



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; Domains	Recommendations and List of Forms
<p>Spinal Cord Injury</p>	<p>These instruments and elements are recommended for use in all Spinal Cord Injury Studies:</p> <p>Core Instruments: International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI)</p> <p>Supplemental – Highly Recommended– for indicated study types:</p> <p>10 Meter Walk Test, 6 Minute Walk Test, Berg Balance Scale, International SCI Upper Extremity Basic Data Set, Spinal Cord Independence Measure, International SCI Core Data Set, International Pain Basic Data Subset, Patient Health Questionnaire 9 (PHQ-9), Hospital Anxiety and Depression Scale (HADS), Peripheral Nerve Studies³</p> <p>Core Elements:</p> <p>See Start-Up Resources Listing document (Spinal Cord Injury Start-Up Resource Listing)</p> <p>³These CRFs include both Supplemental and Supplemental—Highly Recommended CDEs.</p>
<p>Participant History and Family History; General Health History</p>	<p>Core: History of Injury*</p> <p>Supplemental: Medical History¹ Prior and Concomitant Medications¹ Family History Spinal Cord Injury Care CDE Structure¹</p> <p>Exploratory:</p>
<p>Participant History and Family History; Epidemiology/Environmental History</p>	<p>Core: N/A</p> <p>Supplemental: Alcohol and Tobacco Use, Substance Abuse</p> <p>Exploratory: Alcohol Use Disorders Identification Test: Self-Report Version (AUDIT), Food Frequency Questionnaire (FFQ)</p>



Disease; Domains	Recommendations and List of Forms
Disease/Injury Related Event; History of Disease/Injury Related Event	Core: N/A Supplemental: History of Injury*, Pre-Hospital Assessment Form Exploratory: N/A
Assessments and Examinations; Hospital/Care Management	Core: N/A Supplemental: Rehabilitation Admission/Discharge, Acute Admission/Discharge, Adverse Events Exploratory: N/A ¹ These CRFs include both Supplemental and Exploratory CDEs. *These CRFs include Core, Supplemental and Exploratory CDEs.
Assessments and Examinations; Physical Examinations	Core: N/A Supplemental: Clinical Assessment, ¹ Physical Exam, Exploratory: Braden Scale, Spinal Cord Injury Pressure Ulcer Scale (SCIPUS), Swallowing Disturbance Questionnaire (SwDQ)
Assessments and Examinations; Neurological Examination	Core: International Standards for Neurological Classification of SCI Worksheet Supplemental: N/A Exploratory: N/A
Assessments and Examinations; Vital Signs and Laboratory Tests	Core: N/A Supplemental: Laboratory Tests and Vital Signs for Spinal Cord Injury, Vital Signs and Tests, Laboratory Tests Exploratory: N/A
Participant/Characteristics; Demographics	Core: Demographics ² Supplemental: N/A Exploratory: Demographics ² ² These CRFs include both Core and Exploratory CDEs.
Treatment/Intervention Data; Therapies	Core: N/A Supplemental: Surgical and Procedural Interventions, Other Investigational Treatments, Rehabilitation Therapies Exploratory: N/A



Disease; Domains	Recommendations and List of Forms
<p>Outcomes and Endpoints; Electrodiagnostics</p>	<p>Core: N/A</p> <p>Supplemental: Algorithm for Using Spinal Cord Injury Electrodiagnostic CDEs¹, Motor Evoked Potential (MEP), Peripheral Nerve Studies³, Quantitative Sensory Testing (QST), Sympathetic Skin Response, Brain Motor Control Assessment, Electrical Perceptual Threshold, Sensory Evoked Potentials</p> <p>Supplemental—Highly Recommended: Peripheral Nerve Studies³</p> <p>Exploratory: Algorithm for Using Spinal Cord Injury Electrodiagnostic CDEs¹,</p> <p>¹These CRFs include both Supplemental and Exploratory CDEs.</p> <p>³These CRFs include both Supplemental and Supplemental—Highly Recommended CDEs.</p>
<p>Outcomes and Endpoints; Functional Outcomes</p>	<p>Core: N/A</p> <p>Supplemental: 2 Minute Walk Test, Canadian Occupational Performance Measure (COPM), Capabilities Upper Extremity Questionnaire, Five Times to Sit and Stand Test, Jebsen-Taylor Hand Functioning Test, Spinal Cord Injury Functional Ambulation Inventory (SCI-FAI), Stair Climb, Stride Analysis and Gait Variability, Timed Up and Go (TUG), Walking Index for Spinal Cord Injury (WISCI II), Wheelchair Skills Test</p> <p>Supplemental—Highly Recommended: 10 Meter Timed Walk, 6 Minute Walk Test, Berg Balance Scale (BBS), International SCI Upper Extremity Basic Data Set, Spinal Cord Independence Measure</p> <p>Exploratory: Borg Rating of Perceived Exertion (RPE) Scale, Capabilities Upper Extremity Test (CUE-T), Graded Redefined Assessment of Strength, Sensibility and Prehension (GRASSP), Grasp and Release Test, Neuromuscular Recovery Scale, Nine Hole Peg Test, Quadriplegia Index Function, Sollerman Hand Function Test, Spinal Cord Injury Functional Index (SCI-FI), Tetraplegia Hand Activity Questionnaire, The Activities Based Balance Level Evaluation (ABLE) Scale, Toronto Rehabilitation Institute Hand Function Test, Wheelchair Circuit</p>
<p>Assessments and Examinations; Spinal Imaging/Spinal Cord Imaging</p>	<p>Core: N/A</p> <p>Supplemental: Magnetic Resonance Imaging, Diffusion Tensor Imaging</p> <p>Exploratory: N/A</p>
<p>Outcomes and Endpoints; Neurological Outcomes</p>	<p>Core: N/A</p> <p>Supplemental: International Standards for Neurological Classification of SCI Worksheet; Modified Ashworth Scale for Grading Spasticity, NINDS Myotatic Reflex Scale⁴</p> <p>Exploratory: Tardieu Scale, Spinal Cord Assessment for Spastic Reflexes (SCATS), NINDS Myotatic Reflex Scale⁴, Penn Spasm Frequency Scale, Pendulum (Wartenberg) Test</p> <p>⁴This CRF could be used as either Supplemental or Exploratory, depending on the injury.</p>



Disease; Domains	Recommendations and List of Forms
<p>Outcomes and Endpoints; Pain</p>	<p>Core: N/A</p> <p>Supplemental: Multidimensional Pain Inventory (MPI) Pain Severity Subscale</p> <p>Supplemental—Highly Recommended: International SCI Pain Basic Data Subset</p> <p>Exploratory: Douleur Neuropathique 4 (DN4), Neuropathic Pain Questionnaire (NPQ), Neuropathic Pain Symptom Inventory (NPSI), Pain Quality Assessment Scale (PQAS), painDETECT</p>
<p>Outcomes and Endpoints; Participation and Quality of Life</p>	<p>Core: N/A</p> <p>Supplemental: Craig Handicap and Assessment Reporting Technique (CHART-SF), Euro-QoL-5 Dimension Questionnaire, International SCI Quality of Life Basic Data Set, Life Satisfaction Questionnaire (LISAT-9), National Institutes of Health (NIH) Toolbox, Qualiveen, Short Form Health Survey-36 (SF-36) Walk Wheel Modification for Spinal Cord Injury, Satisfaction with Life Scale, World Health Organization Quality of Life Assessment (WHOQOL-BREF)</p> <p>Exploratory: Quality of Life Index (QLI)-SCI Version, Spinal Cord Injury Multidimensional-Quality of Life (SCI-QOL)</p>
<p>Outcomes and Endpoints; Psychological Status</p>	<p>Core: N/A</p> <p>Supplemental: Generalized Anxiety Disorder (GAD-7), Moorong Self-Efficacy Scale (MSES), Multidimensional Scale of Perceived Social Support, Perceived Manageability Scale (PMnac), Positive Affect and Well-Being Scale of the Neurology Quality of Life (Neuro-QOL) Measure</p> <p>Supplemental—Highly Recommended: Hospital Anxiety and Depression Scale (HADS), Impact of Life Event Scale (IES), Patient Health Questionnaire-9 (PHQ-9)</p> <p>Exploratory: N/A</p>
<p>Outcomes and Endpoints; Sleep</p>	<p>Core:</p> <p>Supplemental: The American Academy of Sleep Medicine (AASM): International Classification of Sleep Disorders (ICSD) Criteria, Berlin Questionnaire</p> <p>Exploratory: Epworth Sleepiness Scale (ESS), Functional Outcomes of Sleep Questionnaire (FOSQ), Pittsburgh Sleep Quality Index (PSQI)</p>



Disease; Domains	Recommendations and List of Forms
<p>Outcomes and Endpoints; The International SCI Data Sets</p>	<p>Core: International SCI Core Data Set⁵</p> <p>Supplemental: International Non-Traumatic Spinal Cord Injury Basic and Extended Data Sets, International SCI Activities and Participation Basic Data Set, International SCI Bowel Function Basic Data Set, International SCI Bowel Function Extended Data Set, International SCI Cardiovascular Function Basic Data Set, International SCI Core Data Set⁵, International SCI Endocrine and Metabolic Function Basic Data Set, International SCI Female and Male Sexual Function Basic Data Set, International SCI Lower Urinary Tract Function Basic Data Set, International SCI Musculoskeletal Basic Data Set, International SCI Pain Basic Data Set Version 2.0, International SCI Pulmonary Basic Data Set, International SCI Quality of Life Basic Data Set, International SCI Skin and Thermoregulation Function Basic Data Set, International SCI Spinal Column Injury Basic Data Set, International SCI Upper Extremity Basic Data Set, International SCI Urinary Tract Imaging Basic Data Set, International SCI Urinary Tract Infection Basic Data Set, International SCI Urodynamic Basic Data Set</p> <p>Exploratory: N/A</p> <p>⁵This CRF contains CDEs that are both Core and Supplemental.</p>