

Start-up Resource – NINDS Epilepsy CDE Recommendations

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.

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/Supplemental – Highly Recommended Recommendations: Epilepsy CDEs

<p>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>	<p>NIH Toolbox Patient-Reported Outcomes Measurement Information System (PROMIS) Quality of Life in Neurological Disorders (Neuro-QOL)</p>
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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 CDEs for Epilepsy Studies:

Domain; Sub-Domain	Data element	CDE ID
Disease/Injury Related Events; Classification	Seizure epilepsy classification type	C58581

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



Summary of Core/Supplemental – Highly Recommended Recommendations: Epilepsy CDEs

Domain; Sub-Domain	Data element	CDE ID
Disease/Injury Related Events; Classification	Specific epilepsy etiology classification type	C58580

General Core Instrument for all FDA-regulated epilepsy clinical trials:

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 CDEs for Epilepsy Studies:

Domain; Sub-Domain	Data element	CDE ID
Participant/Subject Characteristics; Social Status	Education level USA type	C00012
Participant/Subject Characteristics; Social Status	Education level maternal USA type	C12607
Disease/Injury Related Events; Classification	Seizure epilepsy focal classification type	C58583
Disease/Injury Related Events; Classification	Seizure epilepsy generalized classification type	C58599
Disease/Injury Related Events; Classification	Seizure unclassified classification status	C58604
Disease/Injury Related Events; Classification	Genetic presumed genetic epilepsy etiology type	C58582
Disease/Injury Related Events; Classification	Data collected date and time	C06005
Disease/Injury Related Events; Classification	Data valid through date and time	C14134

Summary of Core/Supplemental – Highly Recommended Recommendations: Epilepsy CDEs

Domain; Sub-Domain	Data element	CDE ID
Disease/Injury Related Events; Classification	Structural epilepsy etiology type	C58587
Disease/Injury Related Events; Classification	Metabolic toxic epilepsy etiology type	C58605
Disease/Injury Related Events; Classification	Epilepsy etiology specific present likelihood type	C14425
Disease/Injury Related Events; Classification	Epilepsy etiology primary type	C14426
Disease/Injury Related Events; Classification	Epilepsy etiology secondary type	C14427
Disease/Injury Related Events; Classification	Other epilepsy etiology type	C58606
Disease/Injury Related Events; Classification	Epilepsy syndrome age of onset type	C14472
Disease/Injury Related Events; Classification	Epilepsy syndrome likelihood type	C14470
Disease/Injury Related Events; Classification	Epilepsy syndrome neonatal type	C14471
Disease/Injury Related Events; Classification	Epilepsy syndrome infant type	C14473
Disease/Injury Related Events; Classification	Epilepsy syndrome childhood type	C14475
Disease/Injury Related Events; Classification	Epilepsy syndrome adolescence or adult type	C14477
Disease/Injury Related Events; Classification	Epilepsy syndrome less specific age relationship type	C14479
Disease/Injury Related Events; Classification	Epilepsy syndrome distinctive constellation type	C14481

Summary of Core/Supplemental – Highly Recommended Recommendations: Epilepsy CDEs

Domain; Sub-Domain	Data element	CDE ID
Disease/Injury Related Events; Classification	Epilepsy syndromes distinct confidence level type	C14485
Disease/Injury Related Events; Classification	Data collected date and time	C06005
Disease/Injury Related Events; Classification	Data valid through date and time	C14134
Outcomes and End Points; Patient Reported Outcomes	Seizure diary date and time	C10626
Outcomes and End Points; Patient Reported Outcomes	Seizure daily diary seizure type	C10635
Outcomes and End Points; Patient Reported Outcomes	Seizure daily diary no seizure indicator	C14136
Outcomes and End Points; Patient Reported Outcomes	Seizure daily diary seizure type count	C14138
Outcomes and End Points; Patient Reported Outcomes	Seizure diary completer type	C14139
Outcomes and End Points; Patient Reported Outcomes	Seizure diary completer other text	C18904

Supplemental – Highly Recommended Instruments:

1. [American National Adult Reading Test \(AmNART\)](#) (primary IQ estimation measure)
2. [Montreal Cognitive Assessment \(MoCA\)](#) (primary overall mental status measure)
3. [Hopkins Verbal Learning Test \(HVLN\)](#) (primary memory measure)
4. [Boston Naming Test \(BNT\)](#) (secondary cognitive measure for naming)
5. [Controlled Oral Word Association Test \(COWAT\)](#) (secondary cognitive measure for executive function)
6. [Continuous Performance Test-III \(CPT III\)](#) (secondary cognitive measure for attention)
7. [Seizure Diary](#) (primary patient reported outcome measure)
8. [Beck Depression Inventory-II \(BDI-II\)](#) (primary depression measure)
9. [Quality of Life Epilepsy Inventory-31 \(QOLIE-31\)](#)
10. [Quality of Life in Childhood Epilepsy \(QOLCE-55\)](#)
11. [Quality of Life in Neurological Disorders \(Neuro-QOL\) – Measurement System](#)

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