EVIDENCE Checklist

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
- The group outlined the need for "Investigators using new technologies to collect data for clinical trials, need to provide evidence that these unvetted devices have the **accuracy, reliability,** and **sensitivity** to PD needed so that other studies can reproduce their results." And, the subsequent **need for standardized reporting on outcomes** using such devices.

The Resource

- The working group, which released Best Practices for Digital Health Outcomes in 2022, included a summary from the EVIDENCE Checklist in their recommendations and noted that **all studies** using digital health outcomes should ***at least*** **report items noted on the checklist**.

The Impact

The inclusion of the EVIDENCE Checklist in the working group's best practices:

- ✓ Establishes it as a **foundational checklist** to evaluate the usefulness of a digital measurement product.
- ✓ Shows how the DiMe resource is **an essential step** to effectively evaluate and compare the use of digital measurement tools across trials.

[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."