

## Amyotrophic Lateral Sclerosis CDE Revision History

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# Amyotrophic Lateral Sclerosis CDE Revision History

## 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.

## October 2019 Revisions

- The Tardieu Scale classification was revised from Core to Supplemental.
- The ALS Highlight Summary was updated to classify the Tardieu Scale as Supplemental in the Outcomes and End Points; Upper Motor Neuron Signs / Neuromuscular Excitability Disease; domain.
- The ALS Highlight Summary was updated to reflect the classification change to the ALS cognitive/behavioral screening tools: [Abrahams Written Verbal Fluency](#), [ALS Cognitive Behavioral Screen \(ALS-CBS\)](#), [Edinburgh Cognitive and Behavioral ALS Screen](#) from Core to Supplemental – Highly Recommended.

## August 2019 Revisions

- The following ALS cognitive/behavioral screening tools were changed from Core to Supplemental – Highly recommended: [Abrahams Written Verbal Fluency](#), [ALS Cognitive Behavioral Screen \(ALS-CBS\)](#), [Edinburgh Cognitive and Behavioral ALS Screen](#).

## May 2019 Revisions

- The ALS Grip Strength Fatigue CRF instructions were updated to indicate all items on the forms should be classified as Supplemental
- The ALS Highlight Summary was updated to classify the ALS Grip Strength Fatigue as Supplemental in the Outcomes and End Points; Muscle Strength Testing domain

## July 2017 Revisions

- ALS Cognitive Behavioral Screen (ALS-CBS) classification was upgraded from Supplemental to Core; the NOC was updated
- Penn State Screen of Frontal and Temporal Dysfunction Syndromes (PSS-FTDS) classification was downgraded from Core to Supplemental; the NOC was updated
- UCSF Screening Exam, Edinburgh Cognitive and Behavioural ALS Screen (ECAS) and Abrahams Written Verbal Fluency Test NOCs were updated

## **Amyotrophic Lateral Sclerosis CDE Revision History**

- The NOCs Amyotrophic Lateral Sclerosis-Frontotemporal Dementia-Questionnaire (ALS-FTD-Q) and Motor Neuron Disease Behavioural Instrument (MiND-B) were added to the ALS Cognitive CDE recommendations
- The Summary Statement for the ALS Cognitive-Frontotemporal Dementia (FTD) SubGroup was revised based on the ALS Cognitive classification recommendations
- The ALS Start-Up Summary and ALS Highlight were revised based on the ALS Cognitive classification recommendations

### **April 2015 Revisions**

- Reference section on the Schwab and England Daily Activities Scale file was updated.
- Inserted additional reference on the 6 Minute Walk Test file

### **November 2014 Revisions**

- All NOCs on website were tested to ensure that their links worked properly.
- Changes were made to the Edmonton Symptom Assessment System and Quality of Life in Neurological Disorders NOCs.
- Spelling correction to the ALS History of Acknowledgments Text was made.

### **September 2014 Revisions**

- Corrections made to footnotes in Quality of Life in Neurological Disorders and 6 Minute Walk Test to include ALS.
- Links to NeuroQOL, NIH Toolbox, and PROMIS added to ALS website page.
- Core suicidal ideation instrument with link added to Highlight document.

### **August 2014 Revisions**

- 508-compliant versions of various CRFs, NOCs, Guidelines, Startup and Highlights documents, and other downloadable files posted for ALS.

### **July 2014 Revisions**

- Upload of various CRFs and NOCs.
- Upload 508-compliant versions of numerous CRFs, NOCs, and Recommendation spreadsheets.

## **Amyotrophic Lateral Sclerosis CDE Revision History**

- Addition of “NIH Resources” domain listing the NIH Toolbox, PROMIS, and Neuro-QOL as first Domain on Data Standards tab.

### **June 2014 Revisions**

- The Classification changes of 102 CDEs in ALS from Core to Supplemental.
- The Frontal Behavioral Inventory, Penn State Screen of Frontal Temporal Dysfunction Syndromes, and UCSF Screen Battery changed from Core to Supplemental.

### **May 2014 Revisions**

- ALS Start-up Resource and Highlight document was converted to 508-compliant PDF.

### **April 2014 Revisions**

- The following NOCs were updated:
  - 6 Minute Walk Test
  - ALS Cognitive Behavioral Screen
  - ALS Depression Inventory (ADI-12)
  - ALS Functional Rating Scale - Revised (ALSFRS-R)
  - ALS Swallowing Severity Scale (ALSSS)
  - Amyotrophic Lateral Sclerosis Assessment Questionnaire (ALS-AQ40)
  - Barthel Index
  - Baseline Dyspnea Index (BDI)
  - Borg Dyspnea Scale Beck Depression Inventory II (BDI-II)
  - Cambridge Behavioral Inventory - Revised
  - Center for Neurologic Study - Bulbar Function Scale (CNS-BFS)
  - Center for Neurologic Study - Lability Scale for pseudobulbar affect (PBA)
  - Checklist for Individual Strength - Fatigue (CIS)
  - Dynamic Gait Index (DGI)
  - Edinburgh Cognitive Behavioural ALS Screen (ECAS)
  - Edmonton Symptom Assessment System (ESAS)

## **Amyotrophic Lateral Sclerosis CDE Revision History**

- Emotional Lability Questionnaire: Person with MND (ELQ-MND)
- Emotional Lability Questionnaire: Relatives and Carers (ELQ-R and C)
- Epworth Sleepiness Scale (ESS)
- EuroQoL-5 Dimension Questionnaire
- EuroQoL-VAS
- Fatigue Severity Scale (FSS) of Sleep Disorders
- Fixed Dynamometry

### **January 2014 Revisions**

- Posting of revised 508 compliant Start-Up and Highlight summary
- Changes to correct non-functioning links in: Quality of Life in Neurological Disorders NOC.

### **December 2013 Revisions**

- Updated highlight summary and start-up resource document for ALS.

### **November 2013 Revisions**

- ALS Highlight documentation and ALS NOCs loaded to the website.

### **September 2013 Revisions**

#### **Overview**

There have been changes to the content and structure of the Amyotrophic Lateral Sclerosis (ALS) CDE materials in Version 1.1 compared to Version 1.2, including the following:

#### **Form Status Changes**

A Start-up Resource Listing was created to provide investigators with a set of CORE data elements to use when beginning a study.

#### **New Forms:**

- 6 Minute Walk Test
- Barthel Index
- Center for Neurologic Study-Liability Scale (CNS-LS)
- Dynamic Gait Index

## **Amyotrophic Lateral Sclerosis CDE Revision History**

- Epworth Sleeping Scale
- EuroQol-5 Dimension Questionnaire (EuroQol-5D)
- Sensory Organization Test (SOT)
- Timed-Up-and-Go (TUG)
- Baseline Dyspnea Index
- Borg Dyspnea Scale
- Transition Dyspnea Index
- Amyotrophic Lateral Sclerosis Assessment Questionnaire (ALS-AQ40)
- EuroQoL-VAS
- Quality of Life in Neurological Disorders (Neuro-Qol)
- Schedule for the Evaluation of Individual Quality of Life - Direct Weighting (SEIQoL-DW)
- Sickness Impact Profile (SIP)
- Clinical Global Impression (CGI)

### **Updated Forms:**

Notice of Copyright Created (NOC) (Will replace previously existing forms)

- ALS Cognitive Behavioral Screen
- ALS Depression Inventory (ADI-12)
- Beck Depression Inventory-II (BDI-II)
- Cambridge Behavioral Inventory-Revised (CBI-R)
- Center for Neurologic Study - Lability Scale for Pseudobulbar affect (PBA)
- Emotional Lability Questionnaire: Person with MND (ELQ-MND)
- Emotional Lability Questionnaire: Relatives and Carers (ELQ-R and C)
- Frontal Behavior Inventory (FBI)
- Frontal Behavior Inventory-ALS Version (FBI-ALS)
- Frontal Behavioral Inventory - Modified by Heidler Gary (FBI-MOD)

## **Amyotrophic Lateral Sclerosis CDE Revision History**

- Frontal Systems Behavior Scale (FrSbE)
- Geriatric Depression Scale (GDS)
- Hamilton Depression Rating Scale (HDRS)
- Hospital Anxiety and Depression Scale (HADS)
- Neuropsychiatric Inventory - Clinician Version
- Neuropsychiatric Inventory Questionnaire (NPI-Q)
- Penn State Screen of Frontal and Temporal Dysfunction Syndromes (PSS-FTDS)
- Timed 25-Foot Walk (T25FW)
- USCF Screening Exam
- Written Verbal Fluency
- ALS Functional Rating Scale - Revised (ALSFRS-R)
- ALS Severity Score - Hillel et al (ALSSS)
- Center for Neurologic Study - Bulbar Function Scale (CNS-BFS)
- Checklist for Individual Strength - Fatigue (CIS)
- Edmonton Symptom Assessment System (ESAS)
- Fatigue Severity Scale (FSS)
- Madrid Quantitative Neuromuscular Assessment (MAQUINA)
- Modified Fatigue Impact Scale (MFIS)
- Performance-Oriented Mobility Assessment Balance (POMA-B)
- Schwab and England Activities of Daily Living Scale (ADL-Scale)
- Fixed Dynamometry
- Grip Strength
- Grip Strength Fatigue
- Hand Held Dynamometry
- Manual Muscle Testing(MMT)/ Muscle Research Council Scale for Muscle Strength (MRC)

## **Amyotrophic Lateral Sclerosis CDE Revision History**

- 36-Item Short Form Health Survey (SF-36)
- McGill Quality of Life Questionnaire (MQOL)
- Quality of Life in Swallowing Disorders (SWAL-QOL) (SWAL-CARE)
- Caregiver Burden Scale (CGBS)
- Zarit Caregiver Burden Scale
- Modified Ashworth Scale for Grading Spasticity
- Tardieu Scale

### **Removed Forms:**

- None

### **Detailed Form Revisions:**

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



## Amyotrophic Lateral Sclerosis CDE Revision History

**1 ALS Revision History Table**

<b>CRF Module/ Guideline</b>	<b>Current Version</b>	<b>Previous Version</b>	<b>Change Classification</b>	<b>Change Type</b>	<b>Description of Change</b>
6 Minute Walk Test	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Barthel Index	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Center for Neurologic Study- Liability Scale (CNS-LS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Dynamic Gait Index	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

## Amyotrophic Lateral Sclerosis CDE Revision History

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Epworth Sleeping Scale	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
EuroQol-5 Dimension Questionnaire (EuroQol-5D)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Sensory Organization Test (SOT)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Timed-Up-and- Go (TUG)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Baseline Dyspnea Index	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

### Amyotrophic Lateral Sclerosis CDE Revision History

<b>CRF Module/ Guideline</b>	<b>Current Version</b>	<b>Previous Version</b>	<b>Change Classification</b>	<b>Change Type</b>	<b>Description of Change</b>
Borg Dyspnea Scale	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Transition Dyspnea Index	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Amyotrophic Lateral Sclerosis Assessment Questionnaire (ALS-AQ40)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
EuroQoL-VAS	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Quality of Life in Neurological Disorders (Neuro-QoL)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

## Amyotrophic Lateral Sclerosis CDE Revision History

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Schedule for the Evaluation of Individual Quality of Life - Direct Weighting (SEIQoL-DW)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Sickness Impact Profile (SIP)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Clinical Global Impression (CGI)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
ALS Cognitive Behavioral Screen	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
ALS Depression Inventory (ADI-12)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

## Amyotrophic Lateral Sclerosis CDE Revision History

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Beck Depression Inventory-II (BDI- II)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Cambridge Behavioral Inventory- Revised (CBI-R)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Center for Neurologic Study - Lability Scale for Pseudobulbar affect (PBA)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Emotional Lability Questionnaire: Person with MND (ELQ-MND)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Emotional Lability Questionnaire: Relatives and Carers (ELQ-R and C)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

## Amyotrophic Lateral Sclerosis CDE Revision History

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Frontal Behavior Inventory (FBI)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Frontal Behavior Inventory-ALS Version (FBI-ALS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Frontal Behavioral Inventory - Modified by Heidler Gary (FBI- MOD)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Frontal Systems Behavior Scale (FrSbE)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Geriatric Depression Scale (GDS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

## Amyotrophic Lateral Sclerosis CDE Revision History

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Hamilton Depression Rating Scale (HDRS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Hospital Anxiety and Depression Scale (HADS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Neuropsychiatric Inventory - Clinician Version	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Neuropsychiatric Inventory Questionnaire (NPI-Q)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Penn State Screen of Frontal and Temporal Dysfunction Syndromes (PSS- FTDS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

## Amyotrophic Lateral Sclerosis CDE Revision History

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Timed 25-Foot Walk (T25FW)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
USCF Screening Exam	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Written Verbal Fluency	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
ALS Functional Rating Scale - Revised (ALSFRS- R)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
ALS Severity Score - Hillel et al (ALSS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form



## Amyotrophic Lateral Sclerosis CDE Revision History

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Center for Neurologic Study - Bulbar Function Scale (CNS-BFS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Checklist for Individual Strength - Fatigue (CIS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Edmonton Symptom Assessment System (ESAS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Fatigue Severity Scale (FSS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Madrid Quantitative Neuromuscular Assessment (MAQUINA)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

## Amyotrophic Lateral Sclerosis CDE Revision History

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Modified Fatigue Impact Scale (MFIS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Performance- Oriented Mobility Assessment Balance (POMA- B)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Schwab and England Activities of Daily Living Scale (ADL-Scale)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Fixed Dynamometry	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Grip Strength	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

## Amyotrophic Lateral Sclerosis CDE Revision History

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Grip Strength Fatigue	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Hand Held Dynamometry	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Manual Muscle Testing(MMT)/ Muscle Research Council Scale for Muscle Strength (MRC)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
36-Item Short Form Health Survey (SF-36)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
McGill Quality of Life Questionnaire (MQOL)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

## Amyotrophic Lateral Sclerosis CDE Revision History

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Quality of Life in Swallowing Disorders (SWAL-QOL) (SWAL-CARE)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Caregiver Burden Scale (CGBS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Zarit Caregiver Burden Scale	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Modified Ashworth Scale for Grading Spasticity	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Tardieu Scale	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

# Amyotrophic Lateral Sclerosis CDE Revision History

## August 2012 Revisions

### Overview

There have been changes to the content and structure of the Amyotrophic Lateral Sclerosis (ALS) CDE materials in Version 1.1 compared to Version 1.0, including the following:

- Every attempt was made to remove duplication and redundancy in the ALS CDEs;
- The ALS CDEs were harmonized with other large national and international standardization initiatives and efforts [e.g., International Conference on Harmonization (ICH), Logical Observation Identifiers Names and Codes (LOINC), International Classification of Diseases (ICD), Unified Code for Units of Measure (UCUM)]
- The majority of element names and definitions were improved.
- The permissible values and references of some elements were revised; and
- The version numbers of all forms (excluding standardized scales/instruments) were updated.
- Several guideline documents were reorganized and consolidated to make it easier to understand which standardized instruments/scales are recommended, though the recommendations themselves remained unchanged.
- Some of the forms and guideline documents were re-categorized under a different domain or subdomain to be consistent with other NINDS CDEs.
- The corresponding data dictionaries (i.e., CDE Detailed Report) have been modified in accordance with the form changes.

### Form Status Changes

#### New Forms:

- None

#### Modified Forms:

- Biomarkers Other Collection Information Guidelines
- Collection of Fluid - Blood Guidelines
- Collection of Fluid - CSF Guidelines
- Collection of Fluid - Plasma Guidelines
- Collection of Fluid - Urine Guidelines

## Amyotrophic Lateral Sclerosis CDE Revision History

- Demographics
- Family History
- Laboratory Tests
- Magnetic Resonance Imaging (MRI)
- Medical History
- Physical Examination
- Prior and Concomitant Medications
- Social Status
- Tissue Based Marker Collection

**Removed Forms:**

- Clinical Laboratory Counts

**Detailed Form Revisions:**

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

**2 ALS Revision History Table**

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
All	1.1	1.0	Minor	Modified CDEs	Nearly all CDE names and definitions were updated to achieve greater consistency across all NINDS CDEs and for clarity
Various	1.1	1.0	Minor	Deleted CDEs	The following types of CDEs were deleted: CDEs redundant with other CDEs; CDEs specifying unit; and CDEs specifying an "other, specify" response
Various	1.1	1.0	Minor	Modified CDEs	For a number of CDEs, "Unknown" was added to the permissible value set and in some cases "Unknown" replaced "Unknown/Don't Know"
Various	1.1	1.0	Minor	Modified Forms	For forms with Core items, the Core CDE(s) were identified with an asterisk and the following was added as a footnote: *Element is classified as Core.

## Amyotrophic Lateral Sclerosis CDE Revision History

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Various	1.1	1.0	Minor	Modified Forms	Instructions were updated to include additional details.
Biomarker Other Collection Information Guidelines	N/A	1.0	Major	Modified Form	This document is no longer associated with CDE(s) and serves as a guideline and not a CRF. The name of the document was changed from "Biomarker Other Collection Information" to "Biomarker Other Collection Information Guidelines".
Collection of Fluid - Blood Guidelines	N/A	1.0	Major	Modified Form	This document is no longer associated with CDE(s) and serves as a guideline and not a CRF. The name of the document was changed from "Collection of Fluid - Blood" to "Collection of Fluid - Blood Guidelines".
Collection of Fluid - CSF Guidelines	N/A	1.0	Major	Modified Form	This document is no longer associated with CDE(s) and serves as a guideline and not a CRF. The name of the document was changed from "Collection of Fluid - CSF" to "Collection of Fluid - CSF Guidelines".
Collection of Fluid - Plasma Guidelines	N/A	1.0	Major	Modified Form	This document is no longer associated with CDE(s) and serves as a guideline and not a CRF. The name of the document was changed from "Collection of Fluid - Plasma" to "Collection of Fluid - Plasma Guidelines".
Collection of Fluid - Urine Guidelines	N/A	1.0	Major	Modified Form	This document is no longer associated with CDE(s) and serves as a guideline and not a CRF. The name of the document was changed from "Collection of Fluid - Urine" to "Collection of Fluid - Urine Guidelines".
Demographics	1.1	1.0	Minor	Modified CDEs	The definition and/ or permissible values were updated for the following CDE(s): "Gender type"; "Ethnicity USA Category".
Demographics	1.1	1.0	Minor	Modified Form	The instructions for the "Gender type" CDE were updated.
Family History	1.1	1.0	Minor	Modified Form	The form title was changed from "Family History at Baseline" to "Family History".

## Amyotrophic Lateral Sclerosis CDE Revision History

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Family History	1.1	1.0	Minor	Modified CDEs	The permissible values were modified for the "Family history medical condition relative type"
Laboratory Tests	1.1	1.0	Minor	Modified CDEs	The permissible values for the following CDE(s) were modified: "Lab test result status"; "Lab test abnormality significance type"; "Pregnancy test performed indicator"; "Pregnancy test specimen type"; "Pregnancy test not applicable reason"
Magnetic Resonance Imaging	1.1	1.0	Minor	Modified CDEs	The permissible values for the following CDE(s) were modified: "Imaging anatomic site"; "Imaging phase partial Fourier indicator"; "Imaging visual analysis location performed type"
Magnetic Resonance Imaging	1.1	1.0	Minor	Modified Form	The form title was changed from "Diagnostic Magnetic Resonance Imaging" to "Magnetic Resonance Imaging".
Medical History	1.1	1.0	Minor	Deleted CDEs	CDEs were removed from the following sections as they were redundant with other CDEs on the form: "Additional Pediatric Specific Elements"; "Allergies"; "Childbearing Questions"
Medical History	1.1	1.0	Minor	Added CDEs	The following CDE was added: "Body system category"
Physical Exam	1.1	1.0	Minor	Added CDEs	The following CDE(s) were added: "Hand preference type" (previously on Social Status CRF); "Physical exam date and time"
Physical Exam	1.1	1.0	Minor	Modified CDEs	The permissible values were modified for the "Body system category" CDE
Physical Exam	1.1	1.0	Minor	Modified Form	Instructions were added for the following CDE(s): "Physical exam date and time"; "Physical exam performed indicator"; "Body system category"; "Physical exam body system result"; "Physical exam description text"; "Hand preference type"



## Amyotrophic Lateral Sclerosis CDE Revision History

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Prior and Concomitant Medications	1.1	1.0	Minor	Added CDEs	The following CDE(s) were added: "Medication prior or concomitant use indicator"; "Medication prior or concomitant ongoing indicator"
Prior and Concomitant Medications	1.1	1.0	Minor	Modified Form	Instructions were added or updated for the following CDE(s): "Medication prior or concomitant use indicator"; "Medication prior or concomitant name"; "Medication prior or concomitant indication text"; "Medication prior or concomitant dose"; "Medication prior or concomitant dose unit of measure"; "Medication prior or concomitant dose frequency"; "Medication prior or concomitant route type"; "Medication prior or concomitant start date and time"; "Medication prior or concomitant ongoing indicator"; "Medication prior or concomitant end date and time"
Prior and Concomitant Medications	1.1	1.0	Minor	Modified Form	The following reference tables were removed: Frequency; Unit; Route (Route options are now included as a footnote)
Social Status	1.1	1.0	Minor	Modified CDEs	The permissible values were updated for the following CDE(s): "Education years completed value"; "Education level USA type"
Social Status	1.1	1.0	Minor	Deleted CDEs	The following CDE was removed: "Hand preference type" (moved to Physical Exam CRF)
Social Status	1.1	1.0	Minor	Modified Form	Instructions were updated.
Tissue Based Marker	1.1	1.0	Minor	Modified Form	The form title was changed from "Sample Collection Information for Tissue Based Markers" to "Tissue Based Marker Collection".