Appendix XIV: POINT DATA COMPLETION GUIDELINES

**General CRF Completion Guidelines**
For the most recent POINT CRF guidelines, please visit the POINT website Resources and Training section, [https://www.nett.umich.edu/nett/point_resources_and_training](https://www.nett.umich.edu/nett/point_resources_and_training).
General CRF Completion Guidelines

- Although it is not a requirement that you use paper worksheets for data collection, all data defined on the worksheets must be collected and entered into WebDCU™.

- If paper worksheets are used as source documents, they must be retained at the Clinical Site according to local and federal regulations.

- No data should be missing unless allowed by a skip pattern.

- If data for a numerical field is unknown or missing, please leave that field blank. Do not enter 0 (zero).

- Circles or radio buttons "O" indicate that you should choose only one answer.

- Boxes “□” indicate that you should ‘check all that apply’.

- Use the following format for all date fields: DD-MMM-YYYY (e.g., 31-JAN-2010)

- Complete dates should be entered, whenever possible, for all date fields. If the complete date isn’t known, partial dates are allowed for select data points.

- Use the following format for all time fields: hh:mm

  **Please note:** 24:00 is not an allowable response. 24 hour clock time goes from 00:00 to 23:59. Midnight should be entered as 00:00.

<table>
<thead>
<tr>
<th>Time on Clock</th>
<th>24 Hour Clock Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>12:00 AM</td>
<td>00:00</td>
</tr>
<tr>
<td>01:00 AM</td>
<td>01:00</td>
</tr>
<tr>
<td>02:00 AM</td>
<td>02:00</td>
</tr>
<tr>
<td>03:00 AM</td>
<td>03:00</td>
</tr>
<tr>
<td>04:00 AM</td>
<td>04:00</td>
</tr>
<tr>
<td>05:00 AM</td>
<td>05:00</td>
</tr>
<tr>
<td>06:00 AM</td>
<td>06:00</td>
</tr>
<tr>
<td>07:00 AM</td>
<td>07:00</td>
</tr>
<tr>
<td>08:00 AM</td>
<td>08:00</td>
</tr>
<tr>
<td>09:00 AM</td>
<td>09:00</td>
</tr>
</tbody>
</table>
• Name of person who collected the CRF data must be entered on the bottom of the paper worksheet, when the paper worksheet is used as a source document. This field will not be data entered but is required for monitoring purposes.

• Data Entry Timelines:
  - Screen Failure Log - The Clinical Site staff should update the Screen Failure Log forms in WebDCU™ by the 10th of the following month, when a Screen Failure Log is required.
  - Baseline through End of Study CRFs - Within 5 days of collection.
  - Please note that site payments are dependent upon the subject’s data being entered and submitted.

• Data Clarification Request (DCR) Timelines: All responses to DCRs must be submitted within 5 days of query generation with the exception of DCRs for SAEs/Clinical Outcomes which must be submitted within 24 hours of query generation.
Screen Failure Log

The Screen Failure Log is required for all NETT sites. Non-NETT sites should enter the Screen Failure Log if directed by the study team. The most current version of the Screen Failure Log is located in WebDCU™ under Project Documents. Paper versions of the Screen Failure Log will be reviewed during the monitoring visit, if applicable.

The Screen Failure Log is used to help identify the number of potential POINT subjects who are identified by phone or in person within a site’s Emergency Department. Patients that are actively screened (in person or via telephone) for the POINT study by your study team but not randomized at your site should be included on the log.

Sites that are required to track screen failures should enter the data monthly into WebDCU™. Screen failures for the previous month must be reported by the 10th of the following month.

Any screen failures to report? Answer “No” or “Yes.” If “No,” no further information needs to be entered for that month. If “Yes,” enter all screen failures as designated on the form.

Column F (Primary reason patient is not enrolled): Select the code that corresponds with the primary reason for non-enrollment.

Column G (Specify): If primary reason is ‘consent declined for other reason’ or ‘other,’ it must be specified in this column.

Screen Failure Code List:

1= TIA patient with ABCD2 score < 4.
2= Minor ischemic stroke patient with NIHSS > 3.
3= Inability to randomize within 12 hours of time last known free of new ischemic symptoms
4= Head CT or MRI does not rule out hemorrhage or other pathology, such as vascular malformation, tumor, or abscess, that could explain symptoms or contraindicate therapy
5= Age < 18 years
6= Inability to tolerate aspirin at a dose of 50-325 mg/day
7= Symptoms of TIA limited to isolated numbness, isolated visual changes, or isolated dizziness/vertigo
8= In the judgment of the treating physician, a candidate for thrombolysis, endarterectomy, or endovascular intervention.
9= Receipt of any intravenous or intra-arterial thrombolysis within 1 week prior to index event.
10= Gastrointestinal bleed or major surgery within 3 months prior to index event.
11= History of nontraumatic intracranial hemorrhage.
13= Clear indication for anticoagulation (e.g., warfarin, heparin) anticipated during the study period
14= Qualifying ischemic event induced by angiography or surgery.
15= Severe non-cardiovascular comorbidity with life expectancy < 3 months.
16= Contraindication to clopidogrel or aspirin.
17= Anticipated requirement for long-term (>7 day) non-study antiplatelet drugs or NSAIDs affecting platelet function.
18= Inability to swallow medications.
19= At risk for pregnancy: premenopausal or post-menopausal female within 12 months of last

POINT MoP APPENDICES_ver. 4.0_03JUL14 - 4 - Appendix XIV: POINT Data Completion Guidelines
menses without a negative pregnancy test or not committing to adequate birth control
20= Unavailability for follow-up.
21= Inability to provide informed consent.
22= Other neurological conditions that would complicate assessment of outcomes during follow-up.
23= Ongoing treatment in another study of an investigational therapy or treatment in such a study
within the last 7 days
24= Consent declined due to confidentiality issues.
25= Consent declined due to protocol too restrictive.
26= Consent declined due to protocol too time intensive.
27= Consent declined due to travel requirements.
28= Consent declined due to family advised declining.
29= Consent declined for other reason.
30= Not willing or able to discontinue prohibited concomitant medications
96= Other

Column K: If the response to Column F (Primary reason patient not enrolled in POINT) is 24-29 on
the Code List, this item asks if the patient was shown any portion of the Mytrus video during the
consenting process.

Column L: If Column K is “Yes,” this item is where the Mytrus ID is entered.
### POINT: Schedule of Activities and Assessments: CRF Schedule

<table>
<thead>
<tr>
<th>Visit:</th>
<th>Baseline/Randomization</th>
<th>Phone F/U Day 7 +/−2 days</th>
<th>Phone F/U Day 30⁰ (No CRFs to complete)</th>
<th>90 Day FU: Phone or In-Person +/-14 days†</th>
<th>Outcome Event Visit*** (prior to 90 Day FU)</th>
<th>End of Study (-14 days to +60 days)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Measurements:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N/A</td>
<td>Screen Failure Log</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>00</td>
<td>Eligibility Form</td>
<td>X M</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Randomization Form</td>
<td>X M</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>01</td>
<td>Demographics</td>
<td>X M</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>02</td>
<td>ABCD² Score</td>
<td>X M</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>03</td>
<td>modified Rankin Scale (mRS)</td>
<td></td>
<td>X M</td>
<td>X M</td>
<td></td>
<td></td>
</tr>
<tr>
<td>04</td>
<td>NIH Stroke Scale</td>
<td>X M</td>
<td>X M</td>
<td>X M</td>
<td>X M</td>
<td></td>
</tr>
<tr>
<td>05</td>
<td>Medical History</td>
<td>X M</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>06</td>
<td>Prior Medications</td>
<td>X M</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>07</td>
<td>Index TIA/Minor Stroke Sx</td>
<td>X M</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>08</td>
<td>Vital Signs</td>
<td>X M</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Head CT/MRI Scan</td>
<td>X* M R</td>
<td>O* M R</td>
<td>O* M R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>ECG</td>
<td>X* M R</td>
<td>O* M R</td>
<td>O* M R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Carotid Imaging Results</td>
<td>O*² M R</td>
<td>O*² M R</td>
<td>O*² M R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Stroke-Free Questionnaire: QVSFS</td>
<td>X M</td>
<td>X M</td>
<td>X M</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Morisky Questionnaire</td>
<td>X M</td>
<td>O*²</td>
<td>X M</td>
<td>X M</td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>Study Drug Compliance</td>
<td>X M</td>
<td>O*²</td>
<td></td>
<td></td>
<td>X M</td>
</tr>
<tr>
<td>17</td>
<td>End of Study Form</td>
<td>X M</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>Concomitant Medications</td>
<td>X M</td>
<td>X M</td>
<td>X M</td>
<td></td>
<td></td>
</tr>
<tr>
<td>19</td>
<td>SAE/Clinical Outcome</td>
<td>O M R</td>
<td>O M R</td>
<td>O M R</td>
<td>O M R</td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>Final Diagnosis</td>
<td>X M</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>21</td>
<td>Protocol Violation</td>
<td>X M</td>
<td>X M</td>
<td>X M</td>
<td>X M</td>
<td></td>
</tr>
<tr>
<td>22</td>
<td>Ancillary Biomarker</td>
<td>O*² M</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

X=Required O=Optional R=Repeatable M=Monitor Verify Required

*Part of standard evaluation; cost not covered by study.
** As needed (visit can occur more than once).
*** Event Visits for MI can be completed by telephone.
† Preferably as soon as possible after the completion of 90 days.
¹ Encouraged as part of best practices; not required for study entry or at 90 days; if performed, record results on CRF.
² Blood sample obtained with subject’s consent for optional ancillary biomarker study.
Ø No study data collected/no associated CRFs.
**Form 00: Eligibility Form**

This form is intended to document the subject’s eligibility prior to randomization. This form must be data entered and submitted into WebDCU™ with all eligibility criteria met or randomization will be blocked.

To randomize a subject:
- Data enter this form. Then click save. Address any rule violations, then click submit.
- After selecting the “Subject CRF” tab from the main menu page data enter the Randomization Form (Form 10; see below). Then click save. Address any rule violations, then click submit.
- WebDCU™ will display the bottle number to be given to that subject.

Note: All eligibility criteria must be met or randomization will be blocked.

For Baseline labs collected on this form, the following labs must be recorded:
- Glucose
- White blood cell count
- Red blood cell count
- Hemoglobin
- Hematocrit
- Platelet count (must be $\geq 100 \times 10^9$/l for randomization)

Eligibility criteria must be reviewed by a physician investigator before the form can be submitted. The reviewing physician investigator must be listed on the Physician Information form and the Delegation of Authority log.

**NOTE:** In order to generate a randomization number, you must data enter and submit Form 10 after submitting Form 00.

**Form 10: Randomization Form**

Before this form can be submitted and a randomization number assigned to the subject, the Eligibility Form (Form 00) must be data entered and submitted into WebDCU with all eligibility criteria met. See previous section, Form 00.

Select the appropriate responses for this form. Submit the form to obtain a randomization number. Randomization cannot be un-done. Once the randomization number is assigned, this subject is enrolled in the trial and must be followed until the 90 day visit or withdrawal of consent. The time of randomization should be the time the Randomization Form is being submitted in local time, 24 hour format.

The randomization number corresponds to the study drug bottle number assigned to that subject. (The randomization/study bottle number is distinct from the subject ID number assigned to the patient at enrollment.) If you are unable to access the study database due to connectivity issues, please call the WebDCU™ Emergency Randomization Hotline at 1-866-450-2016. If you are
unable to call this number from your hospital, you can call the POINT Emergency Hotline at 1-866-947-6468 (1-866-94-POINT) to be routed to the WebDCU™ Emergency Randomization Hotline by pressing 2.

Remember, the POINT Emergency Hotline is to be used for emergency situations only.

Form 01: Demographics

This form is intended to capture basic demographic information. In addition to this information, the time the informed consent form was signed should also be recorded on this form.

It is important that all demographic information be verified by self-report by the subject, medical records, or a reliable individual accompanying the subject.

Ethnicity is a self-reported or self-identified data field that is required by the NIH. This field should be marked "Unknown" unless the subject/family members/medical records can provide the information.

Form 02: ABCD² Score

This form should be completed for subjects who do not have ongoing symptoms at the time of randomization or evidence of acute infarct on baseline imaging.

This form documents the ABCD² score at baseline. The assessor collecting these data must be a study team member on the Delegation of Authority log who has completed the ABCD² certification. For ABCD² certification, or to review the training information, please visit https://www.nett.umich.edu/nett/point_resources_and_training.

For the POINT trial, the ABCD² score is defined as:

- Age ≥ 60 = 1
- Blood Pressure (systolic ≥ 140 or diastolic ≥ 90 on initial evaluation) = 1
- Clinical (focal weakness=2; speech impairment w/o weakness=1)
- Duration (≥60min=2; 10-59min=1; <10 min=0)
- Diabetes (clinically diagnosed by a physician=1)

For eligibility purposes, the total score must be ≥4 for the subject to be enrolled in POINT.

Form 03: Modified Rankin Scale

The Modified Rankin Scale (mRS) should reflect the subject’s current status. The mRS is a functional disability scale heavily weighted toward neurological disability. It is widely used and has strong face validity worldwide. The scale is best scored by medical personnel in person. However, a structured interview has been shown to have good reproducibility by telephone.
Unlike ABCD\textsuperscript{2}, there is no mRS score cut-off for eligibility purpose in the POINT study.

For mRS certification, or to review the training information, please visit: https://www.nett.umich.edu/nett/point_resources_and_training.

The assessor must be a study team member who has completed the mRS certification, and one who is listed on the Delegation of Authority log.

**Form 04: NIH Stroke Scale**

The NIHSS is a well-validated clinical tool to score the stroke neurological examination. The scale is scored from a minimum of 0, indicating no measurable neurological deficit, to a maximum score of 42. In practice, a score of <5 is a mild stroke, 6-15 is a moderate to severe stroke, and >15 is a severe stroke. The scale can be administered in about 10 minutes. All health care personnel (in any role) can be certified in the use of the scale. Regardless of who administered the scale, the resulting NIHSS must be assessed in person by a clinical investigator at the site who has a current NIHSS certification and is included on the Delegation of Authority log. Certification is available through the American Stroke Association. For more information regarding certification, please visit: https://www.nett.umich.edu/nett/point_resources_and_training

At the baseline visit, this form should be completed for subjects who have ongoing symptoms at the time of randomization or evidence of acute infarct on baseline imaging. At Outcome Event visits, this form should be completed for subjects who experienced a stroke or TIA, as an outcome event. At the 90 Day visit, complete this form for all subjects.

Administer stroke scale items in the order listed. Record performance in each category after each subscale exam. Do not go back and change scores. Follow directions provided for each exam technique. Scores should reflect what the patient does, not what the clinician thinks the patient can do. The clinician should record answers while administering the exam and work quickly. Except where indicated, the patient should not be coached (i.e., repeated requests to patient to make a special effort).

**1a. Level of Consciousness:** The investigator must choose a response, even if a full evaluation is prevented by such obstacles as an endotracheal tube, language barrier, and orotracheal trauma/bandages. A 3 is scored only if the patient makes no movement (other than reflexive posturing) in response to noxious stimulation. For coma, score 3.

0 = Alert; keenly responsive.
1 = Not alert, but aroused by minor stimulation to obey, answer, or respond.
2 = Not alert, requires repeated stimulation to attend, or is obtunded and requires strong or painful stimulation to make movements (not stereotyped).
3 = Responds only with reflex motor or autonomic effects, or totally unresponsive, flaccid, and are flexic.

**1b. LOC Questions:** The patient is asked the month and his/her age. The answer must be correct - there is no partial credit for being close. Aphasic and stuporous patients who do not comprehend the questions will score 2. Patients unable to speak because of endotracheal intubation, orotracheal trauma, severe dysarthria from any cause, language barrier or any other problem not...
secondary to aphasia are given a 1. It is important that only the initial answer be graded and that the examiner not "help" the patient with verbal or non-verbal cues. For coma, score 2.

0 = Answers both questions correctly.
1 = Answers one question correctly.
2 = Answers neither question correctly.

1c. LOC Commands: The patient is asked to open and close the eyes and then to grip and release the non-paretic hand. Substitute another one step command if the hands cannot be used. Credit is given if an unequivocal attempt is made but not completed due to weakness. If the patient does not respond to command, the task should be demonstrated to them (pantomime) and score the result (i.e., follows none, one or two commands). Patients with trauma, amputation, or other physical impediments should be given suitable one-step commands. Only the first attempt is scored. For coma, score 2.

0 = Performs both tasks correctly
1 = Performs one task correctly
2 = Performs neither task correctly

2. Best Gaze: Only horizontal eye movements will be tested. Voluntary or reflexive (oculocephalic) eye movements will be scored but caloric testing is not done. If the patient has a conjugate deviation of the eyes that can be overcome by voluntary or reflexive activity, the score will be 1. If a patient has an isolated peripheral nerve paresis (CN III, IV or VI) score a 1. Gaze is testable in all aphasic patients. Patients with ocular trauma, bandages, pre-existing blindness or other disorder of visual acuity or fields should be tested with reflexive movements and a choice made by the investigator. Establishing eye contact and then moving about the patient from side to side will occasionally clarify the presence of partial gaze palsy. For coma, score as examined.

0 = Normal
1 = Partial gaze palsy. This score is given when gaze is abnormal in one or both eyes, but where forced deviation or total gaze paresis is not present.
2 = Forced deviation, or total gaze paresis not overcome by the oculocephalic maneuver.

3. Visual: Visual fields (upper and lower quadrants) are tested by confrontation, using finger counting or visual threat as appropriate. Patient may be encouraged, but if they look at the side of the moving fingers appropriately, this can be scored as normal. If there is unilateral blindness or enucleation, visual fields in the remaining eye are scored. Score 1 only if a clear-cut asymmetry, including quadrant anopia, is found. If patient is blind from any cause, score 3. Double simultaneous stimulation is performed at this point. If there is extinction, patient receives a 1 and the results are used to answer question 11. Score as examined.

0 = No visual loss
1 = Partial hemianopia
2 = Complete hemianopia
3 = Bilateral hemianopia (blind including cortical blindness)

NOTE: In the case of a patient with blindness that precedes the onset of a minor ischemic stroke that causes the patient to be considered for POINT, it is necessary to add 3 points for blindness. As a result of the total score (NIHSS > 3), the patient would not be eligible for POINT.
4. Facial Palsy: Ask, or use pantomime to encourage, the patient to show teeth or raise eyebrows and close eyes. Score symmetry of grimace in response to noxious stimuli in the poorly responsive or noncomprehending patient. If facial trauma/bandages, orotracheal tube, tape or other physical barrier obscure the face, these should be removed to the extent possible.

0 = Normal symmetrical movements  
1 = Minor paralysis (flattened nasolabial fold, asymmetry on smiling)  
2 = Partial paralysis (total or near-total paralysis of lower face)  
3 = Complete paralysis of one or both sides (absence of facial movement in the upper and lower face)

5 & 6. Motor Arm and Leg: The limb is placed in the appropriate position: extend the arms (palms down) 90 degrees (if sitting) or 45 degrees (if supine) and the leg 30 degrees (always tested supine). Drift is scored if the arm falls before 10 seconds or the leg before 5 seconds. The aphasic patient is encouraged using urgency in the voice and pantomime but not noxious stimulation. Each limb is tested in turn, beginning with the non-paretic arm. In the case of amputation or joint fusion at the shoulder or hip, the examiner should check the appropriate box on the CRF and enter an explanation. For coma, score 4.

0 = No drift; limb holds 90 (or 45) degrees for full 10 seconds.  
1 = Drift; limb holds 90 (or 45) degrees, but drifts down before full 10 seconds; does not hit bed or other support.  
2 = Some effort against gravity, limb cannot get to or maintain (if cued) 90 degrees  
3 = No effort against gravity, limb falls.  
4 = No movement  
Amputation, joint fusion – provide an explanation in the box below if selected.

5a. Left Arm  
5b. Right Arm

0 = No drift, leg holds 30 degrees position for full 5 seconds.  
1 = Drift, leg falls by the end of the 5 second period but does not hit bed.  
2 = Some effort against gravity; leg falls to bed by 5 seconds, but has some effort against gravity.  
3 = No effort against gravity, leg falls to bed immediately.  
4 = No movement  
Amputation, joint fusion – provide an explanation in the box below if selected.

6a. Left Leg  
6b. Right Leg

7. Limb Ataxia: This item is aimed at finding evidence of a unilateral cerebellar lesion. Test with eyes open. In case of visual defect, insure testing is done in intact visual field. The finger-nose-finger and heel-shin tests are performed on both sides, and ataxia is scored only if present out of proportion to weakness. Ataxia is absent in the patient who cannot understand or is paralyzed. In the case of amputation or joint fusion, the examiner should check the appropriate box on the CRF and enter an explanation. In case of blindness, test by touching nose from extended arm position. For coma, score 0.
8. Sensory: Sensation or grimace to pin prick when tested, or withdrawal from noxious stimulus in the obtunded or aphasic patient. Only sensory loss attributed to stroke is scored as abnormal and the examiner should test as many body areas [arms (not hands), legs, trunk, face] as needed to check accurately for hemisensory loss. A score of 2, "severe or total sensory loss," should only be given when a severe or total loss of sensation can be clearly demonstrated. Stuporous and aphasic patients will therefore probably score 1 or 0. The patient with brainstem stroke who has bilateral loss of sensation is scored 2. If the patient does not respond and is quadriplegic, score 2. Patients in coma (item 1a=3) are automatically given a 2 on this item. For coma, score 2.

0 = Normal; no sensory loss.
1 = Mild-to-moderate sensory loss; patient feels pinprick is less sharp or is dull on the affected side; or there is a loss of superficial pain with pinprick, but patient is aware he/she is being touched.
2 = Severe or total sensory loss; patient is not aware of being touched in the face, arm, and leg.

9. Best Language: A great deal of information about comprehension will be obtained during the preceding sections of the examination. The patient is asked to describe what is happening in the attached picture, to name the items on the attached naming sheet, and to read from the attached list of sentences (see the end of this section for the attachments). Comprehension is judged from responses here as well as to all of the commands in the preceding general neurological exam. If visual loss interferes with the tests, ask the patient to identify objects placed in the hand, repeat, and produce speech. The intubated patient should be asked to write. The patient in coma (question 1a=3) will automatically score 3 on this item. The examiner must choose a score in the patient with stupor or limited cooperation but a score of 3 should be used only if the patient is mute and follows no one step commands. For coma, score 3.

0 = No aphasia, normal
1 = Mild to moderate aphasia; some obvious loss of fluency or facility of comprehension, without significant limitation on ideas expressed or form of expression. Reduction of speech and/or comprehension, however, makes conversation about provided material difficult or impossible. For example, in conversation about provided materials, examiner can identify picture or naming card from patient’s response.
2 = Severe aphasia; all communication is through fragmentary expression; great need for inference, questioning, and guessing by the listener. Range of information that can be exchanged is limited; listener carries burden of communication. Examiner cannot identify materials provided from patient response.
3 = Mute, global aphasia; no usable speech or auditory comprehension.

10. Dysarthria: If patient is thought to be normal an adequate sample of speech must be obtained by asking patient to read or repeat words from the attached list. If the patient has severe aphasia, the clarity of articulation of spontaneous speech can be rated. If the patient is intubated or has other physical barrier to producing speech, the examiner should check the appropriate box on the CRF and enter an explanation. Do not tell the patient why he/she is being tested. For coma, score 2.

0 = Normal
1 = Mild to moderate; patient slurs at least some words and, at worst, can be understood with some difficulty.
2 = Severe; patient's speech is so slurred as to be unintelligible in the absence of or out of proportion to any dysphasia, or is mute/anarthric.

Intubated or other physical barrier – check the box and enter an explanation

11. **Extinction and Inattention (formerly Neglect):** Sufficient information to identify neglect may be obtained during the prior testing. If the patient has a severe visual loss preventing visual double simultaneous stimulation, and the cutaneous stimuli are normal, the score is normal. If the patient has aphasia but does appear to attend to both sides, the score is normal. The presence of visual spatial neglect or anosagnosia may also be taken as evidence of abnormality. Since the abnormality is scored only if present, the item is never untestable. For coma, score 2.

0 = No abnormality.
1 = Visual, tactile, auditory, spatial, or personal inattention, or extinction to bilateral simultaneous stimulation in one of the sensory modalities.
2 = Profound hemi-inattention or extinction to more than one modality. Does not recognize own hand or orients to only one side of space.

For NIHSS certification, or to review the training information, please visit: [https://www.nett.umich.edu/nett/point_resources_and_training](https://www.nett.umich.edu/nett/point_resources_and_training).

The assessor must be a study team member who has completed the NIHSS certification, whose certification is current and who is listed on the Delegation of Authority log.

**Form 05: Medical History**

This form is intended to document both the data obtained from the patient, his/her family and the medical record while screening the patient, and pre-existing conditions that are discovered after randomization into the trial.

For pre-existing conditions discovered after a patient is randomized and after the Medical History CRF has been submitted, the Study Coordinator, or data entry staff, should edit the CRF accordingly AND enter a notation in the General Comments section at the bottom of the CRF. The General Comments notation should indicate the date the information became available and a brief description of the circumstances (e.g., dd-mmm-yyyy – Pre-existing condition X revealed by patient when admitted for Y on dd-mmm-yyyy at Hospital Z.)

**Form 06: Prior Medications**

Indicate whether the subject has taken any medications listed on the form within one month prior to randomization. Include any medications received while in the ED prior to randomization.

Lists of prohibited and discouraged medications (specific to the participating country) can be found in the NETT Toolbox [https://weblogin.umich.edu/] (Login ID and Password required for access).
Form 07: Index TIA/Stroke Symptoms

Page 1 of the Index TIA/Stroke Symptoms form is intended to capture the subject’s time and date of ED/clinic arrival, time and date the loading dose was given, and to collect information about the symptoms associated with the index event at the time when symptoms were most severe.

Note: the loading dose should be administered within the first two hours after randomization and witnessed by a member of the study team. It is important that the loading dose time is recorded after all 8 tablets have been swallowed by the subject. The subject should also receive an initial aspirin dose (50–325 mg).

Page 2 of the form is intended to capture the symptoms which were present at the time of randomization. Select “no” for subjects who did not have symptoms ongoing at the time of randomization. If no is selected, complete question 24, then the form is complete. This question should be consistent with the question on the Eligibility Form that asks if the subject’s neurologic symptoms associated with the index event completed resolved at the time of randomization.

The information collected should be based upon the judgment of the evaluating physician.

Form 08: Vital Signs

The first measurements taken in the ED/clinic for systolic/diastolic blood pressure should be recorded on this form.

The vital signs CRF has instructions that say “enter the first measurements taken in the ED/clinic.” If the first professional measurements of blood pressure after presentation with symptoms were taken at an outside hospital, these measurements should be entered on the Vital Signs CRF.

Form 11: CT/MRI Scan

This form should be completed at Baseline and all Event visits for all CT and MRI images obtained. A separate form should be completed for each imaging type. Please record the date as dd-mmm-yyyy; time should be recorded as hh:mm. For the baseline CT/MRI, there should be a scan date/time that is prior to the randomization date/time as the CT/MRI is required to rule out hemorrhage or other pathology.

Form 12: Electrocardiogram (ECG)

The ECG and the presence or absence of atrial fibrillation/atrial flutter must be reviewed by an Investigator (PI, Co-PI or Sub-I) listed on the Delegation of Authority log at Baseline and Event visits if applicable. Please record the date as dd-mmm-yyyy; time should be recorded as hh:mm.

Form 13: Carotid Imaging Results, if needed

This form should be completed whenever carotid imaging is done as part of clinical care. A separate form should be completed for each of the following imaging types:
Form 14: Questionnaire for Verifying Stroke Free Status (QVSFS)

This form should be completed at the Day 7, Day 90, and Event visits. The interviewer should verify whether it is the subject and/or relative, caregiver, or friend providing the information for the survey. This instrument is validated as a questionnaire, and, as such, the responses may not be entered as the result of a medical record review.

The interviewer (listed on the Delegation of Authority log) should only capture the appropriate answers relevant to events that occurred after the index event and since last contact. The index event for which the subject was enrolled in the study should be excluded.

Form 15: Morisky Questionnaire

This form documents the subject’s adherence to both the prescribed study drug and aspirin regimen. The form should be completed at Day 7, Day 90, and any Event visits.

The Morisky scale is a commonly used, validated adherence screening tool. It is important that the interviewer allows the subject to provide a “negative response” (no) or “positive response” (yes) by asking the questions indicated on this form. The interviewer (listed on the Delegation of Authority log) should not provide examples for the questions. Instead, if a subject is asking for clarification, the interviewer should repeat the question on the existing form.

If the subject was instructed to discontinue study medications by his/her physician, check no for ‘data collected’ in the header of the form.

If the subject stopped both study drug and aspirin, mark data collected=no for the form. But, if the subject continued to take aspirin, leave Q1-Q4 about study drug blank (there is only one warning to dismiss for these) and then answer Q5-8.

Form 16: Study Drug Compliance

This form is intended to document the subject’s compliance at the end of the subject’s involvement in the POINT Trial. In order to accurately complete this form, the subject should bring the bottle to the last visit, and the study drug bottle should be emptied. The remaining pills will be counted twice for accuracy. Pill count should be the standard for monitoring medication adherence for the POINT MoP APPENDICES__ver. 4.0_03JUL14 - 15 - Appendix XIV: POINT Data Completion Guidelines
The number of pills remaining in the bottle will be recorded. If the pill bottle is not returned, and/or the visit is conducted by phone, the subject’s self-reporting of the number of study drug pills remaining at the end of study is allowable. Include a General Comment if the study drug bottle was not returned and the reason.

In addition, it is important that the last day the study drug was taken is confirmed with the subject. After confirmation, the date should be recorded on the form as dd-mmm-yyyy. Those taking more than 80% of the tablets based on the last day the study drug was taken, will be considered adherent as assessed by pill count.

Pill counts will not be done for aspirin. Compliance with aspirin regimen will only be captured via the Morisky Questionnaire.

**Form 17: End of Study**

This form should be completed once a subject has completed the study. The site PI, listed on the Delegation of Authority log, must review and affirm (by providing a signature and date the forms were reviewed) the accuracy of the information reflected in ALL of the case report forms for the study subject.

If the subject cannot be reached to schedule or complete the 90 day follow-up visit, contact should be attempted up to 150 days from the date of subject randomization. Only after 150 days should the subject be coded as lost to follow up. If a subject decides to prematurely discontinue the study drug but agrees to be followed off the study drug, that subject has not withdrawn consent and therefore the subject has not prematurely terminated the study. The early study drug discontinuation is captured on Form 16: Study Drug Compliance.

**Form 18: Concomitant Medications**

This form is intended to document whether or not a subject has taken the following medications after the randomization period:

- NSAIDS
  - Anticoagulants (both oral and parenteral)
  - Thienopyridines
  - Thrombolytics
  - Other antiplatelets
  - Proton Pump Inhibitors
  - Other prohibited medications
  - Other discouraged medications
  - Statins

This information should be captured at day 7, day 90, and all Event visits as well as the 30-day phone call even though there is no data collected for this call. Please refer to the current version of the prohibited and discouraged medication list when completing this form.

Lists of prohibited and discouraged medications can be found in the NETT Toolbox https://weblogin.umich.edu/ (Login ID and Password required for access.)
Form 19: SAE/Clinical Outcome Reporting Form, if needed

This form should only be completed if the subject experiences a Serious Adverse Event (SAE) or Clinical Outcome. **This form should be data entered and submitted within five days of discovery.**

An Outcome Event Visit should be conducted only if a subject experiences an **ischemic stroke, TIA, or myocardial infarction**, and Form 19 should be completed under the Outcome Event Visit. Outcome Event Visits can be done by telephone unless the subject experiences an ischemic stroke or TIA, in which case an in-person visit should be conducted. If an in-person visit is not possible a video telemedicine visit may be conducted. **For all ‘other serious adverse events’, Form 19 can be entered under the last visit that was conducted.** It will be known that the ‘other SAE’ did not actually occur at the previous visit because of the date/time of onset questions on the form.

The following events (after randomization) are tracked for SAE/Clinical Outcome Reporting:

- Ischemic Stroke
- TIA
- Symptomatic hemorrhagic transformation of an ischemic stroke
- Asymptomatic hemorrhagic transformation of an ischemic stroke
- Symptomatic Intracerebral Hemorrhage
- Asymptomatic Intracerebral Hemorrhage
- Other Symptomatic Intracranial Hemorrhage
- Other Asymptomatic Intracranial Hemorrhage
- Myocardial Infarction with Coronary Revascularization
- Myocardial Infarction without Coronary Revascularization
- Coronary Revascularization without Myocardial Infarction
- Major Hemorrhage other than Intracranial Hemorrhage (life threatening/non-life-threatening)
- Minor Hemorrhage other than intracranial Hemorrhage
- Other Serious Adverse Event

This form is used for documenting all SAEs/Clinical Outcomes. This form should only be completed when a SAE/Clinical Outcome has occurred. All SAEs/Clinical Outcomes will be documented on the SAE/Clinical Outcome CRF from randomization through end of study.

In the event of a SAE/Clinical Outcome, this CRF must be data entered AND submitted in WebDCU™ within five days of first knowledge of the event. The PI at each Clinical Site is responsible for reviewing all SAEs/Clinical Outcomes, ensuring the submission of SAE/Clinical Outcome data into the study database within the required timelines, and for submitting follow up data in a timely manner.

If a SAE/Clinical Outcome changes in severity or frequency, it is considered a separate SAE/Clinical Outcome and must be reported on a **new** SAE/Clinical Outcome CRF. In this case, the outcome date of the first SAE/Clinical Outcome and the onset date of the new SAE/Clinical Outcome will both be the date upon which the severity or frequency changed.
Regarding hemorrhagic transformation of an ischemic stroke, several scenarios could occur after randomization:

1. If a subject enters into the study with a minor ischemic stroke, and is later discovered to have hemorrhagic transformation, a SAE/Clinical Outcome CRF will be filled out indicating symptomatic or asymptomatic hemorrhagic transformation of an ischemic stroke as the event. In addition, question 15 of this CRF, the “of index stroke” category should be answered.

2. If a subject has an ischemic stroke after randomization, and presents with hemorrhagic transformation on their initial imaging study, a SAE/Clinical Outcome CRF should be filled out, indicating symptomatic or asymptomatic hemorrhagic transformation of ischemic stroke as the event. In addition, question 15 of this CRF, the “of outcome stroke” category should be answered.

3. If a subject has an ischemic stroke after randomization, and does not have any hemorrhagic transformation on the initial imaging study, a SAE/Clinical Outcome CRF should be filled out, indicating ischemic stroke as the event. If the subject is later discovered to have hemorrhagic transformation of the stroke, the SAE/Clinical Outcome CRF that was initially entered for the ischemic stroke should be modified to reflect symptomatic or asymptomatic hemorrhagic transformation of ischemic stroke as the event. In addition, question 15 of this CRF, the “of outcome stroke” category should be answered.

If a SAE/Clinical Outcome fully resolves and then recurs at a later date, the second occurrence is considered a new SAE/Clinical Outcome and a new SAE/Clinical Outcome CRF must be completed. Resolution is the normalization or return to baseline (of laboratory values, clinical signs or symptoms).

**Name of SAE/Clinical Outcome** — Please note that when reporting a SAE/Clinical Outcome, you should report the diagnosis and not each individual symptom. For example, it would be incorrect to report serious pneumonia as 4 separate events (fever, cough, chest pain, crackles). Serious pneumonia should be reported as one SAE with the SAE/Clinical Outcome name (question 1) being ‘pneumonia’.

**Death, surgery, intubation, etc. are not adverse events. They are outcomes of adverse events.** When a subject dies, has surgery, is intubated, etc., please enter the reason for the death, surgery, intubation, etc. in the response to Q1.

**SAEs/Clinical Outcomes** — The SAE/Clinical Outcome in Q1 will correlate to one of the formal definitions. Mark the appropriate circle.

**Severity** — Severity is often used to describe the intensity (severity) of a specific event (as in mild, moderate, severe myocardial infarction). However, the event itself may be of relatively minor medical significance (such as severe headache). Seriousness (not severity) serves as a guide for defining regulatory reporting obligations.

Adverse events will be documented using the NCI Common Terminology Criteria for Adverse Events Version 4.0 (CTCAE) (see MoP). The CTCAE provides a grading (severity) scale for each AE term and AEs are listed alphabetically within categories based on anatomy or pathophysiology.
The CTCAE (v 4.0) displays Grades 1-5 with unique clinical descriptions of severity for each AE based on this general guidance:

- **Grade 1:** Mild AE
- **Grade 2:** Moderate AE
- **Grade 3:** Severe AE
- **Grade 4:** Life-Threatening or Disabling AE
- **Grade 5:** Death related to AE

**Serious** — The seriousness of a Clinical Outcome is based on subject/event outcome or action (i.e., usually associated with events that pose a threat to a subject’s life or functioning).

Serious Adverse Events are:
- Fatal
- Life-Threatening
- Result in hospitalization (or prolonged hospitalization)
- Result in disability/congenital anomaly or
- Require intervention to prevent permanent impairment or damage

**Outcome** — Any SAE that is not resolved must be followed until resolution or end of study, whichever comes first. Once a subject reaches end of study, ‘Continuing (Follow up is required)’ should no longer be selected as the outcome.

**Relationship to study drug** (for non-clinical outcomes only)— This question should be skipped if the event was a clinical outcome. However, this is a required item for reporting SAEs.

One of the most important components of SAE reporting is determining the cause of the SAE. It is imperative that the investigator assess SAE causality in terms of overall study participation and make an independent determination as to whether the SAE was thought to be related to any study-related activity (i.e., study intervention, test article administration, study-related tests or procedures).

For each Serious Adverse Event, the relationship to the study treatment must be recorded as one of the choices on the following scale:

**Not Related**

The temporal relationship between treatment exposure and the serious adverse event is unreasonable or incompatible and/or adverse event is clearly due to extraneous causes (e.g., underlying disease, environment)

**Unlikely (must have 2)**

May have reasonable or only tenuous temporal relationship to intervention.

1. Could readily have been produced by the subject’s clinical state, or environmental or other interventions.
2. Does not follow known pattern of response to intervention.

**Possibly (must have 2)**
1. Has a reasonable temporal relationship to intervention.
2. Could not readily have been produced by the subject’s clinical state or environmental or other interventions.
3. Follows a known pattern of response to intervention.

**Probably (must have all 3)**

1. Has a reasonable temporal relationship to intervention.
2. Could not **readily** have been produced by the subject’s clinical state or have been due to environmental or other interventions.
3. Follows a known pattern of response to intervention.

**Definitely (must have all 3)**

1. Has a reasonable temporal relationship to intervention.
2. Could not **possibly** have been produced by the subject’s clinical state or have been due to environmental or other interventions.
3. Follows a known pattern of response to intervention.


**SAE and Clinical Outcome Narratives** — These sections are used to provide additional relevant details about SAEs/Clinical Outcomes. This section should be as complete as possible, but only include information pertinent to the SAE/Clinical outcome. All narratives must be in English. The Site Manager will utilize an outcome specific checklist to ensure that the event packet is sufficient for the medical monitor’s review. These narratives should not include any patient identifying information.

To assist in the review of all SAEs/Clinical Outcomes, certain information is required for each SAE/Clinical Outcome entered.

**Describe the event in detail.** DO NOT identify any study participant, physician, or institution by name.

The following are specific items to include in the SAE and Clinical Outcome narrative:

1. Provide age, race, gender, most pertinent history, and time and date of enrollment.
2. Indicate whether subject previously experienced a TIA or minor stroke.
3. Include dates and times for the event and relevant procedures/clinical assessments.
4. Include a description of what happened and a summary of all relevant clinical information (medical status prior to the event, signs and or symptoms.
5. Provide differential diagnosis for the event in question.
6. Provide complete clinical course information (relevant test/laboratory data: both positive
and negative results with corresponding dates.
7. Include all treatment outcomes.
8. Provide the discharge summary at length (if applicable).

Please note that Event Packets must be uploaded for all Clinical Outcomes Events and SAEs. The Site/Hub PI will work with the Site Manager to prepare Event Packets, including copies of discharge summaries, neurology, cardiology or other consultation notes, head imaging reports, appropriate laboratory values, and a narrative summary, with all unique participant identifiers removed. **The first page of all event packets should include the event packet checklist, indicating which procedures/tests/notes/etc., are contained in the event packet.** In rare cases where no information was collected for the event packet, the event packet checklist must be uploaded indicating that no information is available and the reason why. All documents should include an English translation if not originally in English. Both the original and the English translation should be included. For more information regarding the Event Packet please refer to the following table, or to the POINT MoP.

### Event Packet Checklist and Cover Page

**POINT Clinical Outcome-Specific Checklist for Preparing Event Packets**

Please use this form as a face page, and order the Event Packet documents in the order in which they appear below.

**NOTE:** All protected health information (PHI) must be removed from documents (Event Packets must be de-identified).

<table>
<thead>
<tr>
<th>Category:</th>
<th>Checklist Item</th>
<th>Submitted</th>
<th>Not Done</th>
<th>Done but Unavailable*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic Packet for ALL Events:</td>
<td>Clinical Outcome Reporting Form (CRF 19)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>Discharge Summary (Index Event)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>Discharge Summary (Outcome Event)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>All Head Imaging Reports (Index Event)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>All Head Imaging Reports (Outcome Event)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>Consult Notes (neurology, cardiology, etc.)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

Depending on event category, also include the following documents in the packet:

| All Deaths | Autopsy Report | ☐ | ☐ | ☐ |
| Includes Fatal SAEs | Death Certificate | ☐ | ☐ | ☐ |
| Ischemic Stroke | Emergency Team/Ambulance Report | ☐ | ☐ | ☐ |
| | Nursing Home Report | ☐ | ☐ | ☐ |
| | Carotid Imaging Report | ☐ | ☐ | ☐ |
| Ischemic Stroke | Operative Report | ☐ | ☐ | ☐ |
| TIA* | Carotid Imaging Report | ☐ | ☐ | ☐ |

*Not adjudicated

| Intracranial Hemorrhage | Operative Report | ☐ | ☐ | ☐ |

(Symptomatic ICH, Asymptomatic ICH, Other Symp ICranialHem & Other Asymp ICranial Hem)

| Cardiac Outcomes | All Cardiac Enzyme Reports | ☐ | ☐ | ☐ |
| (MI with or without | ECG Report(s) | ☐ | ☐ | ☐ |
The basic packet for all events will include the following:

- Event Packet Checklist/Face Page
- Discharge Summary (Index Event)
- Discharge Summary (Outcome Event)
- All Head Imaging Reports (Index Event)
- All Head Imaging Reports (Outcome Event)
- Consultation notes (neurology, cardiology, and other relevant source)

While the event packet items are not limited to the above list, each Clinical Outcome/SAE should be treated as a unique case requiring the submission of all supporting documentation (e.g., all subject deaths will require a death certificate and autopsy report). Depending on the event category, additional documents must be included in the packet. Please be sure that all unique identifiers are removed prior to uploading these documents.

**Investigator Review** — Each SAE/Clinical Outcome must be reviewed by a Site Investigator prior to data submission.

**Form 20: Final Diagnosis**

This form is intended to capture the final diagnosis of the index event based on symptoms, signs, and imaging data. The form should be completed for all subjects. The data should be submitted within 12 days (+/- 2) of randomization but should be updated, as needed, if the final diagnosis for the subject changes prior to the End of Study Visit. The reviewing investigator should be the Principal Investigator at the site.

**Form 21: Protocol Violations**

Protocol deviations include both purposeful and accidental variances in the procedures outlined for a study in its approved protocol or by State or Federal regulations.

This form should be updated, as needed, to capture certain protocol violations that occur from enrollment through the subject’s End of Study Visit. Many deviation/violations can be derived more consistently from CRF data already existing in the study database, as opposed to the self-report data captured on Form 21. Therefore, Form 21 should only be used to document specific protocol deviations.
Examples of deviation/violations that should not be documented on the form because they can be better derived from already existing data:

- Concomitant medications (There is a separate CRF to document prohibited/discouraged medications.)
- Visit is performed outside of the window (This can be derived from visit date.)
- Subject was non-compliant with the study medication (This is captured on Form16: Study Drug Compliance.)
- Inclusion Exclusion Violation (This should be captured on Form 00 Eligibility Form instead.)
- Subject receives a different bottle from the one assigned to which he/she was randomized (This is captured in the Randomization table in the database.)

Examples deviation/violations that should be documented on the form include:

- Overdoses of study medication
- Errors in loading dose

**NOTE:** Your local Institutional Review Board should be notified of such occurrences. In addition, please upload documentation of IRB acknowledgement of the violation(s) to “IRB Study Modification Notification” in WebDCU.

**Form 22: Ancillary Biomarker**

This form is intended to capture information about those subjects who have consented to participate in the Optional Ancillary Biomarker Study, and whether those consenting to the biomarker study also consent to permit their blood sample for future research. The data should be submitted within 12 days (+/- 2) of Ancillary Biomarker Study consent.

Refer to the POINT Ancillary Biomarker Study Blood Specimen Procedure Manual for instructions on specimen collection and preparation, storage, packaging, and shipping.

**********Forms and Visit Checklist **********

**Baseline Visit**

Please submit the following forms for this visit within 5 days of collection (unless otherwise indicated):

- Eligibility (Form 00)
- Consent
- Randomization (Form 10)
- Demographics (Form 01)
- ABCD2 Score (Form 02)
- NIHSS (Form 04)
- Medical History (Form 05)
- Prior Medications (Form 06)
- Index TIA/Minor Stroke Symptoms (Form 07)
- Vital Signs (Form 08)
- Head CT/MRI Scan (Form 11)
- ECG (Form 12)
- Carotid Artery Imaging (Form 13), if needed
- SAE/Clinical Outcome Reporting Form (Form 19), if needed
POINT Data Collection Guidelines

- *Final Diagnosis (Form 20)
- **Protocol Deviations/Violations (Form 21)
- Ancillary Biomarker (Form 22), if site is participating

*Please complete Form 20 within 12 days of randomization. It can be updated, as needed, if the final diagnosis changes prior to the end of study visit.
**Form 21 should be updated as needed

7 Day Follow Up (+/- 2 days)
Please submit the following forms for this visit within 5 days of collection:
- Stroke-Free Questionnaire: QVSFS (Form 14)
- Morisky Questionnaire (Form 15)
- Concomitant Medications (Form 18)
- SAE/Clinical Outcome Reporting Form (Form 19), if needed

30 Day Follow Up Phone Call (+/- 2 days)
The Site Coordinator will contact subjects by telephone at 30 days to uncover any issues or concerns that might impact study drug compliance and/or retention in the study. While no study data will be collected for the 30-day phone contact, if subject contact suggests that a possible stroke, TIA or myocardial infarction may have occurred, an Outcome Event Visit will be scheduled.

90 Day Visit (+/- 14 days)
Please submit the following forms for this visit within 5 days of collection:
- mRS (Form 03)
- NIHSS (Form 04)
- Head CT/MRI Scan (Form 11), if needed
- ECG (Form 12), if needed
- Carotid imaging (Form 13), if needed
- Stroke-Free Questionnaire-QVSFS (Form 14)
- Morisky Questionnaire (Form 15)
- Concomitant Medication (Form 18)
- SAE/Clinical Outcome Reporting Form (Form 19), if needed

Event Visit, if needed
Please submit the following forms for this visit within 5 days of collection:
- mRS (Form 03)
- NIHSS (Form 04)
- Head CT/MRI Scan (Form 11), if needed
- ECG (Form 12), if needed
- Carotid Imaging (Form 13), if needed
- Stroke-Free Questionnaire-QVSFS (Form 14)
- Morisky Questionnaire (Form 15)
- Concomitant Medications (Form 18)
- SAE/Clinical Outcome Reporting Form (Form 19), if needed
**End of Study Visit**

Please submit the following forms for this visit within 5 days of collection:

- End of Study (Form 17)
- Study Drug Compliance (Form 16)
- Update Final Diagnosis Form (Form 20), if needed

*NOTE: This visit may occur prior to the subject reaching the 90 day visit due to withdrawal of consent or death.*