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August 2022 Revisions

- The CDE C00311 Birth weight report value was removed from the Prenatal and Perinatal History CRF and replaced with CDE C59019 Birth weight measurement. CDE C59019 classified as Supplemental.

January 2020 Revisions

- General Core CRF updated to replace ‘Gender’ question with ‘Sex assigned at birth’ and ‘Gender identity’.
- Two new CDEs added to CRF: C58676 (Sex assigned at birth) and C58677 (Gender identity). C00035 has been removed
- Start-Up document updated to reflect these changes.

April 2015 Revisions

- Loaded 508 compliant version of documents for CMD.
- Inserted additional reference on 6 Minute Walk Test file.
- CMD Start-Up Resource Listing was revised for CMD.
- CMD Roster problem was fixed to allow report to populate.

February 2015 Revisions

Overview

- There have been changes to the content and structure of the CMD CDEs since the previous release including:

  Version 1.0 of the CMD CDEs were released. To develop the CMD CDEs, the CMD CDE Working Group met from April 2014 to October 2014. The recommendations were posted for public comment in November 2014 and version 1.0 was released at the end of February 2015.

Form Status Changes

New Forms:

NIH Resources Subdomain

- National Institutes of Health (NIH) Toolbox
Congenital Muscular Dystrophy CDE Revision History Document

- Patient-Reported Outcomes Measurement Information System (PROMIS)
- Quality of Life in Neurological Disorders (Neuro-QOL)

**Summary Documents Subdomain**

- Summary of Recommendations for CMD

**Demographics Subdomain**

- General Core
- Demographics

**Social Status Subdomain**

- Social Status

**General Health History Subdomain**

- Family History
- Intake Medical History
- Interval Medical History
- Prenatal and Perinatal History
- Surgical History

**Imaging Diagnostics Subdomain**

- Brain Magnetic Resonance Imaging (MRI)
- Cardiac Magnetic Resonance Imaging (MRI)
- Diffusion Tensor Imaging (DTI)
- Dual-Energy X-Ray Absorptiometry (DEXA)
- Muscle Imaging

**Laboratory Tests and Biospecimens/Biomarkers Subdomain**

- Muscle Biopsies and Autopsy Tissue
- Peripheral Nerves – Biopsies and Autopsies
- Skin Biopsies for Qualification of Intraepidermal Nerve Fibers

**Non-Imaging Diagnostics Subdomain**
Congenital Muscular Dystrophy CDE Revision History Document

- Echocardiogram
- Electrocardiogram (ECG)
- Electrophysiology
- Short Scalp Electroencephalography (EEG)

**Physical/Neurological Examination Subdomain**
- Electrical Impedance Myography (EIM)

**Drugs Subdomain**
- Prior and Concomitant Medications

**Therapies Subdomain**
- Respiratory Interventions

**Functional Status Subdomain**
- 10 Meter Timed Walk
- 2 Minute Walk Test
- 6 Minute Walk Test
- Alberta Infant Motor Scale
- Barthel Index
- Bayley Scales of Infant Development (Bayley III, BSID)
- Brooke Upper Extremity Scale
- Egen Klassifikation Scale Version 2 (EK2)
- Goniometry
- Gross Motor Function Measure (GMFM-88, GMFM-66)
- Jebsen-Taylor Hand Function Test
- Modified Hammersmith Functional Motor Scale for Children with Spinal Muscular Atrophy (MHFMS-SMA/MHFMS-Extend)
- Nine Hole Peg Test
- North Star Ambulatory Assessment (NSAA)
- Pediatric Evaluation of Disability Inventory (PEDI)
Congenital Muscular Dystrophy CDE Revision History Document

- Stair Climb
- Timed Up and Go (TUG)
- Vignos Lower Extremity Scale
  Muscle Strength Testing Subdomain
- Grip Strength Fatigue
- Hand Held Dynamometry
- Manual Muscle Testing-Using the Medical Research Council Muscle Grading Scale
- Maximum Voluntary Isometric Contraction Testing (MVICT)
- Pinch Strength
  Neuropsychological Testing Subdomain
- Peabody Picture Vocabulary Test 4th Edition (PPVT-4)
- Purdue Pegboard
- Wechsler Abbreviated Scale of Intelligence (WASI)
- Wechsler Individual Achievement Test-III (WIAT-III)
- Wechsler Intelligence Scale for Children-IV (WISC-IV)
- Wechsler Preschool and Primary Scale of Intelligence (WPPSI-III)
  Performance Measures Subdomain
- Motor Function Measure (MFM)
  Pulmonary Function Testing/Respiratory Status Subdomain
- Measures of Gas Exchange
- Pulmonary Assessment Master Outline and Guidelines for Use
- Pulmonary Function Testing
  Quality of Life Subdomain
- Patient-Reported Outcomes Measurement Information System (PROMIS)
- Quality of Life in Neurological Disorders (Neuro-QOL)

Updated Forms:
Congenital Muscular Dystrophy CDE Revision History Document

- NA

**Removed Forms:**
- NA

**Detailed Form Revisions:**

Additional specific changes to the CRF Modules are detailed in the table included below.

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<tr>
<th>CRF Module/ Guideline</th>
<th>Current Version</th>
<th>Previous Version</th>
<th>Change Classification</th>
<th>Change Type</th>
<th>Description of Change</th>
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<td>Prior and Concomitant Medications</td>
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<td>A New Form was created and added to the CMD CDE materials to capture CDEs related to Prior and Concomitant Medications</td>
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<td>Respiratory Interventions</td>
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<td>Alberta Infant Motor Scale</td>
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<tr>
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<td>Major</td>
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<td>Modified Hammersmith Functional Motor Scale for Children with Spinal Muscular Atrophy (MHFMS-SMA/MHFMS-Extend)</td>
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<td>Pediatric Evaluation of Disability Inventory (PEDI)</td>
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## CRF Module/ Guideline | Current Version | Previous Version | Change Classification | Change Type | Description of Change
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Stair Climb | 1.0 | N/A | Major | New Form | A New Form was created and added to the CMD CDE materials to capture CDEs related to
Timed Up and Go (TUG) | 1.0 | N/A | Major | New Form | A Notice of Copyright was created and added to the CMD CDE materials
Vignos Lower Extremity Scale | 1.0 | N/A | Major | New Form | A Notice of Copyright was created and added to the CMD CDE materials
Grip Strength Fatigue | 1.0 | N/A | Major | New Form | A New Form was created and added to the CMD CDE materials to capture CDEs related to
Hand Held Dynamometry | 1.0 | N/A | Major | New Form | A New Form was created and added to the CMD CDE materials to capture CDEs related to
Manual Muscle Testing- Using the Medical Research Council Muscle Grading Scale | 1.0 | N/A | Major | New Form | A Notice of Copyright was created and added to the CMD CDE materials
Maximum Voluntary Isometric Contraction Testing (MVICT) | 1.0 | N/A | Major | New Form | A Notice of Copyright was created and added to the CMD CDE materials
Pinch Strength | 1.0 | N/A | Major | New Form | A Notice of Copyright was created and added to the CMD CDE materials
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**November 2014 Revisions**

Banner announcing the Public Review period for CMD was added to website and is visible on every page. CMD-specific language explaining the public review period and contents of the public review package was added to CMD disease page. Zip files containing the public review materials were added to the CMD disease page. CMD was moved from the CDEs in Development tab to the CDEs Under Review Tab on the NINDs Common Data Elements website homepage. Links to CMD added to the NMD page.

**September 2014 Revisions**

CMD Overview page updated to include a timeline of development. Corrections made to footnotes to correct diseases displayed for Quality of Life in Neurological Disorders, 10 Meter Timed Walk, Bayley Scales of Infant Development and 6 Minute Walk Test. CMD Browser tab labels updated to make it independent from NMD.

**August 2014 Revisions**

CMD Committee membership now displayed on History & Acknowledgments tab. 508 compliant version of various CRFs, NOCs, Guidelines, Start Up and Highlight document and other downloadable files posted for CMD. Links to NeuroQOL, NIH Toolbox, and PROMIS added to CMD website.
July 2014 Revisions

508 compliant versions of CRFs, NOCs and Recommendation spreadsheets updated on CMD website. Addition of “NIH Resources” domain listing NIH Toolbox, PROMIS, and Neuro-QOL as first domain on CMD Data Standards Tab.

June 2014 Revisions

A Reference tab was created in CMD and new publications were added to this page.

January 2014 Revisions

Updated CMD Acknowledgment page.

December 2013 Revisions

CMD document updated. CMD Data Standards page was updated with notification that recommendations would be developed in 2014.

September 2013 Revisions

Overview

The Congenital Muscular Dystrophy (CMD) CDE Materials were previously listed under the outline for Neuromuscular Disease on the NINDS website. The NINDS website has recently expanded to support 4 new diseases and the Congenital Muscular Disease CDE Materials have been removed from the Neuromuscular Disease outline to create a new disease area featuring these materials. The materials listed in this disease area will be considered version 1.0.

New Forms:

Updated Forms:

Removed Forms:

Detailed Form Revisions:
A Start-up Resource Listing was added to the Congenital Muscular Dystrophy disease area to provide investigators with a set of CORE data elements to be used during a research study.

January 2013 Revisions

Link to Start Up Resource Listing added to Highlight Summary documents on CMD webpage.