



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	<p>These instruments and elements are recommended for use in Epilepsy studies:</p> <p>Core elements:</p> <p>See Start-Up Resources Listing document (Epilepsy Start-Up Resource Listing)</p> <p>Supplemental – Highly Recommended instruments:</p> <p>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</p>
Participant Characteristics; Demographics	<p>Core: Demographics, General Core</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Demographics</p>
Participant Characteristics; Social Status	<p>Core: None</p> <p>Supplemental – Highly Recommended: Social Status</p> <p>Supplemental: Social Status</p>



Epilepsy CDE Highlight Summary Document

Disease/Domain; Subdomain	Recommendations
Disease/Injury Related Events; Classification	<p>Core: None</p> <p>Supplemental – Highly Recommended: Classification of Seizures, Classification of Etiology, Syndromes by Age of Onset</p> <p>Supplemental: Classification of Seizures, Classification of Etiology, Syndromes by Age of Onset</p>
Assessments and Examinations; Imaging Diagnostics	<p>Core: None</p> <p>Supplemental – Highly Recommended: None</p> <p>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)</p>
Assessments and Examinations; Physical/Neurological Examination	<p>Core: None</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Physical Exam, Neurological Exam, PROMIS</p>
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	<p>Core: None</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: NINDS Repository Epilepsy Data Elements</p>
Assessments and Examinations; Non-Imaging Diagnostics	<p>Core: None</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Scalp Electroencephalography (EEG), Short Scalp Electroencephalography (EEG)</p>
Assessments and Examinations; Vital Signs and Other Body Measures	<p>Core: None</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Vital Signs</p>
Treatment/Intervention Data; Drugs	<p>Core: None</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: AED Plasma Concentration, AED Resistance Log, Anti Epileptic Drug (AED) Log, Non Anti Epileptic Medication Log</p>
Treatment/Intervention Data; Devices	<p>Core: None</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Device Revision/Replacement Log, Devices Log, Implanted Devices Log</p>



Disease/Domain; Subdomain	Recommendations
Treatment/Intervention Data; Surgeries and Other Procedures	<p>Core: None</p> <p>Supplemental – Highly Recommended: Surgery and Pathology</p> <p>Supplemental: None</p>
Safety Data; Adverse Events	<p>Core: None</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Adverse Event Tracking Log, Hague Side Effects Scale, VA Toxicity Scale</p>
Outcomes and Endpoints; Assessing Comorbidities	<p>Core: None</p> <p>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</p> <p>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)*</p>



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Disease/Domain; Subdomain	Recommendations
<p>Outcomes and Endpoints; Neuropsychological Testing</p>	<p>Core: None</p> <p>Supplemental – Highly Recommended: None</p> <p>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 4th 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)</p>
<p>Outcomes and Endpoints; Quality of Life/Patient Reported Outcomes</p>	<p>Core: None</p> <p>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</p> <p>Supplemental: Childhood Quality of Life in Epilepsy (CHEQOL)</p>
<p>Outcomes and Endpoints; Patient Reported Outcomes</p>	<p>Core: None</p> <p>Supplemental – Highly Recommended: Seizure Diary</p> <p>Supplemental: Liverpool Seizure Severity Scale 2.0 (LSSS 2.0), Seizure Severity Questionnaire (SSQ) V2.2 (Baseline and Follow-Up Versions)</p>