Start-up Resource – NINDS Spinal Cord Injury (SCI) CDE Recommendations

The National Institute of Neurological Disorders and Stroke (NINDS) and other Federal agencies and international organizations have the common mission of developing data standards for clinical research. Through the efforts of subject-specific working groups, topic-driven data elements have been created. The first set of Common Data Elements (CDEs) for Spinal Cord Injury was developed in 2014. The Core and Supplemental – Highly Recommended data elements to be used by an investigator when beginning a research study in this disease/disorder are listed in this resource document. All other recommendations are listed on the website and should be considered based on study type.

Each CDE or instrument could be classified according to the definitions below:

General Core: A data element that is required for all NINDS funded studies.

Disease Core: A data element that collects essential information applicable to any disease-specific study, including all therapeutic areas. The NINDS and its appointed working groups assign the disease "Core" classification based on the current clinical research best practices. In each case, the disease Core CDEs are a small subset of the available CDEs, where it is anticipated that investigators will need to collect the disease Core CDEs on any type of study. These are required for all disease-specific studies.

Disease Supplemental - Highly Recommended: A data element which is essential based on certain conditions or study types in clinical research studies. In most cases, these have been used and validated in the disease area. These data elements are strongly recommended for the specified disease condition, study type or design.

Disease Supplemental: A data element which is commonly collected in clinical research studies. Use depends upon the study design, protocol or type of research involved. These are recommended, but not required, for studies.

Disease Exploratory: A data element that requires further validation, but may fill current gaps in the CDEs and/or substitute for an existing CDE once validation is complete. Such data elements show great promise, but require further validation before they are ready for prime-time use in clinical research studies. They are reasonable to use with the understanding that it has limited validation in the target group.

Summary of Core/Supplemental - Highly Recommended Recommendations: Spinal Cord Injury CDEs

National Institute of Health (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.*	• **NIH Toolbox** • **Quality of Life in Neurological Disorders (Neuro-QOL)** • **Patient-Reported Outcomes Measurement Information System (PROMIS)**

Core CDEs for ALL NINDS Studies*:

CDE Domain	CDE Name	CDE ID	Classification	Study Type
Demographics	Birth date	C00007	CORE	All studies
Demographics	Ethnicity USA category	C00020	CORE	All studies
Demographics	Race USA category	C00030	CORE	All studies
Demographics	Gender Type	C00035	CORE	All studies
General Health History	Medical history condition text	C00322	CORE	All studies
General Health History	Medical history condition SNOMED CT code	C00313	CORE	All studies

Core CDEs for SCI Studies:

CDE Domain; Subdomain	CDE Name	CDE ID
Disease/ Injury Related Events; History of Disease/Injury Event	Visit date	C17409
Disease/ Injury Related Events; History of Disease/Injury Event	Injury date time	C05400
Disease/ Injury Related Events; History of Disease/Injury Event	Spinal cord injury etiology type	C06414
Participant Characteristics; Demographics	Less three years age value	C18386*

* Note: Education year count C00015 is no longer a general Core CDE

Supplemental – Highly Recommended CDEs for SCI Studies:

CDE Domain	CDE Name	CDE ID
Participant Characteristics/Participant History and Family History	Education year count	C00015
Participant Characteristics/Participant History and Family History	Family income range	C00205
Participant Characteristics/Participant History and Family History	Education level primary caregiver USA type	C00013*
Participant Characteristics/Participant History and Family History	Education level USA type	C00012*
Disease/Injury Related Events; History of Disease/Injury Related Events	Multiple birth indicator	C15985*
Disease/Injury Related Events; History of Disease/Injury Related Events	Twin sibling vital status	C21621*
Disease/Injury Related Events; History of Disease/Injury Related Events	Pregnancy or delivery risk factor type	C11066*
Disease/Injury Related Events; History of Disease/Injury Related Events	Respiratory intervention neonatal problem type	C12625*
Disease/Injury Related Events; History of Disease/Injury Related Events	Deliver condition hypotonia grade	C12631*
Disease/Injury Related Events; History of Disease/Injury Related Events	Gestational age range value	C21620*
Disease/Injury Related Events; History of Disease/Injury Related Events	Delivery mode type	C11078*
Disease/Injury Related Events; History of Disease/Injury Related Events	Neonate delivery route type	C11079*

Summary of Core/Supplemental - Highly Recommended Recommendations: Spinal Cord Injury CDEs

CDE Domain	CDE Name	CDE ID
Disease/Injury Related Events; History of Disease/Injury Related Events	Caesarean delivery timing type	C17983*
Disease/Injury Related Events; History of Disease/Injury Related Events	Delivery modality type	C11080*
Disease/Injury Related Events; History of Disease/Injury Related Events	Delivery extraction type	C11083*
Disease/Injury Related Events; History of Disease/Injury Related Events	APGAR one minute score	C12604*
Disease/Injury Related Events; History of Disease/Injury Related Events	APGAR five minute score	C00724*
Disease/Injury Related Events; History of Disease/Injury Related Events	APGAR ten minute score	C00723*
Disease/Injury Related Events; History of Disease/Injury Related Events	Neonatal intensive unit stay indicator	C12628*
Disease/Injury Related Events; History of Disease/Injury Related Events	Neonatal intensive care unit stay duration	C12629*

Core Instruments for all SCI studies:

CDE Domain	Category	Instruments/Data Sets
Neurological	CNS Sensorimotor Impairment (or Preservation)	International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI)
N/A	Columbia Suicidal Ideation Assessment	Guidance for Industry: Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials

Summary of Core/Supplemental - Highly Recommended Recommendations: Spinal Cord Injury CDEs

NINDS Highly-recommended Instrument Recommendations for SCI Studies:

Supplemental – Highly Recommended Instruments and Data Sets by Domain

CDE Domain	Category	Instruments/Data Sets
Functional	Gait	10 Meter Walk Test
Functional	Gait	6 Minute Walk Test
Functional	Balance	Berg Balance Scale**
Functional	Upper Extremity	International SCI Upper Extremity Basic Data Set
Functional	Overall Function	Pediatric Evaluation of Disability Inventory (PEDI)*
Functional	Overall Function	Spinal Cord Independence Measure
Pain	Multiple	International SCI Pain Basic Data Set Version 2.0
Psychological	Depression	Patient Health Questionnaire 9 (PHQ-9)
Psychological	Anxiety and Depression	Hospital Anxiety and Depression Scale (HADS)

*Pediatric SCI recommendation

**Not recommended for youth < 18

For the complete list of NINDS CDE recommendations for SCI, please see the NINDS CDE website.