

**Informed Consent**

Subject to be enrolled as	<input type="checkbox"/> Roll-In <input type="checkbox"/> Randomized
Protocol Version Activated to at time of Informed Consent:	
Date informed consent was signed (DDMMYYYY)	
Site ICF Version /IRB Approval Date DDMMYYYY	
Was this subject screened previously?	<input type="checkbox"/> Yes <input type="checkbox"/> 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?	<input type="checkbox"/> Yes <input type="checkbox"/> No
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**Pregnancy Test**

If yes, was pregnancy test done?	<input type="checkbox"/> Yes <input type="checkbox"/> No <i>If no and the female is of child-bearing age, complete a protocol deviation</i> <input type="checkbox"/> N/A Reason N/A:
Date of pregnancy test	___ / ___ / ___ (DD/MMM/YYYY)
Result	<input type="checkbox"/> Positive (Check I&E Criteria!) <input type="checkbox"/> 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)