DEFINING CONTEXT OF USE AND CHALLENGES TO DEPLOYING WEARABLES AND DIGITAL TECHNOLOGIES IN CLINICAL TRIALS

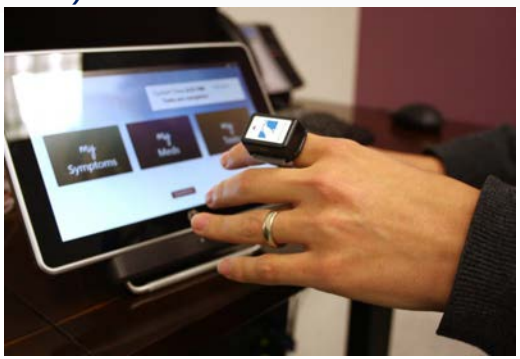
Jesse M. Cedarbaum MD
VP, Neurology Early Clinical Development
Biogen

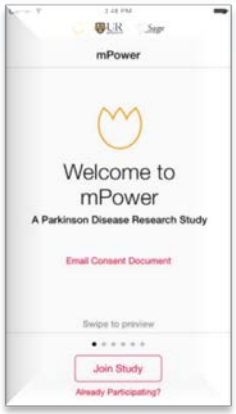
The views expressed in this presentation are my own and do not reflect policies or practices of Biogen

Potential use of Objective Measurement Systems(OMS) as biomarkers in clinical development

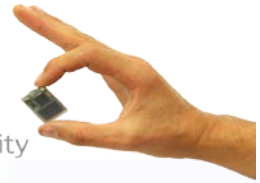
Technology, when used appropriately, has the potential to function as a biomarker to:

- Help with stratification and enrichment of patient population
- Provide a more sensitive and objective outcome measure with higher data density (higher power, smaller n)

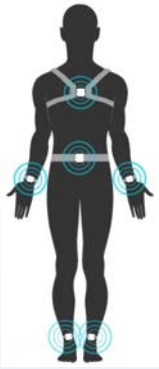




mcroberts



APDM movement monitoring solutions



Aim: Faster, more efficient clinical development programs with higher probability of success

Biogen

Defining Context of Use for Data-Gathering Devices in Clinical Trials – Acceptance Criteria (1)

- **Technical feasibility**
  - User acceptance
    - Intuitive interface
    - Comfort/wearability
    - Patient safety
    - Ability to be used by subjects with physical and/or sensory impairments
    - Technical support available to sites 24/7
  - Accessibility of raw data to sponsors
  - Ease of interface of device database with sponsor data systems

- **Mechanical and computational reliability of the device**

- **Transparency of the measurement method** (preferably no complicated, proprietary “algorithms” on the back end that cannot be independently validated; if such algorithms are used, sponsor should have access to them to aid understanding and to support regulatory submissions)

Defining Context of Use for Data-Gathering Devices in Clinical Trials – Acceptance Criteria (2)

- **Demonstrated satisfactory clinimetric properties in the indication to be studied:**
  - o Test-retest reliability
  - o Inter-and intra-rater (user) reliability
  - o Sensitivity to change
    - Over time
    - Intervention-related
  - o Content and Construct validity
    - Correlation with conventional clinical measures OR demonstrated ability to measure a COI not picked up by traditional scales
    - Available database of normal healthy volunteer data over the full age spectrum, as well as an adequate number of disease subjects to enable assessment of Construct/Content validity
- **At least partial Part 11 compliance** – especially around ability to de-identify patient PHI and availability of a clear audit trial
- **Data easily formatted to meet CDISC standards**
- **Clear understanding of gaps and the path forward to plugging them.**