

NIH & NINDS

The <u>National Institutes of Health</u> (NIH) <u>National Institute of Neurological</u> <u>Disorders and Stroke</u> (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.



- » In 2021 the NINDS convened a <u>working group</u> to revise and develop <u>Common Data Elements</u> (CDEs)¹ for Parkinson's Disease (PD) research.
- >> The Digital Technology Subgroup sought to recommend best practices for:
 - Choice of connected sensor technology for digital health outcome measures for clinical research on PD
 - 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 <u>Best Practices</u> for <u>Digital Health Outcomes</u> in 2022, included a summary from the <u>EVIDENCE Checklist</u> 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.