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:		
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)**