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 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.

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 Resources

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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.

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

[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.”