

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.

Important recommendations have recently been published regarding the types of evidentiary evaluations to make when considering digital technologies for interventional clinical trials ([such as from] the Digital Medicine Society).

— **Digital Technology Subgroup,**
Best Practices for Digital Health Outcomes,
Version 2.0 Parkinson's Disease CDE



The Opportunity

- » There has been a limited uptake in digital measures in Parkinson's Disease (PD) research in part due to a lack of consensus.
- » In 2021 the NINDS convened a [working group](#) to revise and develop [Common Data Elements](#) (CDEs)¹ for 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 Impact

- » The DiMe resources provide the PD field with standardized best practices leveraged in other therapeutic areas, helping to **harmonize data collection** in PD research, enabling **comparison across trials** and encouraging **safer and more sophisticated use of digital tools**.
- » This use of DiMe resources shows how DiMe is helping to **inform approaches to digital data standardization and sharing**.



The Resources

- » The [working group](#), which released [Best Practices for Digital Health Outcomes](#) in 2022, leveraged several DiMe resources, including [Digital Measures that Matter to Patients, V3](#), [EVIDENCE Checklist](#), and [The Playbook: Digital Clinical Measures](#).
- » Authors incorporated these DiMe resources in their recommendations to develop new, **standardized best practices** for improved digital measurement in PD research.

[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.”