NIH & NINDS

The National Institutes of Health (NIH) National Institute of Neurological Disorders and Stroke (NINDS) mission is to seek fundamental knowledge about the brain and nervous system and to use that knowledge to reduce the burden of neurological disease for all people.

The Problem

- In 2021 the NINDS convened a working group to revise and develop Common Data Elements (CDEs)[1] for Parkinson's Disease (PD) research. The Digital Technology Subgroup sought to recommend best practices for:
  1. Choice of connected sensor technology for digital health outcome measures for clinical research on PD
  2. Guidance for digital data sharing for clinical trials on PD
- To evaluate the end-to-end validity and reproducibility of digital measurement products, the working group required a framework.

The Resource

- The working group, which released Best Practices for Digital Health Outcomes in 2022, noted that "whether used as primary, secondary, or exploratory outcomes, digital health outcomes from connected sensor technology should include **evidence of technical verification, analytical validation, and clinical validation for their particular research purpose**," as specified by DiMe's V3 framework.
- Authors use the V3 framework as a blueprint for the "Validation of Digital Medical Products" section of the report to establish how future PD studies using digital technologies should validate measurement products.

The Impact

- The adoption of V3 framework as recommended by the working group will **enable more accurate and reliable outcomes for PD** (as compared to clinical trials) and ensure researchers are using the same standards as technologies continue to advance.
- The working group's recommendation to use V3 also shows the **importance of broadly adopting this framework.**

[1] Per NIH National Library of Medicine, "Common Data Elements (CDEs) are standardized, precisely defined questions paired with a set of specific allowable responses, used systematically across different sites, studies, or clinical trials to ensure consistent data collection."