

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
Spinal Cord Injury	<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>2 Minute Walk Test, 6-Minute Timed Walk, 10 Meter Timed Walk , Neurogenic Bowel Dysfunction Score (NBDS), Patient Health Questionnaire Depression Scale 9 (PHQ-9), QUALIVEEN-30 and QUALIVEEN-SHORT FORM, Spinal Cord Injury Functional Index / Assistive Technology (SCI-FI/AT)*, Spinal Cord Independence Measure</p> <p>Core Elements:</p> <p>See Start-Up Resources Listing document (Spinal Cord Injury Start-Up Resource Listing)</p>
Participant / Characteristics; Demographics	<p>Core: General Core, Demographics</p> <p>Supplemental – Highly Recommended: General Core, Demographics</p> <p>Supplemental: Demographics</p> <p>Exploratory: Demographics</p>
Participant History and Family History; General Health History	<p>Core: Medical History</p> <p>Supplemental: Medical History, Prior and Concomitant Medications, Spinal Cord Injury Care CDE Structure</p> <p>Exploratory: Medical History, Prior and Concomitant Medications, Family History, Spinal Cord Injury Care CDE Structure</p>

Spinal Cord Injury CDE Highlight Summary

Disease; Domains	Recommendations and List of Forms
Participant History and Family History; Epidemiology / Environmental History	<p>Core: N/A</p> <p>Supplemental – Highly Recommended: N/A</p> <p>Supplemental: Alcohol and Tobacco Use, Substance Use, Alcohol Use Disorders Identification Test: Self-Report Version (AUDIT)</p> <p>Exploratory: Calcium Counts Food Frequency Questionnaire, Food Frequency Questionnaire (FFQ), Child and Diet Evaluation Tool*, Youth Adolescent Questionnaire*</p>
Disease/Injury Related Event; History of Disease/Injury Related Event	<p>Core: History of Injury</p> <p>Supplemental – Highly Recommended: Birth Injuries</p> <p>Supplemental: History of Injury, Pre-Hospital Assessment Form</p> <p>Exploratory: History of Injury</p>
Assessments and Examinations; Hospital/Care Management	<p>Core: N/A</p> <p>Supplemental – Highly Recommended: N/A</p> <p>Supplemental: Acute Admission/Discharge, Rehabilitation Admission/Discharge, Adverse Events</p> <p>Exploratory: N/A</p>
Assessments and Examinations; Physical Examinations	<p>Core: N/A</p> <p>Supplemental – Highly Recommended: N/A</p> <p>Supplemental: Clinical Assessment, Physical Exam, Braden Q Scale*</p> <p>Exploratory: Braden Scale, Clinical Assessment, Spinal Cord Injury Pressure Ulcer Scale (SCIPUS), Swallowing Disturbance Questionnaire (SwDQ)</p>
Assessments and Examinations; Vital Signs and Other Body Measures	<p>Core: N/A</p> <p>Supplemental – Highly Recommended: N/A</p> <p>Supplemental: Laboratory Tests and Vital Signs for Spinal Cord Injury, Vital Signs and Tests</p> <p>Exploratory: Laboratory Tests</p>
Assessments and Examinations; Spinal Imaging/Spinal Cord Imaging	<p>Core: N/A</p> <p>Supplemental – Highly Recommended: N/A</p> <p>Supplemental: Imaging, Magnetic Resonance Imaging, Diffusion Tensor Imaging</p> <p>Exploratory: N/A</p>



Disease; Domains	Recommendations and List of Forms
Treatment / Intervention Data; Therapies	<p>Core: N/A</p> <p>Supplemental – Highly Recommended: N/A</p> <p>Supplemental: Assistive/Mobility Devices and Orthoses, Falls Diary, Rehabilitation Therapies, Surgical and Procedural Interventions, Other Investigational Treatments</p> <p>Exploratory: N/A</p>
Outcomes and Endpoints; Bowel and Bladder	<p>Core: N/A</p> <p>Supplemental – Highly Recommended: Neurogenic Bowel Dysfunction Score (NBDS), QUALIVEEN-30 and QUALIVEEN-SHORT FORM</p> <p>Supplemental: Bristol Stool Form Scale (BSFS), King's Health Questionnaire (KHQ) Neurogenic Bladder Symptom Score (NBSS), SCI-QOL Bladder Complications, SCI-QOL Bladder Management Difficulties, SCI-QOL Bowel Management Difficulties</p> <p>Exploratory: N/A</p>
Outcomes and Endpoints; Neurological Outcomes	<p>Core: International Standards for Neurological Classification of SCI Worksheet (ISNCSCI)</p> <p>Supplemental – Highly Recommended: N/A</p> <p>Supplemental: Modified Ashworth Scale for Grading Spasticity</p> <p>Exploratory: Modified Ashworth Scale for Grading Spasticity*, NINDS Myotatic Reflex Scale, Pendulum (Wartenberg) Test, Penn Spasm Frequency Scale, Spinal Cord Assessment Tool for Spastic Reflexes (SCATS), Tardieu Scale</p>
Outcomes and Endpoints; Electrodiagnostics	<p>Core: N/A</p> <p>Supplemental—Highly Recommended: Peripheral Nerve Studies</p> <p>Supplemental: Brain Motor Control Assessment, Electrical Perceptual Threshold, Peripheral Nerve Studies, Quantitative Sensory Testing, Sensory Evoked Potentials, Sympathetic Skin Responses</p> <p>Exploratory: Brain Motor Control Assessment*, Electrical Perceptual Threshold*</p>

Spinal Cord Injury CDE Highlight Summary

Disease; Domains	Recommendations and List of Forms
Outcomes and Endpoints; Functional Outcomes	<p>Core: N/A</p> <p>Supplemental – Highly Recommended: 2 Minute Walk Test, 6 Minute Walk Test, 10 Meter Timed Walk Spinal Cord Independence Measure, Spinal Cord Injury Functional Index / Assistive Technology (SCI-FI/AT)*</p> <p>Supplemental: 6 Minute Walk Test*, 10 Meter Timed Walk*, Berg Balance Scale**, Canadian Occupational Performance Measure (COPM), Capabilities Upper Extremity Questionnaire (CUE-Q), Capabilities Upper Extremity Test (CUE-T)*, Five Times Sit and Stand Test*, Functional Independence Measure for Children (WeeFIM)*, Graded Redefined Assessment of Strength, Sensibility and Prehension (GRASSP), Jebsen-Taylor Hand Function Test, Spinal Cord Injury Functional Ambulation Inventory (SCI-FAI)*, Spinal Cord Injury Functional Index / Assistive Technology (SCI-FI/AT)*, Pediatric Evaluation of Disability Inventory (PEDI)*, Segmental Assessment of Trunk Control (SATCo)*, Stride Analysis and Gait Variability, Timed Up and Go*, Walking Index for SCI (WISCI II), Wheelchair Skills Test</p> <p>Exploratory: 2 Minute Walk Test*, Bayley Scales of Infant Development (Bayley III, BSID), Borg Rating of Perceived Exertion, Bruininks-Osteretsky Test of Motor Proficiency (BOT-2)*, Capabilities Upper Extremity Questionnaire (CUE-Q)*, Grasp and Release Test, Gross Motor Function Measure (GMFM-66), Mini-Balance Evaluation Systems Test (Mini-BESTest), Neuromuscular Recovery Scale, Nine Hole Peg Test, PROMIS-Pediatric*, Peabody Developmental Motor Scale II*, Pediatric Neuromuscular Recovery Scale*, Pediatric SCI Activity Measure (PEDI-SCI AM) Short Forms*, Quadriplegia Index of Function, Neuro-QoL – Pediatric Functional Health*, Sollerman Hand Function Test, Spinal Cord Ability Ruler, Spinal Cord Independence Measure (SCIM)*, Spinal Cord Independence Measure (SCIM-III) for Youth*, Toronto Rehabilitation Institute Hand Function Test, Wheelchair Circuit, Wheelchair Skills Test*</p>
Outcomes and Endpoints; Pain	<p>Core: N/A</p> <p>Supplemental—Highly Recommended: N/A</p> <p>Supplemental: Douleur Neuropathique 4 (DN4), Faces Pain Scale – Revised*, Functional Disability Inventory – Child and Adolescent Form (FDI)*, International SCI Pain Basic Data Subset, Multidimensional Pain Inventory (MPI) Pain Severity Subscale, Neuropathic Pain Symptom Inventory (NPSI), PainDETECT, Spinal Cord Injury Pain Instrument (SCIPI)</p> <p>Exploratory: Adolescent Pediatric Pain Tool (APPT)*, Children’s Activity Limitations Interview (CALI)*, Multidimensional Pain Inventory (MPI) Pain Severity Subscale*, Neuropathic Pain Questionnaire (NPQ), Pain Quality Assessment Scale (PQAS)</p>

Spinal Cord Injury CDE Highlight Summary

Disease; Domains	Recommendations and List of Forms
Outcomes and Endpoints; Psychological Status	<p>Core: N/A</p> <p>Supplemental—Highly Recommended: Patient Health Questionnaire Depression Scale 9 (PHQ-9)</p> <p>Supplemental: Beck Youth Inventories – 2nd Edition (BYI-II)*, Children’s Depression Inventory-2 (CDI-2)*, Generalized Anxiety Disorder (GAD-7), Hospital Anxiety and Depression Scale (HADS), Hospital Anxiety and Depression Scale (HADS)*, Moorong Self-Efficacy Scale (MSES), Multidimensional Scale of Perceived Social Support (MSPSS), Positive Affect and Well-Being Scale of the Neurology Quality of Life (Neuro-QoL) Measure, Revised Children’s Manifest Anxiety Scale: 2nd Edition (RCMAS-2)*</p> <p>Exploratory: Children’s Impact of Events Scale (CRIES-13)*, Children’s PTSD Symptom Scale (CPSS)*, Generalized Anxiety Disorder (GAD-7)*, Impact of Event Scale (IES), Perceived Manageability Scale (PMNac)</p>
Outcomes and Endpoints; Quality of Life / Patient Reported Outcomes	<p>Core: N/A</p> <p>Supplemental-Highly Recommended: N/A</p> <p>Supplemental: Child health Questionnaire (CHQ)*, Craig Handicap and Assessment Reporting Technique (CHART-SF) – Interview & Paper Versions, EuroQoL-5 Dimension Questionnaire (EQ-5D), EuroQoL-5 Dimension Questionnaire-Youth (EQ-5DY)*, International Quality of Life Basic Data Set, Life Satisfaction Questionnaire (LISAT-9), NIH Toolbox, Quality of Life Index-SCI Version, Satisfaction with Life Scale-Child (SWLS-C)*, Spinal Cord Injury-Quality of Life (SCI-QoL), Short Form Health Survey-36 (SF-36) Walk Wheel Modification for SCI, Satisfaction with Life Scale, World Health Organization Quality of Life Assessment (WHOQOL-BREF)*,</p> <p>Exploratory: Child and Adolescent Scale of Participation (CASP)*, Pediatric Measure of Participation (PMoP) Computer Adaptive Test of Short Form*, Short Form 36-Item Health Survey (SF-36)*</p>
Outcomes and Endpoints; Sleep	<p>Core: N/A</p> <p>Supplemental-Highly Recommended: N/A</p> <p>Supplemental: Epworth Sleepiness Scale (ESS)-Adult Version, Epworth Sleepiness Scale – Children and Adolescents (ESS-CHAD)*, Fatigue Severity Scale (FSS)*, Pediatric Sleep Questionnaire (PSQ)*, American Academy of Medicine (AASM): International Classification of Sleep Disorders (ICSD) Criteria</p> <p>Exploratory: Adolescent Sleep Hygiene Scale Revised (ASHSr)*, Adolescent Sleep Wake Scale (ASWS)*, Brief Infant Sleep Questionnaire (BISQ)*, Children’s Sleep Habits Questionnaire (CSHQ) – Preschool and School Age*, Children’s Sleep Habits Questionnaire (CSHQ) – Older Child/Adolescent*, Pittsburgh Sleep Quality Index (PSQI), Tayside Children’s Sleep Questionnaire (TCSQ)*</p>

Spinal Cord Injury CDE Highlight Summary

Disease; Domains	Recommendations and List of Forms
Outcomes and Endpoints; The International SCI Data Sets	<p>Core: International Standards for Neurological Classification of SCI Worksheet (ISNCSCI), International SCI Cardiovascular Function Basic Data Set, International SCI Endocrine and Metabolic Function Basic Data Set, International SCI Musculoskeletal Basic Data Set, International SCI Pulmonary Basic Data Set</p> <p>Supplemental – Highly Recommended: International SCI Core Data Set, International SCI Pain Basic Data Set Version 2.0, International SCI Upper Extremity Basic Data Set</p> <p>Supplemental: International SCI Pain Basic Data Set, International SCI Pain Extended Data Set, International SCI Spinal Column Injury Basic Data Set, 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 Basic Data Set Version 2.0, International SCI Bowel Function Extended Data Set, International SCI Cardiovascular Function Basic Data Set, International SCI Core Data Set v2.0, International SCI Endocrine and Metabolic Function Basic Data Set, International SCI Endocrine and Metabolic Function Extended Data Set, International SCI Female and Male Sexual Function Basic Data Sets, International SCI Female and Male Sexual Function Basic Data Sets v2.0, International SCI Lower Urinary Tract Function Basic Data Set, International SCI Musculoskeletal Basic Data Set, International SCI Pulmonary Basic Data Set, International SCI Quality of Life Basic Data Set, International SCI Quality of Life Basic Data Set Version 2.0, International SCI Skin and Thermoregulation Function Basic Data Set, International SCI Spinal Intervention and Surgical Procedures 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>

*Pediatric-specific recommendation