

## nonizing information. Streamlining research. Multiple Sclerosis (MS) CDE Highlight Summary Document

### **NIH Resources**

The NINDS also strongly encourages researchers to use these NIH developed materials for NINDS-sponsored research, when appropriate. Utilization of these resources will enable greater consistency for NINDS-sponsored research studies. These tools are free of charge.

- National Institutes of Health (NIH) Toolbox
- Quality of Life in Neurological Disorders (Neuro-QOL)
- Patient-Reported Outcomes Measurement Information System (PROMIS)

### **Suicidal Ideation**

Investigators should review the FDA's "Guidance for Industry: Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials" for the most up-to-date information about suicidal ideation and behavior. One scale that FDA suggests is the Columbia Suicide Severity Rating Scale (C-SSRS) (available at Columbia Suicide Severity Rating Scale Website).

Domain; Subdomain	Recommendations
Multiple Sclerosis	These instruments and elements are recommended for use in all Multiple Sclerosis studies:
	<ol> <li>Supplemental – Highly Recommended instruments:         <ol> <li>Expanded Disability Status Scale (EDSS) (Highly recommended to categorize severity of neurological disability)</li> <li>Modified Ashworth Scale for Grading Spasticity (Highly recommended for clinical trials in spasticity)</li> <li>Symbol Digit Modalities Test (SDMT) (Highly recommended for studies involving neuropsychological testing for adult and pediatric patients)</li> </ol> </li> <li>Core elements:         <ol> <li>See Start-Up Resource Listing document (Multiple Sclerosis Start-Up Resource Listing)</li> </ol> </li> </ol>
Participant Characteristics; Demographics	Core: Demographics, General Core  Supplemental – Highly Recommended: None  Supplemental: Demographics  Exploratory: None
Participant Characteristics; Social Status	Core: None Supplemental – Highly Recommended: Social Status
	Supplemental: Social Status  Exploratory: None



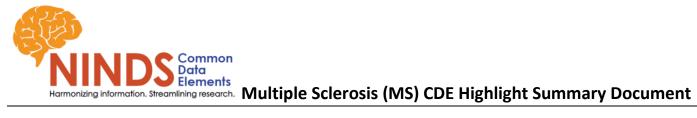
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Domain; Subdomain	Recommendations
Participant History and Family History; General Health History	Core: Medical History
	Supplemental – Highly Recommended: None
	<b>Supplemental:</b> Behavioral History, Family History-Affected Relatives and Pedigree, Godin Leisure – Time Exercise Questionnaire, Medical History, Pediatric Developmental History, Reproductive and Hormonal History
	Exploratory: History Data Source and Reliability
Disease/Injury Related	Core: None
Events; History of Disease/Injury Event	Supplemental – Highly Recommended: Relapse
	Supplemental: Multiple Sclerosis Severity Score (MSSS), Relapse
	Exploratory: Visual Analog Scale
Disease/Injury Related Events; Classification	Core: Diagnosis and Disease Characteristics
	Supplemental – Highly Recommended: None
	Supplemental: Diagnosis and Disease Characteristics
	Exploratory: None
Assessments and	Core: None
Examinations; Physical/Neurological Examination	Supplemental – Highly Recommended: None
	Supplemental: Physical Exam
	Exploratory: Grip Strength Fatigue
Assessments and	Core: None
Examinations; Vital Signs and Other Body Measures	Supplemental – Highly Recommended: None
	Supplemental: Vital Signs
	Exploratory: None
Assessments and	Core: Laboratory Test Recommendations
Examinations; Laboratory Tests and	Supplemental – Highly Recommended: None
Biospecimens/Biomarkers	<b>Supplemental:</b> Biospecimens Summary Statement, Genetics, Laboratory Test Recommendations
	Exploratory: Laboratory Test Recommendations

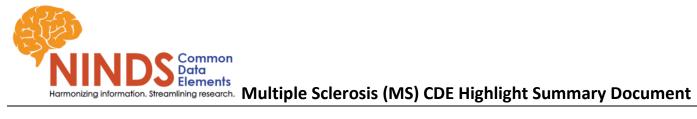


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Domain; Subdomain	Recommendations
Assessments and Examinations; Imaging Diagnostics	Core: None
	Supplemental – Highly Recommended: Imaging Analysis Results- Follow Up, Magnetic Resonance Imaging (MRI)
	<b>Supplemental</b> : Imaging Analysis Results – Follow Up, Imaging Analysis Technique and Results-Baseline, Imaging Optical Coherence Tomography (OCT) Information, Magnetic Resonance Imaging (MRI)
	<b>Exploratory</b> : Imaging Analysis Results – Follow Up, Imaging Analysis Technique and Results – Baseline, Imaging OCT Analysis – Contrast and Visual Acuity, Imaging OCT Analysis – RNFL Thickness Analysis, Imaging OCT Analysis – Spectralis Report Analysis, Imaging OCT Analysis – Stratus Retinal Thickness Report, Imaging OCT Analysis – Cirrus Macular Thickness, Imaging Optical Coherence Tomography (OCT) Information
Assessments and	Core: None
Examinations; Non- Imaging Diagnostics	Supplemental – Highly Recommended: None
	Supplemental: Non-Imaging Diagnostics Recommendations
	Exploratory: Non-Imaging Diagnostics Recommendations
Outcomes and Endpoints;	Core: None
Activities of Daily Living/Performance	Supplemental – Highly Recommended: None
	Supplemental: Activities Specific Balance Confidence Scale (ABC-Scale) Barthel Index, Berg Balance Scale (BBS), Bladder Control Scale (BLCS), Bowel Control Scale (BWCS), Brief Pain Inventory (Short Form), Disease Steps (DS), Fatigue Scale for Motor and Cognitive Functions, Fatigue Severity Scale (FSS), Functional Assessment in Multiple Sclerosis, Functional Independence Measure, Impact of Visual Impairment Scale, McGill Pain Questionnaire, Modified Fatigue Impact Scale (MFIS), MOS Pain Effects Scale (PES), Multiple Sclerosis Impact Scale (MSIS-29), Patient Determined Disease Steps, PROMIS Fatigue Short Form, PROMIS Pain Interference Short Form, Short From 12- Item Health Survey, Short Form 36-Item Health Survey
	<b>Exploratory</b> : Fatigue/Activity Record Diary, Multiple Sclerosis Functional Composite Timed 25-Foot Walk Nine Hole Peg Test Paced Auditory Serial Addition Test



Domain; Subdomain	Recommendations
Outcomes and Endpoints; Neuropsychological Testing	Core: None
	Supplemental – Highly Recommended instruments: Expanded Disability Status Scale (EDSS) and Symbol Digit Modalities Test (SDMT)
	Supplemental: Automated Neuropsychological Assessment Metrics (ANAM), Beery- Buktenica Developmental Test of Visual-Motor integration (Beery VMI); Brief Visuospatial Memory Test Revised (BVMTR), California Verbal Learning Test- Children (CVLT-C), California Verbal Learning Test- Second Edition (CVLT-II), Center for Epidemiologic Studies – Depression Scale (CES-D), Clinical Evaluation of Language Fundamentals, Conner's Continuous Performance Test III, Contingency Naming Test (CNT), Controlled Oral Word Association Test (COWAT) subtest of the Multilingual Aphasia Examination (MAE), Delis Kaplan Executive Functioning System (DKEFS), Expressive One-Word Picture Vocabulary Test, Nonverbal Selective Reminding Test (NVSRT), Rey Auditory Verbal Learning Test [RAVLT], Stroop Test, Test of Memory and Learning (TOMAL-2), Wechsler Abbreviated Scale of Intelligence (WASI), Wechsler Intelligence Scale for Children-IV (WISC-IV), Wide Range Assessment of Memory and Learning, Second Edition (WRAML-2), Wisconsin Card Sorting Test (WCST), Woodcock-Johnson III Test for Cognitive Abilities
	Exploratory: None
Outcomes and Endpoints; Performance Measures	Core: None
	Supplemental – Highly Recommended instruments: Modified Ashworth Scale for Grading Spasticity, Nine Hole Peg Test, Sloan Low Contrast Letter Acuity, Timed 25-Foot Walk (T25FW)
	Supplemental: 10 Meter Timed Walk, 6 Minute Walk Test, Grooved Pegboard Test, Hauser Ambulation Index (AI), Multiple Sclerosis Walking Scale, National Eye Institute Visual Functioning Questionnaire – 25 item (NEI-VFQ-25), Pelli Robson Test, Scale for the Assessment and Rating of Ataxia, Timed Up and Go (TUG)  Exploratory: None



Domain; Subdomain	Recommendations
Outcomes and Endpoints; Quality of Life/Patient Reported Outcomes	Core: None Supplemental – Highly Recommended: None
	Supplemental: Clinical Global Impression Scale; EuroQOL-5 Dimension
	Questionnaire, Euro-QOL-VAS, ICIQ-Lower Urinary Tract Symptoms Quality of Life, MOS Modified Social Support Survey (MSSS), Multiple Sclerosis International Quality of Life Questionnaire (MusiQoL), Multiple Sclerosis Quality of Life Inventory (MSQLI), Multiple Sclerosis Quality of Life-54 Instrument (MSQOL)-54, Multiple Sclerosis Spasticity Scale (MSSS-88), Patient Reported Impact of Multiple Sclerosis (PRIMuS), Sexual Satisfaction Scale (SSS), Treatment Satisfaction Questionnaire for Medication
	Exploratory: None