway could be indicators of reduced mobility capacity.
  Detailed descriptions of these measures are available in the <u>DiMe Core Digital</u>
  <u>Measures of Physical Activity</u>. This work can help the user choose, specify and
  understand the parameters they may need.
  - One reason for the inclusion of postural sway as a potential metric is that it has been shown to be sensitive at the earliest stages of ADRD. It is a predictor of fall risk.



 Depending on the specific diagnosis, the stage of disease, and the potential therapeutic profile of a compound under investigation, different metrics may be more or less relevant for measurement. For example, small changes in non-sedentary behavior may be more relevant at the earlier stages of the disease, whereas gait parameters may be more important later in the disease course.

# Use in clinical research as a digital biomarker

- While measuring activity as outlined in this ontology, other metrics could be collected depending on the capabilities of the selected technology.
  - These additional metrics could be used in early decision-making. For example, using parameters of postural sway or gait that predict fall risk could help to inform efficacy and go/no-go decisions in early phase trials.
  - Identifying predictors of falls is likely to be advantageous because falls themselves are a rare event requiring long study designs and large sample sizes.
  - The movement patterns that precede falls can offer information regarding the likelihood of impacting fall behavior, for study and confirmation in later, larger trials, or in real-world evidence-based studies.

# Use in clinical practice

- The measurement employed in clinical practice will depend on the presentation of the patient. In the earliest stages of ADRD, when the patient presents as pre-clinical or with mild cognitive impairment (MCI), measurement of percent time active in the activity window will allow the clinician to track the disease and offer behavioral interventions to help the individual retain and improve quality of life through staying active.
  - In later stages, measures such as postural sway from the <u>DATAcc</u> by <u>DiMe's Core</u>
     <u>Digital Measures of Physical Activity</u> may help to detect patients who are at risk
     of suffering a fall and intervene with, for example, assistive devices.

# Importance of metadata

- Metadata can be collected to help interpret the results of this measure. This can
  include individual factors (height, age, BMI, use of assistive devices, amount or
  quality of sleep, etc.), environmental factors (location, indoor vs. outdoor, home vs.
  away from home, local weather conditions or season, etc.), baseline health status,
  comorbidities, wear location, and weekday of measurement.
  - In research, metadata should be selected and used as covariates in analyses to control for these factors.
  - In clinical practice, taking these factors into account can help the clinician appraise the patient's behavior score and score trajectory.
- Other important metadata to consider in research include technology type and model and software versioning.



• These elements can impact the results of the task, particularly if they vary between individuals or within-individual over time.