

Summary of Core and Supplemental – Highly Recommended Recommendations: Cerebral Palsy CDEs

Start-up Resource – NINDS Cerebral Palsy 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 Cerebral Palsy was developed in 2016. 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 collects essential information relevant and applicable to any study, regardless of the specific disease area or research domain. The NINDS and its appointed General CDE Steering Committee assign the General Core classification based on the current clinical research best practices. This classification applies to both the General CDEs and the Disease-specific CDEs. These CDEs are strongly recommended. General Core CDEs include information collected in all types of research, e.g., demographics and medical history.

Disease Core: A data element that collects essential information applicable to a disease-specific study. The NINDS and its appointed working groups assign the Disease Core classification based on the current clinical research best practices. The Disease Core CDEs are a small subset of CDEs that are strongly recommended to be collected by investigators 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.

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<p>National Institute of Health (NIH) Resources: <i>The NINDS also strongly encourages researchers to use these NIH developed materials for NINDS-sponsored research, when appropriate.</i> <i>Utilization of these resources will enable greater consistency for NINDS-sponsored research studies. These tools are free of charge.</i></p>	<p>NIH Toolbox</p> <p>Quality of Life in Neurological Disorders (Neuro-QOL)</p> <p>Patient-Reported Outcomes Measurement Information System (PROMIS)</p>
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NINDS disclaimer: Consistent with Executive Order 14168, "gender" should not be used as a replacement for the element "sex" in the NINDS CDE Project.

Core CDEs for all NINDS Studies¹:

Domain; Sub-Domain	CDE Name	CDE ID	Study Type
Participant Characteristics; Demographics	Birth date	C00007	All studies
Participant Characteristics; Demographics	Ethnicity USA category	C00020	All studies
Participant Characteristics; Demographics	Race USA category	C00030	All studies
Participant Characteristics; Demographics	Birth sex assigned type	C58676	All studies
Participant Characteristics; Demographics	Gender identity type	C58677	All studies
Participant Characteristics; Demographics	Medical history condition text	C00322	All studies
Participant Characteristics; Demographics	Medical history condition SNOMED CT code	C00313	All studies

¹ Note: Education year count C00015 is no longer a General Core CDE

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Core CDEs for Cerebral Palsy:

Domain; Subdomain	CDE Name	CDE ID
Participant Characteristics; Demographics	Birth country name	C00005
Participant Characteristics; Demographics	Country of residence code	C10676
Participant Characteristics; Demographics	Gender type	C00035
Participant Characteristics; Social Status	Education year count	C00015
Participant History and Family History; General Health History	Family history medical condition indicator	C00721
Participant History and Family History; General Health History	Adopted indicator	C10813
Participant History and Family History; General Health History	Family history collection source	C17681
Participant History and Family History; General Health History	Body system category	C00312
Participant History and Family History; General Health History	Medical history condition SNOMED CT code	C00313
Participant History and Family History; General Health History	Medical history taken date and time	C00314
Participant History and Family History; General Health History	Medical history global assessment indicator	C00315
Participant History and Family History; General Health History	Medical history condition end date and time	C00316
Participant History and Family History; General Health History	Medical history condition start date and time	C00317
Participant History and Family History; General Health History	Medical history condition ongoing indicator	C00319
Participant History and Family History; General Health History	Medical history for body system indicator	C00321
Participant History and Family History; General Health History	Medical history condition text	C00322
Participant History and Family History; General Health History	Clinical event or milestone type	C10615
Participant History and Family History; General Health History	Clinical event or milestone achieved indicator	C10616
Participant History and Family History; General Health History	Clinical event or milestone achieved age value	C12658
Assessments and Examinations; Imaging Diagnostics	Birth date	C00007
Assessments and Examinations; Physical/Neurological Examination	Hand preference type	C00023
Assessments and Examinations; Vital Signs and Other Body Measures	Respiratory rate	C01535
Assessments and Examinations; Vital Signs and Other Body Measures	Weight measurement	C01541
Assessments and Examinations; Vital Signs and Other Body Measures	Weight unit of measure	C01581
Assessments and Examinations; Vital Signs and Other Body Measures	Heart rate	C01521
Assessments and Examinations; Vital Signs and Other Body Measures	Assessment performed date	C19500
Treatment/Intervention Data; Therapies	Subject ID name	C19247

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General Core for all Studies:

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](#))

Supplemental – Highly Recommended CDEs for Cerebral Palsy:

Domain; Subdomain	CDE Name	CDE ID
Participant Characteristics; Demographics	Education year count	C00015
Participant History and Family History; General Health History	Site name	C17402
Participant History and Family History; General Health History	Subject ID name	C19247
Participant History and Family History; General Health History	Tobacco current use indicator	C00710
Participant History and Family History; General Health History	Tobacco prior use indicator	C00711
Participant History and Family History; General Health History	Alcohol use frequency	C00730
Participant History and Family History; General Health History	Drug or substance current illicit use indicator	C00713
Participant History and Family History; General Health History	Subscribed drug or substance illicitly used category	C00712
Disease/Injury Related Events; Classification	Cerebral palsy predominant motor type	C58653
Disease/Injury Related Events; Classification	Cerebral palsy secondary motor type	C58654
Disease/Injury Related Events; Classification	Timing injury abnormality type	C58660
Disease/Injury Related Events; Classification	Predominant MRI brain pattern type	C58662
Disease/Injury Related Events; Classification	Cerebral palsy gross motor function type	C58663
Disease/Injury Related Events; Classification	Cerebral palsy fine motor function type	C58664
Disease/Injury Related Events; Classification	Cerebral palsy upper limb function type	C58665
Disease/Injury Related Events; Classification	Communication type	C58666
Disease/Injury Related Events; Classification	Eating drinking type	C58667
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Variant mutational analysis results available indicator	C12783
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Variant mutational analysis performed indicator	C12944
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Variant mutational analysis performed family member indicator	C12784
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Gene variant mutation detected result type	C12785
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Gene mutation detected digenic result specify	C18873

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Domain; Subdomain	CDE Name	CDE ID
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Gene additional variants unknown significance indicator	C12782
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Gene sequenced with no variant mutation indicator	C12808
Assessments and Examinations; Imaging Diagnostics	Migration percentage left value	C59184
Assessments and Examinations; Imaging Diagnostics	Migration percentage right value	C59185
Assessments and Examinations; Physical/Neurological Examination	Site name	C17402
Assessments and Examinations; Physical/Neurological Examination	Subject ID name	C19247
Assessments and Examinations; Vital Signs and Other Body Measures	Site name	C17402
Assessments and Examinations; Vital Signs and Other Body Measures	Subject ID name	C19247
Assessments and Examinations; Vital Signs and Other Body Measures	Assistive device use indicator	C58879
Assessments and Examinations; Vital Signs and Other Body Measures	Assistive device type	C58880
Assessments and Examinations; Vital Signs and Other Body Measures	Assistive device type other text	C59189
Assessments and Examinations; Vital Signs and Other Body Measures	Gait velocity barefoot condition measurement	C59194
Assessments and Examinations; Vital Signs and Other Body Measures	Gait cadence barefoot condition measurement	C59195
Assessments and Examinations; Vital Signs and Other Body Measures	Gait stride length barefoot condition left measurement	C59196
Assessments and Examinations; Vital Signs and Other Body Measures	Gait stride length barefoot condition right measurement	C59197
Assessments and Examinations; Vital Signs and Other Body Measures	Gait step length barefoot condition left measurement	C59245
Assessments and Examinations; Vital Signs and Other Body Measures	Gait step length barefoot condition right measurement	C59246
Assessments and Examinations; Vital Signs and Other Body Measures	Gait velocity orthotic condition measurement	C59203
Assessments and Examinations; Vital Signs and Other Body Measures	Gait cadence orthotic condition measurement	C59204

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Domain; Subdomain	CDE Name	CDE ID
Assessments and Examinations; Vital Signs and Other Body Measures	Gait stride length orthotic condition left measurement	C59205
Assessments and Examinations; Vital Signs and Other Body Measures	Gait stride length orthotic condition right measurement	C59206
Assessments and Examinations; Vital Signs and Other Body Measures	Gait step length orthotic condition left measurement	C59247
Assessments and Examinations; Vital Signs and Other Body Measures	Gait step length orthotic condition right measurement	C59248
Treatment/Intervention Data; Therapies	Mobility device use indicator	C12679
Treatment/Intervention Data; Therapies	Subject ID name	C19247

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Disease Specific Instruments for Cerebral Palsy:

1. Pediatric Quality of Life Inventory Cerebral Palsy Module (PedsQL-CP)
2. Cerebral Palsy Quality of Life (CPQOL)
3. Caregiver Priorities and Child Health Index of Life with Disabilities (CPCHILD)

Supplemental – Highly Recommended Instruments for Cerebral Palsy:

1. Activities Scale for Kids© (ASK)
2. Ages & Stages Questionnaire (ASQ) - version 3
3. Alberta Infant Motor Scale (AIMS)
4. Assessment of Life Habits (LIFE-H)
5. Barry Albright Dystonia Scale (BADS)
6. Bayley Scale of Infant Development (Bayley III, BSID)
7. Behavior Rating Inventory of Executive Function - 2nd Ed (BRIEF-2)
8. Behavior Rating Inventory of Executive Function - Adult version (BRIEF-A)
9. Brief Infant Toddler Social Emotional Assessment (BITSEA)
10. Brief Rating Inventory of Executive Function-Preschool Version (BRIEF-P)
11. California Verbal Learning Test - Children (CVLT-C)
12. Canadian Occupational Performance Measure (COPM)
13. Caregiver Priorities and Child Health Index of Life with Disabilities (CPCHILD)
14. Cerebral Palsy Quality of Life (CP QOL)
15. Child Engagement in Daily Life
16. Communication Function Classification System (CFCS)
17. Conners Continuous Performance Test 3rd Edition™ (Conners CPT 3™)
18. Delis–Kaplan Executive Function System™ (D-KEFS)
19. Eating and Drinking Ability Classification System (EDACS)
20. Gross Motor Function Classification System-Expanded & Revised (GMFCS- ER)
21. Gross Motor Function Measure (GMFM-88, GMFM-66)
22. Manual Ability Classification System (MACS)
23. Mullen Scales of Early Learning (MSEL)
24. Participation and Environment Measure for Children and Youth (PEM-CY)
25. Peabody Picture Vocabulary Test 4th Edition (PPVT™-4)
26. Pediatric Quality of Life Inventory (PedsQL)
27. Pediatric Quality of Life Inventory Cerebral Palsy Module (PedsQL-CP)
28. Prechtl's Assessment of General Movements [General Movement Assessments]
29. Social Communication Questionnaire (SCQ) [Formally known as: Autism Screening Questionnaire (ASQ)]
30. Tardieu Scale
31. Test of Infant Motor Performance (TIMP)

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32. Wechsler Adult Intelligence Scale- 4th Ed (WAIS-IV)
33. Wechsler Intelligence Scale for Children-V (WISC-V)
34. Young Children's Participation and Environment Measure (YC-PEM)

For the complete list of NINDS CDE recommendations for Cerebral Palsy, please see the [NINDS CDE website](#).