

Duchenne Muscular Dystrophy and Becker Muscular Dystrophy CDE Revision History Document

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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.

May 2015 Revisions

Forms added to DMD/BMD page to make it stand alone with little need to reference NMD page.

Form (Including F#)	Old Subdomain in DMD/BMD if any	New Subdomain in DMD
F1807 General Core	General Health History	Demographics
F1031 Demographics	N/A	Demographics
F1997 Physical Examination	N/A	Physical/Neurological Examination
F1036 Polysomnography	N/A	Physical/Neurological Examination
F1515 Vital Signs	Vital Signs and Other Body Measures	Vital Signs and Other Body Measures (Note: Subdomain order changed. Moved above Laboratory Subdomain.)
F1052 Biomarkers Sample Data Guidelines	N/A	Laboratory Tests and Biospecimens/Biomarkers
F1045 Biospecimen Collection Guidelines for Use	N/A	Laboratory Tests and Biospecimens/Biomarkers
F1048 Fat Aspirate Tissue Specimens	N/A	Laboratory Tests and Biospecimens/Biomarkers

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Form (Including F#)	Old Subdomain in DMD/BMD if any	New Subdomain in DMD
F1047 Gene Table and Guidelines for Use	N/A	Laboratory Tests and Biospecimens/Biomarkers
F1992 Laboratory Tests and Tracking	N/A	Laboratory Tests and Biospecimens/Biomarkers
F1044 Laboratory Tests and Recommendations Table and Guidelines for Use	N/A	Laboratory Tests and Biospecimens/Biomarkers
F1985 Muscle Biopsy and Autopsy Tissue	N/A	Laboratory Tests and Biospecimens/Biomarkers
F1050 Peripheral Nerves – Biopsies and Autopsies	N/A	Laboratory Tests and Biospecimens/Biomarkers
F1999 Skin Biopsies for Qualification of Intreperidermal Nerve Fibers	N/A	Laboratory Tests and Biospecimens/Biomarkers
F1057 Brain Magnetic Resonance Imaging (MRI)	N/A	Imaging Diagnostics
F1056 Cardiac Magnetic Resonance Imaging (MRI)	N/A	Imaging Diagnostics
F1053 Diffusion Tensor Imaging (DTI)	N/A	Imaging Diagnostics
F1054 Dual-Energy X-Ray Absorptiometry (DEXA)	N/A	Imaging Diagnostics
F1060 Echocardiogram	N/A	Imaging Diagnostics

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Form (Including F#)	Old Subdomain in DMD/BMD if any	New Subdomain in DMD
F1055 Magnetic Resonance Imaging (MRI)	N/A	Imaging Diagnostics
F1058 Magnetic Resonance Spectroscopy (MRS)	N/A	Imaging Diagnostics
F1990 Electrocardiogram (ECG)	N/A	Non-Imaging Diagnostics
F1062 Electrophysiology	N/A	Non-Imaging Diagnostics
F1059 Holter Examination	N/A	Non-Imaging Diagnostics
F1037 Respiratory Interventions	N/A	Therapies
F2030 Medical History of DMD	*NEW FORM* (Copied from Medical History of NMD)	History of Disease/Injury Event

September 2014 Revisions

Moved Grip Strength CRF to Muscle Strength Testing Subdomain

August 2014 Revisions

There have been major changes to the content and structure of the Duchenne/Becker Muscular Dystrophy CDE materials in version 1.2 compared to version 1.1, including the following:

Form Status Changes:

New Forms:

NIH Resources

- NIH Toolbox

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

General Health History

- Family History
- Medical History
- Surgical History
- General Core CDES

Laboratory Tests and Biospecimens/Biomarkers

- Mutation Analysis

Vital Signs and Other Body Measures

- Vital Signs

Devices

- External Devices and Other Treatments

Drugs

- Prior and Current Medications

Therapies

- GI Therapies

Updated Forms:

- None

Removed Forms:

- None

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Detailed Form Revisions:

Additional specific changes to the CRF modules are detailed in the table included on the subsequent page.

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Family History	2.0	1.0	Major	New Form	A New Form was created and added to the DMD/BMD CDE materials to capture CDEs related to Family History.
Medical History	2.0	1.0	Major	New Form	A New Form was created and added to the DMD/BMD CDE materials to capture CDEs related to Medical History.
Surgical History	2.0	1.0	Major	New Form	A New Form was created and added to the DMD/BMD CDE materials to capture CDEs related to Surgical History.

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Mutation Analysis	2.0	1.0	Major	New Form	A New Form was created and added to the DMD/BMD CDE materials to capture CDEs related to Mutation Analysis
Vital Signs	2.0	1.0	Major	New Form	A New Form was created and added to the DMD/BMD CDE materials to capture CDEs related to Vital Signs
External Devices and Other Treatments	2.0	1.0	Major	New Form	A New Form was created and added to the DMD/BMD CDE materials to capture CDEs related to External Devices and Other Treatments

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Prior and Current Medications	2.0	1.0	Major	New Form	A New Form was created and added to the DMD/BMD CDE materials to capture CDEs related to Prior and Current Medications
GI Therapies	2.0	1.0	Major	New Form	A New Form was created and added to the DMD/BMD CDE materials to capture CDEs related to GI Therapies
NIH Toolbox	2.0	1.0	Major	NOC	A Notice of Copyright was created for this form and has been made available for easier access to the instrument

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Quality of Life in Neurological Disorders (Neuro-QOL)	2.0	1.0	Major	NOC	A Notice of Copyright was created for this form and has been made available for easier access to the instrument
Patient Reported Outcomes Measurement Information System (PROMIS)	2.0	1.0	Major	NOC	A Notice of Copyright was created for this form and has been made available for easier access to the instrument
General Core CDES	2.0	1.0	Major	New Form	A New Form was created and added to the DMD/BMD CDE materials

July 2014 Revisions

- Updated Quality of Life in Neurological Disorders NOC, and Recommendations uploaded for DMD/BMD.
- “NIH Resources” domain listing NIH Toolbox, PROMIS and Neuro-QOL added to the DMD/BMD Data Standards tab.

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May 2014 Revisions

- DMD/BMD Start Up document and Highlight document were converted to 508-compliant PDFs.
- A new link was created for the DMD/BMD review package.

April 2014 Revisions

- The CDE Start Up Resource document was updated for DMD/BMD
- The following NOCs were updated:
 - 10 Meter Timed Walk
 - 6 Minute Walk Test
 - Brooke Upper Extremity Scale
 - Canadian Occupational Performance Measure (COPM)
 - Jebsen-Taylor Hand Function Test
 - Manual Muscle Testing-Using the Medical Research Council Muscle Grading Scale
 - Maximum Voluntary Isometric Contraction Testing (MVICT)
 - Nine Hole Peg Test
 - North Star Ambulatory Assessment (NSAA)
 - Pediatric Evaluation of Disability Inventory (PEDI)
 - Pediatric Quality of Life Inventory (PEDSQL)
 - Quality of Life in Neurological Disorders (Neuro-QOL)
 - Vignos Lower Extremity Scale

January 2014 Revisions

Overview

There have been major changes to the content and structure of the Duchenne/Becker Muscular Dystrophy CDE materials in version 1.1 compared to version 1.0, including the following:

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Form Status Changes:

New Forms:

Functional Status

- 10 Meter Timed Walk
- 6 Meter Timed Walk
- Brooke Upper Extremity Scale
- Jebsen-Taylor Hand Functioning Test
- Nine Hole Peg Test
- Northstar Ambulatory Assessment (NSAA)
- Pediatric Evaluation Disability Inventory
- Pediatric Orthopedic Society of North America Measure (PODCI)
- Vignos Lower Extremity Scale

Muscle Strength Testing

- Manual Muscle Testing (MMT)-Using the Medical Research Council (MRC) Grading Scale
- Maximum Voluntary Isometric Contraction Testing (MVICT)

Quality of Life

- Canadian Occupational Performance Measure (COPM)
- Pediatric Quality of Life Inventory (PEDIQL)
- Quality of Life in Neurological Disorders (Neuro-QOL)

Updated Forms:

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- None

Removed Forms:

- None

Detailed Form Revisions:

Additional specific changes to the CRF modules are detailed in the table included on the subsequent page.

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
10 Meter Timed Walk	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
6 Meter Timed Walk	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Brooke Upper Extremity Scale	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
					replace the existing form
Jebsen-Taylor Hand Functioning Test	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Nine Hole Peg Test	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Northstar Ambulatory Assessment (NSAA)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Pediatric Evaluation Disability Inventory	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
					replace the existing form
Pediatric Orthopedic Society of North America Measure (PODCI)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Vignos Lower Extremity Scale	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Manual Muscle Testing (MMT)- Using the Medical Research Council (MRC) Grading Scale	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Maximum Voluntary Isometric	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Contraction Testing (MVICT)					replace the existing form
Canadian Occupational Performance Measure (COPM)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

November 2013 Revisions

DMD/BMD documents were updated.

September 2013 Revisions

Overview

The Duchenne and Becker Muscular Dystrophy 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 Duchene and Becker Muscular Dystrophy 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.

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Form Status Changes:

A Start-up Resource Listing has been added to provide investigators with a CORE set of elements to use when beginning a research study.

New Forms:

- None

Modified Forms:

- Family History
- Medical History
- Surgical and Hospitalization History
- Laboratory Tests Recommendations Table and Guidelines for Use
- Mutation Analysis
- Vital Signs
- External Devices and Other Treatments
- Prior and Concomitant Medications
- Gastrointestinal Therapies
- Pulmonary Function Testing
- DMD and BMD Clinical Outcome Recommendations

Removed Forms:

- None

Detailed Form Revisions:

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Additional specific changes to the CRF modules are detailed in the table included on the subsequent page.

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Family History	1.0	N/A	Major	Modified Form	A Modified Form was created and added to the DMD/BMD CDE materials to capture CDEs related to Family History.
Medical History	1.0	N/A	Major	Modified Form	A Modified Form was created and added to the DMD/BMD CDE materials to capture CDEs related to Medical History.

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Surgical and Hospitalization History	1.0	N/A	Major	Modified Form	A Modified Form was created and added to the DMD/BMD CDE materials to capture CDEs related to Surgical and Hospitalization History.
Laboratory Tests Recommendations Table and Guidelines for Use	1.0	N/A	Major	Modified Form	A Modified Form was created and added to the DMD/BMD CDE materials to outline Recommendations and Guidelines for Laboratory Tests in DMD/BMD.

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Mutation Analysis	1.0	N/A	Major	Modified Form	A Modified Form was created and added to the DMD/BMD CDE materials to capture CDEs related to Mutation Analysis.
Vital Signs	1.0	N/A	Major	Modified Form	A Modified Form was created and added to the DMD/BMD CDE materials to capture CDEs related to Vital Signs in DMD/BMD.
External Devices and Other Treatments	1.0	N/A	Major	Modified Form	A Modified Form was created and added to the DMD/BMD CDE materials to capture CDEs related to External Devices in DMD/BMD.

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Prior and Concomitant Medications	1.0	N/A	Major	Modified Form	A Modified Form was created and added to the DMD/BMD CDE materials to capture CDEs related to Prior and Concomitant Medications in DMD/BMD.
Gastrointestinal Therapies	1.0	N/A	Major	Modified Form	A Modified Form was created and added to the DMD/BMD CDE materials to capture CDEs related to Gastrointestinal Therapies in DMD/BMD.

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Pulmonary Function Testing	1.0	N/A	Major	Modified Form	A Modified Form was created and added to the DMD/BMD CDE materials to capture CDEs related to Pulmonary Function in DMD/BMD.
DMD and BMD Clinical Outcome Recommendations	1.0	N/A	Major	Modified Form	A Modified Form was created and added to the DMD/BMD CDE materials to outline Clinical Outcome Recommendations in DMD/BMD.