

Parkinson's Disease Version 2.0 NINDS CDE Project General and Motor Subgroup Summary

The General and Motor Subgroup for Parkinson's Disease (PD) Common Data Elements focused on the basic intake and descriptive Case Report Forms (General) needed for programs studying PD and the Motor Assessment Tools (Motor) regularly applied for assessing disease severity. The latter elements cover the rating measures for the cardinal features of PD (tremor, bradykinesia, rigidity and postural reflex compromise), and other scales examine the common drug-related and disease-related conditions of motor fluctuations and dyskinesia. Additionally, global assessment measures of severity and change complement the aforementioned materials. Recommendation ratings follow the assessment methodology and standards of the overall Common Data Elements program. In the case of the Unified Parkinson's Disease Rating Scale (UPDRS) and the Movement Disorder Society revision of the UPDRS, because of the different calibration of the rating categories, one is recommended for early and mild disease assessment (MDS-UPDRS) whereas the other is more recommended for advanced disease (UPDRS). All scales considered by this subgroup on local availability are readily available internationally. The ultimate goal is to have common data elements that can be utilized for observational and experimental treatment studies, administered in a standardized way and compared among different studies to examine generalizability and heterogeneity of PD severity and change over time or in response to treatments around the globe.

The subgroup determined that CRFs/instruments within the following subdomains were within their purview: Motor Severity; PD Definition; Global Assessments; Motor Complications: Fluctuations; Motor Complications: Dyskinesia; Demographics/Medication.

Each subgroup member volunteered to be the primary reviewer of CRFs/instruments within a specific subdomain as follows:

- Motor Severity (Christopher Goetz)
- PD Definition (Holly Shill)
- Global Assessments (Michael Schwarzschild)
- Motor Complications: Fluctuations (Piu (Bill) Chan)
- Motor Complications: Dyskinesia (Glenn Stebbins)
- Demographics/Medication (Tanya Simuni)

Each subgroup member was responsible for reviewing General and Motor CRFs/instruments recommended during the Parkinson's Disease v1.0 NINDS CDE Project, as well as recommending new CRFs/instruments within their assigned subdomain. Revisions were made to current CRFs and instrument Notice of Copyright (NOC) documents as necessary. Additionally, NOCs were developed for new instrument recommendations.

Each CRF/instrument recommended by the primary reviewer was discussed during a subgroup teleconference call where the content of the CRFs and NOCs were reviewed, and a vote was undertaken for CDE and instrument classifications.

In the case of the Unified Parkinson's Disease Rating Scale (UPDRS) and the Movement Disorder Society revision of the UPDRS, because of the different calibration of the rating categories, one is recommended for early and mild disease assessment (MDS-UPDRS), whereas the other is more recommended for

advanced disease (UPDRS). Otherwise, all CRF and instrument recommendations were not stratified by disease stage and prodromal PD CDEs were not considered.

Summary of Recommendations

Instrument/CRF Name	Subdomain	Classification
Abnormal Involuntary Movement Scale (AIMS)	Motor Function	Supplemental
Clinical Global Impression Scale-Improvement (CGI-I)	Motor Function	Supplemental – Highly Recommended
Clinical Global Impression Scale-Severity (CGI-S)	Motor Function	Supplemental
Core Assessment Program for Surgical Interventional Therapies in PD (CAPSIT-PD)	Motor Function	Supplemental – Highly Recommended
Hauser Motor Fluctuation Diary	Motor Function	Supplemental – Highly Recommended
Hoehn and Yahr Scale	Motor Function	Core
Movement Disorder Society Clinical Diagnostic Criteria for Parkinson's Disease	Motor Function	Supplemental – Highly Recommended
Movement Disorder Society - Unified Parkinson's Disease Rating Scale (MDS-UPDRS)	Motor Function	Core [select either MDS-UPDRS (for studies focused on all severities and especially on mild/moderate participants) or UPDRS (for studies focused preferentially on advanced PD participants)]
Rush Dyskinesia Rating Scale (RDRS)	Motor Function	Supplemental
Schwab and England Activities of Daily Living Scale	Motor Function	Supplemental – Highly Recommended
UK Parkinson's Disease Society Brain Bank Criteria for the Diagnosis of Parkinson's Disease	Motor Function	Supplemental
Unified Dyskinesia Scale (UDysRS)	Motor Function	Supplemental – Highly Recommended
Unified Parkinson's Disease Rating Scale (UPDRS)	Motor Function	Core [select either UPDRS (for studies focused preferentially on advanced PD participants or MDS-UPDRS (for studies focused on all severities and especially on mild/moderate participants)]
Wearing Off Questionnaire (WOQ)	Motor Function	Supplemental – Highly Recommended
Demographics	Demographics	All CDEs are classified as Core except for two Other specify data elements (Birth sex assigned type other specify; Gender identity type other specify)

Instrument/CRF Name	Subdomain	Classification
		which are classified as Supplemental and should only be collected if “Other, specify” is selected in the parent CDE
Medical History of Parkinson’s Disease	History of Disease/Injury Event	All CDEs are classified as Core except for three Other specify data elements (Dystonia symptom text; Other abnormality posture text; Ambulatory axial difficulty abnormal posture gait other text) which are classified as Supplemental and should only be collected if the parent CDE has been checked
Non-Parkinson’s Disease Medication Log	Drugs	All CDEs are classified as Supplemental
Parkinson’s Disease Medication Log	Drugs	All CDEs are classified as Supplemental – Highly Recommended

Comparison to other Parkinson’s disease standards: None identified, but readers can cross reference Rating Scale Reviews and Recommendations by the International Parkinson and Movement Disorder Society: www.movementdisorders.org.

Issues unique to Parkinson’s disease: No special concerns.

Unmet needs; unanswered questions: Future developments may allow motor elements of PD to be assessed with digital technology that would potentially allow wide application globally and not require on-site rater involvement or judgment. Several programs to digitize such scales as the MDS-UPDRS or UPDRS are underway, but not developed fully or validated at the time of this report.