

# conformal

THE SHAPE OF STROKE PREVENTION



A decorative graphic consisting of a series of blue dots arranged in a large, open arc that frames the top and right sides of the slide.

# WELCOME RESEARCH COORDINATORS

**James Reinstein**, President & CEO

# Developing the Next Generation of LAAO Technology.

The CLAAS® AcuFORM™ System is designed to reduce the risk of stroke without the need for anticoagulants.





# The First & Only LAAO Device to Use Conformable Foam to Seal The LAA

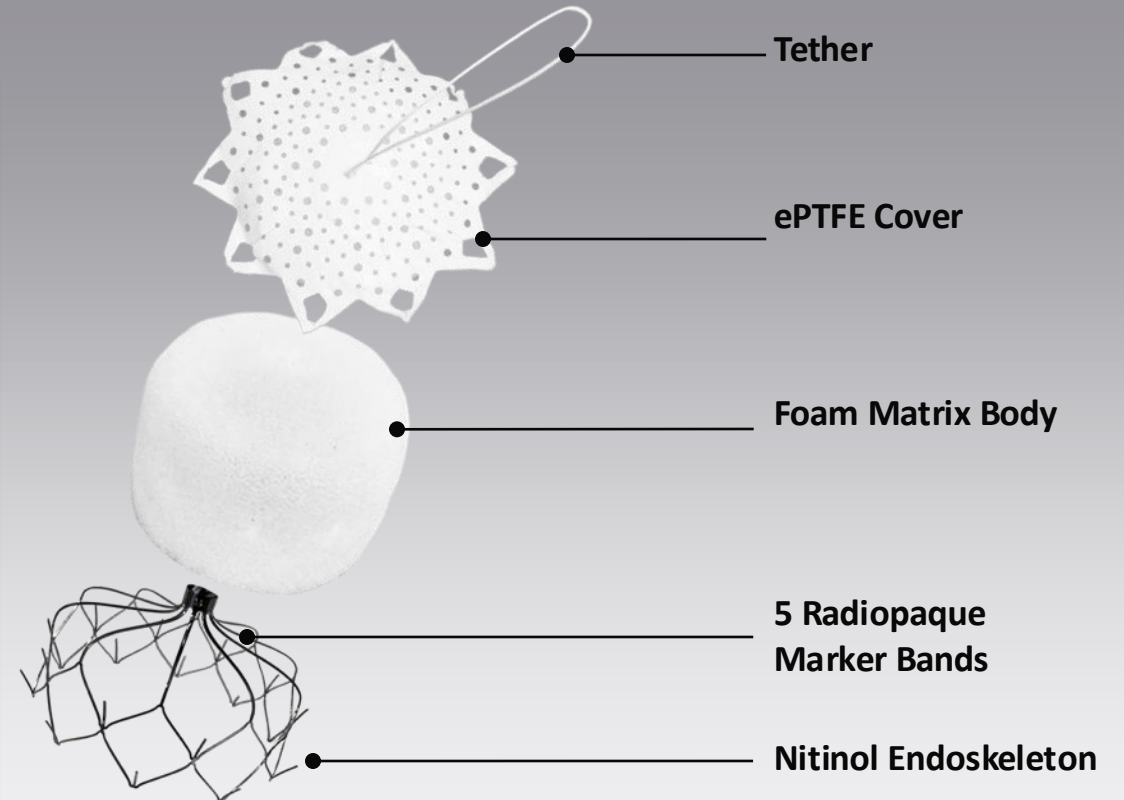
Designed to reduce the risk of stroke without  
the need for anticoagulants.



# The Shape of Stroke Prevention



- Smooth dual-layered ePTFE cover for improved strength and enhanced healing
- No exposed metal, covered with highly conformable foam matrix body, designed to form and fill gaps
- Compliant nitinol endoskeleton that forms to fit the appendage
- Optimized low-profile anchors
- 1 size addresses >90% of patients



# Conformal Product Evolution

CLAAS® AcuFORM™ builds upon the novel CLAAS platform with enhanced clinical performance and ease of use

## CLAAS® System (1<sup>st</sup> Gen)

- Elevated Pericardial Effusion Rates



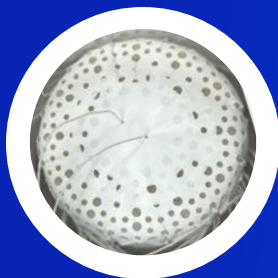
## CLAAS® AcuFORM™ (2<sup>nd</sup> Gen)

- Redesigned Anchors
- Improved Delivery Experience

## Next-Generation LAAO System



**Modified Anchors**  
50% Reduction in  
Penetration



**ePTFE Fluoropolymer**  
Low Thrombogenicity  
High Strength & Durability



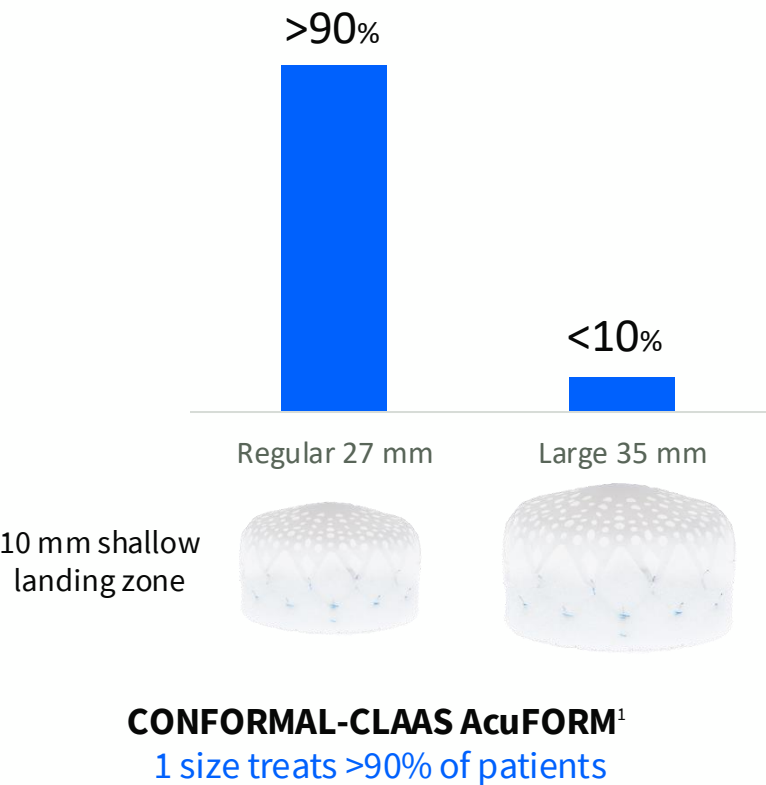
**Intuitive Handle**  
Cable & Tether  
Modes



**Steerable Sheath**  
Precise Coaxial  
Deployment

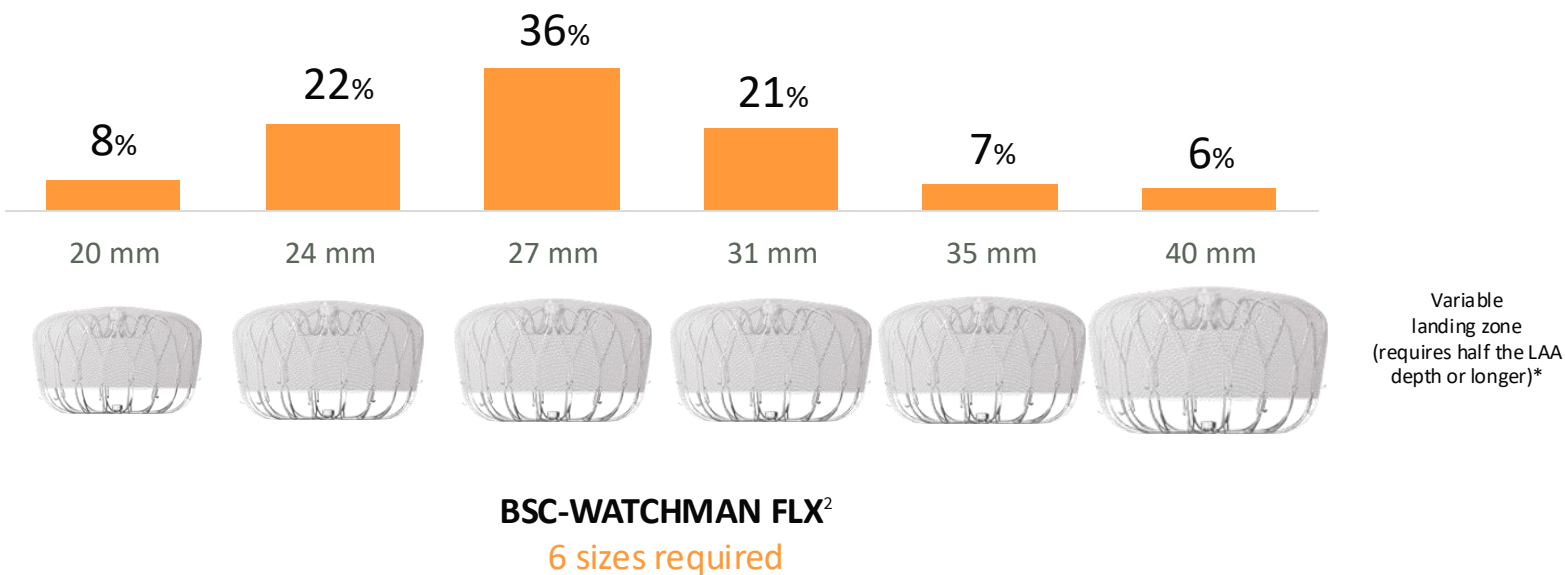


# Simplified Sizing



## CONFORMAL Vs. WATCHMAN

Implant size and percentage used

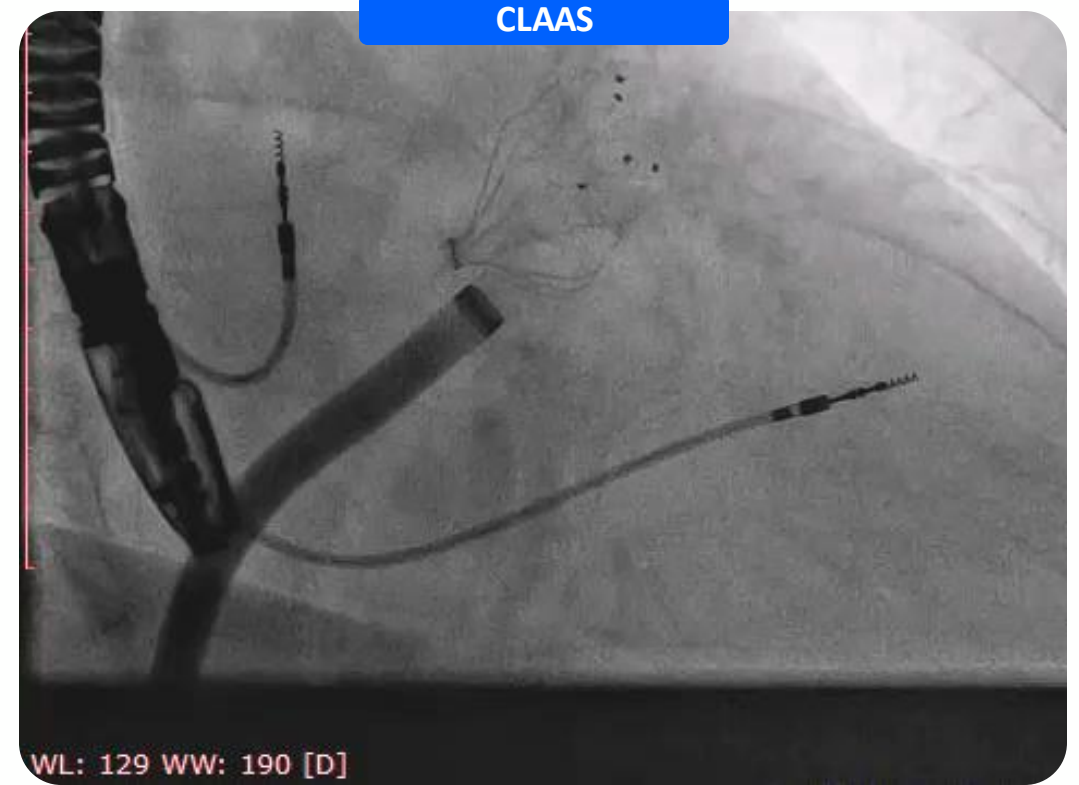
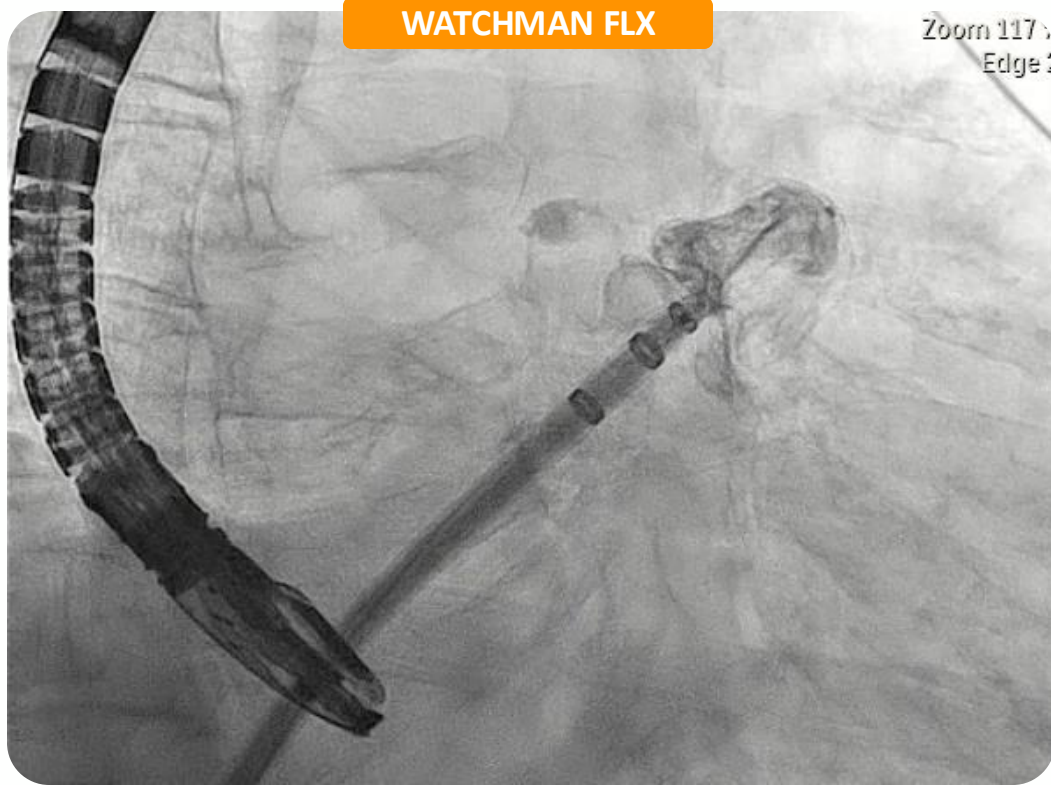


\*IFU BSC-WATCHMAN

1. Conformal Medical Data on File

2. Alli, S., et. al; Left atrial appendage closure with a novel fluoropolymer-coated device: Primary safety and efficacy endpoints of the HEAL-LAA post-approval clinical study. Presented at TCT 2024

# Simplified Seal and Confirmation



97.5% Seal Rate without significant (>3mm) leaks at 12 months, comparing favorably with marketed devices.<sup>1</sup>

1. Gray W, Conformal Early Feasibility Study: 12 Months Results. TCT2023



# Company Update

CLAAS® System clinical experience in >400 patients

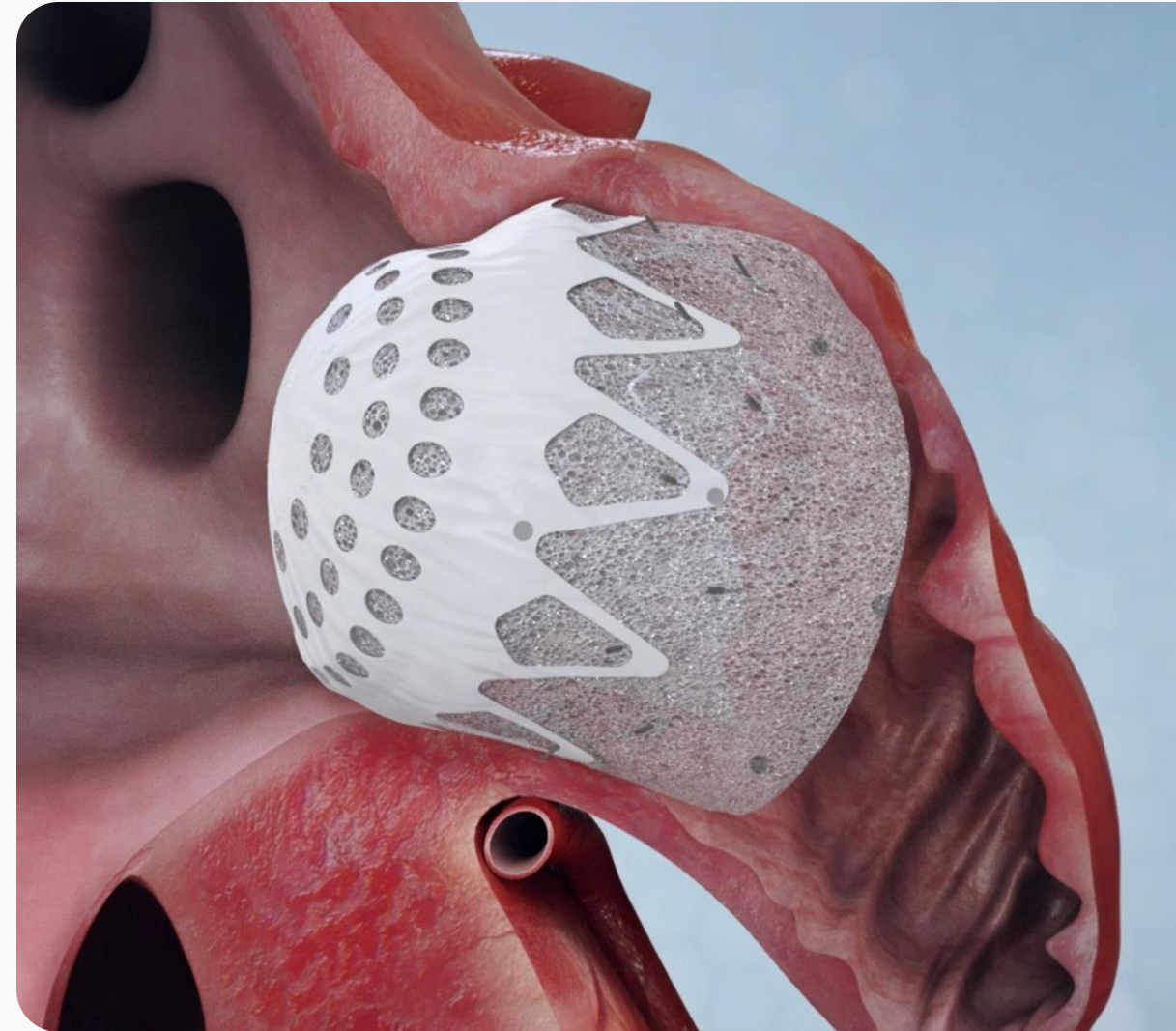
Pivotal Trial: 460 Randomized + 86 Roll-ins\*

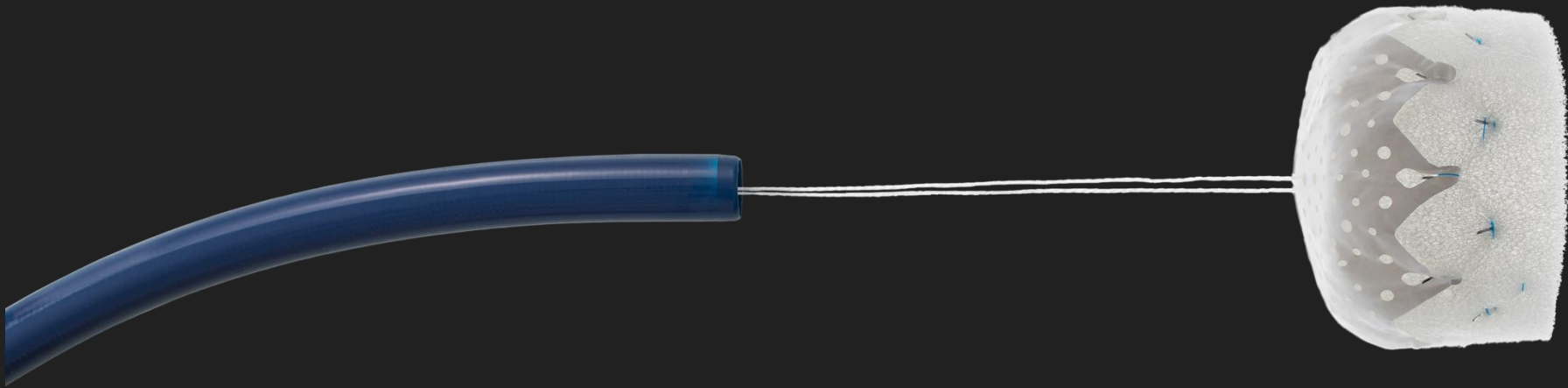
AcuFORM used in 75 patients\*

Funded into 2026

*Expect to close a new funding round this summer*

*\*As of 05/28/2025*





# THE UNSUNG HERO OF CLINICAL RESEARCH

## The Critical Importance of Relationship between Clinical Research Coordinator and Sponsor

*Deborah Reasner, Director Clinical Affairs*

# Research Coordinators: Why This Role Matters

## Key Impact to Data Quality and Data Integrity

- Accurate and timely data entry into the EDC
- Source documentation retrieval completeness
- Query resolution
- Adverse event tracking and reporting

**Outcome:** Higher-quality data and minimizes potential audit findings

# Why This Role Matters

## Front Line Assessment for Regulatory Compliance & Risk Mitigation

- Ensures IRB submissions, renewals/ notifications are on time
- Maintains delegation logs, screening logs, and staff training records
- Supports site audit readiness

**Without you, noncompliance risk increases.**

# Why This Role Matters

## Enhancing Patient Experience

- 1<sup>st</sup> point of contact for subjects → A compassionate and familiar face for patients and families
- Ensure patient understanding the study through the complexities of informed consent and study follow-up processes
- Coordinates visit logistics making things easy for the patient

**Result: Better subject retention = Better study outcomes**

# Why This Role Matters

## Key Partner in Driving Overall Study Success

- Enrollment targets are met
- Visit windows maintained
- Noncompliance minimized
- Facilitate frontline communication between sponsor and investigator and patient
- Keeping sponsor informed of challenges in study

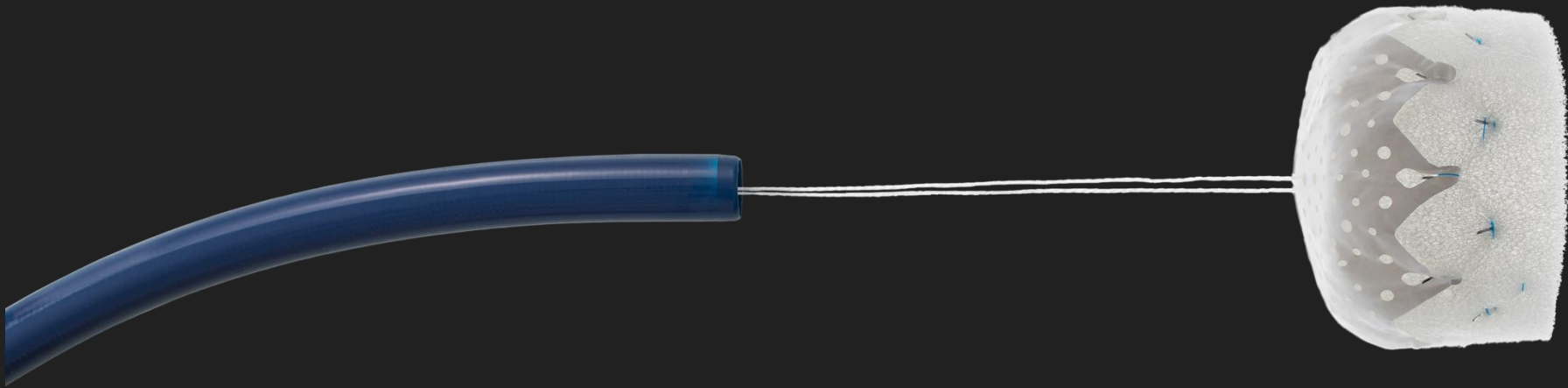


# Why This Role Matters

## Final Thought

Behind every successful clinical trial is a dedicated Clinical Research Professional ensuring that every study detail is accurate, on-time, and compliant.

**Your impact on Patients and contribution to Science is Meaningful!!**



# CONFORM Study Updates

*Aly Dechert*, Manager Clinical Operations

# Site Manager Team



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**Brittany Winton**

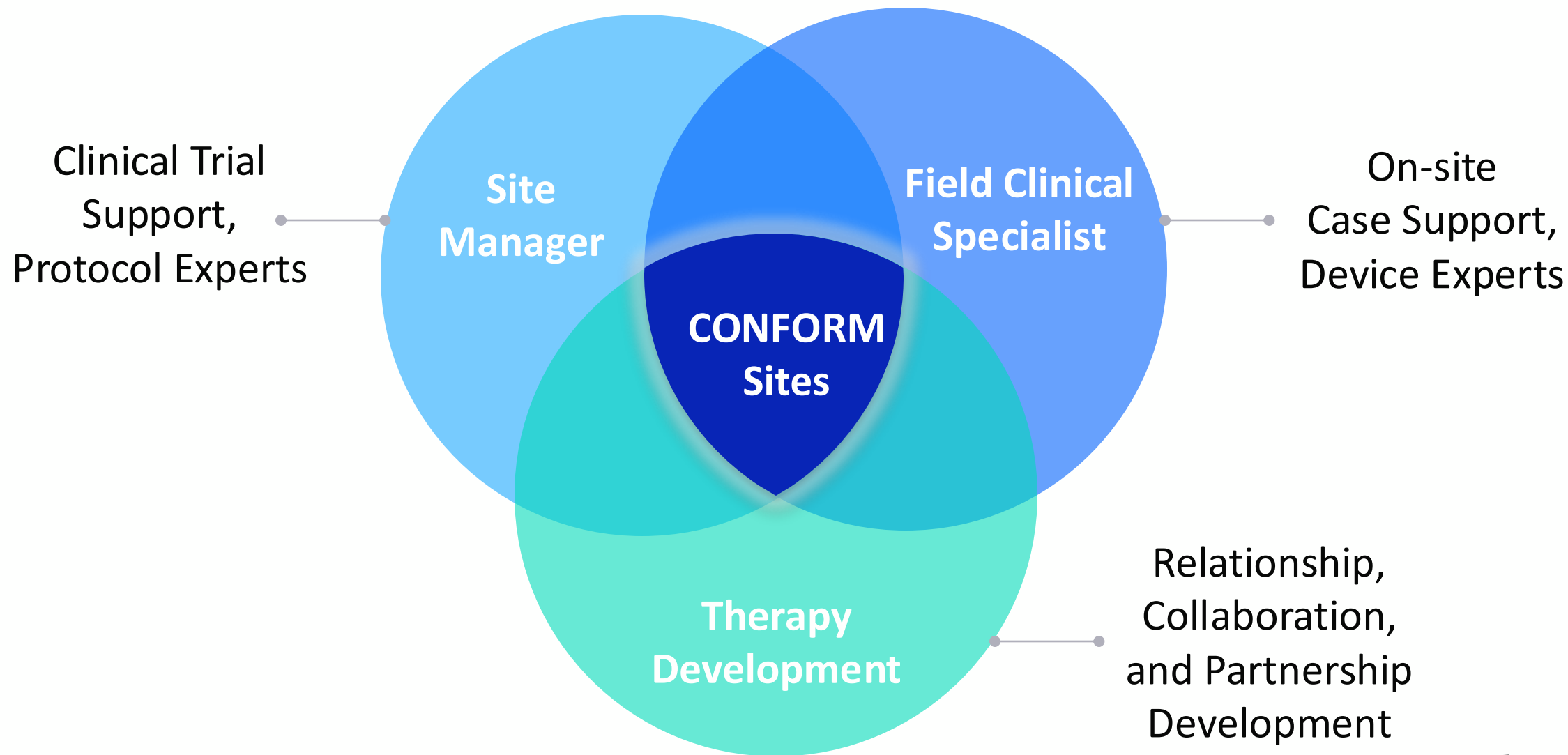
*Clinical Project Specialist*

(978) 549-7599

[bwinton@conformalmedical.com](mailto:bwinton@conformalmedical.com)

# CONFORM Site Team

By working together, we advance the future of LAAO practices



# US Activated Sites

**55** ACTIVATED  
US SITES



# OUS Activated Sites

**6** ACTIVATED  
OUS SITES





# Protocol Update Rev. K

*Aly Dechert,*  
Manager Clinical Operations



# Updates to CONFORM Protocol Revision K

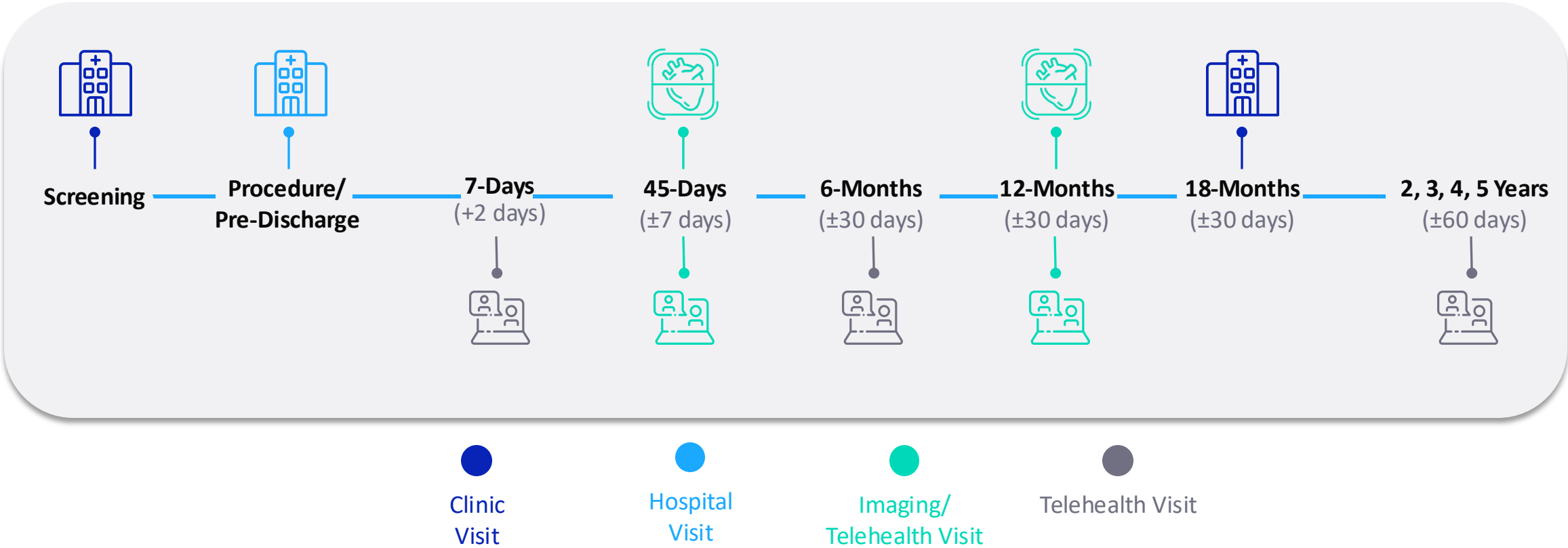
1. **CLAAS AcuFORM:** Next Generation CLAAS device
2. **Roll-In Maximum:** Maximum of 3-4 roll-in patients per site
3. **Study Timeline:** Updated to reflect enrollment pause and GLACE Study
4. **Removal of CHADS2** from eligibility criteria and assessments
5. **Follow Up Schedule - Attempted Population:** Followed for 18-Months (telehealth only)
6. **Screening Imaging: A CT or TEE** is required prior to randomization to properly assess all I/E criteria. Cardiac MRI or TTE alone are not sufficient to randomize the patient
7. **Pre-Discharge TTE: Must be done 4+ hours** after end of procedure
8. **Cardiac CT allowed at 45-day** follow up. Findings of leak or thrombus on CT must be confirmed on TEE and resolution must be documented

# Study Design

Sample Size	Prospective, multicenter, randomized control trial Up to <b>1600 patients randomized; Up to 300 Roll-In Study-Wide</b> ( <i>maximum 3-4 per site</i> )
Sites	Up to 100 investigational sites in North America Up to 5 investigational sites in Japan Up to 10 investigational sites in EU/EEA and Central Asia
Randomization	<b>1:1 randomization</b> ; Non-Inferiority <b>CLAAS : Any commercially available LAAO device</b>
Objective	<p>(1) To <b>evaluate the safety and effectiveness</b> of the CLAAS system by demonstrating non-inferiority to currently marketed LAAO systems in subjects with non-valvular atrial fibrillation</p> <p>(2) To demonstrate <b>the safety of a post-procedure</b> pharmacologic <b>antiplatelet regimen</b> that consists of DAPT alone without concomitant anticoagulation therapy (OAC)</p> <p>(3) To demonstrate the <b>ability to safely deliver the CLAAS Device</b> using a conscious sedation protocol without general anesthesia. To investigate this objective, a separate sub-study will be conducted after recruitment of the RCT is complete at select, qualified sites based on the experience demonstrated in the RCT</p> <p>(4) Support regulatory approval(s) in territories outside US.</p>

# Follow Up Requirements

## Clinic, Telehealth, and Imaging Visits



# Screening Imaging

Imaging shall be done post-consent prior to randomization.  
Historical images within 6 months prior to consent are accepted.



## Anatomical Imaging

Evaluates echo exclusion  
criteria 1, 5, 6, 8

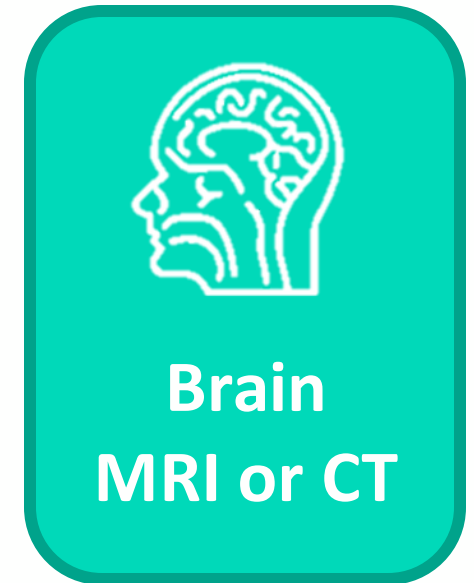
★ **Required for randomization**

## Clinical Imaging

Evaluates echo exclusion  
criteria 2, 3, 4, 7, 9

May be used as supportive imaging

Patient with history  
of stroke or TIA?



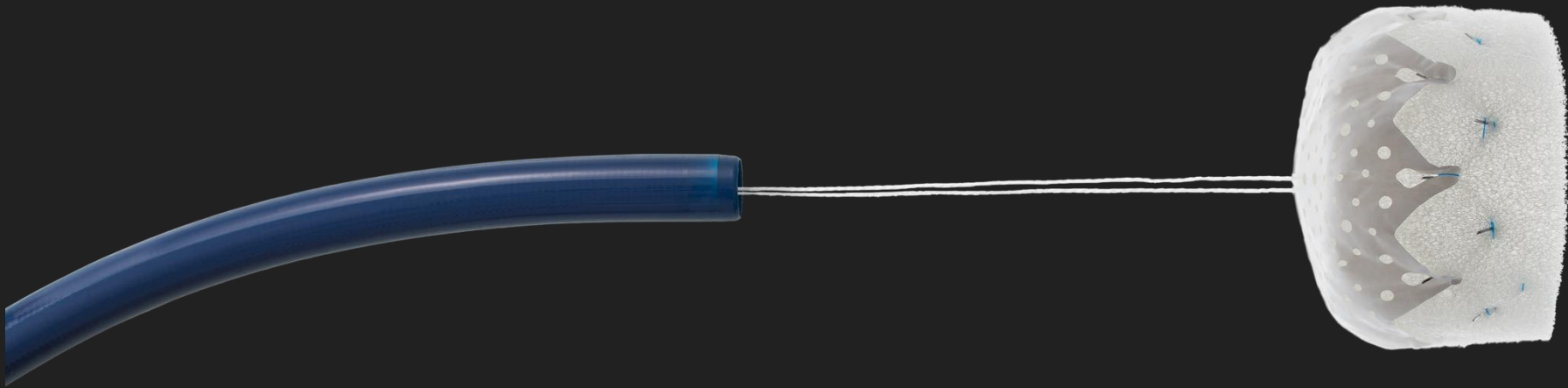
## Brain Imaging

If neuro event was  $\leq 24$  months ago:  
Recent brain scan MRI or CT  
post-neuro event is required

# Full Schedule of Assessments

	Screening	Procedure <sup>0</sup>	Pre-Discharge	7-Day	45-Day	6 Month	12 Month	18 Month	2, 3, 4, 5 Year	Stroke/SE Assessment <sup>1</sup>
		Day 0	4 hours	+2 Days	±7 Days	±30 Days	±30 Days	±30 Days	±60 Days	+14 Days
	Clinic	Hospital	Hospital	Telehealth <sup>2</sup>	Clinic Visit/ Telehealth <sup>2</sup>	Telehealth <sup>4</sup>	Clinic Visit/ Telehealth <sup>2</sup>	Clinic Visit	Telehealth <sup>2</sup>	Clinic
Informed Consent	X									
Medical and Surgical History	X									X
Physical Exam/Assessment	X ★									X
Vital Signs	X									
CHA <sub>2</sub> DS <sub>2</sub> -VASc	X									
HAS-BLED	X									
Serum Creatinine or GFR/eGFR	X									
CBC, Platelet count and Hgb/Hct	X	X <sup>4</sup> ★								
ECG 12 Lead	X									
Pregnancy Test	X									
Neuro Assessment	X		X					X		X
QVSFS	X			X	X	X	X	X	X	X
Cardiac CT	X ★				X <sup>11</sup> ★		X <sup>11</sup>			
TTE	X <sup>10</sup>		X <sup>10</sup>		X <sup>12</sup>					
TEE		X			X <sup>12</sup>		X <sup>12</sup>			X
Brain Imaging	X									X <sup>14</sup>
AE Assessment	X	X	X	X	X	X	X	X	X	X
Medication Review <sup>15</sup>	X	X	X	X	X	X	X	X	X	X
INR	X	X								
Randomization	X <sup>16</sup>									
LAA Measurements		X								





# CLAAS<sup>®</sup> AcuFORM<sup>™</sup>

*Dana Sullivan, VP Therapy Development*

# Drivers of A Rapidly Growing LAAO Market



## Patients

- Increasing Prevalence of Afib
- Evolving Patient Preference



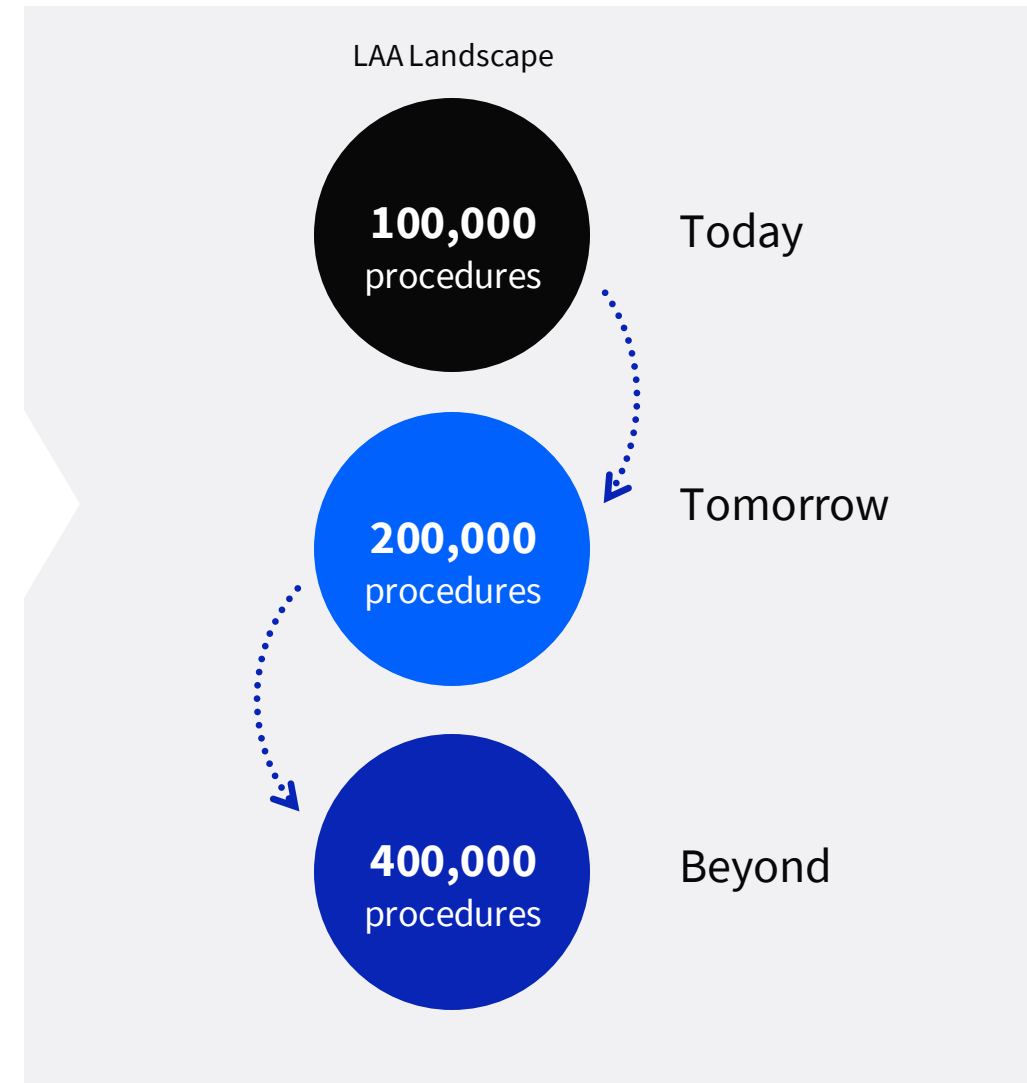
## Physicians

- Growing Physician Adoption
- Advancements in LAAO Technology
- Strong Clinical Evidence and Guideline Integration



## Payors

- Favorable Reimbursement Policies
- Geographic Market Expansion
- Indication Expansion



# A Rapidly Growing Market Needs An Optimized Solution

2023<sup>1</sup>

**100,000 Patients treated**

2025<sup>1</sup>

**150,000 Patients forecasted**

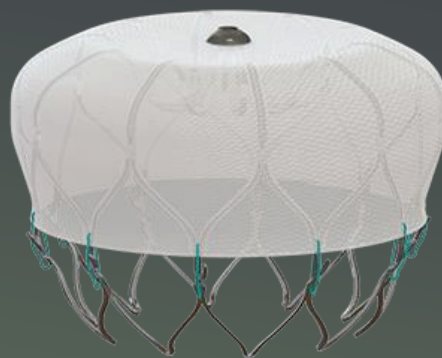
2030<sup>2</sup>

**400,000 Patients forecasted**

1. Piper Sandler Market Update September 2023

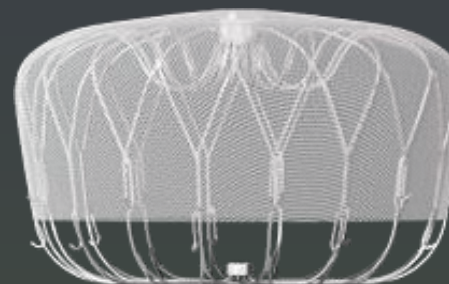
2. Boston Scientific Investor Day September 2023

Watchman



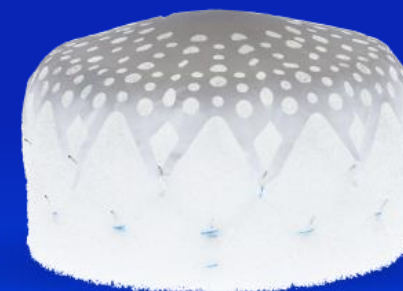
1<sup>st</sup> GEN  
Pioneered Market  
PMA Approval  
CMS Coverage

Watchman  
FLX PRO



3<sup>rd</sup> GEN  
Established Market: >\$1.2B 2023  
TEE/General Anesthesia  
3 Physician Procedure

Conformal  
CLAAS AcuFORM



NEXT GEN  
Transforming Market: Improved  
Closure; Conscious Sedation;  
Single Physician Procedure



# Next-Generation LAAO Technology.

- One Size Strategy Addresses >90% of patients
- Confirm Seal with Peri-procedural Angio
- Efficiency of Workflow Allows for Scale
- Facilitates Single Operator Procedure



# CLAAS<sup>®</sup> AcuFORM<sup>™</sup> Next-Generation LAAO Device



- Builds upon the novel CLAAS device
- Engineered to conform to and seal the LAA
- Only two sizes, one of which effectively treats over 90% of patient anatomies
- A proven delivery technique
  - Potentially eliminating the need for general anesthesia,
  - Enhancing operational efficiency
  - Enabling healthcare providers to easily confirm appendage seal



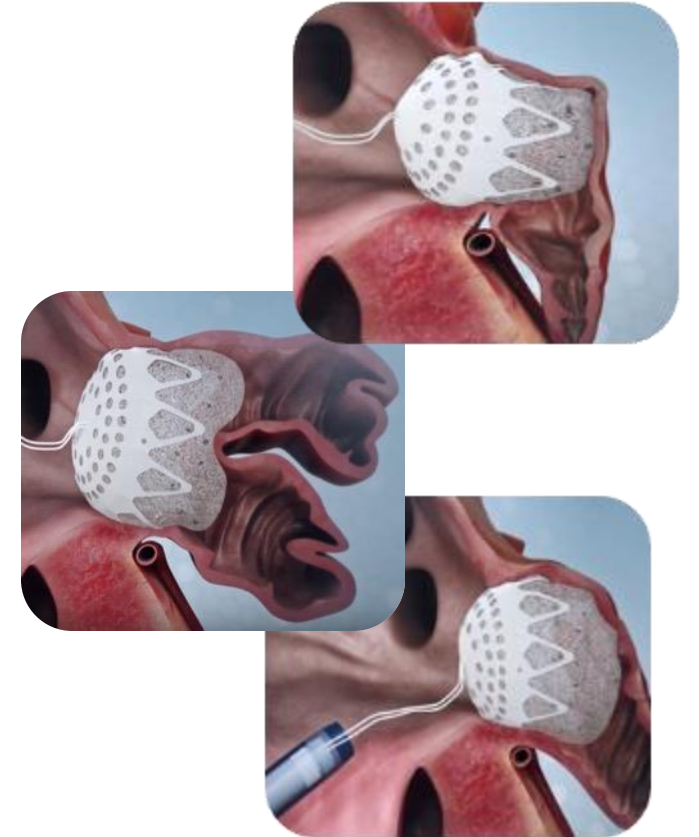
# CLAAS<sup>®</sup> AcuFORM<sup>™</sup>

## Left Atrial Appendage Occlusion System

The logo features the word 'conformal' in a bold, lowercase sans-serif font. The letter 'o' is replaced by a blue circle. Below the main text, the tagline 'THE SHAPE OF STROKE PREVENTION' is written in a smaller, all-caps sans-serif font. The entire logo is centered within a white circle, which is itself set against a background of blue concentric arcs.

**conformal**

THE SHAPE OF STROKE PREVENTION





# The Conformal CLAAS<sup>®</sup> AcuFORM<sup>™</sup> LAAO Implant



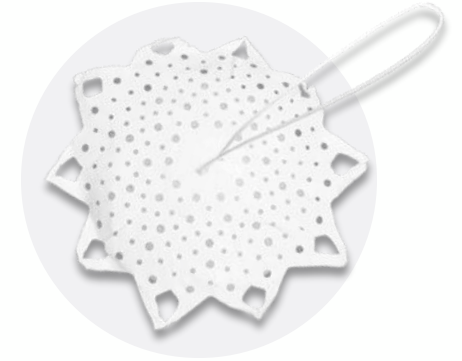
Conformable Implant  
Available in 2 sizes



Compliant Nitinol  
Endoskeleton



Foam Matrix Body  
&  
5 Radiopaque  
Marker Bands



ePTFE Cover  
&  
Flexible Tether

Indication for use: To reduce the risk of thromboembolism from the left atrial appendage in patients with non-valvular atrial fibrillation, without the need for oral anticoagulants.

# Simplified Sizing

1 size address >90% of patients



Shallow  
10mm landing zone



Regular Size CLAAS® Device  
(LAA Ostium Range of 10-33 mm)

Large Size CLAAS® Device  
(LAA Ostium Range of 20-40 mm)

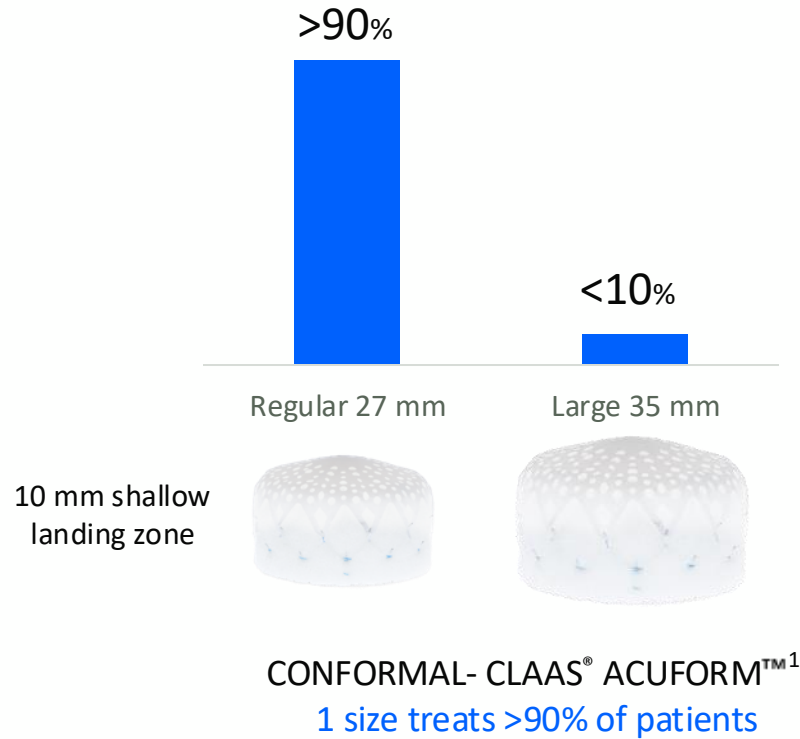
WATCHMAN™



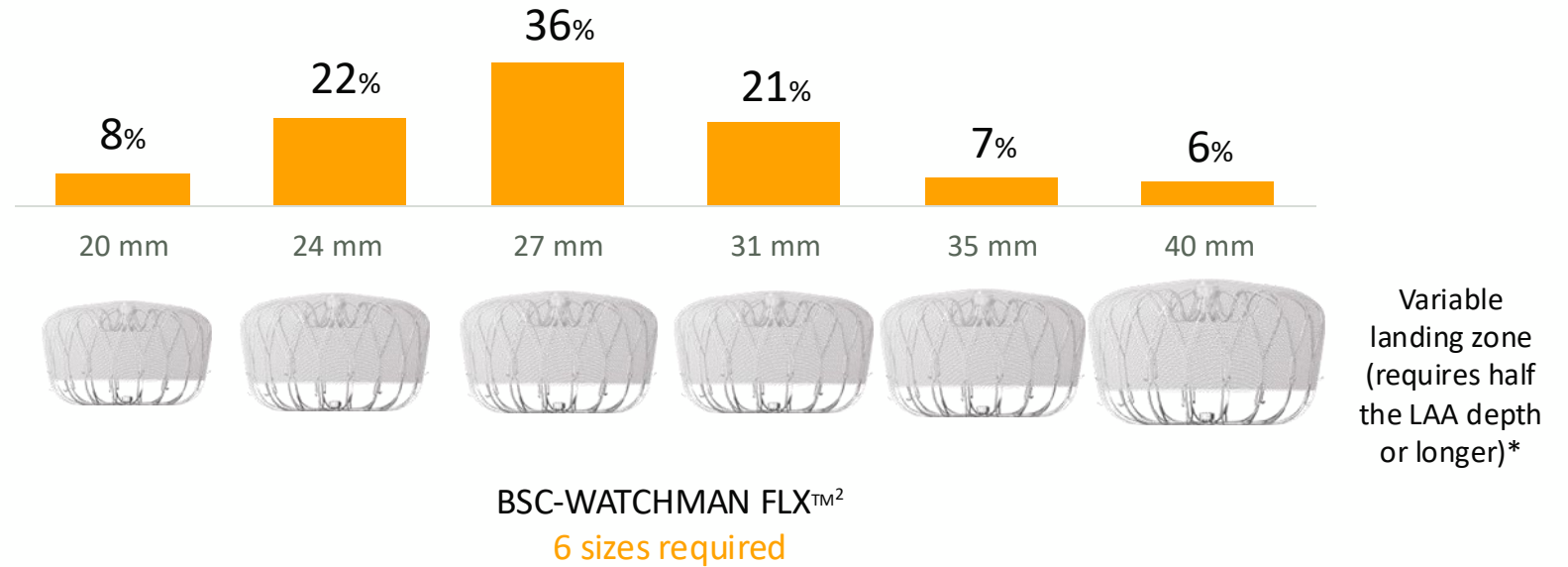
Amulet™



# Simplified Sizing



## CONFORMAL Vs. WATCHMAN™ Implant size and percentage used

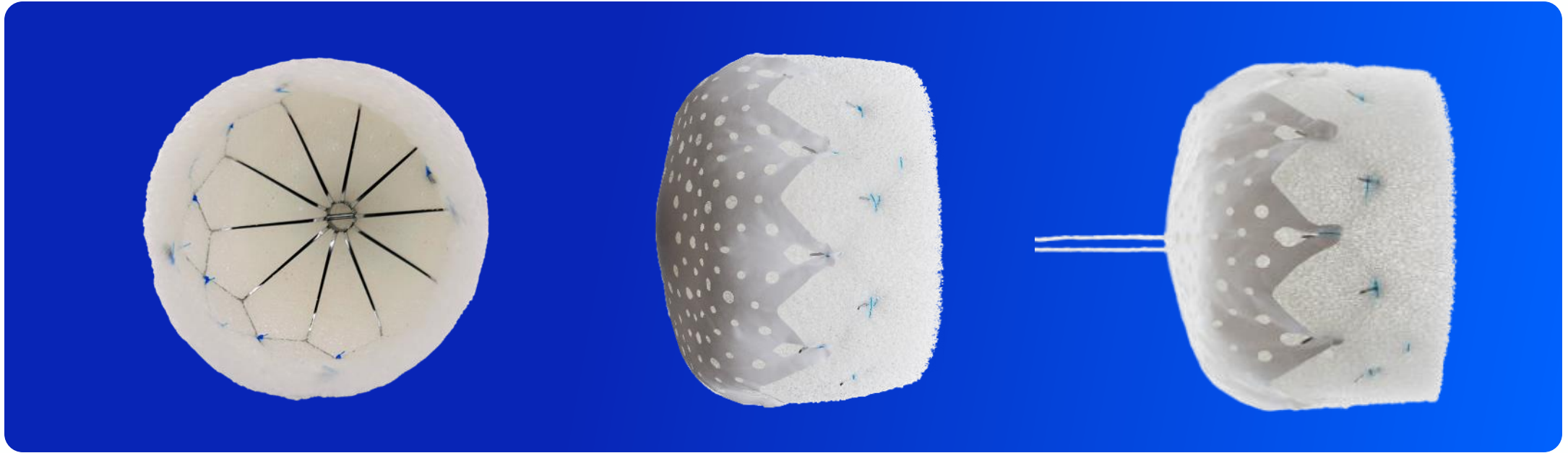


\*IFU BSC-WATCHMAN

1. Conformal Medical Data on File

2. Doshi SK, et, al; PINNACLE FLX Two-Year Outcomes With a Next-Generation Left Atrial Appendage Device: Final Results of the PINNACLE FLX Trial. J Am Heart Assoc. 2023 Feb 21;12(4):e026295.

# Definitive Seal and a Smooth Surface



## Compliant endoskeleton

Conforms

## ePTFE cover

Less thrombogenic

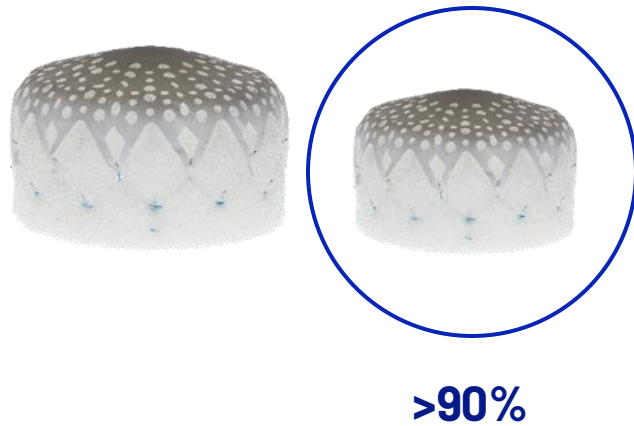
## Flexible tether

Eliminates cable attachment site

Eliminates cable bias

# Eliminating TEE Enables Conscious Sedation

## Simplified Sizing



## Unbiased Positioning



## Ability to Test with Angiography

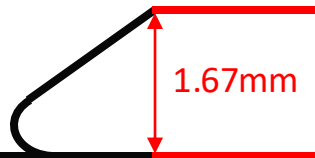


# LAAO Device: Anchor Penetration Depth

12 anchors



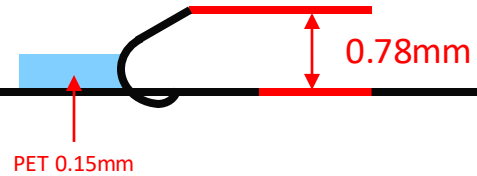
Amulet™



18 anchors



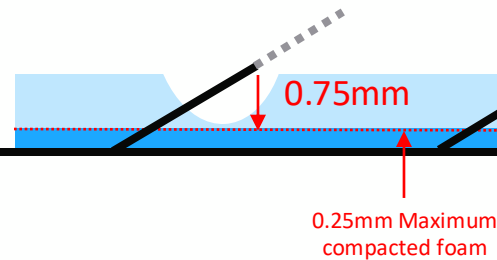
WM FLX™



20 - 24 anchors



CLAAS®  
AcuFORM™



CLAAS®



50%  
Reduction of  
Exposed Anchor

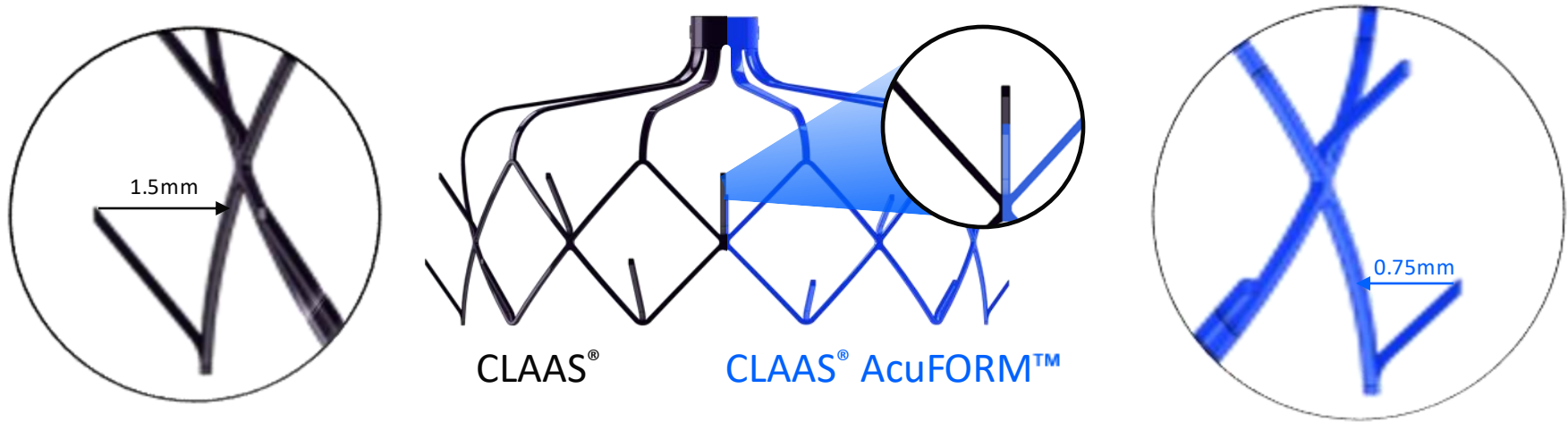
Drawings are illustrative

CLASS Implant (20 anchors regular) (24 anchors large)

# Anchor Pull Forces in Tube & Plate Models<sup>1</sup>

Device	Exposed Anchor Length (mm)	Tube Model* In Pounds	Plate Model In Pounds
CLAAS <sup>®</sup> (27mm)	1.5	0.65 (25 mm ID)	1.22
CLAAS <sup>®</sup> AcuFORM <sup>™</sup> (27mm)	.75	0.60 (25 mm ID)	0.95
Control (27mm WM FLX <sup>™</sup> )	~0.78	0.40 (24 mm ID)	0.30

*\*Tube ID closest size available (without exceeding) to max ostium width from IFU*



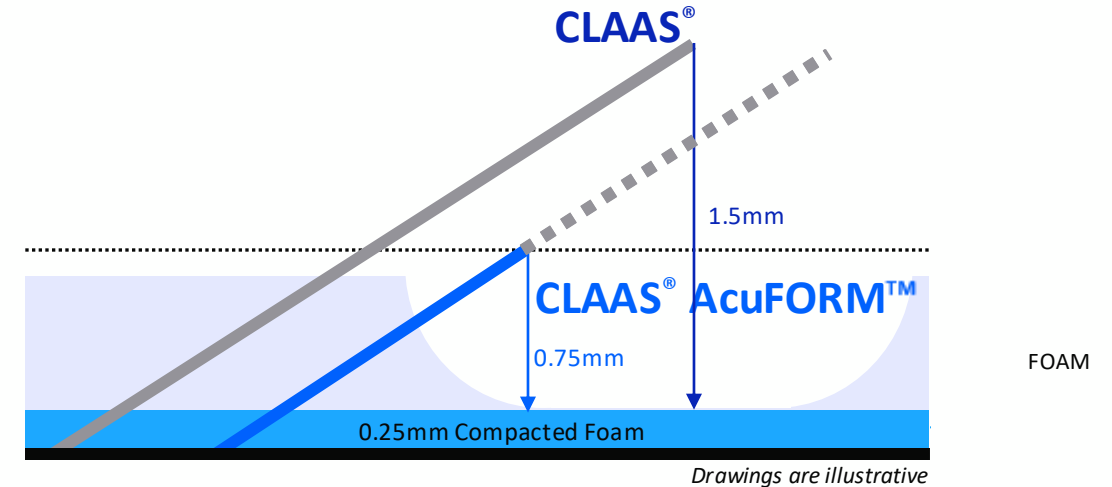
1. Conformal technical report TR-89 Anchor Shortening Analysis.



# CLAAS<sup>®</sup> AcuFORM<sup>™</sup> Tug Test



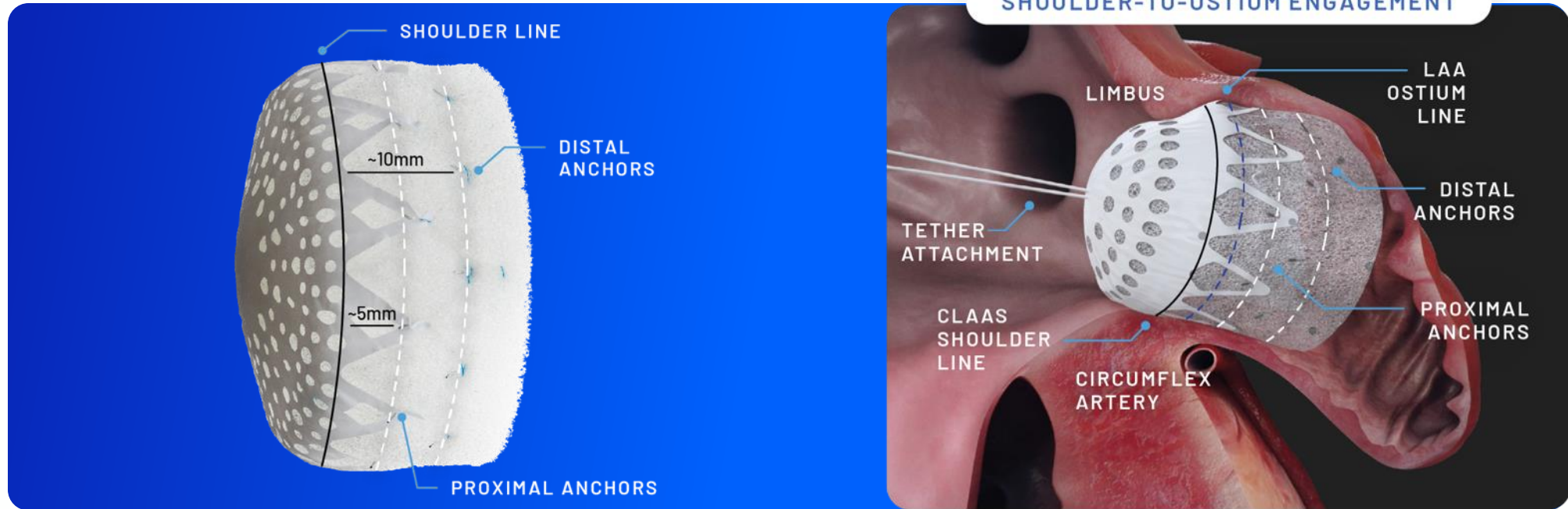
Tug Test CLAAS<sup>®</sup> AcuFORM<sup>™</sup>



- 50% shorter anchors
- Reduced tissue penetration (0.75mm)
- Two rows of anchors (regular=20, large =24)

# CLAAS<sup>®</sup> AcuFORM<sup>™</sup> Anchoring System

- Shoulder line to be <5mm proximal to the LAA ostium and not to exceed 8mm
- Both rows of anchors should engage tissue
- The distance from the shoulder to the anchors does NOT change with compression

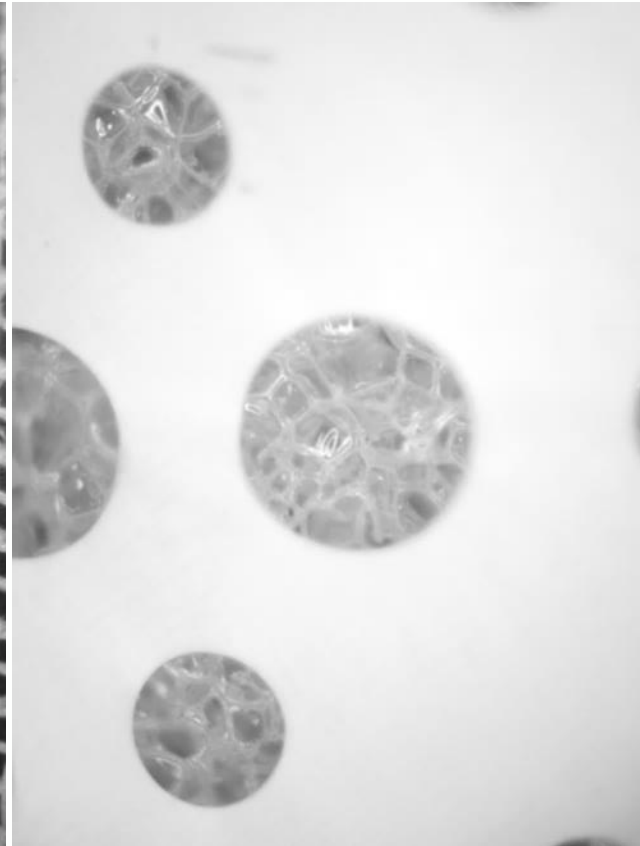


# WM FLX vs. CLAAS<sup>®</sup>



**WM FLX**

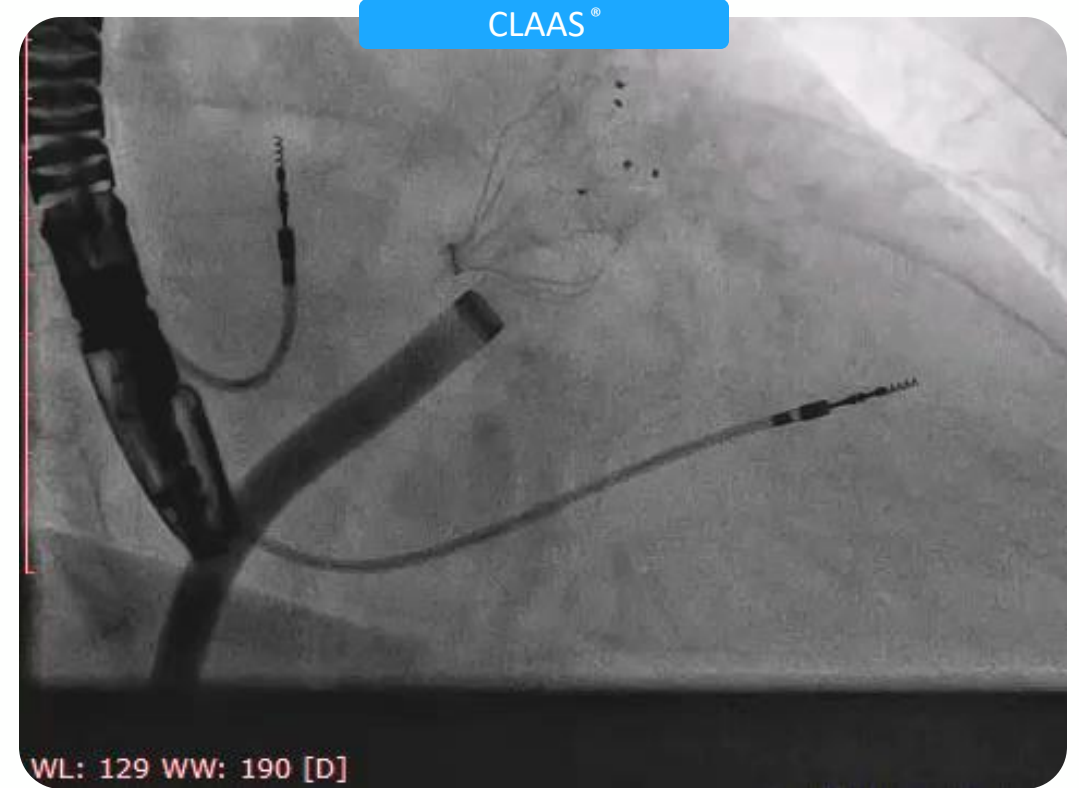
PET



**CLAAS  
AcuFORM**

ePTFE

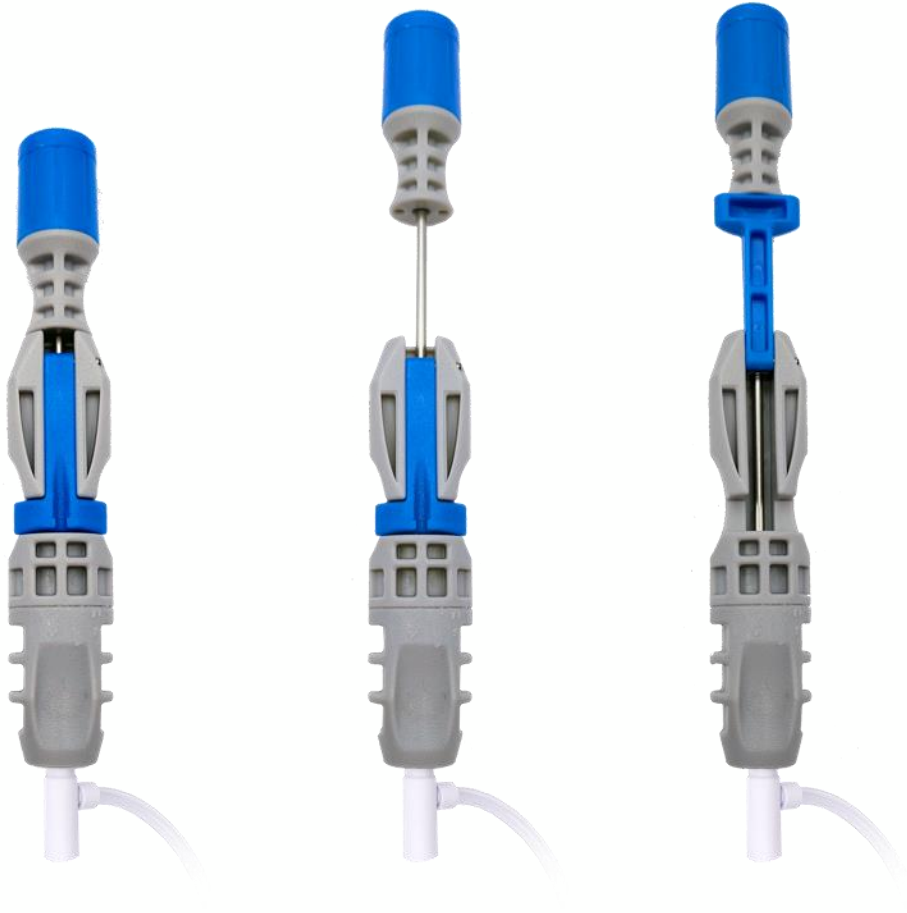
# Confirming Seal



97.7% Seal Rate without significant (>3mm) leaks at 12 months, comparing favorably with marketed devices.<sup>1</sup>

1. Gray W, Conformal Early Feasibility Study: 12 Months Results. TCT 2023 [Study Details](#) | [The CONFORMAL Early Feasibility Study](#) | [ClinicalTrials.gov](#)

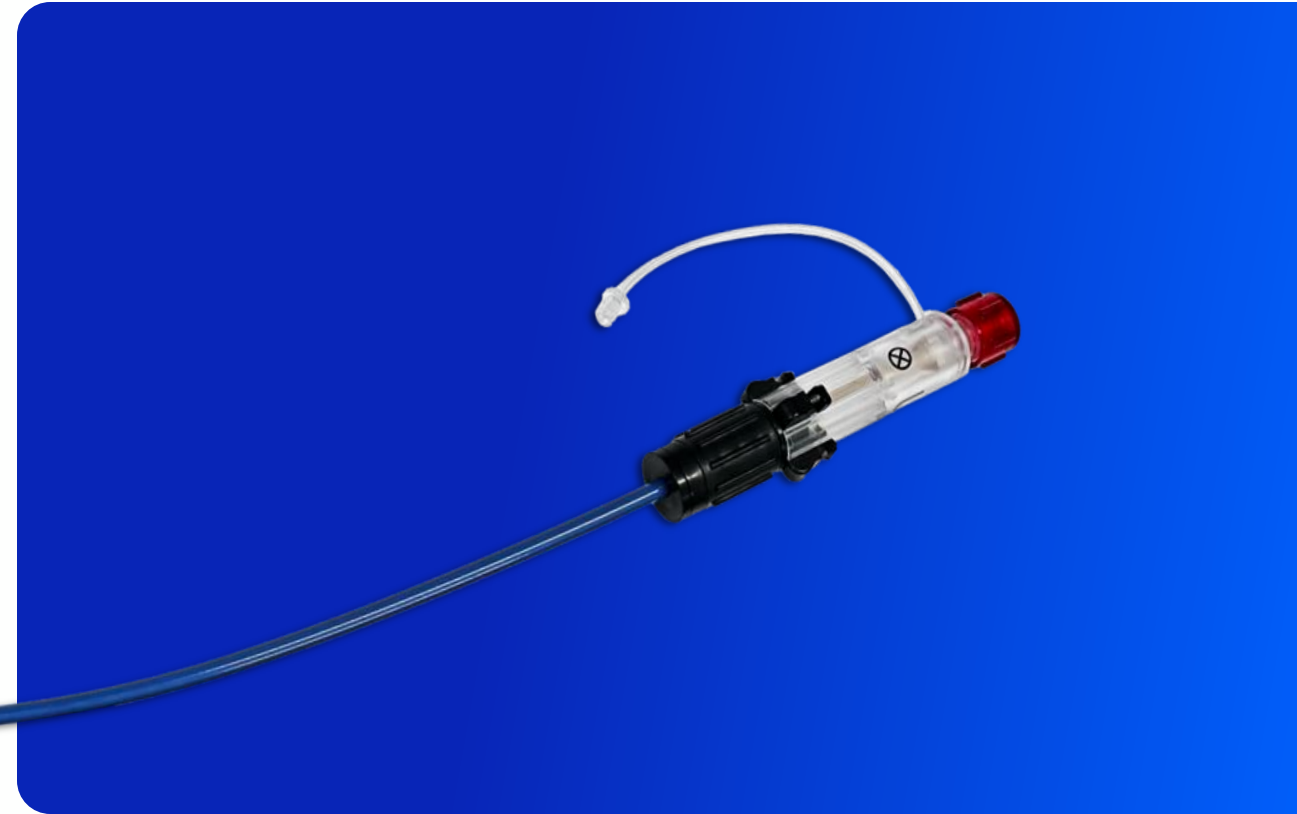
# Intuitive Handle



- Simple and easy to use
- Improved ergonomics
- Effortless tether management
- Increased durability
- Enhanced deployment & confirmation
  - Cable-like delivery
  - Tether permits placement without cable bias

# OEM Steerable Sheath

- Overcomes difficult anatomy; two steering planes
- 15.5F ID sheath, compatible with regular implant device only
- Proximal unidirectional transeptal curve
- Distal curve steerability



# CONFORM Pivotal Trial Early Feasibility Data



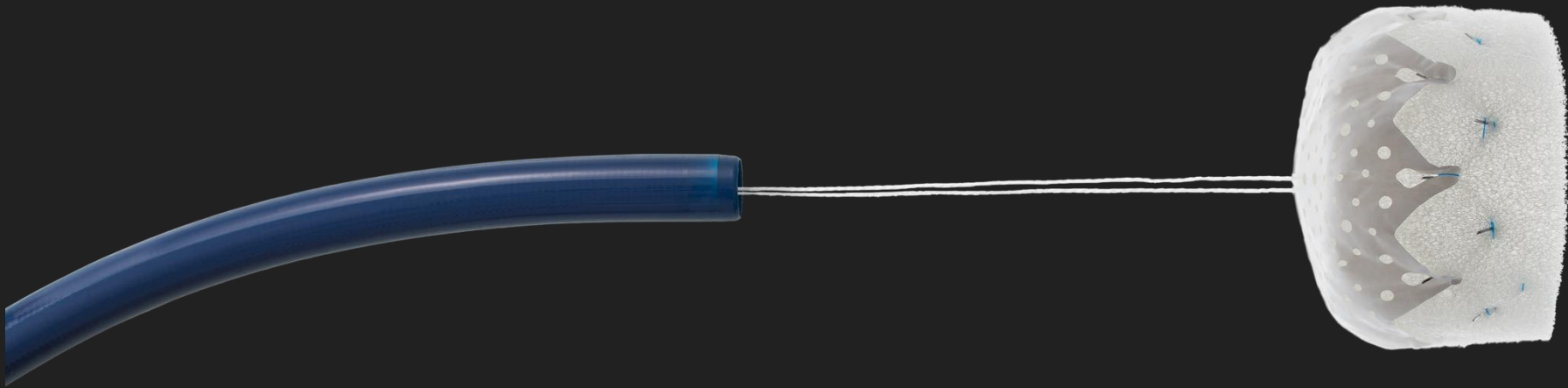
## 97.7% Seal Rate

Seal without significant (>3mm) leaks at 12 months,  
comparing favorably with marketed devices.<sup>1</sup>



1. Data on file, based on core lab evaluable images, study in progress N=40

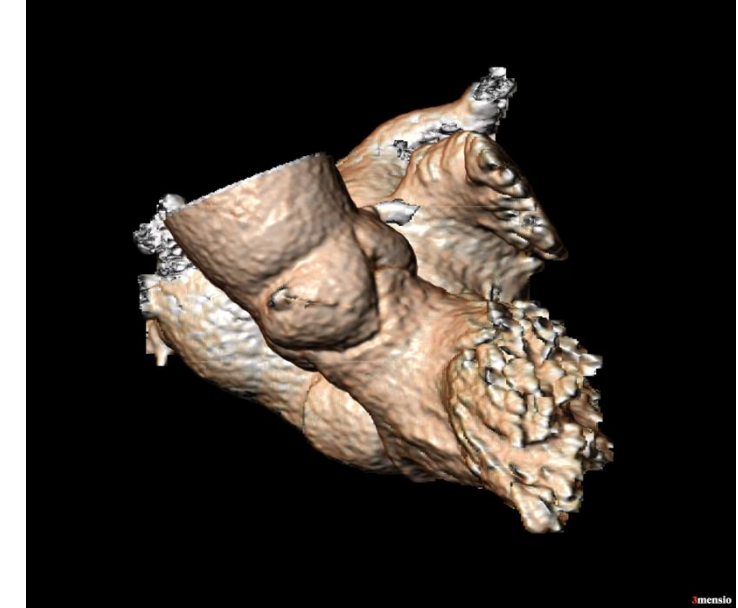
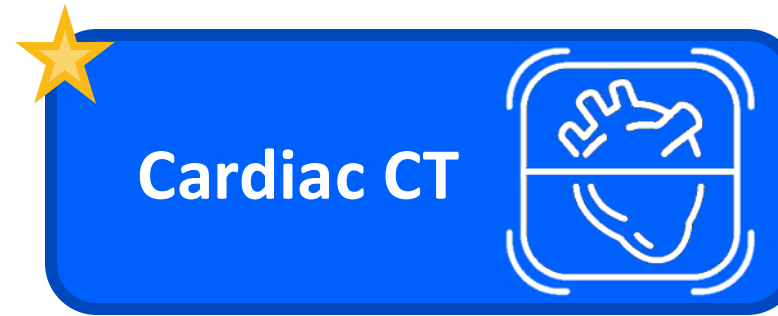




# Imaging Requirements

*Alyssa Smith*, Imaging Manager

# Screening Imaging & Pre-Procedure Review Process



## Anatomical Imaging

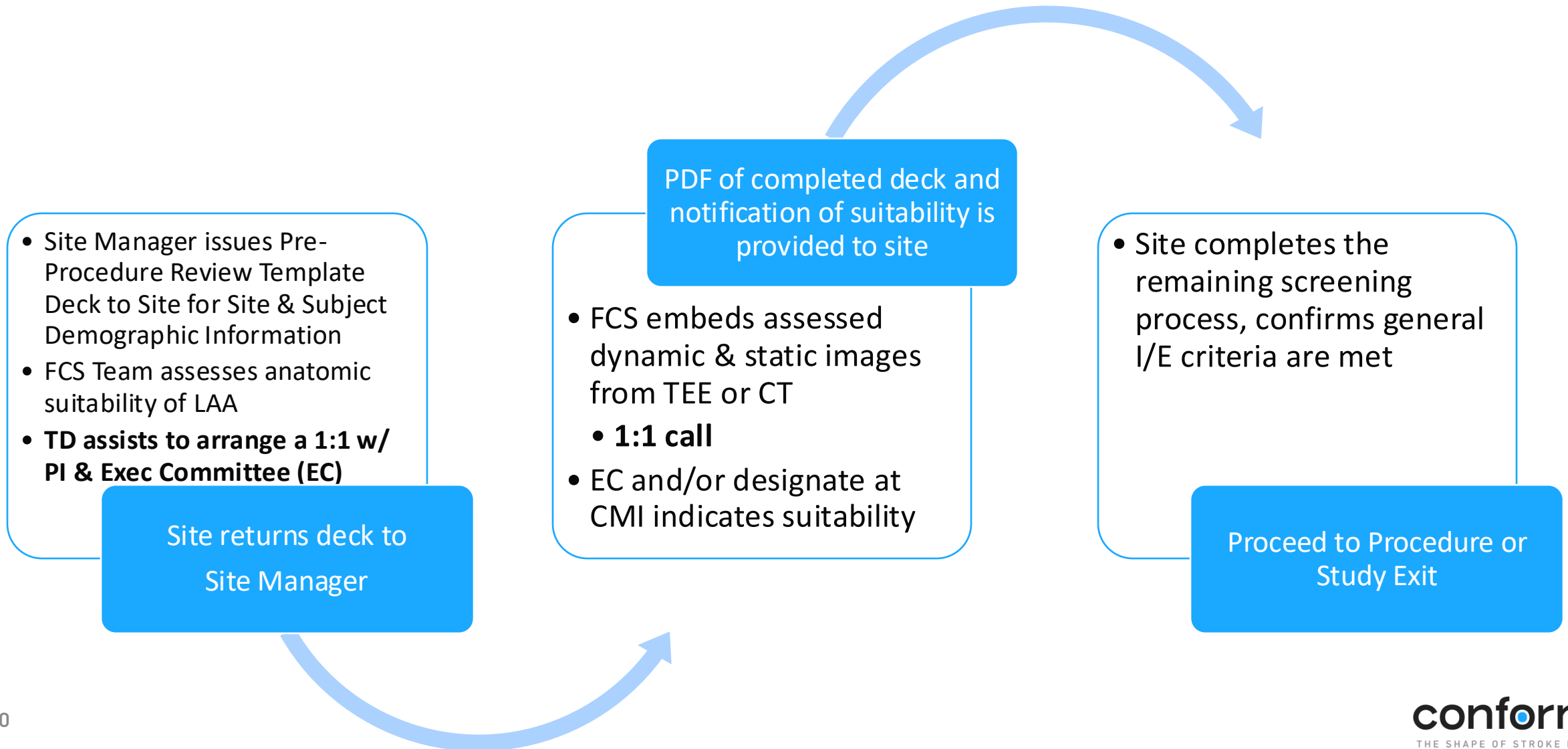
Evaluates echo exclusion  
criteria 1, 5, 6, 8

★ Required for randomization



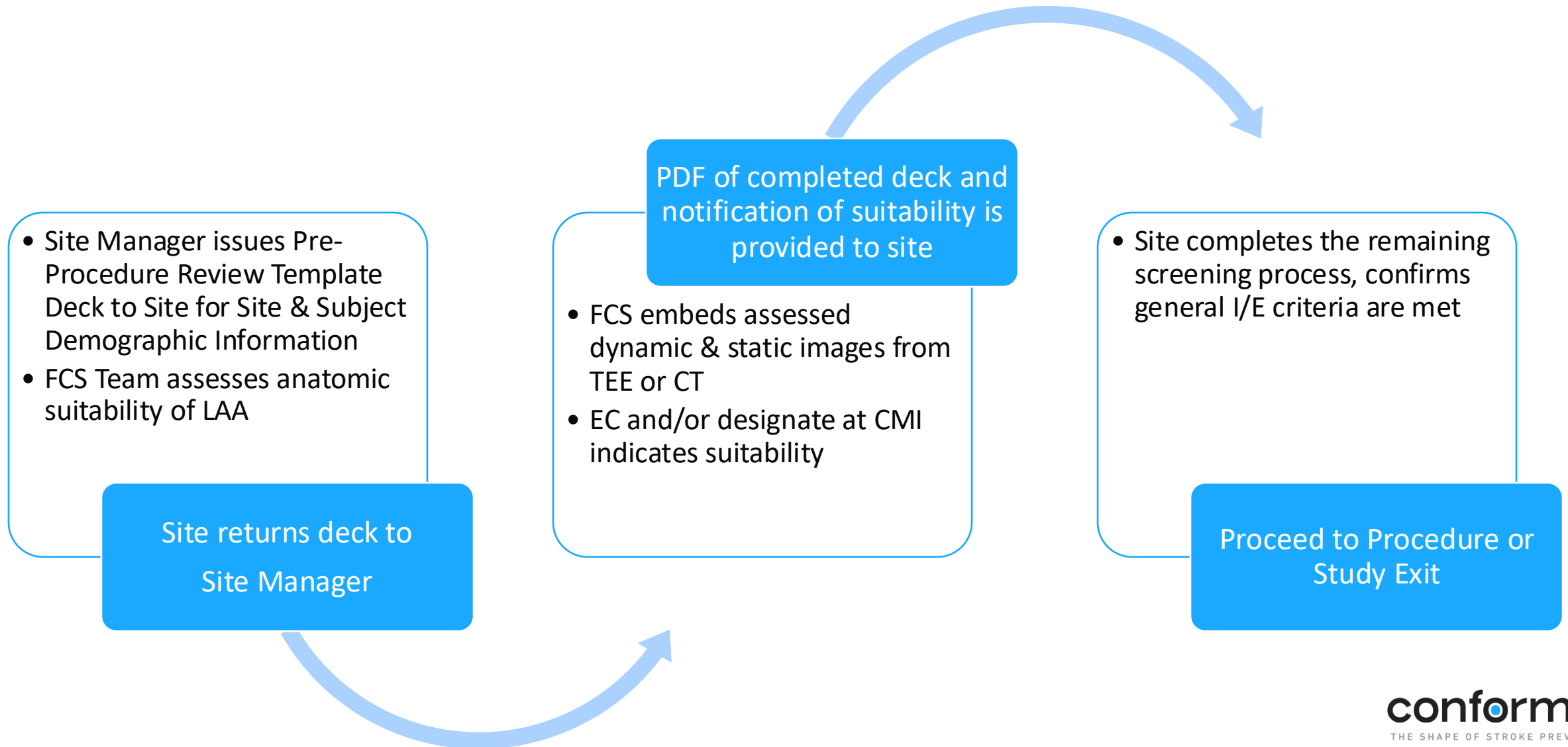
# Screening Imaging & Pre-Procedure Review Process

U.S. Sites with **LESS than 5 Enrollments \*\*FIRST PATIENT\*\***

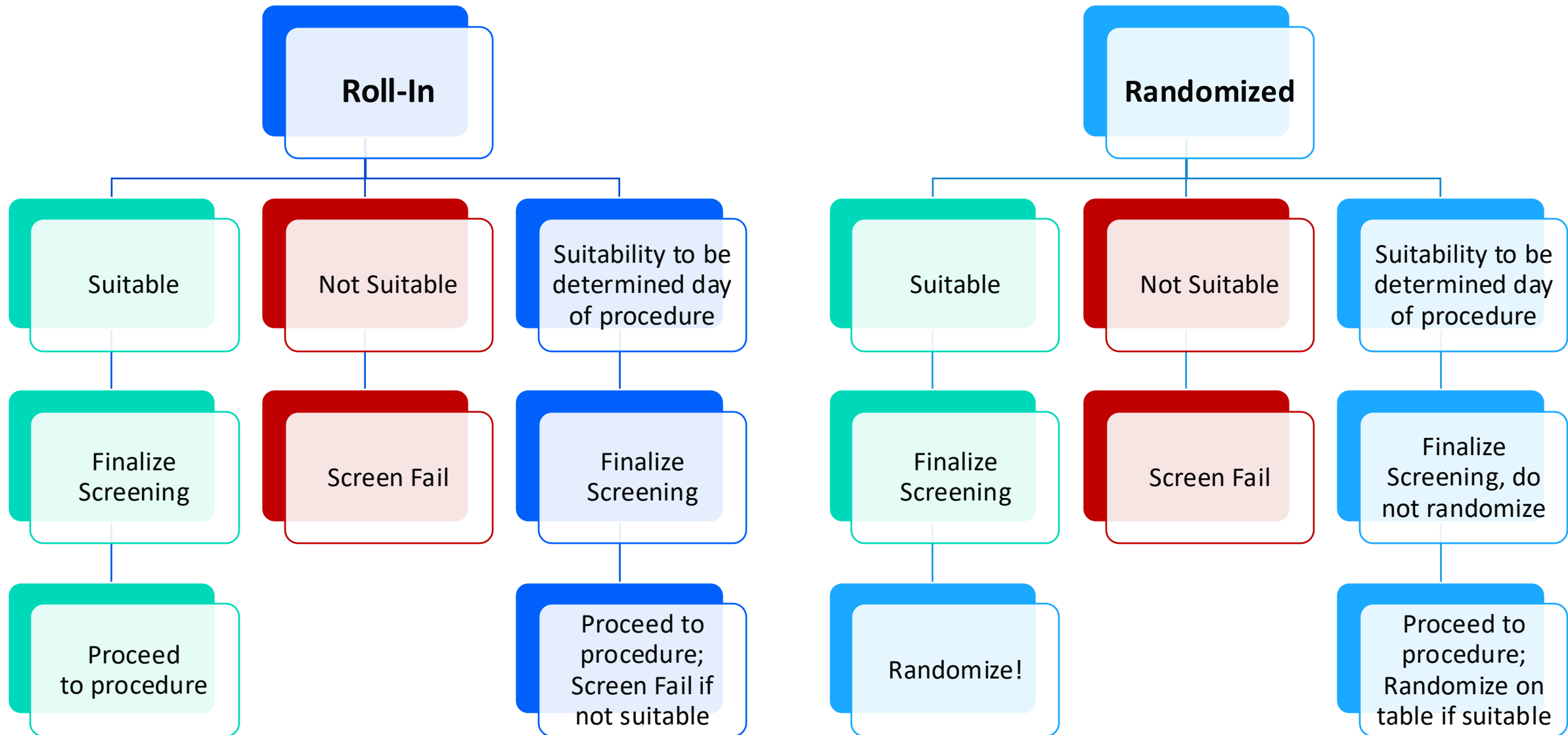


# Screening Imaging & Pre-Procedure Review Process

U.S. Sites with **LESS than 5 Enrollments** **\*\*PATIENT 2-5\*\***



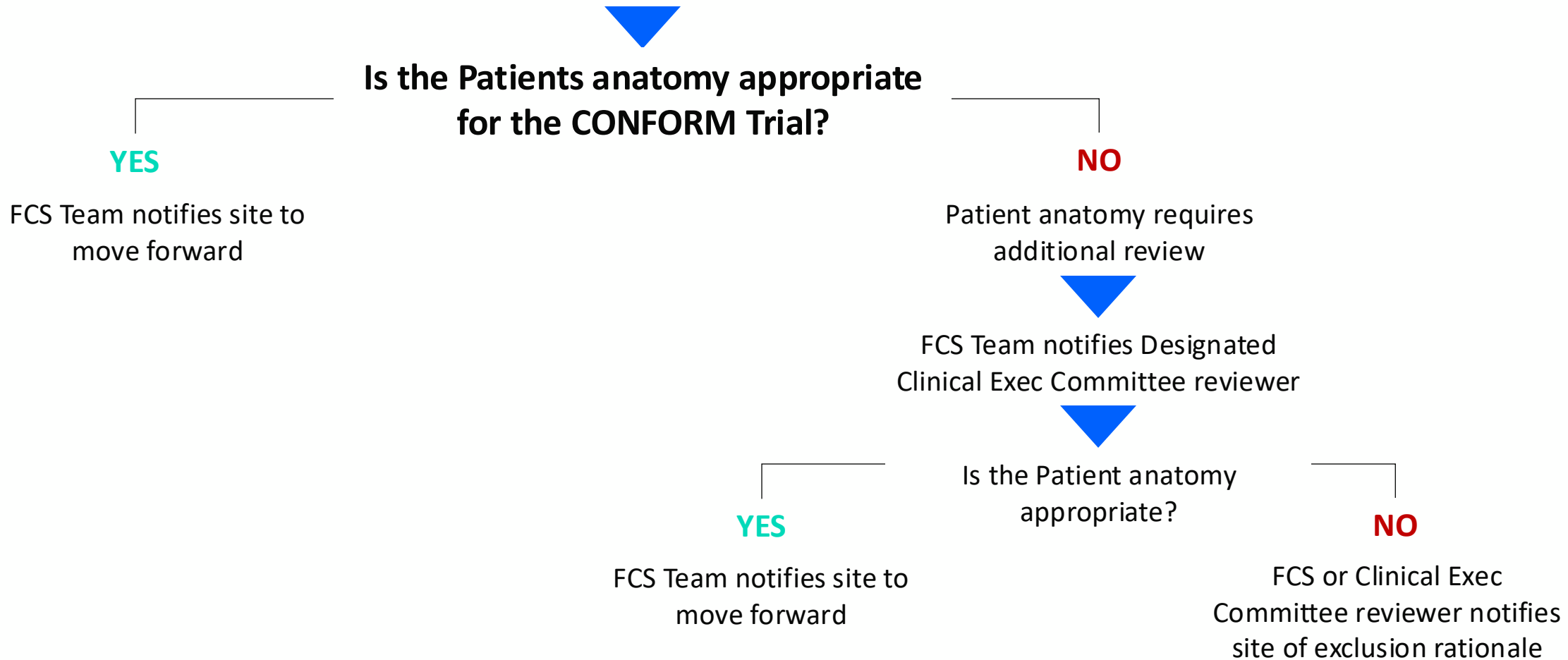
# Screening Imaging & Pre-Procedure Suitability

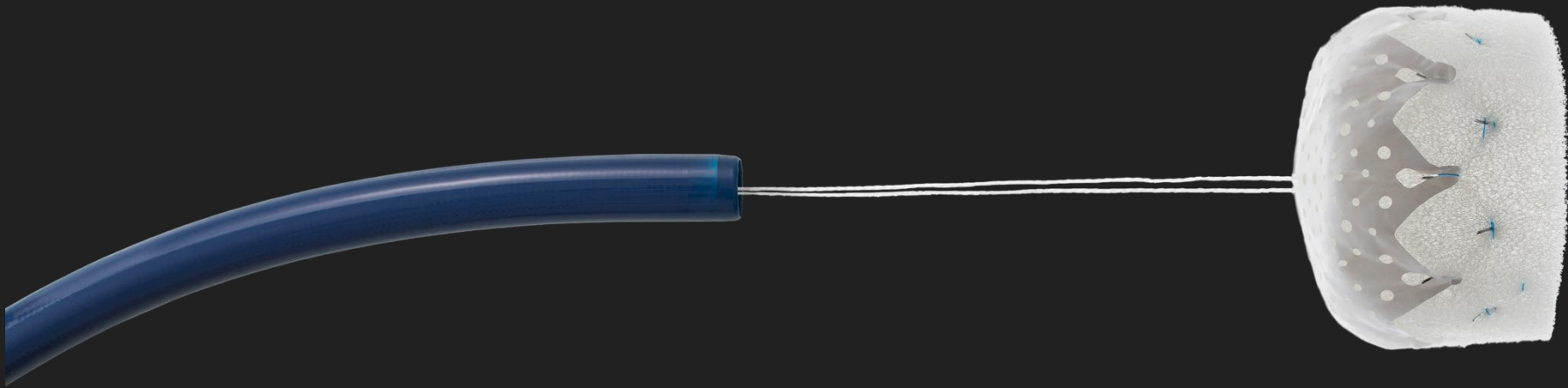


# Screening & Pre-Procedure Review Process

U.S. Sites with **MORE THAN 5 Enrollments**

Conformal Field Clinical Support (FCS) Team reviews images for anatomy  
& imaging per Inclusion/Exclusion criteria within 48 hours





# AE Reporting, EDC Updates and Source Worksheets

*Melissa Ricketts & Eileen Berbary, Senior CRAs*



# AE Reporting, EDC Updates & Source Worksheets

## AE Reporting

- The Basics
- Comp Check

## EDC

- CCGs
- Tips

## Source worksheets

- DTT vs Source
- Updates

# Adverse Event Reporting

- An adverse event (AE) is **any untoward medical occurrence, unintended disease or injury or untoward clinical signs (including an abnormal laboratory finding)** in a subject, whether related to the study device and whether anticipated or unanticipated.
- A reported AE **does not imply** that there is a **relationship between the AE and the study device**.
- Source documentation related to an AE is only required if selected for Clinical Events Committee Adjudication.
- **Roll-In** adverse events collection occurs from the **time of the consent** through subject **study completion**.
- **Randomized** adverse events collection occurs from the **time of randomization** through subject **study completion**.
- For subjects who did not have an implant, study completion is at 45 days.

# Adverse Event Reporting

- An **unanticipated adverse device effect (UADE)** is any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death **was not previously identified in nature, severity, or degree of incidence in the clinical investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.**
- Must be reported to Conformal and your IRB/REB **as soon as possible** but no later than within **2 working days** after you (site personnel) first learn of the event

# Adverse Event Reporting

- All serious adverse events (SAEs)
- All device and procedure-related adverse events
- Unanticipated adverse device effects (UADEs)
- Pre-procedure events (i.e., events related to pre-procedure medication changes)
- The following events regardless of seriousness or relatedness will be collected:
  - Bleeding events
  - Myocardial Infarction
  - Pericardial Effusion Requiring Drainage
  - Embolic events (e.g., stroke, TIA, Systemic Embolism)
  - Neurologic events
  - Device embolization
  - Device Related Thrombus

If an AE is deemed not to be related to the device, procedure implant or medications and is not cardiovascular or neurological in nature **AND**; does not meet serious adverse criteria..... it does not need to be reported.

## Adverse Events of Special Interest

Adverse Event of Special Interest?	<input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, check all that apply
<input type="checkbox"/> Bleeding Event		
<input type="checkbox"/> Myocardial Infarction		
Were cardiac enzymes drawn?		
<input type="checkbox"/> Yes (Complete Cardia Enzyme Form)		
<input type="checkbox"/> No		
<input type="checkbox"/> Unknown		
<input type="checkbox"/> Neurological Event		
<input type="checkbox"/> Vascular Complication		
<input type="checkbox"/> Systemic Embolization		

<b>conformal</b> THE SHAPE OF STROKE PREVENTION	<b>CONFORM Bleeding Event</b> <b>Source Worksheet</b>
Site Number: _____ Subject ID: _____	

Note: This form is not required to be completed if information is readily available on medical records.

Date of Event:	___/___/___ (DD/MMM/YYYY)
Was the subject on antiplatelet therapy at the time of the bleeding event?	<input type="checkbox"/> Yes If Yes, ensure ConMed Log is completed <input type="checkbox"/> No
Was the subject on anticoagulation therapy at the time of the bleeding event?	<input type="checkbox"/> Yes If Yes, ensure ConMed Log is completed <input type="checkbox"/> No
Is the INR level at the time of bleeding event known?	<input type="checkbox"/> Yes, enter INR Level: _____ <input type="checkbox"/> Not applicable <input type="checkbox"/> Unknown

\_\_\_\_\_  
Site Personnel Signature

\_\_\_/\_\_\_/\_\_\_  
Date (DD/MMM/YYYY)

# Adverse Event Reporting Examples

**Are these events reportable per CONFORM Pivotal protocol?**

1. Subject did not receive the roll-in implant and was hospitalized for pre-planned procedure s/p 75 days from index procedure.
2. Randomized subject was hospitalized for less than 24 hours after the 18 month follow up visit occurred.
3. Subject received commercial implant and had a worsening condition that was not neurological or cardiovascular in nature.
4. Roll In subject had a medication change during a prolonged hospitalization and was started on an anticoagulant due to new elevated labs for a blood clotting disorder.
5. Roll-In subject baseline laboratory results report hypomagnesemia and 18 month follow up visit reports a reduction in magnesium levels.

# Adverse Event Reporting **Answers**

## **Are these events reportable per CONFORM Pivotal protocol?**

1. Subject did not receive the roll-in implant and was hospitalized for pre-planned procedure s/p 75 days from index procedure. **Yes**
2. Randomized subject was hospitalized for less than 24 hours after the 18 month follow up visit occurred. **No**
3. Subject received commercial implant and had a worsening condition that was not neurological or cardiovascular in nature. **No**
4. Roll In subject had a medication change during a prolonged hospitalization and was started on an anticoagulant due to new elevated labs for a blood clotting disorder. **Yes**
5. Roll-In subject baseline laboratory results report hypomagnesemia and 18 month follow up visit reports a reduction in magnesium levels. **No**

# Adverse Event Reporting

The following adverse events will be reported for this study:	Screening through 18-Month Follow-up	2, 3, 4, 5 Year Visits
All serious adverse events	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
All device and procedure-related adverse events	<input checked="" type="checkbox"/>	
Unanticipated adverse device effects	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Pre-procedure events (e.g., events related to pre-procedure medication changes)	<input checked="" type="checkbox"/>	
All adverse events of special interest, regardless of seriousness or relatedness: <ul style="list-style-type: none"><li>• Bleeding events</li><li>• Embolic events (e.g., stroke, TIA, systemic embolism)</li><li>• Neurologic events</li><li>• Device embolizations</li><li>• Device Related Thrombus</li></ul>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>



# Reporting Timelines

Event	Reporting Window to Sponsor
Adverse Event	As soon as possible, but <b>no later than 10 days working days from the date of awareness</b> and per your IRB/EC requirements
Serious Adverse Event	No later than <b>2 working days from the date of awareness</b> and per your IRB/EC requirements
Protocol deviations in emergencies	No later than <b>5 working days</b> and per IRB/EC requirements
Unanticipated Adverse Device Effect	No later than <b>2 working days from the date of awareness</b>
Unscheduled Visit	No later than <b>5 working days</b>
AE Requested for Adjudication	Upload source within <b>5 days working days of request</b>

# EDC Tips – CCGs

## Case Report Form Completion Guidelines

Study group  
conformalmedical

Study  
21-101

Environment  
Production

EDCAdminConfiguration ManagementEDC TasksIngestorRave CTMSRave RCM

21002-001

Patient Status

Randomized

Date of Procedure

15 JUN 2022

eCRF Completion

Guidelines

Screening

Randomization

Index Procedure (Day 0)  
15 Jun 2022 (projected)

Pre-Discharge  
15 Jun 2022

7 Days  
22 Jun 2022

45 Days  
01 Aug 2022

6 Months  
05 Jan 2023

21002-001

Actions

Primary Form

	Patient	Screening	Randomization
Subject			
Visit Information			
Informed Consent			
Demographics			
Medical History			
Adverse Event			

https://info.conformalmedical.com/conform-trial-portal-1?utm\_medium=email&hsenc=p2ANqtz--288YdKEMaxMjCy0xmroMAHoZ0RI4f2r-05Tmabqk-Ro0xKICm9H0v7Axca5UkG6\_9NqTETKuS91q\_P1Fwxq\_s1e9cY6LPFS8hUTs-bXF6RyxpSSc&\_...

Get The Entire Manual of Procedures

Download the established operational guidelines and best practices for the CONFORM Pivotal Trial with the CLAAS® Device.

20MAY2025

Download Here

### Access the Individual Files of The MOP Binder

MOP 2 - Study Contact List

V8.0 20MAY2025

Download Here

MOP 3 - Site Personnel Training Requirements

V6.0 20MAY2025

Download Here

MOP 4 - Conformal CCGs

V2.0 14Jan2025

Download Here

[CONFORM TRIAL PORTAL](#)

[21002-001](#)

# EDC Tips

If you need additional support with eCRF Completion Guidelines, or if you encounter issues, *please* reach out to **your assigned Site Manager**.

Contact Information	
Organization	Name
	<a href="mailto:conformalsupport@namsa.com">conformalsupport@namsa.com</a>
Conformal Medical, Inc. (Sponsor)	<b>Aly Dechert</b> Manager of Clinical Operations <a href="mailto:adechert@conformalmedical.com">adechert@conformalmedical.com</a> 15 Trafalgar Square, Ste. 101 Nashua, NH 03063  <b>Michelle Pappas</b> Associate Director, Clinical Safety <a href="mailto:mpappas@conformalmedical.com">mpappas@conformalmedical.com</a> 15 Trafalgar Square, Ste. 101 Nashua, NH 03063

# Source Documents & Source Data

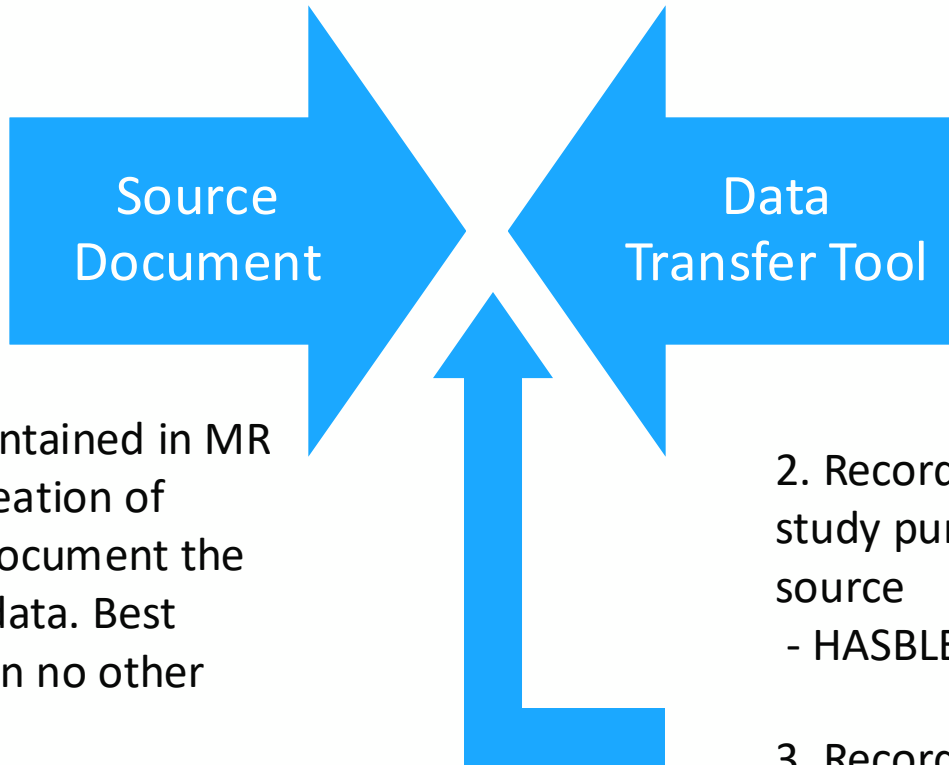
Source Documents are those documents where data regarding study subjects are first recorded and serve as the basis for the information submitted to the Sponsor on the case report forms.

Source documents are ‘*original* documents, data and records’ and include documents such as hospital records, laboratory reports, academic records, memoranda, subject diaries, assessment measures, and device labels or device use records. Source data is the information recorded in a source document, such as clinical findings and observations.

Source Document	Corresponding Source Data
QVSFS	Stroke Assessment number change
TTE Report	Presence of pericardial effusion
Laboratory Report	Platelet Count
Medication list in EMR	Did study medication change ?

# Source Document vs Data Transfer Tool

1. Some procedures, by virtue of their conduct, will result in corresponding source documentation
  - laboratory surveys
  - current medication listings maintained in MR
2. Some procedures will require creation of study- specific source in order to document the conduct of procedure resulting in data. Best Practice: Should only be used when no other option for study documentation:
  - Eligibility Criteria
  - documentation of study-specific procedures/data
  - support compliance



1. Records data that was originally collected for another purpose
  - recording weight from MR
  - recording physical exam notes
2. Records data that was originally collected for study purposes from another study-specific source
  - HASBLED score or Chads2VASC score
3. Records original data
  - Implanter records LAA measurements

try to avoid unnecessary duplication of documentation !!

# Source Document vs Data Transfer Tool



## CONFORM Patient Population Directions & Data Transfer Tool

Site Number: \_\_\_\_\_ Subject ID: \_\_\_\_\_

Did Subject meet eligibility criteria before  
Procedure Day?

- ☐ Yes  
☐ No (Complete the Study Exit form accordingly. Classify subject as "Screen Failure" -- Subject did not meet I/E criteria prior to index procedure.)

Did Subject undergo Procedure TEE?

- ☐ Yes  
☐ No (Complete the Study Exit form accordingly. If the subject did not undergo the procedural TEE, the subject should be exited and classified as a "Screen Failure -- Subject did not meet I/E criteria prior to index procedure" (or "Withdrawn" if the subject withdrew).

CONFORM ECG  
Data Transfer Tool  
Site Number: \_\_\_\_\_ Subject ID: \_\_\_\_\_

Was ECG performed? ☐ Yes ☐ No (Complete a protocol deviation form)

Date of ECG: \_\_\_\_/\_\_\_\_/\_\_\_\_ (DD/MMM/YYYY)

Sinus rhythm ☐ Yes ☐ No

Atrial fibrillation ☐ Yes ☐ No

Atrial flutter ☐ Yes ☐ No

Paroxysmal atrial fibrillation/flutter ☐ Yes ☐ No

Atrial tachycardia ☐ Yes ☐ No

Atrial Arrhythmia ☐ Yes ☐ No

Junctional rhythm ☐ Yes ☐ No

AV node conduction disturbance/heart block ☐ Yes ☐ No

Paced Rhythm ☐ Yes ☐ No

Q-Wave present ☐ Yes ☐ No

Left bundle branch block present ☐ Yes ☐ No

Right bundle branch block present ☐ Yes ☐ No

If yes, what degree? ☐ 1<sup>st</sup> Degree ☐ 2<sup>nd</sup> Degree ☐ 3<sup>rd</sup> Degree



## CONFORM Adverse Event Source

Site Number: \_\_\_\_\_ Subject ID: \_\_\_\_\_

AE #	AE Term	AE Status	Cause	Date Aware	Date Entered	Severity	Serious	Onset Date	Resolved Date
		<input type="checkbox"/> New <input type="checkbox"/> Pre-Existing				<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> No <input type="checkbox"/> Yes * Circle all that apply 1 2 3 4 5 6 7		
	Relationship to implant?	Relationship to access sheath?	Relationship to delivery system?	Relationship to Study Procedure?	Relationship to Study Medication?				
	<input type="checkbox"/> Not related <input type="checkbox"/> Possible <input type="checkbox"/> Probable <input type="checkbox"/> Causal relationship	<input type="checkbox"/> Not related <input type="checkbox"/> Possible <input type="checkbox"/> Probable <input type="checkbox"/> Causal relationship	<input type="checkbox"/> Not related <input type="checkbox"/> Possible <input type="checkbox"/> Probable <input type="checkbox"/> Causal relationship	<input type="checkbox"/> Not related <input type="checkbox"/> Possible <input type="checkbox"/> Probable <input type="checkbox"/> Causal relationship	<input type="checkbox"/> Not related <input type="checkbox"/> Possible <input type="checkbox"/> Probable <input type="checkbox"/> Causal relationship				
Investigator Signature: _____						Date (DD/MMM/YYYY): _____			

AE #	AE Term	AE Status	Cause	Aware	Notified	Severity	Serious	Onset	Resolved Date
		<input type="checkbox"/> New <input type="checkbox"/> Pre-Exist				<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> No <input type="checkbox"/> Yes * Circle all that apply 1 2 3 4 5 6 7		
	Relationship to implant?	Relationship to access sheath?	Relationship to delivery system?	Relationship to Study Procedure	Relationship to Study Medication				
	<input type="checkbox"/> Not related <input type="checkbox"/> Possible <input type="checkbox"/> Probable <input type="checkbox"/> Causal relationship	<input type="checkbox"/> Not related <input type="checkbox"/> Possible <input type="checkbox"/> Probable <input type="checkbox"/> Causal relationship	<input type="checkbox"/> Not related <input type="checkbox"/> Possible <input type="checkbox"/> Probable <input type="checkbox"/> Causal relationship	<input type="checkbox"/> Not related <input type="checkbox"/> Possible <input type="checkbox"/> Probable <input type="checkbox"/> Causal relationship	<input type="checkbox"/> Not related <input type="checkbox"/> Possible <input type="checkbox"/> Probable <input type="checkbox"/> Causal relationship				
Investigator Signature: _____						Date (DD/MMM/YYYY): _____			

\* Serious: 1. Led to chronic disease 2. Led to subject death 3. Resulted in life-threatening illness or injury 4. Resulted in permanent impairment of a body structure or body function 5. Resulted in medical or surgical intervention to prevent life-threatening illness, injury or permanent impairment of body structure or function 6. Required in-subject hospitalization or prolongation of existing hospitalization 7. Led to fetal distress, fetal death or congenital anomaly or birth defect

conformal  
THE SHAPE OF STROKE PREVENTION

CONFORM Procedure Lab Assessments  
Site Number: \_\_\_\_\_ Subject ID: \_\_\_\_\_

Original source should be obtained from a direct laboratory report from Subject Medical Record (here) as relates to subject safety and general INR/EXC Criteria.

Pre-procedure oral anticoagulation should be managed as per site protocol. Warfarin should be discontinued in accordance with site standard of care practices including INR levels on the day of the procedure. We are not collecting day of procedure INR levels.

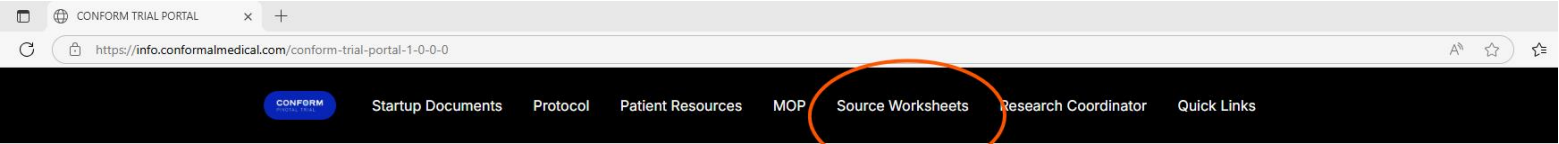
Date of Hematology: \_\_\_\_/\_\_\_\_/\_\_\_\_ (DD/MMM/YYYY)

☐ Not Done (ENTER PD)

Results Value/unit

Clinically Significant  
☐ Yes  
☐ No  
☐ Yes  
☐ No  
☐ Yes  
☐ No

# Source Document vs Data Transfer Tool



## Source Worksheets

CONFORM IDE Trial NCT05147792













### Get The Entire Source Worksheet File

Looking for one file with each PDF.

DOWNLOAD 

DIGITAL DOWNLOAD

### CONFORM Source Worksheet Documents

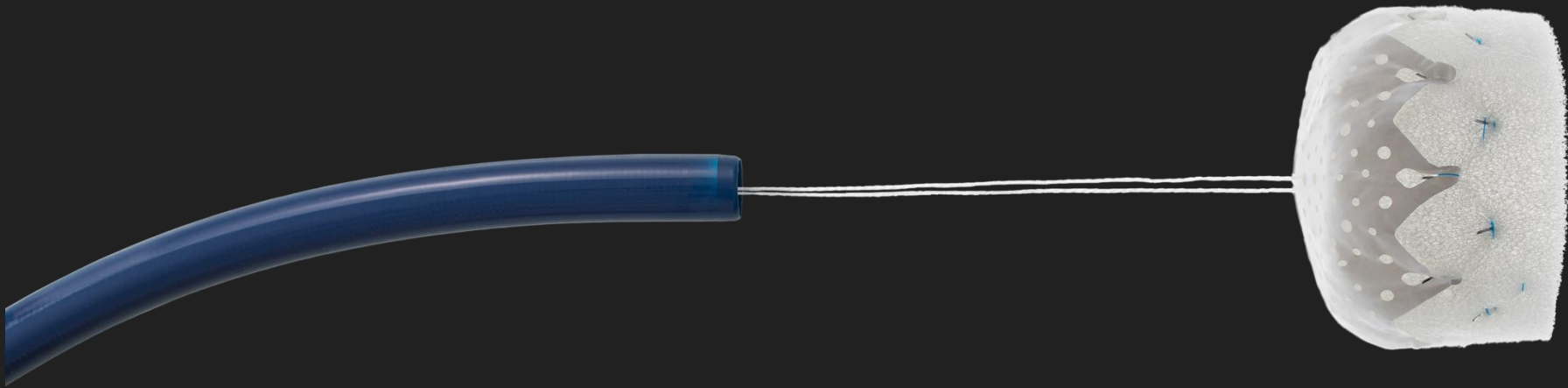
- |  |  |
|--|--|
|  CONFORM L1 - Concomitant Medication<br>Version 3.0, Date: 06DEC2024<br><a href="#">DOWNLOAD HERE</a>                   |  CONFORM L2 - Protocol Deviations<br>Version 3.0, Date: 06DEC2024<br><a href="#">DOWNLOAD HERE</a>                |
|  CONFORM P01 - Procedure Source Worksheet<br>Version 5.0, Date: 06DEC2024<br><a href="#">DOWNLOAD HERE</a>              |  CONFORM P02 - CLASS Implant<br>Version 2.0, Date: 06DEC2024<br><a href="#">DOWNLOAD HERE</a>                     |
|  CONFORM P03 - CLASS Delivery System<br>Version 2.0, Date: 06DEC2024<br><a href="#">DOWNLOAD HERE</a>                   |  CONFORM P04 - CLAAS Device Deficiency Worksheet<br>Version 2.0, Date: 06DEC2024<br><a href="#">DOWNLOAD HERE</a> |
|  CONFORM P05 - Control Implant<br>Version 3.0, Date: 06DEC2024<br><a href="#">DOWNLOAD HERE</a>                       |  CONFORM P06 - Echo Exclusion Criteria<br>V3.0, 06DEC2024<br><a href="#">DOWNLOAD HERE</a>                      |
|  CONFORM P07 - Additional Procedure Source Worksheet<br>Version 1.0, Date: 06DEC2024<br><a href="#">DOWNLOAD HERE</a> |  CONFORM P08 - Patient Population<br>V 1.0 06DEC2024<br><a href="#">DOWNLOAD HERE</a>                           |
|  CONFORM P09 - Procedure Lab Assessments  |  CONFORM Pivotal Trial TEE TTE Sonographer Worksheet  |



# CONFORM Source Worksheet Documents

New formatting / New Forms ★

- Concomitant Medications ★
- CLAAS Implant & CLAAS Delivery System ★
- Echo Exclusion Criteria (*for procedure day only if needed*)
- Additional Procedure Source Worksheet ★
- Patient Population ★
- Procedure Lab Assessments
- Shared Decision - Making Source ★
- Physical Examination – Review of Symptoms
- LAA Measurements
- Adverse Event Source ★
- Death ★
- Study Exit



# Research Coordinator Presentation: *Tips for a Successful CONFORM Program*

*Maddie Peek*, BS, CET, CPT

Lead RC at Memorial Hermann Medical Center  
(West Houston Area Clinical Trial Consultants)

# Disclosures

- No disclosures



# About Me

- *8.5 years as a CRC, 5 years working on LAAC Trials*
- *Coordinate all aspects from start-up and regulatory to enrollment and follow-up for anywhere from 10-12 drug and device studies at a time*
- *Goal of presentation: Help other CRCs be able to streamline enrollment and implant process and help retain patients long term*



# About us (*some ideas*)

- Locations in Katy, TX and Houston, TX
- We work in partnership with Memorial Hermann's Memorial City Hospital. Memorial Hermann is the largest not-for-profit health system in southeast Texas and consists of 17 hospitals, 8 Cancer Centers, 3 Heart & Vascular Institutes, and 27 sports medicine and rehabilitation centers, in addition to other outpatient and rehabilitation centers
- Began LAAO in 2015 with Watchman



- ~400 LAAO annually
- Top 5 highest enrollers in multiple drug and device studies



# Enrollment Strategies

- **The WHO:** Afib patients who are no longer a candidate for long-term OAC (bleeding event, stroke/other embolic event).
- **The WHERE:** Our own patients. Our non-implanting Sub-I or other physician partners referrals. Patients referred directly by their PCP with a new AF diagnosis. Look at ALL patients who have been referred for evaluation for LAAC. We as CRCs don't do chart review for CONFORM. Our LAAC clinic is relatively busy, so there hasn't been a need.
- **EDUCATION:** Have a very in-depth conversation with any potential patients about CONFORM vs commercial implant before they are scheduled to screen (
- **SCHEDULING:** Whenever possible, a CRC is at the same location as PI during clinic hours to streamline scheduling for the patient
- **HANDLING MULTIPLE STUDIES:** Review all options with patients who may qualify for multiple trials to help the patient make an informed decision on the best fit for them







# Overcoming Common Challenges

- **Clinical trial vs commercial device** – Some patients once they learn of other options are excited to be part of moving medicine forward and make excellent trial participants. PI can tell from discussion with patients who is and is not open to an alternative and those truly not open to another device are not referred. **Never push or talk a patient into being part of a trial.**
- **Patient retention strategies – Talk to in person**, give a physical copy of the ICF, and get a screening visit on the schedule versus patients who we call later and schedule over the phone. Flexibility and communication go a long way!
- **Follow up schedule** – Explain that the on-site follow-up visits are very similar to standard of care and all other follow-up can be easily completed by phone. We also make every effort to have a **list of available implant dates** at screening visit, so patients will know approximate follow-up schedule from the first visit.
- **Patient consent** – PI has an in-depth discussion before patients are referred to a trial. CRC and PI review again at screening and ensure patients understand randomization, follow-up schedule and their rights in relationship to the study before they decide to sign ICF.



# Helpful Conformal Tools

- Demo device – PI will show patients. They get a “hands on” visual
- Patient schedule magnets – many patients find these helpful
- Flip books for education

conformal<sup>®</sup>

—

**Thank you for being a participant in the CONFORM pivotal trial!**

We look forward to checking in with you at these important follow-up visits.

QUESTIONS? CONTACT:

7 day
45 day
6 month
12 month
18 month
2 year
3 year
4 year
5 year

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# Key Lessons Learned

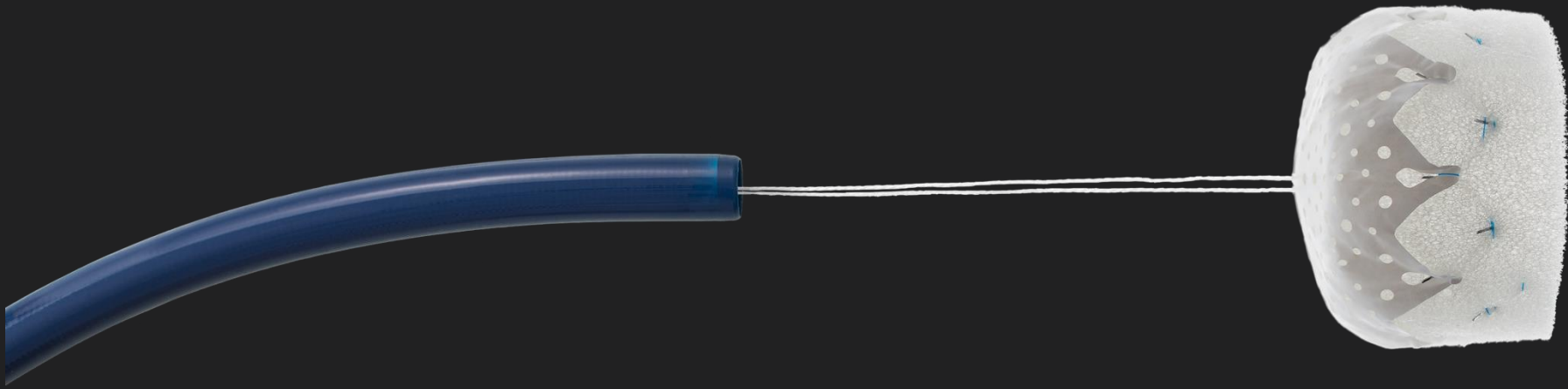
- Try to have **dates available for pre-planning imaging** (if historical will not be available) and index procedure ready to review and confirm with patient day of screening visit. Everything goes MUCH smoother for both patient and site staff when majority of schedule can be set at screening visit.
- When PI is open to this, it's best for CRC to have **multiple cases on one day**.
- Record in real time and **enter data in a timely manner**, for implant specifically – verify all CRC collected data against procedure log for Index Procedure
- **Patient Education!** This is a team effort! Begins with PI, but CRCs play a big roll here as well.



# More Key Lessons

- **Know your people!** Get to know your scheduling nurses, cath lab staff, billing/auth staff, imaging staff, etc. Any unforeseen issues are much easier to solve when everyone is working as a team. Understand how much time each team needs to get things scheduled.
- If you manage **multiple studies**, reference your protocols and use your resources. No one can keep the finer details of multiple protocols straight from memory. Knowing how **to search your protocols and manuals** saves time and stress.
- **Network with other coordinators!** Always helpful to have a sounding board when you run into an issue!





# Training Requirements

*Lizzy Raskulinecz, CRA II*



# Training Requirements At-A-Glance

## Site Personnel Training Requirements

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

Source: MOP03 Site Training Personnel Requirements V6.0 20May2025



## Imaging Personnel Training Requirements

Role	Imager for Screening Imaging (CT <sup>1</sup> , TEE <sup>1</sup> , TTE, MRI)	Imager for Procedural TEE	Imager for Pre-Discharge TTE	Imager for Follow-up TEEs (45 D, 6 M <sup>2</sup> , 12 M, Unscheduled)	Lead Echo-cardiographer
<b>Training Required to:</b>					
CONFORM Protocol Synopsis & Amendments <sup>4</sup>	O	X	O	X	X
CONFORM TEE Imaging Acquisition Protocol <sup>4</sup>	O	X	O	X	X
Protocol & Amendments <sup>4</sup>	O	O	O	O	O
Didactic Device Training	O	O	O	O	O
Hands on Device Training	O	O	O	O	O
<b>Documents Maintained:</b>					
GCP Certification	O	X <sup>3</sup>	X <sup>3</sup>	X <sup>3</sup>	X
CV (signed/dated within past 2 years)	O	X <sup>3</sup>	X <sup>3</sup>	X <sup>3</sup>	X
Active Medical License	O	X <sup>3</sup>	X <sup>3</sup>	X <sup>3</sup>	X
<b>FAQs:</b>					
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
<b>Key:</b>					
X = Required <sup>1</sup> = Required prior to randomization <sup>2</sup> = 6 Month imaging only required if 45 Day TEE has findings of leak or thrombus O = Optional <sup>3</sup> = Only required for Imagers on DOA <sup>4</sup> = Read & Acknowledge training permitted					

# Takeaways Re: Echocardiographer

- At least one echocardiographer must be on the DOA at your site
- If one or more echocardiographers is/are not on the DOA, your site must delegate a “Lead Echocardiographer”
- If all echocardiographers are on the DOA, no “Lead Echocardiographer” required
- Training is same for echocardiographers on the DOA and not on the DOA
  - CONFORM Protocol Synopsis
  - CONFORM TEE Imaging Acquisition Protocol
  - *Applies for Procedural TEE and all follow-up TEEs*

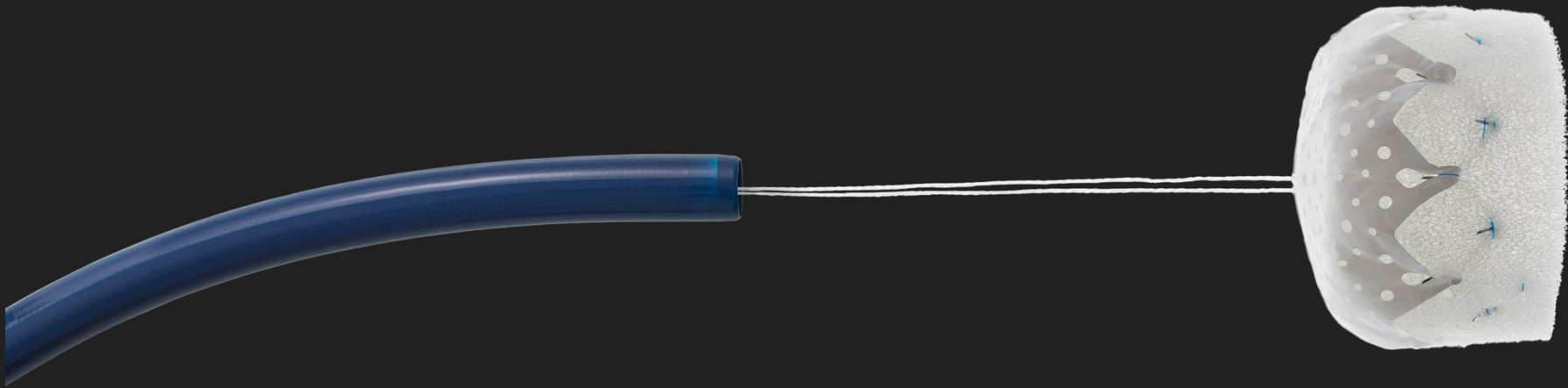
# Your Training Team

FCS trains personnel to:

- Didactic Device Training (required for Implanting Investigator)
- Hands-on Device Training (required for Implanting Investigator)
- TEE Imaging Acquisition Protocol (required for Procedural TEE imager)

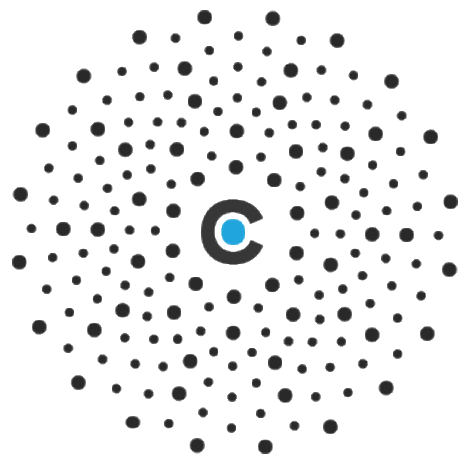
Site Manager trains personnel to:

- CONFORM Protocol
- Medidata (EDC, AE Adjudicate, Intelemage)
- Device Accountability App



# CONFORM Trial Digital Resources

*Alexander Smith*, Marketing Manager



# CONFORM Trial Digital Resources

*Alexander Smith*, Marketing Manager

CONFORM  
PIVOTAL TRIAL

CONFORM Trial About Atrial Fibrillation Patients

A Clinical Trial  
for Patients with  
Non-valvular Atrial  
Fibrillation

NOW ENROLLING

The FDA approved CONFORM Pivotal Trial is evaluating the CLAAS® A compared to other commercially available Left Atrial Appendage Occlusion patients with non-valvular Atrial Fibrillation (AFib).

Learn More About The CONFORM Trial >

CONFORM PIVOTAL TRIAL

CONFORMTrial.com

A new site to help inform and educate prospective patients seeking an alternative to long-term blood thinners for stroke risk reduction in non-valvular atrial fibrillation.

Launched 2025

CONFORM

Startup Documents Protocol Patient Resources MOP Source Worksheets

RESEARCH COORDINATORS

CONFORM Pivotal  
Trial Resource Hub

Welcome to your central location for all your CONFORM Study tools, guides, and quick links.

These resources are intended for clinical site research personnel involved in the CONFORM IDE Trial and is not intended to be distributed.

Scroll down to access and to view available resources.

CONFORM PIVOTAL TRIAL

Research Coordinator  
Portal/Hub

A new site to help inform and educate prospective patients seeking an alternative to long-term blood thinners for stroke risk reduction in non-valvular atrial fibrillation.

Launched 2024

117

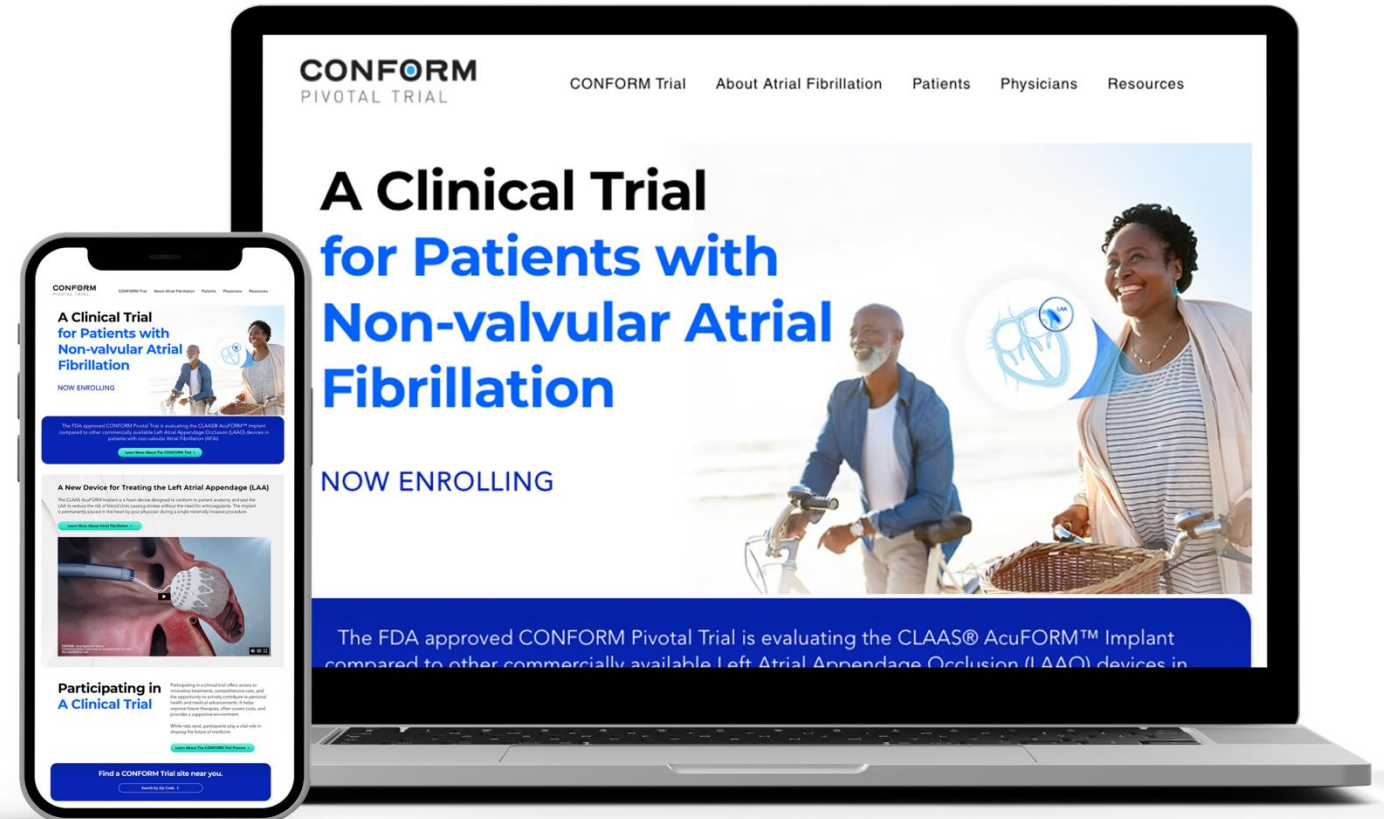
conformal  
THE SHAPE OF STROKE PREVENTION

Launched May 2025

## THE NEW CONFORMTRIAL.COM

A new site to help inform and educate prospective patients seeking an alternative to long-term blood thinners for stroke risk reduction in non-valvular atrial fibrillation.

[CONFORMTrial.com](https://conformtrial.com) offers study information in one digital location.





The image is a collage of various promotional materials for the CONFORM Clinical Trial. It includes several brochures, posters, and social media content. The materials feature the CONFORM logo, trial details, patient eligibility criteria, and a large QR code. Text includes "A Clinical Trial for Patients with Non-valvular Atrial Fibrillation", "Now Enrolling", "Learn More About the CONFORM Trial", "A New Device for Treating the Left Atrial Appendage (LAA)", "Participating in A Clinical Trial", "Find a CONFORM Trial site near you", "What is Atrial Fibrillation?", "Clinical Trial Details", "Additional CONFORM Trial Resources", and "Frequently Asked Questions".



# Benefits For You and Patients

- Easier access to information about the CONFORM Trial
- Trial details and animation
- Participating in a clinical trial overview
- Site finder tool
- FAQ Section and downloadable resources

The screenshot shows the top of the CONFORM PIVOTAL TRIAL website. The header includes the logo and navigation links: CONFORM Trial, About Atrial Fibrillation, Patients, Physicians, and Resources. The main heading is "A Clinical Trial for Patients with Non-valvular Atrial Fibrillation", followed by "NOW ENROLLING". Below this is a blue box with text about the FDA-approved trial and a "Learn More About The CONFORM Trial" button. The next section, "A New Device for Treating the Left Atrial Appendage (LAA)", describes the CLAAS AcuFORM Implant and includes a "Learn More About Atrial Fibrillation" button. A 3D anatomical animation of the heart with the implant is shown below. A "CAUTION" note at the bottom of the animation states: "Investigational device. Limited by United States law to investigational use only. Not available for sale."

## Participating in A Clinical Trial

Participating in a clinical trial offers access to innovative treatments, comprehensive care, and the opportunity to actively contribute to personal health and medical advancements. It helps improve future therapies, often covers costs, and provides a supportive environment.

While risks exist, participants play a vital role in shaping the future of medicine.

[Learn About The CONFORM Trial Process](#)

[Find a CONFORM Trial site near you.](#)

This screenshot shows the "Find A CONFORM Pivotal Trial Site" section. It features a map of the United States with location pins. A search bar is at the top left. A callout box for "M Health Fairview St. John's Hospital" in Maplewood, MN, displays its address, website, principal investigator, and phone number, along with a "Get Directions" button. Below the map, a disclaimer states: "Conformal Medical provides this listing as a service. We have no interest in any specific physicians, nor do we provide any recommendation, assurance, or guarantee with respect to their service. Information on this site should not be used as a substitute for talking with your doctor. Always talk with your doctor about joining a Clinical Study and available treatment options." The footer includes the CONFORM logo, a "CAUTION" note about the investigational device, and links for Terms of Use, Privacy Policy, and the Conformal Medical Website. An "in f" logo is also present.



Launched March 2024

## THE CONFORM RC Portal/Hub

### Exclusive access to the following tools:

- Study Startup package for those new to the trial
- Clinical investigational protocol and associated resources
- Patient facing materials for prospective subjects
- Established operational guidelines and best practices
- Source worksheet PDFs in one file
- Safety information, inventory applications, and more!

# Walkthrough of the RC Portal/Hub

## CONFORM Pivotal Trial Resource Hub

Welcome to your central location for all your CONFORM study tools, grants, and quick links.

[Visit these resources to learn more about CONFORM.](#)

---

### Your Digital Resource Center

Use the sections below to access and download source documents.

**Site Startup Documents**

Here is the CONFORM Clinical Trial site.

[View More](#)

**Protocol Documents**

Clinical investigation protocol and associated materials.

[View More](#)

**Patent Materials**

Supporting research materials.

[View More](#)

**Manual of Procedures**

Extensive operational protocol and procedures.

[View More](#)

**Source Worksheets**

Research and data collection worksheets and CTA's.

[View More](#)

**Conform Conferral**

Get or create worksheets, forms, and other materials.

[View More](#)

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### CONFORM CASE Submit your Planned/Scheduled Cases

Please visit this link to notify the Conform team about a planned or scheduled case for the CONFORM Pivotal Trial. Please attach all applicable case information. Please use the "Report" button to provide any additional relevant information to the team.

*If you have any questions or require assistance, please contact your Conform Site Manager.*

[Submit CONFORM Case](#)

---

### Access to the sites you need in one place

Use the quick links below to jump to resources related to the CONFORM IDE Trial.

**Mediation EDC**

Your platform for clinical research.

[Access Site](#)

**Inventory Application**

Log and track device accountability using the inventory system.

[Log In](#)

**Clinical Data**

Clinical research data database.

[Access Site](#)

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### SAE/AESI

When you receive reports of an event enter it into the EDC and notify the safety team using:

[Report SAE/AESI](#)

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### MRI Safety Information

For MRI safety information, please refer to the MRI Safety Information document located in the MRI Safety Information section of the CONFORM IDE Trial.

[View MRI Safety Information](#)

## Site Startup Documents

Welcome New Sites Participating in the CONFORM IDE Trial

Use the links below to access and download source documents.

---

### Protocols & ICF Documents

<p><b>Protocol Rev. K</b></p> <p><a href="#">Download PDF</a></p>	<p><b>Protocol Synopsis Rev. K</b></p> <p><a href="#">Download PDF</a></p>	<p><b>CONFORM Pivotal Trial Informed Consent Protocol</b></p> <p><a href="#">Download PDF</a></p>
<p><b>CONFORM Angio Protocol</b></p> <p><a href="#">Download PDF</a></p>	<p><b>CONFORM CT Acquisition Protocol Rev. A</b></p> <p><a href="#">Download PDF</a></p>	<p><b>Template Consent Form Rev. B</b></p> <p><a href="#">Download PDF</a></p>
<p><b>CONFORM Template ICF Rev. K</b></p> <p><a href="#">Download PDF</a></p>		

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### Budget & CTA Documents

<p><b>CONFORM Pivotal Payment Terms Template</b></p> <p><a href="#">Download PDF</a></p>	<p><b>CONFORM Pivotal Trial Detailed Budget Rev. A</b></p> <p><a href="#">Download PDF</a></p>	<p><b>CONFORM Investigator Agreement SWS</b></p> <p><a href="#">Download PDF</a></p>
<p><b>Conformal - Pivotal Clinical Trial Agreement Template</b></p> <p><a href="#">Download PDF</a></p>	<p><b>Conformal Medical CONFORM IDE Supplemental Guide</b></p> <p><a href="#">Download PDF</a></p>	<p><b>Conformal Medical CONFORM IDE Supplemental Letter - Sample Prior Authorization Letter</b></p> <p><a href="#">Download PDF</a></p>
<p><b>A-90 Financial Disclosure Form Rev. B</b></p> <p><a href="#">Download PDF</a></p>	<p><b>WFO Conformal Medical</b></p> <p><a href="#">Download PDF</a></p>	<p><b>Subject Injury Language Support</b></p> <p><a href="#">Download PDF</a></p>
<p><b>Subject Injury Language Support</b></p> <p><a href="#">Download PDF</a></p>	<p><b>Subject Injury Language Support</b></p> <p><a href="#">Download PDF</a></p>	<p><b>CONFORM IDE Case Report Form to be Filled on Case</b></p> <p><a href="#">Download PDF</a></p>

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### FDA & CMS Approval Documents

<p><b>CEB Approval CONFORM IDE Trial Letter</b></p> <p><a href="#">Download PDF</a></p>	<p><b>FDA Approval, Supplemental ENDA001</b></p> <p><a href="#">Download PDF</a></p>	<p><b>FDA Approval, Supplemental ENDA002</b></p> <p><a href="#">Download PDF</a></p>
<p><b>FDA Approval Letter to Resume CONFORM IDE Trial</b></p> <p><a href="#">Download PDF</a></p>		

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### Instructions for Use Documents

**CLASS System CPU Rev. L**

[Download PDF](#)

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### Patient Facing Materials

<p><b>CLASS Device for Demonstration</b></p> <p><a href="#">Download PDF</a></p>	<p><b>CONFORM IDE Clinical Trial Patient Rev. C</b></p> <p><a href="#">Download PDF</a></p>	<p><b>Conformal Medical Implant Card Rev. B</b></p> <p><a href="#">Download PDF</a></p>
<p><b>Conformal Medical Patient Brochure Rev. C</b></p> <p><a href="#">Download PDF</a></p>	<p><b>Conformal Medical Patient Magnet Rev. A</b></p> <p><a href="#">Download PDF</a></p>	<p><b>Implant Flipbook CONFORM IDE</b></p> <p><a href="#">Download PDF</a></p>

## Protocol & IFU Documents

Protocol Rev. K

Protocol Synopsis Rev. K

CLASS System CPU Rev. L

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## Manual of Procedures

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## Site Login: [AcuFORM2025!](#)

## Source Worksheets

Get The Entire Source Worksheet File

[Download PDF](#)

---

### CONFORM Source Worksheet Documents

<p><b>CONFORM L1 - Consent Mechanism</b></p> <p><a href="#">Download PDF</a></p>	<p><b>CONFORM L2 - Protocol Deviations</b></p> <p><a href="#">Download PDF</a></p>
<p><b>CONFORM P01 - Procedure Source Worksheet</b></p> <p><a href="#">Download PDF</a></p>	<p><b>CONFORM P02 - CLASS Implant</b></p> <p><a href="#">Download PDF</a></p>
<p><b>CONFORM P03 - CLASS Battery System</b></p> <p><a href="#">Download PDF</a></p>	<p><b>CONFORM P04 - CLASS Device Diffusion Worksheet</b></p> <p><a href="#">Download PDF</a></p>
<p><b>CONFORM P05 - Control Implant</b></p> <p><a href="#">Download PDF</a></p>	<p><b>CONFORM P06 - Echo Evaluation Criteria</b></p> <p><a href="#">Download PDF</a></p>
<p><b>CONFORM P07 - Additional Procedure Source Worksheet</b></p> <p><a href="#">Download PDF</a></p>	<p><b>CONFORM P08 - Patient Population</b></p> <p><a href="#">Download PDF</a></p>
<p><b>CONFORM P09 - Procedure Data Assessments</b></p> <p><a href="#">Download PDF</a></p>	<p><b>CONFORM P10 - Patient Trial TEE T1E Biomechanical Worksheet</b></p> <p><a href="#">Download PDF</a></p>
<p><b>CONFORM S01 - Visit Information</b></p> <p><a href="#">Download PDF</a></p>	<p><b>CONFORM S02 - Screening Data Worksheet</b></p> <p><a href="#">Download PDF</a></p>
<p><b>CONFORM S03 - Shared Decision Making Source</b></p> <p><a href="#">Download PDF</a></p>	<p><b>CONFORM S04 - Inclusion/Exclusion Criteria</b></p> <p><a href="#">Download PDF</a></p>
<p><b>CONFORM S05 - Medical History</b></p> <p><a href="#">Download PDF</a></p>	<p><b>CONFORM S06 - VSA Signs</b></p> <p><a href="#">Download PDF</a></p>
<p><b>CONFORM S07 - Physical Examination - Reason of System</b></p> <p><a href="#">Download PDF</a></p>	<p><b>CONFORM S08 - CHADVASI</b></p> <p><a href="#">Download PDF</a></p>
<p><b>CONFORM S09 - HAD-BLED</b></p> <p><a href="#">Download PDF</a></p>	<p><b>CONFORM S10 - ECO</b></p> <p><a href="#">Download PDF</a></p>
<p><b>CONFORM S11 - Echocardiography-CT Screening</b></p> <p><a href="#">Download PDF</a></p>	<p><b>CONFORM S12 - Echocardiography-CT Procedure</b></p> <p><a href="#">Download PDF</a></p>
<p><b>CONFORM S13 - LAA Measurements</b></p> <p><a href="#">Download PDF</a></p>	<p><b>CONFORM S14 - Echo-CT Pre Discharge</b></p> <p><a href="#">Download PDF</a></p>
<p><b>CONFORM S15 - Echo-CT Follow Up</b></p> <p><a href="#">Download PDF</a></p>	<p><b>CONFORM S16 - Screening Lab Assessments</b></p> <p><a href="#">Download PDF</a></p>
<p><b>CONFORM S17 - WHIS</b></p> <p><a href="#">Download PDF</a></p>	<p><b>CONFORM S18 - DVT/PE</b></p> <p><a href="#">Download PDF</a></p>
<p><b>CONFORM S19 - HES</b></p> <p><a href="#">Download PDF</a></p>	<p><b>CONFORM S20 - Adverse Event Source Worksheet</b></p> <p><a href="#">Download PDF</a></p>
<p><b>CONFORM S21 - Adverse Event Source</b></p> <p><a href="#">Download PDF</a></p>	<p><b>CONFORM S22 - Neurological Event</b></p> <p><a href="#">Download PDF</a></p>
<p><b>CONFORM S23 - Systemic Embolization</b></p> <p><a href="#">Download PDF</a></p>	<p><b>CONFORM S24 - Death</b></p> <p><a href="#">Download PDF</a></p>
<p><b>CONFORM S25 - Chemistry - Cardiac Enzymes</b></p> <p><a href="#">Download PDF</a></p>	<p><b>CONFORM S26 - Study Exit</b></p> <p><a href="#">Download PDF</a></p>
<p><b>CONFORM S27 - Pericardial Effusion Source Worksheet</b></p> <p><a href="#">Download PDF</a></p>	<p><b>CONFORM S28 - Delegation of Authority Log Template</b></p> <p><a href="#">Download PDF</a></p>

## Contact Your CONFORM Trial Site Manager

Our Clinical Operations Team is here for you. We ensure the smooth coordination and execution of clinical trials and provide support and guidance. Whether you have questions, need assistance with protocols, or require any other support related to the CONFORM IDE Trial, our team is here to help. Use the links below to email your site manager.

<p><b>Elaine Berkley</b></p> <p><a href="#">elaine@conformmedical.com</a></p>	<p><b>Bethany Wilson</b></p> <p><a href="#">bethany@conformmedical.com</a></p>	<p><b>Kelly Treng</b></p> <p><a href="#">kelly@conformmedical.com</a></p>
<p><b>Elizabeth Kukulsky</b></p> <p><a href="#">elizabeth@conformmedical.com</a></p>	<p><b>Matthew Kukulsky</b></p> <p><a href="#">matt@conformmedical.com</a></p>	<p><b>Aly Doherty</b></p> <p><a href="#">aly@conformmedical.com</a></p>

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## Download the CONFORM APP

The app provides real-time updates on patient enrollment status, allowing hospitals to quickly identify and address any enrollment obstacles or delays. Additionally, the app generates reports and analytics to give hospital leaders insights into their enrollment performance and identify areas for improvement.

[Get the CONFORM app on iOS or Android](#)

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## Subscribe to CONFORM IDE Trial Communications

If you are a Research Site or Hospital, please subscribe to the CONFORM IDE Trial communications. Please enter your email address and select your role.

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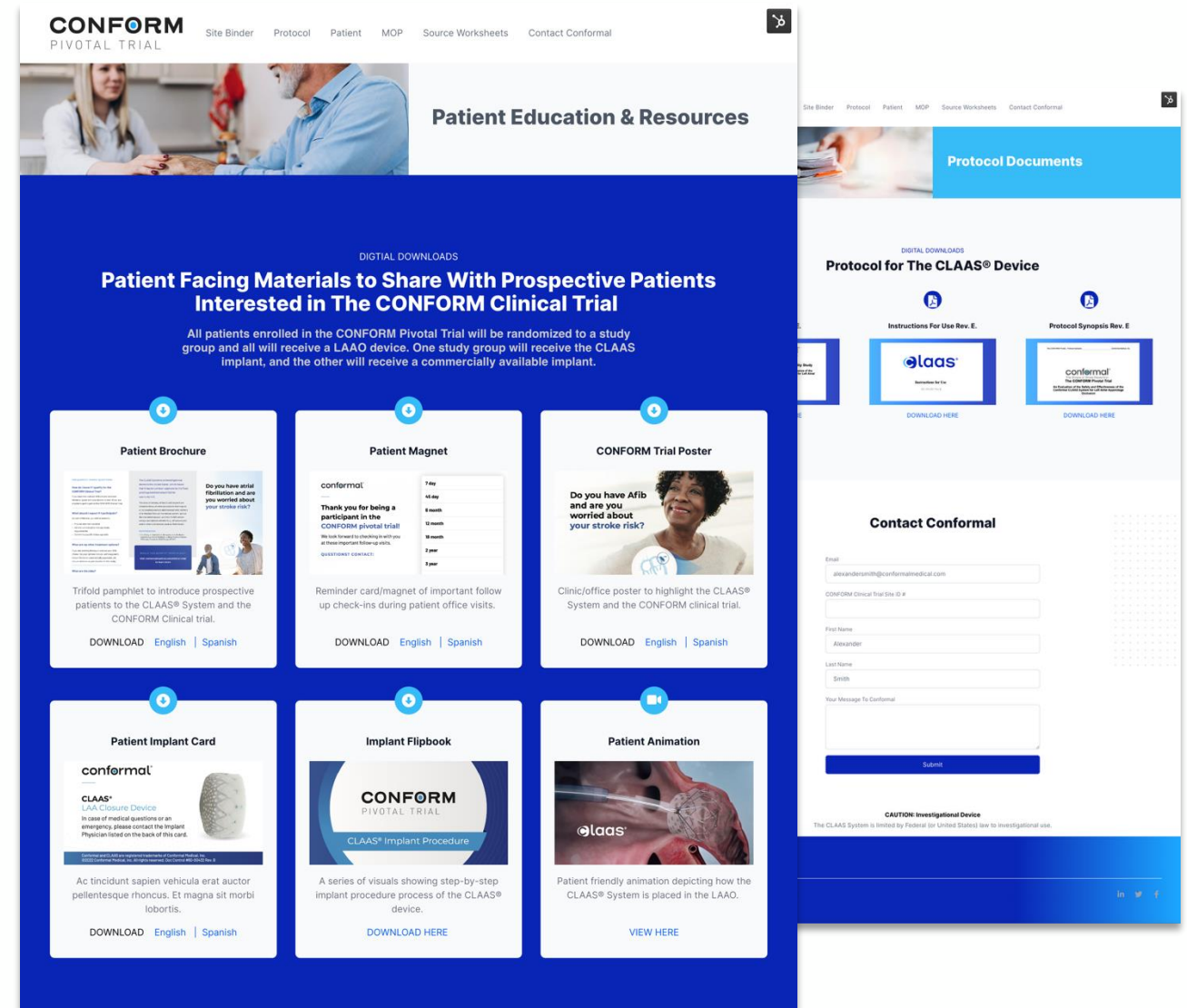
## CONFORM Investigational Device

The CONFORM System is a Class II medical device. It is a Class II medical device. It is a Class II medical device.

[View CONFORM IDE Trial](#)

# The RC Portal is for You


- Easier access to information
- On-Demand downloads of the most up to date CONFORM Trial documentation
- Study Start-up tools
- Latest Protocol and IFU Revisions
- Request patient facing print materials
- Easy access to CONFORM Clin Ops Team





Share with your patients  
and their caregivers the  
**CONFORMTrial.com** site.

We Encourage you to  
explore these digital tools.



**CONFORM PIVOTAL TRIAL**

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NOW ENROLLING

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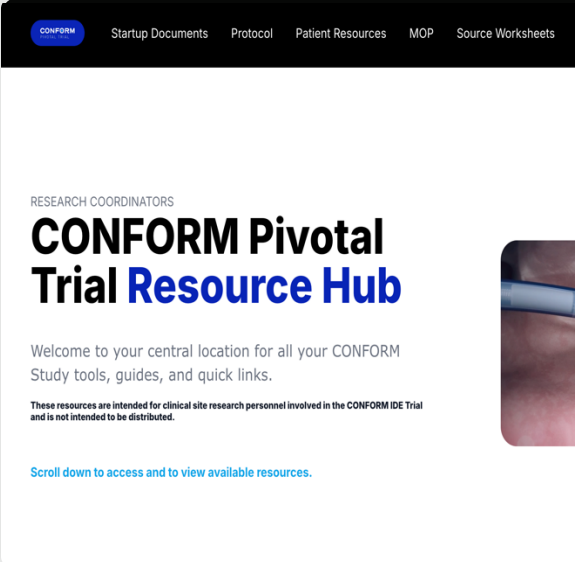
[Learn More About The CONFORM Trial >](#)

[CONFORM PIVOTAL TRIAL](#)

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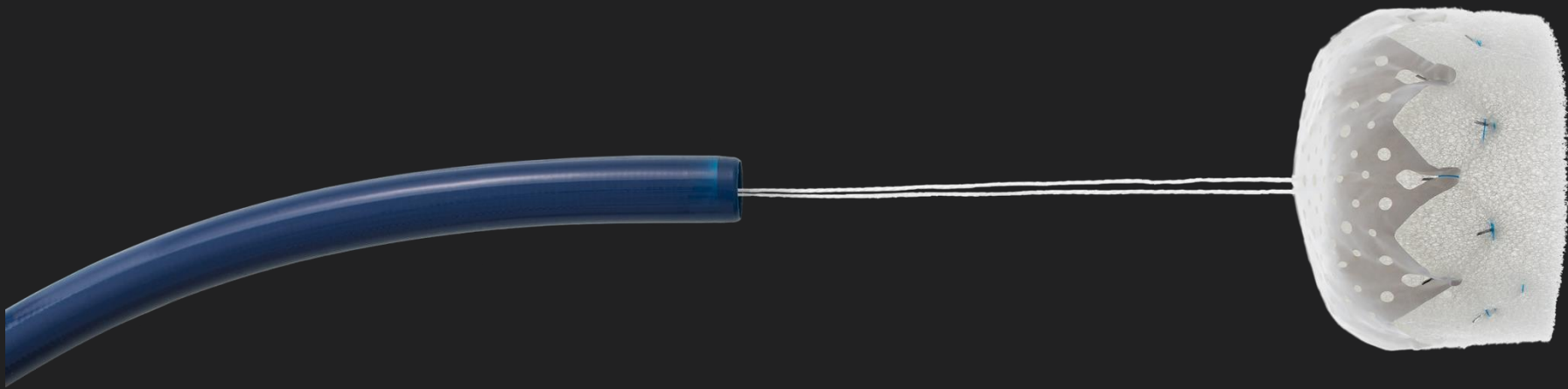
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[Launched 2024](#)



# Enrollment Programs & the CONFORM App

*Jeff Bednar*, Director of Therapy Development

# Single Day Multiple Cases — Recognition Program

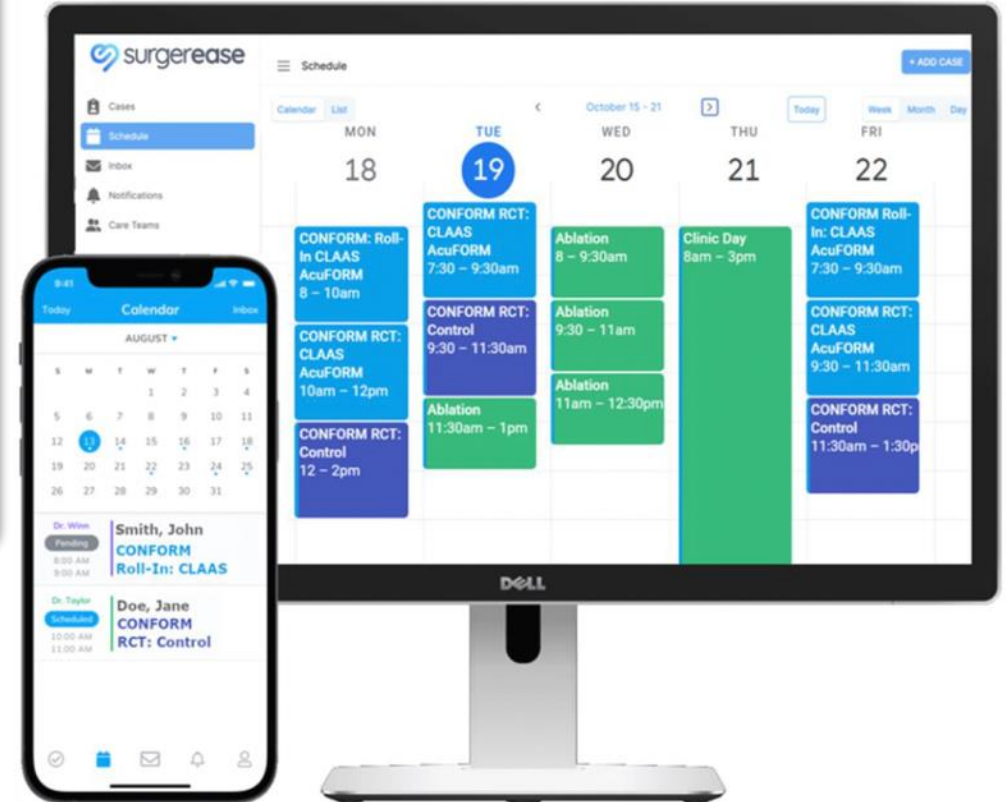
## Criteria

### \$1,000 for Each Additional Enrollment in a Single Day!

To both encourage the efficient deployment of Conformal resources, as well as recognize the extra work required of staff when scheduling multiple cases in a day, sites will receive **\$1,000** for each additional enrollment scheduled on the same day.


### Example:

- 1<sup>st</sup> CLAAS Roll-in or Randomization to CLAAS (\$0)
- **3 ADDITIONAL CONFORM Enrollment**  
*(regardless of randomization stratification)*
- As recognition for the extra effort required the **site receives \$3,000**





# CONFORM Trial App



**Conformal Medical** 12+

National Enrollment Rankings

Conformal Medical

Free



Download on the  
App Store

iPhone Screenshots

Each user will be invited to create a profile

There will be 4 categories

- Elective Physician
- Interventional Cardiologist
- Site Coordinator
- Conformal Employee

Each conform site will have a home screen

Where we will track enrollments by site and by month

List of enrollments by site ranked (last to first)

List of enrollment by site leaderboard (first to last)

Scan this  
QR Code!



# Conformal Medical

CONFORMAL MEDICAL

10+ Downloads | Everyone

**GET IT ON Google Play**

**Install** | Add to wishlist

You don't have any devices

Each user will be invited to create a profile

There will be 4 categories

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CAUTION: Investigational Device

The CLAAS System is limited by Federal (or United States) law to investigational use.

[www.conformalmedical.com](http://www.conformalmedical.com)