

## Unruptured Cerebral Aneurysms and Subarachnoid Hemorrhage CDE Highlight Summary

### 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](#)).

Disease/Domain	Recommendations and List of Forms
SAH	<p><b>Core CDEs:</b></p> <p>See Start-Up Resource Listing document <a href="#">SAH Start-Up Resource Listing</a></p> <p><a href="#">Guidance for Industry: Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials</a></p> <p><b>Supplemental – Highly Recommended instruments:</b> <a href="#">Modified Rankin Scale</a>; <a href="#">Montreal Cognitive Assessment</a></p>
Participant Characteristics/ Demographics	<p><b>Core:</b> General Core, Demographics, Demographics – Unruptured Intracranial Aneurysms</p> <p><b>Supplemental – Highly Recommended:</b> General Core, Demographics – Unruptured Intracranial Aneurysms</p> <p><b>Supplemental:</b> Demographics</p> <p><b>Exploratory:</b> Demographics, Demographics – Unruptured Intracranial Aneurysms</p>
Participant/Subject Characteristics/Social Status	<p><b>Exploratory:</b> Social Status</p>

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<b>Participant History and Family History/General Health History</b>	<p><b>Core:</b> Behavioral History, Family History; History Data Source and Reliability; Medical History; Risk Factors; Prior Functional Status</p> <p><b>Supplemental – Highly Recommended:</b> Behavioral History; Risk Factors; Prior Functional Status</p> <p><b>Supplemental:</b> Behavioral History; Family History; History Data Source and Reliability; Medical History; Pregnancy and Perinatal History; Risk Factors</p> <p><b>Exploratory:</b> Behavioral History; History Data Source and Reliability; Medical History; Pregnancy and Perinatal History; Risk Factors; Prior Functional Status</p>
<b>Disease/Injury Related Events/History of Disease/Injury Event</b>	<p><b>Core:</b> Clinical Presentation</p> <p><b>Supplemental – Highly Recommended:</b> Clinical Presentation</p> <p><b>Supplemental:</b> Prehospital/Emergency Status; Aneurysm History; Clinical Presentation</p> <p><b>Exploratory:</b> Headache Pain</p>
<b>Disease/Injury Related Events/Classification</b>	<p><b>Supplemental:</b> SAH Grading; UIA Consult/Diagnosis</p>
<b>Disease/Injury Related Events/Discharge Information</b>	<p><b>Supplemental:</b> Discharge Status; Discharge Medications</p>
<b>Assessments and Examinations/Physical / Neurological Examination</b>	<p><b>Supplemental – Highly Recommended:</b> Concomitant Diseases; Neurological Complications</p> <p><b>Supplemental:</b> Baseline Assessment; Concomitant Diseases; Neurological Complications; Neurological Exam</p> <p><b>Exploratory:</b> Concomitant Diseases; Cranial Nerve Function</p>
<b>Assessments and Examinations / Vital Signs and Other Body Measures</b>	<p><b>Supplemental:</b> Intracranial Pressure (ICP) Monitoring; Vital Signs and Acute Physiological Measurements; Vital Signs and Blood Gases</p>
<b>Assessments and Examinations/Laboratory Tests and Biospecimens / Biomarkers</b>	<p><b>Core:</b> Biospecimen Collection and Processing</p> <p><b>Supplemental:</b> Biospecimen Collection and Processing; Laboratory Tests</p> <p><b>Exploratory:</b> Biospecimen Collection and Processing</p>

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<b>Assessments and Examinations/Imaging Diagnostics</b>	<p><b>Core:</b> Imaging; Radiological Findings; Vessel Imaging Angiography</p> <p><b>Supplemental – Highly Recommended:</b> Radiological Findings; Vessel Imaging Angiography</p> <p><b>Supplemental:</b> Cardiac Magnetic Resonance Imaging (MRI); Echocardiogram; Echocardiogram II; Imaging; Radiological Findings; Vessel Imaging Angiography</p> <p><b>Exploratory:</b> Radiological Findings; Vessel Imaging Angiography</p>
<b>Assessments and Examinations/Non-Imaging Diagnostics</b>	<p><b>Supplemental:</b> Electrocardiogram (ECG); Electroencephalography (EEG); Holter Exam</p>
<b>Treatment / Intervention Data/Drugs</b>	<p><b>Supplemental:</b> Concomitant Medications</p> <p><b>Exploratory:</b> Concomitant Medications</p>
<b>Treatment/ Intervention Data/Surgeries and Other Procedures</b>	<p><b>Core:</b> Surgical/Procedural Interventions</p> <p><b>Supplemental – Highly Recommended:</b> Surgical/Procedural Interventions</p> <p><b>Supplemental:</b> Aneurysm Recanalization; Surgical/Procedural Interventions</p> <p><b>Exploratory:</b> Aneurysm Retreatment and Re-rupture; Surgical/Procedural Interventions</p>
<b>Treatment/ Intervention Data/Therapies</b>	<p><b>Supplemental:</b> ICU Therapies; Unruptured Intracranial Aneurysms Management; Palliative/Comfort Care and End of Life Issues; Rescue Therapy</p> <p><b>Exploratory:</b> Unruptured Intracranial Aneurysms Management</p>
<b>Outcomes and Endpoints/Neurological Outcomes</b>	<p><b>Supplemental:</b> Neurobehavioral Symptom Inventory; NIH Stroke Scale</p> <p><b>Exploratory:</b> Shunt Dependency</p>
<b>Outcomes and Endpoints/Activities of Daily Living/Performance</b>	<p><b>Supplemental – Highly Recommended:</b> Modified Rankin Scale (mRS)</p> <p><b>Supplemental:</b> Glasgow Outcome Scale (GOS); Glasgow Outcome Scale Extended (GOSE)</p> <p><b>Exploratory:</b> Barthel Index; Computerized Test of Attentional Performance (TAP 2.3) – Subtest alertness, Subtest Divided attention, Subtest Go-NoGo, Subtest Neglect; Digit Span Subtest; Multidimensional Assessment of Fatigue (MAF); Reintegration to Normal Living Index</p>

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<b>Outcomes and Endpoints/ Functional Outcomes</b>	<p><b>Supplemental:</b> Los Angeles Motor Scale</p> <p><b>Exploratory:</b> Action Research Arm Test; Arm Motor Abilities Test; Berg Balance Scale (BBS); Chelsea Critical Care Assessment; de Morton Mobility Index (DEMMI); Fugl-Meyer Assessment; Functional Ambulation Category; Functional Gait Assessment; Functional Independence Measure; London Handicap Scale; Physical Function ICU Test (PFIT); Progressive Upright Mobility Protocol (PUMP) Plus; Rivermeade Mobility Index; Mobilizing ICU Patients: Safety Assessment Guidelines; Overall Measurement Schema for ICU-Acquired Weakness and Related Conditions</p>
<b>Outcomes and Endpoints/ Emotional and Cognitive Status</b>	<p><b>Supplemental – Highly Recommended:</b> Montreal Cognitive Assessment (MoCA)</p> <p><b>Supplemental:</b> Galveston Orientation and Amnesia Test (GOAT)</p> <p><b>Exploratory:</b> Beck Anxiety Inventory (BAI); Beck Depression Inventory II (BDI-II); Boston Naming Test (BNT); Brief Symptom Inventory-18; Center for Epidemiological Studies Depression Scale (CES-D); General Anxiety Disorder – 7 (GAD-7); Hospital Anxiety and Depression Scale (HADS); Impact of Event Scale (IES); Mini-Mental State Examination (MMSE); Neuropsychiatric Inventory Questionnaire; Patient Health Questionnaire - 9 (PHQ-9) Depression Scale; PTSD Checklist – Civilian (PCL-C); Similarities Subtest of the Wechsler Adult Intelligence Scale-Fourth Edition (WAIS-IV); Standardized Link’s Probe; Telephone Interview for Cognitive Status (TICS); Token Test; Visual Span Forward; Written Verbal Fluency Test</p>
<b>Outcomes and Endpoints/ Family and Environment</b>	<p><b>Exploratory:</b> Home Time</p>
<b>Outcomes and Endpoints/ Neuropsychological Impairment</b>	<p><b>Supplemental:</b> Color-Word Interference test of the Delis-Kaplan Executive Function System (D-KEFS); Five-Point test (5-PT); Grooved Pegboard Test; Rey Auditory Verbal Learning Test (RAVLT); Rey-Osterreith Complex Figure (ROCF): Copy and Delay; Trail Making Test (TMT) Delis-Kaplan Executive Function System (D-KEFS)</p>
<b>Outcomes and Endpoints/ Behavioral Function</b>	<p><b>Exploratory:</b> Frontal Systems Behavioral Scale (FrSBE)</p>

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<b>Outcomes and Endpoints/ Quality of Life</b>	<p><b>Supplemental:</b> EuroQoL-5 Dimension Questionnaire</p> <p><b>Exploratory:</b> 12-Item Short Form Health Survey (SF-12); Disease Burden; Patient-Reported Outcomes Measurement Information System (PROMIS); Quality of Life in Neurological Disorders (Neuro-QOL); Short Form 36-Item Health Survey (SF-36); Stroke Impact Scale (SIS); Stroke-Specific Quality of Life (SS-QOL); Utrecht Scale for Evaluation of Rehabilitation-Participation (USER-P); Return to Work</p>
<b>Outcomes and Endpoints/Clinical Event End Points</b>	<p><b>Supplemental:</b> Death</p>