

Guidance for Digital Data Sharing

GOALS

The goals of this subgroup are to recommend: 1) Best Practices for choice of connected sensor technology (digital health/mobile technology) outcome measures for clinical research on Parkinson's Disease (PD) and 2) Guidance for digital data sharing for clinical trials on PD. Connected sensor technologies use sensors, computing platforms, connectivity, and algorithms to measure clinical signs, behaviors, and events for clinical research. Outcomes generated by connected sensor technologies in this report include measures derived from prescribed activities/tests (e.g., PD signs during the UPDRS III or gait disorders from a 6-minute walk test) or unprescribed health behaviors during activities of daily living (e.g., PD signs, gait, sleep, activity, etc.). These Practices and Guidance do not include electronically-collected, patient-reported outcomes about self-perceived feelings, observations, judgements (e.g., quality of life, medication or sleep diaries, etc.), or clinician-reported outcomes about signs and symptoms (clinical rating scales, etc.) that do not rely upon sensors for data generation.

Digital health data sharing should include information about:

- 1) Subject Demographics and Study Design
- 2) Parkinson's Disease
- 3) Technology
- 4) Environment/Context

Raw data, as well calculated outcomes, should be uploaded to the server, if possible. Contact information of investigators should be included. The following summarizes the type of metadata, technology and environment information that should be included when uploading Digital Health Data to a database.

SUBJECT DEMOGRAPHICS AND STUDY DESIGN

Guidance for subject demographics (age, sex, race, etc.) and study design/purpose are the same for all NINDS CDE projects:

<https://www.commondataelements.ninds.nih.gov/General%20%28For%20all%20diseases%29>

PARKINSON'S DISEASE

- Guidance for PD are in detail elsewhere
- Diagnosis criteria and severity grade (Hoehn and Yahr and/or MDS-UPDRS)
- Time of digital health data collection since anti-Parkinson medication
- Levodopa equivalent dose and On and/or Off state

TECHNOLOGY

- Intended use of technology (e.g., diagnosis, prognosis, progression, monitoring/treatment effects)
- Type of device(s) (e.g., accelerometer, gyroscope, magnetometer, touch screen, etc. with manufacturers name)
- Location of device (e.g., where on body or home, sensors x-y-z orientation)
- Sampling frequency and filters
- Synchronization among sensors (if relevant)
- Sampling methods (passive, active tasks, etc.)
- Description of novel algorithms with publications, if available

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- Raw data and processed, primary outcome measures

ENVIRONMENT/CONTEXT

- Instructions to subjects about behavior and how to use the technology (e.g., prescribed tasks, passive monitoring in daily living, etc.)
- Locations of technologies in community or home

DATA REPOSITORIES

1) PhysioNet (<https://physionet.org/>)

- Community resource for physiological data
 - Digital recording of physiologic signals
 - Cardiopulmonary, neural, and other
- Software “Physiotoolkit”
- Tutorials
- Support by National Institute of Biomedical Imaging and Bioengineering (NIBIB)

2) dHealth (<https://dhealth.synapse.org/>)

- Public resource of digital health data, tools, and associated publications
 - Directly focused on digital health
 - 29% of data is from Parkinson’s Disease (PD) patients
 - Will be repository for the National Institute on Aging’s (NIA) Mobile Toolbox
- Built on the same platform as several National Institutes of Health (NIH) data repositories (supported by NIA, National Cancer Institute (NCI), National Institute of Mental Health (NIMH), National Heart, Lung, and Blood Institute (NHLBI), National Institute of Neurological Disorders and Stroke (NINDS), etc.)

3) figshare (<https://figshare.com/>)

- Public resource including several types of physiological and non-physiological data
 - Does not only contain data but also preprints, figures, etc.
 - Large community of users
 - Tutorials
 - Difficult to identify relevant entries

DATA AND METADATA STANDARDS

1) Open mHealth (<https://opensource.ieee.org/omh/1752/-/tree/main>)

- Developed as part of IEEE P1752 Open Mobile Health Working Group
- Focuses on physical activity, mobility, and sleep
- JSON Schema

2) ResearchKit/ResearchStack (<https://github.com/Sage-Bionetworks/AssessmentModel-JsonSchema/tree/main/schemas>)

- JSON Schema

3) dHealth Metadata standards: <https://github.com/Sage-Bionetworks/digital-health-portal/blob/master/Digital%20Health%20Annotation%20Schema.csv>

- Links to existing ontologies
- JSON Schema