Demographics 0 When attempting to register a new patient (whether with the intent to randomize or just a prior screen failure), you must first resolve any red errors (displayed after saving the form) before the registration will succeed. After a successful registration, you will see the visit tabs and a screening patient number.

> age\_at\_registration Age: Gender: Male ▼ gender gender Male Hispanic="Yes"Hispanic or Latino Ethnicity: Female Hispanic="No"Not Hispanic or Latino ☐ Indian or Alaskan="Indian or Alaskan "American Indian or Alaskan Native African American="African-Hawaiian\_or\_Pacific="Hawaiian or American Black or African Pacific"Native Hawaiian or Other Pacific American Race: Islander Asian="Asian"Asian Aboriginal Torres="Aboriginal/Torres White="White"White Strait Islander "Aboriginal/Torres Strait Islander (Australia) Initial Eligibility (Early Exclusion)

Type of Screen: O type of entry="Historic" Historic - Not screened until after 72h window • type of entry="Current - Patient still within enrollment window" Current - Patient still within enrollment window

# **Initial Eligibility:**

initial eligibility="No Early Exclusion"Proceeding to further evaluation

Immediate un-resolvable protocol exclusion (per preliminary chart review or presenting medical history)

- initial\_eligibility="ICH due to trauma"ICH due to trauma or other non-spontaneous etiology (hemorrhagic conversion of ischemic stroke) initial eligibility="Onset window"Symptom onset more than 24h prior to Diagnostic CT or unknown (if found down, known to be normal < 24h ago) initial\_eligibility="Historic Rankin"Historic (pre-stroke) Modified Rankin Score not 0 or 1 initial eligibility="Age exclusion" Age < 18 or > 80 years initial eligibility="Coagulopathy"Irreversible coagulopathy or clotting disorder initial\_eligibility="Anticoagulated"Will be unable to maintain normalized coagulation (INR <= 1.4) for 30 days initial eligibility="Dabigatran" Use of dabigatran at time of, or shortly before, symptom initial eligibility="Internal bleeding"Internal bleeding (retroperitoneal, GI, GU or respiratory sites, etc.) initial eligibility="External bleeding" External bleeding (vascular access or surgical sites, etc.) initial\_eligibility="Pregnancy"Pregnancy or suspected pregnancy initial eligibility="Allergy"Allergy/sensitivity to tPA initial eligibility="Prior enrollment"Prior enrollment (i.e., previously enrolled in this or a prior MISTIE study) initial eligibility="Interventional trial" Planned or simultaneous participation in another interventional trial initial\_eligibility="DNR status"DNR/DNI status or not expected to survive 365 days initial eligibility="Illness"Concurrent serious illness that would confound safety or efficacy assessments initial\_eligibility="Mechanical valve" Mechanical heart valve initial eligibility="Embolism risk" Risk of embolism (e.g., has thrombus, stenosis, carditis, afib, etc.)
- Radiographic exclusion (per diagnostic CT or other early imaging)

\*Note: Selecting any in this category will blank-out and hide the diagnostic CT form.

- initial eligibility="Infratentorial"Infratentorial hemorrhage
- initial eligibility="IVH requiring treatment" IVH requiring treatment

initial eligibility="Hazard"Condition posing significant hazard if enrolled

- initial eligibility="Midbrain extension"Midbrain extension of thalamic bleed with 3<sup>rd</sup>nerve palsy or dilated non-reactive pupils, posterior fossa ICH or cerebellar hematoma
- initial eligibility="Brain stem impaired"Irreversible impaired brain stem function or GCS <= 4</p>

 initial eligibility="Addiction"Drug or alcohol dependence that might impact schedule compliance initial eligibility="Unstable" Unstable & would benefit from a specific intervention (e.g., crainotomy)

- initial eligibility="Vascular etiology"Vascular anomaly as likely etiology of the bleed Specify:
  - initial\_eligibility\_vascular="Moyamoya"Moyamoya disease
  - initial\_eligibility\_vascular="Aneurysm"Aneurysm, mycotic aneurysm AVM or other vascular anomaly

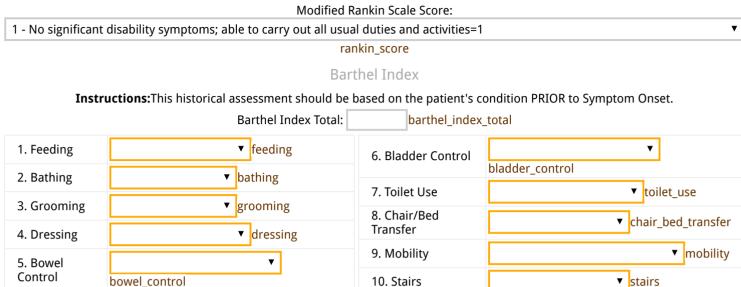
initial_eligibility="Tumor"Unstable mass/tumor or evolving intra	acranial compa	tment syndrome		
End-of-Window Exclusions				
initial_eligibility="ICH less than 30ml"ICH size < 30ml				
initial_eligibility="GCS score greater than 14 or NIHSS less than	6"GCS score >	4 or NIHSS < 6		
initial_eligibility="ICH not stable"ICH not stable				
initial_eligibility="SBP could not be maintained below 180"SBP	could not be ma	nintained below 180		
initial_eligibility="INR, PLT, PT or aPTT could not be regulated" I	INR, PLT, PT or a	PTT could not be regulated		
initial_eligibility="Unable to randomize within 72h"Unable to ra		•		
Other screening failure				
initial_eligibility="Not consented"Patient eligible but consent re	efused, other in	bility to obtain consent		
List staff conducting: consent	t_by			
Reason unable to obtain: consent	_refused_reaso	า		
initial_eligibility="Missed screen"Not evaluated within 72h wind missed screen specify	dow (and <u>NO</u> ot	ner <u>IMMEDIATE</u> exclusion) <b>Expla</b>	n why missed	:
initial_eligibility="Excluded other"Other reason* for immediate	exclusion			
Please verify that the exclusion is not already available in the above	e list. If it is, ple	ase select the appropriate exclus	on.	
Specify:	exclude	d_other_specify		
*Do not use this "Other reason" option to give multiple reasons! List only Cabove (e.g., "Anticipating non-compliance with follow-ups because no perm Symptom Onse  Symptom Onset Date/Time(Last Known to Be Well): 06-Jul-2015	nanent address.	"). Il Admission		symptom_onset_minute
Patient is excluded if symptom onset was more than 24 hours prior to diagnostic CT Please upload ambulance records and any other evidence (witness interview) of hou			ours; see imme	diate exclusions above.
Arrival at Enro	olling Site (you	hospital):		
prior_admit="on"Patient already in this h		-	nosed.	
Arrival date/time: 07-Jul-2015 site_arrival_	_date 10 ▼	site_arrival_hour: 00 ▼ site_a	rival_minute	
Was ICH first diagnosed at an outside facility (other than your h  Please obtain and upload outside hospital records, including the CT which from an outside facility, a  Arrival at Outside Facility:  osh_arr	was used to did	ngnose ICH. The FIRST scan that stained and uploaded.	outside_diagr hows ICH is to _arrival_minu	he diagnostic CT, even if
Arrival at Outside Lacility.	i ivai_uate	osn_arrival_nour . osn		
Patient Status (Computed upon Save):	patient_statu: patient_statu:	="In Screening" In-Screening ="Prescreen Fail" Pre-Screen Fai ="Randomized" Randomized ="Screen Failure" Screen Failure	ure	
	patient_statu:			
		Signature	State	Date/Time
		testsc TEST SITE ONLY - Coordina	tor In-Work	07-Jul-2015 01:59 CDT



Study: MISTIE III Training | Site: Testing - 888 | Patient: 888-6037 | Form: Screening-Scales-Historic

## Modified Rankin Scale

Instructions: This historical assessment should be based on the patient's condition PRIOR to Symptom Onset.



Signature		State	Date/Time	
	testsc TEST SITE ONLY - Coordinator	In-Work	07-Jul-2015 01:59 CDT	

# Dropdown box codes

rankin\_score 0=No symptoms

1=No significant disability symptoms

2=Slight disability 3=Moderate disability

4=Moderate to severe disability

5=Severe disability 6=Death

feeding 0=Unable 5=Needs help

0=Unable

5=Major help

10=Minor help

15=Independent

10=Independent

chair\_bed\_transfer

0=Dependent =Independent

bathing grooming 0=Needs help 5=Independent

mobility 0=Immobile

5=Wheel chair dependent 10=Walks with help 5=Independent

dressing bowel control 0=Dependent 0=Incontinent =Needs help =Occasional accident 10=Independent 10=Continent

stairs

0=Unable

5=Needs help

10=Independent

bladder\_control 0=Incontinent =Occasional accident 10=Continent

toilet\_use 0=Dependent =Needs some help 10=Independent



Study: MISTIE III Training | Site: Testing - 888 | Patient: 888-6037 | Form: Screening-Diagnostic CT

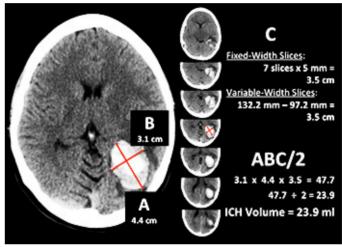
Identification ct not done="on" CT Not Done

The FIRST scan that shows ICH is the diagnostic CT, even if from an outside facility, and the imaging must be obtained and uploaded. Patient cannot be enrolled without this scan as it establishes the enrollment window and clot location needed to adaptively randomize.

Date & Time of CT: 07-Jul-2015 CT\_date 11 ▼ CT\_hour: 00 ▼ CT\_minute







**Eligibility Verification** 

If any of the below exclusions are noted while reviewing this CT, do the following

- If noted during initial screening (prior to consent), go back to the Registration form and click the appropriate button, doing so will hide all subsequent forms including this one.
- If discovered after randomization, enter on the protocol deviation form.

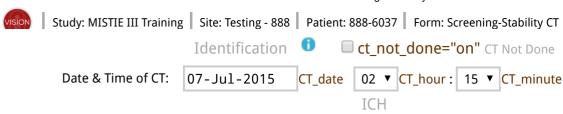
## Exclusions:

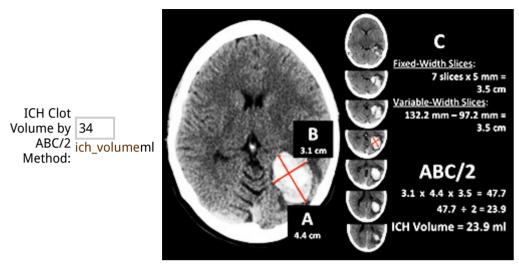
- ICH size less than 30 mL on last pre-RND stability CT
- Infratentorial hemorrhage
- IVH requiring treatment
- Midbrain extension of a thalamic bleed with 3rd nerve palsy or dilated non-reactive pupils, posterior fossa ICH or cerebellar hematoma
- Irreversible impaired brain stem function or GCS ≤ 4
- Vascular anomaly as likely etiology of the bleed (Moyamoya, aneurysm, AVM, etc.)
- Unstable mass/tumor or evolving intracranial compartment syndrome

# Dropdown box codes

clot\_location
Temporal
Parietal
Ocupital
Caudate
Lobar
Thalamus
Globus Pallidus
Putamen
Other

Signature	State	Date/Time	
testsc TEST SITE ONLY - Coordinator	In-Work	07-Jul-2015 02:00 CDT	





**Eligibility Verification** 

If any of the below exclusions are noted while reviewing this CT, do the following

- If noted during initial screening (prior to consent), go back to the Registration form and click the appropriate button, doing so will hide all subsequent forms including this one.
- If discovered after consent, document in the Baseline > Randomization > Final Eligibility Verification section.
- If discovered after randomization, enter on the protocol deviation form.

### **Exclusions:**

- ICH size less than 30 mL on last pre-RND stability CT
- · Infratentorial hemorrhage
- IVH requiring treatment
- Midbrain extension of a thalamic bleed with 3rd nerve palsy or dilated non-reactive pupils, posterior fossa ICH or cerebellar hematoma
- Irreversible impaired brain stem function or GCS ≤ 4
- Vascular anomaly as likely etiology of the bleed (Moyamoya, aneurysm, AVM, etc.)
- Unstable mass/tumor or evolving intracranial compartment syndrome

# New Bleeding:

If any of the following are noted, enter on the Adverse Event (MH/AE) form. (Note: all bleeds are considered Medical Events of Interest and therefore also require adding an SAE/MEOI form to provide additional details.)

- Any new (non-index) ICH site > 5 ml
- Enlargement of the Index ICH clot size by more than 5 ml
- Enlargement of the Index IVH clot size by more than 5 ml
- Any bleeding along a catheter tract
- Any other new intracranial bleed

Remember to upload the DICOM (CT) files to the Source Documents page, whether or not the patient was randomized.

Signature	State	Date/Time	
testsc TEST SITE ONLY - Coordinator	In-Work	07-Jul-2015 02:07 CDT	

#	Imaging Studies (Was MRI done?)	Date and Time
	▼ imaging_study(1)	imaging_date(1) ▼
1 [	imaging_study_other_specify(1)	
Plea	ase upload DICOM images to the Source Docs tab	
Finding(s	5):	
Note: Ple		ding possible structural etiology for bleed and associated ization form.
	aneurysm="on"Aneurysm or mycotic aneurysm	mass="on"Mass or tumor
	avm="on"AVM	other_finding="on"Other, specify:
	□ moyamoya="on"Moyamoya	other_finding_specify Factors
CH Risk	factors present at the time of symptom onset:	ractors
	anticoagulated="on"Anticoagulated	renal_failure="on"Renal failure
	coagulopathy="on"Coagulopathy	ischemic_stroke="on"History of ischemic stroke or TIA
(	antiplatelets="on"Antiplatelets (i.e., aspirin, clopidogrel, ticlopidine)	hemorrhagic_stroke="on"History of hemorrhagic stroke o microbleeds
	thrombolytic="on"Thrombolytic agents (i.e., for schemic stroke)	trauma="on"Traumatic injury (note: ICH due to trauma is excluded)
	hormone_replacement_therapy="on"Hormone replacement therapy (estrogen)	<ul><li>obesity="on"Obesity</li><li>amphetamines="on"Amphetamines</li></ul>
	hypertension="on"Hypertension	current_smoker="on"Current Smoker
	hyperlipidemia="on"Hyperlipidemia/high	prior_smoker="on"Prior Smoker
	cholesterol	alcohol_abuse="on"Alcohol abuse
	Cocame= on Cocame	
(	diabetes_hyperglycemia="on"Diabetes/hyperglycemia	
	coronary_artery_disease="on"Coronary artery	
(		

imaging\_study CTA MRI/MRA Angiogram Specify other

Study: MISTIE III Training | Site: Testing - 888 | Patient: 888-6037 | Form: Baseline-Labs

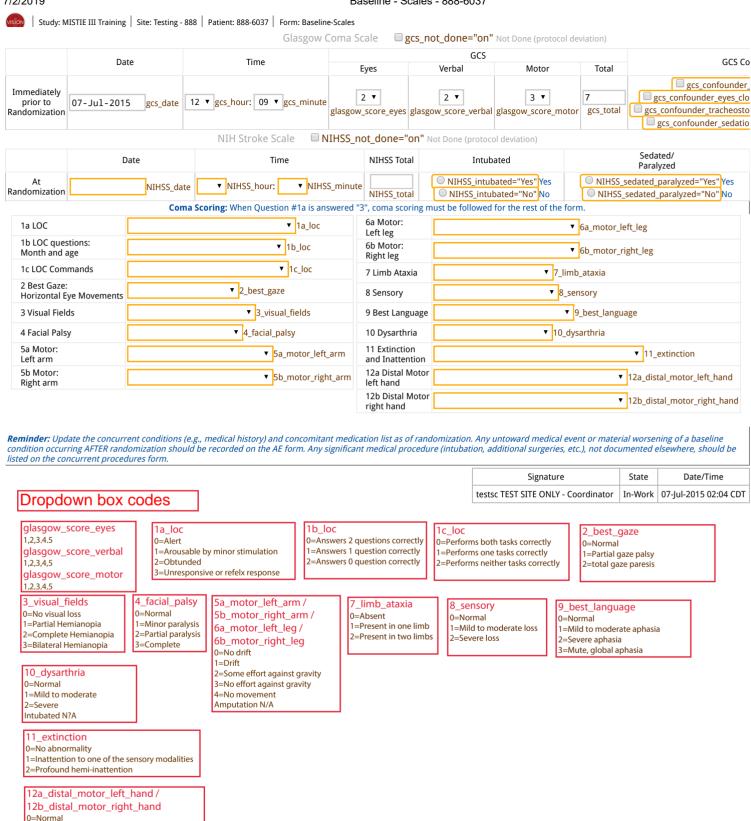
aPTT\_value

# IMPORTANT: enter lab results closest to pre-randomization date/time.

		Chemistry and Her	natology 🔲 lab_not_do	ne="on"	Not Done	
Γ	Date of collection:	collection_date	e Time of collection:	▼ col	lection_hour  ▼ collecti minute	on_minute
Test		Result	Refer	Flag		
1030	Value Not Done		Low to High	Unit	not avail.	1146
WBC Count	WBC_count_value \	WBC_count_not_done="on"	WBC_count_low_normal to WBC_count_high_normal	SI: x10 <sup>9</sup> / US: x10 <sup>3</sup> / or k/mm	μL WBC count not avail="o	n" WBC_count_flag
Glucose	glucose_value	glucose_not_done="on"	glucose_low_normal to glucose_high_normal	SI: mmol		glucose_flag
		Coagulation	coagulation_lab_not_don	e="on" N	ot Done	
Date of c	ollection:	coag_collection_date	Time of collection:	ur	minute	ion_minute
Test	Result		Reference Range		•	Flag
Platelet Count	Value  platelet_count_value	Not Done  platelet_count_not_done="on"	platelet_count_low_normal to	Unit SI: x10 <sup>9</sup> /L, US: x10 <sup>3</sup> / µL or k/mm <sup>3</sup>	not avail.  atelet_count_not_avail="on"	platelet_count_flag
INR	INR_value	☐ INR_not_done="on"	INR_low_normal to INR_high_normal		INR_not_avail="on"	INR_flag
aPTT	aDTT value	aPTT_not_done="on"	aPTT_low_normal to	sec	aPTT_not_avail="on"	aptt flag

aPTT\_high\_normal

aPTT\_flag



1=Some extension after 5 seconds 2=No voluntary extension after 5 seconds



Study: MISTIE III Training | Site: Testing - 888 | Patient: 888-6037 | Form: Baseline-TIL

Therapy Intensity Level

When did this change occur?

- when\_change\_occured="First 24 hours post symptom onset" First 24 hours post symptom onset when\_change\_occured="24 to 48 hours post symptom onset" 24 to 48 hours post symptom onset
- when\_change\_occured="48 to 72 hours post symptom onset" 48 to 72 hours post symptom onset when\_change\_occured="After 72 hours post symptom onset" After 72 hours post symptom onset

Instruction: Characterize the patient's condition and intensity of therapy between symptom onset and randomization. In each category, select the ONE MOST SEVERE (lowest in the list) that applies for this period of time. Be careful that you consider only the patient's PRE-RANDOMIZATION condition!

INR	<ul> <li>inr="No reading above 1.4" No reading above 1.4</li> <li>inr="INR &gt; 1.4 with reversal within 2 hours of first elevation" INR &gt; 1.4 with reversal (to ≤ 1.4) within 2 hours of first elevation</li> <li>inr="INR &gt; 1.4 NOT reversed within 2 hours of first elevation" INR &gt; 1.4 NOT reversed within 2 hours of first elevation</li> </ul>
How many agents were given to reverse INR to 1.4 or below WITHIN 2 HOURS OF FIRST ELEVATED INR?	<ul> <li>how_many_agents="None" None</li> <li>how_many_agents="One" One</li> <li>how_many_agents="Two or more" Two or more</li> </ul>
GLASGOW COMA SCORE	gcs="Lowest non-sedated reading was 13 or above" Lowest non-sedated reading was 13 or above gcs="Lowest non-sedated reading was 9-12" Lowest non-sedated reading was 9-12 gcs="Lowest non-sedated reading was 8 or below" Lowest non-sedated reading was 8 or below
HYPERTENSION	<ul> <li>hypertension="Not an issue" Not an issue (No sustained pressures above 139 systolic)</li> <li>hypertension="Stage 1 hypertension" Stage 1 hypertension (SBP 140 to 159 on 2 readings at least 20 minutes apart)</li> <li>hypertension="Stage 2 hypertension" Stage 2 hypertension (SBP 160 to 179 on 2 readings at least 20 minutes apart)</li> <li>hypertension="Hypertensive urgency" Hypertensive urgency (SBP ≥180 and/or MAP ≥130 lasting 20 minutes or more)</li> <li>hypertension="Recurrence of hypertensive urgency" Recurrence of hypertensive urgency after an initial episode (counting only episodes prior to randomization)</li> <li>hypertension="Hypertensive emergency" Hypertensive emergency (any reliable reading of SBP &gt;230, typically treated with nitroprusside)</li> </ul>
Was a specific target blood pressure established?	bp_target="No specific target" No specific target bp_target="SBP <180, and/or MAP <130" SBP <180, and/or MAP <130 bp_target="SBP <170, and/or MAP <125" SBP <170, and/or MAP <125 bp_target="SBP <160, and/or MAP <120" SBP <160, and/or MAP <120 bp_target="SBP <150, and/or MAP <115" SBP <150, and/or MAP <115 bp_target="SBP <140, and/or MAP <110" SBP <140, and/or MAP <110
Was the target blood pressure achieved WITHIN 2.5 HOURS OF FIRST 2 READINGS ABOVE THE TARGET (or SBP>180 if no target specified)?	<pre>general_target="Yes" Yes general_target="No" No general_target="N/A" N/A-No confirmed SBP reading above target (or ≥ 180 if no target) during this period</pre>
HYPOTENSION	hypotension="Not an issue" Not an issue (no SBP < 90 on 2 readings at least 5 min apart) hypotension="One episode" One episode of hypotension, reversed (to SBP sustained above 90) within 2 hours hypotension="Recurrence" Recurrence of hypotension, after an initial episode (counting only episodes prior to randomization)
HYPERPYREXIA	hyperpyrexia="Not an issue" Not an issue (no body temp readings above 38.3C lasting over an hour) hyperpyrexia="Reversed" Hyperpyrexia reversed within 4 hours hyperpyrexia="Not reversed" Hyperpyrexia, NOT reversed within 4 hours hyperpyrexia="Recurrence" Recurrence of hyperpyrexia after an initial episode (counting only episodes prior to randomization)
HYPERGLYCEMIA	<ul> <li>hyperglycemia="Not an issue" Not an issue (serum glucose did not exceed 200 mg/dL or 11.1 mmol/L)</li> <li>hyperglycemia="Reversed" Elevation of serum glucose (&gt;200 mg/dL), reversed within 4 hours (to below 140 if no specified target)</li> <li>hyperglycemia="Not reversed" Elevation of serum glucose, NOT reversed within 4 hours</li> <li>hyperglycemia="Recurrence" Recurrence of hyperglycemia after a first episode (counting only episodes prior to randomization)</li> </ul>
INTRACRANIAL PRESSURE A diagnosis of INTRACRANIAL HYPERTENSION (for ICP >30 lasting 5 minutes, or >20 lasting 2 hours) should be recorded on the Adverse Event/Medical History form (expected per protocol in this population) and as an SAE if it requires barbiturate coma or is Grade 4 or higher.	intracranial_pressure="Not monitored or not an issue" Not monitored or not an issue (no spikes to 20 mmHg or higher were sustained for more than 5 minutes) intracranial_pressure="20-30 mmHg reversed" One or more sustained increases to 20-30 mmHg reversed within 2 hours of first elevation above 20 intracranial_pressure="20-30 mmHg NOT reversed" One or more sustained increases to 20-30 mmHg NOT reversed (lasting more than 2 hours) intracranial_pressure="Above 30 mmHg reversed" One or more sustained increases to above 30 mmHg reversed within 60 minutes of first elevation above 30 intracranial_pressure="Above 30 mmHg NOT reversed" One or more sustained increases above 30 mmHg NOT reversed (lasting more than 60 minutes)
CEREBRAL HERNIATION	cerebral_herniation="None detected" None detected cerebral_herniation="Reversal of herniation" Clinical reversal of herniation within 60 minutes of detection cerebral_herniation="Persistent herniation" Persistent herniation that could not be clinically reversed within 60 minutes



Study: MISTIE III Training | Site: Testing - 888 | Patient: 888-6037 | Form: Baseline-Randomization

Informed Consent

## Was Informed Consent properly obtained?

consent obtained="Yes"Yes consent\_obtained="No"No (protocol deviation)

#### Date of Consent

07-Jul-2015 consent date 13 ▼ consent hourhh 00 ▼ consent\_minutemm

#### Date of Birth

01 DOB daydd Feb ▼ DOB monthmmm 1965 DOB\_yearyyyy

# Age At Consent

50 age\_at\_consent(calculated upon randomization)

In signing this form, you are attesting that the informed consent process has been appropriately documented in the patient's medical chart, that the original fully-executed consent is appropriately on file at the research site, and that the patient/legal representative has been given a copy of the consent.

■ subject\_in\_mti\_m3="on" Subject is participating in MTI-M3
■ subject\_in\_premise="on" Subject is participating in Premise

Verification of Eligibility

# **Summary of Stability Measurements**

Label	D/T	Time since Previous	ICH Volume Per Site (ABC/2)	ICH Volume Per RC Volumetrics	IVH Volume Per RC Volumetrics
dCT	07-Jul-2015 11:00 CDT		32		
sCT 1	07-Jul-2015 02:15 CDT		34		
Radiographic findings from the Reading Center (Please independently confirm!):					

New/Expanded bleeding noted by Reading Center (Please independently confirm!):

## **Response to Reading Center Findings:**

rc\_findings\_comment

Eligibility Criteria

Fail

Request Waiver

Patient must pass the following criteria to be randomized into the treatment period.

1. Continues to meet all initial eligibility criteria (i.e., no immediate exclusions) from the Registration Form. If fail, go back and indicate on the Registration page

instead. This page

initial\_eligibility\_verification="Pass" initial\_eligibility\_verification="Fail" initial\_eligibility\_verification="Request Waiver"

7/2	/2019	Е	Baseline - Randomization - 888-6037	
	(and most others) will then be hidden.			
2.	No mass, vascular malformation or other radiographic finding identified as the likely etiology of the ICH or which represents a risk to patient safety.	etiologic_verification="Pass"	etiologic_verification="Fail"	etiologic_verification="Request Waiver"
	Etiologic Findings: None			
3.	Most-recent INR ≤ 1.4, PLT ≥ 100, aPTT below upper limit of normal on the lab form.	lab_eligibility_verification="Pass"	lab_eligibility_verification="Fail"	lab_eligibility_verification="Request Waiver"
	SBP < 180 mmHg			
4.	sustained for 6 hours immediately preceding randomization	sbp_verification="Pass"	sbp_verification="Fail"	sbp_verification="Request Waiver"
5.	ICH is stable. Specifically, the two most recent CTs that are at least 6 hours apart show no more than a 5ml increase in ICH size using the ABC/2 method.	• ich_stability_verification="Pass"	ich_stability_verification="Fail"	ich_stability_verification="Request Waiver"
6.	IVH is stable.	IVH_stability_verification="Pass"	○ IVH_stability_verification="Fail"	○ IVH_stability_verification="Request Waiver"
7.	No <u>clinically-</u> <u>significant</u> new/expanded bleeding	• bleeding_verification="Pass"	O bleeding_verification="Fail"	<ul><li>bleeding_verification="Request Waiver"</li></ul>
8.	Intention to initiate surgery within 12 and 72 hours post diagnostic CT and to administer first dose within 76 hours (if randomized to surgical group)	surgical_window_verification="Pass"	○ surgical_window_verification="Fail"	surgical_window_verification="Request Waiver"
9.	All other inclusion/exclusion criteria have been met	• other_verification="Pass"	other_verification="Fail"	other_verification="Request Waiver"

# **Action Taken**

action\_taken="Screen Failure" action\_taken="Screening Waiver" Screening Waiver requested action\_taken="Eligible"Eligible



Patient has been Randomized
Randomization Date-Time
07-Jul-2015 02:07 CDT
randomization_date_time
Treatment Group
surgical
treatment_group

Signature	State	Date/Time
testsc TEST SITE ONLY - Coordinator	In-Work	07-Jul-2015 02:06 CDT

VISION   Study: MISTIE III Training   Site: Te	sting - 888   Patient: 888-6037   Form: S		eter y Planning 🏮		
Catheter #: 1	catheter_number		Surgery Not Done:	form_not_n	eeded="on"
Expla	in why surgery was not done:		surgery_n	ot_done_expl	anation
Designation	ICH Characteristics		Selected Entry Point		Chosen Trajectory
Designation	ICH Characteristics		Selected Entry Point		Chosen trajectory
○ trajectory_planned="Type A" Type A					
	Deep-seated occupying the anterior basal ganglia with typical "oval" shapshape)	pe (football n	Type A ICH should have an entry point in the midline near the eyebrow, and the trajector the clot.		
• trajectory_planned="Type B" Type B		,			
	Deep-seated occupying the posterio basal ganglia; the shape can range f roundish to elliptical	rom more la	Type B ICH should have an entry point in the ateral from the midline to avoid the occipita to be along the longitudinal axis of the clot.		rietal-occipital area frequently several cm horn, and the trajectory of the catheter has
trajectory_planned="Type C" Type C					
	Superficial (lobar) with variable shap more spherical	ve, but often	Type C ICH should have an entry point at th widest "equatorial point" of a spherical-sha he widest, or "equatorial", axis of the clot.		
	Entry Po	F	<ul><li>entry_point_type_C="Left Frontal" Left Frontal</li><li>entry_point_type_C="Left Temporal" Left Temporal</li></ul>	Frontal	y_point_type_C="Right Frontal" Right y_point_type_C="Right Temporal" Right al
		F	entry_point_type_C="Left Parietal" Left Parietal	Parietal	y_point_type_C="Right Parietal" Right
			<pre>entry_point_type_C="Left Occipital" <lef occipital<="" pre=""></lef></pre>	t Occipita	y_point_type_C="Right Occipital" Right I
Does the 3D cl	ot image have more than one axis? (i.		omulti_axis_image="Yes" Yes omulti_axi	is_image="No	'No
	Reason(s) this trajed	ctory selected:	along_axis="on" Along the longest axis avoids_ventricle="on" Avoids ventricle		shortest_distance="on"   Shortest distance to target   Optimal access obstructed (steel plate, etc.)   avoids_eloquent_region="on" Avoids
		l [	avoids_sinus="on" Avoids large frontal s	ify:	eloquent region
	lin	load IDEGs from	other_reason_specif	У	
Upload JPEGs from the navigation system  Upload JPEG: Choose File No file chosen upload_file					
Surgeon's Name: Bo Yang	surgeons_name Phone i	number: 137	surgeons_phone_number (for c	ontact by Sur	gical Center)
	TO BE COMPLETED BY		Center Review ITER AFTER SITE HAS ENTERED DATA ABO	VE:	
Surgical Center Determina			rgical_center_determination	-	
=			ternative_trajectory="Type B"Type B	rnative_trajec	tory="Type C"Type C
		Co	omments:		

Not done Positive Negative

emember to record AEs. Death must be reported via an SAE form within 24 hours.	removal removal removal removal	reason="Dislodgement R reason="Infection" Infec reason="Death" Death o reason="Other" Other olete associated SAE entry	eplacement" Acci ction or decision to without	dental disl draw life si	lodgement upport
pliance with Safety Protocol					
Elapsed Time Since Last Dose (this	catheter):	elapsed_since_last_	dose		
arly_removal="on" Removed EARLIER than 24 hours after the last dose » Reason:			early_removal_spe	cify	
ate_removal="on" Removed LATER than 36 hours after the last dose » Reason:		late	_removal_specify		
arly_reposition="on" Repositioned without waiting at least 24 hours after previous dose	» Reason:		e	arly_repos	ition_specify
not_drained_before_removal="on" Not left open to drain for 24 hours before removal » Reason:					ecify
Manip	ulation 📵				
Date/Time of Manipulation		Reason for	Manipulation		
during_this_surgery(1)="on" During this surgery  manipulation_date(1)   manipulation_hour(1):   manipulation_minute(1)  (insertion used for date/time)	manipulation_reason(1)="Pull back to better position"Pull-back to better position catheter port manipulation_reason(1)="Other Reason"Other Reason: other_reason_specify(1)			position catheter ports	
		Signat	ure	State	Date/Time
		testsc TEST SITE ON	LY - Coordinator	In-Work	07-Jul-2015 02:08 CDT
propdown box codes    Irrigical_center_determination   Irrigical_c	number_of_sites 1 2 3 4 5 N/A	1	A 3 5	er_traject	troy
	Elapsed Time Since Last Dose (this arly_removal="on" Removed EARLIER than 24 hours after the last dose "Reason:	removal remova	removal reason="Dislodgement Re removal reason="Infection" large removal reason="Dislodgement Re removal reason="Disloggement Re removal reason="Disloggement Re removal reason="Other" Other (Please complete associated SAE entry specify: removentry)    Plance with Safety Protocol   Elapsed Time Since Last Dose (this catheter):   elapsed_since_last_elapse	removal_reason="Dislogement Replacement" Acci removal_reason="Dislogement Replacement" Acci removal_reason="Dislogement Replacement" Acci removal_reason="Dislogement Replacement" Acci removal_reason="Dislogement Replacement" Other removal_reason="Dislogement of decision to with removal_reason="Dislogement Pother removal_reas	removal reason="Death" of decision to withdraw life so removal reason="Death" other of their other oth

drain\_stop\_unknown(1)="on"Unknown

VISION	Study: MISTIE III Training	Site: Testing - 888	Patient: 888-6037	Form: Surgery-Punctures/Drains
	-	form_not_neede	ed="on" Form N	ot Needed (No punctures/drains during acute hospitalization)

drain\_start\_unknown(1)="on"Unknown

	Lu	mbar Punctures				
#	Duration					
#	Start	Stop	Comments			
	puncture_start_date(1)	puncture_stop_date(1)				
1	▼ puncture_start_hour(1) hr ▼ puncture_start_minute(1) min	▼ puncture_stop_hour(1) hr ▼ puncture_stop_minute(1) min				
puncture_start_unknown(1)="on"Unknown		puncture_stop_unknown(1)="on"Unknown	puncture_comments(1)			
Lumbar Drains						
#	Dura	ation	Comments			
#	Start	Stop	Comments			
	drain_start_date(1)	drain_stop_date(1)				
1	▼ drain_start_hour(1) hr	▼ drain_stop_hour(1) hr ▼ drain_stop_minute(1) min				

drain\_comments(1)

VISION Stu	dy: MISTIE III Training   Site: Testing - 888   Patient: 888-6037	Form: Surgery-EVD-1			
		EVD Info	0		
	Catheter #: 1 catheter_number		Not Ap	plicable: form_not_needed="on"	
		EVD Placer			
	D	ate of insertion:	insertion_date	Time of insertion: vinsertion_hour	hour insertion_mi
Initial surgical target:	initial_surgical_target="L Lateral"L Lateral	initial_surgica	l_target="R Lateral"R Latera	☐ initial_surgical_target="3	3rd"3rd
Site of insertion:	▼ area_of_insertion ○ site_side="Right"Rig	ght osite_side="Left"Left			
Method of Insertion:	f omethod_of_insertion="New Twist Drill Hole"New Twi	st Drill Hole omethod_of_in	sertion="New Burr Hole"Ne	w Burr Hole omethod_of_insertion="P	rior Twist Drill Hole"Prior
Ventricle Cannulation Number of passes (cannulation attempts): Number of sites (burr/drill holes):	n number_passes				
				new_ivc="Yes"Yes new_ivc="No"N  d. Please see new tab above after savin	
		EVD Remo		i. I rease see new tab above arter savii	ng rorm.
	Date of removal: removal_		removal: removal_	nour removal_minute minute	
	Reason for Rei	removal_reason="F" removal_reason="I" removal_reason="I" removal_reason="A"	ccidental"Accidental Vithdraw of Care"Dea <mark>th or V</mark>		y
		EVD	Manipulation		
#	Date/Time of Manipulatio	on		Reason for Manip	oulation
Date:	manipulation_date(1)  Time: mani	v ipulation_hour(1) manipulatio minute		on_reason(1)="Pull back to better positic on_reason(1)="Other Reason"Other Reas specify(1)	

# Dropdown box codes

area\_of\_insertion
Frontal
Parietal
Occipital
Temporal

Parietal
Occipital
Temporal

Parietal
Occipital
Temporal

Parietal
Occipital
Temporal

Parietal
Occipital
Societa
Socie



Study: MISTIE III Training | Site: Testing - 888 | Patient: 888-6037 | Form: Surgery-Post-Surg CT-Site

Identification ct not done="on" CT Not Done

Date & Time of CT: 08-Jul-2015

03 ▼ CT hour: 06 ▼ CT minute

CT date

Fixed-Width Slices: Variable-Width Slices: **ICH Clot** 132.2 mm - 97.2 mm = Volume by 12 ABC/2 ich\_volumeml Method: ICH Volume = 23.9 ml

DOSING CONSIDERATIONS: If any of the following are noted, you should not dose the subject until stability can be established by a repeat CT 6 hours later (Use the Post-Surg Stability form here or one of the day 1-6 CT forms for this purpose). Also, be sure to enter all such events on the Adverse Event (MH/AE) form. All bleeds additionally require completing an SAE/MEOI form as well to provide additional details.

- Any new (non-index) ICH site > 5 ml
- Enlargement of the Index ICH clot size by more than 5 ml
- Any bleeding along a catheter tract
- Any other new intracranial bleed
- Any new discovery of a radiographic exclusion

Signature	State	Date/Time
testsc TEST SITE ONLY - Coordinator	In-Work	07-Jul-2015 02:09 CDT

VISION Study: MISTIE	III Training   Site: Testing - 888   Patient: 888-6037   Form: Dosing-Dosir	ng				
	Dosing of form_no	t_needed="on"	Surgery Not Done			
	Explain why surgery was not done:		surgery_not_done_explanation			
	Was this the last dose?					
	<ul><li>last_dose="No dose required"No dose requi</li><li>last_dose="Yes"Yes</li><li>last_dose="No"No</li></ul>	red (ICH reduced	to ≤ 10ml with surgical aspiration only).			
	Specify:					
	<ul> <li>last_dose_specify="Maximum doses"Gave maximum 9 doses without achieving ICH reduction to ≤ 10ml</li> <li>last_dose_specify="Dosing success"After 1 to 9 doses, achieved endpoint (ICH reduction to ≤ 10ml)</li> <li>last_dose_specify="Approaching endpoint"After 1 to 9 doses, approaching endpoint, additional dose not warranted</li> <li>last_dose_specify="Catheter position not suitable"Catheter position not suitable</li> <li>last_dose_specify="Adverse Event"Adverse event requiring premature discontinuation of dosing*</li> <li>*List on AE form, create corresponding MEOI/SAE and check box: "Required discontinuation of dosing"</li> </ul>					
	Date ar	nd Time of Dose	2			
Dose Date/Time: To	day dose_date Now dose_time Hrs since Symptom Onset:	hrs_since_s	ymptom_onset (min:12) Hrs since Diagnostic CT: hrs_since_diagnostic_c			
Administered using catheter #:	▼ dosing_catheter_number	Catheter Type: Date Inserted: Trajectory Used: Entry Point Used:	ICH Catheter			
		Most Recent Lab:	most_recent_lab			
Elapsed Time since	time_since_last_catheter_placedhrs:min	Most Recent INR: Most Recent	Inost_recent_ini			
last catheter Placed:	last catheter Placed: ( hrs_since_catheter_manipulatedhrs)		most_recent_ptt most_recent_plt			
Time Catheter to Drain Bag Clamped:	▼ catheter_clamped_hour: ▼ catheter_clamped_minu	PLT:				
ICP Immediately before Dose:	icp_before_dose or icp_not_monitored="on"ICP no	t monitored				
Systolic BP Immediately before Dose:	systolic_before_dosemmHg	Diastolic BP Immediately before Dose:	diastolic_before_dosemmHg			
Dose Administered by:	<pre>dose_administered_by_name specify not_certified="Yes"Not trained/supervised on dosing procedur</pre>		not_certified_administered_name			
Volume of <u>Test</u>	test_article_administered="1ml"1ml, per protocol	Volume				
Article Administered (mL):	test_article_administered="Other"Other  Specify: test_article_admin_otherml	of <u>Flush</u> Used (mL):	flush_injectedml			
Time Catheter Unclamped:	▼ catheter_unclamped_hour: ▼ catheter_unclamped_minute					
Systolic BP Immediately before Unclamping:	systolic_before_unclampingmmHg	Diastolic BP Immediately before Unclamping:	diastolic_before_unclampingmmHg			
ICP Immediately before Unclamping:	icp_before_unclamping	Was catheter unclamped on schedule?	unclamped_on_schedule="Yes"Yes unclamped_on_schedule="High ICP"No, due to high ICP unclamped_on_schedule="Adverse Event"No, due to Adverse Event Specify: unclamped_ae_specify unclamped_on_schedule="Protocol Deviation"No, due to Protocol Deviation Specify: unclamped_deviation_specify unclamped_on_schedule="Other reason"No, due to other reason Specify: unclamped_other_specify			

Study: MISTIE III Training   Site: Testing - 888   Patient: 888-6037   Form: Day 1-Patient Status						
P	Patient Status  visit_not_done="on" Visit Not Done  to Done					
NOTE	NOTE: Day 1 is ALWAYS the date of randomization!					
	e considered lost-to-follow-up un g methods and attempts to collec		randomization. If unable to contact patient,			
Actual Visit Date:	visit_date	Allowed Window:	07-Jul-2015 earliest_allowed_window to 07-Jul-2015 latest_allowed_window			
		Expected Visit Date:	07-Jul-2015 expected_visit_date			
Elapsed Calendar Days:		Patient Status:				
Since Symptom Onset:	days_since_symptom_onset		opatient_status="Alive" Alive			
Since Randomization:	days_since_randomization		patient_status="Dead" Dead> Stop. Sign this form. IMMEDIATELY enter the event of death on the MH/AE form, select grade 5, then complete an SAE form!			
Since Last Dose:	days_since_last_dose		opatient_status="Withdrawn" Withdrawn			

ICP

(mmHg)

Study: MISTIE III Training | Site: Testing - 888 | Patient: 888-6037 | Form: Day 1-ICU Care

icp(1)

ICU Care not done="on" Not Done

Select and enter a non-artifact value that is representative of each period. You have discretion to accommodate shift changes, patient availability, questionable readings, etc., but otherwise try to be consistent from day-to-day and space times about 6h apart, for example: 0200, 0800, 1400, 2000. Measurements do not have to be collected after the patient leaves the ICU (check the not done box at the top of this page).

#### Vitals

	Period 1 0000 - 0559	Period 2 0600 - 1159	Period 3 1200 - 1759		Period 4 1800 - 2359
BP systolic_bp(1) / diastolic_bp(1)		systolic_bp(2) / diastolic_bp(2) systolic_bp(3) / diastolic_bp(3) systolic_bp(3)			pp(4) / diastolic_bp(4)
	ICP Monitoring				
Was ICP monitored today?  icp_monitoring_today="No" No icp_monitoring_today="Yes started prior to today" Yes, started prior to today icp_monitoring_today="Yes started today" Yes,		icp_monitoring_stopped="Yes" Yes			Site of pressure reading  reading_site
started today		removal_reason			reading_site_specify
Period 1 0000 - 0559		Period 2 0600 - 1159	Period 3 1200 - 1759		Period 4 1800 - 2359

A diagnosis of Intracranial Hypertension (ICP > 30 mm Hg for five or more minutes or >20 mmHg for 2 or more consecutive hours) must be listed as an AE, and as an SAE (expected per protocol in this population) if it requires barbiturate coma or is Grade 4 or higher.

icp(3)

icp(4)

icp(2)

#### Glasgow Coma Scale

Score verbal as 1 if intubated, score eyes as 1 if unable to test due to eye swelling or damage.

Period 1 0000 - 0559	Period 2 0600 - 1159	Period 3 1200 - 1759	Period 4 1800 - 2359	
GCS	GCS	GCS	GCS	
Eyes Verbal Motor	Eyes Verbal Motor	Eyes Verbal Motor	Eyes Verbal Motor	
<b>T</b>		<b>,</b> , , , , ,	T   T   T   T   T   T   T   T   T	
gcs_eyes(1) gcs_verbal(1) gcs_moto	1) gcs_eyes(2) gcs_verbal(2) gcs_motor(2)	gcs_eyes(3) gcs_verbal(3) gcs_motor(3)	gcs_eyes(4) gcs_verbal(4) gcs_motor(4)	
Total: gcs_score(1)	Total: gcs_score(2)	Total: gcs_score(3)	Total: gcs_score(4)	
gcs_accurate(1)="on" Accurate	gcs_accurate(2)="on" Accurate	gcs_accurate(3)="on" Accurate	gcs_accurate(4)="on" Accurate	
gcs_eyes_swell(1)="on" Eyes Closed to Swelling gcs_eyes_swell(2)="on" Eyes Closed Swelling		gcs_eyes_swell(3)="on" Eyes Closed to Swelling	gcs_eyes_swell(4)="on" Eyes Closed to Swelling	
gcs_tracheostomy(1)="on" gcs_tracheostomy(2)="on" Tracheostomy/Intubation Tracheostomy/Intubation		gcs_tracheostomy(3)="on" Tracheostomy/Intubation	gcs_tracheostomy(4)="on" Tracheostomy/Intubation	
☐ gcs_sedation_paralysis(1)="on" Deep Sedation/Paralysis ☐ gcs_sedation_paralysis(2)="on" Deep Sedation/Paralysis		gcs_sedation_paralysis(3)="on" Deep Sedation/Paralysis	gcs_sedation_paralysis(4)="on" Deep Sedation/Paralysis	
gcs_not_done(1)="on" Not Done	gcs_not_done(2)="on" Not Done	gcs_not_done(3)="on" Not Done	gcs_not_done(4)="on" Not Done	
Neuroworsening is defined as a spo	taneous decrease in the GCS motor score >2 poir	nts sustained for at least 8 hours. Record neur	roworsening on the adverse event form as	

Neuroworsening is defined as a spontaneous decrease in the GCS motor score >2 points sustained for at least 8 hours. Record neuroworsening on the adverse event form as "Depressed level of consciousness" and, if life-threatening, on the SAE form as well.

Reminder: enter all events/treatments/changes on the appropriate forms. Examples to watch for:

Adverse Events: hypotension, hypertension, seizure, fever, infection (by specific type such as meningitis, ventriculitis, cerebritis), intracranial hypertension, herniation, deep vein thrombosis, hyperglycemia, hemorrhages (by type/location), apnea, aspiration, dyspnea hypoxia, respiratory failure, resuscitation, alkalosis

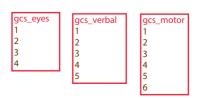
**Procedures:** cooling blanket, head elevation, ventilation, oxygen per nasal cannula, tracheostomy, aggressive hyperventilation, craniectomy, craniotomy, VP shunt, elastic stockings, pneumatic compression, ICP monitor placement

Surgery: ICH catheter or EVD insertion/removal/manipulation, lumbar puncture, lumbar drain

**ConMeds:** vasopressors (phenylephrine, norepinephrine, dopamine), antihypertensives (esmolol, labetalol, hydralazine, nicardipine, diltiazem, verapamil, fenoldopam, nitroprusside), anticonvulsants (lorazepam, phenobarbital, phenytoin), analgesics/antipyretics (acetaminophen, morphine), major sedatives (propofol, phenobarbital, thiopental), osmotics (mannitol, hypertonic saline), paralytics, antibiotics, Clotting agents (plasma, vitamin K, factor 7), anticoagulants (heparin, dabigitran)

Utilization: any change in treatment venue (ICU, Step-down unit, general ward, etc.)

# Dropdown box codes



7/2/2019	Day 1 to	Day 6 - Safety Labs	
Study: MISTIE III Training   Site	Testing - 888   Patient: 888-6037	Form: Day 1-Labs	
	Chemistry and Hematolog	y ab_not_done="on" Not I	Done
IMPORTANT: Only enter POST-RAND		orm. <b>This form is usually not neede</b> n the Baseline Labs form.	d. Day 1 PRE-RANDOMIZATION lab results
Date of collection:	collection_date	Time of collection: ▼ collecti	on_hour ▼ collection_minute

[	Date of collection:	collection_date	e Time of collection:	▼ c	collection_hour  ▼ collection_minute	ion_minute	
Test		Result	Refer	Flag			
1631	Value	Not Done	Low to High	Unit	t not avail.	riag	
WBC Count	WBC_count_value \	WBC_count_not_done="on"	WBC_count_low_normal to WBC_count_high_normal	SI: x10 US: x10 or k/m	<sup>3</sup> /μL WBC count not avail="o	on" WBC_count_flag	
Glucose			SI: mmo		n" glucose_flag		
	Coagulation Coagulation_lab_not_done="on" Not Done						
Date of collection:  coag_collection_date  Time of collection:  coag_collection_hour hour  Result  Reference Range					ion_minute		
Test	Result Value Not Done		Low to High	Unit	not avail.	Flag	
Platelet Count		platelet_count_not_done="on"	platelet_count_low_normal to platelet_count_high_normal	SI: x10 <sup>9</sup> /L, US:		platelet_count_flag	
INR	INR_value	☐ INR_not_done="on"	INR_low_normal to INR_high_normal		「INR_not_avail="on"	INR_flag	
aPTT	aPTT value	aPTT_not_done="on"	aPTT_low_normal to	sec	aPTT_not_avail="on"	aPTT_flag	

Study: MISTIE III Training | Site: Testing - 888 | Patient: 888-6037 | Form: Day 1-CT Scan

Identification

ct not done="on" CT Not Done or Not Needed

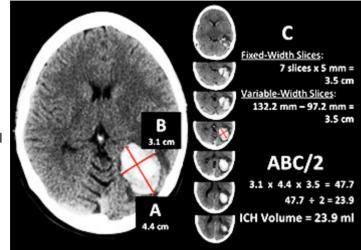
IMPORTANT: Only record POST-RANDOMIZATION CTs on this form. This form is usually not needed. Day 1 PRE-RANDOMIZATION CTs are recorded on Screening Stability CT scans forms.

CT establish stability="on"CT is being used to establish stability after a bleed or catheter manipulation.

Date & Time of CT:

CT date ▼ CT\_hour: ▼ CT minute

**ICH Clot** Volume by ABC/2 ich\_volumeml Method:



DOSING CONSIDERATIONS: If any of the following are noted, you should not dose the subject until stability can be established by a repeat CT 6 hours later (Use the Post-Surg Stability form here or one of the day 1-6 CT forms for this purpose). Also, be sure to enter all such events on the Adverse Event (MH/AE) form. All bleeds additionally require completing an SAE/MEOI form as well to provide additional details.

- Any new (non-index) ICH site > 5 ml
- Enlargement of the Index ICH clot size by more than 5 ml
- Any bleeding along a catheter tract
- Any other new intracranial bleed
- Any new discovery of a radiographic exclusion

7/2/2019	9 Day 7 - Patient Status - 888-6037				
Study: MISTIE III T	Study: MISTIE III Training   Site: Testing - 888   Patient: 888-6037   Form: Day 7-Patient Status				
	Patient Status  visit_not_done="on" Visit Not Done  i				
	d not be considered lost-to-follow-up un garding methods and attempts to collec		st randomization. If unable to contact patient,		
Actual Visit Date:	visit_date	Allowed Window:	13-Jul-2015 earliest_allowed_window to 13-Jul-2015 latest_allowed_window		
		Expected Visit Date:	13-Jul-2015 expected_visit_da		

days\_since\_symptom\_onset

days\_since\_randomization

days\_since\_last\_dose

**NIH Stroke Scale** 

Status of Outcomes

Patient

Status:

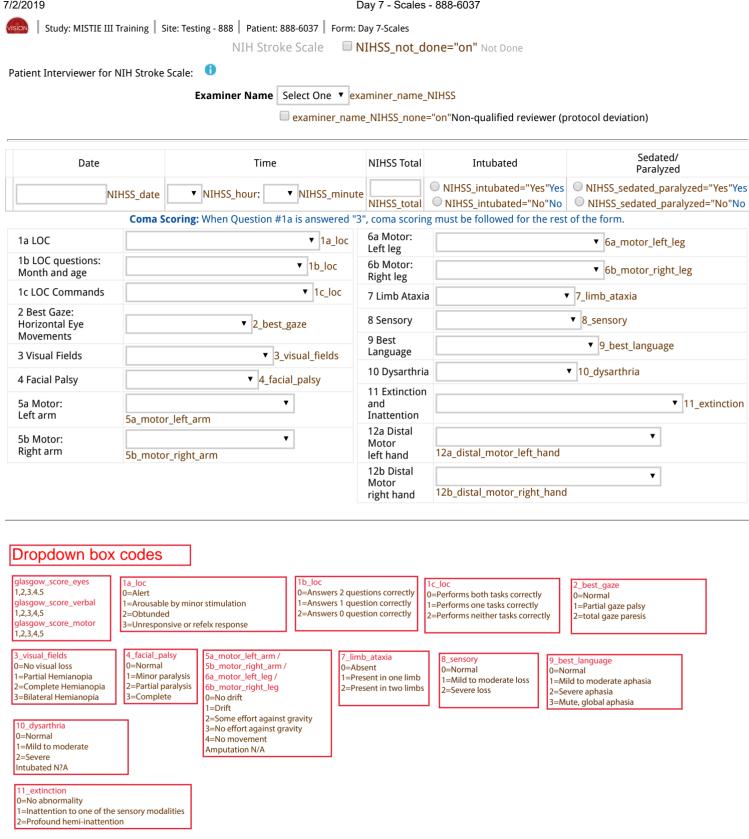
	latest_	_allowed_wind	wob	
ed sit e:	13-Ju	ıl-2015		expected_visit_date
nt s:				
	Ора	tient_status='	"Aliv	e" Alive
	Sign the	nis form. IMM of death on t	1EDI he N	ad" Dead> Stop. ATELY enter the MH/AE form, select an SAE form!
	Ора	tient_status='	"Wit	:hdrawn" Withdrawn
S				
Not Done				

Elapsed Calendar Days:

Since Symptom Onset:

Since Randomization:

Since Last Dose:



12a\_distal\_motor\_left\_hand / 12b\_distal\_motor\_right\_hand

1=Some extension after 5 seconds 2=No voluntary extension after 5 seconds

0=Normal



Study: MISTIE III Training | Site: Testing - 888 | Patient: 888-6037 | Form: Day 7-TIL

Therapy Intensity Level

Was there a DNR/DNI order AT ANY TIME SINCE SYMPTOM ONSET?	<pre>O dnr_dni_order="Yes" Yes O dnr_dni_order="No" No</pre>
When did this change occur?	<ul> <li>when_change_occured="First 24 hours post symptom onset" First 24 hours post symptom onset</li> <li>when_change_occured="24 to 48 hours post symptom onset" 24 to 48 hours post symptom onset</li> <li>when_change_occured="48 to 72 hours post symptom onset" 48 to 72 hours post symptom onset</li> <li>when_change_occured="After 72 hours post symptom onset" After 72 hours post symptom onset</li> </ul>

Instruction: Characterize the patient's condition and intensity of therapy between randomization through the end of Day 7. In each category, select the ONE MOST SEVERE (lowest in the list) that applies for this period of time. Be careful that you consider only the patient's POST-RANDOMIZATION condition!

INR	<ul> <li>inr="No reading above 1.4" No reading above 1.4</li> <li>inr="INR &gt; 1.4 with reversal within 2 hours of first elevation" INR &gt; 1.4 with reversal (to ≤ 1.4) within 2 hours of first elevation</li> <li>inr="INR &gt; 1.4 NOT reversed within 2 hours of first elevation" INR &gt; 1.4 NOT reversed within 2 hours of first elevation</li> </ul>
How many agents were given to reverse INR to 1.4 or below WITHIN 2 HOURS OF FIRST ELEVATED INR?	how_many_agents="None" None how_many_agents="One" One how_many_agents="Two or more" Two or more
GLASGOW COMA SCORE	gcs="Lowest non-sedated reading was 13 or above" Lowest non-sedated reading was 13 or above gcs="Lowest non-sedated reading was 9-12" Lowest non-sedated reading was 9-12 gcs="Lowest non-sedated reading was 8 or below" Lowest non-sedated reading was 8 or below
HYPERTENSION	<ul> <li>hypertension="Not an issue" Not an issue (No sustained pressures above 139 systolic)</li> <li>hypertension="Stage 1 hypertension" Stage 1 hypertension (SBP 140 to 159 on 2 readings at least 20 minutes apart)</li> <li>hypertension="Stage 2 hypertension" Stage 2 hypertension (SBP 160 to 179 on 2 readings at least 20 minutes apart)</li> <li>hypertension="Hypertensive urgency" Hypertensive urgency (SBP ≥180 and/or MAP ≥130 lasting 20 minutes or more)</li> <li>hypertension="Recurrence of hypertensive urgency" Recurrence of hypertensive urgency after an initial episode (counting only episodes since randomization)</li> <li>hypertension="Hypertensive emergency" Hypertensive emergency (any reliable reading of SBP &gt;230, typically treated with nitroprusside)</li> </ul>
Was a specific target blood pressure established?	<ul> <li>bp_target="No specific target" No specific target</li> <li>bp_target="SBP &lt;180, and/or MAP &lt;130" SBP &lt;180, and/or MAP &lt;130</li> <li>bp_target="SBP &lt;170, and/or MAP &lt;125" SBP &lt;170, and/or MAP &lt;125</li> <li>bp_target="SBP &lt;160, and/or MAP &lt;120" SBP &lt;160, and/or MAP &lt;120</li> <li>bp_target="SBP &lt;150, and/or MAP &lt;115" SBP &lt;150, and/or MAP &lt;115</li> <li>bp_target="SBP &lt;140, and/or MAP &lt;110" SBP &lt;140, and/or MAP &lt;110</li> </ul>
Was the target blood pressure achieved WITHIN 2.5 HOURS OF FIRST 2 READINGS ABOVE THE TARGET (or SBP>180 if no target specified)?	<ul> <li>general_target="Yes" Yes</li> <li>general_target="No" No</li> <li>general_target="N/A" N/A-No confirmed SBP reading above target (or ≥ 180 if no target) during this period</li> </ul>
HYPOTENSION	hypotension="Not an issue" Not an issue (no SBP < 90 on 2 readings at least 5 min apart) hypotension="One episode" One episode of hypotension, reversed (to SBP sustained above 90) within 2 hours hypotension="Recurrence" Recurrence of hypotension, after an initial episode (counting only episodes since randomization)
HYPERPYREXIA	<ul> <li>hyperpyrexia="Not an issue" Not an issue (no body temp readings above 38.3C lasting over an hour)</li> <li>hyperpyrexia="Reversed" Hyperpyrexia reversed within 4 hours</li> <li>hyperpyrexia="Not reversed" Hyperpyrexia, NOT reversed within 4 hours</li> <li>hyperpyrexia="Recurrence" Recurrence of hyperpyrexia after an initial episode (counting only episodes since randomization)</li> </ul>
HYPERGLYCEMIA	<ul> <li>hyperglycemia="Not an issue" Not an issue (serum glucose did not exceed 200 mg/dL or 11.1 mmol/L)</li> <li>hyperglycemia="Reversed" Elevation of serum glucose (&gt;200 mg/dL), reversed within 4 hours (to below 140 if no specified target)</li> <li>hyperglycemia="Not reversed" Elevation of serum glucose, NOT reversed within 4 hours</li> <li>hyperglycemia="Recurrence" Recurrence of hyperglycemia after a first episode (counting only episodes since randomization)</li> </ul>
INTRACRANIAL PRESSURE A diagnosis of INTRACRANIAL HYPERTENSION (for ICP >30 lasting 5 minutes, or >20 lasting 2 hours) should be recorded on the Adverse Event/Medical History form (expected per protocol in this population) and as an SAE if it requires	intracranial_pressure="Not monitored or not an issue" Not monitored or not an issue (no spikes to 20 mmHg or higher were sustained for more than 5 minutes) intracranial_pressure="20-30 mmHg reversed" One or more sustained increases to 20-30 mmHg reversed within 2 hours of first elevation above 20 intracranial_pressure="20-30 mmHg NOT reversed" One or more sustained increases to 20-30 mmHg NOT reversed (lasting more than 2 hours) intracranial_pressure="Above 30 mmHg reversed" One or more sustained increases to above 30 mmHg reversed within 60 minutes of first elevation above 30 intracranial_pressure="Above 30 mmHg NOT reversed" One or more sustained increases above 30 mmHg NOT reversed (lasting more than 60 minutes)

barbiturate coma or is Grade 4 or higher.	
CEREBRAL HERNIATION	cerebral_herniation="None detected" None detected cerebral_herniation="Reversal of herniation" Clinical reversal of herniation within 60 minutes of detection cerebral_herniation="Persistent herniation" Persistent herniation that could not be clinically reversed within 60 minutes

Study: MISTIE III Training   Site: Testing - 888   Patient: 888-6037   Form: Day 7-MRI					
MRI no_imaging_study="Not_done" No MRI Done					
Date/Time of MRI:   MRI_date   ▼ MRI_hour :   ▼ MRI_minute					
Please upload DICOM images to the Source Docs tab					

/2/2019		Day 30 - F	Patient Status - 8	88-6037	
Stud	y: MISTIE III Training	Site: Testing - 888 Patient: 888-6	037   Form: Da	y 30-Patient Status	
	Pa	atient Status	done="on"	Visit Not Done 🏻 🕕	
		e considered lost-to-follow-up un methods and attempts to collec		ost randomization. If unabl	e to contact patient,
Actu	al Visit Date:	visit_date	Allowed Window:	29-Jul-2015 earliest_allowed_wind 12-Aug-2015 latest_allowed_windo	
Visit Sc	cheduled on:		Expected Visit Date:	05-Aug-2015	expected_visit_date
	Schedule this v scored.	isit early in the window to allow	for repeating (	of the Modified Rankin if th	e video cannot be
Elap	osed Calendar Days:		Patient Status:		
Since Sym	ptom Onset:	days_since_symptom_onset		opatient_status="A	live" Alive
Since Rar	ndomization:	days_since_randomization		patient_status="Dead" Dead> Stop. Sign this form. IMMEDIATELY enter the event of death on the MH/AE form, select grade 5, then complete an SAE form!	
Sinc	e Last Dose:	days_since_last_dose		opatient_status="V	Vithdrawn" Withdrawn
f lumbar pu		ns/Procedures form if a VP shunt ement was done. Update ConMed			
		Status of O	utcomes		
	Mini Mental S	tatus Exam		mmse score status	

Mini Mental Status Exam	mmse_score_status
Modified Rankin Scale	rankin_score_status
Glasgow Reported Rankin Scale	glasgow_rankin_score_status
Barthel Index	barthel_index_status
NIH Stroke Scale	NIHSS_total_status
Glasgow Outcome Scale Extended	gose_score_status
Stroke Impact Scale	sis_score_status
EQ-5D	EQ_score_status
PBSI	normalized_score_status
Video Upload Accepted	video_upload_status

NIHSS\_date

▼ NIHSS\_hour:

▼ NIHSS minute

▼ 1a\_loc

NIHSS total

Coma Scoring: When Question #1a is answered "3", coma scoring must be followed for the rest of the form. 6a Motor:

Left leg

NIHSS\_intubated="No"No

Day

30

1a LOC

NIHSS\_sedated\_paralyzed="No"No

▼ |6a\_motor\_left\_leg

1=Drift

10\_dysarthria

11 extinction 0=No abnormality

1=Mild to moderate

1=Inattention to one of the sensory modalities

2=Profound hemi-inattention

0=Normal

2=Severe Intubated N?A 2=Some effort against gravity

12a\_distal\_motor\_left\_hand / 12b\_distal\_motor\_right\_hand

1=Some extension after 5 seconds 2=No voluntary extension after 5 seconds

3=No effort against gravity

4=No movement

Amputation N/A

0=Normal



Study: MISTIE III Training | Site: Testing - 888 | Patient: 888-6037 | Form: Day 90-Scales

Patient Interviewer 0

Date of Interview		interview_date				
Source of Information	hospital_cli	nic="on"Hospital/Clinic Visit	tal/Clinic Visit		phone_with_spouse="on"Phone interview with spouse other_via_phone="on"Other source via phone interview	
	local_medi	local_medical_doctor="on"Report from local m		interview		
				specify:		specify_other_phone
	phone_witl	n_subject="on"Phone intervi	ew with subject	other="o	on"Other	specify_other
	Modi	fied Rankin Scale	rankin_not_do	one="on" N	Not Done 🕕	
Patient Interviewer	for Modified Ran	kin Scale: 🌐				
	Ex	caminer Name   Select One	▼ examiner_n	ame_rankin		
		examine	 r_name_rankin_	none="on"N	on-qualified revie	ewer (protocol deviation)
		Modified Ra	ankin Scale Scor	e:		
			L			▼
		ran	kin_score			
		Barthel Index  bar	thel_not_don	e="on" Not	Done	
Patient Interviewer	for Barthel Index	0				
	Examin	er Name Select One ▼ ex	aminer name l	parthel		
					ualified reviewer	(protocol deviation)
-		= exammer_nam				
Date of	Survey	barthel_date Tin	ne of Survey	▼ barthel	_hour: ▼ ba	arthel_minute
		Barthel Index Total:	barthe	el_index_tota	I	
1. Feeding		▼ feeding	6. Bladder Co	ontrol		▼ bladder_control
2. Bathing		▼ bathing	7. Toilet Use		▼ toilet_use	
3. Grooming		▼ grooming	8. Chair/Bed Transfer		▼ chair_bed_transfe	
4. Dressing	<b>▼</b> dressing		9. Mobility		▼ mobility	
5. Bowel Control		▼ bowel_control	10. Stairs			▼ stairs
Dropdown box	codes					
rankin_score 0=No symptoms 1=No significant disability sympt 2=Slight disability 3=Moderate disability	feeding 0=Unable 5=Needs help 10=Independent	0=Dependent 0=Needs help	0=Dependent 0=1 5=Needs help 5=1	wel_control Incontinent Occasional accident =Continent	bladder_control 0=Incontinent 5=Occasional accident 10=Continent	toilet_use 0=Dependent 5=Needs some help 10=Independent

0=Unable 5=Needs help 10=Independent

chair\_bed\_transfer 0=Unable

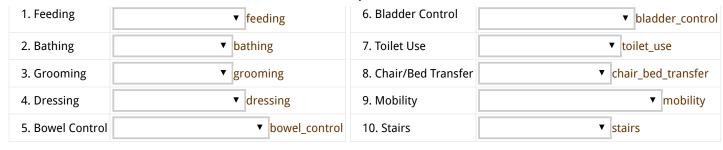
5=Major help

10=Minor help 15=Independent mobility 0=lmmobile

5=Wheel chair dependent 10=Walks with help 15=Independent

4=Moderate to severe disability 5=Severe disability 6=Death

Study: MIST	TIE III Training   Site: Testing - 888   Patient: 888-6037   Form: Day 180-Scales  Patient Interviewer	Ð	
Date of Interview			
		="on"Phone interview with spouse	
	local_medical_doctor="on"Report from local medical doctor	other_via_phone="o specify:	n"Other source via phone interview specify_other_phone
	phone_with_subject="on"Phone interview with subject	other="on"Other specify:	specify_other
	Mini Mental Status Exam ☐ not_done	="on" Not Done	
Patient Interviewe	er for Mini Mental Status Exam: 1		
	Examiner Name Select One ▼ examiner_name	e_MMSE	
	examiner_name_MMSE_non	ne="on"Non-qualified reviewe	r (protocol deviation)
Patient Interviewe	er for Modified Rankin Scale:  Examiner Name Select One ▼ examiner_name_r  examiner_name_rankin_none=		protocol deviation)
	Modified Rankin Scale Score	e:	▼ rankin_score
	Barthel Index Darthel_not_don	e="on" Not Done	
Patient Interviewe	er for Barthel Index:		
	Examiner Name Select One ▼ examiner_name_barthel  □ examiner_name_barthel_none="on"No	on-qualified reviewer (protoco	ol deviation)
	Date of Survey barthel_date Time of Survey  Barthel Index Total: barthe	▼ barthel_hour : ▼ ba	arthel_minute



■ NIHSS not done="on" Not Done NIH Stroke Scale

Patient Interviewer for NIH Stroke Scale:

**Examiner Name** | Select One ▼ examiner name NIHSS

examiner\_name\_NIHSS\_none="on"Non-qualified reviewer (protocol deviation)



Personal Health Utility Assessment Interview (Time Trade Off) ☐ interview\_not\_done="on" Not Done

Patient Interviewer for PHUA:

<b>Examiner Name</b> Select One ▼ examiner_name_p	huai
examiner_name_phuai_none="	on"Non-qualified reviewer (protocol deviation)
interview_not_assessable="on" Not assessable due to con Utility Score:	ma, obtunded, non-communicative, etc. (vs. not done in error)  vutility_score
Depression Scale (CESD)	CESD_not_done="on" Not Done
cesd_not_assessable="on" Not assessable due to com	a, obtunded, non-communicative, etc. (vs. not done in error)
Score: CESI	O_score out of 60 possible points
Answered: CESI	D_answered out of 20 questions
1. I was bothered by things that usually don't bother me	11. My sleep was restless
▼ CESD_q1	▼ CESD_q11
2. I didn't feel like eating; my appetite was poor	12. I was happy
▼ CESD_q2	▼ CESD_q12
3. I felt that I could not shake off the blues even with help from my family or friends	13. I talked less than usual
▼ CESD_q3	▼ CESD_q13
4. I felt I was just as good as other people	14. I felt lonely
▼ CESD_q4	▼ CESD_q14
5. I had trouble keeping my mind on what I was doing	15. People were unfriendly
▼ CESD_q5	▼ CESD_q15
6. I felt depressed	16. I enjoyed life
▼ CESD_q6	▼ CESD_q16
7. I felt that everything I did was an effort	17. I had crying spells
▼ CESD_q7	▼ CESD_q17
8. I felt hopeful about the future	18. I felt sad
▼ CESD_q8	▼ CESD_q18
9. I thought my life had been a failure	19. I felt that people dislike me

0=No symptoms 1=No significant disability symptoms 2=Slight disability 3=Moderate disability 4=Moderate to severe disability 5=Severe disability 6=Death

eeding 0=Unable 5=Needs help 10=Independent

toilet\_use 0=Dependent

5=Needs some help

10=Independent

athing 0=Dependent 5=Independent

chair bed transfer

0=Unable

5=Major help

10=Minor help

15=Independent

0=Needs help 5=Independent

nobility

0=Immobile

5=Wheel chair dependent

10=Walks with help

5=Independent

dressing 0=Dependent 5=Needs help 10=Independent

owel\_control 0=Incontinent 5=Occasional accident 10=Continent

ladder control 0=Incontinent 5=Occasional accident 10=Continent

glasgow\_score\_eyes 1,2,3.4.5

glasgow\_score\_verbal 1,2,3,4,5 glasgow\_score\_motor

1a\_loc 0=Alert

1=Arousable by minor stimulation

2=Obtunded

3=Unresponsive or refelx response

0=Answers 2 questions correctly 1=Answers 1 question correctly 2=Answers 0 question correctly

0=Absent

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

2\_best\_gaze 0=Normal

1=Partial gaze palsy 2=total gaze paresis

3 visual fields

1,2,3,4,5

0=No visual loss 1=Partial Hemianopia

2=Complete Hemianopia 3=Bilateral Hemianopia

1=Minor paralysis 2=Partial paralysis 3=Complete

4\_facial\_palsy

0=Normal

5b\_motor\_right\_arm / 6a\_motor\_left\_leg / 6b\_motor\_right\_leg 0=No drift

5a\_motor\_left\_arm /

1=Drift

3=No effort against gravity

2=Some effort against gravity

4=No movement Amputation N/A

7 limb ataxia

1=Present in one limb 2=Present in two limbs

8\_sensory 0=Normal

0=Unable

5=Needs help

10=Independent

1=Mild to moderate loss 2=Severe loss

9\_best\_language 0=Normal

1=Mild to moderate aphasia 2=Severe aphasia

3=Mute, global aphasia

10\_dysarthria 0=Normal

1=Mild to moderate 2=Severe Intubated N?A

11 extinction

0=No abnormality

1=Inattention to one of the sensory modalities 2=Profound hemi-inattention

2a\_distal\_motor\_left\_hand /

12b\_distal\_motor\_right\_hand

0=Normal

1=Some extension after 5 seconds

2=No voluntary extension after 5 seconds

# CESD q1-q3, q5-q7, q9-q11, q13-q15, q17-q20

0=Rarely or none of the time(<1 day)

1=Some or a little of the time (1-2 days)

2=Occasionally or a moderate amount of the time (3-4 days)

3=Most or all of the time (5-7 days)

# CESD q4, q8, q12, q16

3=Rarely or none of the time(<1 day)

2=Some or a little of the time (1-2 days)

1=Occasionally or a moderate amount of the time (3-4 days) 0=Most or all of the time (5-7 days)

utility\_score 0.0

0.1 0.2

0.3 0.4 0.5

0.6 0.7

0.8 0.9 1.0



Study: MISTIE III Training | Site: Testing - 888 | Patient: 888-6037 | Form: Day 30-GOS-E

Extended Outcome Scale ont\_done="on" Not Done

Reminder: Questions should be answered using the best available information, including information from a care giver.

	CONSCIOUSNESS	Yes	No		
1a.	Are you able to communicate effectively? For example, are you able to hold a conversation, answer questions without confusion?	effectively_communicate="Yes"			
1b.	If no, are you able to obey simple commands, or say any words? (NOTE: Anyone who shows ability to obey even simple commands, or utter any word or communicate specifically in any other way is no longer considered to be in the vegetative state. Eye movements are not reliable evidence of meaningful responsiveness. Corroborate with nursing staff. Confirmation of VS requires full assessment as in the Royal College of Physician Guidelines.)	obey_simple_commands="Yes"	obey_simple_commands="No"		
	INDEPENDENCE IN THE HOME	Yes	No		
2a.	Do you require the assistance of another person at home every day for some activities of daily living? For example, are you unable to look after yourself (themselves) at home for 24 hours if necessary? Are you unable to get washed up, put on clean clothes without help or reminding, prepare food, answer the phone and deal with the caller, handle minor domestic crises, and capable of being left alone overnight?	require_assistance="Yes"	require_assistance="No"		
2b.	Do you need frequent help or someone to be around at home most of the time? For example, are you unable to look after yourself (themselves) at home for up to 8 hours during the day if necessary?	frequent_help="Yes"	ofrequent_help="No"		
2c.	Did you require assistance at home before the injury?	assistance_before_injury="Yes"	assistance_before_injury="No"		
	INDEPENDENCE OUTSIDE THE HOME	Yes	No		
3a.	Are you able to shop without assistance? This would include being able to plan what to buy, taking care of money, and behaving appropriately in public. (NOTE: The subject need not normally shop, but must be able to do so.)	shop_wo_assistance="Yes"	shop_wo_assistance="No"		
3b.	Were you able to shop without assistance before the injury?	shop_before_injury="Yes"	oshop_before_injury="No"		
4a.	Are you able to travel locally without assistance? This would mean driving or using public transportation to get around or using a taxi as long as you (they) can phone for yourself (themselves) and instruct the driver.	travel_locally="Yes"	o travel_locally="No"		
4b.	Were you able to travel without assistance before the injury?	travel_before_injury="Yes"	travel_before_injury="No"		
	WORK	Yes	No		
5a.	Are you (they) currently able to work to your (their) previous capacity?  (NOTE: If they were working before, then their	oable_to_work="Yes"	able_to_work="No"		

	current capacity for work should be at the same level. If they were seeking work before, then the injury should not have adversely affected their chances of obtaining work or the level of work for which they are eligible. If the patient was a student before injury, then their capacity for study should not have been adversely affected.)		
	How restricted are you?		
5b.	Are you only able to work in a sheltered workshop or non-competitive job, or currently unable to work?		
	how_restricted="work in a sheltered workshop"		
5c.	Were you either working or seeking employment before the injury?  Yes work_before_injury="either_or"		
JC.	OR Were you doing neither? Yes work_before_injury="neither"		
	SOCIAL AND LEISURE ACTIVITIES	Yes	No
6a.	Are you able to resume regular social and leisure activities outside of the home? You need not have resumed all your previous leisure activities, but should not be prevented by physical or mental impairment.  (NOTE: If they have stopped the majority of activities because of loss of interest or motivation then this is also considered a disability.)	able_to_social="Yes"	able_to_social="No"
6b.	What is the extent of restriction on your (their) social and leisure activities?  Participate a bit less: at least half as often as before injury. social_leisure_extent="Participate a bit less"  Participate much less: less than half as often. social_leisure_extent="Participate much less"  Unable to participate: rarely, if ever, take part. social_leisure_extent="Unable to participate"		
6c.	Did you engage in regular social and leisure activities outside of the home before injury?	osocial_before="Yes"	osocial_before="No"
	FAMILY AND FRIENDSHIPS	Yes	No
7a.	Have there been psychological problems which have resulted in ongoing family disruption or disruption of friendships? For example, do you have a quick temper, irritability, anxiety, insensitivity to others, mood swings, depression, or unreasonable or childish behavior?	opsych_problems="Yes"	opsych_problems="No"
	What has been the extent of disruption or strain?		
76	Occasional - less than weekly odisruption_extent="Occasional"		
7b.	disruption_extent="Frequent"		
	Constant - daily and intolerable disruption_extent="Constant"		
7c.	Were there problems with family or friends before the injury? (NOTE: If there were some problems before	family_problems_before="Yes"	family_problems_before="No"

//2/2	Day 30 - Glasg	ow Outcome Scale Extended (GOSE) - 888	-6037
	injury, but these have become markedly worse since injury then answer "No" to Q7c)		
	RETURN TO NORMAL LIFE	Yes	No
8a.	Do you have any other current problems relating to the injury which affect daily life? Other typical problems may include headaches, dizziness, tiredness, sensitivity to noise or light, slowness, memory failures, and concentration problems.	odaily_life_problems="Yes"	odaily_life_problems="No"
8b.	Were similar problems present before the injury? (NOTE: If there were some problems before injury, but these have become markedly worse since injury then answer "No" to Q8b)	odaily_problems_before="Yes"	O daily_problems_before="No"
	EPILEPSY	Yes	No
1.	Since the injury have you had any epileptic fits?	epileptic_fits="Yes"	epileptic_fits="No"
2.	Have you been told that you are currently at risk for developing epilepsy?	epilepsy_risk="Yes"	epilepsy_risk="No"
	OTHER		
1.	What is the most important factor in your recovery?  The effects of the head injury recovery_factor="head injury"  The effects of illness or injury to another part of the body recovery_factor="other body part"  A mixture of these recovery_factor="mixture"		
	Gose Score (calculated):		▼ score

7/2/2019			Day 30 / Da	ay 180 / Day 365 - S	troke	Impact Scale	╛			
VISION Study: N	MISTIE III Training   Site: Testing - 888	Patient: 88	88-6037   Form: Day 30-SIS Stroke Impact Scale	(SIS) 🕕 🗆 not done:	="on" N	lot Done				
Stroke Impact Scale (SIS) In not_done="on" Not Done  Examiner Name Select One vexaminer_name examiner_name_none="on"Non-qualified reviewer (protocol deviation)										
unconscio	us_with_no_proxy="on" Not able t	to score	Sourc	ce: osource_of_scale="Pat	ient"Pati	ent osource_o	f_scale="Proxy"Pro	оху		
The purpose of this questionnaire is to evaluate how stroke has impacted your health and life. We want to know from YOUR POINT OF VIEW how stroke has affected you. We will ask you questions about impairments and disabilities caused by your stroke, as well as how stroke has affected your quality of life. Finally, we will ask you to rate how much you think you have recovered from your stroke.  These questions are about the physical problems which may have occurred as a result of your stroke.										
	eek, how would you rate the streng	gth of	A lot of strength	Quite a bit of strength	So	me strength	A little stren	gth	No strength at all	
your a. Arm that was	s <u>most affected</u> by your stroke?		strength_arm="5" 5	ostrength_arm="4" 4	O stre	ength_arm="3" 3	strength_arn	n="2" 2	strength_arm="1" 1	
<b. grip="" of="" td="" you<=""><td>r hand that was <u>most affected</u> by yo</td><td>our stroke?</td><td>0</td><td>5 strength_hand_grip="4" 4</td><td></td><td>0</td><td>0</td><td></td><td>0</td></b.>	r hand that was <u>most affected</u> by yo	our stroke?	0	5 strength_hand_grip="4" 4		0	0		0	
c. Leg that was	most affected by your stroke?		strength_leg="5" 5	strength_leg="4" 4	str	ength_leg="3" 3	strength_leg	g="2" 2	strength_leg="1" 1	
	nat was <u>most affected</u> by your strok		strength_foot="5" 5	ostrength_foot="4" 4		ength_foot="3" 3	strength_foo	t="2" 2	strength_foot="1" 1	
Actual raw sco			Transformed score:	transformed_score	_physica					
These question  2. In the past	s are about your memory and think	ing.								
week, how difficult was it for you to	Not difficult at all	,	A little difficult	Somewhat difficult		Very di	fficult	E	xtremely difficult	
a. Remember things that people just told you?	oremember_things_told="5" 5	O reme	mber_things_told="4" 4	remember_things_told=	="3" 3	oremember_th	ings_told="2" 2	O remo	ember_things_told="1" 1	
b. Remember things that happened the day before?	oremember_things_happened="5" 5	remember		remember_things_happened	d="3" 3 r	remember_things_	happened="2" 2	remember_things_happened="1" 1		
c. Remember to do things (e.g. keep scheduled appointments or take medication)?	to do things (e.g. keep scheduled appointments or take		ember_do_things="4" 4	remember_do_things=	remember_do_things="3" 3		remember_do_things="2" 2		remember_do_things="1" 1	
d. Remember the day of the week?   or remember_day_of_week="5" 5			nber_day_of_week="4" 4	remember_day_of_week	remember_day_of_week="3" 3		y_of_week="2" 2	O reme	mber_day_of_week="1" 1	
e. Concentrate?	oconcentrate="5" 5	0,	concentrate="4" 4	oconcentrate="3" 3	oconcentrate="3" 3		rate="2" 2	С	concentrate="1" 1	
f. Think quickly?	think_quickly="5" 5	Ot	hink_quickly="4" 4	othink_quickly="3"	think_quickly="3" 3		ickly="2" 2	$\circ$	think_quickly="1" 1	
g. Solve everyday problems?	solve_everyday_problems="5" 5	solve_eve	eryday_problems="4" 4	solve_everyday_problems="3" 3 solve_everyday_proble				solve_e\	veryday_problems="1" 1	
Actual raw sco	actual_raw_score_t	hinking	Transformed score:	transformed_score	_thinking	5				
·	s are about how you feel, about cha	anges in you	ur mood and about your a	ability to control your emotion	ons since	your stroke.				
3. In the past w how often did you	None of the time		A little of the time	Some of the time	е	Most of	the time		All of the time	
a. Feel sad?	ofeel_sad="5" 5		O feel_sad="4" 4	○ feel_sad="3"	3	O feel_	sad="2" 2		O feel_sad="1" 1	
b. Feel that the nobody you are close to?	e feel_nobody_is_close="5"	" 5	eel_nobody_is_close="4" 4	feel_nobody_is_clos	se="3" 3	G feel_nobod	y_is_close="2" 2	ofeel_nobody_is_close="1" 1		
c. Feel that you are a burden to others?			eel_burden_to_others="4"	4	ofeel_burden_to_others="3" 3		_to_others="2" 2	O feel	_burden_to_others="1" 1	
d. Feel that you have nothing to look forward to	nothing_to_look_forward_to="	5" 5 nothin	og_to_look_forward_to="4"	4 nothing_to_look_forward	_to="3" 3	nothing_to_look	o_ _forward_to="2" 2	nothing_	to_look_forward_to="1" 1	
e. Blame yours for mistakes th you made?	at Oblame_yourself="5" 5		blame_yourself="4" 4	O blame_yourself=	"3" 3	O blame_y	ourself="2" 2	0	blame_yourself="1" 1	
f. Enjoy things a much as ever?	enjoy_things_as_much="1	" 1 er	njoy_things_as_much="2"	2 enjoy_things_as_mu	ch="3" 3	enjoy_thing	s_as_much="4" 4	o enjo	oy_things_as_much="5" 5	
g. Feel quite nervous?	feel_quite_nervous="5"	5	feel_quite_nervous="4" 4	feel_quite_nervous	s="3" 3	ofeel_quite	_nervous="2" 2	O fe	el_quite_nervous="1" 1	
h. Feel that life worth living?	is	" 1 O f	eel_life_worth_living="2" 2	2	ig="3" 3	o feel_life_wo	orth_living="4" 4	O fee	l_life_worth_living="5" 5	
i. Smile and lau at least once a		I" 1 smile	at_least_once_a_day="2"	2 smile_at_least_once_a_d	ay="3" 3	smile_at_least_d	once_a_day="4" 4	smile_a	t_least_once_a_day="5" 5	
Actual raw sco	7 12 12 12 12 12 12 13		Transformed score:	transformed_scor			,		,	
The following q	uestions are about your ability to co	ommunicat	e with other people, as w	ell as your ability to underst	and wha	t you read and wh	at you hear in a c	onversati	ion.	
4. In the past w			A little difficult	Somewhat diffi	cult	Very	difficult		Extremely difficult	
how difficult wa	as it to								411	

11212013				Day	00 - O	tione impact ocale (or	J) - U	100-0007		
a. Say the name of someone who was in front of you?		say_someones_na	me="5" 5	say_someones_name	e="4" 4	say_someones_name='	"3" 3	say_someones_name="2" 2	2 say_someones_name="1" 1	
b. Understand what was being said to you in a conversation?		understand_conversat	ion="5" 5	="5" 5 understand_conversation="		understand_conversation=	:"3" 3	understand_conversation="2"	2 understand_conversation="1" 1	
	questions?	reply_to_question	ıs="5" 5	reply_to_questions=	-"4" 4	"4" 4		oreply_to_questions="2" 2	reply_to_questions="1" 1	
d. Correctl objects?	y name	correctly_name_object	ts="5" 5	correctly_name_objects	="4" 4	"4" 4 correctly_name_objects="3" 3		correctly_name_objects="2" 2	correctly_name_objects="1" 1	
e. Participa conversation group of p	on with a	oconverse_with_gro	up="5" 5	o="5" 5		4" 4 converse_with_group="3" 3		oconverse_with_group="2"	converse_with_group="1" 1	
f. Have a co	onversation phone?	converse_on_telepho	ne="5" 5	converse_on_telephone	="4" 4	converse_on_telephone="	'3" 3	converse_on_telephone="2" 2	converse_on_telephone="1" 1	
on the tele	selecting the one number	call_another_on_teleph	one="5" 5	one="5" 5 call_another_on_telephone		" 4 call_another_on_telephone="3"		call_another_on_telephone="2"	2 call_another_on_telephone="1" 1	
Actual rav		actual_raw_score	_commun	nication Transformed	score:	transformed_sco	re_cor	mmunication		
The follow	ing questions	ask about activities you	might do	during a typical day.						
5. In the past 2 weeks, how difficult wa		lot difficult at all		A little difficult		Somewhat difficult		Very difficult	Could not do at all	
a. Cut your food with a knife and fork?	a	O vith_knife_and_fork="5"	5 cut_food	O d_with_knife_and_fork="4"	4 cut_f	 cut_food_with_knife_and_fork="3" 3 c		t_food_with_knife_and_fork="2"	Q cut_food_with_knife_and_fork="1"	
b. Dress th top part of your body	o dre	ess_top_of_body="5" 5	0 (	dress_top_of_body="4" 4	(	odress_top_of_body="3" 3		odress_top_of_body="2" 2	Odress_top_of_body="1" 1	
c. Bathe yourself?	0 b	athe_yourself="5" 5		obathe_yourself="4" 4		obathe_yourself="3" 3		obathe_yourself="2" 2	bathe_yourself="1" 1	
d. Clip you toenails?	r clip	o_your_toenails="5" 5		oclip_your_toenails="4" 4		oclip_your_toenails="3" 3		clip_your_toenails="2" 2	clip_your_toenails="1" 1	
e. Get to th toilet on time?		to_toilet_on_time="5" 5	○ ge	et_to_toilet_on_time="4" 4	C	get_to_toilet_on_time="3" 3		Oget_to_toilet_on_time="2" 2	get_to_toilet_on_time="1" 1	
f. Control your bladder (ne have an accident)?	ot cont	control_your_bladder="5" 5		ocontrol_your_bladder="4" 4		O control_your_bladder="3" 3		ocontrol_your_bladder="2" 2	ocontrol_your_bladder="1" 1	
g. Control your bowe (not have a accident)?	an cont	crol_your_bowels="5" 5	© cc	ocontrol_your_bowels="4" 4		ocontrol_your_bowels="3" 3		ocontrol_your_bowels="2" 2	control_your_bowels="1" 1	
		O household_chores="5" 5	do_ligh	○ nt_household_chores="4" 4	do_l	ight_household_chores="3" :	3 d	o_light_household_chores="2" 2	do_light_household_chores="1" 1	
i. Go shopping?	0	ogo_shopping="5" 5		ogo_shopping="4" 4		ogo_shopping="3" 3		ogo_shopping="2" 2	go_shopping="1" 1	
j. Do heavy household chores (e.g.			ousehold_chores="5" 5			'3 do	o_heavy_household_chores="2" 2	do_heavy_household_chores="1"		
Actual rav	v score:	actual_raw_score	_activities	Transformed score:		transformed_score_activ	vities			
The follow	ing questions	are about your ability to	be mobil	e, at home and in the com	munity.					
6. In the past 2 weeks, how difficult was it to	Not o	Not difficult at all		A little difficult		Somewhat difficult		Very difficult	Could not do at all	
a. Stay sitting without losing your balance?	stay_sitt	ing_balanced="5" 5	O stay_	sitting_balanced="4" 4	○st	ay_sitting_balanced="3" 3	C	stay_sitting_balanced="2" 2	stay_sitting_balanced="1" 1	
balance?  b. Stay standing without losing your balance?  stay_standing_balanced="5" 5		o stay_s	tanding_balanced="4" 4	O sta	y_standing_balanced="3" 3	0 9	stay_standing_balanced="2" 2	Stay_standing_balanced="1" 1		

limited\_ability\_help\_others="3" 3

limited\_ability\_help\_others="2" 2

help others? Actual raw score: Transformed score: transformed\_score\_participation actual raw score participation **AVERAGE SIS SCORE (Questions 1-8):** average\_sis\_score

limited\_ability\_help\_others="4" 4

## 9. Stroke Recovery

wish? h. Your ability to

limited\_ability\_help\_others="5" 5

limited\_ability\_help\_others="1"

On a scale of 0 to 100, with 100 representing full recovery and 0 representing no recovery, how much have you recovered from your stroke?

stroke\_recovery

EQ-Visual Analog Scale VAS\_not\_done="on" Not Done

EQ-VAS: EQ\_VAS\_score

EQ-5D:

**Anxiety/Depression** 

depressed

depressed

not anxious="1" I am not anxious or depressed

moderately\_anxious="2" I am moderately anxious or

extremely\_anxious="3" I am extremely anxious or

EQ score

How would you best describe your ability to speak?

- ability\_to\_speak="1" I can be completely understood when speaking with strangers
- ability\_to\_speak="2" I can be completely understood when speaking with those who know me well but only partially understood by strangers
- ability\_to\_speak="3" I can hardly be understood by anyone

# Self-esteem

How would you best describe your appreciation of yourself?

- self\_esteem="1" I am satisfied with myself most of the time
- self\_esteem="2" I sometimes feel I have good qualities but do not consider myself equal to others
- self esteem="3" I often feel I am a failure, with much less worth than others

#### Coping

How would you best describe your ability to deal with life problems?

- O life\_problems="1" I can cope with life problems as they come
- O life\_problems="2" I am sometimes overwhelmed by life problems
- O life problems="3" I often feel helpless when dealing with life problems

#### **Health Status**

It is important for us to know if your health today reflects your typical health. Compared to two weeks ago, would you say your health is:

- relative\_health="1" better than usual
- relative\_health="2" about the same
- relative health="3" worse than usual If worse, can you explain why?

health\_worse\_explain

PBSI Preference-weighted Cumulative Score:

normalized score

ct\_not\_done="on" CT/MRI Not Done

Study: MISTIE III Training | Site: Testing - 888 | Patient: 888-6037 | Form: Day 30-CT Scan

Identification

○ type\_of\_imaging="CT"CT ○ type\_of\_imaging="MRI"MRI Date & Time:

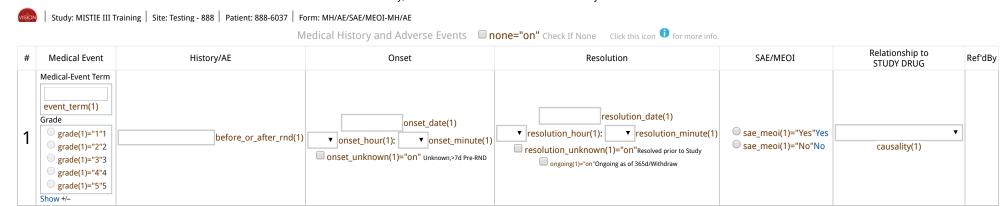
▼ CT\_minute

CT\_date

▼ CT\_hour :

Study: MISTIE III Training | Site: Testing - 888 | Patient: 888-6037 | Form: Meds/Procedures-Meds Meds no\_reportable\_meds="on" No Reportable Meds Click this icon for more info. Click a column header to sort the list Drug Description Start Date Stop Date Reason Taken ▼ ae\_reason(1) AE/MH: stop\_date(1) RXNorm Drug Name start\_date(1) Procedures: ▼ stop\_hour(1): ▼ stop\_minute(1) 1 procedure\_reason ▼ start\_hour(1): ▼ start\_minute(1) stop\_pre\_randomization(1)="on" Stopped prior to Study drug\_name(1) drug\_description(1) start\_unknown(1)="on" Unknown,>7d Pre-RND Other: duration\_ongoing(1)="on"Ongoing as of 365d/Withdraw other\_reason(1)

Study: MISTIE III Training | Site: Testing - 888 | Patient: 888-6037 | Form: Meds/Procedures-Procedures Click this icon for more info. Procedures no\_reportable\_procedure="on" No Reportable Procedure Click a column header to sort the list Procedure Timeframe Comments Start Stop Procedure Term term(1) stop\_date(1) Other, specify: start\_date(1) ▼ stop\_hour(1)hr ▼ stop\_minute(1)min timeframe(1) ▼ start\_hour(1)hr ▼ start\_minute(1)min stop\_unknown(1)="on"Stopped prior to Study comments(1) proc\_other(1) start\_unknown(1)="on"Unknown,> 7d Pre-RND duration\_ongoing(1)="on"ongoing as of 365d/Withdraw Procedure SOC system\_organ\_class(1)



# Dropdown box codes

causality

Unrelated Possibly related Probably related Related

Study: MISTIE III Training   Site: Testing - 888   Patient: 888-6037   Form: MH/AE/SAE/MEOI-SAE/MEOI	
Serious Adverse Event Report	
Please submit the otherwise blank form for review.	
Subject Ethnicity: No	
Site Principal Investigator Name:	
Local IRB Protocol #:irb_prot  Sponsor Protocol #: IVH06	
Sponsor: NIH/NINDS/Dan Hanley, MD	
Study Drug/Intervention: Activase/Cathflo®	
Indication for Use: Intracerebral/Intraventricular Hemorrhage	
First enter AE on MH/AE form, then select it in the Primary AE field.	
Primary AE Meddra CODE Start D/T Stop D/T Grade Relationship to STUDY DRUG Comment on Relationship	
▼ primary_ae primary_ae_relationship	
Date event became serious:  Time event became serious:  Treatment Given:  IRP Notified	-ا-
Do not enter for MEOIs.  Treatment Given:  IRB Notified="Yes"Yes   treatment given="No"No   IRB_notified="Yes"Yes   IRB	
	IND_Hounce 140 140
Reason(s) Reported	
persistent_disability="on"Persistent or significant disability/incapacity	
persistent_disability="oil" Persistent of significant disability/incapacity  immediately_life_threatening="on"Required discontinuation of dosing  required_stopping_dosing="on"Required discontinuation of dosing  required_stopping_study="on"Required patient withdrawal from follow-up	
required_hospitalization="on"Required in-patient hospitalization or prolonged current in-patient hospitalization	
resulted_in_death="on"Resulted in death  other_reason="on"Other , specify:other_reason_specify	
Was an Autopsy Performed?	
Date of Death: death_date Time of Death (if known): death_hour: death_minute autopsy="No" No autopsy="Yes" Yes	
if available, attach report: Choose File No file chosen autopsy	report
Primary cause of death Contributing Causes	
primary_cause_of_death="initial bleed" initial_bleed_contribution="on" Direct effect of initial bleed	
primary_cause_of_death="vasospasm" vasospasm_contribution="on" Vasospasm Vasospasm	
primary_cause_of_death="ischemia" ischemia_contribution="on" Ischemia due to other causes	
primary_cause_of_death="bleeding event" bleeding_event_contribution="on" Bleeding_event post randomization	
primary_cause_of_death="hydrocephalus" hydrocephalus_contribution="on" Hydrocephalus	
primary_cause_of_death="complications of ivc"   ivc_contribution="on"   Complications of IVC placement	
primary_cause_of_death="other cause of death" other_reported_reason="on" other, specify_other_reported_reason	
primary_cause_of_death="unknown" unknown_contribution="on" Unknown	
withdrawal_contribution="on" Check here if there was Withdrawal of Care (then answer the additional questions)	
Withdrawal of Care	
1. Ask each of the following, "Do you think that withdrawal of care was appropriate for this patient?"	
Investigator: Name investigator investigator investigator	
Attending: Name attending attending attending attending	
2. Patient status in the 24 hours before withdrawal of care	
Hours before withdrawal of care  24 12 6	
ICP max icp_24 icp_12 icp_6	
Acute infection acute_infection_24="Yes"Yes acute_infection_12="Yes"Yes acute_infection_12="No"No acute_infection_12="No"No acute_infection_6="Yes"Yes acute_infection_6="Yes"Yes acute_infection_6="No"No	acute_infection
problems	acute_cardio_problem
3. Did the last CT before decision to withdraw care show:	
Acute obstructive hydrocephalus acute_hydrocephalus="Yes"Yes acute_hydrocephalus="No"No  Mass effect with midline shift mass_effect_midline_shift="Yes"Yes mass_effect_midline_shift="No"No	
4. Other observations:	

.,_,_								o. j, / .a. o. o. =		000 000.				
		Report:	Choose File No	file chosen	EEC	i_report				Repo	rt: Choose Fil	e No file chosen	EP_report	
Is living will st	atus document	ed in chart notes?	will_status_doc	umented="Y	es"Yes will_s	tatus_documen	ited="No"No							
5. Planned family	discussion:													
	Who led the	discussion		▼ who_led	_discussion S	specify:		who_led_discussion	_specify					
Relation of prim	ary family decis	sion maker	▼ relatio	on_primary_d	ecision_maker	Spec	ify:	relation_	specify					
		Discussed	discussed="Pro			ania i laval af a			Did decoupling of prognosis and	level of care discussion	ns decouplii	ng_prognosis_care="Ye ng_prognosis_care="No	es"Yes	
6. Reason for with	hdrawal of care		discussed="Pro t apply):	ignosis + ieve	ei of care Progn	osis + level of ca	are			occu	· · O decoupili	ng_prognosis_care="iNi	0"N0	
	will 🗌 witdraw		ng_will="on" F	Prior stateme	ents by patient	witdrawal_re	eason_prior_stat	tement="on"	Dependent outcome anticipated	witdrawal_reason_ou	itcome="on"	Verified brain death	witdrawal_reason_brain_death="on"	
7. Date and time					event to the		—							
Date of Withdray	wal:	with	drawal_date	Time	of Withdrawal:	▼ withdra		▼ withdrawal_minu						
	Contails at a - 1	411/45		Charle D./T		D/T		s that possibly co	ntributed to this event			Comment	Delegande	
	Contributing N			Start D/T	· · · · · ·	Stop D/T	Grade		Relationship to STUDY DRUG			Comment on	Relationship	
	▼ sae_factor	r_ae(1)										ae_relatio	nship(1)	
Co	ontributing Con	Meds	Start	D/T	Stop D/T	Reasons Ta	aken		Contribution to this ever	t		Co	mment on Contribution	
▼	sae_factor_con	med(1)							▼ conmed	d_contribution(1)				
						_							onmed_relationship(1)	
	Contributing Pro			Start D/T	Stop D	/1			Contribution to this event			Comm	nent on Contribution	
L	▼ sae_factor_c	onpro(1)							▼ conpro_contribution	(1)	-	con	pro_relationship(1)	
	List (	Other Contrib	uting Factors (inc	luding protoco	ol deviations)				Contribution to this event			Con	nment on Contribution	
			sae	e_factor_othe	er(1)				▼ other_co	ntribution(1)				
												C	other_relationship(1)	
Dosing was:	tes	t_article_statu	S		Abateo	upon Stopping		_	r_stopping="Yes"Yes ○ abated_after_sto ribution of the Catheters	pping="No"No				
Catheter #	Location	Date/Tir	me Placed	Date/T	ime Removed	Da	ate/Time of Mar	ne of Manipulations Contribution to this event				Comment on Contribution		
1 ICH Cath										▼ catheter_cont	ribution(1)		ivc_contribution_comment(1)	
1 EVD										▼ catheter_cont	ribution(2)		ive_containation_comment(1)	
1245										cutiletei_cont	ibution(2)		ivc_contribution_comment(2)	
								Narra	ntive					
								i na aanatui lanati						
								ivc_contribution Investigator						
Re	eport Version						Click bo	x and save to sign				Signed b	y/Date Signed	
	rsion(1)="Initial						investigator_apr	proval(1)="Yes"(click	to sign)		Dr.	inv	vestigator_approval_name(1)	
	rsion(1)="Upda rsion(1)="Final"		I have reviewed	d the data on			all corrections and notes made as of the time of my signature), attest that the data is complete and acc release this information for potential reporting to regulatory agencies.				Date:		investigator_approval_date(1	
○ IIIv_report_ve	ision(i)- rinai	rillai				□ICU	M_review_no	t_required="on"	ICU Monitor Review Not Required					
								ICU Monitor	r Signature					
Re	eport Version			Re	lationship to rt-	PA Admin			Relationship to MIS Procedure			Signed b	y/Date Signed	
icu mor	n_report_versio	n(1)			▼	icu_mon_drug_r	relation(1)		▼ icu_mon_n	nis_relation(1)	Fia.,	Ficu_mon_approval(1)="Yes"(click and save to sign)		
ica_mor	i_report_version	(1)				Comme	nt:				Dr.		ı_mon_approval_name(1)	
											Date:		icu_mon_approval_date(1)	
						icu_mon_com	ments(1)							
								Medical Monit						
Re	eport Version			Re	lationship to rt-	PA Admin			Relationship to MIS Procedure		_		y/Date Signed	
		. !									medical	_mon_approval(1)="Ye	s"(click and save to sign)	

# Med History, Adverse Events and SAEs - SAE/MEOI - 888-6037

and the Language and the Control of	Drmedical_mon_approval_name(1) Date:
	medical_mon_approval_date(1)
medical_mon_comments(1)	
Study Chairman Comments	
Comment	Signed by/Date Signed
	study_chair_approval(1)="Yes"(click and save to sign)  Dr. study_chair_approval_name(1)
study_chair_comment(1)	Date: study_chair_approval_date(1)

# Dropdown box codes

conmed\_contribution / conpro\_contribution / other\_contribution / medical\_mon\_drug\_relation / medical\_mon\_mis\_relation

Unrelated Possibly related Probably related Related

catheter\_contribution(1) / catheter\_contribution(2)

Unrelated Possibly related Probably related Related N/A



Study: MISTIE III Training | Site: Testing - 888 | Patient: 888-6037 | Form: Protocol-Utilization

### Resource Utilization

#	Location	Date Arrived at Location	Date Departed Location
1	V	admit_date(1)	discharge_date(1)
	unit(1)	admit_date(1)	uischarge_aate(1)

# unit

Enrolling Hospital - Neuro ICU,
Enrolling Hospital - General ICU,
Enrolling Hospital - General Ward,
Home with self care only,
Home with supporting nursing/rehab/etc.,
Hospice, at a hospice facility or hospice ward of hospital,
Long-term care facility,
Inpatient rehab facility,
General/short-term inpatient hospital facility,
Specialized in-patient facility

Study: MISTIE III Training | Site: Testing - 888 | Patient: 888-6037 | Form: Protocol-Deviations **Protocol Deviations** Protocol Stage Reference Date Significant Acknowledge Comment Deviation **Additional Deviations** Reference Date Significant Comment deviation\_sig(1)="Yes" Yes
 deviation\_sig(1)="No" No deviation\_reference\_date(1) deviation\_text(1) deviation\_comment(1)

Principal Investigator Approval

Latest change on 02-Jul-2019 10:24 CDT Coordinator Malathi Ram edited entry Day 1-ICU Care Icp monitoring today

#	PI Signature: Check Box and Save Form to Sign	Signed By	Signed Date
1	principal_inv_approval(1)="Yes" (Investigator to Check)		
		principal_inv_approval_name(1)	principal_inv_approval_date(1)

study\_termination\_reason="Other" Other reason ->specify:

other specify