STROKE (CVA) AND TRANSIENT ISCHEMIC ATTACK (TIA)

Protocol Identifier	Subject Identifier		Visit Description
			Treatment Period Visit XYZ

PAST MEDICAL HISTORY

History and/or clinical examination which clearly defines the new onset of focal or global neurological deficit. [Y] ☐Yes [N] ☐No

Date and time of onset of symptoms: Day Month Year Hrs:Mins (00:00-23:59)

Did symptoms resolve? [Y] ☐Yes [N] ☐N

If , yes, date and time of resolution of symptoms: Day Month Year Hrs:Mins (00:00-23:59)

HOSPITALISATION

Was subject hospitalized due to event? [Y] ☐Yes [N] ☐No

Admission date and time: Day Month Year Hrs:Mins (00:00-23:59)

Discharge date and time: Day Month Year Hrs:Mins (00:00-23:59)

Was event due to trauma? [Y] ☐Yes [N] ☐No

Was atrial fibrillation present? [Y] ☐Yes [N] ☐No

If Yes, complete the Arrhythmia eCRF:

Was event associated with an acute coronary syndrome? (If Yes, fill out ACS eCRF) [Y] ☐Yes [N] ☐No

If Yes, complete the ACS eCRF

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SYMPTOMS

If Yes, and this event is reported as an SAE, record details in the _____section of the SAE.
If Yes, and this event has not been reported as an SAE, record details below the appropriate question.

Motor and/or sensory loss in face, arm or leg on right side?	[Y] ☐Yes [N] ☐No
Motor and/or sensory loss in face, arm or leg on left side?	[Y] ☐Yes [N] ☐No
Aphasia (Difficulty remembering words or with understanding language)?	[Y] ☐Yes [N] ☐No
Dysphagia (Difficulty swallowing)?	[Y] ☐Yes [N] ☐No
Dysarthria (Weakness or difficulty in coordinating muscles needed to speak)?	[Y] ☐Yes [N] ☐No
Dizziness/vertigo?	[Y] ☐Yes [N] ☐No
Heminopsia (Blindness or distinct visual field deficits)?	[Y] ☐Yes [N] ☐No
Ataxia (Lack of voluntary coordination of muscle movements)?	[Y] ☐Yes [N] ☐No
Nystagmus (Involuntary eye movement)?	[Y] ☐Yes [N] ☐No
Diplopia (Double-vision)?	[Y] ☐Yes [N] ☐No
Acute confusion/cognitive change?	[Y] ☐Yes [N] ☐No
Decreased consciousness?	[Y] ☐Yes [N] ☐No
Did subject have abnormal neurologic exam or history prior to event?	[Y] ☐Yes [N] ☐No

Option 2 to how questions re: motor/sensory loss are asked (first 2 questions above)
If Yes, and this event is reported as an SAE, record details in the _____section of the SAE.
If Yes, and this event has not been reported as an SAE, record details below the appropriate question.

Motor and/or sensory loss	Right-side	Left-side
Face	[Y] ☐Yes [N] ☐No	[Y] ☐Yes [N] ☐No
Arm	[Y] ☐Yes [N] ☐No	[Y] ☐Yes [N] ☐No

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Leg	[Y] ☐Yes [N] ☐No	[Y] ☐Yes [N] ☐No

BRAIN IMAGING

Was a Computerized Tomography (CT) scan performed? [Y] ☐Yes [N] ☐No

If Yes, date and time of CT scan: Day Month Year Hrs:Mins (00:00-23:59)

Evidence of hemorrhage [Y] ☐Yes [N] ☐No

Evidence of hemorrhagic conversion [Y] ☐Yes [N] ☐No

Evidence of infarction [Y] ☐Yes [N] ☐No

Evidence of tumor [Y] ☐Yes [N] ☐No

Evidence of aneurysm [Y] ☐Yes [N] ☐No

Other ____________________________

Was Magnetic Resonance Imaging (MRI) performed? [Y] ☐Yes [N] ☐No

If Yes, date and time of MRI scan: Day Month Year Hrs:Mins (00:00-23:59)

Result of MRI scan ✓one: ☐ Normal ☐ Abnormal

If Abnormal, evidence of acute/sub acute event [Y] ☐Yes [N] ☐No

If Abnormal, evidence of chronic event [Y] ☐Yes [N] ☐No

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Evidence of hemorrhage	[Y] ☐Yes [N] ☐No
Evidence of hemorrhagic conversion	[Y] ☐Yes [N] ☐No
Evidence of infarction	[Y] ☐Yes [N] ☐No
Evidence of tumor	[Y] ☐Yes [N] ☐No
Evidence of aneurysm	[Y] ☐Yes [N] ☐No

Was a Magnetic Resonance Angiogram (MRA) scan performed?	[Y] ☐Yes [N] ☐No
If Yes, date and time of MRA scan:	☐☐ Day ☐☐☐ Month ☐☐ Year ☐☐ ☐☐ Hrs:Mins (00:00-23:59)
Result of MRA scan ✓one:	☐ Normal ☐ Abnormal
If Abnormal, evidence of acute/sub acute event	[Y] ☐Yes [N] ☐No
If Abnormal, evidence of chronic event	[Y] ☐Yes [N] ☐No
Evidence of hemorrhage	[Y] ☐Yes [N] ☐No
Evidence of hemorrhagic conversion	[Y] ☐Yes [N] ☐No
Evidence of infarction	[Y] ☐Yes [N] ☐No
Evidence of tumor	[Y] ☐Yes [N] ☐No
Evidence of aneurysm	[Y] ☐Yes [N] ☐No
If no CT, MRI or MRA examination was performed, what was the clinical diagnosis of the cause of event (e.g. cerebral thrombosis, hemorrhage, embolus).	____________________ ____________________

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***OUTCOME** (? Immediate or x days/weeks or 90 days, or more than one)*

Were there any long term sequelae? [Y] ☐Yes [N] ☐No

If Yes, complete the following: [Y] ☐Yes [N] ☐No

Able to perform ADL's (activities of daily living) without assistance? [Y] ☐Yes [N] ☐No

Was the subject confined to bed? [Y] ☐Yes [N] ☐No

Scale	Disability
0	No symptoms at all
1	No significant disability despite symptoms; able to carry out all usual duties and activities
2	Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance
3	Moderate disability; requiring some help, but able to walk without assistance
4	Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance
5	Severe disability; bedridden, incontinent and requiring constant nursing care and attention
6	Dead

FINAL DIAGNOSIS

✓only one:

STROKE

Ischemic stroke is defined as an acute episode of focal cerebral, spinal, or retinal dysfunction caused by infarction of central nervous system tissue.

☐ Ischemic stroke

☐ Ischemic stroke with hemorrhagic conversion

Hemorrhagic stroke is defined as an acute episode of focal or global cerebral or spinal dysfunction caused by intraparenchymal, intraventricular, or subarachnoid hemorrhage.

☐ Hemorrhagic stroke, intraparenchymal

☐ Hemorrhagic stroke, intraventricular

☐ Hemorrhagic stroke, subarachnoid,

Undetermined stroke is defined as an acute episode of focal or global neurological dysfunction caused by presumed brain, spinal cord, or retinal vascular injury as a result of hemorrhage or infarction but with insufficient information to allow categorization

☐ Undetermined Stroke

TRANSIENT ISCHEMIC ATTACK

☐TIA

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"Additional Supplemental information (to what has already been highlighted in yellow in the form): Source documents for data requested in the eCRF (e.g., labs, CXR) as well as admission History and Physical and Discharge Summary".

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