Date information collected:

## **Intravenous (IV) Thrombolytic Therapy**

1. \*\*Was IV thrombolytic agent initiated at the current hospital?

[ ]  Yes - within 0 - 3 hour window [ ]  Yes - within 3 - 4.5 hour window [ ]  Yes - beyond 4.5 hour using imaging selection [ ]  No (Skip to 2)

1. \*\*Date and Time thrombolytic agent initiated:
2. Total IV thrombolytic agent dose given: (please specify) mg
3. Type of IV thrombolytic agent used:

[ ]  Alteplase

[ ]  Tenecteplase

[ ]  Other, specify:

1. Reason(s) no IV thrombolytic agent started at the current hospital: (choose all that apply)

**Contraindications:**

[ ]  Active internal bleeding (<22 days)

[ ]  CT findings (ICH, SAH, or major infarct signs)

[ ]  History of intracranial hemorrhage or brain aneurysm or vascular malformation or brain tumor

[ ]  Platelets <100,000, PTT> 40 sec after heparin use, or PT > 15 or INR > 1.7, or known bleeding diathesis

[ ]  Recent intracranial or spinal surgery, head trauma, or stroke (<3 mo.)

[ ]  Recent surgery/trauma (<15 days)

[ ]  SBP > 185 or DBP > 110 mmHg despite treatment

[ ]  Seizure at onset

[ ]  Suspicion of subarachnoid hemorrhage

[ ]  Subacute Bacterial Endocarditis (SBE*)*

**Hospital-related or Other Factors:**

[ ]  Delay in Participant Arrival

[ ]  Delay in Stroke diagnosis

[ ]  In-hospital Time Delay

[ ]  No IV access

[ ]  MRI not feasible

[ ]  CTP not feasible

[ ]  Other, specify:

**Other reasons thrombolytic agent is not started:**

[ ]  Advanced age

[ ]  Care-team unable to determine eligibility

[ ]  Glucose < 50 or > 400 mg/dl

**[ ]**  Increased risk of bleeding due to Acute pericarditis, SBE, Hemostatic defects, Diabetic hemorrhagic retinopathy, Septic thrombophlebitis or occluded AV cannula, or currently receiving oral anticoagulants

**[ ]**  IV or IA thrombolytic agent given at outside hospital

**[ ]** Left heart thrombus

**[ ]** Life expectancy < 1 year or severe co-morbid illness or CMO on admission

**[ ]** Pregnancy

**[ ]**  Participant/ Family refused

**[ ]** Rapid improvement

**[ ]** Stroke severity nondisabling

**[ ]** Stroke severity - Too severe (e.g., NIHSS >22)

### **Other reasons thrombolytic agent is not started for participants treated between 3-4.5 hours:**

[ ]  Age > 80

[ ]  Prior Stroke AND Diabetes

[ ]  Any anticoagulant use prior to admission (even if INR < 1.7)

[ ]  NIHSS > 25

[ ]  CT findings of >1/3 MCA

**\*\*\* Other reasons thrombolytic agent is not started for participants treated using MRI imaging selection beyond 4.5 hours:**

[ ]  Treatment cannot be started within 4.5 hours of symptom recognition

[ ]  Age > 80

[ ]  Parenchymal hyperintensity visible on FLAIR

[ ]  NIHSS > 25

[ ]  CT findings of >1/3 MCA or >50% of ACA or PCA territories, or > 100ml

[ ]  Any MRI findings indicative of a high risk of SICH

1. Was IV thrombolytic agent initiated at an outside hospital?[ ]  Yes [ ]  No

## **Intra-arterial (IA) Thrombolytic Therapy**

1. \*\*Was an IA procedure initiated at the current hospital? [ ]  Yes [ ]  No (Skip to 5)
2. \*\*Type of IA procedure: [ ]  Pharmacological [ ]  Mechanical [ ]  Both
3. Date and Time of groin puncture for IA procedure:
4. Date and Time IA catheter-based reperfusion initiated:
5. Date and Time of last angiographic image or the end time for mechanical/ pharmacologic intervention:
6. Was IA catheter-based reperfusion initiated at an outside hospital?

[ ]  Yes [ ]  No

## **Intra-sinus Thrombolytic Therapy**

1. Was an intra-sinus intervention (i.e., for cerebral venous thrombosis) performed?

[ ]  Yes [ ]  No (Skip to 7)

1. Type of intra-sinus procedure: [ ]  Pharmacological [ ]  Mechanical [ ]  Both
2. Date and Time of groin puncture for intra-sinus procedure:
3. Date and Time intra-sinus intervention initiated:

## **Other** **Thrombolytic Therapy**

1. Do the medical records suggest any type of investigational or experimental protocol for thrombolysis was used during provision of care?

[ ]  Yes [ ]  No

If YES, explain the protocol used:

Recorder Signature: Date:

## General Instructions

This case report form (CRF) contains data elements related to thrombolytic/ reperfusion therapy the participant is treated with during the acute hospital stay for the stroke event. Several of the elements were taken from the Get With The Guidelines® Stroke Patient Management Tool and/or the Paul Coverdell National Acute Stroke Registry.

Some of the CDEs are Supplemental-Highly Recommended based on study type, recent new data, disease stage and disease type or Exploratory as indicated by asterisks below. Please refer to Start-Up document for details.

\*\*Element is classified as Supplemental – Highly Recommended

\*\*\*Element is classified as Exploratory

The remaining data elements are Supplemental and should only be collected if the research team considers them appropriate for their study.

Please see the Data Dictionary for element classifications.

## Specific Instructions

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

The CRF includes most of the instructions available for the data elements at this time. The following elements have some additional instructions not included on the CRF.

* IV thrombolytic agent initiated – This refers to IV thrombolytic agent given at the FDA approved dose and within FDA approved guidelines.
* Date and Time IV thrombolytic agent initiated - This refers to IV thrombolytic agent given at the FDA approved dose and within FDA approved guidelines. If there are discrepancies in the documentation of bolus administration, the nursing documentation on the medication administration sheets should be treated as the most reliable source, followed by the stroke physician's documented time or ED note. Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](https://www.iso.org/iso-8601-date-and-time-format.html); YYYY-MM-DD T:hh:mm:ss.
* This data element applies only to participants for whom IV thrombolytic therapy was initiated at the current hospital. Do not abstract this data element if IV thrombolytic therapy was initiated at another hospital and participant was subsequently transferred to the current hospital.
* Total IV thrombolytic agent dose given - It is important to consult these other data elements when calculating the IV thrombolytic agent dose: Stroke Onset Time/ Time Participant Last Seen Well and Body Weight in kilograms.
* Endovascular procedure initiated - endovascular procedures include mechanical thrombectomy and all uses of intra-arterial thrombolytic therapy. Mechanical thrombectomy may be used alone or in conjunction with intra-arterial thrombolytic therapy.
* Date and time endovascular reperfusion initiated - The start time for endovascular reperfusion therapy should be either the date and time on the angio showing evidence of treatment, or the start time of the infusion or mechanical deployment if the angio time is not available. Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](https://www.iso.org/iso-8601-date-and-time-format.html); YYYY-MM-DD T:hh:mm:ss.
* Date and Time of the last mechanical or pharmacological intervention - If time of the last mechanical or pharmacological intervention not available, use the time on the last angiographic image. Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](https://www.iso.org/iso-8601-date-and-time-format.html); YYYY-MM-DD T:hh:mm:ss.
* Intra-sinus Intervention - Relevant to venous sinus and their large draining veins
* Date and Time intra-sinus intervention initiated - The start time for IS therapy should be either the date and time on the angio showing evidence of treatment, or the start time of the infusion or mechanical deployment if the angio time is not available. Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](https://www.iso.org/iso-8601-date-and-time-format.html); YYYY-MM-DD T:hh:mm:ss.
* Investigational or experimental protocol for thrombolysis - If investigational or experimental protocol was used there should be a signed IRB consent in the medical record.

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