

## Pre-Procedure Review Process

**This process is required for each implanting physician’s 1<sup>st</sup> CLAAS Case. This applies to Roll-In and Randomized subjects (CLAAS® Cases only).** The purpose of this Pre-Procedure Review Process is to review the subject candidate’s LAA anatomy suitability prior to roll-in or randomization. Once the subject has consented, Implanters will present their site’s first subject candidate TEE or CT images to at least one Conformal Field Clinical Specialist.

Sites who previously met these criteria are not required to complete this process prior to enrolling subjects into the CONFORM Pivotal Trial.



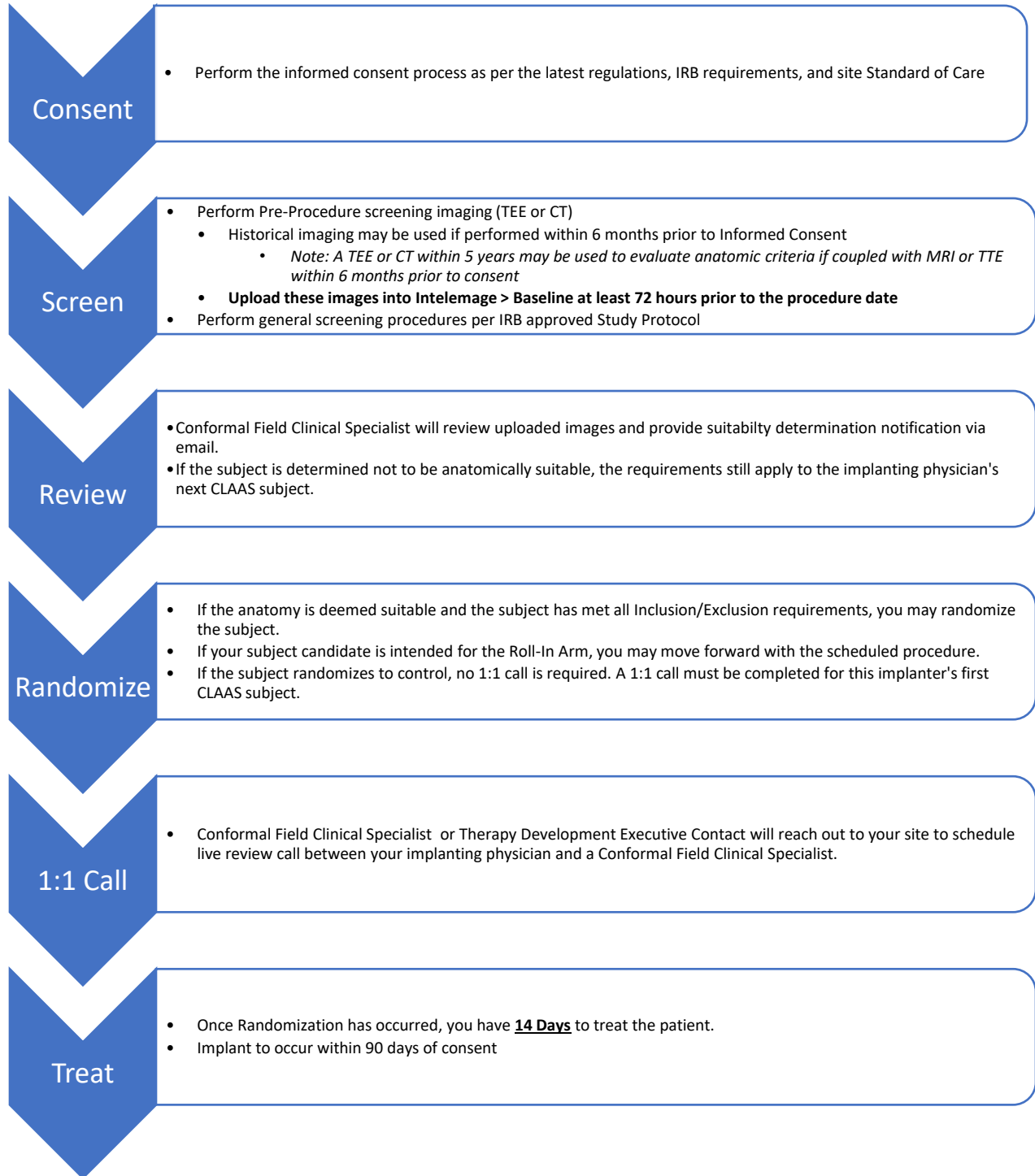
**For all subjects at all sites, screening imaging must be uploaded to Medidata Inteleimage and reviewed by Conformal prior to randomizing a subject or confirming a roll-in case.**

	First CLAAS Case (per implanter)	All future cases
TEE or CT imaging uploaded >72 hours before case	✓	✓
1:1 call between implanter and Conformal Field Clinical Specialist	✓	✗
Conformal approval of imaging required <b>prior to randomization</b>	✓	✓

Pre-Procedure Review Process.....Page 2

Frequently Asked Questions.....Pages 3-4

**Figure 1 Pre-Procedure Review Process**



### **Frequently Asked Questions**

**Q: Does the requirement to screen the first case apply to the site or to each operator?**

A: This process is intended to apply to each operator's first CLAAS case.

**Q: If the Pre-Procedure Review process only applies to each operator's first CLAAS Case, what should I do if the first case is a Randomized (RCT) subject that randomizes to control?**

A: This would mean the requirement is skipped if it is an RCT subject that randomizes to control. This requirement would then apply to that implanter's next case that randomizes to CLAAS.

**Q: What do I need to do to prepare for the Pre-Procedure Review?**

A: Ensure that you have uploaded required baseline imaging into Medidata Intelemma, as a Conformal Field Clinical Specialist will review these images to determine anatomical suitability.

**Q: When does the Pre-Procedure Imaging Review occur?**

A: Once TEE or Cardiac CT images have been uploaded into Medidata Intelemma and Conformal Field Clinical Specialist has reviewed and approved the images for anatomical suitability, 1:1 call can occur as soon as implanting physician is available.

Note: If it is a randomized patient, randomization must also occur prior to the 1:1 call, as this call only occurs for CLAAS patients.

**Q: Can I use a historical TEE or CT Image within 6 months of consent?**

A: Yes. Note: A TEE or CT within 5 years of consent may be used to evaluate anatomic criteria if coupled with MRI or TTE within 6 months prior to consent.

**Q: How do I schedule the live 1:1 call and how long does that review take?**

A: Communicate your screening/imaging plans with your Site Manager as soon as your subject is consented, and a possible implant date has been determined. Your Executive Contact, and/or a Conformal Field Clinical Specialist will work with you to schedule a time for the 1:1 live call. The call will likely take 15 minutes or less.

**Q: What format will the call be in?**

A: The 1:1 call may be via video conference or phone call, which Conformal Medical will set up, with video conference link if applicable.

**Q: After each implanting physician's 1<sup>st</sup> case, do we still have to wait for Conformal to review baseline imaging prior to randomization?**

A: Yes, *for all subjects*, wait for the notification from Conformal of anatomical suitability before randomizing the subject in Medidata.