



**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
Stroke	<p><b>Core CDEs:</b></p> <p>See Start-Up Resource Listing document: <a href="#">Stroke 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>NIH Stroke Scale (NIHSS) (Ischemic Stroke only)</p> <p><b>Supplemental-Highly Recommended– for indicated study types:</b></p> <p>Boston Naming Test (BNT) - 30-item version; Delis-Kaplan Executive Function System (D-KEFS); EuroQoL-5 Dimension Questionnaire (EQ-5D); Fugl-Meyer Assessment; Glasgow Coma Scale (GCS); Modified Rankin Scale (mRS); Montreal Cognitive Assessment (MoCA); NIH Stroke Scale (NIHSS); Patient Health Questionnaire - 9 (PHQ-9) Depression Scale; Patient-Reported Outcomes Measurement Information System (PROMIS); PROMIS Item Bank v1.2 - Global Health; PROMIS-29; Quality of Life in Neurological Disorders (Neuro-QOL); Questionnaire for Verifying Stroke-Free Status (QVSFS); Stroke and Aphasia Quality of Life-39 (SAQOL-39); Walking Speed; Western Aphasia Battery Revised</p> <p><b>Supplemental-Highly Recommended– for pediatric studies:</b></p> <p>Pediatric Stroke Outcomes Measure Short Neuro Exam (PSOM-SNE) - Child Version (Children Aged 2 Year and Older) or Infant Version (Infants Term Birth to Two Years)</p>
Participant Characteristics/ Demographics	<p><b>Core:</b> General Core; Demographics</p> <p><b>Supplemental-Highly Recommended:</b> General Core</p> <p><b>Supplemental:</b> Demographics</p> <p><b>Exploratory:</b> Demographics</p>



## Stroke CDE Highlight Summary

Disease/Domain	Recommendations and List of Forms
<b>Participant Characteristics/Social Status</b>	<p><b>Core:</b> N/A</p> <p><b>Supplemental-Highly Recommended:</b> N/A</p> <p><b>Supplemental:</b> Social Status</p> <p><b>Exploratory:</b> Social Status</p>
<b>Participant History and Family History/General Health History</b>	<p><b>Core:</b> Medical History; Prior Functional Status; Pregnancy and Perinatal History</p> <p><b>Supplemental-Highly Recommended:</b> Behavioral History; Family History; Medical History; Pregnancy and Perinatal History</p> <p><b>Supplemental:</b> Behavioral History; Family History; History Data Source and Reliability; Medical History; Prior Functional Status</p> <p><b>Exploratory:</b> Family History; Medical History; Pregnancy and Perinatal History;</p>
<b>Disease/Injury Related Events/History of Disease/Injury Event</b>	<p><b>Core:</b> N/A</p> <p><b>Supplemental-Highly Recommended:</b> Hospital Arrival/Admission; Pre-Hospital/Emergency Medical Service (EMS) Course</p> <p><b>Supplemental:</b> Hospital Arrival/Admission; Pre-Hospital/Emergency Medical Service (EMS) Course; Assessment of Transient Neurologic Deficits Resolved Prior to Presentation</p> <p><b>Exploratory:</b> Hospital Arrival/Admission</p>
<b>Disease/Injury Related Events/Classification</b>	<p><b>Core:</b> Stroke Types and Subtypes</p> <p><b>Supplemental-Highly Recommended:</b> Stroke Types and Subtypes</p> <p><b>Supplemental:</b> Stroke Types and Subtypes</p> <p><b>Exploratory:</b> N/A</p>
<b>Disease/Injury Related Events/Discharge Information</b>	<p><b>Core:</b> N/A</p> <p><b>Supplemental-Highly Recommended:</b> Hospital Discharge</p> <p><b>Supplemental:</b> Hospital Discharge</p> <p><b>Exploratory:</b> N/A</p>
<b>Assessments and Examinations/Physical/Neurological Examination</b>	<p><b>Core:</b> NIH Stroke Scale (NIHSS) (Ischemic Stroke only)</p> <p><b>Supplemental-Highly Recommended:</b> Glasgow Coma Scale (GCS); NIH Stroke Scale (NIHSS)</p> <p><b>Supplemental:</b> Neurobehavioral Symptom Inventory (NSI); Physical/Neurological Exam</p> <p><b>Exploratory:</b> Physical/Neurological Exam</p>



Disease/Domain	Recommendations and List of Forms
<b>Assessments and Examinations/Vital Signs and Other Body Measures</b>	<p><b>Core:</b> Vital Signs</p> <p><b>Supplemental-Highly Recommended:</b> Vital Signs</p> <p><b>Supplemental:</b> Vital Signs</p> <p><b>Exploratory:</b> N/A</p>
<b>Assessments and Examinations/Laboratory Tests and Biospecimens/Biomarkers</b>	<p><b>Core:</b> N/A</p> <p><b>Supplemental-Highly Recommended:</b> Biospecimen Collection and Processing</p> <p><b>Supplemental:</b> Biospecimen Collection and Processing; Laboratory Tests; Laboratory Tests Permissible Values for Stroke (Spreadsheet)</p> <p><b>Exploratory:</b> Biospecimen Collection and Processing</p> <p><b>Guidance Documents:</b> Appendix 1: Biomarker Targets in Stroke; Appendix 2: Biospecimen Standard Operating Procedure Guidance; NINDS Repository Cerebrovascular Data Elements (NINDS-Coriell)</p>
<b>Assessments and Examinations/Imaging Diagnostics</b>	<p><b>Core:</b> N/A</p> <p><b>Supplemental-Highly Recommended:</b> Perfusion and Penumbra Imaging; Vessel Carotid Ultrasound; Vessel Imaging Angiography</p> <p><b>Supplemental:</b> Aneurysm Location and Dimensions; Cardiac Magnetic Resonance Imaging (MRI); Echocardiogram; Echocardiogram II; Imaging Acquisition; Parenchymal Imaging; Perfusion and Penumbra Imaging; Vessel Carotid Ultrasound; Vessel Imaging Angiography; Vessel Imaging Transcranial</p> <p><b>Exploratory:</b> Aneurysm Location and Dimensions; Parenchymal Imaging; Vessel Imaging Angiography</p>
<b>Assessments and Examinations/Non-Imaging Diagnostics</b>	<p><b>Core:</b> N/A</p> <p><b>Supplemental-Highly Recommended:</b> N/A</p> <p><b>Supplemental:</b> Electrocardiogram (ECG)</p> <p><b>Exploratory:</b> N/A</p>
<b>Treatment/Intervention Data/Drugs</b>	<p><b>Core:</b> N/A</p> <p><b>Supplemental-Highly Recommended:</b> Antithrombotics and Risk Factor Controlling Medications; Thrombolytic/Reperfusion Therapies</p> <p><b>Supplemental:</b> Antithrombotics and Risk Factor Controlling Medications; Prior and Concomitant Medications; Thrombolytic/Reperfusion Therapies</p> <p><b>Exploratory:</b> Prior and Concomitant Medications; Thrombolytic/Reperfusion Therapies</p>



Disease/Domain	Recommendations and List of Forms
<b>Treatment/Intervention Data/Surgeries and Other Procedures</b>	<p><b>Core:</b> N/A</p> <p><b>Supplemental-Highly Recommended:</b> SAH Surgical/Procedural Interventions</p> <p><b>Supplemental:</b> SAH Surgical/Procedural Interventions; Stroke Surgical and Procedural Interventions</p> <p><b>Exploratory:</b> SAH Surgical/Procedural Interventions</p>
<b>Treatment/Intervention Data/Therapies</b>	<p><b>Core:</b> N/A</p> <p><b>Supplemental-Highly Recommended:</b> Rehabilitation Therapies</p> <p><b>Supplemental:</b> Lifestyle Modification Therapies; Palliative/Comfort Care and End of Life Issues; Rehabilitation Therapies; Unruptured Intracranial Aneurysm Management</p> <p><b>Exploratory:</b> Rehabilitation Therapies; Unruptured Intracranial Aneurysm Management</p>
<b>Outcomes and End Points/Activities of Daily Living/Performance</b>	<p><b>Core:</b> N/A</p> <p><b>Supplemental-Highly Recommended:</b> Modified Rankin Scale (mRS); Quality of Life in Neurological Disorders (Neuro-QOL)</p> <p><b>Supplemental:</b> Assessment of Motor and Process Skills (AMPS); Barthel Index; Functional Independence Measure; Glasgow Outcome Scale (GOS) and Glasgow Outcome Scale - Extended (GOSE); National Institutes of Health (NIH) Toolbox; Patient-Reported Outcomes Measurement Information System (PROMIS)-Physical Function Assessments</p> <p><b>Exploratory:</b> N/A</p>



Disease/Domain	Recommendations and List of Forms
<p><b>Outcomes and End Points/ Cognitive Status</b></p>	<p><b>Core:</b> N/A</p> <p><b>Supplemental-Highly Recommended:</b> Boston Naming Test (BNT) - 30-item version; Delis-Kaplan Executive Function System (D-KEFS); Montreal Cognitive Assessment (MoCA); Western Aphasia Battery Revised</p> <p><b>Supplemental:</b> Color-Word Interference Test Delis-Kaplan Executive Function System (D-KEFS); Hopkins Verbal Learning Test – Revised (HVLTR); Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE); Repeatable Battery for Assessment of Neuropsychological Status (RBANS); Rey Auditory Verbal Learning Test (RAVLT); Rey-Osterrieth Complex Figure Test (ROCF); Six-Item Screener; Stroop Test; Telephone Interview for Cognitive Status (TICS); Trail Making Test (TMT), Delis-Kaplan Executive Function System (D-KEFS); Wechsler Adult Intelligence Scale - Fourth Edition IV (WAIS-IV)</p> <p><b>Exploratory:</b> Similarities Subtest of the Wechsler Adult Intelligence Scale-Fourth Edition (WAIS-IV)</p>
<p><b>Outcomes and End Points/ Emotional Status</b></p>	<p><b>Core:</b> N/A</p> <p><b>Supplemental-Highly Recommended:</b> Patient Health Questionnaire - 9 (PHQ-9) Depression Scale</p> <p><b>Supplemental:</b> Beck Anxiety Inventory (BAI); Beck Depression Inventory II (BDI-II); Center for Epidemiologic Studies-Depression Scale (CES-D)</p> <p><b>Exploratory:</b> Generalized Anxiety Disorder (GAD-7); Neuropsychiatric Inventory Questionnaire (NPI-Q); PTSD Checklist - Civilian (PCL-C)</p>
<p><b>Outcomes and End Points/ Quality of Life/ Patient Reported Outcomes</b></p>	<p><b>Core:</b> N/A</p> <p><b>Supplemental-Highly Recommended:</b> EuroQoL-5 Dimension Questionnaire (EQ-5D); PROMIS Item Bank v1.2 - Global Health; PROMIS-29; Stroke and Aphasia Quality of Life-39 (SAQOL-39)</p> <p><b>Supplemental:</b> Canadian Occupational Performance Measure (COPM); Return to Work; Short Form 36-Item Health Survey (SF-36); Stroke Impact Scale (SIS); Stroke Specific Quality of Life Scale (SS-QOL)</p> <p><b>Exploratory:</b> Home Time; Utrecht Scale for Evaluation of Rehabilitation-Participation (USER-P)</p>



Disease/Domain	Recommendations and List of Forms
<p><b>Outcomes and End Points/Performance Measures</b></p>	<p><b>Core:</b> N/A</p> <p><b>Supplemental-Highly Recommended:</b> Fugl-Meyer Assessment; Walking Speed</p> <p><b>Supplemental:</b> 6 Minute Walk Test; Action Research Arm Test; Animal Naming; Berg Balance Scale (BBS); Brief Visuospatial Memory Test Revised (BVMT-R); Controlled Oral Word Association Test (COWAT) Subtest of the Multilingual Aphasia Examination (MAE); Grooved Pegboard Test; Motor Evaluation Scale for Upper Extremity in Stroke Patients (MESUPES); Token Test</p> <p><b>Exploratory:</b> N/A</p>
<p><b>Outcomes and End Points/Pediatric</b></p>	<p><b>Core:</b> N/A</p> <p><b>Supplemental-Highly Recommended:</b> Pediatric Stroke Outcome Measure Short Neuro Exam (PSOM-SNE) - Child Version (Children Aged 2 Year and Older); Pediatric Stroke Outcome Measure Short Neuro Exam (PSOM-SNE) - Infant Version (Infants Term Birth to Two Years)</p> <p><b>Supplemental:</b> Bayley Scales of Infant Development (Bayley III, BSID); Pediatric Quality of Life Inventory (PedsQL); Pediatric Stroke Recurrence and Recovery Questionnaire (RRQ); Perceived Efficacy and Goal Setting System (PEGS)</p> <p><b>Exploratory:</b> King's Outcome Scale for Childhood Head Injury (KOSCHI); Pediatric Modified Rankin Scale (mRS)</p>
<p><b>Outcomes and End Points/Clinical Event End Points</b></p>	<p><b>Core:</b> Death</p> <p><b>Supplemental-Highly Recommended:</b> Questionnaire for Verifying Stroke-Free Status (QVSFS)</p> <p><b>Supplemental:</b> Death; Stroke Adjudication Form</p> <p><b>Exploratory:</b> Death</p>
<p><b>Outcomes and End Points/Caregiver Reported Outcomes</b></p>	<p><b>Exploratory:</b> Zarit Burden Interview (ZBI)</p>