Definition of Source Vs. Data Transfer Tool

Study teams should try to avoid unnecessary duplication of documentation to prevent transcription and data entry errors. Some procedures will result in:

- Corresponding source documentation (e.g., a history and physical, a laboratory report, etc.).
- The creation of study-specific records to document the conduct of the procedures and resulting data. The CONFORM Pivotal Trial provides source worksheet templates to assist you. it is best practice to make maximum use of original source documentation and utilize this Trial-specific tool only for:

1. Procedures lacking an original source (e.g., assessments of eligibility criteria, verbal interviews, or other study-specific procedures); or
2. To support compliance.

You may choose to use these worksheets as delivered, alter the worksheets to your site's practice, utilize only some of these worksheets, **OR** you may choose to create your own worksheets.

- Note: Monitors cannot monitor from a Data Transfer Tool.

Indicating Use of Each Form

- ☐ **Source** ☐ **Data Transfer Tool** One Box **must** be checked in the header of the worksheet prior to Monitor SDV of the worksheet.
- Worksheets may denote "Source" in the title. These include:
  - Shared Decision Making
  - CONFORM Adverse Event
- If utilized, these forms should be used as source and will be monitored as such

Data Transfer Tool Directions

- If EDC data is changed related to a query – updates are not required to be made to a data transfer tool.
  - Queries are typically created because the original source does not match the eCRF data entry.
  - These documents should be used only as you can adhere to your own Standard of Practice.

Examples of Source vs. Data Transfer Tool:

EDC	☒ Source	☒ Data Transfer Tool
Screening Folder		
ICF/Demographics/ Shared Decision Making		Data Transfer Tool for guidance through EDC entry; original Source is expected
Shared Decision Making	Use, if not documented in Medical record	
Medical History	If recorded by RC/ Inv and no other source available	Original Source is expected
Vital Signs	If recorded by RC/ Inv and no other source available	Original Source expected
Physical Exam	If recorded by Provider and no other source available	Original Source expected
HAS-BLED /CHA_2DS_2-VASc scoring	Sometimes only total score is recorded in original source	
EKG	Investigator sign off as needed	Original source expected
Imaging results	If all questions cannot be obtained from Imaging Report/ Echo CT Screening	Original source expected
Screening Labs	If CS/NCS documentation required	Original source expected
NIHSS / mRS / QVSFS	Use, if only total score is recorded in original source	
Inclusion /Exclusion/ Echo Exclusion	Likely not recorded elsewhere in MR	
Randomization		
Patient Population		choices per direction/ This source will be reflected within subject's MR
Echo Exclusion Criteria	Likely not recorded elsewhere in MR	
Index Procedure		
Procedure Echo	If all questions cannot be obtained from Echo report/ Echo-CT Procedure	Original source expected
Procedure Labs	CS/NCS documentation is required	Original source expected
LAA measurements	If not documented in procedure report or elsewhere	If measurements documented in Procedure report

EDC Index Procedure (cont'd)	☒ Source	☒ Data Transfer Tool
Implant procedure Additional Procedure Report / Procedure Log/ TEE Report/ Anesthesia Report	If any required data is not located in direct source	Original source is expected
Device Info	If place stickers here &/or any required data is not located in direct source CLASS Implant CLASS Delivery System Control Implant	Original source is expected
Pre-Discharge (no other new forms)		
Visit information		Original source expected
7 Days through 5 Years		
Visit information Use for source phone calls if not documented in MR		Use for in person visits, if needed
Study Exit		
	If not recorded elsewhere in MR	
Other Worksheets		
Concomitant Medications		
	For ease of documentation of Study Specific Medication	Original source is expected
Protocol Deviations		
	If not recorded elsewhere within source or on related source worksheet	
Adverse Events & Supplements **2 Types of worksheets provided – 1) direct reflection of EDC OR 2) PI assessments – 2 AEs per page**		
Adverse Event	PI Assessment of Event	Original source of event is expected
Neuro Event	If details not recorded elsewhere within AE source	Original source is expected
Systemic Embolization	Details likely not recorded elsewhere in source	
Chemistry -Cardiac Enzymes	If details not recorded elsewhere within AE source	Original source is expected
Pericardial Effusion	If details not recorded elsewhere within AE source	Original source is expected
Death	Details likely not recorded elsewhere in source	

conformal
THE SHAPE OF STROKE PREVENTION

Table of Contents

conformal THE SHAPE OF STROKE PREVENTION	**CONFORM Concomitant Medication** **☐ Source ☐ Data Transfer Tool**
	Site Number: _____ Subject ID: _____

Note: Data collection includes the use of antiplatelet, anticoagulation and prophylactic antibiotic medication only.
Collect prescribed antiplatelet, anticoagulant, and P2Y12 therapies from subject's relevant medical history through study exit.

Med Number in EDC	Med Name	Dose/Units/Route	Frequency	Start Date	Stop Date
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

conformal THE SHAPE OF STROKE PREVENTION	**CONFORM Concomitant Medication** **☐ Source ☐ Data Transfer Tool**
	Site Number: _____ Subject ID: _____

Med Number in EDC	Med Name	Dose/Units/Route	Frequency	Start Date	Stop Date
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					

conformal THE SHAPE OF STROKE PREVENTION	**CONFORM Concomitant Medication** **☐ Source ☐ Data Transfer Tool**
	Site Number: _____ Subject ID: _____

Time point Con Meds reviewed/ updated by RC	Site Personnel Signature	Date of Review
SCREENING		
PROCEDURE		
PRE-DISCHARGE		
7 DAY		
45 DAY		
6 MONTH		
1 YR		
18 MONTH		
2 YEAR		
3 YEAR		
4 YEAR		
5 YEAR		
STUDY EXIT		

Data collection includes the use of antiplatelet, anticoagulation and prophylactic antibiotic medication only.

conformal THE SHAPE OF STROKE PREVENTION	**CONFORM Protocol Deviation** **☒ Source ☐ Data Transfer Tool**
	Site Number: _____ Subject ID: _____

Note: Please complete only one deviation per form. ***PD # in EDC _____***

Date of Deviation	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)	
Date of Site Awareness	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)	
Time Period of Deviation	☐ Screening ☐ Index Procedure ☐ Discharge ☐ Day 7 ☐ Day 45 ☐ 6 Months ☐ 12 Months ☐ 18 Months	☐ 2 Year ☐ 3 Year ☐ 4 Year ☐ 5 Year ☐ Not related to a study visit ☐ Unscheduled visit
Deviation Category *(Select one)*	☐ Eligibility ☐ Adverse event not reported per protocol ☐ Informed Consent ☐ Randomization ☐ Study medications ☐ Procedure/assessment complete out of window ☐ Procedure/assessment done but not per protocol ☐ Procedure/assessment incomplete or not done ☐ Visit not done ☐ Visit out of window ☐ Other, specify: _____	
If procedure/assessment *(Check all that apply)*	☐ Study Index Procedure ☐ Physical Exam ☐ Angiography ☐ Echocardiography/CT ☐ ECG ☐ Laboratory Assessment ☐ NIHSS ☐ mRS ☐ QVSFS ☐ Other, specify: _____	

Deviation Reason	☐ Oversight in protocol requirements ☐ Subject refusal or non-compliance ☐ Unable to reach subject ☐ Site scheduling difficulty/error ☐ Investigator decision to protect the rights, safety and welfare of subject ☐ Equipment failure ☐ User error ☐ COVID-19 – Subject diagnosed ☐ COVID-19 – Other, specify: _____ ☐ Disaster/Weather related ☐ Other, specify: _____	
Additional Description of Deviation		
Action Taken	☐ None ☐ Documented site retraining ☐ Subject education/review of study requirements with subject ☐ Other, specify: _____	
Does this Protocol Deviation (PD) require prompt reporting to the IRB?	☐ Yes ☐ No	
	If yes, submitted on:	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)

_____

Site Personnel Signature

__ __ / __ __ __ / __ __ __ __

Date (DD/MMM/YYYY)

conformal THE SHAPE OF STROKE PREVENTION	**CONFORM Procedure** ☐ Source ☐ Data Transfer Tool
	Site Number: _____ Subject ID: _____

Date of procedure	_____/ _____/ _____(DD/MMM/YYYY)
Randomized to	☐ CLAAS ☐ Control
Study Procedure	☐ CLAAS ☐ Watchman ☐ Amulet
Investigator (Operating Physician) First Name	
Investigator (Operating Physician) Last Name	
Primary Imager First Name	
Primary Imager Last Name	
What loading dose was prescribed to the patient prior to the procedure?	☐ 81-100 mg Aspirin ☐ 325 mg Aspirin ☐ No loading dose prescribed prior to index procedure ☐ Other: _____
Procedure start time (24 HR) *(Defined as time of first sheath insertion in primary venous access site)*	_____ : _____
Access Sheath Insertion site ****Access sheath*** *refers to the investigational/control access sheath*	☐ Right femoral vein ☐ Left femoral vein ☐ Both right and left insertion sites
Access Sheath ****Access sheath*** *refers to the investigational/control access sheath*	☐ Single Curve ☐ Double Curve ☐ Both Single Curve and Double Curve used ☐ VizaraMed Multiflex Steerable Sheath ☐ None of the above, other, specify: __
Final Access Sheath used	_____Fr.
Transseptal method	☐ Mechanical needle puncture ☐ Radiofrequency needle puncture

What imaging was used to determine release criteria	☐ TEE ☐ Flouro/Angio	
Peri-device leak present?	☐ Yes, _____mm ☐ No	
Time of Access Sheath removal (24 HR) ****Access sheath*** *refers to the investigational/control access sheath*	_____ : _____	
Vascular hemostasis method *(Please select at least one response)*	☐ Vascular closure device ☐ Suture-mediated ☐ Manual compression	
Low ACT during procedure		
High ACT during procedure		
Total fluoroscopy time (minutes)		
Total contrast used (mL)		
Estimated blood loss (mL)		
Total Heparin Used	☐ _____ml ☐ _____Units ☐ Other: _____	
Was protamine used?	☐ Yes ☐ No	
Time subject left catheterization lab (24 HR)	_____ : _____	
Were any other medical procedures performed?	☐ Yes ☐ No	
	If Yes, specify *(Check all that apply)*	☐ LAA Device, specify: _____ ☐ Pericardial Drain ☐ Pericardiocentesis ☐ Conversion to open heart surgery ☐ Sternotomy ☐ Other, specify: _____

Complete left atrial seal?	☐ Yes ☐ No	
Were there any new adverse events?	☐ Yes *(Complete an Adverse Event Form)* ☐ No	
Did the subject receive the intended implant?	☐ Yes ☐ No	If No, specify why:
Additional Procedure Notes		

_____
Site Personnel Signature

__ __/ __ __ __/ __ __ __ __
Date (DD/MMM/YYYY)

_____
Implanting Investigator Signature

__ __/ __ __ __/ __ __ __ __
Date (DD/MMM/YYYY)

conformal THE SHAPE OF STROKE PREVENTION	**CONFORM CLAAS Implant** ☐ **Source** ☐ **Data Transfer Tool**
	Site Number: _____ Subject ID: _____

Note: Please keep the Investigational Product Sticker of any device opened/used. If more than 2 devices were used, please complete another form if using as source.

CLAAS Device Size	☐ Regular (27 MM) ☐ Large (35 MM)	CLAAS Device Size	☐ Regular (27 MM) ☐ Large (35 MM)
Lot #	*Place product sticker here*	Lot #	*Place product sticker here*
Device Outcome	☐ Used ☐ Opened, Not Used ☐ Opened, Used, Disposed ☐ Opened, Used, Returned ☐ Opened, Not Used, Returned	Device Outcome	☐ Used ☐ Opened, Not Used ☐ Opened, Used, Disposed ☐ Opened, Used, Returned ☐ Opened, Not Used, Returned
Did device meet position criteria?	☐ Yes ☐ No	Did device meet position criteria?	☐ Yes ☐ No
Did device meet anchor criteria?	☐ Yes ☐ No	Did device meet anchor criteria?	☐ Yes ☐ No
Did device meet seal criteria?	☐ Yes ☐ No	Did device meet seal criteria?	☐ Yes ☐ No
Was partial resheath attempted?	☐ Yes, number of partial attempts: _____ ☐ No	Was partial resheath attempted?	☐ Yes, number of partial attempts: _____ ☐ No
Was a full resheath attempted?	☐ Yes ☐ No	Was a full resheath attempted?	☐ Yes ☐ No
Did device deficiency or device malfunction occur?	☐ Yes *If yes, complete a Device Deficiency Form* ☐ No	Did device deficiency or device malfunction occur?	☐ Yes *If yes, complete a Device Deficiency Form* ☐ No

_____
Site Personnel Signature

__ __/ __ __ __/ __ __ __ __
Date (DD/MMM/YYYY)

conformal THE SHAPE OF STROKE PREVENTION	**CLAAS Delivery System** ☐ **Source** ☐ **Data Transfer Tool**
	Site Number: _____ Subject ID: _____

Note: Please keep the Investigational Product Sticker of any device opened/used. If more than 2 devices were used, please complete another form if utilizing as source.

Access Sheath	☐ Regular (27 MM) Single Curve ☐ Regular (27 MM) Double Curve ☐ Large (35 MM) Single Curve ☐ Large (35 MM) Double Curve ☐ VizaraMed Multiflex Steerable Sheath	Access Sheath	☐ Regular (27 MM) Single Curve ☐ Regular (27 MM) Double Curve ☐ Large (35 MM) Single Curve ☐ Large (35 MM) Double Curve ☐ VizaraMed Multiflex Steerable Sheath
Lot Number	*Place Product Sticker here*	Lot Number	*Place Product Sticker here*
Outcome	☐ Used ☐ Opened, Not Used ☐ Opened, Used, Disposed ☐ Opened, Used, Returned ☐ Opened, Not Used, Returned	Outcome	☐ Used ☐ Opened, Not Used ☐ Opened, Used, Disposed ☐ Opened, Used, Returned ☐ Opened, Not Used, Returned
Did device deficiency or device malfunction occur?	☐ Yes *If yes, complete a Device Deficiency Form* ☐ No	Did device deficiency or device malfunction occur?	☐ Yes *If yes, complete a Device Deficiency Form* ☐ No

_____
Site Personnel Signature

__ __ / __ __ __ / __ __ __ __
Date (DD/MMM/YYYY)

conformal THE SHAPE OF STROKE PREVENTION	**Device Deficiency** ☐ **Source** ☐ **Data Transfer Tool**
	Site Number: _____ Subject ID: _____

This Device Deficiency form is for both CLAAS and CONTROL devices.

Note: If an Adverse Event occurred related to a Device Deficiency, please complete an Adverse Event Form and follow reporting guidelines per protocol.

Date of Device Deficiency	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)
Date Sponsor was notified	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)
Component (select one)	☐ CLAAS Implant Regular 27mm ☐ CLAAS Implant Large 35mm ☐ Access Sheath Regular (27mm) Single Curve ☐ Access Sheath Regular (27mm) Double Curve ☐ Access Sheath Large (35mm) Single Curve ☐ Access Sheath Large (35mm) Double Curve ☐ VizaraMed Multiflex Steerable Sheath ☐ Delivery Catheter Regular 27mm ☐ Delivery Catheter Large 35mm ☐ Watchman - Implant ☐ Watchman - Delivery Catheter ☐ Watchman - Access Sheath ☐ Amulet - Implant ☐ Amulet – Delivery Catheter ☐ Amulet – Access Sheath
Conformal Lot #	
Deficiency occurred	☐ During procedure prep ☐ During procedure ☐ Other, specify: _____
Deficiency due to	☐ Device malfunction ☐ Use error ☐ Inadequate labeling ☐ Other, specify: _____
Summary of device deficiency	
Did an adverse event occur due to the deficiency?	☐ Yes (*Complete an Adverse Event Form and follow reporting guidelines per protocol)* ☐ No If Yes, What is the AE#? : _____ If Yes, was it a Serious Adverse Event?: ☐Yes ☐No

	If No, could it have led to a Serious Adverse Device Effect (SADE)?: ☐Yes ☐No • if appropriate action had not been taken • if intervention had not occurred, or • if circumstances had been less fortunate
Location of Device	☐ Sponsor / Manufacturer ☐ Investigational /Study Site ☐ Remains Implanted ☐ Discarded ☐ Unknown ☐ Other *Specify:* _____
Action / Outcome of the device deficiency	☐ Used another CLAAS product ☐ Continued to use product ☐ CLAAS device embolized ☐ Procedure terminated ☐ Other, describe: _____
Will the device be returned to Sponsor/Manufacturer?	☐ Yes, *please follow the device return instructions* ☐ No

Note: If utilizing as source (no other source exists)- form should be signed by device implanter.

_____ __ __ / __ __ __ / __ __ __ __
Site Personnel Signature **Date (DD/MMM/YYYY)**

conformal THE SHAPE OF STROKE PREVENTION	**CONFORM Control Implant** **☐ Source ☐ Data Transfer Tool**
	Site Number: _____ Subject ID: _____

Control Product Used		
☐ Amulet	☐ 16 mm ☐ 18 mm ☐ 20 mm ☐ 22 mm	☐ 25 mm ☐ 28 mm ☐ 31 mm ☐ 34 mm
☐ Watchman FLX	☐ 20 mm ☐ 24 mm ☐ 27 mm ☐ 31 mm ☐ 35 mm	
☐ Watchman FLX PRO	☐ 40 mm	
Please confirm the primary reason for selection of the commercially available device	☐ Subject Anatomy ☐ Investigator Preference ☐ Other, specify: _____	
Device Outcome	☐ Used ☐ Opened, Not Used ☐ Opened, Used, Disposed ☐ Opened, Used, Returned ☐ Opened, Not Used, Returned	
Did device meet release criteria per Manufacturer DFU/IFU?	☐ Yes ☐ No	
Was partial recapture attempted?	☐ Yes, number of partial attempts: _____ ☐ No	
Was full recapture attempted?	☐ Yes ☐ No	
Did device deficiency or device malfunction occur?	☐ Yes ☐ No	

Note: If utilizing as source (no other source exists) - form should be signed by device implanter.

_____
Site Personnel Signature

__ __ / __ __ __ / __ __ __ __
Date (DD/MMM/YYYY)

conformal THE SHAPE OF STROKE PREVENTION	**CONFORM Implant Exclusion Criteria** **☐ Source ☐ Data Transfer Tool**
	Site Number: _____ Subject ID: _____

Echocardiographic Exclusion Criteria
REMINDER: Procedural ultrasound imaging will be performed by a qualified physician who is *not* the implanting physician.
*Potential subjects will be excluded if **ANY** of the following conditions apply*

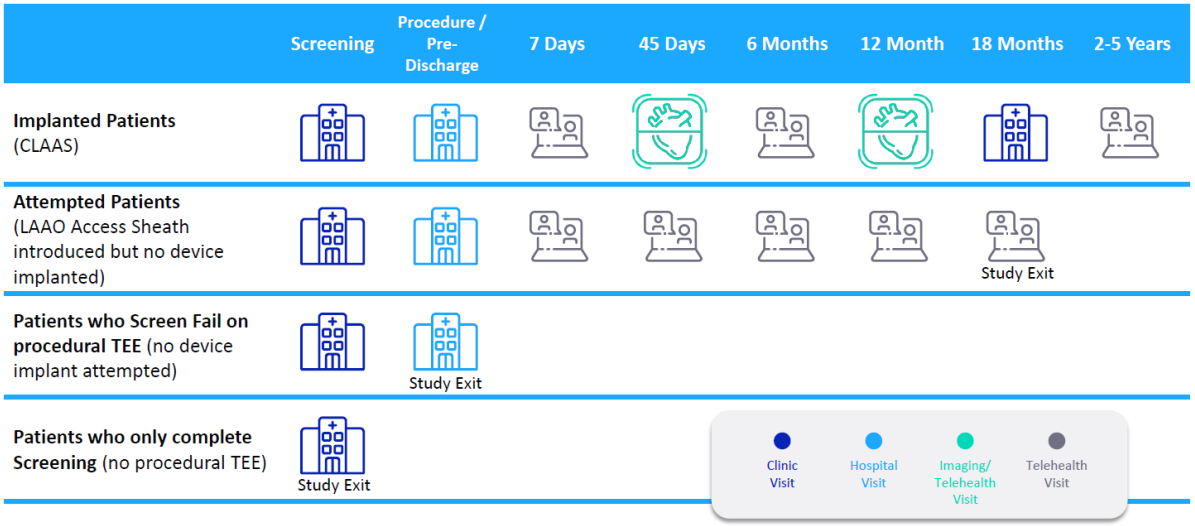
Exclusion Criteria	Yes	No
1. Left atrial appendage cannot accommodate either a commercially available device of the CLAAS device per manufacturer IFU (e.g., the anatomy and sizing must be appropriate for both devices in order to be enrolled in the trial)?	☐	☐
2. Intracardiac thrombus or dense spontaneous echo contrast consistent with thrombus, as visualized by TEE prior to implant?	☐	☐
3. Left ventricular ejection fraction (LVEF) < 30%?	☐	☐
4. Existing circumferential pericardial effusion > 10 mm or symptomatic pericardial effusion, signs, or symptoms of acute or chronic pericarditis, or evidence or tamponade physiology?	☐	☐
5. Atrial septal defect that warrants closure?	☐	☐
6. High risk patent foramen ovale (PFO), defined as an atrial septal aneurysm (exclusion > 15 mm or length > 15 mm) or large shunt (early [within 3 beats] and/or substantial passage of bubbles, e.g. > 20)?	☐	☐
7. Moderate or severe mitral valve stenosis (mitral valve area < 1.5 cm^2)?	☐	☐
8. Complex atheroma with mobile plaque of the descending aorta and/or aortic arch?	☐	☐
9. Evidence of cardiac tumor?	☐	☐

If utilizing as source (no other source exists)- form should be signed by device implanter or echocardiographer present at implant.

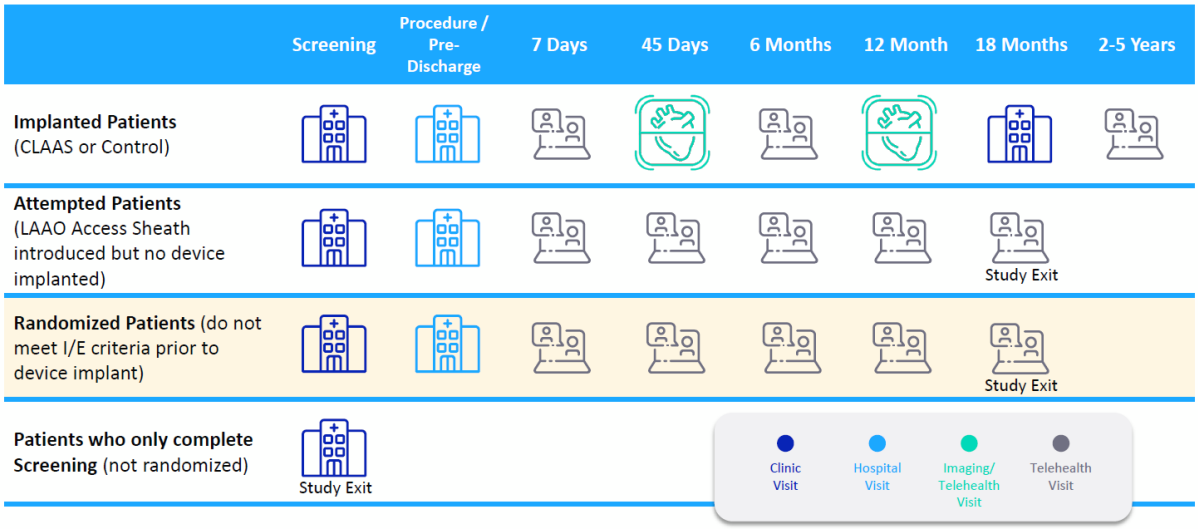
_____ __ __ / __ __ __ / __ __ __ __
Site Personnel Signature **Date (DD/MMM/YYYY)**

* If any of the listed exclusions are marked as YES, the subject shall be considered a Screen Failure and will be followed for 18 months to evaluate safety.

CONFORM PIVOTAL TRIAL | Patient Follow Up – Roll-in Subjects



CONFORM PIVOTAL TRIAL | Patient Follow Up – Randomized Subjects



conformal THE SHAPE OF STROKE PREVENTION	**CONFORM Additional Procedure** ☐ Source ☐ Data Transfer Tool
	Site Number: _____ Subject ID: _____

Date of Additional Procedure	_____/ _____/ _____(DD/MMM/YYYY)
Study Procedure	☐ Watchman FLX ☐ Watchman FLX Pro ☐ Amulet ☐ Other
Investigator (Operating Physician) First Name	
Investigator (Operating Physician) Last Name	
Primary Imager First Name	
Primary Imager Last Name	
What loading dose was prescribed to the patient prior to the procedure?	☐ 81-100 mg Aspirin ☐ 325 mg Aspirin ☐ No loading dose prescribed prior to index procedure ☐ Other: _____
Procedure start time (24 HR) *(Defined as time of first sheath insertion in primary venous access site)*	_____ : _____
Access Sheath Insertion site ****Access sheath*** *refers to the investigational/control access sheath*	☐ Right femoral vein ☐ Left femoral vein ☐ Both right and left insertion sites
Access Sheath ****Access sheath*** *refers to the investigational/control access sheath*	☐ Single Curve ☐ Double Curve ☐ Both Single Curve and Double Curve used ☐ VizaraMed Multiflex Steerable Sheath ☐ None of the above, other, specify: __
Final Access Sheath used	_____Fr.
Transseptal method	☐ Mechanical needle puncture ☐ Radiofrequency needle puncture

Complete left atrial seal?	☐ Yes ☐ No
What imaging was used to determine release criteria	☐ TEE ☐ Flouro/Angio
Peri-device leak present?	☐ Yes, _____mm ☐ No
Time of Access Sheath removal (24 HR) ****Access sheath*** *refers to the investigational/control access sheath*	_____ : _____
Vascular hemostasis method *(Please select at least one response)*	☐ Vascular closure device ☐ Suture-mediated ☐ Manual compression

Did any device deficiencies occur?	☐ Yes Specify: ☐ No
Were there any new adverse events?	☐ Yes *(Complete an Adverse Event Form)* ☐ No

_____
Site Personnel Signature

__ __ / __ __ __ / __ __ __ __
Date (DD/MMM/YYYY)

_____
Implanting Investigator Signature

__ __ / __ __ __ / __ __ __ __
Date (DD/MMM/YYYY)

conformal THE SHAPE OF STROKE PREVENTION	**CONFORM Patient Population Directions & Data Transfer Tool**
	Site Number: _____ Subject ID: _____

Did Subject meet eligibility criteria before Procedure Day ?	☐ **Yes** ☐ **No**
Did Subject undergo Procedure TEE ?	☐ **Yes** ☐ **No**
Did Subject continue to meet eligibility criteria after the Procedural TEE ?	☐ **Yes** ☐ **No**
Did any component of the investigational or control device (e.g. access sheath) enter the subject's body ?	☐ **Yes** ☐ **No**
Did the subject receive an LAAO implant?	☐ **Yes** ☐ **No**
Did the subject receive the intended LAAO implant (e.g., the device they were randomized to)?	☐ **Yes** ☐ **No** *Protocol Deviation should be entered for "Procedure /Assessment incomplete or not done" and, Additional Description of Deviation text box should include "Randomized to CLAAS – received CONTROL"*

_____
Site Personnel Signature

__ __ / __ __ __ / __ __ __ __
Date (DD/MMM/YYYY)

conformal THE SHAPE OF STROKE PREVENTION	**CONFORM Procedure Lab Assessments** ☐ Source ☐ Data Transfer Tool
	Site Number: _____ Subject ID: _____

Original source should be obtained from a direct laboratory report from Subject Medical Record. Laboratory results to be reviewed by delegated investigator (either directly on lab report or as Source here) as relates to subject safety and general INC/EXC Criteria.

Pre-procedure oral anticoagulation should be managed as per site protocol. Warfarin should be discontinued in accordance with site standard of care practices including INR levels on the day of the procedure. We are not collecting day of procedure INR levels.

Laboratory Collection at Procedure required **within 48 hours of implant.**

Date of Hematology	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)
	☐ Not Done *(ENTER PD)*

Laboratory Assessment	***Results Value/ unit***	***Clinically Significant***
Hemoglobin		☐ Yes ☐ No
Hematocrit		☐ Yes ☐ No
Platelet Count		☐ Yes ☐ No

If utilizing this form as source (i.e., no other source exists), this form should be signed by Site Investigator.

_____ __ __ / __ __ __ / __ __ __ __

Site Personnel Signature **Date (DD/MMM/YYYY)**

Yale Cardiovascular Research Group
Yale Echocardiographic Core Laboratory

CONFORM Pivotal Trial

TEE/TTE Sonographer Worksheet

Please submit completed TEE/TTE Sonographer Worksheet with image uploads

---

Site ID: _____ **Subject ID:** _____

Echo Study Date: _____/_____/_____
dd mon yyyy

Modality: ☐ TEE ☐ TTE

Procedure Type:

☐ Diagnostic/Screening ☐ 45-Day ☐ Unscheduled

☐ Index Procedure ☐ 6-Month ☐ Adverse Event

☐ Pre-Discharge ☐ 12-Month ☐ Optional TEE at Baseline

Ultrasound Manufacturer: **Transducer Type:**

_____ _____

Comments _____

_____

_____

Site personnel completing form:

_____ _____ ____/____/_____
Name (print) Sign dd mon yyyy

conformal
THE SHAPE OF STROKE PREVENTION

CONFORM Visit Information

☐ Source ☐ Data Transfer Tool

Site Number: _____ Subject ID: _____

Visit Timepoint	☐ Pre-Discharge ☐ Day 7 ☐ Day 45 ☐ 6 Months ☐ 12 Months ☐ 18 Months	☐ 2 Year ☐ 3 Year ☐ 4 Year ☐ 5 Year ☐ Not related to a study visit ☐ Unscheduled visit
Was visit completed?	☐ Yes ☐ No	
Visit Date	_____ / _____ / _____ (DD/MMM/YYYY)	
Visit Type	☐ Office/clinic visit ☐ Telephone contact ☐ Video link	
Were there any new or changes to existing Adverse Events? *If yes, please complete or update an Adverse Event CRF*	☐ Yes Was the event a suspected stroke or systemic embolism? ☐ Yes ☐ No ☐ No	
Did the subject have any ER visits or hospitalizations since the last visit?	☐ Yes ☐ No	
Were there any changes in patient medical history that are cardiovascular in etiology?	☐ Yes *If yes, specify*: _____ ☐ No	
Were there any new changes to existing Concomitant Medications?	☐ Yes (*If yes, please add new or update Concomitant Medication CRF)* ☐ No	
Was visit imaging done?	☐ Yes Are required images for this visit available? ☐ Yes ☐ No ☐ No ☐ N/A Imaging not required per protocol	

_____ __ __ / __ __ __ / __ __ __ __

Site Personnel Signature **Date (DD/MMM/YYYY)**

conformal THE SHAPE OF STROKE PREVENTION	**CONFORM Screening Data** **☐ Source ☐ Data Transfer Tool**
	Site Number: _____ Subject ID: _____

Informed Consent

Subject to be enrolled as	☐ Roll-In ☐ Randomized	
Protocol Version Activated to at time of Informed Consent:		
Date informed consent was signed (DDMMMYYYY)		
Site ICF Version /IRB Approval Date DDMMMYYYY		
Was this subject screened previously?	☐ Yes ☐ No	Previous Subject ID: _____ - _____

Randomization: ☐ N/A

Randomization shall be within **90 days of informed consent.** The LAA occlusion **procedure shall take place within and including 14 days from the date of randomization.**

Randomization takes place in MEDIDATA Conform Study Data Base. Reference MOPs Binder, as needed

☐ Print off Randomization eCRF and place in Subject Binder.

Screening Demographics

If female, is subject of childbearing age?	☐ Yes ☐ No

Pregnancy Test

If yes, was pregnancy test done?	☐ Yes ☐ No *If no and the female is of child-bearing age, complete a protocol deviation* ☐ N/A Reason N/A:
Date of pregnancy test	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)
Result	☐ Positive *(Check I&E Criteria!)* ☐ Negative

Documentation of Shared Decision Making

Source must be present in Subject Record to document that INCLUSION 6 has been met.
Deemed appropriate for LAA closure by the site investigator and a clinician not a part of the procedural team using a shared decision-making process in accordance with standard of care

☐ Confirmation that shared decision-making already documented in other medical records

_____ __ __ / __ __ __ / __ __ __ __

Site Personnel Signature **Date (DD/MMM/YYYY)**

conformal THE SHAPE OF STROKE PREVENTION	**CONFORM Shared Decision Making Source**
	Site Number: _____ Subject ID: _____

Documentation of Shared Decision Making	☐ N/A, shared decision-making already documented in other medical records
Implanting Physician Name (First Last)	
Implanting Physician Specialty	☐ Interventional Cardiology ☐ Electrophysiology
Referring Physician (First Last)	
Referring Physician Specialty	
Attestation: Based on my review of the patient's medical history, and in conjunction with a formal and shared decision-making process involving the patient and multidisciplinary team, the patient is suitable for the following:	☐ LAA Closure ☐ Short Term Oral Anticoagulation

Source must be present in Subject Record, or Subject Study Binder to document that INCLUSION 6 has been met. If utilizing this source, i.e., no source in other MR is available, this Attestation Source should be signed by Subject's Implanting Study Investigator or the Principal Investigator

_____ **Site Personnel Signature**

__ __ / __ __ __ / __ __ __ __ **Date (DD/MMM/YYYY)**

conformal THE SHAPE OF STROKE PREVENTION	**CONFORM Inclusion/Exclusion Criteria** ☐ Source ☐ Data Transfer Tool
	Site Number: _____ Subject ID: _____

Have all the inclusion criteria and none of the exclusion criteria, as specified by the protocol, been met for this subject?	☐ Yes ☐ No ☐ N/A – Inclusion and Exclusion Criteria not assessed
What primary imaging modality was used to assess Echo Exclusion Criteria?	☐ TTE – Transthoracic echocardiogram ☐ CT ☐ MRI ☐ TEE – Transesophageal echocardiogram ☐ None

Inclusion Criteria

*Potential subjects must meet **ALL** of the following criteria to be eligible for inclusion in the study:*

Inclusion Criteria	Yes	No	N/A – Not assessed
1. Male or nonpregnant female aged ≥ 18 years?	☐	☐	☐
2. Documented non-valvular AF (paroxysmal, persistent, or permanent)?	☐	☐	☐
3. High risk of stroke or systemic embolism, defined as CHA_2DS_2-VASc score of ≥ 3?	☐	☐	☐
4. Has an appropriate rationale to seek a non-pharmacologic alternative to long-term oral anticoagulation?	☐	☐	☐
5. Deemed by the site investigator to be suitable for short term oral anticoagulation therapy but deemed less favorable for long-term oral anticoagulation?	☐	☐	☐
6. Deemed appropriate for LAA closure by the site investigator and a clinician not a part of the procedural team using a shared decision-making process in accordance with standard of care?	☐	☐	☐
7. Able to comply with the protocol-specified medication regimen and follow-up evaluations?	☐	☐	☐
8. The subject (or legally authorized representative, where allowed) has been informed of the nature of the study, agrees to its provisions, and has provided written informed consent approved by the appropriate Institutional Review Board (IRB)/Regional Ethics Board (REB)?	☐	☐	☐

Exclusion Criteria

*Potential subjects will be excluded if **ANY** of the following conditions apply*

Exclusion Criteria	Yes	No	N/A – Not assessed
1. Pregnant or nursing subjects and those who plan pregnancy in the period up to 1 year following index procedure? Female subjects of childbearing potential must have a negative pregnant test (per site standard test) **within 7 days** prior to index procedure	☐	☐	☐
2. Anatomic conditions that would prevent performance of an LAA occlusion procedure (e.g., prior atrial septal defect [ASD] or high-risk patent foramen ovale [PFO], surgical repair or implanted closure device, or obliterated or ligated left atrial appendage)?	☐	☐	☐
3. Atrial fibrillation that is defined by a single occurrence or that is transient or reversible (e.g., secondary thyroid disorders, acute alcohol intoxication, trauma, recent major surgical procedures)?	☐	☐	☐
4. A medical condition (other than atrial fibrillation) that mandates long-term oral anticoagulation (e.g., history of unprovoked deep vein thrombosis or pulmonary embolism, or mechanical heart valve)?	☐	☐	☐
5. History of bleeding diathesis or coagulopathy, or subjects in whom antiplatelet and/or anticoagulant therapy is contraindicated?	☐	☐	☐
6. Documented active infection?	☐	☐	☐
7. Symptomatic carotid artery disease (defined as >50% stenosis with symptoms of ipsilateral transient or visual TIA evidence by amaurosis fugax, ipsilateral hemispheric TIAs or ipsilateral stroke)? If subject has a history of carotid stent or endarterectomy, the subject is eligible if there is <50% stenosis at the site of prior treatment	☐	☐	☐
8. Recent (**within 30 days** of index procedure) or planned (**within 60 days** post-procedure) cardiac or non-cardiac interventional or surgical procedure?	☐	☐	☐
9. Recent (**within 30 days** of index procedure) stroke or transient ischemic attack?	☐	☐	☐
10. Recent (**within 30 days** of index procedure) myocardial infarction?	☐	☐	☐
11. Vascular access precluding delivery of implant with catheter-based system?	☐	☐	☐
12. Severe heart failure (New York Heart Association Class IV)?	☐	☐	☐
13. Prior cardiac transplant, history of mitral valve replacement or transcatheter mitral valve intervention, or any mechanical valve implant?	☐	☐	☐
14. Renal insufficiency, defined as estimated glomerular filtration rate (eGFR) <30 mL/min/1.73m^2 (by the Modification of Diet in Renal Disease equation)?	☐	☐	☐

Exclusion Criteria	Yes	No	N/A – Not assessed
15. Platelet count < 75,000 cells/mm^3 or > 700,000 cells/ mm^3, or white blood cell count < 3,000 cells/ $mm^{3?}$	☐	☐	☐
16. Known allergy, hypersensitivity or contraindication to aspirin, heparin, or device materials (e.g., nickel, titanium) or that would preclude any P2Y12 inhibitor therapy, or the subject has contrast sensitivity that cannot be adequately pre-medicated?	☐	☐	☐
17. Actively enrolled or plans to enroll in a concurrent clinical study in which the active treatment arm may confound the results of this trial?	☐	☐	☐
18. Unable to undergo general anesthesia?	☐	☐	☐
19. Known other medical illness or known history of substance abuse that may cause non-compliance with the protocol or protocol-specified medication regimen, confound the data interpretation, or is associated with a life expectancy of less than 5 years?	☐	☐	☐
20. A condition which precludes adequate transesophageal echocardiographic (TEE) assessment?	☐	☐	☐

Screening Echocardiographic Exclusion Criteria

*This is based on historical imaging (performed within 6 months prior to consent) at Screening. Cardiac CT or TEE can be used to assess all criteria TTE and MRI studies are limited to the confirmed assessment of #3 and #4. Potential subjects will be excluded if **ANY** of the following conditions are known to apply*

Exclusion Criteria	Yes	No	N/A – Not assessed
1. Left atrial appendage cannot accommodate either a commercially available device of the CLAAS device per manufacturer IFU (e.g., the anatomy and sizing must be appropriate for both devices in order to be enrolled in the trial)?	☐	☐	☐
2. Intracardiac thrombus or dense spontaneous echo contrast consistent with thrombus, as visualized by TEE prior to implant?	☐	☐	☐
3. Left ventricular ejection fraction (LVEF) < 30%?	☐	☐	☐
4. Existing circumferential pericardial effusion > 10 mm or symptomatic pericardial effusion, signs, or symptoms of acute or chronic pericarditis, or evidence or tamponade physiology?	☐	☐	☐
5. Atrial septal defect that warrants closure?	☐	☐	☐
6. High risk patent foramen ovale (PFO), defined as an atrial septal aneurysm (exclusion > 15 mm or length > 15 mm) or large shunt (early [within 3 beats] and/or substantial passage of bubbles, e.g., > 20)?	☐	☐	☐
7. Moderate or severe mitral valve stenosis (mitral valve area < 1.5 cm^2)?	☐	☐	☐
8. Complex atheroma with mobile plaque of the descending aorta and/or aortic arch?	☐	☐	☐
9. Evidence of cardiac tumor?	☐	☐	☐

Reminder: *If a significant cardiac event (potentially related to a change in cardiac status, e.g., CHF decompensation) occurs after cardiac imaging is obtained and before randomization takes place- then imaging should be repeated.*

_____ __ __ / __ __ __ / __ __ __ __
Site Personnel Signature **Date (DD/MMM/YYYY)**

_____ __ __ / __ __ __ / __ __ __ __
Investigator Signature **Date (DD/MMM/YYYY)**

conformal THE SHAPE OF STROKE PREVENTION	**CONFORM Medical History** ☐ Source ☐ Data Transfer Tool
	Site Number: _____ Subject ID: _____

Date Medical History Performed	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)		
Rationale for seeking a non-pharmacologic alternative to OAC (Check all that apply)	☐ Drug regimen not compatible with OAC ☐ Non-compliance to medication or monitoring schedule ☐ History of bleeding or high bleeding risk ☐ Renal failure ☐ High fall risk ☐ Other, specify: _____		
Documented type of non-valvular atrial fibrillation:	☐ Paroxysmal ☐ Persistent ☐ Permanent		
Does the subject have a medical condition that mandates long term oral anticoagulation?	☐ Yes *(Review for I&E!)* ☐ No		
Diabetes mellitus (DM)?	☐ Yes ☐ No ☐ Unknown If yes, please select one:	☐ Insulin dependent diabetes mellitus (IDDM) ☐ Type I DM ☐ Type II DM ☐ Unknown ☐ Non-insulin Dependent Diabetes Mellitus How is NIDDM controlled? ☐ Diet ☐ Oral Hypoglycemics ☐ Unknown ☐ Unknown	
History of hypertension (Systolic BP > 140 mmHg, or Diastolic BP >90 mmHg)?	☐ Yes ☐ No ☐ Unknown	If yes, currently requires medication?	☐ Yes ☐ No ☐ Unknown
History of hyperlipidemia (medical diagnosis) or total cholesterol >200?	☐ Yes ☐ No ☐ Unknown	If yes, currently requires medication?	☐ Yes ☐ No ☐ Unknown
History of peripheral vascular disease?	☐ Yes ☐ No ☐ Unknown	If yes, prior intervention?	☐ Yes (check all that apply) ☐ Percutaneous ☐ Surgical ☐ Unknown ☐ No ☐ Unknown

History of carotid artery disease?	☐ Yes ☐ No ☐ Unknown	If yes, location	☐ Right ☐ Left ☐ Bilateral	
		If yes, prior intervention?	☐ Yes, specify: ☐ Endarterectomy ☐ Stent ☐ No ☐ Unknown	
Prior cerebral vascular accident?	☐ Yes ☐ No ☐ Unknown	If yes, date of most recent CVA:	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)	
		If yes, is imaging available?	☐ Yes Date of most recent Brain Scan MRI or CT Imaging: __ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY) ☐ No	
		If yes, specify type (Check all that apply)	☐ Ischemic ☐ Hemorrhagic ☐ Unknown	
Prior traumatic intracranial hemorrhage?	☐ Yes ☐ No ☐ Unknown	If yes, date of most recent intracranial hemorrhage:	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)	
		If yes, is imaging available?	☐ Yes Date of most recent imaging: __ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY) ☐ No	
		If yes, specify type (Check all that apply)	☐ Spontaneous ☐ Traumatic	
Prior transient ischemic attack?	☐ Yes ☐ No ☐ Unknown	If yes, date of most recent TIA:	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)	
History of coronary artery disease?	☐ Yes ☐ No ☐ Unknown	If yes, current anginal status	☐ Asymptomatic ☐ Stable Angina ☐ Unstable Angina	
		If yes, prior coronary artery intervention?	☐ Yes ☐ No ☐ Unknown	If yes, specify type: ☐ Percutaneous ☐ Surgical

History of congestive heart failure?	☐ Yes ☐ No ☐ Unknown	If yes, NYHA Functional Class	☐ Class I ☐ Class II ☐ Class III ☐ Class *IV (Review for I&E!)*
What is the most recently documented LVEF (%)? *(xx)*	_____%	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)	
History of intracardiac mass, thrombus or vegetation?	☐ Yes ☐ No ☐ Unknown	If yes, specify location	☐ Left Ventricle ☐ Left Atrium ☐ Left Atrial Appendage ☐ Other, specify: _____
History of severe valvular heart disease?	☐ Yes ☐ No ☐ Unknown	If yes, specify type (*Check all that apply)*	☐ Aortic valve stenosis ☐ Aortic valve regurgitation ☐ Mitral valve stenosis ☐ Mitral valve regurgitation ☐ Tricuspid valve stenosis ☐ Tricuspid valve regurgitation ☐ Unknown
Does the subject have history of prior cardiac transplant, history of mitral valve replacement or transcatheter mitral valve intervention, or any mechanical valve implant?	☐ Yes *(Review for I&E!)* ☐ No		
History of procedure to convert atrial fibrillation to atrial flutter?	☐ Yes ☐ No ☐ Unknown	If yes, specify type	☐ Cardioversion ☐ Ablation ☐ Both Cardioversion and Ablation
History of acute or chronic pericarditis?	☐ Yes ☐ No ☐ Unknown		
Has the subject had a cardiac or non-cardiac intervention or surgical procedure within 30 days of the index procedure?	☐ Yes *(Review for I&E!)* ☐ No		
Does the subject have a planned surgical procedure within 60 days AFTER the date of the planned Index Procedure Date?	☐ Yes *(Review for I&E!)* ☐ No		

History of myocardial infarction?	☐ Yes ☐ No ☐ Unknown	If yes, most recent date:	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)
History of cardiomyopathy?	☐ Yes ☐ No ☐ Unknown		
History of patent foramen ovale (PFO)	☐ Yes ☐ No ☐ Unknown	If yes, treated?	☐ Yes ☐ No ☐ Unknown
History of atrial septal defect (ASD)?	☐ Yes ☐ No ☐ Unknown	If yes, treated?	☐ Yes ☐ No ☐ Unknown
History of gastrointestinal bleeding?	☐ Yes ☐ No ☐ Unknown		
History of other form of recurrent systemic bleeding?	☐ Yes ☐ No ☐ Unknown		
History of anemia requiring transfusion?	☐ Yes ☐ No ☐ Unknown		
History of renal disease?	☐ Yes ☐ No ☐ Unknown		
History of malignancy?	☐ Yes ☐ No ☐ Unknown		
History of dementia?	☐ Yes ☐ No ☐ Unknown		
Does subject have history of COVID-19?	☐ Yes ☐ No ☐ Unknown ☐ Patient declined to answer		
Has subject received COVID-19 vaccination?	☐ Yes ☐ No ☐ Unknown ☐ Patient declined to answer		

_____ **Site Personnel Signature**

____ / _____ / _____ **Date (DD/MMM/YYYY)**

conformal THE SHAPE OF STROKE PREVENTION	**CONFORM Vital Signs** ☐ Source ☐ Data Transfer Tool
	Site Number: _____ Subject ID: _____

Were vital signs performed?	☐ Yes ☐ No
Date of vital sign measurements	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)
Height *(xxx.xx)*	_____ (cm / in) (circle one)
Weight *(xxx.x)*	_____ (kg / lb) (circle one)
BMI *(xx.x)*	_____ (kg/m^2)
Systolic Blood Pressure *(xxx)*	_____ (mmHg)
Diastolic Blood Pressure *(xxx)*	_____ (mmHg)
Heart Rate *(xxx)*	_____ (bpm)

_____ __ __ / __ __ __ / __ __ __ __

Site Personnel Signature **Date (DD/MMM/YYYY)**

conformal THE SHAPE OF STROKE PREVENTION	**CONFORM Physical Examination – Review of Systems** ☐ Source ☐ Data Transfer Tool
	Site Number: _____ Subject ID: _____

Should be performed as per Standard of Care

Was Physical Examination - Review of Systems performed?	☐ Yes ☐ No
Date of examination	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)
If subject has suspected incident of neurologic event based off responses to QVSFS, NIHSS or other signs/symptoms, was neurologic exam performed by neurologist/clinical designee?	☐ N/A – Patient doesn't have suspected incident of neurologic event ☐ Yes ☐ No
Date of neurologic examination	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)

Body System Examined	**Normal**	**Abnormal (CS)**	**Abnormal (NCS)**	**Not Done**	**Description of abnormal findings**
☐ General Appearance	☐	☐	☐	☐	
☐ Cardiovascular	☐	☐	☐	☐	
☐ Dermatological	☐	☐	☐	☐	
☐ Ears/Nose/Throat	☐	☐	☐	☐	
☐ Gastrointestinal	☐	☐	☐	☐	
☐ Genito-urinary	☐	☐	☐	☐	
☐ Musculoskeletal	☐	☐	☐	☐	
☐ Neurological	☐	☐	☐	☐	
☐ Respiratory	☐	☐	☐	☐	

CS = Clinically significant
NCS = Not clinically significant

_____ __ __ / __ __ __ / __ __ __ __
Site Personnel Signature **Date (DD/MMM/YYYY)**

conformal THE SHAPE OF STROKE PREVENTION	**CONFORM CHA_2DS_2VASc** ☐ Source ☐ Data Transfer Tool
	Site Number: _____ Subject ID: _____

Note: It is not required to complete this source worksheet if the information below is clearly documented in other records.

Was CHA_2DS_2VASc completed?	☐ Yes ☐ No *(Complete Protocol Deviation Form)*
Date completed	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)

If CHA_2DS_2 VASc is selected *(Select all that apply)*	☐ Age (years): ☐ <65 ☐ 65-74 ☐ ≥75 ☐ Female sex ☐ Congestive Heart Failure history ☐ Hypertension history ☐ Stroke or TIA symptoms previously ☐ Vascular disease history ☐ Diabetes mellitus history
Score	*Auto-calculated in EDC*

_____ **Site Personnel Signature**

__ __ / __ __ __ / __ __ __ __ **Date (DD/MMM/YYYY)**

conformal
THE SHAPE OF STROKE PREVENTION

HAS-BLED Score

☐ Source ☐ Data Transfer Tool

Site Number: _____ Subject ID: _____

Note: It is not required to complete this source worksheet if the information below is clearly documented in other records.

Was the HAS-BLED Score completed? *(Select only one)*	☐ Yes ☐ No *If no, complete a protocol deviation*
Date completed	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)
HAS-BLED Score *(Check all that apply)*	☐ None of the below ☐ Hypertension *(Uncontrolled, >160 mmHg systolic)* ☐ Renal disease (*Dialysis, transplant, CR >2.26 mg/dL or >200 µmol/L*) ☐ Liver disease (*Cirrhosis or bilirubin >2x normal with AST/ALT/AP >3x normal*) ☐ Stroke history ☐ Prior major bleed or predisposition to bleeding ☐ Labile INR (*Unstable/high INRs, time in therapeutic range <60%*) ☐ Age > 65 years ☐ On medications that predispose to bleeding (*aspirin, clopidogrel, NSAIDs*) ☐ Alcohol use (*≥8 drinks/week*)
Score	*Auto-Calculated in EDC*

_____ __ __ / __ __ __ / __ __ __ __

Site Personnel Signature **Date (DD/MMM/YYYY)**

conformal
THE SHAPE OF STROKE PREVENTION

CONFORM ECG

☐ Source ☐ Data Transfer Tool

Site Number: _____ Subject ID: _____

Was ECG performed?	☐ Yes ☐ No (*Complete a protocol deviation form)*		
Date of ECG	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)		
Sinus rhythm	☐ Yes ☐ No		
Atrial Arrhythmia	☐ Yes ☐ No	Atrial fibrillation	☐ Yes ☐ No
		Atrial flutter	☐ Yes ☐ No
		Paroxysmal atrial fibrillation/flutter	☐ Yes ☐ No
		Atrial tachycardia	☐ Yes ☐ No
Junctional rhythm	☐ Yes ☐ No		
AV node conduction disturbance/heart block	☐ Yes ☐ No	If yes, what degree?	☐ 1st Degree ☐ 2nd Degree ☐ 3rd Degree
Paced Rhythm	☐ Yes ☐ No		
Q-Wave present	☐ Yes ☐ No		
Left bundle branch block present	☐ Yes ☐ No		
Right bundle branch block present	☐ Yes ☐ No		

_____
Site Personnel Signature

__ __ / __ __ __ / __ __ __ __
Date (DD/MMM/YYYY)

conformal
THE SHAPE OF STROKE PREVENTION

CONFORM Echocardiogram/CT – SCREENING

☐ Source ☐ Data Transfer Tool

Site Number: _____Subject ID: _____

This Worksheet is to be used at the Screening Visit.

Was Echocardiogram/CT performed?	☐ Yes ☐ No *(Complete protocol deviation form)*
Are the required images for this visit available?	☐ Yes ☐ No *(Complete protocol deviation form)*
Were images uploaded into the Imaging Module?	☐ Yes ☐ No
Date echocardiogram/CT completed	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)
Imaging Type	☐ TTE – Transthoracic echocardiogram ☐ TEE – Transesophageal echocardiogram ☐ Cardiac CT ☐ Cardiac MRI ☐ Brain CT ☐ MRI
Left atrial appendage visible	☐ Yes ☐ No ☐ Not Available

If available, confirm if the following was noted on echo/CT:

Dense spontaneous echo contrast consistent with thrombus?	☐ Yes *(Review for I&E!)* ☐ No ☐ Not Available		
Intra-cardiac thrombus	☐ Yes *(Review for I&E!)* ☐ No ☐ Not available	If yes, confirm location	☐ Left atrium ☐ Left atrial appendage ☐ Left ventricle ☐ Right atrium ☐ Right ventricle ☐ Other, specify: _____
Intra-cardiac vegetation	☐ Yes ☐ No ☐ Not available	If yes, confirm location	☐ Left atrium ☐ Left atrial appendage ☐ Left ventricle ☐ Right atrium ☐ Right ventricle ☐ Other, specify: _____

Patent foramen ovale warranting closure?	☐ Yes ☐ No ☐ Not available	If yes, is this a high risk PFO?	☐ Yes *(Review for I&E!)* ☐ No
Atrial septal defect?	☐ Yes ☐ No ☐ Not available	If yes, specify	☐ Right to left shunt present ☐ Left to right shunt present ☐ Bidirectional shunt present ☐ Unable to determine
		If yes, does defect warrant closure?	☐ Yes *(Review for I&E!)* ☐ No
Pericardial effusion present?	☐ Yes ☐ No ☐ Not available	If yes, select type	☐ Circumferential ☐ Loculated
		If yes, select size	☐ Trivial ☐ Small (<1 cm) ☐ Moderate (1-2 cm) ☐ Large (>2 cm and <5cm) ☐ Large (> 5 cm) *(Review for I&E!)*
		If yes, Do any of the following apply? Check all that apply *(Review for I&E!)*	☐ Symptomatic ☐ Sign or symptom of acute or chronic pericarditis ☐ Evidence of tamponade physiology

_____
Site Personnel Signature

__ __/ __ __ __/ __ __ __ __
Date (DD/MMM/YYYY)

conformal THE SHAPE OF STROKE PREVENTION	**CONFORM Echocardiogram/CT – INDEX PROCEDURE** ☐ Source ☐ Data Transfer Tool
	Site Number: _____Subject ID: _____

Was Echocardiogram/CT performed?	☐ Yes ☐ No *(Complete protocol deviation form)*		
Are the required images for this visit available?	☐ Yes ☐ No *(Complete protocol deviation form)*		
Was imaging uploaded into the Imaging Module?	☐ Yes ☐ No		
Date echocardiogram/CT completed	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)		
Imaging Type	☐ TTE – Transthoracic echocardiogram ☐ TEE – Transesophageal echocardiogram ☐ Cardiac CT ☐ Cardiac MRI ☐ Brain CT ☐ MRI		
Left atrial appendage visible	☐ Yes ☐ No ☐ Not Applicable	Left atrial appendage ostium > 40 mm	☐ Yes *(Review for I&E!)* ☐ No
		Left atrial appendage ostium < 10 mm	☐ Yes *(Review for I&E!)* ☐ No
If available, confirm if the following was noted on echo/CT:			
Dense spontaneous echo contrast consistent with thrombus?	☐ Yes *(Review for I&E!)* ☐ No ☐ Not Available		
Intra-cardiac thrombus	☐ Yes *(Review for I&E!)* ☐ No ☐ Not Available	If yes, confirm location	☐ Left atrium ☐ Left atrial appendage ☐ Left ventricle ☐ Right atrium ☐ Right ventricle ☐ Other, specify: _____

Intra-cardiac vegetation	☐ Yes ☐ No ☐ Not Available	If yes, confirm location	☐ Left atrium ☐ Left atrial appendage ☐ Left ventricle ☐ Right atrium ☐ Right ventricle ☐ Other, specify: _____
Patent foramen ovale?	☐ Yes ☐ No ☐ Not Available	If yes, is this a high risk PFO?	☐ Yes *(Review for I&E!)* ☐ No
Atrial septal defect?	☐ Yes ☐ No ☐ Not Available	If yes, specify	☐ Right to left shunt present ☐ Left to right shunt present ☐ Bidirectional shunt present ☐ Unable to determine
		If yes, does defect warrant closure?	☐ Yes ☐ No
Pericardial effusion present?	☐ Yes ☐ No ☐ Not Available	If yes, select type	☐ Circumferential ☐ Loculated
		If yes, select size	☐ Trivial ☐ Small (<1 cm) ☐ Moderate (1-2 cm) ☐ Large (>2 cm and <5cm) ☐ Large (> 5cm) *(Review for I&E!)*
		If yes, Do any of the following apply? *(Review for I&E!)*	☐ Symptomatic ☐ Sign or symptom of acute or chronic pericarditis ☐ Evidence of tamponade physiology

_____
Site Personnel Signature

__ __/ __ __ __/ __ __ __ __
Date (DD/MMM/YYYY)

conformal THE SHAPE OF STROKE PREVENTION	**Implant LAA Measurements** **☐ Source ☐ Data Transfer Tool**
	Site Number: _____ Subject ID: _____

Note: *All three measurements must be collected for CLAAS Subjects. LAA Perpendicular Depth measurements are not required for Control patients.*

Pre-Implant LAA Measurements:

Angle	LAA Ostium Diameter *(mm)*	LAA Perpendicular Depth *(mm)*	LAA Maximum Length *(mm)*
0 Degree			
45 Degree			
90 Degree			
135 Degree			

_____
Site Personnel Signature

__ __ / __ __ __ / __ __ __ __
Date (DD/MMM/YYYY)

conformal THE SHAPE OF STROKE PREVENTION	**CONFORM Echocardiogram/CT – PRE-DISCHARGE** ☐ Source ☐ Data Transfer Tool
	Site Number: _____Subject ID: _____

TTE is required to surveil for pericardial effusion. The study must be performed a minimum of 4 hours after discharge from cardiac catheterization laboratory.

Was Echocardiogram/CT performed?	☐ Yes ☐ No *(Complete protocol deviation form)*		
Are the required images for this visit available?	☐ Yes ☐ No *(Complete protocol deviation form)*		
Was imaging uploaded into the Imaging Module?	☐ Yes ☐ No		
Date echocardiogram/CT completed	__ __ / __ __ __ / __ __ __ __(DD/MMM/YYYY)		
What time was pre-discharge TTE performed?	_____ : _____		
Imaging Type	☐ TTE – Transthoracic echocardiogram ☐ TEE – Transesophageal echocardiogram ☐ Cardiac CT ☐ Cardiac MRI ☐ Brain CT ☐ MRI		
If available, confirm if the following was noted on echo/CT:			
Left atrial appendage visible	☐ Yes ☐ No ☐ Not Available		
Dense spontaneous echo contrast consistent with thrombus?	☐ Yes ☐ No ☐ Not Available		
Intra-cardiac thrombus	☐ Yes *(Complete AE form)* ☐ No ☐ Not available	If yes, confirm location	☐ Left atrium ☐ Left atrial appendage ☐ Left ventricle ☐ Right atrium ☐ Right ventricle ☐ Other, specify: _____

Intra-cardiac vegetation	☐ Yes ☐ No ☐ Not available	If yes, confirm location	☐ Left atrium ☐ Left atrial appendage ☐ Left ventricle ☐ Right atrium ☐ Right ventricle ☐ Other, specify: _____
Patent foramen ovale warranting closure?	☐ Yes ☐ No ☐ Not Available	If yes, is this a high risk PFO?	☐ Yes *(Complete AE Form)* ☐ No
Atrial septal defect?	☐ Yes ☐ No ☐ Not available	If yes, specify	☐ Right to left shunt present ☐ Left to right shunt present ☐ Bidirectional shunt ☐ Unable to determine
		If yes, does defect warrant closure?	☐ Yes *(Complete AE form)* ☐ No
Pericardial effusion present?	☐ Yes ☐ No ☐ Not available		
		If yes, select type	☐ Circumferential ☐ Loculated
		If yes, select size *(Pericardial effusion deemed as trivial or small does not meet adverse event reporting criteria)*	☐ Trivial ☐ Small (<1 cm) ☐ Moderate (1-2 cm) ☐ Large (>2 cm and <5cm) ☐ Large (>5 cm) (Review for I&E!)
		If yes, Do any of the following apply? *(Check all that apply)*	☐ Symptomatic ☐ Sign or symptom of acute or chronic pericarditis ☐ Evidence of tamponade physiology

_____ __ __/ __ __ __/ __ __ __ __
Site Personnel Signature **Date (DD/MMM/YYYY)**

conformal THE SHAPE OF STROKE PREVENTION	**CONFORM Echocardiogram/CT – FOLLOW UP** ☐ Source ☐ Data Transfer Tool
	Site Number: _____ Subject ID: _____

For use with Follow Up Visits as needed (45-Day, 12 Months, and Unscheduled).

Reminders:

- **At 45 Days and 12 Months**:
- TEE or CT is mandatory per protocol at 45 Days and 12 Months for Implanted Subjects
- If a CT is completed and shows findings (i.e., leak or thrombus), a TEE is required to confirm the finding as soon as possible

Was Echocardiogram/CT performed?	☐ Yes ☐ No *(Complete protocol deviation form)*		
Are the required images for this visit available?	☐ Yes ☐ No *(Complete protocol deviation form)*		
Were images uploaded into the Imaging Module?	☐ Yes ☐ No		
Time period of Imaging	☐ 45 Day ☐ 12 Months ☐ Unscheduled, specify: _____		
Date echocardiogram/CT completed	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)		
Imaging Type	☐ TTE – Transthoracic echocardiogram ☐ TEE – Transesophageal echocardiogram ☐ Cardiac CT ☐ Cardiac MRI ☐ Brain CT ☐ MRI		
Left atrial appendage visible	☐ Yes ☐ No ☐ Not Available		
If available, confirm if the following was noted on echo/CT:			
Dense spontaneous echo contrast consistent with Thrombus?	☐ Yes ☐ No ☐ Not Available		
Intra-cardiac thrombus	☐ *Yes (Complete AE form)* ☐ No ☐ Not available	If yes, confirm location	☐ Left atrium ☐ Left atrial appendage ☐ Left ventricle ☐ Right atrium ☐ Right ventricle ☐ Other, specify: _____

Intra-cardiac vegetation	☐ Yes ☐ No ☐ Not available	If yes, confirm location	☐ Left atrium ☐ Left atrial appendage ☐ Left ventricle ☐ Right atrium ☐ Right ventricle ☐ Other, specify: _____
Patent foramen ovale warranting closure?	☐ Yes ☐ No ☐ Not available	Is this a high risk PFO?	☐ Yes ☐ No
Atrial septal defect?	☐ Yes ☐ No ☐ Not available	If yes, specify	☐ Right to left shunt present ☐ Left to right shunt present ☐ Bidirectional shunt ☐ Unable to determine
		If yes, does defect warrant closure?	☐ Yes ☐ No
Left atrial appendage occlusion device position stable and position unchanged?	☐ Yes ☐ No ☐ Not available		
Peri-device leak present?	☐ Yes ☐ No ☐ Not available	If yes, specify (mm)	_____ mm
Pericardial effusion present?	☐ Yes *(Assess for AE)* ☐ No ☐ Not available		
	If yes, select type	☐ Circumferential ☐ Loculated	
	If yes, select size **AE is reportable for pericardial effusions Moderate or larger*	☐ Trivial ☐ Small (<1 cm) ☐ Moderate (1-2 cm) ☐ Large (>2 cm and <5cm) ☐ Large (> 5 cm)	
	If yes, do any of the following apply?	☐ Symptomatic ☐ Sign or symptom of acute or chronic pericarditis ☐ Evidence of tamponade physiology	

Device embolization?	☐ Yes *(Complete AE form)* ☐ No ☐ Not available

_____ __ __ / __ __ __ / __ __ __ __
Site Personnel Signature **Date (DD/MMM/YYYY)**

conformal THE SHAPE OF STROKE PREVENTION	**CONFORM Screening Lab Assessments** ☐ Source ☐ Data Transfer Tool
	Site Number: _____ Subject ID: _____

Original source should be obtained from a direct laboratory report from Subject Medical Record. Laboratory results to be reviewed by delegated investigator (either directly on lab report or as Source here) as relates to subject safety and INC/EXC Criteria.

Laboratory Collection at screening collected per standard of care ***up to 60 days prior to consent***

Date of Hematology	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)
	☐ Not Done *(ENTER PD)*

Laboratory Assessment	***Results***	***Clinically Significant***
Hemoglobin		☐ Yes ☐ No
Henatocrit		☐ Yes ☐ No
WBC		☐ Yes ☐ No
Platelet Count		☐ Yes ☐ No

CHEMISTRY – SERUM CREATININE OR GFR eGFR

Date of serum Chemistry	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)
	☐ Not Done *(ENTER PD if neither Cr or GFR/eGFR were not obtained)*

Laboratory Assessment	***Results***	***Clinically Significant***
Creatinine		☐ Yes ☐ No
GFR or eGFR		☐ Yes ☐ No

COAGULATION as Relevant

Was INR sample collected?	☐ Yes ☐ No ☐ Not applicable
Date of INR	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)

Laboratory Assessment	***Results***	***Clinically Significant***
INR		☐ Yes ☐ No

_____ __ __ / __ __ __ / __ __ __ __

Site Personnel Signature **Date (DD/MMM/YYYY)**

Reminder: Pre-procedure oral anticoagulation (Warfarin or DOAC) should be managed as per site protocol. Warfarin should be discontinued in accordance with site standard of care practices including the monitoring of INR levels on the day of the procedure.

conformal THE SHAPE OF STROKE PREVENTION	**CONFORM NIHSS** ☐ Source ☐ Data Transfer Tool
	Site Number: _____ Subject ID: _____

Was the NIHSS assessment completed?	☐ Yes ☐ No *(Complete Protocol Deviation form)*
Date of NIHSS assessment	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)

1(a) – Level of consciousness	
Alert, keenly responsive	☐ (**0**)
Not alert; but arousable by minor stimulation to obey, answer or respond	☐ (**1**)
Not alert' requires repeated stimulation to attend, or is obtunded and requires strong or painful stimulation to make movements (not stereotyped)	☐ (**2**)
Responds only with reflex motor or autonomic unresponsive, flaccid or areflexic	☐ (**3**)
1(b) – Level of consciousness questions	
Answers both questions correctly	☐ (**0**)
Answers one question correctly	☐ (**1**)
Answers neither question correctly	☐ (**2**)
1(c) – Level of consciousness command	
Performs both tasks correctly	☐ (**0**)
Performs one task correctly	☐ (**1**)
Performs neither task correctly	☐ (**2**)
2 – Best gaze	
Normal	☐ (**0**)
Partial gaze palsy; gaze is abnormal in one or both eyes, but forced deviation or total gaze paresis is not present	☐ (**1**)
Forced deviation, or total gaze paresis not overcome by the oculocephalic maneuver	☐ (**2**)
3 – Visual	
No visual loss	☐ (**0**)
Partial hemianopia	☐ (**1**)
Complete hemianopia	☐ (**2**)
Bilateral hemianopia (blind including cortical blindness)	☐ (**3**)

4 – Facial palsy	
Normal symmetrical movements	☐ (**0**)
Minor paralysis (flattened nasolabial fold, asymmetry on smiling)	☐ (**1**)
Partial paralysis (total or near-total paralysis of lower face)	☐ (**2**)
Complete paralysis of one or both sides (absence of facial movement in the upper and lower face)	☐ (**3**)
5(a) – Motor arm - left	
No drift, limb holds 90 (or 45) degrees for 10 full seconds	☐ (**0**)
Drift; limb holds 90 (or 45) degrees, but drifts down before full 10 seconds; does not hit bed or other support	☐ (**1**)
Some effort against gravity; limb cannot get to or maintain (if cued) 90 (or 45) degrees; drifts down to bed, but has some effort against gravity	☐ (**2**)
No effort against gravity, limb falls	☐ (**3**)
No movement	☐ (**4**)
Amputation or joint fusion, Explain	☐ (**UN**)
5(b) – Motor arm - right	
No drift, limb holds 90 (or 45) degrees for 10 full seconds	☐ (**0**)
Drift; limb holds 90 (or 45) degrees, but drifts down before full 10 seconds; does not hit bed or other support	☐ (**1**)
Some effort against gravity; limb cannot get to or maintain (if cued) 90 (or 45) degrees; drifts down to bed, but has some effort against gravity	☐ (**2**)
No effort against gravity, limb falls	☐ (**3**)
No movement	☐ (**4**)
Amputation or joint fusion, Explain:	☐ (**UN**)

6(a) Motor leg - left	
No drift, leg holds 30-degree position for full 5 seconds	☐ (**0**)
Drift: leg falls by the end of the 5-second period but does not hit bed	☐ (**1**)
Some effort against gravity; leg falls to bed by 5 seconds, but has some effort against gravity	☐ (**2**)
No effort against gravity, leg falls to bed immediately	☐ (**3**)
No movement	☐ (**4**)
Amputation or joint fusion, Explain:	☐ (**UN**)
6(a) Motor leg - right	
No drift, leg holds 30-degree position for full 5 seconds	☐ (**0**)
Drift: leg falls by the end of the 5-second period but does not hit bed	☐ (**1**)
Some effort against gravity; leg falls to bed by 5 seconds, but has some effort against gravity	☐ (**2**)
No effort against gravity, leg falls to bed immediately	☐ (**3**)
No movement	☐ (**4**)
Amputation or joint fusion, Explain:	☐ (**UN**)
7 – Limb ataxia	
Absent	☐ (**0**)
Present in one limb	☐ (**1**)
Present in two limbs	☐ (**2**)
Amputation or joint fusion, Explain:	☐ (**UN**)
8 – Sensory	
Normal; no sensory loss	☐ (**0**)
Mild-to-moderate sensory loss; patient feels pinprick less sharp or dull on the affected side; or there is a loss of superficial pain with pinprick, but patient is aware of being touched	☐ (**1**)
Severe to total sensory loss; patient is not aware of being touched in the face, arm, and leg	☐ (**2**)

9 – Best language	
No aphasia; normal	☐ (**0**)
Mild-to-moderate aphasia; some obvious loss of fluency or facility or comprehension, without significant limitation on ideas expressed or form of expression. Reduction of speech and/or comprehension, however, makes conversion about provided materials difficult or impossible. ***For example, in conversation about provided materials, examiner can identify picture or naming card content from patient's response.***	☐ (**1**)
Severe aphasia; all communication is through fragmentary expression; great need for inference questioning and guessing by the listener. Range of information that can be exchanged is limited; listener carries burden of communication. Examiner cannot identify materials provided form patient response.	☐ (**2**)
Mute, global aphasia; no usable speech or auditory comprehension	☐ (**3**)
10 – Dysarthria	
Normal	☐ (**0**)
Mild-to-moderate dysarthria; patient slurs at least some word and, at worst, can be understood with some difficult.	☐ (**1**)
Severe dysarthria; patient's speech is so slurred as to be unintelligible in the absence or out of proportion to any dysphasia, or is mute/anarthric	☐ (**2**)
Intubated or another physical barrier, Explain:	☐ (**UN**)
11 – Extinction and inattention (formerly neglect)	
No abnormality	☐ (**0**)
Visual, tactile, auditory, spatial, or personal inattention or extinction to bilateral simultaneous stimulation in one of the sensory modalities.	☐ (**1**)
Profound hemi-inattention or extinction to more than one modality; does not recognize own hand or orients to only one side of space.	☐ (**2**)

_____ __ __ / __ __ __ / __ __ __ __

Site Personnel Signature **Date (DD/MMM/YYYY)**

conformal THE SHAPE OF STROKE PREVENTION	**CONFORM QVSFS** ☐ Source ☐ Data Transfer Tool
	Site Number: _____ Subject ID: _____

Was the QVSFS assessment completed?	☐ Yes ☐ No *(Complete protocol deviation form)*
Is this assessment performed because of a neurological event?	☐ Yes *If yes, assess for an adverse event* ☐ No
Date of QVSFS assessment	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)

Since the last study contact (by phone or clinic)	**Yes**	**No**	**Unknown**
1. Were you told by a physician that you had a stroke?	☐	☐	☐
2. Were you ever told by a physician that you had a TIA, ministroke, or a transient ischemic attack?	☐	☐	☐
3. Have you ever had a sudden weakness on one side of your body?	☐	☐	☐
4. Have you ever had a sudden numbness or dead feeling on one side of your body?	☐	☐	☐
5. Have you ever had a sudden painless loss of vision in one or both eyes?	☐	☐	☐
6. Have you ever suddenly lost one half of your vision?	☐	☐	☐
7. Have you ever suddenly lost the ability to understand what people are saying?	☐	☐	☐
8. Have you ever suddenly lost the ability to express yourself verbally or in writing?	☐	☐	☐

_____ **Site Personnel Signature**

__ __ / __ __ __ / __ __ __ __ **Date (DD/MMM/YYYY)**