



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	<p>These instruments and elements are recommended for use in all Multiple Sclerosis studies:</p> <p>Supplemental – Highly Recommended instruments:</p> <ol style="list-style-type: none"> 1. Kurtzke Expanded Disability Status Scale (EDSS) (Highly recommended to categorize severity of neurological disability) 2. Symbol Digit Modalities Test (SDMT) (Highly recommended for studies involving neuropsychological testing for adult and pediatric patients) 3. Modified Ashworth Scale for Grading Spasticity (Highly recommended for clinical trials in spasticity) <p>Core elements: See Start-Up Resource Listing document (Multiple Sclerosis Start-Up Resource Listing)</p>
Participant/Subject Characteristics; Demographics	<p>Core: Demographics, General Core</p> <p>Supplemental: Demographics</p>
Participant/Subject Characteristics; Social Status	<p>Core: Social Status</p> <p>Supplemental: Social Status</p>
Participant/Subject History and Family History; General Health History	<p>Core: None</p> <p>Supplemental: Behavioral History, Family History-Affected Relatives and Pedigree, Godin Leisure- Time Exercise Questionnaire, History Data Source and Reliability, Medical History, Pediatric Developmental History, Reproductive and Hormonal History</p>



Domain; Subdomain	Recommendations
Disease/Injury Related Events; History of Disease/Injury Event	Core: None Supplemental: Multiple Sclerosis Severity Score (MSSS), Relapse
Disease/Injury Related Events; Classification	Core: Diagnosis and Disease Characteristics Supplemental –Highly Recommended: Diagnosis and Disease Characteristics Supplemental: Diagnosis and Disease Characteristics
Assessments and Examinations; Neurological Examination	Core: None Supplemental: Physical Exam
Assessments and Examinations; Vital Signs	Core: None Supplemental: Vital Signs
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Core: None Supplemental: Biospecimens Summary Statement, Genetics, Laboratory Test Recommendations
Assessments and Examinations; Imaging Diagnostics	Core: None Supplemental –Highly Recommended: Imaging Analysis Results- Follow Up, Imaging Analysis Technique and Results-Baseline, Magnetic Resonance Imaging (MRI) Supplemental: 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, Magnetic Resonance Imaging (MRI)
Assessments and Examinations; Non-Imaging Diagnostics	Core: None Supplemental: Non- Imaging Diagnostics Recommendations
Outcomes and Endpoints; Summary of All Outcome Recommendations	Clinical Outcomes Summary Statement; MS CDE Instrument Recommendations by Outcome Domain and Classification



Domain; Subdomain	Recommendations
<p>Outcomes and Endpoints; Activities of Daily Living/Performance</p>	<p>Core: None</p> <p>Supplemental: Barthel Index, Berg Balance Scale (BBS), McGill Pain Questionnaire, 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), Modified Fatigue Impact Scale (MFIS), Functional Assessment in Multiple Sclerosis, Functional Independence Measure, Impact of Visual Impairment Scale, MOS Pain Effects Scale (PES), Multiple Sclerosis Impact Scale, Patient Determined Disease Steps, PROMIS Fatigue Short Form, PROMIS Pain Interference Short Form, Symbol Digit Modality Test, The Activities- specific Balance Confidence (ABC) Scale, NIH Toolbox</p>
<p>Outcomes and Endpoints; Neuropsychological Testing</p>	<p>Core: None</p> <p>Supplemental – Highly Recommended instruments: Kurtzke Expanded Disability Status Scale (EDSS) and Symbol Digit Modalities Test (SDMT)</p> <p>Supplemental: 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), Clinical Evaluation of Language Fundamentals, Conner’s Continuous Performance Test II Version 5, Contingency Naming Test (CNT), Controlled Oral Work Association Test (COWAT) subtest of the Multilingual Aphasia Examination (MAE), Delis Kaplan Executive Functioning System (DKEFS)- Trail Making Tests, 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</p>
<p>Outcomes and Endpoints; Performance Measures</p>	<p>Core: None</p> <p>Supplemental – Highly Recommended instruments: Modified Ashworth Scale for Grading Spasticity</p> <p>Supplemental: 10 Meter Timed Walk, 6 Minute Walk Test, Grip Strength, Grooved Pegboard Test, Hauser Ambulation Index (AI), Multiple Sclerosis Spasticity Scale, Multiple Sclerosis Walking Scale, National Eye Institute Visual Functioning Questionnaire- 25 item (NEI-VFQ-25), Nine Hole Peg Test, Pelli Robson Test, Scale for the Assessment and Rating of Ataxia, Sloan Low Contrast Letter Acuity, Timed 25-Foot Walk (T25FW), Timed Up and Go (TUG)</p>



Domain; Subdomain	Recommendations
Outcomes and Endpoints; Quality of Life	Clinical Global Impression; 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, Multiple Sclerosis Quality of Life (MSQOL)-54, Multiple Sclerosis Quality of Life Inventory, Patient Reported Impact of Multiple Sclerosis, Sexual Satisfaction Scale (SSS), Treatment Satisfaction Questionnaire for Medication