

Pre-Procedure Review Process

This process is required for each implanting physician’s 1st procedure. This applies to Roll-In and Randomized subjects (CLAAS® or Control). 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 member of the Executive Committee or designee(s), the “Committee.”

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 Intelimage and reviewed by Conformal prior to randomizing a subject or confirming a roll-in case.

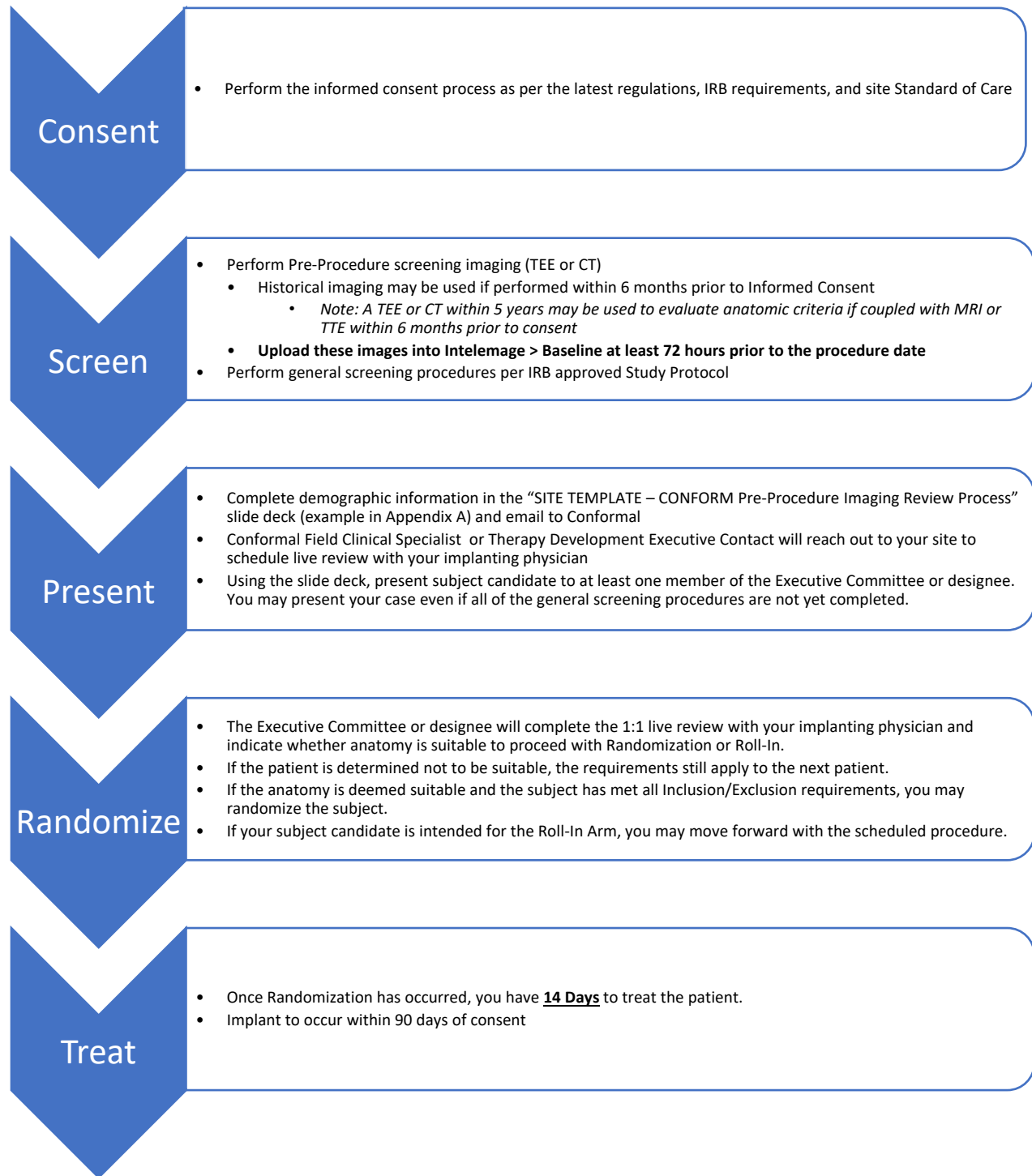
	First Approved Case (per implanter)	All future cases
1:1 call between implanter and Conformal exec committee member	✓	✗
Pre-Procedure Review Slide Deck	✓	✗
TEE or CT imaging uploaded >72 hours before case	✓	✓
Conformal approval of imaging required prior to randomization	✓	✓

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Example Power Point/Slide Presentation.....Appendix A

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 case.

Q: When do I initiate the Pre-Procedure Review Process?

A: Once a subject has signed the consent form, we recommend you initiate the Pre-Procedure Review Process as soon as feasibly possible. If not already in receipt, contact your Site Manager and they will forward you the Slide Deck template. A Conformal Field Clinical Specialist or Therapy Development Executive Contact will reach out to your site to schedule the live review with the implanting physician. Reminder: Initiating this process 10-14 days before the scheduled procedure is recommended.

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

A: Using the Sponsor-generated PowerPoint template (example in Appendix A), you will provide general background information for each subject candidate planned for Pre-Procedure review. Ensure that you have uploaded required baseline imaging into Medidata Intelimage, as a Conformal Field Clinical Specialist or Imaging Manager will embed these TEE or CT images into the PowerPoint template.

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

A: If you have historical TEE or CT images on file and uploaded into Medidata Intelimage, we can schedule it as soon as the implanter is available. If you still have to conduct a Screening TEE or CT, we will wait to complete the Pre-Procedure Imaging Review until after imaging is available and uploaded into Intelimage.

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 Pre-Procedure Review 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 Site Manager, Executive Contact, and/or a Conformal Field Clinical Specialist will work with you to schedule a time for the 1:1 live Pre-Procedure Imaging Review. The call will likely take 15 minutes or less.

Q: Who from the Site will present the Subject Candidate to the Committee member or designee?

A: The Implanter will present the Subject Candidate to the Committee member or designee. Any site personnel who may benefit from joining the discussion can attend.

Q: What format will the presentation be in?

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

Q: How do I obtain the Sponsor generated PowerPoint template?

A: Your Site Manager will provide the Sponsor generated PowerPoint template that the Implanter will use to present to the Committee.

Q: What am I expected to fill in the Sponsor generated PowerPoint template?

A: The PowerPoint template highlights the sections for your site to fill. This includes Pages 2 –4. You will need to provide basic information about the case to be presented such as procedural team, subject demographics and brief medical history.

Q: Do I need to upload these images to Intelemage?

A: Yes, you will upload the TEE or CT images used for screening in Intelemage. Navigate to the Baseline Visit timepoint to upload your images.

Q: How do I document that our site has completed the required Pre-Procedure Review Process:

A: A Conformal Field Clinical Specialist will email your team after the 1:1 live Pre-Procedure Imaging Review. Please file a copy of this correspondence in your Investigator Site File.

Q: After each implanting physician's 1st 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.

Appendix A Follows

[SITE TEMPLATE - CONFORM Pre-Procedure Imaging Review Process Example V5.0 05MAR2025](#)