

# Harmonizing information. Streamlining research. Epilepsy CDE Highlight Summary Document

## **NIH Resources**

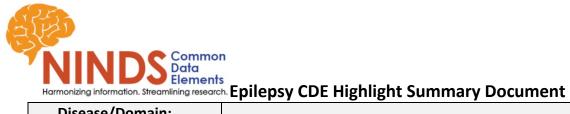
The NINDS also strongly encourages researchers to use these NIH developed materials for NINDS-sponsored research, when appropriate. Utilization of these resources will enable greater consistency for NINDS-sponsored research studies. These tools are free of charge.

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

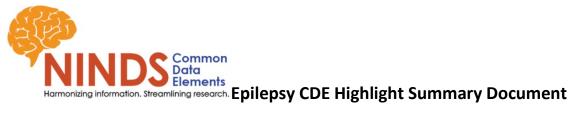
### **Suicidal Ideation**

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 http://www.cssrs.columbia.edu

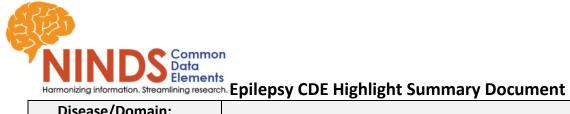
Disease/Domain; Subdomain	Recommendations
Epilepsy	These instruments and elements are recommended for use in Epilepsy studies:
	Core elements:
	See Start-Up Resources Listing document (Epilepsy Start-Up Resource Listing)
	Supplemental – Highly Recommended instruments:
	American National Adult Reading Test (AmNART), Montreal Cognitive
	Assessment (MoCA), Hopkins Verbal Learning Test (HVLT), Boston Naming Test
	(BNT), Controlled Oral Word Association (COWAT), Continuous Performance
	Test-III, Beck Depression Inventory-II, Seizure Diary, Quality of Life Epilepsy
	Inventory-31 (QOLIE-31), Quality of Life in Childhood Epilepsy (QOLCE-55),
	Quality of Life in Neurological Disorders (Neuro-QOL) – Measurement System
Participant Characteristics; Demographics	Core: Demographics, General Core
	Supplemental – Highly Recommended: None
	Supplemental: Demographics
Participant Characteristics; Social Status	Core: None
	Supplemental – Highly Recommended: Social Status
	Supplemental: Social Status



Disease/Domain; Subdomain	Recommendations
Disease/Injury Related Events; Classification	Core: None
	<b>Supplemental – Highly Recommended:</b> Classification of Seizures, Classification of Etiology, Syndromes by Age of Onset
	<b>Supplemental:</b> Classification of Seizures, Classification of Etiology, Syndromes by Age of Onset
Assessments and Examinations; Imaging Diagnostics	Core: None
	Supplemental – Highly Recommended: None
	Supplemental: Magnetic Resonance Imaging (MRI), Functional Magnetic Resonance Imaging (fMRI), Ictal Single-photon Emission Computed Tomography (SPECT) Localization, Magnetoencephalography (MEG) Acquisition, MRI for Registration of MEG, Positron Emission Tomography (PET)
Assessments and Examinations;	Core: None
	Supplemental – Highly Recommended: None
Physical/Neurological Examination	Supplemental: Physical Exam, Neurological Exam, PROMIS
Assessments and	Core: None
Examinations; Laboratory Tests and	Supplemental – Highly Recommended: None
Biospecimens/Biomarkers	Supplemental: NINDS Repository Epilepsy Date Elements
Assessments and	Core: None
Examinations; Non- Imaging Diagnostics	Supplemental – Highly Recommended: None
	Supplemental: Scalp Electroencephalography (EEG), Short Scalp Electroencephalography (EEG)
Assessments and Examinations; Vital Signs and Other Body Measures	Core: None
	Supplemental – Highly Recommended: None
	Supplemental: Vital Signs
Treatment/Intervention Data; Drugs	Core: None
	Supplemental – Highly Recommended: None
	<b>Supplemental:</b> AED Plasma Concentration, AED Resistance Log, Anti Epileptic Drug (AED) Log, Non Anti Epileptic Medication Log
Treatment/Intervention Data; Devices	Core: None
	Supplemental – Highly Recommended: None
	Supplemental: Device Revision/Replacement Log, Devices Log, Implanted Devices Log



Disease/Domain; Subdomain	Recommendations
Treatment/Intervention Data; Surgeries and Other Procedures	Core: None Supplemental – Highly Recommended: Surgery and Pathology Supplemental: None
Safety Data; Adverse Events	Core: None Supplemental – Highly Recommended: None Supplemental: Adverse Event Tracking Log, Hague Side Effects Scale, VA Toxicity Scale
Outcomes and Endpoints; Assessing Comorbidities	Core: None  Supplemental – Highly Recommended: American National Reading Test (Amnart), Montreal Cognitive Assessment (MoCA), Hopkins Verbal Learning Test- Revised (HVLT-R), Boston Naming Test (BNT), Controlled Oral Word Association Test (COWAT), Conner's Continuous Performance Test-III, Beck Depression Inventory-II
	Supplemental: Adult ADHD Self-Report Scale (ASRS), Checklist for Autism in Toddlers (CHAT), Longitudinal Interval Follow-Up Evaluation (DSM-IV Version (LIFE DSM-IV), Patient Health Questionnaire - 9 (PHQ-9) Depression Scale, Generalized Anxiety disorder (GAD-7), ADHD Comprehensive Teachers Rating Scale (ACTeRS), Adolescent Symptom Inventory (ASI), Beck Anxiety Inventory (BAI), Brief Psychiatric Rating Scale (BPRS), Child Behavior Checklist (CBCL), Child Depression Inventory (CDI), Child Health Questionnaire (CHQ), Child Symptom Inventory (CSI), Childhood Autism Rating Scale (CARS), Conners' (Teacher and Parent) Rating Scale (CRS-R), Davidson Trauma Scale (DTS), Headache Diagnosis Questionnaire, Migraine Headaches Questionnaire 21-Item, Mini International Neuropsychiatric Interview (MINI), Modified Checklist for Autism in Toddlers (M-CHAT), National Institute of Mental Health Diagnostic Interview Schedule for Children (NIMH-DISC), Neurological Disorders Depression Inventory in Epilepsy (NDDI-E), Post-Traumatic Epilepsy Screening Form, Psychiatric Diagnostic Screening Questionnaire (PDSQ), Social Communication Questionnaire (SCQ), World Health Organization (WHO) Composite International Diagnostic Interview (WMH-CIDI)*



Disease/Domain; Subdomain	Recommendations
Outcomes and Endpoints; Neuropsychological Testing	Core: None
	Supplemental – Highly Recommended: None
	Supplemental: Neuropsychological Testing Background Information, Brief Visuospatial Memory Test Revised (BVMTR), California Verbal learning Test-Children's Version (CVLT-C), California Verbal Learning Test - Second Edition (CVLT-II), Clinical Evaluation of Language Fundamentals - Fifth Edition (CELF-5), Delis Kaplan Executive Functioning System (DKEFS), Grooved Pegboard Test, Mullen Scales of Early Learning (MSEL), Peabody Picture Vocabulary Test 4 <sup>th</sup> Edition (PPVT-4), Rey Auditory Verbal Learning Test (RAVLT), Wechsler Abbreviated Scale of Intelligence (WASI), Wisconsin Card Sorting Test (WCST), Rey-Osterrieth Complex Figure (ROCF) Copy and Delay, Bayley Scales of Infant Development (Bayley III, BSID), Adaptive Behavior Assessment Scale (ABAS-II), Behavior Rating Inventory of Executive Function (BRIEF), Conners Kiddie Continuous Performance Test 2 (K-CPT 2), Processing Speed Index of the Wechsler Intelligence Scale for Children-IV/ Wechsler Preschool and Primary Scale of Intelligence (WISC-IV/WPPSI-III), Processing Speed Index of the Wechsler Adult Intelligence Scale-Fourth Edition (WAIS-IV), Purdue Pegboard, Scales of Independent Behavior-Revised (SIB-R), Test of Variable Attention (TOVA), Vineland Adaptive Behavior Scales, second edition (Vineland-II), Wechsler Preschool and Primary Scale of Intelligence (WPPSI-III)
Outcomes and Endpoints; Quality of Life/Patient Reported Outcomes	Core: None  Supplemental – Highly Recommended: Quality of Life in Epilepsy Inventory-31 (QOLIE-31), Quality in Childhood Epilepsy (QOLCE-55), Quality of Life in
	Neurological Disorders (Neuro-Qol) - Measurement System
	Supplemental: Childhood Quality of Life in Epilepsy (CHEQOL)
Outcomes and Endpoints; Patient Reported Outcomes	Core: None
	Supplemental – Highly Recommended: Seizure Diary
	<b>Supplemental:</b> Liverpool Seizure Severity Scale 2.0 (LSSS 2.0), Seizure Severity Questionnaire (SSQ) V2.2 (Baseline and Follow-Up Versions)