

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.

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.*

NIH Toolbox
Patient-Reported Outcomes Measurement Information System (PROMIS)
Quality of Life in Neurological Disorders (Neuro-QOL)

Core CDEs for all NINDS Studies¹:

CDE Domain	CDE Name	CDE ID	Classification	Study Type
Demographics	Birth date	C00007	CORE	All studies
Demographics	Ethnicity USA category	C00020	CORE	All studies
Demographics	Race USA category	C00030	CORE	All studies
Demographics	Gender Type	C00035	CORE	All studies
General Health History	Medical history condition text	C00322	CORE	All studies
General Health History	Medical history condition SNOMED CT code	C00313	CORE	All studies

Core CDEs for Epilepsy Studies:

Domain; Sub-Domain	Data element	CDE ID
Disease/Injury Related Events; Classification	Seizure type	C14126
Disease/Injury Related Events; Classification	Epilepsy etiology specific type	C14424

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

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
Participant/Subject Characteristics; Social Status	Education level maternal USA type	C12607
Disease/Injury Related Events; Classification	Generalized seizure subtype	C14127
Disease/Injury Related Events; Classification	Focal seizure subtype	C14130
Disease/Injury Related Events; Classification	Seizure type or subtype present likelihood type	C14125
Disease/Injury Related Events; Classification	Seizures distinct likelihood type	C14132
Disease/Injury Related Events; Classification	Data collected date and time	C06005
Disease/Injury Related Events; Classification	Data valid through date and time	C14134
Disease/Injury Related Events; Classification	Epilepsy etiology classification genetic or unknown likelihood type	C14422
Disease/Injury Related Events; Classification	Epilepsy etiology classification structural or metabolic likelihood type	C14423
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	Epilepsy etiology multiple etiologies specify text	C20332

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

Domain; Sub-Domain	Data element	CDE ID
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
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



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

Domain; Sub-Domain	Data element	CDE ID
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 \(HVLTL\)](#) (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)

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