



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	Recommendations
Chiari I Malformation	<p>These instruments and elements are recommended for use in Chiari I Malformation studies:</p> <p>Core elements:</p> <p>See Start-Up Resources Listing document (Chiari I Malformation Start-Up Resource Listing)</p> <p>Supplemental – Highly Recommended instruments: Nurick (Ambulatory Function) Grade; ASIA Motor Scale; Headache Disability Index; Meaningful Improvement</p>



Disease/Domain	Recommendations
Summary Documents	Chiari I Malformation CDE Overall Summary; Comorbidities Working Group Summary View document; Demographics Working Group Summary; Imaging, Spinal Anomaly, Stability Working Group Summary View document; Outcomes Working Group Summary View document; Presentations, Natural History, Signs and Symptoms Working Group Summary View document; Treatment Working Group Summary View document
Participant Characteristics; Demographics	Core: Demographics*, General Core Supplemental – Highly Recommended: None Supplemental: Demographics* Exploratory: None



Chiari I Malformation CDE Highlight Summary Document

Disease/Domain	Recommendations
Participant Characteristics; Social Status	<p>Core: None</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Social Status</p> <p>Exploratory: None</p>
Participant History and Family History; General Health History	<p>Core: None</p> <p>Supplemental – Highly Recommended: Past History (on intake)*; CMI - Hereditary Disorder of Connective Tissue Screening (1)*; CMI - Hereditary Disorders of Connective Tissue Screening (2)*</p> <p>Supplemental: General Exam; Past History (on intake); CMI - Hereditary Disorder of Connective Tissue Screening (1)*; CMI - Hereditary Disorders of Connective Tissue Screening (2)*</p> <p>Exploratory: Past History (on intake)</p>
Participant History and Family History; Epidemiology/Environmental History	<p>Core: None</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Allergy; Strain-Related Headache</p> <p>Exploratory: Allergy</p>
Disease / Injury Related Events; Classification	<p>Core: Chiari I Malformation Presenting Exam*</p> <p>Supplemental – Highly Recommended: Chiari List of 10*; Chiari I Malformation Presenting Exam*</p> <p>Supplemental: Chiari I Malformation Presenting Exam *</p> <p>Exploratory: Chiari I Malformation Presenting Exam*</p>
Disease / Injury Related Events; History of Disease/Injury Event	<p>Core: CMI - Headache Score*</p> <p>Supplemental – Highly Recommended: CMI - Headache Score*</p> <p>Supplemental: CMI - Tethered Cord Screening; Chiari Symptom Onset; CMI - Headache Score*</p>
Assessments and Examinations; Physical/Neurological Exam	<p>Core: Self-Reporting Testing (On Intake)*</p> <p>Supplemental – Highly Recommended: Self-Reporting Testing (On Intake)*; Beighton Score</p> <p>Supplemental: Neurological Exam; Brainstem Signs/Symptoms; Self-Reporting Testing (On Intake)*; Sensory Symptoms</p> <p>Exploratory: Brainstem Signs/Symptoms</p>



Disease/Domain	Recommendations
Assessments and Examinations; General and Motor	<p>Core: None</p> <p>Supplemental – Highly Recommended: Reflex Testing*; Nystagmus/Strabismus*</p> <p>Supplemental: Motor Strength Testing; Reflex Testing*; Spine Range of Motion Assessment; Coordination; Imbalance; Modified Ashworth Scale – Limb Tone Testing; Nystagmus/Strabismus*; Provocative – Other Testing</p> <p>Exploratory: Reflex Testing*; Spine Range of Motion Assessment; Nystagmus/Strabismus*; Provocative – Other Testing</p>
Assessments and Examinations; Imaging Diagnostics	<p>Core: Chiari I Malformation Imaging*</p> <p>Supplemental – Highly Recommended: Chiari I Malformation Imaging*</p> <p>Supplemental: Chiari I Malformation Imaging*</p> <p>Exploratory: Chiari I Malformation Imaging*</p>
Treatment / Intervention Data; Drugs	<p>Core: None</p> <p>Supplemental – Highly Recommended: Medications (Prior & Current)*</p> <p>Supplemental: Medications (Prior & Current)*</p> <p>Exploratory: None</p>
Treatment / Intervention Data; Surgeries and Other Procedures	<p>Core: None</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Surgical Site Assessment</p> <p>Exploratory: None</p>
Treatment / Intervention Data; Therapies	<p>Core: None</p> <p>Supplemental – Highly Recommended: Chiari I Malformation Treatment Outcomes*</p> <p>Supplemental: Chiari I Malformation Treatment Outcomes*</p> <p>Exploratory: Chiari I Malformation Treatment Outcomes*</p>
Outcomes and Endpoints; Assessing Comorbidities	<p>Core: Co-Morbidities*</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Co-Morbidities*</p> <p>Exploratory: Co-Morbidities*</p>



Disease/Domain	Recommendations
<p>Outcomes and Endpoints; Functional Outcomes</p>	<p>Core: None</p> <p>Supplemental – Highly Recommended: Nurick (Ambulatory Function) Grade; ASIA Motor Scale;</p> <p>Supplemental: Functional Status Karnofsky Score; Functional Status Lansky Score; ASIA Sensory Scale; Functional Independence Measure; Functional Independence Measure for Children (WeeFIM); Modified Japanese Orthopaedic Association Score</p> <p>Exploratory: McCormick Scale; Chicago Chiari Outcome Scale</p>
<p>Outcomes and Endpoints; Emotional and Cognitive Outcomes</p>	<p>Core: Note - Suicidal Ideation</p> <p>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)</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: None</p> <p>Exploratory: Zung Depression Score</p>
<p>Outcomes and Endpoints; Other Non-Motor</p>	<p>Core: None</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Assessment of Shunt Function</p> <p>Exploratory: Assessment of Shunt Function</p>
<p>Outcomes and Endpoints; Pain</p>	<p>Core: None</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Brief Pain Inventory (Short Form); McGill Pain Questionnaire; Numeric Rating Scale – Neck Pain</p> <p>Exploratory: None</p>



Disease/Domain	Recommendations
Outcomes and Endpoints; Quality of Life	<p>Core: None</p> <p>Supplemental – Highly Recommended: Headache Disability Index; Meaningful Improvement</p> <p>Supplemental: Chiari Symptom Profile; EuroQoL-5 Dimension Questionnaire-Youth (EQ-5DY); Health Transition Index; Neck Disability Index; Patient Reported Outcomes Measurement Information System (PROMIS); Quality of Life in Neurological Disorders (Neuro-QOL); Short Form Health Survey-12; Short Form 36-Item Health Survey (SF-36); The North American Spine Society Satisfaction Questionnaire</p> <p>Exploratory: Patient Reported Outcomes Measurement Information System (PROMIS) – Pediatric; Quality of Life in Neurological Disorders (Neuro-QOL) - Pediatric Functional Health</p>

* Include one or more data elements that are Core or Supplemental-Highly Recommended