This checklist presents an outline of the case report form (CRF) modules. It can be used to help you and your staff members identify CDEs which appear to berelevant to your clinical trial. Headings followed by a group of modules are denoted with an alphabetic character.If an item or group of items are not relevant to your hypothesis or study design, then you do not need to include them in your study.

**NINDS STROKE CDE CHECKLIST**

| CRF Module | Location(Disease Standards Page Name → Data Standards Domain → Sub-Domain) | Needed? | Comments |
| --- | --- | --- | --- |
| Screening Log[[1]](#footnote-1) | General → Protocol Experience → Participant/Subject Identification, Eligibility, and Enrollment | [ ] Yes [ ] No | Data to be entered by site |
| Inclusion and Exclusion Criteria[[2]](#footnote-2) | General → Protocol Experience → Participant/Subject Identification, Eligibility, and Enrollment | [ ] Yes [ ] No | Data to be entered by site |
| Informed Consent and Enrollment2 | General → Protocol Experience → Participant/Subject Identification, Eligibility, and Enrollment | [ ] Yes [ ] No | Data to be entered by site |
| Visit Schedule1 | General → Protocol Experience → Study Management | [ ] Yes [ ] No | Data to be entered by site |
| 1. Participant/Subject Characteristics
 | N/A | N/A | N/A |
| Demographics | Stroke → Participant/Subject Characteristics → Demographics | [ ] Yes [ ] No | Data to be entered by site |
| Social Status | Stroke → Participant/Subject Characteristics → Social Status | [ ] Yes [ ] No | Data to be entered by site |
| Medical History | Stroke → Participant /Subject History and Family History → General Health History | [ ] Yes [ ] No | Data to be entered by site |
| Family History | Stroke → Participant /Subject History and Family History → General Health History | [ ] Yes [ ] No | Data to be entered by site |
| Medication History | Stroke → Participant /Subject History and Family History → General Health History | [ ] Yes [ ] No | Data to be entered by site |
| Behavioral History | Stroke → Participant /Subject History and Family History → General Health History | [ ] Yes [ ] No | Data to be entered by site |
| Pregnancy and Prenatal History | Stroke → Participant /Subject History and Family History → General Health History | [ ] Yes [ ] No | Data to be entered by site |
| Prior Functional Status | Stroke → Participant /Subject History and Family History → Prior Health Status | [ ] Yes [ ] No | Data to be entered by site |
| 1. Event Onset
 | N/A | [ ] Yes [ ] No | Data to be entered by site |
| Pre-Hospital/ EMS Course | Stroke → Disease/Injury Related Events → History of Disease/Injury Event | [ ] Yes [ ] No | Data to be entered by site |
| Hospital Arrival/ Admission | Stroke → Disease/Injury Related Events → History of Disease/Injury Event | [ ] Yes [ ] No | Data to be entered by site |
| Stroke Symptoms/ Comorbid Events | Stroke → Disease/Injury Related Events → History of Disease/Injury Event | [ ] Yes [ ] No | Data to be entered by site |
| Stroke Type/Subtype | Stroke → Disease/Injury Related Events → Classification | [ ] Yes [ ] No | Data to be entered by site |
| 1. Baseline Assessments
 | N/A | N/A | N/A |
| Physical/ Neurological Exam | Stroke → Assessments and Examinations → Physical/Neurological Examination | [ ] Yes [ ] No | Data to be entered by site |
| NIH Stroke Scale | Stroke → Outcomes and End Points → Neurological Impairment | [ ] Yes [ ] No | Data to be entered by site |
| Vital Signs | Stroke → Assessments and Examinations → Vital Signs and Other Body Measures | [ ] Yes [ ] No | Data to be entered by site |
| ECG | Stroke → Assessments and Examinations → Non-Imaging Diagnostics | [ ] Yes [ ] No | Data to be entered by site |
| C.1 Laboratory Tests and Biospecimens/Biomarkers | N/A | N/A | N/A |
| Laboratory Tests | Stroke → Assessments and Examinations → Laboratory Test and Biospecimens/Biomarkers | [ ] Yes [ ] No | Data to be entered by site |
| Biospecimen Collection and Processing | Stroke → Assessments and Examinations → Laboratory Test and Biospecimens/Biomarkers | [ ] Yes [ ] No | Data to be entered by site |
| Coriell’s Cerebrovascular Data Elements | Stroke→ Assessments and Examinations → Laboratory Tests and Biospecimens/Biomarkers | [ ] Yes [ ] No | Data to be entered by site |
| C.2 Imaging/Non-Imaging Diagnostics | N/A | N/A | N/A |
| Parenchymal Imaging | Stroke → Assessments and Examinations → Imaging Diagnostics | [ ] Yes [ ] No | Data to be entered by site |
| Perfusion and Penumbral Imaging | Stroke → Assessments and Examinations → Imaging Diagnostics | [ ] Yes [ ] No | Data to be entered by site |
| Vessel Imaging Angiography | Stroke → Assessments and Examinations → Imaging Diagnostics | [ ] Yes [ ] No | Data to be entered by site |
| Vessel Carotid Ultrasound | Stroke → Assessments and Examinations → Imaging Diagnostics | [ ] Yes [ ] No | Data to be entered by site |
| Vessel Imaging TCCS | Stroke → Assessments and Examinations → Imaging Diagnostics | [ ] Yes [ ] No | Data to be entered by site |
| Vessel Imaging TCD | Stroke → Assessments and Examinations → Imaging Diagnostics | [ ] Yes [ ] No | Data to be entered by site |
| [Randomization/ Treatment assignment] | Data to be entered by site | Data to be entered by site | Data to be entered by site |
| 1. Treatment Interventions
 | N/A | N/A | N/A |
| Study Drug Dosing2 | General → Treatment/Intervention Data → Drugs | [ ] Yes [ ] No | Data to be entered by site |
| Study Drug Compliance2 | General → Treatment/Intervention Data → Drugs | [ ] Yes [ ] No | Data to be entered by site |
| Concomitant Medications2 | General → Treatment/Intervention Data → Drugs | [ ] Yes [ ] No | Data to be entered by site |
| Rehabilitation Therapies | Stroke → Treatment/Intervention Data → Therapies | [ ] Yes [ ] No | Data to be entered by site |
| 1. Follow-up
 | N/A | N/A | N/A |
| Hospital Discharge | Stroke → Disease/Injury Related Events → Discharge Information | [ ] Yes [ ] No | Data to be entered by site |
| E.1 Adverse Events | N/A | N/A | N/A |
| Adverse Events2 | General → Safety Data → Adverse Events | [ ] Yes [ ] No | Data to be entered by site |
| Serious Adverse Events2 | General → Safety Data → Adverse Events | [ ] Yes [ ] No | Data to be entered by site |
| E.2 Outcomes and End Points | N/A | N/A | N/A |
| NIH Stroke Scale | Stroke → Outcomes and End Points → Neurological Impairment | [ ] Yes [ ] No | Data to be entered by site |
| Barthel Index | Stroke → Outcomes and End Points → Activities of Daily Living/Functional Status | [ ] Yes [ ] No | Data to be entered by site |
| Modified Rankin Scale | Stroke → Outcomes and End Points → Activities of Daily Living/Functional Status | [ ] Yes [ ] No | Data to be entered by site |
| [Choose additional appropriate outcomes/ endpoints] | (See Stroke → Outcomes and End Points → Summary of all Outcome Recommendations) | [ ] Yes [ ] No | Data to be entered by site |
| Study Discontinuation/ Completion2 | General → Protocol Experience → Off Treatment /Off Study | [ ] Yes [ ] No | Data to be entered by site |
| E.3 Other | Data to be entered by site | Data to be entered to site | Data to be entered by site |
| [Repeat appropriate assessments under C.] | Data to be entered by site | Data to be entered to site | Data to be entered by site |
| Protocol Deviations1 | General → Protocol Experience → Protocol Deviations | [ ] Yes [ ] No | Data to be entered by site |

1. Administrative forms relevant to most, if not all clinical trials [↑](#footnote-ref-1)
2. Case Report Forms are part of the General CDEs [↑](#footnote-ref-2)