

Myotonic Dystrophy CDE Revision History Document

Contents

January 2020 Revisions	2
April 2015 Revisions	2
March 2015 Revisions	2
February 2015 Revisions	2
January 2015 Revisions	11
November 2014 Revisions	11
September 2014 Revisions.....	11
August 2014 Revisions	11

Myotonic 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 DM.
- Inserted additional reference on 6 Minute Walk Test file.
- Start-Up Resource Listing was revised for DM.
- DM Roster problem was fixed to allow report to populate.
- Inserted an additional reference on 6 Minute Walk Test file.

March 2015 Revisions

- Start-Up Resource Listing was revised for DM.

February 2015 Revisions

Overview

DM was moved from the “CDEs under Review” tab on the main landing page to the “CDEs Now Available” tab on the main landing page

The addition of new standardized disease-specific text was added explaining the mission of the NINDS CDE project and the CDE development process on the landing page for DM.

Eighty-eight new CRFs and 113 NOCs were created in DM.

Form Status Changes

New Forms:

Myotonic Dystrophy CDE Revision History Document

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

Demographics Subdomain

- General Core
- Demographics

Social Status Subdomain

- Social Status

General Health History Subdomain

- Family History
- Pregnancy

Imaging Diagnostics Subdomain

- Cardiac Magnetic Resonance Imaging (MRI)
- Muscle Imaging

Laboratory Tests and Biospecimens/Biomarkers Subdomain

- Laboratory Tests and Tracking
- Muscle Biopsies and Autopsy Tissue
- Mutation Analysis

Non-Imaging Diagnostics Subdomain

- Echocardiogram
- Electrocardiogram (ECG)

Myotonic Dystrophy CDE Revision History Document

- Electrophysiology

Physical/Neurological Examination Subdomain

- Bedside Myotonia
- Epworth Sleepiness Scale
- Evoked Myotonia through Electrical Stimulation

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
- Barthel Index
- Gross Motor Function Measure (GMFM-88, GMFM-66)
- Jebsen-Taylor Hand Function Test
- Nine Hole Peg Test
- Stair Climb
- Timed Up and Go (TUG)

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)

Myotonic Dystrophy CDE Revision History Document

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.

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 New Form was created and added to the DM materials
Patient-Reported Outcomes Measurement Information System (PROMIS)	1.0	N/A	Major	New Form	A New Form was created and added to the DM materials

Myotonic Dystrophy CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Quality of Life in Neurological Disorders (Neuro-QOL)	1.0	N/A	Major	New Form	A New Form was created and added to the DM materials
Summary of Recommendations for DM	1.0	N/A	Major	New Form	A New Form was created and added to the DM materials
General Core	1.0	N/A	Major	New Form	A New Form was created and added to the DM materials
Demographics	1.0	N/A	Major	New Form	A New Form was created and added to the DM 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 DM 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 DM materials to capture CDEs related to Family History

Myotonic Dystrophy CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Pregnancy	1.0	N/A	Major	New Form	A New Form was created and added to the DM materials to capture CDEs related to Prenatal and Perinatal History
Cardiac Magnetic Resonance Imaging (MRI)	1.0	N/A	Major	New Form	A New Form was created and added to the DM CDE materials to capture CDEs related to Cardiac Magnetic Resonance Imaging
Muscle Biopsies and Autopsy Tissue	1.0	N/A	Major	New Form	A New Form was created and added to the DM CDE materials to capture CDEs related to Muscle Biopsies and Autopsy Tissue
Echocardiogram	1.0	N/A	Major	New Form	A New Form was created and added to the DM 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 DM CDE materials to capture CDEs related to Electrocardiogram

Myotonic Dystrophy CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Electrophysiology	1.0	N/A	Major	New Form	A New Form was created and added to the DM CDE materials to capture CDEs related to
Electrical Impedance Myography (EIM)	1.0	N/A	Major	New Form	A New Form was created and added to the DM 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 DM CDE materials to capture CDEs related to Respiratory Interventions
2 Minute Walk Test	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the DM CDE materials
10 Meter Timed Walk	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the DM CDE materials

Myotonic Dystrophy CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
6 Minute Walk Test	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the DM CDE materials
Barthel Index	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the DM CDE materials
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 DM CDE materials
Jebesen-Taylor Hand Function Test	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the DM CDE materials
Nine Hole Peg Test	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the DM CDE materials
Stair Climb	1.0	N/A	Major	New Form	A New Form was created and added to the DM 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 DM CDE materials
Grip Strength	1.0	N/A	Major	New Form	A New Form was created and added to the DM materials to capture CDEs related to

Myotonic Dystrophy CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Hand Held Dynamometry	1.0	N/A	Major	New Form	A New Form was created and added to the DM 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 DM 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 DM CDE materials
Motor Function Measure (MFM)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the DM CDE materials
Measures of Gas Exchange	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the DM 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

Myotonic Dystrophy CDE Revision History Document

January 2015 Revisions

- DM Acknowledgement tab updated

November 2014 Revisions

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

September 2014 Revisions

- No changes.

August 2014 Revisions

- DM Committee membership now displayed on History & Acknowledgments tab.
- Landing pages for DM updated to read “Please contact the NINDS CDE Project Officer, Joanne Odenkirchen, or NINDSCDE@emmes.com for further information.”