

Parkinson's Disease CDE Revision History Document

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August 2022 Revisions

Overview

The Parkinson's Disease (PD) Version 2.0 CDE Working Group comprehensively reviewed and updated the PD Version 1.0 CDEs. There have been significant changes to the content of the PD CDE materials in Version 2.0 compared to Version 1.0.

Subgroup Summaries were posted for PD Version 2.0 CDE Subgroups.

New Subdomains: Daily Cognitive Function and Digital Technology were added to the Outcomes and End Points Domain.

The following guidance documents were updated or newly added to the PD Version 2.0 recommendations.

Updated Guidance Documents (3)

1. Imaging Guidance for CDE Use
2. Other Non-Motor Guidance for CDE Use
 - a. Question text was added for corresponding data dictionary.
 - b. C10181 Thermoregulatory sweat test sweat chemical text was removed.
3. Summary of Diagnostic Criteria and Assessments for Psychosis in Parkinson's Disease

New Guidance Documents (3)

1. PhenX Social Determinants of Health Guidance
2. Best Practices for Digital Health Outcomes
3. Guidance for Digital Data Sharing

The following case report forms (CRFs) were updated, removed or newly added to the PD Version 2.0 recommendations. The corresponding data dictionaries (i.e., CDE Detail Reports) have been modified in accordance with the form changes. Population for all CDEs was corrected to Adult, as needed. Notably, there were 9 CDEs added to the list of Core CDEs for all PD studies: C00314 Medical history taken date and time; C08006 Symptoms first appear date and time; C08007 Diagnosis first given date and time; C08008 Diagnostic feature criterion type; C08009 Diagnostic feature criterion presence status; C59020 Diagnosis certainty category; C08012 Motor symptom parkinsonian initial type; C02411 Laterality type; C00023 Hand preference type. C18679 Family history medical condition relative other text was reclassified from Core to Supplemental for v2.0. C08004 Relative type other neurological disorder member number was Core in v1.0 but removed from the v2.0 recommendations.

Updated CRFs (10)

1. Demographics F2944
 - a. CDEs Added
 - i. C58676 Birth sex assigned type

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- ii. C58780 Birth sex assigned type other text
- iii. C58677 Gender identity type
- iv. C58781 Gender identity type other text
- v. C00030 Race USA category
- b. CDEs Removed
 - i. C00035 Gender type
 - ii. C00031 Race expanded category
- c. Classification Changes
 - i. None
- d. Permissible Value Modifications
 - i. C00020 Ethnicity USA category
 - 1. Removed: Unknown
 - ii. C00012 Education level USA type
 - 1. Added: 7th Grade or less; 8th to 12th Grade; High school graduate; 2-year college; 4-year college; Postgraduate
 - 2. Removed: Never attended/Kindergarten only; 1st Grade; 2nd Grade; 3rd Grade; 4th Grade; 5th Grade; 6th Grade; 7th Grade; 8th Grade; 9th Grade; 10th Grade; 11th Grade; 12th Grade, no diploma; High school graduate; GED or equivalent; Some college, no degree; Associate degree: occupational/technical/vocational program; Associate degree: academic program; Bachelor's degree (e.g., BA, AB, BS, BBA); Master's degree (e.g., MA, MS, MEng, MEd, MBA); Professional school degree (e.g., MD, DDS, DVM, JD); Doctoral degree (e.g., PhD, EdD)
- 2. History of Early Exposure F2945
 - a. CDEs Added
 - i. C59062 Birth weight known indicator
 - ii. C00311 Birth weight report value
 - iii. C01581 Weight unit of measure
 - iv. C59063 Birth weight source
 - v. C59064 Breastfed duration range
 - vi. C59073 Full biological sibling indicator
 - vii. C59065 Older full biological sibling count
 - viii. C59066 Twin sibling birth sex assigned type
 - ix. C59067 Twin pea pod look indicator
 - x. C59068 Twin difficult tell apart indicator
 - xi. C16170 Menstrual period occurrence indicator
 - xii. C52710 Menarche begin age value
 - xiii. C59069 Menarche begin age category
 - xiv. C59070 Shave facial hair regular begin age value
 - xv. C59071 Shave facial hair regular begin age category
 - xvi. C59072 Height in twenties measurement
 - xvii. C01582 Height unit of measure
 - b. CDEs Removed
 - i. C08077 Full biological sibling indicator
 - ii. C08082 Sibling rank type
 - iii. C08083 Sibling name
 - iv. C08084 Sibling gender type
 - v. C08085 Sibling alive indicator

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- vi. C08086 Sibling current age value
- vii. C08087 Sibling death age value
- viii. C08088 Age value unit of measure
- c. Classification Changes
 - i. None
- d. Permissible Value Modifications
 - i. C08112 Birth weight category
 - 1. Added: Below average weight
 - ii. C08081 Twin sibling type
 - 1. Removed: Unknown
- 3. Non-prescribed Drug Use Questionnaire F2947
 - a. CDEs Added
 - i. C17683 Non-prescribed controlled psychoactive drug substance marijuana text
 - ii. C17684 Non-prescribed controlled psychoactive drug substance stimulant cocaine text
 - iii. C17685 Non-prescribed controlled psychoactive drug substance stimulant amphetamine text
 - iv. C17686 Non-prescribed controlled psychoactive drug substance sedative tranquilizer text
 - v. C17688 Non-prescribed controlled psychoactive drug substance opioid text
 - vi. C17687 Non-prescribed controlled psychoactive drug substance sedative barbiturate text
 - vii. C59021 Non-prescribed controlled psychoactive drug substance heroin text
 - viii. C17689 Non-prescribed controlled psychoactive drug substance inhalant text
 - ix. C17690 Non-prescribed controlled psychoactive drug substance hallucinogen text
 - x. C59022 Non-prescribed controlled psychoactive drug substance L-Dopa supplement text
 - xi. C59023 Non-prescribed controlled psychoactive drug substance anti-psychotic text
 - xii. C59024 Subscribed drug or substance illicitly used specify other text
 - b. CDEs Removed
 - i. None
 - c. Classification Changes
 - i. None
 - d. Permissible Value Modifications
 - i. C00712 Subscribed drug or substance illicitly used category
 - 1. Added: Anti-psychotics (Thorazine or Haldol); CBD (Cannabidiol); L-Dopa supplements
 - 2. Revised: Tranquilizers or anti-anxiety drugs (e.g., Valium, Librium, muscle relaxants, or Xanax) to Anti-anxiety drugs (Valium, Librium, muscle relaxants, or Xanax); Painkillers (e.g., Codeine, Darvon, Percodan, Dilaudid, or Demerol) to Opioids (Codeine, Fentanyl, Oxycontin, Darvon, Percodan, Dilaudid, or Demerol); Stimulants (e.g., Preludin, Benzedrine, Methadrine, uppers, or speed) to Stimulants (Crystal Meth, uppers, or speed); Other, specify (e.g., Methadone, Elavil, steroids, Thorazine, or Haldol) to Other, specify (e.g., anabolic steroids)
- 4. Family History F2948
 - a. CDEs Added
 - i. C59027 Family history relative type healthy member count
 - ii. C59028 Family history relative type neurological disorder not parkinsonian code
 - iii. C59029 Family history relative type neurological disorder not parkinsonian code other text
 - iv. C59030 Family history relative type psychiatric disorder member count
 - b. CDEs Removed

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- i. C08004 Relative type other neurological disorder member number
 - c. Classification Changes
 - i. C18679 Family history medical condition relative type other text: Core (v1.0) to Supplemental (v2.0)
 - d. Permissible Value Modifications
 - i. C00722 Family history medical condition relative type
 - 1. Added: Biological daughter; Biological son; Dizygotic twin; Monozygotic twin
 - 2. Removed: Child; Grandchild; Great-grandchild; Maternal cousin; Maternal niece/nephew; Paternal cousin; Paternal niece/nephew
- 5. Medical History of Parkinson's Disease F2949
 - a. CDEs Added
 - i. C59020 Diagnosis certainty category
 - ii. C00023 Hand preference type
 - b. CDEs Removed
 - i. C18029 Other abnormality posture text
 - ii. C08010 Diagnosis certainty percentage range
 - iii. C08011 Diagnostic alternative reason
 - iv. C08015 Motor symptom parkinsonian develop type
 - v. C05404 Symptom onset date and time
 - c. Classification Changes
 - i. C00314 Medical history taken date and time: Supplemental (v1.0) to Core (v2.0)
 - ii. C08006 Symptoms first appear date and time: Supplemental (v1.0) to Core (v2.0)
 - iii. C08007 Diagnosis first given date and time: Supplemental (v1.0) to Core (v2.0)
 - iv. C08008 Diagnostic feature criterion type: Supplemental (v1.0) to Core (v2.0)
 - v. C08009 Diagnostic feature criterion presence status: Supplemental (v1.0) to Core (v2.0)
 - vi. C08012 Motor symptom parkinsonian initial type: Supplemental (v1.0) to Core (v2.0)
 - vii. C02411 Laterality type: Supplemental (v1.0) to Core (v2.0)
 - d. Permissible Value Modifications
 - i. C08012 Motor symptom parkinsonian initial type
 - 1. Revised: added specify to the PV text for Dystonia (specify symptoms) and Ambulatory/Axial Difficulties-Other abnormality of posture or gait (other, specify)
- 6. MRI and Spectroscopy F2950
 - a. CDEs Added
 - i. C20247 Imaging scanner model name text
 - ii. C02498 Imaging scanner software version number
 - iii. C59025 Imaging radio frequency coil manufacturer name
 - iv. C59026 Imaging radio frequency coil manufacturer name other text
 - v. C10568 Imaging radio frequency coil channel count
 - vi. C18714 Imaging radio frequency coil channel count other text
 - vii. C10685 Imaging slice orientation type
 - viii. C18719 Imaging slice orientation type other text
 - ix. C10927 Imaging inversion time
 - x. C10591 Imaging phase encode direction text
 - xi. C59031 Imaging slice order text
 - xii. C59582 Imaging blood oxygenation level dependent collect minute value
 - xiii. C59032 Imaging eye status
 - xiv. C57934 Imaging multiband use indicator

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- xv. C59033 Imaging band count
- xvi. C59034 Imaging multiecho indicator
- xvii. C59035 Imaging echo count
- xviii. C59036 Imaging scan initiation time
- xix. C59037 Medication Parkinsons disease indicator
- xx. C59038 Medication Parkinsons disease last dose date time
- b. CDEs Removed
 - i. C18613 Imaging medication pre-treatment withheld name
 - ii. C02497 Imaging scanner model name
 - iii. C18717 Imaging scanner model other text
 - iv. C08246 Imaging pre-scan procedure type
 - v. C18707 Imaging pre-scan procedure other text
 - vi. C08247 Imaging medication pre-treatment status
 - vii. C08248 Imaging medication pre-treatment withheld duration
 - viii. C08249 Imaging medication pre-treatment withheld duration unit of measure
 - ix. C08250 Imaging head position text
 - x. C18721 Imaging visual analysis other text
 - xi. C08253 Imaging visual analysis status
 - xii. C18720 Imaging visual analysis location performed other text
 - xiii. C08254 Imaging visual analysis location performed type
 - xiv. C08255 Imaging visual analysis blinded indicator
 - xv. C08252 Imaging parameter quantified type
 - xvi. C18704 Imaging parameter quantified other text
 - xvii. C18753 Spectroscopy software other text
 - xviii. C08256 Spectroscopy software type
 - xix. C08257 Spectroscopy metabolite type
 - xx. C18752 Spectroscopy metabolite other text
- c. Classification Changes
 - i. All CDEs: Supplemental (v1.0) to S-HR (v2.0)
- d. Permissible Value Modifications
 - i. C02496 Imaging scanner manufacturer name
 - 1. Removed: Agfa; Hitachi; Carestream; Toshiba; Hologic; Konica Minolta
 - ii. C02495 Imaging scanner strength value
 - 1. Removed: 4.0T
 - iii. C02499 Imaging pulse sequence type
 - 1. Added: PROTON; MRS
 - 2. Removed: T1; T2; FLAIR; DWI; MRSI; PWI; Gradient-echo; Pulsed-ASL; Continuous-ASL; Pseudocontinuous-ASL; Post-contrast FLAIR; Post-contrast T1-weighted; COW MRA; TOF Neck MRA; CE MRA; SPACE/VISTA; TSE/FSE; Dual echo PD/T2W SE; PD SE; T2W SE; T1W SE; T1W 3D gradient-echo; T1-weighted spin echo with contrast; T1-weighted spin echo without contrast; PD/T2W FSE; DIR; PSIR; fMRI; Spectroscopic imaging 2D; Spectroscopic imaging 3D; Spin echo; Pulsed-ASL; Continuous-ASL; Pseudocontinuous-ASL; Unlocalized spectroscopy; ISIS; DWI/ADC; rFOV
 - iv. C08243 Imaging matrix size value
 - 1. Removed: 256 x 256
- 7. PET-SPECT Localization F2951
 - a. CDEs Added

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- i. C59042 Imaging radioligand type dihydrotetrabenazine specify text
 - ii. C59043 Imaging camera type
 - iii. C59044 Imaging camera type other text
 - iv. C20247 Imaging scanner model name text
 - v. C59045 Imaging pre-scan procedure type carbidopa specify text
 - vi. C59036 Imaging scan initiation time
 - vii. C59037 Medication Parkinsons disease indicator
 - viii. C59038 Medication Parkinsons disease last dose date time
 - ix. C59046 Imaging observe method status
 - x. C59047 Imaging scatter correction indicator
 - xi. C59048 Imaging deadtime correction indicator
 - xii. C59049 Imaging randoms correction indicator
 - xiii. C59050 Imaging reconstruct image resolution full width half maximum millimeter value
 - xiv. C59051 Imaging MRI acquire co-registration indicator
 - xv. C59052 Imaging MRI acquire co-registration date and time
 - xvi. C59053 Imaging quantitative outcome indicator
 - xvii. C59054 Imaging quantitative outcome dopamine transporter radioligand type
 - xviii. C59055 Imaging quantitative outcome vesicular monoamine transporter 2 radioligand type
 - xix. C59056 Imaging quantitative outcome tyrosine hydroxylase radioligand type
 - xx. C59057 Imaging amyloid centiloid anatomic site
 - xxi. C59058 Imaging amyloid centiloid anatomic site other text
- b. CDEs Removed
- i. C18038 Isotope other text
 - ii. C18717 Imaging scanner model other text
 - iii. C02497 Imaging scanner model name
 - iv. C18039 Scanner manufacturer other text
 - v. C08247 Imaging medication pre-treatment status
 - vi. C08248 Imaging medication pre-treatment withheld duration
 - vii. C08249 Imaging medication pre-treatment withheld duration unit of measure
 - viii. C18040 Radioligand dose other unit of measure
 - ix. C18613 Imaging medication pre-treatment withheld name
 - x. C18041 Imaging matrix size other scale
 - xi. C18042 Post-injection management other text
 - xii. C18043 Raw data reconstruction other text
 - xiii. C18044 Attenuation correction other text
 - xiv. C18706 Imaging post reconstruction filter other text
 - xv. C18045 Post reconstruction filter other text
 - xvi. C18046 Visual analysis result other text
 - xvii. C18047 Visual analysis perform location other text
 - xviii. C18049 Imaging outcome other name
 - xix. C08273 Imaging F-dopa binding ratio value
 - xx. C18053 Fdopa binding ratio other text
 - xxi. C18688 Imaging amyloid standard uptake value anatomic other text
 - xxii. C08274 Imaging amyloid standard uptake value anatomic site name
 - xxiii. C08275 Imaging amyloid standard uptake value anatomic site value
 - xxiv. C18054 Imaging amyloid standard uptake value anatomic site other name

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- c. Classification Changes
 - i. C08258 Imaging radioligand type: Supplemental (v1.0) to S-HR (v2.0)
 - ii. C18711 Imaging radioligand type other text: Supplemental (v1.0) to S-HR (v2.0)
 - iii. C08259 Imaging radioligand specific activity value: Supplemental (v1.0) to S-HR (v2.0)
 - iv. C18037 Imaging radioligand specific activity value indicator: Supplemental (v1.0) to S-HR (v2.0)
 - v. C08260 Imaging isotope type: Supplemental (v1.0) to S-HR (v2.0)
 - vi. C18699 Imaging isotope type other text: Supplemental (v1.0) to S-HR (v2.0)
 - vii. C02496 Imaging scanner manufacturer name: Supplemental (v1.0) to S-HR (v2.0)
 - viii. C18716 Imaging scanner manufacturer name other text: Supplemental (v1.0) to S-HR (v2.0)
 - ix. C08236 Imaging scanner software name: Supplemental (v1.0) to S-HR (v2.0)
 - x. C08261 Imaging radioligand dose value: Supplemental (v1.0) to S-HR (v2.0)
 - xi. C08262 Imaging radioligand dose unit of measure: Supplemental (v1.0) to S-HR (v2.0)
 - xii. C18710 Imaging radioligand dose other text: Supplemental (v1.0) to S-HR (v2.0)
 - xiii. C08263 Imaging radioligand injection to acquisition duration: Supplemental (v1.0) to S-HR (v2.0)
 - xiv. C08242 Imaging acquisition duration: Supplemental (v1.0) to S-HR (v2.0)
 - xv. C08243 Imaging matrix size value: Supplemental (v1.0) to S-HR (v2.0)
 - xvi. C18700 Imaging matrix size value other text: Supplemental (v1.0) to S-HR (v2.0)
 - xvii. C08244 Imaging slice thickness value: Supplemental (v1.0) to S-HR (v2.0)
 - xviii. C08246 Imaging pre-scan procedure type: Supplemental (v1.0) to S-HR (v2.0)
 - xix. C18707 Imaging pre-scan procedure type other text: Supplemental (v1.0) to S-HR (v2.0)
 - xx. C02014 Medication prior or concomitant name: Supplemental (v1.0) to S-HR (v2.0)
 - xxi. C01541 Weight measurement: Supplemental (v1.0) to S-HR (v2.0)
 - xxii. C08251 Imaging post injection management type: Supplemental (v1.0) to S-HR (v2.0)
 - xxiii. C18705 Imaging post injection management type other text: Supplemental (v1.0) to S-HR (v2.0)
 - xxiv. C08264 Imaging raw data reconstruction method type: Supplemental (v1.0) to S-HR (v2.0)
 - xxv. C18712 Imaging raw data reconstruction method other text: Supplemental (v1.0) to S-HR (v2.0)
 - xxvi. C08265 Imaging attenuation correction method type: Supplemental (v1.0) to S-HR (v2.0)
 - xxvii. C18692 Imaging attenuation correction method type other text: Supplemental (v1.0) to S-HR (v2.0)
 - xxviii. C08266 Imaging post reconstruction filter type: Supplemental (v1.0) to S-HR (v2.0)
 - xxix. C08253 Imaging visual analysis status: Supplemental (v1.0) to S-HR (v2.0)
 - xxx. C18721 Imaging visual analysis status other text: Supplemental (v1.0) to S-HR (v2.0)
 - xxxi. C08254 Imaging visual analysis location performed type: Supplemental (v1.0) to S-HR (v2.0)
 - xxxii. C18720 Imaging visual analysis location performed type other text: Supplemental (v1.0) to S-HR (v2.0)
 - xxxiii. C08255 Imaging visual analysis blinded indicator: Supplemental (v1.0) to S-HR (v2.0)
 - xxxiv. C18048 Imaging visual analysis blinded other text: Supplemental (v1.0) to S-HR (v2.0)
 - xxxv. C08267 Imaging outcome variable name: Supplemental (v1.0) to S-HR (v2.0)
 - xxxvi. C18702 Imaging outcome variable name other text: Supplemental (v1.0) to S-HR (v2.0)
 - xxxvii. C08268 Imaging volume of interest placement method type: Supplemental (v1.0) to S-HR (v2.0)

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- xxxviii. C18723 Imaging volume of interest placement method type other text: Supplemental (v1.0) to S-HR (v2.0)
- xxxix. C08269 Imaging volume of interest anatomic location type: Supplemental (v1.0) to S-HR (v2.0)
 - xl. C18722 Imaging volume of interest anatomic location type other text: Supplemental (v1.0) to S-HR (v2.0)
 - xli. C08270 Imaging reference region text: Supplemental (v1.0) to S-HR (v2.0)
- d. Permissible Value Modifications
 - i. C08258 Imaging radioligand type
 - 1. Added: Ioflupane; IACFT; DTBZ, specify
 - 2. Removed: DaTSCAN; Altoprane; Florbetamol; 2-deoxy-glucose (either C14 or H3); AMT; FCWAY; H2O15; FMZ; ECD; HMPAO
 - ii. C18037 Imaging radioligand specific activity value indicator
 - 1. Removed: Yes; No; Unknown
 - iii. C02496 Imaging scanner manufacturer name
 - 1. Removed: Agfa; Hitachi; Carestream; Toshiba; Hologic; Konica Minolta
 - iv. C08243 Imaging matrix size value
 - 1. Removed: 256 x 256
 - v. C08246 Imaging pre-scan procedure type
 - 1. Added: Carbidopa, specify
 - 2. Removed: Withhold medications
 - vi. C08266 Imaging post reconstruction filter type
 - 1. Removed: Gaussian; Other, specify
 - vii. C08254 Imaging visual analysis location performed type
 - 1. Removed: Central read; Local read; Local report
 - viii. C08271 Imaging quantitative outcome type
 - 1. Added: VMAT2; Tyrosine Hydroxylase; Amyloid Imaging Binding Potential; Amyloid Imaging Volume of Distribution; Amyloid Imaging Mean Cortical Binding Potential; Amyloid Imaging Centiloids
 - 2. Removed: Altoprane; β -CIT; Fluoro-metatyrosine (FMT)
 - 3. Revised: DAT Scan to DAT
- 8. Functional Neurosurgery: Deep Brain Stimulation F2952
 - a. CDEs Added
 - i. C59085 Parkinsons disease motor sign year duration
 - ii. C59583 Parkinsons disease motor sign month duration
 - iii. C59086 Motor fluctuation year duration
 - iv. C59584 Motor fluctuation month duration
 - v. C59087 Dyskinesia troublesome dyskinesia year duration
 - vi. C59585 Dyskinesia troublesome month duration
 - vii. C59088 Deep brain stimulation indication type
 - viii. C59089 Deep brain stimulation indication type medication side effect other text
 - ix. C59090 Deep brain stimulation indication type other text
 - x. C59092 Unified Parkinsons Disease Rating Scale version type
 - xi. C59094 Unified Parkinsons Disease Rating Scale part three off levodopa score
 - xii. C59095 L-Dopa pre-operative challenge off levodopa duration
 - xiii. C59096 L-Dopa pre-operative challenge off dopamine agonist duration
 - xiv. C59097 Dopamine agonist specify text

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- xv. C59099 Unified Parkinsons Disease Rating Scale part three on medication score
- xvi. C59100 Functional neurosurgery target anatomic site multiple ipsilateral lead specify text
- xvii. C59101 Functional neurosurgery target planning software type text
- xviii. C59103 Functional neurosurgery target planning adjunct type
- xix. C59105 Anesthesia type
- xx. C59106 Surgery head fixation status
- xxi. C59107 Surgery head fixation text
- xxii. C59586 Stereotactic surgery mini-frame type other text
- xxiii. C59108 Stereotactic surgery robotic guidance lead insert indicator
- xxiv. C59109 Stereotactic surgery robotic guidance lead insert platform text
- xxv. C59110 Surgery intra-operative target verify lead placement MRI type
- xxvi. C59111 Microelectrode record microstimulation sedation type
- xxvii. C59113 Microelectrode record type
- xxviii. C59115 Test stimulation sedation type
- xxix. C59117 Brain lead insert count
- xxx. C59118 Brain lead type
- xxxi. C59120 Brain lead directional type other text
- xxxii. C59121 Brain lead cylindrical type other text
- xxxiii. C59122 Brain lead intercontact space interval type
- xxxiv. C59123 Brain lead intercontact space interval type other text
- xxxv. C14517 Device manufacturer name
- xxxvi. C59124 Device model name
- xxxvii. C59125 Pulse generator insert count
- xxxviii. C59126 Pulse generator battery type
- xxxix. C59127 Pulse generator sensing function indicator
 - xl. C59587 Surgery procedure hour duration
 - xli. C54898 Surgery procedure minute duration
 - xl. C59128 Imaging processing software name
 - xl. C59588 Anterior commissure posterior commissure target x coordinate value
 - xl. C59589 Anterior commissure posterior commissure target y coordinate value
 - xl. C59590 Anterior commissure posterior commissure target z coordinate value
 - xlvi. C59129 Stimulation brain parameter contact configuration text
 - xlvi. C59130 Stimulation brain parameter negative contact text
 - xlvi. C59131 Stimulation brain parameter positive contact text
 - xlix. C59132 Stimulation brain parameter directional steering indicator
 - l. C59133 Stimulation brain parameter amplitude value
 - li. C59134 Stimulation brain parameter amplitude unit of measure
 - lii. C59135 Stimulation brain parameter frequency value
 - liii. C59136 Stimulation brain parameter pulse width value
 - liv. C59137 Stimulation brain paradigm type
 - lv. C59138 Stimulation brain paradigm type other text
 - lvi. C59139 Optimal programming limit stimulation adverse effect indicator
 - lvii. C59140 Optimal programming limit stimulation adverse effect indicator specify text
 - lviii. C59142 Unified Parkinsons Disease Rating Scale part three on DBS off medication score
 - lix. C59143 Unified Parkinsons Disease Rating Scale part three on DBS on medication score
 - lx. C59144 Brain lead post implant interval
 - lxi. C59145 Brain lead post implant interval unit of measure

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- lxii. C59146 Surgical complication hemorrhage symptom status
- lxiii. C59147 Adverse event treatment specify text
- lxiv. C59148 Adverse event outcome status other text
- lxv. C59149 Surgical complication hardware related type
- lxvi. C59150 Hardware component remove type
- lxvii. C59151 Brain lead remove count
- lxviii. C59152 Implantable pulse generator remove count
- lxix. C59153 Lead extender remove count
- lxx. C59154 Brain lead replacement manipulation count
- lxxi. C59155 Pulse generator replacement manipulation count
- lxxii. C59156 Pulse generator replacement reason
- lxxiii. C59158 Pulse generator replacement reason other text
- lxxiv. C59159 Lead extender replacement manipulation count
- lxxv. C59160 Lead extender replacement reason
- lxxvi. C59162 Lead extender replacement reason other text
- b. CDEs Removed
 - i. C08019 Disease duration
 - ii. C18759 Surgery reason indication other text
 - iii. C08020 Surgery reason indication type
 - iv. C08021 Surgery indication drug or medication side effects type
 - v. C08024 L-Dopa pre-operative stim-on time
 - vi. C08025 L-Dopa pre-operative stim-off time
 - vii. C08027 Functional neurosurgery type
 - viii. C18683 Functional neurosurgery other text
 - ix. C08029 Functional neurosurgery bilateral procedure type
 - x. C08030 Anterior commissure posterior commissure target coordinate value
 - xi. C08032 Risk Factor Questionnaire (RFQ) - significant injury surgery anesthesia administered type
 - xii. C18750 Risk Factor Questionnaire (RFQ) - significant injury surgery anesthesia administered other text
 - xiii. C08043 Lead implanted pulse generator model type
 - xiv. C18733 Lead implanted pulse generator model other text
 - xv. C08044 Operating room total time
 - xvi. C08048 Medication anti-parkinsonian added after surgery indicator
 - xvii. C08049 Stimulation brain parameters monopolar range
 - xviii. C08050 Stimulation brain parameters bipolar range
 - xix. C08052 Stimulation brain parameters amplitude range
 - xx. C08053 Stimulation brain parameters frequency range
 - xxi. C08054 Stimulation brain parameters pulse width range
 - xxii. C08055 Stimulation brain mean value
 - xxiii. C08056 Stimulation brain range value
 - xxiv. C08057 L-Dopa post-operative stim - on time
 - xxv. C08058 L-Dopa post-operative stim - off time
 - xxvi. C08059 Surgery hardware replacement type
 - xxvii. C08060 Leads replaced number
 - xxviii. C08061 Implanted pulse generator replaced number
 - xxix. C08062 Extenders replaced number

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- xxx. C08063 Lead repositioned indicator
- xxxi. C08068 Surgical complications post-operative mechanical malfunction type
- xxxii. C18762 Surgical complications post-operative mechanical malfunction other text
- xxxiii. C08069 Aborted procedures indicator
- xxxiv. C08070 Aborted procedures number
- xxxv. C18662 Aborted procedures other text
- xxxvi. C08071 Aborted procedures reason
- xxxvii. C08072 Surgical complication intracranial anatomic site
- xxxviii. C18664 Adverse event relatedness other text
- xxxix. C08073 Adverse event relatedness source
 - xl. C08074 Adverse event relatedness source device type
 - xli. C08075 Adverse event expected status
- c. Classification Changes
 - i. None
- d. Permissible Value Modifications
 - i. C08026 Functional neurosurgery target anatomic site
 - 1. Added: Ventrolateral thalamus; None; Multiple ipsilateral leads, specify
 - 2. Revised: Globus pallidus, pars interna (GPi) to Globus pallidus
 - ii. C08031 Functional neurosurgery target planning method type
 - 1. Added: Indirect targeting on CT; Surgical planning software; Surgical planning adjuncts
 - 2. Removed: Atlas; Imaging; Ventriculography
 - 3. Revised: Direct to Direct targeting on MRI; Indirect to Indirect targeting on MRI; Other, specify to Other targeting methods, specify
 - iii. C08034 Surgery head position status
 - 1. Revised: Elevated to Head of bed elevated; Flat to Head of bed flat
 - iv. C08035 Stereotactic surgery frame type
 - 1. Revised: CRW to CRW headframe; Leksell to Leksell headframe; Mini-Frame to Single use mini-frame
 - v. C08036 Stereotactic surgery mini-frame type
 - 1. Added: MRI interventions SmartFrame; Other, specify
 - 2. Revised: Medtronic to Medtronic Nexframe; FHC to FHC Starfix
 - vi. C08038 Surgery intra-operative target verification source
 - 1. Added: CT or cone beam CT; MRI; Microelectrode recording and/or microstimulation; Test stimulation through DBS lead or other microcontact
 - 2. Removed: Image guidance platform; Software; Microstimulation; Macrostimulation; X-ray; Microelectrode recording; Serial single microelectrode recording; Multiple-electrode recording (BEN-GUN)
 - vii. C08046 Medication anti-parkinsonian reduced after surgery indicator
 - 1. Removed: N/A; Unknown
 - 2. Revised: Yes, % reduction to Yes, % reduction in levodopa equivalents
 - viii. C08066 Surgical complication intra-operative type
 - 1. Added: Procedure aborted
 - 2. Removed: Infarct
 - 3. Revised: Added event to Cardiovascular event (e.g., arrhythmia, heart attack, etc.)
 - ix. C08067 Surgical complication post-operative type
 - 1. Added: Delirium

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2. Removed: Infection; Mechanical malfunction
 3. Revised: Infarct to Ischemic infarct
 - x. C02302 Adverse event other action taken type
 1. Revised: Non-Study Treatment Required to Treatment Required, specify
 - xi. C02303 Adverse event outcome status
 1. Added: Recovered/resolved without neurological deficit; Produced persistent neurological deficit; Other
 2. Removed: Recovered/Resolved; Recovered/Resolved with Sequelae; Recovering/Resolving; Not Recovered/Not Resolved; Fatal; Unknown
 - xii. C08064 Lead reposition reason
 1. Added: Migration of lead from initial position; Lead fracture or electrical malfunction
 2. Removed: Mechanical breakdown; Infection
 3. Revised: Poor positioning to Poor initial positioning
9. Non-Parkinson's Disease Medication Log F2953
- a. CDEs Added
 - i. C59040 Medication prior use report duration
 - ii. C59041 Medication prior or concomitant as needed dose average frequency
 - b. CDEs Removed
 - i. C02011 Medication prior or concomitant dose frequency
 - ii. C18035 Medication prior name
 - c. Classification Changes
 - i. None
 - d. Permissible Value Modifications
 - i. None
10. Parkinson's Disease Medication Log F2954
- a. CDEs Added
 - i. C02006 Medication prior or concomitant dose
 - ii. C02015 Medication prior or concomitant route type
 - iii. C59179 Medication prior or concomitant suppository route type
 - iv. C18737 Medication prior or concomitant route type other text
 - v. C59180 Medication prior or concomitant daily dose frequency
 - vi. C59181 Medication prior or concomitant total daily intake text
 - vii. C02016 Medication prior or concomitant start date and time
 - viii. C02008 Medication prior or concomitant end date and time
 - b. CDEs Removed
 - i. C02002 Medication prior or concomitant use indicator
 - ii. C08218 Parkinson's Disease medication class category
 - iii. C02025 Medication prior or concomitant RXNorm code
 - iv. C08219 Parkinson's Disease medication maximum dose
 - v. C08221 Parkinson's Disease medication exposure duration
 - vi. C08222 Parkinson's Disease medication exposure duration unit of measure
 - vii. C02003 Medication prior or concomitant ongoing indicator
 - viii. C18735 Medication prior or concomitant discontinuation other text
 - ix. C08223 Medication prior or concomitant discontinuation reason
 - x. C08224 Parkinson's Disease medication side effect text
 - c. Classification Changes

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- i. C02022 Medication prior or concomitant dose unit of measure: Supplemental (v1.0) to S-HR (v2.0)
- ii. C18736 Medication prior or concomitant dose unit of measure other text: Supplemental (v1.0) to S-HR (v2.0)
- iii. C02013 Medication prior or concomitant dose unit of measure UCUM code: Supplemental (v1.0) to S-HR (v2.0)
- d. Permissible Value Modifications
 - i. C02022 Medication prior or concomitant dose unit of measure
 - 1. Added: gr; gtt; mg/mL; tbspc; tsp; U
 - 2. Removed: N/A

Removed CRFs (2)

1. Neuropathology: The National Alzheimer's Coordinating Center (NACC) Neuropathology Data Form instrument was recommended in place of this CRF from v1.0.
2. MR: The MR CRF content was duplicative of the MRI and Spectroscopy CRF.

New CRFs (1)

1. Parkinson's Disease Genetics

The following instruments were reclassified, removed, or newly added. Information in the instrument summaries was also updated as necessary. Notably, there were two instruments added to the list of Core CDEs for all PD studies: Hoehn and Yahr Scale and Montreal Cognitive Assessment (MoCA)

Updated Instrument Classifications (19)

Instrument	V1.0 Classification	V2.0 Classification
CDR System	Supplemental – Highly Recommended	Supplemental
Composite Autonomic Symptom Scale (COMPASS-31)	Supplemental	Supplemental – Highly Recommended
Hamilton Anxiety Rating Scale (HAM-A)	Supplemental – Highly Recommended	Supplemental
International Restless Legs Syndrome Study Group Severity Rating Scale (IRLS)	Supplemental	Supplemental – Highly Recommended
Lille Apathy Rating Scale (LARS)	Supplemental	Supplemental – Highly Recommended
Montreal Cognitive Assessment (MoCA)	Supplemental	Core
Multiple Sleep Latency Test (MSLT) and Guidelines	Supplemental	Supplemental – Highly Recommended

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Instrument	V1.0 Classification	V2.0 Classification
Parkinson's Disease Quality of Life Questionnaire (PDQL)	Supplemental – Highly Recommended	Supplemental
Parkinson's Disease Quality of Life Scale (PDQUALIF)	Supplemental – Highly Recommended	Supplemental
Parkinson's Disease Sleep Scale 2nd Version (PDSS-2)	Supplemental	Supplemental – Highly Recommended
Quality of Life in Neurological Disorders (Neuro-QOL)	Supplemental	Supplemental – Highly Recommended
Questionnaire for Impulsive-Compulsive Behaviors in Parkinson's Disease (QUIP) (Long Form)	Supplemental	Supplemental – Highly Recommended
Questionnaire for Impulsive-Compulsive Behaviors in Parkinson's Disease (QUIP) (Short Form)	Supplemental	Supplemental – Highly Recommended
Questionnaire Impulsive-Compulsive Disorders Parkinson's Disease-Rating Scale (QUIP-RS)	Supplemental	Supplemental – Highly Recommended
Scale for Outcomes in Parkinson's Disease-Sleep (SCOPA-Sleep)	Supplemental	Supplemental – Highly Recommended
Scale for the Assessment of Positive Symptoms (SAPS)	Supplemental – Highly Recommended	Supplemental
Schedule for the Evaluation of Individual Quality of Life (SEIQOL)	Supplemental	Exploratory
The American Academy of Sleep Medicine (AASM): International Classification of Sleep Disorders (ICSD) Criteria	Supplemental	Supplemental – Highly Recommended
The International Restless Legs Syndrome Study Group Diagnostic Criteria	Supplemental	Supplemental – Highly Recommended

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Instruments Removed (23)

1. Alzheimer's Disease Cooperative Study-Clinical Global Impression of Change (ADCS-CGIC)
2. Belastungsfragebogen Parkinson kurzversion (BELA-P-k)
3. Brief Index of Sexual Functioning for Women (BISF-W)
4. Cambridge-Hopkins Restless Legs Syndrome Diagnostic Questionnaire (CH-RLSQ)
5. Composite Autonomic Severity Scale (CASS)
6. Geriatric Depression Scale (GDS)
7. Haraldsson's Questionnaire
8. Neuropsychiatric Inventory Questionnaire (NPI-Q)
9. Non-Motor Symptom Assessment Scale for Parkinson's Disease (NMSS)
10. Nottingham Health Profile (NHP)
11. Parkinson's Neuropsychometric Dementia Assessment (PANDA)
12. PD DOC Mini Environmental Risk Questionnaire for Parkinson's Disease Patients Baseline (PD DOC MERQ-PD-B)
13. Proposed Criteria for Diagnosis of the Syndrome of Apathy
14. Quantitative Sudomotor Axon Reflex Test (QSART)
15. Questions on Life Satisfaction - Movement Disorder (QLS-MD) and Deep Brain Stimulation (QLS-DBS) Modules
16. Risk Factor Questionnaire (RFQ) - All
17. Short Portable Mental Status Questionnaire (SPMSQ)
18. Sickness Impact Profile (SIP)
19. Sleep Apnea Scale of Sleep Disorders Questionnaire (SA-SDQ)
20. STOP Questionnaire
21. Structured Clinical Interview for DSM-IV Axis Disorders-Patient Version (SCID-I/P)
22. Structured Clinical Interview for Pathological Gambling (SCI-PG)
23. Survey Screen for Sleep Apnea (SSSA)

New Instrument Recommendations (63)

Instrument	Subdomain	V2.0 Classification
Cambridge Neuropsychological Test Automated Battery (CANTAB) Connect	Cognitive	Exploratory
Cogstate Brief Battery	Cognitive	Exploratory
Lumos Labs NeuroCognitive Performance Tests (NCPT)	Cognitive	Exploratory
NeuroTrax BrainCare	Cognitive	Exploratory
Parkinson's Disease - Cognitive Function Rating Scale (PD-CFRS)	Daily Cognitive Function	Supplemental
Penn Parkinson's Daily Activities Questionnaire-15 (PDAQ-15)	Daily Cognitive Function	Supplemental
Secondhand Smoke Microenvironment Questionnaire	Epidemiology/Environmental History	Supplemental
Abnormal Involuntary Movement Scale (AIMS)	Motor Function	Supplemental
Clinical Global Impression Scale-Improvement (CGI-I)	Motor Function	Supplemental – Highly Recommended

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Instrument	Subdomain	V2.0 Classification
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
Rush Dyskinesia Rating Scale (RDRS)	Motor Function	Supplemental
Schwab and England Activities of Daily Living Scale	Motor Function	Supplemental – Highly Recommended
Unified Dyskinesia Scale (UDysRS)	Motor Function	Supplemental – Highly Recommended
Wearing Off Questionnaire (WOQ)	Motor Function	Supplemental – Highly Recommended
National Alzheimer's Coordinating Center (NACC) Neuropathology Data Form	Other Clinical Data	Supplemental
Actigraphy (with Sleep Diary)	Other Non-Motor	Supplemental
Epworth Sleepiness Scale (ESS) - Adult Version	Other Non-Motor	Supplemental – Highly Recommended
Female Sexual Function Index (FSFI)	Other Non-Motor	Supplemental
Gastrointestinal Symptoms in Neurodegenerative Diseases Scale (GIND)	Other Non-Motor	Supplemental
Hyposmia Rating Scale (HRS)	Other Non-Motor	Exploratory
Innsbruck REM Sleep Behavior Disorder Inventory (RBD-I-5)	Other Non-Motor	Supplemental
International Consultation on Incontinence Questionnaire Bladder Diary (ICIQ-Bladder Diary)	Other Non-Motor	Supplemental
King's Parkinson's Disease Pain Questionnaire (KPPQ)	Other Non-Motor	Exploratory
King's Parkinson's Disease Pain Scale (KPPS)	Other Non-Motor	Supplemental
Mayo Sleep Questionnaire	Other Non-Motor	Supplemental
Munich Dysphagia Test - Parkinson's Disease (MDT-PD)	Other Non-Motor	Exploratory
Neurogenic Bladder Symptom Score (NBSS)	Other Non-Motor	Supplemental

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Instrument	Subdomain	V2.0 Classification
Orthostatic Hypotension Questionnaire (OHQ)	Other Non-Motor	Supplemental – Highly Recommended
Orthostatic Symptom Grading Scale	Other Non-Motor	Supplemental
Parkinson's Disease Fatigue Scale (PFS-16)	Other Non-Motor	Supplemental
Polysomnography (PSG) and Guidelines	Other Non-Motor	Supplemental – Highly Recommended
Radboud Oral Motor Inventory for Parkinson's Disease (ROMP)	Other Non-Motor	Supplemental
Sniffin' Sticks Test	Other Non-Motor	Supplemental
STOP-BANG Questionnaire	Other Non-Motor	Supplemental
The Gastrointestinal Dysfunction Scale for Parkinson's Disease	Other Non-Motor	Supplemental
The International Parkinson and Movement Disorder Society – Non-Motor Rating Scale (MDS-NMS)	Other Non-Motor	Supplemental – Highly Recommended
The International Parkinson and Movement Disorder Society – Non-Motor Rating Scale (MDS-NMS) (GI Domain)	Other Non-Motor	Supplemental
The REM Sleep Behavior Disorder (RBD) Questionnaire – Hong Kong (RBDQ-HK)	Other Non-Motor	Supplemental
The REM Sleep Behavior Disorder Single-Question Screen (RBD1Q)	Other Non-Motor	Supplemental
The Swallowing Clinical Assessment Score in Parkinson's Disease (SCAS-PD)	Other Non-Motor	Supplemental
Visual Impairment in Parkinson's Disease Questionnaire (VIPD-Q)	Other Non-Motor	Exploratory
15 - Item Geriatric Depression Scale (GDS-15)	Psychiatric and Psychological Functions	Supplemental – Highly Recommended
Apathy Motivation Index (AMI)	Psychiatric and Psychological Functions	Supplemental
Apathy Motivation Index Caregiver Version (AMI-CG)	Psychiatric and Psychological Functions	Supplemental
Brief Dimensional Apathy Scale (b-DAS)	Psychiatric and Psychological Functions	Supplemental
Columbia - Suicide Severity Rating Scale (C-SSRS) Screener Version	Psychiatric and Psychological Functions	Supplemental – Highly Recommended
Columbia - Suicide Severity Rating Scale (C-SSRS)	Psychiatric and Psychological Functions	Supplemental – Highly Recommended
Cornell Scale for Depression in Dementia (CSDD)	Psychiatric and Psychological Functions	Supplemental
Dimensional Apathy Scale (DAS)	Psychiatric and Psychological Functions	Supplemental – Highly Recommended

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Instrument	Subdomain	V2.0 Classification
Dimensional Apathy Scale (DAS) Informant/Carer-Rated Version	Psychiatric and Psychological Functions	Supplemental – Highly Recommended
Enhanced Scale for the Assessment of Positive Symptoms in Parkinson's Disease (eSAPS-PD)	Psychiatric and Psychological Functions	Supplemental – Highly Recommended
Neuropsychiatric Inventory (NPI)	Psychiatric and Psychological Functions	Supplemental
Parkinson's Psychosis Questionnaire (PPQ)	Psychiatric and Psychological Functions	Supplemental
Parkinson's Psychosis Rating Scale (PPRS)	Psychiatric and Psychological Functions	Supplemental
Patient Health Questionnaire-2 (PHQ-2)	Psychiatric and Psychological Functions	Supplemental
Patient Health Questionnaire-9 (PHQ-9) Depression Scale	Psychiatric and Psychological Functions	Supplemental
Psychosis and Hallucinations Questionnaire (PsychH-Q)	Psychiatric and Psychological Functions	Supplemental
PROMIS Item Bank v1.2 - Global Health	Quality of Life/Patient Reported Outcomes	Supplemental
PROMIS-29 Profile	Quality of Life/Patient Reported Outcomes	Supplemental

January 2020 Revisions

- General Core CRF updated to replace 'Gender' question with 'Sex assigned at birth' and 'Gender identity'.
- Two new CDEs added to CRF: C58676 (Birth sex assigned type) and C58677 (Gender identity type). C00035 has been removed.
- Start-Up document updated to reflect these changes.

March 2017 Revisions

The Cognitive Subgroup made updates to the Cognitive Guidelines document

The following changes were made to the CDE Working Group – Cognitive Table (Each of the above scales are being given a score of 1, 2, 3 for suitability (1= highest or best, 3= lowest or worst):

Addenbrooke's Cognitive Examination - Revised (ACE-R): The instrument is now called ACE – III. Cognitive Guidelines table were updated along with the instruments Notice of Copyright (NOC) with explanation for the change

Clinician Global Impression of Change (CGIC): Longitudinal rating scale usage was change from 2 to 1.5.

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Montreal Cognitive Assessment (MoCA): Longitudinal rating scale usage was change from N/A to 1.

SCOPA-COG: Longitudinal rating scale usage was change from N/A to 2.

The following Notice of Copyrights (NOCs) were updated:

- Lille Apathy Rating Scale (LARS)
- The Parkinson Anxiety Scale (PAS)
- Scale for the Assessment of Positive Symptoms Parkinson's Disease (SAPS-PD)
- Questionnaire for Impulsive Compulsive Disorders in Parkinson's Disease-Rating Scale (QUIP-RS)

July 2016 Revisions

The following NOCs were updated and added to the website:

- Pathological Gambling Adaptation of the Yale-Brown Obsessive Compulsive Scale, (PG-YBOCS)
- Drooling Rating Scale(DRS)
- Parkinson's Disease-Cognitive Rating Scale (PD-CRS)
- Movement Disorder Society Unified Parkinson's Disease Scale

Classification revisions were made to the following instruments:

Subgroup	Recommendations	Previous Classification	Updated Classification / Removal
Quality of Life	Parkinson's Disease Quality of Life Scale (PDQUALIF)	Core	Supplemental – Highly Recommended

May 2016 Revision

- Revisions to Hamilton Anxiety Depression Scale NOC. The NOC was revised to reflect the correct name of the instrument, Hamilton Anxiety Rating Scale and Hamilton Depression Rating Scale.

April 2015 Revisions

No updates.

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March 2015 Revisions

- Corrections made to PD Acknowledgment section.

February 2015 Revisions

- Start-Up Resource Listing was updated with a link to the Data Standards page for PD.

January 2015 Revisions

- Revised 508 Compliant Start-Up and Highlight summaries were posted to PD.

November 2014 Revisions

- CDEs in use page was updated with new studies in PD.

September 2014 Revisions

- Page numbering in PD CRF Neuropathology was corrected.
- Revisions made to PD Roster.

August 2014 Revisions

- PD Start-up and Highlight documents changed to reflect instrument classification changes requested by the committee.
- General Core CRF posted on PD webpage.
- Links to NeuroQOL, NIH Toolbox, and PROMIS added to PD webpage.
- Core suicidal ideation instrument, with link, added to PD Highlight document.

July 2014 Revisions

- 508-compliant versions of CDEs, NOCs and Recommendation spreadsheets uploaded.
- Addition of "NIH Resources" domain, listing the NIH Toolbox, PROMIS, and Neuro-QOL as first domain on PD webpage.

June 2014 Revisions

No updates.

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May 2014 Revisions

- Start-Up Resource and Highlight documents converted to 508-compliant PDFs.

April 2014 Revisions

No updates.

March 2014 Revisions

No updates.

February 2014 Revisions

No updates.

January 2014 Revisions

- Links to Start-Up Resource Listings added to Highlight Summary documents.
- Revision History document updated for PD.

December 2013 Revisions

- Highlight summary and start-up documents for PD updated.
- New NOCs added to PD website.

November 2013 Revisions

Overview

There have been changes to the content and structure of the Parkinson's Disease (PD) CDE materials in Version 1.2 compared to Version 1.1, including the following:

Form Status Changes

New Forms:

Nurses' Health Study Questionnaire (NHQ)

Ohio State University TBI Identification Method Short Form

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Alzheimer's Disease Assessment Scale–Cognition (ADAS-cog)

Alzheimer's Disease Cooperative Study-Clinical Global Impression of Change (ADCS-CGIC)

Cambridge Cognitive Assessment –Revised (CAMCOG-R)

Mattis Dementia Rating Scale (MDRS)

Mini-Mental State Examination (MMSE)

Montreal Cognitive Assessment (MoCA)

UK Parkinson's Disease Society Brain Bank Criteria for the Diagnosis of Parkinson's Disease

Brief Index of Sexual Functioning for Women (BISF-W)

Brief Smell Identification Test (Brief-SIT)

Composite Autonomic Scoring Scale (CASS)

Composite Autonomic Symptom Scale (COMPASS-8) (COMPASS-31)

Epworth Sleepiness Scale (ESS)

Haraldsson's Questionnaire

Instrument for the Assessment of Restless Legs Syndrome Severity (IRLSSG- Rating Scale)

International Consultation on Incontinence Modular Questionnaire-Overactive Bladder (ICIQ-OAB)

International Index of Erectile Function (IIEF-5)

International Prostate Symptom Scale (IPSS)

Karolinska Sleepiness Scale (KSS)

Numerical Rating Scale (NRS) - BOX 21 Scale

Parkinson's Neuropsychometric Dementia Assessment (PANDA)

Pelli-Robson Chart

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Pittsburgh Sleep Quality Index (PSQI)

Quantitative Sudomotor Axon Reflex Test (QSART)

The American Academy of Sleep Medicine (AASM): International Classification of Sleep Disorders (ICSD) Criteria

The International Association for the Study of Pain (IASP) Definition of Pain

The International Restless Leg Syndrome Study Group Diagnostic Criteria

The REM Sleep Behavior Disorder (RBD) Screening Questionnaire (RBDSQ)

University of Pennsylvania Smell Identification Test (UPSIT)

Beck Depression Inventory – II (BDI-II)

Diagnostic and Statistical Manual of Mental Disorders (DSM-5)

Hospital Anxiety and Depression Scale (HADS)

McElroy Diagnostic Criteria for Compulsive Buying

Montgomery-Asberg Depression Rating Scale (MADRS)

Neuropsychiatric (NPI) Inventory

Structured Clinical Interview for DSM-IV Axis Disorders-Patient Version (SCID-I/P)

Belastungsfragebogen Parkinson kurzversion (BELA-P-k)

EuroQol 5-Dimension Questionnaire (EQ-5D)

Nottingham Health Profile (NHP)

Parkinson's disease questionnaire (PDQ-39)

Quality of Life in Neurological Disorders (Neuro-QOL)

Questions on Life Satisfaction– Movement Disorder (QLS-MD) and Deep Brain Stimulation (QLS-DBS) Modules

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Schedule for the Evaluation of Individual Quality of Life - Direct Weighting (SEIQoL-DW)

Schedule for the Evaluation of Individual Quality of Life (SEIQoL)

Sickness Impact Profile (SIP)

Updated Forms:

Notice of Copyright Created (NOC) (Will replace previously existing forms)

Food Frequency Questionnaire

PD DOC Mini Environmental Risk Questionnaire for Parkinson's Disease Patients Baseline (PD DOC
MERQ-PD-B

Risk Factor Questionnaire (RFQ) – All

Risk Factor Questionnaire - NSAIDS and Calcium Channel Blockers (RFQ)

Risk Factor Questionnaire - Occupation and Employment Status (RFQ)

Risk Factor Questionnaire - Physical Activity and Sleep (RFQ)

Risk Factor Questionnaire - Residential History (RFQ)

Risk Factor Questionnaire – Toxicants (RFQ)

Risk Factor Questionnaire - Height and Weight (RFQ-U)

Risk Factor Questionnaire – Pesticides (Home) (RFQ-U)

Risk Factor Questionnaire – Pesticides (Work) (RFQ-U)

Risk Factor Questionnaire - Smoking and Tobacco (RFQ-U)

Addenbrooke's Cognitive Examination-Revised (ACE-R)

Scales for Outcomes in Parkinson's Disease-Cognitive (SCOPA-COG)

Short Portable Mental Status Questionnaire (SPMSQ)

Movement Disorder Society - Unified Parkinson's Disease Rating Scale (MDS-UPDRS)

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Unified Parkinson's Disease Rating Scale (UPDRS)

Berlin Questionnaire

Brief Pain Inventory (Short Form)

Cambridge-Hopkins Restless Legs Syndrome Diagnostic Questionnaire (CH-RLSQ)

Drooling Severity and Frequency Scale (DSFS)

Fatigue Severity Scale (FSS) of Sleep Disorders

Insomnia Severity Index (ISI)

Mini Nutritional Assessment (MNA)

Multiple Sleep Latency Test and Guidelines (MSLT)

Non-Motor Symptom assessment scale for Parkinson's Disease (NMSS)

Non-Motor Symptom Questionnaire (NMS-Quest)

Parkinson's Disease Sleep Scale (PDSS)

Quality of Life in Swallowing Disorders (SWAL-QOL)

Rome III Constipation Module

Scales for Outcomes in Parkinson's Disease-Autonomic (SCOPA-Aut)

Scales for Outcomes in Parkinson's Disease-Sleep (SCOPA-Sleep)

Sialorrhea Clinical Scale for PD (SCS-PD)

Sleep Apnea Scale of Sleep Disorders Questionnaire (SA-SDQ)

Stanford Sleepiness Scale (SSS)

STOP Questionnaire

Survey Screen for Sleep Apnea (SSSA)

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Swallowing Disturbance Questionnaire (SwDQ)

Apathy Scale (AS)

Brief Psychiatric Rating Scale (BPRS)

Gambling Symptom Assessment Scale (G-SAS)

Geriatric Depression Scale (GDS)

Hamilton Anxiety Rating Scale (HAM-A)

Hamilton Depression Rating Scale (HDRS)

Proposed Criteria for Diagnosis of the Syndrome of Apathy

Questionnaire about Buying Behavior (QABB)

Questionnaire for Impulsive-Compulsive Behaviors in Parkinson's Disease (QUIP) (Short form)

Questionnaire for Impulsive-Compulsive Behaviors in Parkinson's Disease (QUIP) (Long form)

Scale for the Assessment of Positive Symptoms (SAPS)

Sexual Compulsivity Scale (SCS)

South Oaks Gambling Screen (SOGS)

Structured Clinical Interview for Pathological Gambling (SCI-PG)

36-Item Short Form Health Survey (SF-36)

Parkinson's Disease Quality of Life Scale (PDQUALIF)

Parkinson's Impact Scale (PIMS)

Scales for Outcomes in Parkinson's Disease-Psychosocial (SCOPA-PS)

World Health Organization Quality of Life Assessment (WHOQOL-BREF)

Removed Forms:

None

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Detailed Form Revisions:

Additional specific changes to the CRF modules are detailed in the table included on the subsequent page.

1 Parkinson's Disease Revision History Table

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Nurses' Health Study Questionnaire (NHQ)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Ohio State University TBI Identification Method Short Form	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Alzheimer's Disease Assessment Scale– Cognition (ADAS- cog)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Alzheimer's Disease Cooperative Study- Clinical Global Impression of Change (ADCS-CGIC)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Cambridge Cognitive Assessment – Revised (CAMCOG- R)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Mattis Dementia Rating Scale (MDRS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Mini-Mental State Examination (MMSE)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Montreal Cognitive Assessment (MoCA)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
UK Parkinson's Disease Society Brain Bank Criteria for the Diagnosis of Parkinson's Disease	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Brief Index of Sexual Functioning for Women (BISF-W)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Brief Smell Identification Test (Brief-SIT)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Composite Autonomic Scoring Scale (CASS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Composite Autonomic Symptom Scale (COMPASS-8) (COMPASS-31)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Epworth Sleepiness Scale (ESS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Haraldsson's Questionnaire	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Instrument for the Assessment of Restless Legs Syndrome Severity (IRLSSG- Rating Scale)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
International Consultation on Incontinence Modular Questionnaire- Overactive Bladder (ICIQ-OAB)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
International Index of Erectile Function (IIEF-5)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
International Prostate Symptom Scale (IPSS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Karolinska Sleepiness Scale (KSS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Numerical Rating Scale (NRS) - BOX 21 Scale	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Parkinson's Neuropsychometric Dementia Assessment (PANDA)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Pelli-Robson Chart	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

Parkinson's Disease CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Pittsburgh Sleep Quality Index (PSQI)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Quantitative Sudomotor Axon Reflex Test (QSART)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
The American Academy of Sleep Medicine (AASM): International Classification of Sleep Disorders (ICSD) Criteria	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
The International Association for the Study of Pain (IASP) Definition of Pain	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
The International Restless Leg Syndrome Study Group Diagnostic Criteria	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
The REM Sleep Behavior Disorder (RBD) Screening Questionnaire (RBDSQ)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
University of Pennsylvania Smell Identification Test (UPSIT)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Beck Depression Inventory – II (BDI-II)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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Diagnostic and Statistical Manual of Mental Disorders (DSM-5)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Hospital Anxiety and Depression Scale (HADS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
McElroy Diagnostic Criteria for Compulsive Buying	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Montgomery-Asberg Depression Rating Scale (MADRS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Neuropsychiatric (NPI) Inventory	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Structured Clinical Interview for DSM- IV Axis Disorders- Patient Version (SCID-I/P)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Belastungsfragebogen Parkinson kurzversion (BELA-P- k)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
EuroQol 5- Dimension Questionnaire (EQ- 5D)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Nottingham Health Profile (NHP)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Parkinson's disease questionnaire (PDQ-39)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Quality of Life in Neurological Disorders (Neuro-QOL)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Questions on Life Satisfaction– Movement Disorder (QLS-MD) and Deep Brain Stimulation (QLS-DBS) Modules	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Schedule for the Evaluation of Individual Quality of Life - Direct Weighting (SEIQoL-DW)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Schedule for the Evaluation of Individual Quality of Life (SEIQoL)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Sickness Impact Profile (SIP)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Food Frequency Questionnaire	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
PD DOC Mini Environmental Risk Questionnaire for Parkinson's Disease Patients Baseline (PD DOC MERQ-PD- B	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Risk Factor Questionnaire (RFQ) – All	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Risk Factor Questionnaire - NSAIDS and Calcium Channel Blockers (RFQ)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Risk Factor Questionnaire - Occupation and Employment Status (RFQ	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Risk Factor Questionnaire - Physical Activity and Sleep (RFQ)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Risk Factor Questionnaire - Residential History (RFQ)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Risk Factor Questionnaire – Toxicants (RFQ)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Risk Factor Questionnaire - Height and Weight (RFQ-U)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Risk Factor Questionnaire – Pesticides (Home) (RFQ-U)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Risk Factor Questionnaire – Pesticides (Work) (RFQ-U)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Risk Factor Questionnaire - Smoking and Tobacco (RFQ-U)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Addenbrooke's Cognitive Examination-Revised (ACE-R)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Scales for Outcomes in Parkinson's Disease-Cognitive (SCOPA-COG)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Short Portable Mental Status Questionnaire (SPMSQ)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Movement Disorder Society - Unified Parkinson's Disease Rating Scale (MDS- UPDRS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Unified Parkinson's Disease Rating Scale (UPDRS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Berlin Questionnaire	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Brief Pain Inventory (Short Form)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Cambridge-Hopkins Restless Legs Syndrome Diagnostic Questionnaire (CH- RLSQ)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Drooling Severity and Frequency Scale (DSFS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

Parkinson's Disease CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Fatigue Severity Scale (FSS) of Sleep Disorders	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Insomnia Severity Index (ISI)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Mini Nutritional Assessment (MNA)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Multiple Sleep Latency Test and Guidelines (MSLT)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Non-Motor Symptom assessment scale for Parkinson's Disease (NMSS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Non-Motor Symptom Questionnaire (NMS-Quest)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Parkinson's Disease Sleep Scale (PDSS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Quality of Life in Swallowing Disorders (SWAL- QOL)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Rome III Constipation Module	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Scales for Outcomes in Parkinson's Disease-Autonomic (SCOPA-Aut)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Scales for Outcomes in Parkinson's Disease-Sleep (SCOPA-Sleep)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Sialorrhea Clinical Scale for PD (SCS- PD)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Sleep Apnea Scale of Sleep Disorders Questionnaire (SA- SDQ)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Stanford Sleepiness Scale (SSS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
STOP Questionnaire	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Survey Screen for Sleep Apnea (SSSA)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Swallowing Disturbance Questionnaire (SwDQ)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Apathy Scale (AS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Brief Psychiatric Rating Scale (BPRS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Gambling Symptom Assessment Scale (G-SAS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Geriatric Depression Scale (GDS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Hamilton Anxiety Rating Scale (HAM- A)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Hamilton Depression Rating Scale (HDRS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Proposed Criteria for Diagnosis of the Syndrome of Apathy	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Questionnaire about Buying Behavior (QABB)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Questionnaire for Impulsive- Compulsive Behaviors in Parkinson's Disease (QUIP) (Short form)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Questionnaire for Impulsive- Compulsive Behaviors in Parkinson's Disease (QUIP) (Long form)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Scale for the Assessment of Positive Symptoms (SAPS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Sexual Compulsivity Scale (SCS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
South Oaks Gambling Screen (SOGS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Structured Clinical Interview for Pathological Gambling (SCI-PG)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
36-Item Short Form Health Survey (SF- 36)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Parkinson's Disease Quality of Life Scale (PDQUALIF)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Parkinson's Impact Scale (PIMS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Scales for Outcomes in Parkinson's Disease- Psychosocial (SCOPA-PS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
World Health Organization Quality of Life Assessment (WHOQOL-BREF)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

Parkinson's Disease CDE Revision History Document

August 2012 Revisions

Overview

There have been changes to the content and structure of the Parkinson's Disease (PD) CDE materials in Version 1.1 compared to Version 1.0, including the following:

- Every attempt was made to remove duplication and redundancy in the PD CDEs;
- The PD CDEs were harmonized with other large national and international standardization initiatives and efforts [e.g., International Conference on Harmonisation (ICH), Logical Observation Identifiers Names and Codes (LOINC), International Classification of Diseases (ICD), Unified Code for Units of Measure (UCUM)]
- The majority of element names and definitions were improved.
- The permissible values and references of some elements were revised; and
- The version numbers of all forms (excluding standardized scales/instruments) were updated.
- Several guideline documents were reorganized and consolidated to make it easier to understand which standardized instruments/scales are recommended, though the recommendations themselves remained unchanged.
- Some of the forms and guideline documents were re-categorized under a different domain or subdomain to be consistent with other NINDS CDEs.

The corresponding data dictionaries (i.e., CDE Detailed Report) have been modified in accordance with the form changes.

Form Status Changes

New Forms:

- None

Updated Forms:

- Demographics

Parkinson's Disease CDE Revision History Document

- Family History
- Functional Neurosurgery
- History of Early Exposure
- Infection History
- Medical History
- MR
- MRI and Spectroscopy
- Neuropathology
- Non-Parkinson's Disease Medication Log
- Non-Prescribed Drug Use Questionnaire
- Parkinson's Disease Medication Log
- PET-SPECT

Removed Forms:

- None

Detailed Form Revisions:

Additional specific changes to the CRF modules are detailed in the table included on the subsequent page.

Parkinson's Disease CDE Revision History Document

2 Parkinson's Disease Revision History Table

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
All	1.1	1.0	Minor	Modified CDEs	Nearly all CDE names and definitions were updated to achieve greater consistency across all NINDS CDEs and for clarity
Various	1.1	1.0	Minor	Deleted CDEs	The following types of CDEs were deleted: CDEs redundant with other CDEs; CDEs specifying unit; and CDEs specifying an "other, specify" response
Various	1.1	1.0	Minor	Modified CDEs	For a number of CDEs, "Unknown" was added to the permissible value set and/or "Don't know" and "Missing/Unknown" were removed
Demographics	1.1	1.0	Minor	Modified CDEs	The following CDE definition and permissible values were updated: Ethnicity USA Category
Demographics	1.1	1.0	Minor	Modified CDEs	The following CDE instructions were updated: Gender type; Education level USA type

Parkinson's Disease CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Demographics	1.1	1.0	Minor	Modified Form	The following changes were made to the form: reordering of questions; removed "or" before last permissible value choice; capitalization; changes to header
Family History	1.1	1.0	Minor	Modified Form	The following changes were made to the form: wording in column headers; changes to header; updated to reflect new number of Core elements
Family History	1.1	1.0	Minor	Modified CDEs	Permissible values were modified for CDE "Family history medical condition relative type"
Functional Neurosurgery	1.1	1.0	Minor	Modified Form	The following changes were made to the form: changes to header; capitalization; grammar
Functional Neurosurgery	1.1	1.0	Major	New CDE	The following CDEs were added: "Surgical or therapeutic procedure start date and time"

Parkinson's Disease CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Functional Neurosurgery	1.1	1.0	Major	Modified CDEs	Permissible values were updated for: Surgical complications post-operative type; Aborted procedures reason; Adverse event severity scale; Adverse event other action taken type; Adverse event outcome status
Functional Neurosurgery	1.1	1.0	Minor	Modified CDEs	Instructions were updated for: Surgical Complications
History of Early Exposure to PD	1.1	1.0	Minor	Modified Form	The following changes were made to the form: header and footer modified; skip logic modified; instruction to specify units added; relabeled "sex" as "gender"
History of Early Exposure to PD	1.1	1.0	Minor	Modified CDEs	Permissible values were updated for the following CDEs: Sibling gender type; Sibling alive indicator
Infection History	1.1	1.0	Minor	Modified Form	The following changes were made to the form: header modified; skip logic modified
Infection History	1.1	1.0	Minor	Modified CDEs	Permissible values were updated for the following CDEs: Influenza vaccine received frequency; Meningitis or encephalitis diagnosed type

Parkinson's Disease CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Medical History of Parkinson's Disease	1.1	1.0	Minor	Modified Form	The following changes were made to the form: modified header
Medical History of Parkinson's Disease	1.1	1.0	Minor	Deleted CDEs	The following CDE was removed from the form: Form not Done
Medical History of Parkinson's Disease	1.1	1.0	Minor	New CDE	The following CDE was added to the body of the form: Medical history taken date and time
Medical History of Parkinson's Disease	1.1	1.0	Minor	Modified CDEs	Permissible values were updated for: Symptom laterality type
MR	1.1	1.0	Minor	Modified Form	The following was modified on the form: header; instructions; label of CDE "Medication prior or concomitant name"
MR	1.1	1.0	Minor	Modified CDEs	Permissible values were updated for "imaging matrix size value"
MRI and Spectroscopy	1.1	1.0	Minor	Modified Form	The header was modified on the form
MRI and Spectroscopy	1.1	1.0	Minor	Modified CDEs	Permissible values were updated for "imaging matrix size value"
Neuropathology	1.1	1	Minor	Modified form	The following changes were made to the form; Header updated; Codes for permissible values were removed

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Neuropathology	1.1	1	Minor	Modified CDEs	Permissible values were updated for most CDEs on this form
Non-Parkinson's Disease Medication Log	1.1	1.0	Minor	Modified Form	The following was modified on the form: grammar; header; reformatted table; instructions for table
Non-Parkinson's Disease Medication Log	1.1	1.0	Major	New CDEs	The following CDEs were added: Medication prior or concomitant RXNorm code; Medication prior or concomitant dose unit of measure UCUM code
Non-prescribed Drug Use Questionnaire	1.1	1.0	Minor	Modified Form	The following changes were made to the form: capitalization; grammar
Non-prescribed Drug Use Questionnaire	1.1	1.0	Minor	Modified CDEs	Updated permissible values for "Drug or substance illicitly used category"
Parkinson's Disease Medication Log	1.1	1.0	Minor	Modified Form	The following was modified on the form: header; removed line numbers in table; relabeled column headers; reordered permissible values in table; removed note regarding side effects chart; PD Medication name reference table

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Parkinson's Disease Medication Log	1.1	1.0	Minor	Modified CDEs	Permissible values were updated for the following CDE: Medication prior or concomitant class name
Parkinson's Disease Medication Log	1.1	1.0	Minor	Modified CDEs	Instructions were updated for the following CDEs: Medication prior or concomitant name; Medication prior or concomitant side effect type
Parkinson's Disease Medication Log	1.1	1.0	Major	New CDEs	The following CDEs were added: Medication prior or concomitant RXNorm code; Medication prior or concomitant dose unit of measure UCUM code
PET-SPECT	1.1	1.0	Minor	Modified Form	The following was modified on the form: grammar; instructions; header; labeling of PVs for "Imaging radioligand type" and "Imaging quantitative outcome type"
PET-SPECT	1.1	1.0	Minor	Modified CDEs	Permissible values were updated for "imaging matrix size value"