Date information collected: mm/dd/yyyy

## Intravenous (IV) Thrombolytic Therapy

1. \*\*Was IV tPA initiated at this 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 tPA initiated: (mm/dd/yyyy) (hh:mm, 24 hr clock)
2. Total IV tPA dose given: (please specify) mg
3. Reason(s) no IV tPA started at this 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 Patient Arrival

Delay in Stroke diagnosis

In-hospital Time Delay

No IV access

MRI not feasible

CTP not feasible

Other, specify:

**Other reasons tPA 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 tPA given at outside hospital

Left heart thrombus

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

Pregnancy

Patient/ Family refused

Rapid improvement

Stroke severity nondisabling

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

### Other reasons tPA is not started for patients 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 tPA is not started for patients 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 tPA initiated at an outside hospital? Yes  No

## Intra-arterial (IA) Thrombolytic Therapy

1. \*\*Was an IA procedure initiated at this hospital?  Yes  No (Skip to 5)
2. \*\*Type of IA procedure:  Pharmacological  Mechanical  Both
3. Date and Time of groin puncture for IA procedure:

(mm/dd/yyyy), (hh:mm, 24 hr clock)

1. Date and Time IA catheter-based reperfusion initiated:

(mm/dd/yyyy), (hh:mm, 24 hr clock)

1. Date and Time of last angiographic image or the end time for mechanical/ pharmacologic intervention:

(mm/dd/yyyy), (hh:mm, 24 hr clock)

1. 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:

(mm/dd/yyyy), (hh:mm, 24 hr clock)

1. Date and Time intra-sinus intervention initiated:

(mm/dd/yyyy), (hh:mm, 24 hr clock)

## 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:

## General Instructions

This case report form (CRF) contains data elements related to thrombolytic/ reperfusion therapy the participant/ subject 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.

## 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 tPA initiated – This refers to IV tPA given at the FDA approved dose and within FDA approved guidelines.
* Date and Time IV tPA initiated - This refers to IV tPA 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.
* This data element applies only to patients for whom IV thrombolytic therapy was initiated at this hospital. Do not abstract this data element if IV thrombolytic therapy was initiated at another hospital and patient was subsequently transferred to this hospital.
* Total IV tPA dose given - It is important to consult these other data elements when calculating the IV tPA dose: Stroke Onset Time/ Time Patient 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 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.
* 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.
* Investigational or experimental protocol for thrombolysis - If investigational or experimental protocol was used there should be a signed IRB consent in the medical record.

References:

* Albers GW, Marks MP, Kemp S, Christensen S, Tsai JP, Ortega-Gutierrez S, McTaggart RA, Torbey MT, Kim-Tenser M, Leslie-Mazwi T, Sarraj A, Kasner SE, Ansari SA, Yeatts SD, Hamilton S, Mlynash M, Heit JJ, Zaharchuk G, Kim S, Carrozzella J, Palesch YY, Demchuk AM, Bammer R, Lavori PW, Broderick JP, Lansberg MG; DEFUSE 3 Investigators. Thrombectomy for Stroke at 6 to 16 Hours with Selection by Perfusion Imaging. N Engl J Med. 2018;378(8):708-718.
* Nogueira RG, Jadhav AP, Haussen DC, Bonafe A, Budzik RF, Bhuva P, Yavagal DR, Ribo M, Cognard C, Hanel RA, Sila CA, Hassan AE, Millan M, Levy EI, Mitchell P, Chen M, English JD, Shah QA, Silver FL, Pereira VM, Mehta BP, Baxter BW, Abraham MG, Cardona P, Veznedaroglu E, Hellinger FR, Feng L, Kirmani JF, Lopes DK, Jankowitz BT, Frankel MR, Costalat V, Vora NA, Yoo AJ, Malik AM, Furlan AJ, Rubiera M, Aghaebrahim A, Olivot JM, Tekle WG, Shields R, Graves T, Lewis RJ, Smith WS, Liebeskind DS, Saver JL, Jovin TG; DAWN Trial Investigators. Thrombectomy 6 to 24 Hours after Stroke with a Mismatch between Deficit and Infarct. N Engl J Med. 2018;378(1):11-21.
* Powers WJ, Rabinstein AA, Ackerson T, Adeoye OM, Bambakidis NC, Becker K, Biller J, Brown M, Demaerschalk BM, Hoh B, Jauch EC, Kidwell CS, Leslie-Mazwi TM, Ovbiagele B, Scott PA, Sheth KN, Southerland AM, Summers DV, Tirschwell DL; American Heart Association Stroke Council. 2018 Guidelines for the Early Management of Patients With Acute Ischemic Stroke: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association. [published correction appears in Stroke. 2018 Mar;49(3):e138] [published correction appears in Stroke. 2018 Apr 18;:]. Stroke. 2018;49(3):e46–e110.
* Thomalla G, Simonsen CZ, Boutitie F, Andersen G, Berthezene Y, Cheng B, Cheripelli B, Cho TH, Fazekas F, Fiehler J, Ford I, Galinovic I, Gellissen S, Golsari A, Gregori J, Günther M, Guibernau J, Häusler KG, Hennerici M, Kemmling A, Marstrand J, Modrau B, Neeb L, Perez de la Ossa N, Puig J, Ringleb P, Roy P, Scheel E, Schonewille W, Serena J, Sunaert S, Villringer K, Wouters A, Thijs V, Ebinger M, Endres M, Fiebach JB, Lemmens R, Muir KW, Nighoghossian N, Pedraza S, Gerloff C; WAKE-UP Investigators. MRI-Guided Thrombolysis for Stroke with Unknown Time of Onset. N Engl J Med. 2018;379(7):611-622.