

Cerebral Palsy (CP) CDE Highlight Summary Document

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/Domain; Subdomain	Recommendations
Cerebral Palsy	<p>These instruments and elements are recommended for use in all Cerebral Palsy studies:</p> <p>Core instruments: None</p> <p>Core elements: See Start-Up Resource Listing document (CP Start-Up Resource Listing)</p>
NIH Resources	<p>Core: None</p> <p>Supplemental: National Institutes of Health (NIH) Toolbox</p> <p>Supplemental – Highly Recommended: None</p> <p>Exploratory: Patient-Reported Outcomes Measurement Information System (PROMIS); Quality of Life in Neurological Disorders (Neuro-QOL)</p>
Summary Documents	<p>Neuromotor Skill Functional Assessments Working Group Summary, Neurocognitive Social Emotional Assessments Working Group Summary, Engagement Quality of Life Assessments Data Working Group Summary, Participant Characteristics Disease Injury/Related Events Working Group Summary, Health, Growth, Genetics, Comorbidities and Labs Working Group Summary</p>
Participant Characteristics; Demographics	<p>Core: Demographics*, General Core</p> <p>Supplemental – Highly Recommended: Demographics*</p> <p>Supplemental: Demographics*</p> <p>Exploratory: None</p>

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Participant Characteristics; Social Status	<p>Core: Social Status*</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Social Status*</p> <p>Exploratory: None</p>
Participant History and Family History; General Health History	<p>Core: Family History*, Medical History*, Motor Development History*, Surgical and Hospitalization History*, Vaccination History*</p> <p>Supplemental – Highly Recommended: Behavioral History*, Motor Development History*, Surgical and Hospitalization History*</p> <p>Supplemental: Behavioral History*, Family History*, Medical History*, Motor Development History*, Vaccination History*</p> <p>Exploratory: Medical History*</p>
Disease/Injury Related Events; Classification	<p>Core: None</p> <p>Supplemental – Highly Recommended: Communication Function Classification System (CFCS), Eating and Drinking Ability Classification System (EDACS), Gross Motor Function Classification System-Expanded & Revised (GMFCS- ER), Manual Ability Classification System (MACS)</p> <p>Supplemental: Participant Condition Characteristics*</p> <p>Exploratory: Bimanual Fine Motor Function (BFMF)</p>
Disease/Injury Related Events; Epidemiology / Environmental History	<p>Core: None</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Risk Factor Questionnaire (RFQ) - Physical Activity and Sleep, Risk Factor Questionnaire (RFQ) - Residential History</p> <p>Exploratory: None</p>
Assessments and Examinations; Imaging Diagnostics	<p>Core: None</p> <p>Supplemental – Highly Recommended: Pelvic Radiographs*</p> <p>Supplemental: Neuroimaging Cerebral Palsy Magnetic Resonance Imaging, Pelvic Radiographs</p>

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	Exploratory: None
Assessments and Examinations; Laboratory Tests and Biospecimens / Biomarkers	<p>Core: None</p> <p>Supplemental – Highly Recommended: Mutation Analysis*</p> <p>Supplemental: Mutation Analysis</p> <p>Exploratory: None</p>
Assessments and Examinations; Physical and Neurological Examination	<p>Core: Physical Exam*</p> <p>Supplemental – Highly Recommended: Physical Exam*</p> <p>Supplemental: Lower Extremity Passive Range of Motion Physical Exam, Neurological Examination</p> <p>Exploratory: None</p>
Assessments and Examinations; Vital Signs and Other Body Measures	<p>Core: Vital Signs*</p> <p>Supplemental – Highly Recommended: Vital Signs*, Gait Analysis*</p> <p>Supplemental: Vital Signs, Gait Analysis</p> <p>Exploratory: None</p>
Treatments / Intervention Data; Therapies	<p>Core: None</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: External Devices – CP, Occupational Therapy Treatment Session: Cerebral Palsy, Physical Therapy Individual Session, Rehabilitation Therapies - Episodes of care, Speech and Language Therapy Treatment Session</p> <p>Exploratory: None</p>
Treatments / Intervention Data; Surgeries and Other Procedures	<p>Core: None</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Baclofen Pump Surgery, Lumbosacral Dorsal Ventral Rhizotomy Surgery, Orthopedic Surgical Procedures – Ankle, Orthopedic Surgical Procedures – Hip, Orthopedic Surgical Procedures – Knee, Upper Extremity Orthopedic Surgical</p>

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	<p>Procedures – Elbow/Shoulder, Upper Extremity Orthopedic Surgical Procedures – Fingers-Thumb, Upper Extremity Orthopedic Surgical Procedures – Wrist/Forearm</p> <p>Exploratory: None</p>
<p>Outcomes and End Points; Cognitive and Emotional Status</p>	<p>Core: None</p> <p>Supplemental – Highly Recommended: Ages & Stages Questionnaire (ASQ)- Version 3, Bayley Scale of Infant Development (Bayley III, BSID), Wechsler Adult Intelligence Scale-4th Ed (WAIS-IV)*, Wechsler Intelligence Scale for Children-V (WISC-V)</p> <p>Supplemental: Cognitive Battery – NIH Toolbox, Leiter International Performance Scale-3 (Leiter-3), Wechsler Abbreviated Scale of Intelligence (WASI), Wechsler Preschool and Primary Scale of Intelligence (WPPSI-III, WPPSI-IV)</p> <p>Exploratory: Pediatric Sleep Questionnaire, PROMIS Bank v1.0 – Sleep Disturbance, Sleep Disorders Inventory for Students</p>
<p>Outcomes and End Points; Executive Functioning</p>	<p>Core: None</p> <p>Supplemental – Highly Recommended: Behavior Rating Inventory of Executive Function- 2nd Ed (BRIEF-2), Behavior Rating Inventory of Executive Function- Adult version (BRIEF-A), Brief Rating Inventory of Executive Function-Preschool Version (BRIEF-P), Conners Continuous Performance Test 3rd Edition™ (Conners CPT 3™), Delis–Kaplan Executive Function System™ (D-KEFS), Mullen Scales of Early Learning (MSEL)</p> <p>Supplemental: Corsi Block Test, Kaufman Assessment Battery for Children, Symbol Digit Modalities Test (SDMT), Test of Everyday Attention for Children (Tea-Ch)*, Test of Variables of Attention (TOVA)</p> <p>Exploratory: Conners Kiddie Continuous Performance Test 2nd Edition™ (Conners K–CPT 2™)</p>
<p>Outcomes and End Points; Family and Environment</p>	<p>Core: None</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Child and Adolescent Scale of Environment (CASE), Family Assessment Device (FAD)</p> <p>Exploratory: None</p>

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Outcomes and End Points; Functional Outcomes	<p>Core: None</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: 10 Meter Timed Walk, 6 Minute Walk Test, Edinburgh Visual Gait Score (EVGS), Functional Independence Measure for Children (WeeFIM), Functional Mobility Scale, Gait Deviation Index, Gait Profile Score (GPS), Instrumented Gait Analysis, NIH Toolbox Walking Speed (4-Meter Walk Gait Speed Test), Observational Gait Scale, Pediatric Evaluation of Disability Inventory (PEDI), Pediatric Outcomes Data Collection Instrument (PODCI), Stride Analysis and Gait Variability, Timed Up and Go (TUG)</p> <p>Exploratory: Functional Independence Measure (FIM), Goal Attainment Scale (GAS)</p>
Outcomes and End Points; Memory	<p>Core: None</p> <p>Supplemental – Highly Recommended: California Verbal Learning Test - Children (CVLT-C)</p> <p>Supplemental: Brief Visuospatial Memory Test– Revised (BVRT-R), California Verbal Learning Test II (CVLT-II), Rey Auditory Verbal Learning Test (RAVLT), Wechsler Memory Scale IV (WMS IV)</p> <p>Exploratory: None</p>
Outcomes and End Points; Motor Function	<p>Core: None</p> <p>Supplemental – Highly Recommended: Alberta Infant Motor Scale (AIMS), Canadian Occupational Performance Measure (COPM), Gross Motor Function Measure (GMFM-88, GMFM-66), Prechtl's Assessment of General Movements [General Movement Assessments], Test of Infant Motor Performance (TIMP)</p> <p>Supplemental: ABILHAND-Kids, Assisting Hand Assessment (AHA), Manual Muscle Testing- Using the Medical Research Council Muscle Grading Scale, Maximum Voluntary Isometric Contraction Testing (MVICT), Melbourne Assessment 2: A Test of Unilateral Upper Limb Function, Quality of Upper Extremity Skills Test (QUEST), Shriners Hospital for Children Upper Extremity Evaluation (SHUEE)</p> <p>Exploratory: Box and Blocks Test of Manual Dexterity, Jebsen Taylor Hand Function Test, Nine-Hole Peg Test (9-HPT), Purdue Pegboard</p>
Outcomes and End Points; Pain	<p>Core: None</p> <p>Supplemental – Highly Recommended: None</p>

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	<p>Supplemental: Bath Adolescent Pain Questionnaire (BAPQ), Brief Pain Inventory (BPI) Long Form, Brief Pain Inventory (BPI) Short Form, Faces Pain Scale-Revised (FPS-R), Noncommunicating Children's Pain Checklist-Revised (NCCPC-R), Numeric Pain Rating Scale (NPRS), Pain Interference Index (PII), Pediatric Pain Profile (PPP), PROMIS Pain Interference Short Forms</p> <p>Exploratory: Body Diagram, Child Activity Limitations Interview (CALI), Child Self-Efficacy Scale-Child (CSES), Face, Legs, Activity, Cry, Consolability Scale (FLACC), Pediatric Pain Questionnaire (PPQ), PROMIS Pain Behavior Short Forms, Visual Analog Scale (VAS)</p>
<p>Outcomes and End Points; Participation</p>	<p>Core: None</p> <p>Supplemental – Highly Recommended: Activities Scale for Kids© (ASK), Assessment of Life Habits (LIFE-H), Child Engagement in Daily Life, Participation and Environment Measure for Children and Youth (PEM-CY), Young Children's Participation and Environment Measure (YC-PEM)</p> <p>Supplemental: Assessment of Preschool Children's Participation (APCP), Children's Assessment of Participation and Enjoyment Scale (CAPE)/ Preferences for Activities of Children (PAC), School Function Assessment (SFA)</p> <p>Exploratory: Child and Adolescent Scale of Participation (CASP)*, Evaluation of Social Interaction (ESI) (2nd Edition), Lifestyle Assessment Questionnaire for CP (LAQ-CP of LAQ-G), Participation Assessment with Recombined Tools-Objective (PART-O)</p>
<p>Outcomes and End Points; Quality of life</p>	<p>Core: None.</p> <p>Supplemental –Highly Recommended: Caregiver Priorities and Child Health Index of Life with Disabilities (CPCHILD), Cerebral Palsy Quality of Life (CPQOL), Pediatric Quality of Life Inventory (PedsQL), Pediatric Quality of Life Inventory Cerebral Palsy Module (PedsQL-CP)</p> <p>Supplemental: DISABKIDS, Generic Children's Quality of Life Measure (GCQ), KIDSCREEN-52 HRQOL</p> <p>Exploratory: Assessment of Quality of Life (AQoL), Child Health and Illness Profile (CHIP-CE), Child Health Assessment Questionnaire (CHAQ), Child Health Questionnaire, EuroQoL-5 Dimension Questionnaire-Youth (EQ-5DY), Health Utilities Index (HUI), Health Related Quality of Life (HRQOL-14), Multidimensional Students' Life Satisfaction Scale (MSLSS), Patient-Reported Outcomes Measurement Information System (PROMIS), Quality of Life in Neurological Disorders (Neuro-</p>

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	QOL), Short Form 36-Item Health Survey (SF-36), World Health Organization Quality of Life Assessment (WHOQOL-BREF)
Outcomes and End Points; Social Emotional	<p>Core: None</p> <p>Supplemental – Highly Recommended: Brief Infant Toddler Social Emotional Assessment (BITSEA), Social Communication Questionnaire (SCQ) [Formally known as: Autism Screening Questionnaire (ASQ)]</p> <p>Supplemental: Wide Range Assessment of Memory and Learning, Second Edition (WRAML-2), Wisconsin Card Sorting Test (WCST)</p> <p>Exploratory: None</p>
Outcomes and End Points; Spasticity / Movement	<p>Core: None</p> <p>Supplemental – Highly Recommended: Barry Albright Dystonia Scale (BADs), Tardieu Scale</p> <p>Supplemental: Hypertonia Assessment tool (HAT), Modified Ashworth Scale – Limb Tone Testing, Selective Control Assessment of the Lower Extremity (SCALE)</p> <p>Exploratory: Dyskinesia Impairment Scale</p>
Outcomes and End Points; Speech, Language and Communication	<p>Core: None</p> <p>Supplemental – Highly Recommended: Peabody Picture Vocabulary Test 4th Edition (PPVT™-4)</p> <p>Supplemental: Clinical Evaluation of Language Fundamentals – Fifth Edition (CELF-5), Clinical Evaluation of Language Fundamentals Preschool 2 (CELF Preschool 2), Comprehensive Test of Phonological Processing, Second Edition (CTOPP-2), Edinburgh Cognitive and Behavioral ALS Screen (ECAS), Goldman-Fristoe Test of Articulation 2 (GFTA-2), Language Sample Analysis, Percentage of Consonants Correct-Revised (PCC-R), Preschool Language Scales – Fifth Edition (PLS-5), Pure Tone Threshold Audiometry, Speech Language Profile Groups (SLPG), Verbal Motor Production Assessment for Children (VMPAC), Viking Speech Scale (VSS)</p> <p>Exploratory: Dynamic Evaluation of Motor Speech Skills (DEMSS), Test of Children's Speech (TOCS)</p>

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Outcomes and End Points; Trunk Control/Balance	<p>Core: None</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Berg Balance Scale (BBS), Functional Reach Test, Segmental Assessment of Trunk Control (SATCo), Trunk Control Measurement Scale (TCMS)</p> <p>Exploratory: Early Assessment of Balance (EAB), Level of Sitting Scale (LSS)</p>
Outcomes and End Points; Visual-Spatial Processing	<p>Core: None</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Beery-Buktenica Developmental Test of Visual -Motor Integration, Sixth Edition (Beery VMI)</p> <p>Exploratory: None</p>

*Include one or more data elements that are Core or Supplemental – Highly Recommended