

Headache Version 2.0 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 [Columbia Suicide Severity Rating Scale Website](#)).

Disease/Domain; Subdomain	Recommendations
Headache Version 2.0 Recommendations	<p>Core Instruments: The International Classification of Headache Disorders - III (ICHD-3) is recommended for use in all Headache studies.</p> <p>Supplemental Highly Recommended Instruments: Generalized Anxiety Disorder (GAD-7), Headache Impact Test-6 (HIT-6), ID Migraine Screener, Migraine Disability Assessment Test (MIDAS) <i>OR</i> Pediatric Migraine Disability Assessment Questionnaire (PedMIDAS), Migraine Specific Quality of Life Questionnaire (MsQoL v2.1), Patient Health Questionnaire-4 (PHQ-4) <i>OR</i> Patient Health Questionnaire-9 (PHQ-9) Depression Scale</p> <p>Core and Supplemental Highly Recommended elements: See 'Start-Up Resource Listing' document (Headache Start-Up Resource Listing Document)</p>
Participant/Subject Characteristics; Demographics	Supplemental: Demographics
Participant/Subject Characteristics; Social Status:	Supplemental: Social Status
Participant/Subject History and Family History; General Health History:	<p>Supplemental: Behavioral History, Medical and Family History</p> <p>Exploratory: Pregnancy Information, Pregnancy Outcome</p>
Disease/Injury Related Events; History of Disease/Injury Event	Supplemental: Medical and Family History of Migraine, Post-traumatic Headache (PTH) – Headaches Prior to TBI Questionnaire, Post-traumatic Headache (PTH) Mild TBI Questionnaire
Disease/Injury Related Events; Classification:	<p>Core: International Classification of Headache Disorders -3 Criteria (ICHD-III)</p> <p>Supplemental Highly Recommended: Migraine Diagnosis Questionnaire, ID Migraine Screener</p> <p>Supplemental: Structured Diagnostic Interview for Headache (SDIH)</p>



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Disease/Domain; Subdomain	Recommendations
Assessments and Examinations; Physical/Neurological Examination:	Supplemental: Physical Exam
Assessments and Examinations; Vital Signs and Other Body Measures:	Supplemental: Vital Signs
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers:	Supplemental: Biospecimens Collection and Processing, DNA Elements
Assessments and Examinations; Imaging Diagnostics:	Supplemental: Anatomical Imaging, Cortical Evoked Potentials, Functional Magnetic Resonance Imaging (fMRI), Magnetic Resonance Angiography (MRA), Magnetic Resonance Spectroscopy (MRS), Magnetoencephalography Recording (MEG), Nociceptive Blink Reflex and Pain-Related Evoked Potentials, Positron Emission Tomography Localization (PET), Quantitative Sensory Testing (QST), Transcranial Magnetic Stimulation (TMS)
Treatment/Intervention Data; Drugs:	Supplemental: Concomitant Medications, Rescue Treatments
Outcomes and Endpoints	
Outcomes and Endpoints; Activities of Daily Living/Functional Status:	<p>Supplemental Highly Recommended: Migraine Disability Assessment Test (MIDAS)</p> <p><i>Pediatric Recommendation:</i> Pediatric Migraine Disability Assessment Questionnaire (PedMIDAS)</p> <p>Supplemental: Functional Impairment Scale (4-point), Functional Disability Inventory (FDI)-Parent Form, Headache Needs Assessment Survey (HANA), Migraine Interictal Burden Scale (MIBS), NIH Toolbox</p> <p><i>Pediatric Recommendation:</i> Functional Disability Inventory (FDI)-Child and Adolescent Form</p> <p>Exploratory: Migraine Functional Impact Questionnaire (MFIQ), Migraine Physical Function Impact Diary (MPFID)</p>
Outcomes and Endpoints; Assessing Comorbidities:	Supplemental: Mini International Neuropsychiatric Interview (M.I.N.I.), Mood Disorder Questionnaire (MDQ), Structured Clinical Interview for DSM V-TR Axis I Disorders Research Version (SCID-V-RV)



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Disease/Domain; Subdomain	Recommendations
Outcomes and Endpoints; Emotional Status:	<p>Supplemental Highly Recommended: Generalized Anxiety Disorder (GAD-7), Patient Health Questionnaire-4 (PHQ-4) <u>OR</u> Patient Health Questionnaire-9 (PHQ-9) Depression Scale</p> <p>Supplemental: Beck Anxiety Inventory (BAI), Beck Depression Inventory II (BDI-II), Behavior Rating Inventory of Executive Function – Second Edition Self Report Version (BRIEF 2-SR), Columbia-Suicide Severity Rating Scale (C-SSRS), Hospital Anxiety and Depression Scale (HADS), Kiddie-Schedule for Affective Disorders and Schizophrenia (K-SADS), State-Trait Anxiety Inventory (STAI)</p> <p><i>Pediatric Recommendation:</i> Children Depression Inventory - 2 (CDI-2)</p>
Outcomes and Endpoints; Cognitive Status:	<p>Supplemental: Mig-SCog</p>
Outcomes and Endpoints; Patient Reported Outcomes:	<p>Supplemental Highly Recommended: Headache Diary - Acute Therapies, Headache Diary- Preventive Therapies, Headache Calendar</p> <p>Supplemental: PROMIS (Anxiety, Depression, and Sleep Scales)</p> <p><i>Pediatric Recommendation:</i> PROMIS Pediatric (Anxiety and Depression Scale)</p> <p>Exploratory: Patient Global Impression of Change (PGIC)</p>
Outcomes and Endpoints; Quality of Life:	<p>Supplemental Highly Recommended: Headache Impact Test-6 (HIT-6), Migraine Specific Quality of Life Questionnaire (MsQoL v2.1)</p> <p>Supplemental: 24-Hour Migraine Quality of Life Questionnaire (24-Hr-MQoLQ), EuroQoL-5 Dimension Questionnaire, Pediatric Quality of Life Inventory (PEDSQL), Short Form Health Survey v2 36-Item (SF-36) <u>OR</u> Short Form Health Survey 12-Item v2 (SF-12)</p> <p>Exploratory: Clinical Global Impression Scale, Headache Impact Questionnaire (HImQ), Health Related Quality of Life-14 (HRQOL-14), Quality of Life in Neurological Disorders (Neuro-QoL)</p>