

Start-up Resource – NINDS Amyotrophic Lateral Sclerosis 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 Amyotrophic Lateral 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.



Summary of Core Recommendations: Amyotrophic Lateral Sclerosis CDEs

<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 Studies¹:

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
Participant History and Family History; General Health History	Medical history condition SNOMED CT code	C00313	All studies

Core Elements for Amyotrophic Lateral Sclerosis Studies:

Domain; Sub-Domain	Data element	CDE ID
Participant Characteristics; Demographics	Race expanded category	C00031
Participant History and Family History; General Health History	Body system category	C00312
Participant History and Family History; General Health History	Medical history condition start date and time	C00317

¹ Note: Education year count C00015 is no longer a general Core CDE



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Domain; Sub-Domain	Data element	CDE ID
Participant History and Family History; General Health History	Medical history for body system indicator	C00321
Participant History and Family History; General Health History	Family history medical condition type	C00720
Participant History and Family History; General Health History	Family history medical condition indicator	C00721
Participant History and Family History; General Health History	Family history medical condition relative type	C00722
Participant History and Family History; General Health History	Adopted indicator	C10813
Disease/Injury Related Event; Classification	Symptom onset date and time	C05404
Disease/Injury Related Event; Classification	Diagnosis first given date and time	C08007
Disease/Injury Related Event; Classification	Gene screened type	C19515
Disease/Injury Related Event; Classification	Positive gene type	C19517
Disease/Injury Related Event; Classification	Body part first affected text	C11119
Disease/Injury Related Event; Classification	El Escorial revised criteria indicator	C11124
Assessments and Examinations; Physical/Neurological Examination	Physical exam date and time	C01010
Assessments and Examinations; Physical/Neurological Examination	Physical exam body system result type	C01012
Assessments and Examinations; Physical/Neurological Examination	Physical exam description text	C01013
Assessments and Examinations; Physical/Neurological Examination	Physical exam performed indicator	C01015
Assessments and Examinations; Physical/Neurological Examination	Body system other text	C18666
Assessments and Examinations; Vital Signs and Other Body Measures	Blood pressure diastolic measurement	C01507
Assessments and Examinations; Vital Signs and Other Body Measures	Vital signs date and time	C01519



Summary of Core Recommendations: Amyotrophic Lateral Sclerosis CDEs

Domain; Sub-Domain	Data element	CDE ID
Assessments and Examinations; Vital Signs and Other Body Measures	Height measurement	C01522
Assessments and Examinations; Vital Signs and Other Body Measures	Weight measurement	C01541
Assessments and Examinations; Vital Signs and Other Body Measures	Blood pressure systolic measurement	C01565
Assessments and Examinations; Vital Signs and Other Body Measures	Weight unit of measure	C01581
Assessments and Examinations; Vital Signs and Other Body Measures	Height unit of measure	C01582
Outcomes and Endpoints; Pulmonary Function Testing/Respiratory Status	Forced vital capacity result	C10172
Outcomes and Endpoints; Pulmonary Function Testing/Respiratory Status	Slow vital capacity percent of predicted normal value	C10177
Outcomes and Endpoints; Pulmonary Function Testing/Respiratory Status	Pulmonary function test date and time	C11098
Outcomes and Endpoints; Pulmonary Function Testing/Respiratory Status	Pulmonary function test type	C11099
Outcomes and Endpoints; Pulmonary Function Testing/Respiratory Status	Pulmonary function slow vital capacity (sVC) result value	C11104

Supplemental – Highly Recommended Elements for Amyotrophic Lateral Sclerosis Studies:

Domain; Sub-Domain	Data element	CDE ID
Participant Characteristics; Social Status	Education year count	C00015

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](#)).



Summary of Core Recommendations: Amyotrophic Lateral Sclerosis CDEs

Core Instruments for Amyotrophic Lateral Sclerosis Studies:

1. [Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised \(ALSRFS-R\)](#)
2. [Manual Muscle Testing](#) or [Quantitative Dynamometry](#) (Hand Held Dynamometry and Fixed Dynamometry are available on the website)

Supplemental – Highly Recommended Instruments for Amyotrophic Lateral Sclerosis Studies:

1. *One of the following three Supplemental-Highly Recommended cognitive/behavioral screening tools should be used based on study requirements:
 - o [Abrahams Written Verbal Fluency](#)
 - o [ALS Cognitive Behavioral Screen \(ALS-CBS\)](#)
 - o [Edinburgh Cognitive and Behavioral ALS Screen](#)

*Include one or more data elements that are Core or Supplemental – Highly Recommended

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