

Site Personnel Training Requirements

	Principal Investigator	Implanting Sub-Investigator	Non-Implanting Sub-Investigator	Research Coordinator	Regulatory
Training Required to:					
CONFORM Protocol & Amendments	X	X	X	X	
CONFORM TEE Imaging Acquisition Protocol	O	O			
Protocol Synopsis & Amendments					X ³
CLAAS AcuFORM Instructions for Use	X	X	O	O	
Didactic Device Training	X ¹	X			
Hands on Device Training	X ¹	X			
Device Accountability App				X	
EDC System/ AE Adjudicate / Imaging Module				X	
EDC – Sign Off	X				
Documents Maintained:					
Listed on the DOA	X	X	X	X	O
Financial Disclosure	X	X	X		
Investigator Agreement	X	X	X		
GCP Certification (current at activation)	X	X	X	X	X ³
CV (signed/dated within past 2 years)	X	X	X	X	X ³
Active Medical License	X	X	O	O	
NIHSS and mRS ²				X	
Key:					
X = Required O = Optional ¹ = Didactic training must be completed by a Conformal FCS team member prior to the first implant. ² = Training/certification must be current; at least one member of study team must have NIHSS/mRS certification ³ = Only required if listed on DOA					

Note: Neurologists (or designee, e.g., neurology fellow) performing neurological assessments do not require study-specific training and do not need to be included on the DOA as their role is non-study-specific.

Imaging Personnel Training Requirements

Role	Imager for Screening Imaging (CT ¹ , TEE ¹ , TTE, MRI)	Imager for Procedural TEE	Imager for Pre-Discharge TTE	Imager for Follow-up TEEs (45 D, 6 M ² , 12 M, Unscheduled)	Lead Echo-cardiographer
Training Required to:					
CONFORM Protocol Synopsis & Amendments ⁴	O	X	O	X	X
CONFORM TEE Imaging Acquisition Protocol ⁴	O	X	O	X	X
Protocol & Amendments ⁴	O	O	O	O	O
CLAAS AcuFORM Instructions for Use ⁴	O	O	O	O	O
Didactic Device Training	O	O	O	O	O
Hands on Device Training	O	O	O	O	O
Documents Maintained:					
GCP Certification (current at activation)	O	X ³	X ³	X ³	X
CV (signed/dated within past 2 years)	O	X ³	X ³	X ³	X
Active Medical License	O	X ³	X ³	X ³	X
FAQs:					
Does this person need to be listed on the DOA?	No	No	No	No	Yes
Does this person need to be a physician?	No	Yes	No	Yes	Yes
Can the PI also act as this role?	Yes	No	Yes	Yes	No
Can this person be the same as Procedural Implanter?	Yes	No	Yes	Yes	No
Key:					
X = Required ¹ = Required prior to randomization ² = 6 Month imaging only required if 45 Day TEE has findings of leak or thrombus O = Optional ³ = Only required for Imagers on DOA ⁴ = Read & Acknowledge training permitted					

Note on Lead Echocardiographers:

- All imagers conducting study specific imaging must train on the CONFORM Protocol Synopsis and CONFORM TEE Imaging Acquisition Protocol.
- Not all imagers need to be listed on the DOA.
- All imagers who are listed on the DOA must have their CV, medical license, and GCP training on file.
- If the Investigational Site utilizes one or more imaging personnel who are not listed on the DOA, that investigational site shall delegate one Lead Echocardiographer to assume the responsibility of study imaging performed by non-delegated imagers (i.e., respond to Core Lab inquiries, imaging queries, possible overreads or imaging safety inquiries).
- The Lead Echocardiographer must be a qualified physician to perform imaging and cannot be the Principal Investigator.
- If the Investigational Site lists all imagers on the DOA, no Lead Echocardiographer delegation is required.