



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. Expanded Disability Status Scale (EDSS) (Highly recommended to categorize severity of neurological disability) 2. Modified Ashworth Scale for Grading Spasticity (Highly recommended for clinical trials in spasticity) 3. Symbol Digit Modalities Test (SDMT) (Highly recommended for studies involving neuropsychological testing for adult and pediatric patients) <p>Core elements: See Start-Up Resource Listing document (Multiple Sclerosis Start-Up Resource Listing)</p>
Participant Characteristics; Demographics	<p>Core: Demographics, General Core</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Demographics</p> <p>Exploratory: None</p>
Participant Characteristics; Social Status	<p>Core: None</p> <p>Supplemental – Highly Recommended: Social Status</p> <p>Supplemental: Social Status</p> <p>Exploratory: None</p>



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



Domain; Subdomain	Recommendations
<p>Assessments and Examinations; Imaging Diagnostics</p>	<p>Core: None</p> <p>Supplemental – Highly Recommended: Imaging Analysis Results- Follow Up, Magnetic Resonance Imaging (MRI)</p> <p>Supplemental: Imaging Analysis Results – Follow Up, Imaging Analysis Technique and Results-Baseline, Imaging Optical Coherence Tomography (OCT) Information, Magnetic Resonance Imaging (MRI)</p> <p>Exploratory: 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</p>
<p>Assessments and Examinations; Non-Imaging Diagnostics</p>	<p>Core: None</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Non-Imaging Diagnostics Recommendations</p> <p>Exploratory: Non-Imaging Diagnostics Recommendations</p>
<p>Outcomes and Endpoints; Activities of Daily Living/Performance</p>	<p>Core: None</p> <p>Supplemental – Highly Recommended: None</p> <p>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 Form 12-Item Health Survey, Short Form 36-Item Health Survey</p> <p>Exploratory: Fatigue/Activity Record Diary, Multiple Sclerosis Functional Composite Timed 25 Foot Walk 9-Hole Peg Test Paced Auditory Serial Addition Test</p>



Domain; Subdomain	Recommendations
<p>Outcomes and Endpoints; Neuropsychological Testing</p>	<p>Core: None</p> <p>Supplemental – Highly Recommended instruments: Expanded Disability Status Scale (EDSS) and Symbol Digit Modalities Test (SDMT)</p> <p>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</p> <p>Exploratory: None</p>
<p>Outcomes and Endpoints; Performance Measures</p>	<p>Core: None</p> <p>Supplemental – Highly Recommended instruments: Modified Ashworth Scale for Grading Spasticity, Nine Hole Peg Test, Sloan Low Contrast Letter Acuity, Timed 25-Foot Walk (T25FW)</p> <p>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)</p> <p>Exploratory: None</p>



Domain; Subdomain	Recommendations
Outcomes and Endpoints; Quality of Life/ Patient Reported Outcomes	<p>Core: None</p> <p>Supplemental – Highly Recommended: None</p> <p>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</p> <p>Exploratory: None</p>