## Multiple Sclerosis CDE Revision History Document

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August 2022 Revisions

- The CDE C00311 Birth weight report value was removed from the Medical History CRF and replaced with CDE C59019 Birth weight measurement. CDE C59019 classified as Supplemental.

June 2020 Revisions

- The Highlight Summary document has been updated to reflect these changes.
- The Social Status CRF and CDE Details in the Participant Characteristics; Social Status Domain; Subdomain were reclassified from Core to Supplemental – Highly Recommended.
- The Relapse CRF and CDE Details were added as Supplemental – Highly Recommended and the Visual Analog Scale CRF and CDE Details were added as Exploratory to the Disease/Injury Related Events; History of Disease/Injury Event Domain; Subdomain.
- The Grip Strength Fatigue CRF and CDE Details were added as Exploratory to the Assessments and Examinations; Physical/Neurological Examination Domain; Subdomain.
- The Imaging Analysis Technique and Results Baseline CRF and CDE Details were reclassified from Supplemental – Highly Recommended to Exploratory in the Assessments and Examinations; Imaging Diagnostics Domain; Subdomain.
- The Multiple Sclerosis Functional Composite Timed 25 Foot Walk 9-Hole Peg Test Paced Auditory Serial Addition Test Notice of Copyright was reclassified from Supplemental to Exploratory in the Outcomes and Endpoints; Activities of Daily Living/Performance Domain; Subdomain.
- The Multiple Sclerosis Spasticity Scale (MSSS) classified as Supplemental was removed from Outcomes and Endpoints; Performance Measures Domain; Subdomain and added to the Outcomes and Endpoints; Quality of Life/ Patient Reported Outcomes Domain; Subdomain.
- Grip Strength CRF and CDE Details were removed from the Exploratory classification of the Outcomes and Endpoints; Performance Measures Domain/Subdomain.

April 2020 Revisions

- Additional references were added on the Nine Hole Peg Test, Multiple Sclerosis Quality of Life Inventory (MSQLI), and Patient Reported Impact of Multiple Sclerosis (PRIMuS).
- Current availability links updated for the Multiple Sclerosis Functional Composite Timed 25 Foot Walk 9-Hole Peg Test Paced Auditory Serial Addition Test.
- The Biospecimens Summary Statement was updated.
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- Text added to the Comments/Special instructions section on the Multiple Sclerosis Functional Composite Timed 25 Foot Walk 9-Hole Peg Test Paced Auditory Serial Addition Test.
- Strengths/Weaknesses section was updated on the 6 Minute Walk Test, 10 Meter Timed Walk Test, Sloan Low Contrast Acuity Test, and Timed 25 Foot Walk Test.
- Scoring section updated on the Sloan Low Contrast Acuity Test and Timed 25 Foot Walk Test.

January 2020 Revisions

- General Core CRF updated to replace 'Gender' question with 'Sex assigned at birth' and 'Gender identity'.
- Two new CDEs added to General Core CRF: C58676 (Sex assigned at birth) and C58677 (Gender identity). C00035 has been removed
- Start-Up document updated to reflect these changes.
- Current instrument availability links were updated for the Patient Determined Disease Steps, Multiple Sclerosis Quality of Life-54 Instrument (MSQOL-54), and Patient Reported Impact of Multiple Sclerosis (PRIMuS).
- Reference added for Patient Reported Impact of Multiple Sclerosis (PRIMuS) NOC.

April 2015 Revisions

- Inserted additional reference on the 6 Minute Walk Test file.

March 2015 Revisions

No changes.

February 2015 Revisions

No changes.

January 2015 Revisions

- Classifications for the Symbol Digit Modalities Test, Modified Ashworth Scale and Kurtzke Expanded Disability Status were updated for MS.

November 2014 Revisions

No changes.
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September 2014 Revisions

- Revisions to Rosters in MS to list Joy Esterlitz and Maniza Sheikh under the NINDS CDE Team section.

August 2014 Revisions

No changes.

July 2014 Revisions

- Reassignment of several MS NOCs between Subdomains, to reflect committee recommendations.

June 2014 Revisions

- A problem with the MS Committee Roster Report was corrected so that it reflects the correct report.

May 2014 Revisions

No changes.

April 2014 Revisions

No changes.

March 2014 Revisions

No changes.

February 2014 Revisions

No changes.

January 2014 Revisions

No changes.
Overview
There have been Major changes to the content and structure of the Multiple Sclerosis (MS) CDE materials in Version 3.0 compared to Version 2.0, including the following:

Form Status Changes
New Forms:
Beck Depression Index
Beery-Buktenica VMI
Brief Visuospatial Memory Test
California Verbal Learning Test 2
California Verbal Learning Test Children
Center for Epi Studies Depression Scale
Clinical Evaluation of Language Fundamentals
Connors Continuous Performance Test
Contingency Naming Test
Controlled Oral Word Association Test
Delis Kaplan Executive Functioning System
Expressive One Word Picture Vocabulary Test
Multiple Sclerosis Severity Score
Nonverbal Selective Reminding Test
Rey Auditory Verbal Learning Test
Stroop Test
Symbol Digit Modality Test
TOMAL-2
Wechsler Abbreviated Scale for Intelligence
Wechsler Scale for Intelligence for Children
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Wide Range Assess of Memory and Learning
Wisconsin Card Sorting Test
Woodcock-Johnson Tests of Cognitive Abilities

**Updated Forms:**
Notice of Copyright Created (NOC) (Will replace previously existing forms)
Godin Leisure-Time Exercise
Multiple Sclerosis Severity Score
Barthel Index
Berg Balance Scale
Bladder Control Scale
Bowel Control Scale
Brief Pain Inventory Short Form
Disease Steps
Fatigue Scale for Motor and Cognitive Functions
Fatigue Severity Scale
Functional Assessment in Multiple Sclerosis
Functional Independence Measure
Impact of Visual Impairment Scale
McGill Pain Questionnaire
Modified Fatigue Impact Scale
MOS Pain Effects Scale
Multiple Sclerosis Functional Composite
Multiple Sclerosis Impact Scale
Patient Determined Disease Steps
PROMIS Fatigue Short Form
PROMIS Pain Interference Short Form
The Activities Specific Balance Scale
Expanded Disability Status Scale
10 Meter timed walk
6-minute walk Test
Grooved Pegboard Test
Hauser Ambulation Index
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Modified Ashworth Scale
Multiple Sclerosis Walking Scale
National Eye Institute Visual Functioning Questionnaire
Pelli-Robson Test
Scale for the Assessment and Rating of Ataxia
Sloan Low Contrast Letter Acuity
Timed Up and Go
Short Form Health Survey-36
Clinical Global Impression
EuroQol -5 Dimension Test
EuroQol-VAS
ICIQ-LUTS Quality of Life
MOS Modified Social Support Survey
Multiple Sclerosis International Quality of Life Questionnaire
Multiple Sclerosis Quality of Life-54
Multiple Sclerosis Quality of Life Inventory
Patient Reported Impact of Multiple Sclerosis
Sexual Satisfaction Scale
Short Form Health Survey-12
Treatment Satisfaction Questionnaire for Medication

Removed Forms:
None

Detailed Form Revisions:
Additional specific changes to the CRF modules are detailed in the table included on the subsequent page.
## Multiple Sclerosis CDE Revision History Table

<table>
<thead>
<tr>
<th>CRF Module/ Guideline</th>
<th>Current Version</th>
<th>Previous Version</th>
<th>Change Classification</th>
<th>Change Type</th>
<th>Description of Change</th>
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<td>Beck Depression Index</td>
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<td>2.0</td>
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## Multiple Sclerosis CDE Revision History Document

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<td>2.0</td>
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<td>Wechsler Scale for Intelligence for Children</td>
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<td>2.0</td>
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<td>Wide Range Assess of Memory and Learning</td>
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<td>A Notice of Copyright was created for this form and will replace the existing form</td>
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<td>Wisconsin Card Sorting Test</td>
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<td>2.0</td>
<td>Major</td>
<td>Notice of Copyright</td>
<td>A Notice of Copyright was created for this form and will replace the existing form</td>
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<td>Woodcock-Johnson Tests of Cognitive Abilities</td>
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<td>Major</td>
<td>Notice of Copyright</td>
<td>A Notice of Copyright was created for this form and will replace the existing form</td>
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<tr>
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<td>Major</td>
<td>Notice of Copyright</td>
<td>A Notice of Copyright was created for this form and will replace the existing form</td>
</tr>
</tbody>
</table>

October 2012 Revisions

Overview

There have been changes to the content and structure of the Multiple Sclerosis (MS) CDE materials in Version 2.0 compared to Version 1.0, including the following:

- Every attempt was made to remove duplication and redundancy in the MS CDEs;
- The MS CDEs were harmonized with other large national and international standardization initiatives and efforts [e.g., International Conference on Harmonization (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 many 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:
- Physical Exam
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Social Status

History Data Source and Reliability

Vital Signs

The above forms were created using CDEs that were previously included on other forms.

Updated Forms:

- Demographics
- Medical History
- Behavioral History
- Family History – Affected Relatives and Pedigree
- Reproductive and Hormonal History
- Pediatric Developmental History
- Relapse
- Diagnosis and Disease Characteristics
- Genetics

Removed Forms:

None

Detailed Form Revisions:

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

2 Multiple Sclerosis Revision History Table

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<tbody>
<tr>
<td>All</td>
<td>1.1</td>
<td>1.0</td>
<td>Minor</td>
<td>Modified CDEs</td>
<td>Nearly all CDE names and definitions were updated to achieve greater consistency across all NINDS CDEs and for clarity</td>
</tr>
<tr>
<td>Various</td>
<td>1.1</td>
<td>1.0</td>
<td>Minor</td>
<td>Deleted CDEs</td>
<td>The following types of CDEs were deleted: CDEs redundant with other CDEs; CDEs specifying unit; and CDEs specifying an &quot;other, specify&quot; response</td>
</tr>
<tr>
<td>CRF Module/ Guideline</td>
<td>Current Version</td>
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</tr>
<tr>
<td>Various</td>
<td>1.1</td>
<td>1.0</td>
<td>Minor</td>
<td>Modified CDEs</td>
<td>For a number of CDEs, &quot;Unknown&quot; was added to the permissible value set and in some cases &quot;Unknown&quot; replaced &quot;Unknown/Don't Know&quot;</td>
</tr>
<tr>
<td>Various</td>
<td>1.1</td>
<td>1.0</td>
<td>Minor</td>
<td>Modified Forms</td>
<td>Instructions were updated to include additional details.</td>
</tr>
<tr>
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<td>1.1</td>
<td>1.0</td>
<td>Minor</td>
<td>Modified Forms</td>
<td>Added footnote identifying certain CDEs as Core; relabeled Sex to Gender on form; rearranged CDE order; reworded zip code CDE.</td>
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<td>Demographics</td>
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<td>1.0</td>
<td>Minor</td>
<td>Deleted CDEs</td>
<td>Deleted City/Town CDE</td>
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<tr>
<td>Demographics</td>
<td>1.1</td>
<td>1.0</td>
<td>Minor</td>
<td>Modified Forms</td>
<td>Moved Marital or partner status, Education years number, Employment status, Job classification category, and Hand preference type to another form</td>
</tr>
<tr>
<td>Physical Exam</td>
<td>1.0</td>
<td>N/A</td>
<td>Minor</td>
<td>New Form</td>
<td>Created Physical Exam form using Hand preference type and General CDEs</td>
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<td>Social Status</td>
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<td>Minor</td>
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<td>Created Social Status form with CDEs previously on Demographics form.</td>
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<td>Major</td>
<td>Modified CDEs</td>
<td>Modified Education years number, Employment status, and Job classification category permissible values</td>
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<td>N/A</td>
<td>Minor</td>
<td>New Form</td>
<td>Created History Data Source and Reliability form with CDEs previously on Medical History form</td>
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</tbody>
</table>
## Multiple Sclerosis CDE Revision History Document

<table>
<thead>
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<th>CRF Module/ Guideline</th>
<th>Current Version</th>
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<th>Change Type</th>
<th>Description of Change</th>
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<td>History Data Source and Reliability</td>
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<td>N/A</td>
<td>Minor</td>
<td>Modified Forms</td>
<td>Minor edits to wording on form</td>
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<td>Behavioral History</td>
<td>1.1</td>
<td>1.0</td>
<td>Major</td>
<td>Modified CDEs</td>
<td>Updated CDEs on form to make consistent with General CDEs</td>
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<td>Behavioral History</td>
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<td>1.0</td>
<td>Minor</td>
<td>Deleted CDEs</td>
<td>Deleted Year started smoking and Year quit smoking</td>
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<td>Behavioral History</td>
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<td>1.0</td>
<td>Minor</td>
<td>New CDEs</td>
<td>Added Tobacco use duration</td>
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<td>1.0</td>
<td>Minor</td>
<td>Modified Forms</td>
<td>Edited name of form; added note regarding use of interview questions to document a complete medical history</td>
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<td>Medical History</td>
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<td>New CDEs</td>
<td>Added CDEs to make form consistent with General CDEs</td>
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<tr>
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<td>1.1</td>
<td>1.0</td>
<td>Minor</td>
<td>Modified Forms</td>
<td>Moved Gestational age value and Birth weight value to this form from another form</td>
</tr>
<tr>
<td>Medical History</td>
<td>1.1</td>
<td>1.0</td>
<td>Minor</td>
<td>Modified Forms</td>
<td>Moved Data Source and Reliability elements to new form</td>
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<td>Pediatric Developmental History</td>
<td>1.1</td>
<td>1.0</td>
<td>Minor</td>
<td>Modified Forms</td>
<td>Edited name of form; formatting changes</td>
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<td>Pediatric Developmental History</td>
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<td>1.0</td>
<td>Minor</td>
<td>Modified Forms</td>
<td>Moved Gestational age value, Birth weight value, Weight measurement, Height measurement, Head circumference measurement, Education years number to other forms</td>
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<td>Revised Breastfed indicator and Formula fed indicator permissible values</td>
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<td>New CDEs</td>
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<td>Pediatric Developmental History</td>
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<td>Minor</td>
<td>Deleted CDEs</td>
<td>Deleted Regular classroom indicator</td>
</tr>
<tr>
<td>Family History – Affected Relatives and Pedigree</td>
<td>1.1</td>
<td>1.0</td>
<td>Minor</td>
<td>Modified Forms</td>
<td>Renamed the form “Family History – Affected Relatives and Pedigree”; moved information on relation of relative to tables; other minor formatting changes</td>
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<tr>
<td>Family History – Affected Relatives and Pedigree</td>
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<td>Minor</td>
<td>Modified CDEs</td>
<td>Revised Twin sibling type permissible values</td>
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<td>Family History – Affected Relatives and Pedigree</td>
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<td>1.0</td>
<td>Minor</td>
<td>Deleted CDEs</td>
<td>Deleted Twin gender type</td>
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<td>Reproductive and Hormonal History</td>
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<td>1.0</td>
<td>Minor</td>
<td>Modified Forms</td>
<td>Revised skip logic</td>
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<tr>
<td>Reproductive and Hormonal History</td>
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<td>1.0</td>
<td>Minor</td>
<td>Modified CDEs</td>
<td>Modified Pregnancy outcome type permissible values</td>
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## Multiple Sclerosis CDE Revision History Document

<table>
<thead>
<tr>
<th>CRF Module/ Guideline</th>
<th>Current Version</th>
<th>Previous Version</th>
<th>Change Classification</th>
<th>Change Type</th>
<th>Description of Change</th>
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</thead>
<tbody>
<tr>
<td>Vital Signs</td>
<td>1.0</td>
<td>N/A</td>
<td>Minor</td>
<td>New Form</td>
<td>New CRF using General CDEs and several CDEs from Pediatric Elements form</td>
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<tr>
<td>Relapse</td>
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<td>1.0</td>
<td>Minor</td>
<td>Modified CDEs</td>
<td>Remove Visit Date CDE; other minor changes</td>
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<td>Diagnosis and Disease Characteristics</td>
<td>1.0</td>
<td>1.0</td>
<td>Minor</td>
<td>Modified CDEs</td>
<td>Modified Laterality type permissible values and changed Present/Absent permissible values to Yes/No for several CDEs</td>
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<td>Diagnosis and Disease Characteristics</td>
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<td>1.0</td>
<td>Minor</td>
<td>Modified Forms</td>
<td>Minor edits to wording on form</td>
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<td>1.0</td>
<td>Minor</td>
<td>Modified CDEs</td>
<td>Modified Family history medical condition relative type permissible values</td>
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<td>1.1</td>
<td>1.0</td>
<td>Minor</td>
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<td>Moved CDEs into table format</td>
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