



Summary of Core/Supplemental—Highly Recommended Recommendations: Multiple Sclerosis CDEs

Start-up Resource – NINDS Multiple Sclerosis (MS) CDE Recommendations

The National Institute of Neurological Disorders and Stroke (NINDS) and other Federal agencies and international organizations have the common mission of developing data standards for clinical research. Through the efforts of subject-specific working groups, topic-driven data elements have been created. The first set of Common Data Elements (CDEs) for Multiple Sclerosis was developed in 2011. The Core data elements to be used by an investigator when beginning a research study in this disease/disorder are listed in this resource document. All other recommendations are listed on the website and should be considered based on study type.

Each CDE or instrument could be classified according to the definitions below:

General Core: A data element that is required for all NINDS funded studies.

Disease Core: A data element that collects essential information applicable to any disease-specific study, including all therapeutic areas. The NINDS and its appointed working groups assign the disease “Core” classification based on the current clinical research best practices. In each case, the disease Core CDEs are a small subset of the available CDEs, where it is anticipated that investigators will need to collect the disease Core CDEs on any type of study. These are required for all disease-specific studies.

Disease Supplemental - Highly Recommended: A data element which is essential based on certain conditions or study types in clinical research studies. In most cases, these have been used and validated in the disease area. These data elements are strongly recommended for the specified disease condition, study type or design.

Disease Supplemental: A data element which is commonly collected in clinical research studies. Use depends upon the study design, protocol or type of research involved. These are recommended, but not required, for studies.

Disease Exploratory: A data element that requires further validation but may fill current gaps in the CDEs and/or substitute for an existing CDE once validation is complete. Such data elements show great promise but require further validation before they are ready for prime-time use in clinical research studies. They are reasonable to use with the understanding that it has limited validation in the target group.

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<p>National Institute of Health (NIH) Resources: <i>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.</i></p>	<ul style="list-style-type: none"> • NIH Toolbox <ul style="list-style-type: none"> • Quality of Life in Neurological Disorders (Neuro-QOL) • Patient-Reported Outcomes Measurement Information System (PROMIS)
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Core CDEs for all NINDS Studies*:

Domain/Sub-Domain	CDE Name	CDE ID	Study Type
Participant Characteristics; Demographics	Birth date	C00007	All studies
Participant Characteristics; Demographics	Ethnicity USA category	C00020	All studies
Participant Characteristics; Demographics	Race USA category	C00030	All studies
Participant Characteristics; Demographics	Birth sex assigned type	C58676	All studies
Participant Characteristics; Demographics	Gender identity type	C58677	All studies
Participant History and Family History; General Health History	Medical history condition text	C00322	All studies

* Note: Education year count C00015 is no longer a general Core CDE

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Domain/Sub-Domain	CDE Name	CDE ID	Study Type
Participant History and Family History; General Health History	Medical history condition SNOMED CT code	C00313	All studies

Core CDE for Multiple Sclerosis Studies:

Domain/Sub-domain	CDE Name	CDE ID	Classification	Study Type
Participant History and Family History; General Health History	Medical history taken date and time	C00314	Core	All Multiple Sclerosis studies
Participant History and Family History; General Health History	Body system category	C00312	Core	All Multiple Sclerosis studies
Disease/Injury Related Events/Classification	MS current diagnosis type	C16118	Core	All Multiple Sclerosis studies
Disease/Injury Related Events/Classification	MS onset course type	C16119	Core	All Multiple Sclerosis studies
Disease/Injury Related Events/Classification	MS current disease course type	C16120	Core	All Multiple Sclerosis studies
Disease/Injury Related Events/Classification	MS family medical history indicator	C17457	Core	All Multiple Sclerosis studies
Disease/Injury Related Events/ Classification	Symptom onset date and time	C05404	Core	All Multiple Sclerosis studies

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Domain/Sub-domain	CDE Name	CDE ID	Classification	Study Type
Disease/Injury Related Events/ Classification	Diagnosis first given date and time	C08007	Core	All Multiple Sclerosis studies

Supplemental—Highly Recommended CDEs for MS Studies:

CDE Domain/Sub-domain	CDE Name	CDE ID	Classification	Study Type
Participant Characteristics; Social Status	Education year count	C00015	Supplemental – Highly Recommended	All studies
Disease/Injury Related Events; History of Disease/Injury Event	Symptoms new or worsening neurologic indicator	C16100	Supplemental – Highly Recommended	Clinical studies
Disease/Injury Related Events/Classification	MS current disease course type	C16120	Supplemental – Highly recommended*	Clinical trials; Outcome studies
Assessments and Examinations/Imaging Diagnostics	Imaging clinical visit type	C15330	Supplemental – Highly recommended*	Imaging

*CDE is required for NIH-funded studies that include the stroke study type(s) indicated in subsequent column unless rationale for not using this element is provided.

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CDE Domain/Sub-domain	CDE Name	CDE ID	Classification	Study Type
Assessments and Examinations/Imaging Diagnostics	Imaging T2 lesion total count	C15338	Supplemental – Highly recommended*	Clinical trials of disease-modifying therapies
Assessments and Examinations/Imaging Diagnostics	Imaging T2W brain lesion volume measurement	C15321	Supplemental – Highly recommended*	Imaging
Assessments and Examinations/Imaging Diagnostics	Imaging T2 lesion volume change measurement	C15328	Supplemental – Highly recommended*	Imaging
Assessments and Examinations/Imaging Diagnostics	New enlarging T2 lesion count	C15337	Supplemental – Highly recommended*	Imaging
Assessments and Examinations/Imaging Diagnostics	Imaging gadolinium administered in window indicator	C15358	Supplemental – Highly recommended*	Imaging
Assessments and Examinations/Imaging Diagnostics	Imaging new Gadolinium-enhancing lesion count	C15378	Supplemental – Highly recommended*	Clinical trials of disease-modifying therapies

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CDE Domain/Sub-domain	CDE Name	CDE ID	Classification	Study Type
Assessments and Examinations/Imaging Diagnostics	Imaging change in brain volume value	C15403	Supplemental – Highly recommended*	Imaging
Assessments and Examinations/Imaging Diagnostics	Imaging brain volume fraction value	C15405	Supplemental – Highly recommended*	Imaging
Assessments and Examinations/Imaging Diagnostics	Brain volumetric analysis measurement	C02400	Supplemental – Highly recommended*	Imaging
Assessments and Examinations/Imaging Diagnostics	Imaging elapsed time from injection to post-Gd T1-weighted sequence value	C15647	Supplemental – Highly recommended*	Imaging

General Core for all Studies:

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](#)).

Supplemental – Highly Recommended Instruments for MS Studies:



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1. 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)
4. Nine Hole Peg Test
5. Sloan Low Contrast Letter Acuity
6. Timed 25-Foot Walk (T25FW)

For the complete list of NINDS CDE recommendations for MS, please see the [NINDS CDE website](#).