



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>Core CDEs:</p> <p>See Start-Up Resource Listing document Stroke Start-Up Resource Listing</p> <p>Guidance for Industry: Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials</p> <p>Supplemental – Highly Recommended– for indicated study types: National Institutes of Health Stroke Scale (NIHSS); Modified Rankin Scale (mRS); Center for Epidemiologic Studies Depression Scale (CES-D); Glasgow Coma Scale (GCS); Barthel Index; Montreal Cognitive Assessment (MoCA); Delis Kaplan Executive Functioning System (DKEFS) - Trail Making Test Parts A&B; EuroQoL-5 Dimension Questionnaire (EQ-5D); Walking Speed</p> <p>Supplemental – Highly Recommended– for pediatric studies:</p> <p>Pediatric Stroke Outcomes Measure (PSOM) Short Neuro Exam (SNE) - Child Version (Children Aged 2 Year and Older) or Infant Version (Infants Term Birth to Two Years)</p>
Participant Characteristics/ Demographics	<p>Core: General Core; Demographics</p> <p>Supplemental-Highly Recommended: General Core</p> <p>Supplemental: Demographics</p> <p>Exploratory: N/A</p>
Participant Characteristics/Social Status	<p>Core: N/A</p> <p>Supplemental-Highly Recommended: Social Status</p> <p>Supplemental: Social Status</p> <p>Exploratory: N/A</p>



Stroke CDE Highlight Summary

Disease/Domain	Recommendations and List of Forms
Participant History and Family History/General Health History	<p>Core: Family History; Medical History; Prior Functional Status</p> <p>Supplemental-Highly Recommended: Behavioral History</p> <p>Supplemental: Behavioral History; Family History; History Data Source and Reliability; Medical History; Pregnancy and Perinatal History; Prior Functional Status</p> <p>Exploratory: N/A</p>
Disease/Injury Related Events/History of Disease/Injury Event	<p>Core: N/A</p> <p>Supplemental-Highly Recommended: Glasgow Coma Scale (GCS); Hospital Arrival/Admission; Pre-Hospital/Emergency Medical Service (EMS) Course</p> <p>Supplemental: Hospital Arrival/Admission; Pre-Hospital/Emergency Medical Service (EMS) Course; Stroke Symptoms/Comorbid Events</p> <p>Exploratory: Hospital Arrival/Admission</p>
Disease/Injury Related Events/Classification	<p>Core: Stroke Types and Subtypes</p> <p>Supplemental-Highly Recommended: Stroke Types and Subtypes</p> <p>Supplemental: Stroke Types and Subtypes</p> <p>Exploratory: N/A</p>
Disease/Injury Related Events/Discharge Information	<p>Core: N/A</p> <p>Supplemental-Highly Recommended: Hospital Discharge</p> <p>Supplemental: Hospital Discharge</p> <p>Exploratory: N/A</p>
Assessments and Examinations/Physical / Neurological Examination	<p>Core: N/A</p> <p>Supplemental-Highly Recommended: N/A</p> <p>Supplemental: Physical/Neurological Exam</p> <p>Exploratory: Physical/Neurological Exam</p>
Assessments and Examinations Vital Signs and Other Body Measures	<p>Core: Vital Signs</p> <p>Supplemental-Highly Recommended: Vital Signs</p> <p>Supplemental: Vital Signs</p> <p>Exploratory: N/A</p>



Stroke CDE Highlight Summary

Disease/Domain	Recommendations and List of Forms
Assessments and Examinations/Laboratory Tests and Biospecimens / Biomarkers	<p>Core: Biospecimen Collection and Processing; Laboratory Tests</p> <p>Supplemental-Highly Recommended: N/A</p> <p>Supplemental: Biomarker Guidelines (Recommendations); Biospecimen Collection and Processing; Laboratory Tests; Laboratory Tests Permissible Values for Stroke (Spreadsheet); NINDS Repository Cerebrovascular Data Elements (NINDS-Coriell)</p> <p>Exploratory: N/A</p>
Assessments and Examinations/Imaging Diagnostics	<p>Core:</p> <p>Supplemental-Highly Recommended: Parenchymal Imaging; Perfusion and Penumbra Imaging; Vessel Carotid Ultrasound; Vessel Imaging Angiography; Vessel Imaging Transcranial Color-Coded Real-time Sonography (TCCS); Vessel Imaging Transcranial Doppler (TCD)</p> <p>Supplemental: Parenchymal Imaging; Perfusion and Penumbra Imaging; Vessel Carotid Ultrasound; Vessel Imaging Angiography; Vessel Imaging Transcranial Color-Coded Real-time Sonography (TCCS); Vessel Imaging Transcranial Doppler (TCD)</p> <p>Exploratory: N/A</p>
Assessments and Examinations/Non-Imaging Diagnostics	<p>Core: N/A</p> <p>Supplemental-Highly Recommended: N/A</p> <p>Supplemental: Electrocardiogram (ECG)</p> <p>Exploratory: N/A</p>
Treatment/Intervention Data/Drugs	<p>Core: N/A</p> <p>Supplemental-Highly Recommended: Antithrombotics and Risk Factor Controlling Medications; Thrombolytic/Reperfusion Therapies</p> <p>Supplemental: Antithrombotics and Risk Factor Controlling Medications; Prior and Concomitant Medications; Thrombolytic/Reperfusion Therapies</p> <p>Exploratory: N/A</p>
Treatment/Intervention Data/Surgeries and Other Procedures	<p>Core: N/A</p> <p>Supplemental-Highly Recommended: N/A</p> <p>Supplemental: Surgical and Procedural Interventions</p> <p>Exploratory: N/A</p>



Stroke CDE Highlight Summary

Disease/Domain	Recommendations and List of Forms
Treatment/Intervention Data/Therapies	<p>Core: N/A</p> <p>Supplemental-Highly Recommended: Rehabilitation Therapies</p> <p>Supplemental: Lifestyle Modification Therapies; Palliative/Comfort Care and End of Life Issues; Rehabilitation Therapies</p> <p>Exploratory: N/A</p>
Outcomes and End Points/Neurological Outcomes	<p>Core: N/A</p> <p>Supplemental – Highly Recommended [for Acute, Prevention (2°), Recovery]: NIH Stroke Scale (NIHSS)</p> <p>Supplemental: N/A</p> <p>Exploratory: N/A</p>
Outcomes and Endpoints/Activities of Daily Living/Performance	<p>Core: N/A</p> <p>Supplemental – Highly Recommended [for Acute, Prevention (2°), Recovery]: Barthel Index; Modified Rankin Scale (mRS)</p> <p>Supplemental: Functional Independence Measure, Glasgow Outcome Scale (GOS) and Glasgow Outcome Scale - Extended (GOSE); Summary of NINDS Recommended Measures for Activities of Daily Living/Functional Status</p> <p>Exploratory: National Institutes of Health (NIH) Toolbox; Patient-Reported Outcomes Measurement Information System (PROMIS)-Physical Function Assessments; Post Acute Care Admission Continuity Assessment Record and Evaluation (PAC Admission CARE) Tool - Section VI: Functional Status; Quality of Life in Neurological Disorders (Neuro-QOL);</p>
Outcomes and End Points/Emotional and Cognitive Status	<p>Core: N/A</p> <p>Supplemental – Highly Recommended [for Acute, Prevention (2°), Recovery]: Center for Epidemiologic Studies-Depression Scale (CES-D); Delis Kaplan Executive Functioning System (DKEFS) - Trail Making Tests; Montreal Cognitive Assessment (MoCA)</p> <p>Supplemental: Boston Naming Test (BNT) - 30-item version; Hopkins Verbal Learning Test – Revised (HVLT-R); Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE); Neuropsychiatric Inventory Questionnaire (NPI-Q); Rey-Osterrieth Complex Figure (ROCF); Stroop Test; Summary of NINDS Recommended Measures for Emotional and Cognitive Status; Telephone Interview for Cognitive Status (TICS); Wechsler Adult Intelligence Scale IV (WAIS-IV) - Digit Symbol and Symbol Search subtests</p> <p>Exploratory: N/A</p>



Disease/Domain	Recommendations and List of Forms
Outcomes and End Points/Quality of Life/Patient Reported Outcomes	<p>Core: N/A</p> <p>Supplemental – Highly Recommended [for Acute, Prevention (2°), Recovery]: EuroQoL-5 Dimension Questionnaire</p> <p>Supplemental: 36-Item Short Form Health Survey (SF-36); Canadian Occupation Performance Measure (COPM); Stroke Impact Scale (SIS); Stroke Specific Quality of Life Scale (SS-QOL); Summary of NINDS Recommended Measures for Participation/Quality of Life</p> <p>Exploratory: N/A</p>
Outcomes and End Points/Performance Measures	<p>Core: N/A</p> <p>Supplemental – Highly Recommended [for Acute, Prevention (2°), Recovery]: Walking Speed</p> <p>Supplemental: Summary of NINDS Recommended Measures for Performance</p> <p>Exploratory: N/A</p>
Outcomes and End Points/Pediatric	<p>Core: N/A</p> <p>Supplemental-Highly Recommended: 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>Supplemental: Bayley Scales of Infant Development (Bayley III; BSID); King's Outcome Scale for Childhood Head Injury (KOSCHI); Perceived Efficacy and Goal Setting System (PEGS); Summary of NINDS Recommended Measures for Pediatrics</p> <p>Exploratory: N/A</p>
Outcomes and End Points/Clinical Event End Points	<p>Core: N/A</p> <p>Supplemental-Highly Recommended: N/A</p> <p>Supplemental: Atherosclerosis Risk in Communities Study (ARIC) TIA/Stroke Form; Questionnaire for Verifying Stroke-Free Status (QVSFS); Stroke Adjudication Form; Summary of NINDS Recommended Measures for Clinical Event End Points</p> <p>Exploratory: N/A</p>