NINDS CDE Project
Stroke Version 2.0
Medical History & Prior Health Status Subgroup

The Medical History & Prior Health Status subgroup was assigned to review Stroke v1.0 and Unruptured Cerebral Aneurysms and Subarachnoid Hemorrhage (SAH) CRFs/CDEs within their purview by the Working Group Co-Chairs. The subgroup Chair assigned members as primary and secondary reviewers for two CRF topics. Members used spreadsheets that compared the details for the CDEs across Stroke and SAH. Feedback from members was discussed during teleconferences and via email.

In most cases, the classification assigned to the Stroke v2.0 CDEs is the same as for the SAH CDEs. There may be some differences in classifications for risk factors that are more relevant in one than another. We endeavored to limit differences for sake of simplicity, also recognizing that investigators have leeway to choose CDEs that are classified as Supplemental and Exploratory. There were some risk factors for SAH that were thought more relevant to SAH than to Stroke, for example: thoracic aortic aneurysm. Similarly, some were more relevant to Stroke than to SAH, for example some of the childhood causes of stroke, such as facial segmental hemangioma PHACE syndrome, recent chicken pox, and acquired heart disease.

The subgroup addressed differential application of CDEs to adult and pediatric populations in their revisions. Features that were germane to children were reviewed and updated as deemed necessary by the subgroup. These are summarized in the table on page 2.

The subgroup considered other data standards in their updates to the Stroke CDEs. The CDEs include questions used in instruments like the Alcohol Use Disorders Identification Test (AUDIT) and Behavioral Risk Factor Surveillance System Survey Questionnaire (BRFSS). The subgroup also recommended that the NINDS General CDE Steering Committee (SC) update the gender type CDE. The revisions made by the SC are aligned with how this information is collected by other data standards such as LOINC and CDISC.

Issues unique to stroke, unmet needs, and unanswered questions were identified during the Stroke v2.0 CDE development process. Topics and CRFs related to pre-morbid function (and probably outcome after stroke) are particularly relevant for stroke, if not entirely unique to it among other neurological and medical disorders. Unmet needs include standardized question administration, including telephone administration. Additionally, the subgroup thought that it would be valuable to conduct an analysis of how many of the CDEs and which ones are being included in ongoing and planned trials. Similarly, it would be helpful to know how much data is available on these different CDEs at different levels of classification (Core vs Supplemental – Highly Recommended vs Supplemental vs Exploratory). It would be helpful to understand the frequency of use and the value of different classifications in order to justify continuing with certain CDEs and certain levels of classification. Fundamentally: have any meta-analyses of these data across trials been done? Perhaps a study of this should be commissioned?

Instrument/ CRF Name	Domain/ Subdomain	Population	Classification	Updates for Stroke v2.0
Behavioral History	Participant History and Family History/ General Health History	Adult and Pediatric	**Supplemental – Highly Recommended**: Behavioral history assessment date and time; Tobacco current use indicator; Tobacco prior use indicator; Tobacco smoke pack-year value; Alcohol current use indicator; Alcohol 30 day use indicator; Alcohol prior use indicator; Alcohol use frequency; Drug or substance current illicit or recreational use indicator; Drug or substance illicit or recreational use category; Drug or substance illicit or recreational use other text The remaining CDEs are classified as Supplemental.	
Demographics	Participant Characteristics/ Demographics	Adult and Pediatric	**Core:** Birth sex assigned type; Gender identity type; Birth date; Ethnicity USA category; Race USA category The remaining CDEs are classified as Supplemental or Exploratory.	Expanded racial and ethnicity categories, countries of origin; In pediatric categories expanded the racial categories for mother and father as Exploratory categories; Discussed importance of capturing both sex and gender and of deferring to broader CDE project to maintain consistency
Family History	Participant History and Family History/ General Health History	Adult and Pediatric	**Supplemental – Highly Recommended:** Family history medical condition type (Stroke, Coronary artery disease) The remaining CDEs are classified as Supplemental or Exploratory.	
History Data Source and Reliability	Participant History and Family History/ General Health History	Adult and Pediatric	**Supplemental**	
Medical History	Participant History and Family History/ General Health History	Adult and Pediatric	**Core:** Medical history condition text; Medical history condition SNOMED CT code **Supplemental – Highly Recommended:** Pregnancy indicator; Postpartum indicator; Medical history global assessment indicator; Medical history condition type (Stroke, Ischemic stroke, Hemorrhagic stroke) The remaining CDEs are classified as Supplemental or Exploratory.	

Instrument/ CRF Name	Domain/ Subdomain	Population	Classification	Updates for Stroke v2.0
Pregnancy and Perinatal History	Participant History and Family History/ General Health History	Adult and Pediatric	**Core:** Birth date **Supplemental – Highly Recommended:** Data collected date and time; Pregnant ever indicator; Gravida maternal value; Delivery or pregnancy termination last date and time; Spontaneous miscarriage count; Pregnancy medical terminations count; Maternal delivery age value; Parity maternal value; Pregnancy or delivery risk factor type; Pregnancy or delivery risk factor other text; Pregnancy or delivery risk factor indicator; Pregnancy or delivery risk factor status; Pregnancy or delivery risk factor illness other text; Pregnancy or delivery risk factor fetal abnormal recognize in utero text; Pregnancy or delivery risk factor maternal infection text; Birth weight value; Gestational age value; APGAR one minute score; APGAR five minute score; APGAR ten minute score; Delivery mode type; Delivery mode induced other text; Neonate delivery route type; Delivery caesarean timing status; Delivery modality type; Delivery extraction type The remaining CDEs are classified as Exploratory.	Modifications for greater detail regarding pregnancy and perinatal status/events; mostly Supplemental – Highly Recommended
Pre-morbid Modified Rankin Scale Score	Outcomes and End Points/ Activities of Daily Living/Performance	Adult	**Supplemental – Highly Recommended**	
Prior and Concomitant Medications	Treatment/Intervention Data/ Drugs	Adult and Pediatric	All CDEs are classified as Supplemental or Exploratory.	
Prior Functional Status	Participant History and Family History/ General Health History	Adult and Pediatric	**Core:** Ambulatory status The remaining CDEs are classified as Supplemental.	Minor modifications for pediatric pre-existing developmental/academic function
Social Status	Participant Characteristics/ Social Status	Adult and Pediatric	All CDEs are classified as Supplemental or Exploratory.	