



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 [Columbia Suicide Severity Rating Scale Website](#)).

Disease/Domain	Recommendations
Headache	<p>These instruments and elements are recommended for use in all Headache studies:</p> <p>Core instruments: Functional Disability Inventory (FDI)-Child and Adolescent Form, Functional Disability Inventory (FDI)-Parent Form, Headache Impact Test-6 (HIT-6), Migraine Specific Quality of Life Questionnaire (MSQoL v.2.1), and Pediatric Migraine Disability Assessment (PedMIDAS)</p> <p>Core elements: See Start-Up Resource Listing document (Headache Start-Up Resource Listing Document)</p>
Participant/Subject Characteristics; Demographics	<p>Core: None</p> <p>Supplemental: Demographics</p>
Participant/Subject Characteristics; Social Status:	<p>Core: None</p> <p>Supplemental: Social Status</p>
Participant/Subject History and Family History; General Health History:	<p>Core: None</p> <p>Supplemental: Medical and Family History, Pregnancy Information, Pregnancy Outcome</p>
Disease/Injury Related Events; Classification:	<p>Core: None</p> <p>Supplemental: Headache Diagnosis, Headache Mail Questionnaire, Henry Ford Claims Headache Telephone Interview, Visual Aura Rating Scale (VARs)</p> <p>Exploratory: CATI Headache Diagnostic Telephone Interview</p>



Headache CDE Highlight Summary Document

Disease/Domain	Recommendations
Assessments and Examinations; Physical/Neurological Examination:	<p>Core: None</p> <p>Supplemental: Physical Exam</p>
Assessments and Examinations; Vital Signs and Other Body Measures:	<p>Core: None</p> <p>Supplemental: Vital Signs</p>
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers:	<p>Core: None</p> <p>Supplemental: Biospecimens Collection and Processing, DNA Elements</p>
Assessments and Examinations; Imaging Diagnostics:	<p>Core: None</p> <p>Supplemental: Anatomical Functional Imaging, Blink Reflex and Evoked potential Imaging, Functional Imaging, Magnetic Resonance Angiography (MRA), Magnetic resonance Spectroscopy (MRS), Positron Emission Tomography Localization (PET), Quantitative Sensory Testing (QST), Transcranial Magnetic Stimulation (TMS)</p>
Treatment/Intervention Data; Drugs:	<p>Core: None</p> <p>Supplemental: Concomitant Medications and Rescue Medications</p>
Treatment/Intervention Data; Surgeries and Other Procedures	<p>Core: None</p> <p>Supplemental: Hospitalizations</p>
Outcomes and Endpoints; Activities of Daily Living/Functional Status:	<p>Core: Functional Disability Inventory (FDI)-Child and Adolescent Form, Functional Disability Inventory (FDI)-Parent Form</p> <p>Supplemental: Headache Needs Assessment Survey (HANA), Migraine Disability Assessment Test (MIDAS), NIH Toolbox</p>
Outcomes and Endpoints; Assessing Comorbidities:	<p>Core: None</p> <p>Supplemental: Mood Disorder Questionnaire (MDQ), Structured Clinical Interview for DSM IV-TR Axis I Disorders Research Version (SCID-I-RV), Mini International Neuropsychiatric Interview (M.I.N.I.), Patient Health Questionnaire-9 (PHQ-9)</p>
Outcomes and Endpoints; Emotional and Cognitive Status:	<p>Core: None</p> <p>Supplemental: Behavior Rating Inventory of Executive Function - Self Report Version (BRIEF-SR), Beck Depression Inventory II, Beck Anxiety Inventory (BAI), State-Trait Anxiety Inventory (STAI), Hospital Anxiety and Depression Scale (HADS), Patient Health Questionnaire Generalized Anxiety disorder (GAD-7)</p>



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Disease/Domain	Recommendations
Outcomes and Endpoints; Patient Reported Outcomes:	<p>Core: Headache Diary, Headache Patient Reported Outcomes Guidelines - Acute Therapies, Headache Patient Reported Outcomes Guidelines - Preventive Therapies</p> <p>Supplemental: Headache Record - Acute Therapies, Headache Record - Preventive Therapies, PROMIS</p>
Outcomes and Endpoints; Pediatric:	<p>Core: Pediatric Migraine Disability Assessment Questionnaire (PedMIDAS)</p> <p>Supplemental: Children Depression Inventory - 2 (CDI-2), Kiddie-Schedule for Affective Disorders and Schizophrenia (K-SADS), Pediatric Quality of Life Inventory (PEDSQL)</p>
Outcomes and Endpoints; Quality of Life:	<p>Core: Headache Impact Test-6 (HIT-6), Migraine Specific Quality of Life Questionnaire (MsQoL v2.1)</p> <p>Supplemental: 36-Item Short Form Health Survey (SF-36), 24-Hour Migraine Quality of Life Questionnaire (24-Hr-MQoLQ), EuroQoL-5 Dimension Questionnaire, Healthy Days Core Module (CDC HRQOL-4), Quality of Life in Neurological Disorders (Neuro-QoL)</p> <p>Exploratory: Clinical Global Impression, Headache Impact Questionnaire (HImQ), Health Related Quality of Life-14 (HRQOL-14), Short Form Health Survey-12</p>