Facioscapulohumeral muscular dystrophy (FSHD) CDE Revision History

Facioscapulohumeral muscular dystrophy (FSHD) CDE Revision History

January 2020 Revisions

April 2015 Revisions

March 2015 Revisions

February 2015 Revisions

January 2015 Revisions

November 2014 Revisions

September 2014 Revisions

August 2014 Revisions
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 versions of documents for FSHD.
- Inserted additional reference on the 6 Minute Walk Test file.

March 2015 Revisions

- Start-Up Resource Listing was revised for FSHD.
- Repaired problem in FSHD roster preventing roster report from populating.

February 2015 Revisions

Overview

Version 1.0 of the FSHD CDEs was released. The recommendations were posted for public comment in November 2014 and version 1.0 was released at the end of February 2015.

- FSHD moved from “CDEs under Review” tab on the main landing page to the “CDEs Now Available” tab on the main landing page.
- New standardized disease-specific text explaining the mission of the NINDS CDE project and the CDE development process added to FSHD landing page.
- Eighty-eight CRFS and 113 NOCs were posted to FSHD.

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 FSHD

**Demographics Subdomain**

• General Core

• Demographics

**Social Status Subdomain**

• Social Status

**General Health History Subdomain**

• Family History

**Imaging Diagnostics Subdomain**

• Dual X-Ray Absorptiometry (DXA)

• Magnetic Resonance Imaging (MRI)

• MRI Quantitative Measurements Guidelines

**Laboratory Tests and Biospecimens/Biomarkers Subdomain**

• Laboratory Tests and Tracking

• Laboratory Tests Recommendations Table and Guidelines for Use

• Mutation Analysis

**Non-Imaging Diagnostics Subdomain**

• Electrocardiogram (ECG)

**Physical/Neurological Examination Subdomain**

• Electrical Impedance Myography (EIM)

**Drugs Subdomain**
Prior and Concomitant Medications

**Therapies Subdomain**

- Respiratory Interventions

**Functional Status Subdomain**

- 2 Minute Walk Test
- 6 Minute Walk Test
- Goniometry
- 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)
- Pinch Strength

**Pain**

- Brief Pain Inventory (Short Form)
- McGill Pain Questionnaire
- Pain Assessment in FSHD Guidelines for Use

**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.

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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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</table>
January 2015 Revisions

- Revised Acknowledgement FSHD page.

November 2014 Revisions

- A banner announcing the Public Review period for FSHD was added to the website and is visible on every page.
- Disease-Specific language explaining the public review period and contents of the public review package was added to the FSHD disease page.
- FSHD was moved from the CDES in Development tab to the CDEs Under Review Tab on the NINDS Common Data Elements website homepage.
- FSHD page was linked to the NMD homepage.

September 2014 Revisions

- Updated Overview pages for diseases in development to include an updated timeline of development for FSHD.

August 2014 Revisions

- Committee membership for FSHD now displayed on History & Acknowledgement tab for FSHD
- Landing page for FSHD updated to read: “Please contact the NINDS CDE Project Officer, Joanne Odenkirchen or NINDSCDE@emmes.com for further information.”
- Links to NeuroQOL, The NIH Toolbox, and PROMIS added to FSHD webpage.