

Stroke 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.

December 2018 Revisions

- F1161 Glasgow Coma Scale:
 - Scoring information section text was corrected to state that lower, not higher, scores indicate patients in comatose.

August 2018 Revisions

- F1151 Social Status:
 - Classification revised to Supplemental – Highly Recommended for:
 - C00015 Education year count
 - CRF revised
- F1171 Perfusion and Penumbral Imaging:
 - Classification revised to Supplemental – Highly Recommended for:
 - C13750 Imaging study ID number
 - C02494 Imaging study date and time
 - C13245 National Institutes of Health Stroke Scale (NIHSS) - Severity total score added to form
- F1176 Vessel Imaging Transcranial Doppler (TCD):
 - Classification revised to Supplemental- Highly Recommended for:
 - C13750 Imaging study ID number
 - C02494 Imaging study date and time
 - C13942 Imaging vessel category
 - C02411 Laterality type
 - C14056 Imaging depth measurement
 - C13947 Imaging peak velocity measurement
 - C13948 Imaging mean blood velocity measurement
 - C14007 Imaging Transcranial Doppler (TCD) findings result type
 - C13949 Imaging flow/probe direction type
 - CRF revised

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July 2018 Revisions

- F1154 Behavioral History CRF was revised. Question 7 text was corrected to query six or more drinks instead of five or more drinks.

April 2017 Revisions

- The Unruptured Cerebral Aneurysms and Subarachnoid Hemorrhage (SAH) CDEs were posted to the NINDS website under their own [landing page](https://www.commondataelements.ninds.nih.gov/SAH.aspx#tab=Data_Standards):
https://www.commondataelements.ninds.nih.gov/SAH.aspx#tab=Data_Standards.

October 2016 Revisions

- CRFs updated:
 - Pregnancy and Perinatal History: formatting updates
 - Hospital Discharge: formatting; ICD-9 codes updated to ICD-10
 - Surgical and Procedural Interventions: formatting; ICD-9 codes updated to ICD-10; ISO 8601 link added

February 2016 Revisions

- Revised Start-Up Resources to reflect C00015 Education year count CDE is now Supplemental – Highly Recommended

May 2015 Revisions

- Revised Start-Up Resources based on revised Core classification.

April 2015 Revisions

No changes.

March 2015 Revisions

No changes.

February 2015 Revisions

No changes.

January 2015 Revisions

- Posting of revised 508 compliant Start-Up and Highlight Summaries.
- The CDEs in use page was updated with new studies in Stroke.

November 2014 Revisions

No changes.

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September 2014 Revisions

No changes.

August 2014 Revisions

No changes.

July 2014 Revisions

- Upload of various CRFs and NOCs Stroke with editorial corrections.

June 2014 Revisions

No changes.

May 2014 Revisions

No changes.

April 2014 Revisions

No changes.

March 2014 Revisions

No changes.

February 2014 Revisions

No changes.

January 2014 Revisions

No changes.

December 2013 Revisions

- Updated highlight summaries and start-up resource documents for Stroke

November 2013 Revisions

No changes.

August 2013 Revisions

Overview

There have been Minor changes to the content and structure of the Stroke CDE materials in Version 2.0 compared to Version 1.3, including the following:

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Form Status Changes

New Forms:

- None

Updated Forms:

- Summary of NINDS Recommended Measures for Neurological Impairment
- Summary of NINDS Recommended Measures for Activities of Daily Living
- Summary of NINDS Recommended Measures for Emotional and Cognitive Status
- Summary of NINDS Recommended Measures for Participation/Quality of Life
- Summary of NINDS Recommended Measures for Performance
- Summary of NINDS Recommended Measures for Pediatrics
- Summary of NINDS Recommended Measures for Clinical Event End Points

Removed Forms:

- None

Detailed Form Revisions:

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

1 Stroke Revision History Document Table

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Summary of NINDS Recommended Measures for Neurological Impairment	2.0	1.3	Major	Notice of Copyright	All Redundant Information was removed and the title was changed for easier understanding of the document
Summary of NINDS Recommended Measures for Activities of Daily Living	2.0	1.3	Major	Notice of Copyright	All Redundant Information was removed and the title was changed for easier understanding of the document

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Summary of NINDS Recommended Measures for Emotional and Cognitive Status	2.0	1.3	Major	Notice of Copyright	All Redundant Information was removed and the title was changed for easier understanding of the document
Summary of NINDS Recommended Measures for Participation/Quality of Life	2.0	1.3	Major	Notice of Copyright	All Redundant Information was removed and the title was changed for easier understanding of the document
Summary of NINDS Recommended Measures for Performance	2.0	1.3	Major	Notice of Copyright	All Redundant Information was removed and the title was changed for easier understanding of the document
Summary of NINDS Recommended Measures for Pediatrics	2.0	1.3	Major	Notice of Copyright	All Redundant Information was removed and the title was changed for easier understanding of the document
Summary of NINDS Recommended Measures for Clinical Event End Points	2.0	1.3	Major	Notice of Copyright	All Redundant Information was removed and the title was changed for easier understanding of the document

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May 2013 Revisions

Overview

There have been Major changes to the content and structure of the Stroke CDE materials in Version 1.2 compared to Version 1.1, including the following:

Form Status Changes

New Forms:

- Barthel Index
- The National Institute of Health Toolbox (NIH Toolbox)
- Patient-Reported Outcomes Measurement Information System (PROMIS)
- Post-Acute Continuity Assessment Record and Evaluation (PAC Admission CARE)
- Quality of Life in Neurological Disorders (Neuro-QoI)
- Boston Naming Test (BNT)
- Delis Kaplan Executive Functioning System- Trail Making Test Parts A&B subtest (DKEFS)
- Hopkins Verbal Learning Test Revised (HVLTR)
- Montreal Cognitive Assessment (MOCA)
- Neuropsychiatric Inventory Questionnaire (NPI)
- Rey Osterrieth Complex Figure and Delay
- Stroop Test
- Telephone Interview for Cognitive Status (TICS)
- Wechsler Adult Intelligence Scale III-Digit Symbol and Symbol Search Subtests
- Woodcock-Johnson III Test of Cognitive Abilities
- Canadian Occupation Performance Measure (COPM)
- EuroQol 5-Dimension Questionnaire (EQ-5D)
- Stroke Impact Scale (SIS)
- Bayley Scales of Infant Development (Bayley III, BSID)
- Perceived Efficacy and Goal Setting System (PEGS)

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Updated Forms:

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

- The National Institute of Health Stroke Scale (NIHSS)
- Glasgow Outcome Scale (GOS) and Glasgow Outcome Scale-Extended (GOSE)
- Modified Rankin Scale (mRs)
- Center for Epidemiologic Studies Depression Scale (CES-D)
- Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE)
- 36-Item Short Form Survey (SF-36)
- Stroke Specific Quality of Life (SS-QOL)
- Walking Speed (Subtest of NIH Toolbox)
- Kings Outcome Scale for Childhood Head Injury (KOSCHI)
- Pediatric Stroke Outcome Measure Short Neuro Exam (PSOM-SNE) Child Version
- Pediatric Stroke Outcome Measure Short Neuro Exam (PSOM-SNE) Infant Version
- Atherosclerosis Risk in Communities Study (ARIC) TIA/Stroke Form
- Questionnaire for Verifying Stroke-Free Status (QVSFS)
- Stroke Adjudication Worksheet

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
Barthel Index	1.2	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
The National Institute of Health Toolbox (NIH Toolbox)	1.2	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Patient- Reported Outcomes Measurement Information System (PROMIS)	1.2	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Post-Acute Continuity Assessment Record and Evaluation (PAC Admission CARE)	1.2	1.1	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)	1.2	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Boston Naming Test (BNT)	1.2	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Delis Kaplan Executive Functioning System- Trail Making Test Parts A&B subtest (DKEFS)	1.2	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Hopkins Verbal Learning Test Revised (HVLTR)	1.2	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Montreal Cognitive Assessment (MOCA)	1.2	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Neuropsychiatric Inventory Questionnaire (NPI)	1.2	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Rey Osterrieth Complex Figure and Delay	1.2	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Stroop Test	1.2	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Telephone Interview for Cognitive Status (TICS)	1.2	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Wechsler Adult Intelligence Scale III-Digit Symbol and Symbol Search Subtests	1.2	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Woodcock- Johnson III Test of Cognitive Abilities	1.2	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Canadian Occupation Performance Measure (COPM)	1.2	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
EuroQol 5-Dimension Questionnaire (EQ-5D)	1.2	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Stroke Impact Scale (SIS)	1.2	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Bayley Scales of Infant Development (Bayley III, BSID)	1.2	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Perceived Efficacy and Goal Setting System (PEGS)	1.2	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
The National Institute of Health Stroke Scale (NIHSS)	1.2	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Glasgow Outcome Scale (GOS) and Glasgow Outcome Scale-Extended (GOSE)	1.2	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Modified Rankin Scale (mRs)	1.2	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Center for Epidemiologic Studies Depression Scale (CES-D)	1.2	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE)	1.2	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
36-Item Short Form Survey (SF- 36)	1.2	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Stroke Specific Quality of Life (SS-QOL)	1.2	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Walking Speed (Subtest of NIH Toolbox)	1.2	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Kings Outcome Scale for Childhood Head Injury (KOSCHI)	1.2	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Pediatric Stroke Outcome Measure Short Neuro Exam (PSOM-SNE) Child Version	1.2	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Pediatric Stroke Outcome Measure Short Neuro Exam (PSOM-SNE) Infant Version	1.2	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Atherosclerosis Risk in Communities Study (ARIC) TIA/Stroke Form	1.2	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Questionnaire for Verifying Stroke-Free Status (QVSFS)	1.2	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Stroke Adjudication Worksheet	1.2	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

October 2012 Revisions

Overview

There have been changes to the content and structure of the Stroke 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 Stroke CDEs;

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- The Stroke 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:

History Data Source and Reliability (items/questions originally on the Medical History form)

Updated Forms:

- Antithrombotics and Risk Factor Controlling Medications
- Behavioral History
- Biospecimen Collection and Processing
- Demographics
- Electrocardiogram
- Family History
- Hospital Arrival/Admission
- Hospital Discharge
- Lifestyle Modification Therapies
- Medical History
- Palliative, Comfort Care, and End of Life Issues
- Physical/Neurological Examination

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- Pregnancy and Perinatal History
- Pre-Hospital/Emergency Medical Services (EMS) Course
- Prior and Concomitant Medications
- Prior Functional Status
- Rehabilitation Therapies
- Social Status
- Stroke Symptoms, Comorbid Events
- Surgical and Procedural Interventions
- Thrombolytic/Reperfusion Therapies
- Vital Signs

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
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

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
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	Instructions were updated to include additional details.
Various	1.1	1.0	Minor	Modified Forms	Reworded footnote identifying certain CDEs as Core.
Antithrombotics and Risk Factor Controlling Medications	1.1	1.0	Minor	Modified Forms	Added note referring to General Prior and Concomitant Medications form.
Behavioral History	1.1	1.0	Minor	Added CDEs	Added Tobacco product used type and Tobacco cigarettes smoked daily average number
Behavioral History	1.1	1.0	Minor	Deleted CDEs	Deleted CDEs for Current Average Packs Smoked per day and Use of Cigars, Pipe, or Chewing Tobacco
Behavioral History	1.1	1.0	Minor	Modified CDEs	Modified Drug or substance illicitly used category permissible values
Behavioral History	1.1	1.0	Minor	Modified Forms	Reworded several questions to be consistent with other disease areas and modified skip logic.
Biospecimen Collection and Processing	1.1	1.0	Minor	Modified Forms	Removed footnote identifying certain CDEs as Core.
Biospecimen Collection and Processing	1.1	1.0	Minor	Modified Forms	Modified location of Lab specimen collection date and time on form.
Biospecimen Collection and Processing	1.1	1.0	Minor	Modified Forms	Changed a number of questions that were CDEs previously to specifications to be documented

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Demographics	1.1	1.0	Minor	Modified Forms	Relabeled Sex to Gender on form and reworded footnote.
Demographics	1.1	1.0	Minor	Modified Forms	Removed Hand Preference Type from form and moved to Physical Exam form.
Demographics	1.1	1.0	Minor	New CDEs	Added Language spoken fluently text, Language spoken fluently ISO 639-2 code, Country of residence name, and Country of residence ISO 3166-1 alpha-2 code
Electrocardiogram	1.1	1.0	Minor	Added CDEs	Added ECG heart rate and ECG global result
Electrocardiogram	1.1	1.0	Minor	Deleted CDEs	Removed Atrial arrhythmia and Ventricular arrhythmia from form.
Electrocardiogram	1.1	1.0	Minor	Modified CDEs	Modified ECG heart rhythm result permissible values
Electrocardiogram	1.1	1.0	Minor	Modified Forms	Reworded footnote and units for ECG PR interval, ECG QRS duration, ECG QT interval, and ECG QTc interval
Family History	1.1	1.0	Minor	Modified CDEs	Modified Family history medical condition type permissible values
History Data Source and Reliability	1.1	1.0	Minor	New form	New form created using CDEs previously on Medical History form.
Hospital Arrival/Admission	1.1	1.0	Minor	Modified CDEs	Modified Hospital transport type and Hospital location patient first received care type permissible values
Hospital Discharge	1.1	1.0	Minor	Modified CDEs	Revised Diagnosis new indicator and Stroke initial residence or discharge destination type permissible values
Lifestyle Modification Therapies	1.1	1.0	Minor	Modified CDEs	Changed permissible value for "No/ND" to "No" for several CDEs

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Medical History	1.1	1.0	Minor	Added CDEs	Added table to capture medical history items according to body system to ensure consistency with General CDEs.
Medical History	1.1	1.0	Minor	Added CDEs	Added Medical history taken date and time and Medical history global assessment indicator
Medical History	1.1	1.0	Minor	Modified Forms	Removed footnote identifying certain CDEs as Core.
Medical History	1.1	1.0	Minor	Modified Forms	Added additional instructions to form, including notes about the problem/condition that is the study focus and specific medical history queries.
Medical History	1.1	1.0	Minor	Modified Forms	Moved Data Source and Reliability CDEs to separate form.
Palliative, Comfort Care, and End of Life Issues	1.1	1.0	Minor	Modified CDEs	Modified Comfort care indicator permissible values
Physical/Neurological Examination	1.1	1.0	Minor	Added CDEs	Added Hand Preference Type (item originally on Demographics form)
Physical/Neurological Examination	1.1	1.0	Minor	Modified Forms	Removed NIH Stroke Scale, Heart Rate Abnormality Indicator, and Heart Rate Abnormality Type from form.
Pregnancy and Perinatal History	1.1	1.0	Minor	Added CDEs	Added Gravida maternal value, Delivery mode type, Delivery route type, and Delivery modality type
Pregnancy and Perinatal History	1.1	1.0	Minor	Deleted CDEs	Removed Second stage of labor longer, Mother's mode of delivery, Instruments used indicator, required resuscitation indicator, history of umbilical cord abnormalities, other pregnancy/delivery risk factors

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Pregnancy and Perinatal History	1.1	1.0	Minor	Modified Forms	Reworded a number of CDEs on form.
Pregnancy and Perinatal History	1.1	1.0	Minor	Modified Forms	Changed ordering of several CDEs on form.
Pre-Hospital/Emergency Medical Services (EMS) Course	1.1	1.0	Minor	Modified Forms	Made minor edits to formatting of questions on form.
Prior and Concomitant Medications	1.1	1.0	Minor	Deleted CDEs	Removed Date Medication History taken.
Prior and Concomitant Medications	1.1	1.0	Minor	Modified Forms	Modified Prior and Concomitant Medications form to be consistent with General CDEs.
Prior and Concomitant Medications	1.1	1.0	Minor	Modified Forms	Modified form name - previously called Medication History
Prior and Concomitant Medications	1.1	1.0	Minor	Modified Forms	Removed footnote identifying certain CDEs as Core.
Prior Functional Status	1.1	1.0	Minor	Modified Forms	Split CDE querying for presence of ADD/ADHD into separate CDEs for ADD and ADHD.
Prior Functional Status	1.1	1.0	Minor	Modified Forms	Reworded School placement type
Prior Functional Status	1.1	1.0	Minor	Modified Forms	Removed Grade level CDE from form as redundant with data captured on the Social Status form.

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Rehabilitation Therapies	1.1	1.0	Minor	Modified CDEs	Revised Therapy or rehabilitation assessment made indicator, Mobility device use indicator, Mobility device type, Adjunctive treatment indicator, Orthoses or positioning devices indicator, Durable medical equipment indicator, Follow up care from stroke specialist indicator, Follow up care from PCP indicator, and Follow up care from rehab doctor indicator permissible values
Social Status	1.1	1.0	Minor	Modified CDEs	Modified Living with persons relationship type and Family income range permissible values
Social Status	1.1	1.0	Minor	Modified Forms	Removed footnote identifying certain CDEs as Core.
Social Status	1.1	1.0	Minor	New CDEs	Added Education years number
Stroke Symptoms, Comorbid Events	1.1	1.0	Minor	Modified CDEs	Edited Stroke symptom/ comorbid event seizure type permissible values
Surgical and Procedural Interventions	1.1	1.0	Minor	Added CDEs	Added Surgical or Therapeutic Procedure CDEs to be consistent with General CDEs.
Surgical and Procedural Interventions	1.1	1.0	Minor	Modified Forms	Removed footnote identifying certain CDEs as Core; added note that detailed questions can be used as interview questions rather than CDEs; and edited wording of questions on form
Vital Signs	1.1	1.0	Minor	Added CDEs	Added Blood pressure measurement position type, Waist-hip ratio value, and Body mass index value

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Vital Signs	1.1	1.0	Minor	Modified CDEs	Modified Temperature measurement anatomic site permissible values
Vital Signs	1.1	1.0	Minor	Modified Forms	Reworded a number of CDEs on form.