

ARGATROBAN TIMELINE

*PLEASE REMEMBER TO USE STUDY SOURCE DOCUMENTS FOR BASELINE ASSESSMENTS

Updated 04/17/2013

BASELINE/Day 0:	Initial
Screening Inclusion/Exclusion Criteria - Don't forget to make sure PTT is sent and processing in the lab.	
TIME OUT W/ TEAM: **Verify patient weight is correct**	
Notify pharmacy for potential Argatroban pt and pt's weight in kg _____ IDS Telephone #: 4-1557	
History & Physical Exam	
ER Arrival time: Date: _____ Time: _____	
Stroke onset: Date: _____ Time: _____	
NIHSS pre-tPA bolus Time: _____, Score: _____ Pre-mRS: _____	
Baseline Tests: <input type="checkbox"/> ECG <input type="checkbox"/> CXR <input type="checkbox"/> CT brain w/o contrast	
Baseline Labs: <input type="checkbox"/> Chemistry (don't forget about bilirubin direct/indirect, AST/ALT) <input type="checkbox"/> Hematology <input type="checkbox"/> Serum HCG: if child-bearing age female Baseline PTT _____, INR _____	
CTA: TIMI Score: _____ OR TCD: TIBI Score: _____	
Informed Consent signed	
HAT score: _____ History of Diabetes mellitus or baseline blood glucose >200: No <input type="checkbox"/> 0 points Yes <input type="checkbox"/> 1 point NIHSS score: ≤14 <input type="checkbox"/> 0 points 15-20 <input type="checkbox"/> 1 point ≥21 <input type="checkbox"/> 2 points Hypodensity on CT scan: No <input type="checkbox"/> 0 points <1/3 of MCA territory <input type="checkbox"/> 1 point ≥1/3 of MCA territory <input type="checkbox"/> 2 point	
Randomization Website: https://cru.ccts.uth.tmc.edu/Stroke ***PRINT RANDOMIZATION PAGE*** <ul style="list-style-type: none"> • Print a dose calculation form, if applicable KEEP 2HR NIHSS ASSESSOR BLINDED TO TREATMENT ARM	
Vital signs Pre-tPA bolus: Time: _____ BP: _____ HR: _____ Continue every 15 min. for 2 hrs; then every 30 min for 6 hrs; then every 1hr until 24hrs from tPA bolus.	
tPA bolus dose: _____ Time given: _____ (TIME ZERO)	
Infusion dose: _____ Time given _____ Time completed _____	
Call Rigo Delgado (For sub-study analysis) about study patient: 713-899-3206	
Administer Argatroban (** Must administered ASAP within 60 min from tPA bolus/before tPA complete). Bolus dose: _____ Time given: _____ Infusion dose: _____ Time given: _____ Initial Rate: _____ NA if tPA Alone Arm	
NIHSS: 2h post-tPA bolus (± 30 min). (ALL STUDY ARMS) COVER IV BAG/PUMP, AS ASSESSOR MUST BE BLINDED.	

Signature _____ Print Name _____ Date _____ Time _____ 1

Time _____, Score _____	
TCD/CTA: 2-3 hr post-tPA (ALL STUDY ARMS-if enrolled with TCD/CTA)	
CTA: TIMI Score: _____ OR TCD: TIBI Score: _____	
PTT for Argatroban Arms: Scheduled: pre-tPA, 2, 6,12, 24hrs, 48 hr (± 30 min.) Unscheduled: 2-4 hr post dose change. (± 30 min.) ***PTTs LINKED TO ARGATROBAN BOLUS TIME***	

Day 1	Initial
NIHSS: 24h (± 4h) (ALL STUDY ARMS)	
Time: _____ Score: _____	
Labs: (ARGATROBAN ARMS ONLY)	
Scheduled: 2, 6, 12, 24hrs, (± 30 min.)	
Unscheduled: 2-4 hr post dose change. (± 30 min.)	

Signature _____ Print Name _____ Date _____ Time _____

Day 2 (48h post-tPA/end Argatroban) (± 4h) (ALL STUDY ARMS)	Initial
Scheduled Date: _____ Time: _____	
Vital Signs (24-48 hrs):	
Every 4 ± 1 hr	
Physical Exam	
Labs:	
<input type="checkbox"/> Chemistry	
<input type="checkbox"/> Hematology	
Tests:	
<input type="checkbox"/> CT brain w/o contrast	
NIHSS: Time _____, Score _____	
Adverse event and concomitant medication assessments (within 24 h after the completion of the infusion or prior to hospital discharge).	
Discontinue Argatroban	
D/C Time: _____	

Signature _____ Print Name _____ Date _____ Time _____

Day 7 or Discharge (whichever comes first) (ALL STUDY ARMS)	Initial
Physical Exam	
NIHSS : Time _____, Score _____	
mRS: Score _____	
Health Utilities Forms (standard gamble, VAS, EQ-5D)	
ACE, MoCA	

Day 90 (± 10 days) (ALL STUDY ARMS)	Initial
NIHSS : Time _____, Score _____	
mRS: Score _____	
ACE, MoCA	
Concomitant medications	
AE reporting	
Health Utilities Forms (standard gamble, VAS, EQ-5D)	

Signature _____ Print Name _____ Date _____ Time _____ 2

Scheduled PTT Lab draws (\pm 30 min):
With exception of baseline, please make sure to order PTT ONLY for the rest of the blood draws. NO PT & INR

	Initial
Baseline pre-tPA bolus	
2 Hours post-Argatroban bolus	
6 Hours	
12 Hours	
24 Hours	
48 Hours: End of Argatroban infusion/48 hrs Post tPA bolus	

*****Please repeat PTT 2-4 hours after any dosage changes *****

The unscheduled draw may be used as the scheduled draw if draw time is within 30 minutes of scheduled draw time

Please notify the ARTSS-2 TEAM of any adverse events or serious adverse events in this study.

ARTSS-2 Coordinating Center Contact Information:

PI: Andrew Barreto, MD	(O) 713-500-7002	(C) 713-702-6721
Project Manager: Loren Shen RN	(O) 713-500-7084	(C) 832-515-7582
Study Coordinator: Amber Jacobs	(O) 713-500-7194	(C) 281-851-3717
Study Coordinator: Hari Indupuru	(O) 713-500-7537	(C) 617-417-5140
Fax: 713-500-0628		

Data Coordinating Center Contact Information (for randomization or website questions):

Li Xiaobao (Bob):	(O) 713-500-7961	(C) 713-371-8093
Rick Sline:	(O) 713-500-7067	(C) 832-969-1248

ARTSS-2 STUDY CASE REPORT FORMS

Patient # - Initials

Vital Signs

From To

M M D D Y Y Y Y M M D D Y Y Y Y

Record Vital Signs at: Pre-tPA Bolus, Q 15 min x 2 hours, Q 30 min x 6 hours, Q 1 hour x 16 hours. Then Q4 hours +/-1 hour from 24-48hr.

	TIME	HR	BP	Not done
Pre-bolus			/	<input type="checkbox"/>
			/	<input type="checkbox"/>
Q15min			/	<input type="checkbox"/>
			/	<input type="checkbox"/>
			/	<input type="checkbox"/>
			/	<input type="checkbox"/>
			/	<input type="checkbox"/>
			/	<input type="checkbox"/>
Q30min			/	<input type="checkbox"/>
			/	<input type="checkbox"/>
			/	<input type="checkbox"/>
			/	<input type="checkbox"/>
			/	<input type="checkbox"/>
			/	<input type="checkbox"/>
			/	<input type="checkbox"/>
			/	<input type="checkbox"/>
			/	<input type="checkbox"/>
			/	<input type="checkbox"/>

	TIME	HR	BP	Not done
Q1hr			/	<input type="checkbox"/>
			/	<input type="checkbox"/>
			/	<input type="checkbox"/>
			/	<input type="checkbox"/>
			/	<input type="checkbox"/>
			/	<input type="checkbox"/>
			/	<input type="checkbox"/>
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			/	<input type="checkbox"/>
			/	<input type="checkbox"/>
			/	<input type="checkbox"/>
			/	<input type="checkbox"/>
			/	<input type="checkbox"/>
	Q4hr			/
			/	<input type="checkbox"/>
			/	<input type="checkbox"/>
			/	<input type="checkbox"/>

Comment: _____

Please add on the following laboratory tests for
_____ (MRN: _____)

Direct bilirubin

Indirect bilirubin

(Investigators, please retain a copy of this sheet for
the patient's research chart)

Patient Name: _____

MRN: _____ Patient ID: _____ - _____

ARTSS-2 Study Source Document

Baseline Physical Exam

Visit Type:	
Date : _____	Time: _____

	Normal	Abnormal	Not Done	Comments
General Appearance				
Head/Ears/Eyes/ Nose/Mouth/Throat				
Neck/Thyroid				
Respiratory				
Cardiovascular				
Gastrointestinal				
Musculoskeletal				
Genito-Urinary				
Skin				
Lymph Nodes				
Neurological* (Should NOT include current findings related to stroke deficit)				
Other, specify:				

Name of person performing physical exam

Signature of person performing physical exam

Date

Patient Name: _____

MRN: _____ Patient ID: _____

ARTSS-2 Study Source Document

NIHSS

Assessment :	
<input checked="" type="checkbox"/> Baseline	<input type="checkbox"/> 48 hours \pm 4 hr post-TPA bolus
<input type="checkbox"/> 2 \pm 30 min post-TPA bolus	<input type="checkbox"/> Day 7/Discharge
<input type="checkbox"/> 24 hours \pm 4 hr post-TPA bolus	<input type="checkbox"/> Day 90

NIHSS

1a-LOC

0-alert 1-drowsy 2-stupor 3-comatose

1b-LOC questions

0-both 1-one 2-neither

1c-LOC commands

0-both 1-one 2-neither

2-Best Gaze

0-nl 1-partial 2-forced gaze

3-Visual Fields

0-nl 1-partial 2-complete 3-bilateral

4-Facial Paresis

0-nl 1-minor 2-partial 3-complete

5-8 MOTOR

____ 5-Left Arm

____ 6-Right Arm

____ 7-Left Leg

____ 8-Right Leg

0 = no drift

1 = drift

2 = some effort vs gravity

3 = no effort vs gravity

4 = no movement

x = untestable

9-Limb Ataxia

0-abs 1-1 limb 2-2 + limbs x-untestable

10-Sensory

0-nl 1-partial loss 2-dense loss

11-Best Language/Aphasia

0-nl 1-mild/mod 2-severe 3-mute

12-Dysarthria

0-nl 1-mild/mod 2-severe x-untestable

13-Neglect/Inattention

0-non 1-partial 2-complete

NAME: _____

SIGNATURE: _____

mRS: Pre-Morbid

Day _____

DC

2 \pm 30 min post-TPA bolus & Day 90 ONLY

Was the rater blinded to treatment arm? Yes No N/A

Patient Name: _____

MRN: _____ Patient ID: _____

ARTSS-2 Study Source Document

Modified Rankin Scale

Date : _____	Time: _____
<input checked="" type="checkbox"/> Baseline	<input type="checkbox"/> Day 7/Discharge <input type="checkbox"/> Day 90

- | Score | Description |
|-------|--|
| 0 | No symptoms at all |
| 1 | No significant disability despite symptoms; |
| 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 assistanceable to carry out all usual duties and activities |
| 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 |

Name of rater

Signature of rater

Date

Patient Name: _____

MRN: _____ Patient ID: ___ - ___

ARTSS-2 Study Source Document

Medical History

History of Prior Stroke

Yes No Unknown

Date of most recent prior stroke: _____

Number of prior strokes: _____

History of TIA

Yes No Unknown

Date of most recent prior TIA: _____

Number of prior TIAs: _____

Current Stroke Symptoms:

Weakness	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Sensory Chan	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Dysarthria	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Visual Change	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Aphasia	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Dizziness/Ver	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown

Please indicate if patient had any medical problems involving the following systems:

Cardiac

Myocardial Infarction	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown	Gastrointestinal	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
CHF	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown	Genitourinary	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
Atrial Fibrillation	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown	Pulmonary	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
Hypertension	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown	Endocrine	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
Previous CABG	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown	Cancer	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
Hypercholesterolemia	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown	Diabetes	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown

Other , specify _____

Has patient ever had:

			If Yes, check on		Right	Left	Both
Carotid Endarterectomy	<input type="checkbox"/> Yes	<input type="checkbox"/> No			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Fem./ Pop. Bypass	<input type="checkbox"/> Yes	<input type="checkbox"/> No			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cigarette Smoking	<input type="checkbox"/> Never	<input type="checkbox"/> Former	<input type="checkbox"/> Current	<input type="checkbox"/> Unknown			
Alcohol Consumption	<input type="checkbox"/> Never	<input type="checkbox"/> Former	<input type="checkbox"/> Current	<input type="checkbox"/> Unknown			

Ethnicity: Hispanic or Latino Not Hispanic or Latino Unknown Not reported

Race: American Indian or Alaskan Black White Asian Native Hawaiian or Pacific Unknown Other

Handedness Right Left Both

Name of person completing form

Signature of person completing form

Date

Patient Name: _____

MRN: _____ Patient ID: _____-_____-_____

ARTSS-2 Study Source Document

Baseline CT

Date : _____ Time: _____

Was an intracranial hemorrhage (ICH) Noted? Yes No

Is there acute hypoattenuation present or any other lesion that would preclude treatment? Yes No

If Yes to either, describe below:

ASPECTS Score : 10 Points · _____ = _____ points

*Please check the box for each area with a hypodensity

Subcortical:

- Caudate head Lentiform nucleus
- Internal Capsule

MCA Cortex:

- Insular cortex M1 (low frontal)
- M2 (temporal) M3 (low parietal)
- M4 (high frontal) M5 (lateral MCA territory)
- M6 (high posterior parietal)

Comments: _____

Name of person completing form

Signature of person completing form

Date

Patient Name: _____

MRN: _____ Patient ID: _____

ARTSS-2 Study Source Document

CT-Angiogram

Date : _____	Time: _____
<input type="checkbox"/> Baseline	<input type="checkbox"/> 2-3 hours post TPA bolus

Vessel Occlusion Location (SELECT ONLY ONE SYMPTOMATIC VESSEL)

MCA

M1 M2 (proximal)

ICA (terminal)

PCA

P1 P2 (proximal)

Vertebro-basilar

other: _____

TIMI Score

0—Abrupt cut-off of vessel, complete occlusion

1—Artery penetrated by contrast, but no distal branch filling

2- Perfusion and incomplet or slow distal branch filling

3- Full perfusion with filling of all distal branches

Name of person completing form

Signature of person completing form

Date

Investigational Drug Study: ARTSS-2
Argatroban Intravenous Administration Orders

Checklist	
<input type="checkbox"/> Was Home Med List faxed to Pharmacy (Must be faxed to Pharmacy prior to dispensing of Study Drug) <input type="checkbox"/> Admit to: <input type="checkbox"/> Stroke Unit/Neuro Step-down Unit <input type="checkbox"/> MICU Attending: _____ Diagnosis: _____ Secondary diagnoses: _____ Allergies: _____ Weight: _____ <input type="checkbox"/> Patient/family informed of benefits and risks of Argatroban Height: _____ <input type="checkbox"/> Symptom onset between 3 to 4.5 hours <input type="checkbox"/> Check if the informed consent has been signed by the patient or authorized representative and has been placed in the patient's medical record.	
Contact Pharmacy at ext 2854/2856 at the time of alteplase administration to inform them that there is a potential ARTSS-2 patient who might be randomized to receive Argatroban. Monday –Friday between 9:30 am – 5:30 pm please contact Research Pharmacy at ext 4340.	
Pharmacy Orders	
Investigational Study – Argatroban Drip (ARTSS-II) Loading Dose (Note: Argatroban must be initiated prior to the end of alteplase infusion given in ER; prepare STAT) Prepare Argatroban 250 mg/250 ml NS: Bolus dose: (_____ kg) x (100 micrograms/kg) = _____ mcg Infuse Loading dose from bag (drip) to be given over 5 minutes (please use pump to infuse loading dose) Remainder of drug in infusion bag is to be used for maintenance dose	Investigational Study – Argatroban Drip (ARTSS-II) Maintenance Dose (250mg argatroban in 250ml 0.9% NS) Start Argatroban IV infusion at (check): <input type="checkbox"/> Low Dose: 1 micrograms/kg/min <input type="checkbox"/> High Dose: 3 micrograms/kg/min Titrate based on aPTT results per protocol up to a maximum of 10 micrograms/kg/min Goal is to achieve a target aPTT of 1.75 and 2.25 times of baseline for low dose and high dose group respectively
Nurse Instructions: Infusion bag of Argatroban 250mg/250ml of 0.9% NS must not hang for more than 24 hours Initial bag hung on: Date _____ Time _____ Discontinue Argatroban Infusion at the end of 48 hours . Infusion not to exceed 48 hour period on Date _____ Time _____	
ICH Protocol	
1. Discontinue alteplase and Argatroban 2. Type and Cross 3. Check fibrinogen level stat and every 6 hours 4. Give 10-20 units cryoprecipitate 5. Repeat cryoprecipitate (cryo) to bring fibrinogen > 100 mg/dl (1 unit cryo raises fibrinogen 5-10 mg/dl); May give fresh frozen plasma in case of no cryo (1 unit of cryo is made from 1 bag of FFP); 6. Give platelet concentrate if platelet count is low	
Investigators and Sub-investigators: (only prescribers listed on FDA 1572 may prescribe study drug) <input type="checkbox"/> Volodymyr Vulkanov Please check off your name and sign and date below <input type="checkbox"/> Steven Levine <input type="checkbox"/> Richard Sinert <input type="checkbox"/> Pia Chatterjee <input type="checkbox"/> Diana Rojas-Soto <input type="checkbox"/> Jennifer Martindale <input type="checkbox"/> Ethan Brandler <input type="checkbox"/> Lorenzo Paladino <input type="checkbox"/> Helen Valsamis <input type="checkbox"/> Benedict Tan <input type="checkbox"/> Priyank Khandelwal Prescriber signature: _____ Date/Time: _____ <input type="checkbox"/> Adrian Marchidann	
RN Name/Signature	Date/Time:

Patient Name: _____

MRN: _____ Patient ID: _____

ARTSS-2 STUDY SOURCE DOCUMENT

aPTT Worksheet

Weight (kg): _____	SCHEDULED PTT DRAWS: 2 Hour TARGET TIME: _____ 6 Hour TARGET TIME: _____ 12 Hour TARGET TIME: _____ 24 Hour TARGET TIME: _____ 48 Hour TARGET TIME: _____					Target aPTT Range: _____ Baseline aPTT: _____				
						Arg. Bolus Date: _____ Time: _____ Infusion Start Date: _____ Time: _____ Infusion Stop Date: _____ Time: _____				
Date (mm-dd-yyyy)	Actual Draw Time (0000-2359)	Type for Draw -Scheduled: 2hr, 6hr, 12hr, 24hr, 48hr -Unscheduled: PRN	Comments *provide reason for PRN draws	aPTT Lab Result Time	aPTT (sec)	Argatroban Dose Adjustment [‡]		New Infusion Rate		Initials
						Date & Time of Change	Amount of rate change µg/kg/min	µg/kg/min	cc/hour	
							↑ by _____ µg/kg/min ↓ by _____ µg/kg/min <input type="checkbox"/> infusion held <input type="checkbox"/> infusion stopped <input type="checkbox"/> infusion restarted <input type="checkbox"/> No change			
							↑ by _____ µg/kg/min ↓ by _____ µg/kg/min <input type="checkbox"/> infusion held <input type="checkbox"/> infusion stopped <input type="checkbox"/> infusion restarted <input type="checkbox"/> No change			
							↑ by _____ µg/kg/min ↓ by _____ µg/kg/min <input type="checkbox"/> infusion held <input type="checkbox"/> infusion stopped <input type="checkbox"/> infusion restarted <input type="checkbox"/> No change			
							↑ by _____ µg/kg/min ↓ by _____ µg/kg/min <input type="checkbox"/> infusion held <input type="checkbox"/> infusion stopped <input type="checkbox"/> infusion restarted <input type="checkbox"/> No change			

°aPTT will be checked at: baseline (prior to the rt-PA and Argatroban bolus dose); 2 hrs (±30 min); 6 hrs (± 30 min); 12 hrs (± 30 min); 24 hrs (± 30 min) and 48 hrs (± 30 min).

°aPTT will be drawn every 2-4 hours after each dose change (unless the scheduled pTT is due within 30 minutes).

‡Use dose calculation guideline for adjustments.

Name: _____

Signature: _____

Page ___ of ___

Patient Name: _____

MRN: _____ Patient ID: _____

ARTSS-2 STUDY SOURCE DOCUMENT
aPTT Worksheet

Date (mm-dd-yyyy)	Actual Draw Time (0000-2359)	Type for Draw -Scheduled: 2hr, 6hr, 12hr, 24hr, 48hr -Unscheduled: PRN	Comments *provide reason for PRN draws	aPTT Lab Result Time	aPTT (sec)	Argatroban Dose Adjustment [‡]		New Infusion Rate		Initials
						Date & Time of Change	Amount of rate change µg/kg/min	µg/kg/min	cc/hour	
							↑ by _____ µg/kg/min ↓ by _____ µg/kg/min <input type="checkbox"/> infusion held <input type="checkbox"/> infusion stopped <input type="checkbox"/> infusion restarted <input type="checkbox"/> No change			
							↑ by _____ µg/kg/min ↓ by _____ µg/kg/min <input type="checkbox"/> infusion held <input type="checkbox"/> infusion stopped <input type="checkbox"/> infusion restarted <input type="checkbox"/> No change			
							↑ by _____ µg/kg/min ↓ by _____ µg/kg/min <input type="checkbox"/> infusion held <input type="checkbox"/> infusion stopped <input type="checkbox"/> infusion restarted <input type="checkbox"/> No change			
							↑ by _____ µg/kg/min ↓ by _____ µg/kg/min <input type="checkbox"/> infusion held <input type="checkbox"/> infusion stopped <input type="checkbox"/> infusion restarted <input type="checkbox"/> No change			
							↑ by _____ µg/kg/min ↓ by _____ µg/kg/min <input type="checkbox"/> infusion held <input type="checkbox"/> infusion stopped <input type="checkbox"/> infusion restarted <input type="checkbox"/> No change			

◦aPTT will be checked at: baseline (prior to the rt-PA and Argatroban bolus dose); 2 hrs (±30 min); 6 hrs (± 30 min); 12 hrs (± 30 min); 24 hrs (± 30 min) and 48 hrs (± 30 min).

◦aPTT will be drawn every 2-4 hours after each dose change (unless the scheduled pTT is due within 30 minutes).

‡Use dose calculation guideline for adjustments.

Name: _____

Signature: _____

Page ___ of ___

Patient Name: _____

MRN: _____ Patient ID: _____

ARTSS-2 STUDY SOURCE DOCUMENT

aPTT Worksheet

Date (mm-dd-yyyy)	Actual Draw Time (0000-2359)	Type for Draw -Scheduled: 2hr, 6hr, 12hr, 24hr, 48hr -Unscheduled: PRN	Comments *provide reason for PRN draws	aPTT Lab Result Time	aPTT (sec)	Argatroban Dose Adjustment [‡]		New Infusion Rate		Initials
						Date & Time of Change	Amount of rate change µg/kg/min	µg/kg/min	cc/hour	
							↑ by _____ µg/kg/min ↓ by _____ µg/kg/min <input type="checkbox"/> infusion held <input type="checkbox"/> infusion stopped <input type="checkbox"/> infusion restarted <input type="checkbox"/> No change			
							↑ by _____ µg/kg/min ↓ by _____ µg/kg/min <input type="checkbox"/> infusion held <input type="checkbox"/> infusion stopped <input type="checkbox"/> infusion restarted <input type="checkbox"/> No change			
							↑ by _____ µg/kg/min ↓ by _____ µg/kg/min <input type="checkbox"/> infusion held <input type="checkbox"/> infusion stopped <input type="checkbox"/> infusion restarted <input type="checkbox"/> No change			
							↑ by _____ µg/kg/min ↓ by _____ µg/kg/min <input type="checkbox"/> infusion held <input type="checkbox"/> infusion stopped <input type="checkbox"/> infusion restarted <input type="checkbox"/> No change			
							↑ by _____ µg/kg/min ↓ by _____ µg/kg/min <input type="checkbox"/> infusion held <input type="checkbox"/> infusion stopped <input type="checkbox"/> infusion restarted <input type="checkbox"/> No change			

◦aPTT will be checked at: baseline (prior to the rt-PA and Argatroban bolus dose); 2 hrs (±30 min); 6 hrs (± 30 min); 12 hrs (± 30 min); 24 hrs (± 30 min) and 48 hrs (± 30 min).

◦aPTT will be drawn every 2-4 hours after each dose change (unless the scheduled pTT is due within 30 minutes).

‡Use dose calculation guideline for adjustments.

Name: _____

Signature: _____

Updated

Patient Name: _____

MRN: _____ Patient ID: _____

ARTSS-2 Study Source Document

NIHSS

Assessment :	
<input type="checkbox"/> Baseline	<input type="checkbox"/> 48 hours \pm 4 hr post-TPA bolus
<input checked="" type="checkbox"/> 2 \pm 30 min post-TPA bolus	<input type="checkbox"/> Day 7/Discharge
<input type="checkbox"/> 24 hours \pm 4 hr post-TPA bolus	<input type="checkbox"/> Day 90

NIHSS

1a-LOC

0-alert 1-drowsy 2-stupor 3-comatose

1b-LOC questions

0-both 1-one 2-neither

1c-LOC commands

0-both 1-one 2-neither

2-Best Gaze

0-nl 1-partial 2-forced gaze

3-Visual Fields

0-nl 1-partial 2-complete 3-bilateral

4-Facial Paresis

0-nl 1-minor 2-partial 3-complete

5-8 MOTOR

____ 5-Left Arm

____ 6-Right Arm

____ 7-Left Leg

____ 8-Right Leg

0 = no drift

1 = drift

2 = some effort vs gravity

3 = no effort vs gravity

4 = no movement

x = untestable

9-Limb Ataxia

0-abs 1-1 limb 2-2 + limbs x-untestable

10-Sensory

0-nl 1-partial loss 2-dense loss

11-Best Language/Aphasia

0-nl 1-mild/mod 2-severe 3-mute

12-Dysarthria

0-nl 1-mild/mod 2-severe x-untestable

13-Neglect/Inattention

0-non 1-partial 2-complete

NAME: _____

SIGNATURE: _____

mRS: Pre-Morbid

Day _____

DC

2 \pm 30 min post-TPA bolus & Day 90 ONLY

Was the rater blinded to treatment arm? Yes No N/A

Patient Name: _____

MRN: _____ Patient ID: _____

ARTSS-2 Study Source Document

CT-Angiogram

Date : _____	Time: _____
<input type="checkbox"/> Baseline	<input checked="" type="checkbox"/> 2-3 hours post TPA bolus

Vessel Occlusion Location (SELECT ONLY ONE SYMPTOMATIC VESSEL)

MCA

M1 M2 (proximal)

ICA (terminal)

PCA

P1 P2 (proximal)

Vertebro-basilar

other: _____

TIMI Score

0—Abrupt cut-off of vessel, complete occlusion

1—Artery penetrated by contrast, but no distal branch filling

2- Perfusion and incomplet or slow distal branch filling

3- Full perfusion with filling of all distal branches

Name of person completing form

Signature of person completing form

Date