

# Congenital Muscular Dystrophy CDE Revision History Document

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# Congenital Muscular Dystrophy CDE Revision History Document

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

##### *Summary Documents Subdomain*

- Summary of Recommendations for CMD

# **Congenital Muscular Dystrophy CDE Revision History Document**

## *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*

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

## *Physical/Neurological Examination Subdomain*

- Electrical Impedance Myography (EIM)

# **Congenital Muscular Dystrophy CDE Revision History Document**

## *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)
  - 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

## **Congenital Muscular Dystrophy CDE Revision History Document**

- 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:**

- NA

### **Removed Forms:**

- NA

### **Detailed Form Revisions:**

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

## Congenital Muscular Dystrophy CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
National Institutes of Health (NIH) Toolbox	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the CMD CDE materials
Patient-Reported Outcomes Measurement Information System (PROMIS)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the CMD CDE materials
Quality of Life in Neurological Disorders (Neuro-QOL)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the CMD CDE materials
Summary of Recommendations for CMD	1.0	N/A	Major	New Form	A New Form was created and added to the CMD CDE materials
General Core	1.0	N/A	Major	New Form	A New Form was created and added to the CMD CDE materials
Demographics	1.0	N/A	Major	New Form	A New Form was created and added to the CMD CDE materials to capture CDEs related to Demographics
Social Status	1.0	N/A	Major	New Form	A New Form was created and added to the CMD CDE materials to capture CDEs related to Social Status
Family History	1.0	N/A	Major	New Form	A New Form was created and added to the CMD CDE materials to capture CDEs related to Family History

## Congenital Muscular Dystrophy CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Intake Medical History	1.0	N/A	Major	New Form	A New Form was created and added to the CMD CDE materials to capture CDEs related to Intake Medical History
Interval Medical History	1.0	N/A	Major	New Form	A New Form was created and added to the CMD CDE materials to capture CDEs related to Interval Medical History
Prenatal and Perinatal History	1.0	N/A	Major	New Form	A New Form was created and added to the CMD CDE materials to capture CDEs related to Prenatal and Perinatal History
Surgical History	1.0	N/A	Major	New Form	A New Form was created and added to the CMD CDE materials to capture CDEs related to Surgical History
Brain Magnetic Resonance Imaging (MRI)	1.0	N/A	Major	New Form	A New Form was created and added to the CMD CDE materials to capture CDEs related to Brain Magnetic Resonance Imaging
Diffusion Tensor Imaging (DTI)	1.0	N/A	Major	New Form	A New Form was created and added to the CMD CDE materials to capture CDEs related to Diffusion Tensor Imaging

## Congenital Muscular Dystrophy CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Cardiac Magnetic Resonance Imaging (MRI)	1.0	N/A	Major	New Form	A New Form was created and added to the CMD CDE materials to capture CDEs related to Cardiac Magnetic Resonance Imaging
Dual-Energy X-Ray Absorptiometry (DEXA)	1.0	N/A	Major	New Form	A New Form was created and added to the CMD CDE materials to capture CDEs related to Dual-Energy X-Ray Absorptiometry
Muscle Imaging	1.0	N/A	Major	New Form	A New Form was created and added to the CMD CDE materials to capture CDEs related to Muscle Imaging
Muscle Biopsies and Autopsy Tissue	1.0	N/A	Major	New Form	A New Form was created and added to the CMD CDE materials to capture CDEs related to Muscle Biopsies and Autopsy Tissue
Peripheral Nerves – Biopsies and Autopsies	1.0	N/A	Major	New Form	A New Form was created and added to the CMD CDE materials to capture CDEs related to Peripheral Nerves – Biopsies and Autopsies
Skin Biopsies for Qualification of Intraepidermal Nerve Fibers	1.0	N/A	Major	New Form	A New Form was created and added to the CMD CDE materials to capture CDEs related to Skin Biopsies for Qualification of Intraepidermal Nerve Fibers

## Congenital Muscular Dystrophy CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Echocardiogram	1.0	N/A	Major	New Form	A New Form was created and added to the CMD CDE materials to capture CDEs related to Echocardiogram
Electrocardiogram (ECG)	1.0	N/A	Major	New Form	A New Form was created and added to the CMD CDE materials to capture CDEs related to Electrocardiogram
Electrophysiology	1.0	N/A	Major	New Form	A New Form was created and added to the CMD CDE materials to capture CDEs related to
Short Scalp Electroencephalography (EEG)	1.0	N/A	Major	New Form	A New Form was created and added to the CMD CDE materials to capture CDEs related to Short Scalp Electroencephalography
Electrical Impedance Myography (EIM)	1.0	N/A	Major	New Form	A New Form was created and added to the CMD CDE materials
Prior and Concomitant Medications	1.0	N/A	Major	New Form	A New Form was created and added to the CMD CDE materials to capture CDEs related to Prior and Concomitant Medications
Respiratory Interventions	1.0	N/A	Major	New Form	A New Form was created and added to the CMD CDE materials to capture CDEs related to Respiratory Interventions

## Congenital Muscular Dystrophy CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Alberta Infant Motor Scale	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the CMD CDE materials
2 Minute Walk Test	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the CMD CDE materials
10 Meter Timed Walk	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the CMD CDE materials
6 Minute Walk Test	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the CMD CDE materials
Barthel Index	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the CMD CDE materials
Bayley Scales of Infant Development (Bayley III, BSID)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the CMD CDE materials
Brooke Upper Extremity Scale	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the CMD CDE materials
Egen Klassifikation Scale Version 2 (EK2)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the CMD CDE materials
Goniometry	1.0	N/A	Major	New Form	A New Form was created and added to the CMD CDE materials to capture CDEs related to
Gross Motor Function Measure (GMFM-88, GMFM-66)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the CMD CDE materials
Jebesen-Taylor Hand Function Test	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the CMD CDE materials

## Congenital Muscular Dystrophy CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Modified Hammersmith Functional Motor Scale for Children with Spinal Muscular Atrophy (MHFMS-SMA/MHFMS-Extend)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the CMD CDE materials
Nine Hole Peg Test	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the CMD CDE materials
North Star Ambulatory Assessment (NSAA)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the CMD CDE materials
Pediatric Evaluation of Disability Inventory (PEDI)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the CMD CDE materials
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

## Congenital Muscular Dystrophy CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
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
Peabody Picture Vocabulary Test 4th Edition (PPVT-4)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the CMD CDE materials
Purdue Pegboard	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the CMD CDE materials
Wechsler Abbreviated Scale of Intelligence (WASI)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the CMD CDE materials
Wechsler Individual Achievement Test-III (WIAT-III)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the CMD CDE materials
Wechsler Intelligence Scale for Children-IV (WISC-IV)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the CMD CDE materials

## Congenital Muscular Dystrophy CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Wechsler Preschool and Primary Scale of Intelligence (WPPSI-III)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the CMD CDE materials
Motor Function Measure (MFM)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the CMD CDE materials
Pulmonary Assessment Master Outline and Guidelines for Use	1.0	N/A	Major	New Form	A New Form was created and added to the CMD CDE materials
Pulmonary Function Testing	1.0	N/A	Major	New Form	A New Form was created and added to the CMD CDE materials to capture CDEs related to Pulmonary Function Testing

### 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.

## **Congenital Muscular Dystrophy CDE Revision History Document**

### **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:**

# **Congenital Muscular Dystrophy CDE Revision History Document**

## **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.