

CONFORM Pivotal Manual of Procedures

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Tool Summary

Tool Summary Sheet

Tool: Manual of Procedures (MOP)

Purpose: This document provides a work instructions, references, and contact lists to assist investigators and study coordinators with the execution of the CONFORM Pivotal Trial. The purpose of the MOP is to facilitate consistency in protocol implementation and data collection across participants and clinical sites. Use of the MOP increases the likelihood that the results of the study will be scientifically credible and provides reassurance that patient safety and scientific integrity are closely monitored.

Audience/User: Investigators and Study Coordinators may use this document as a reference tool.

Details: A MOP (also known as Manual of Operations [MOO]) is a handbook that guides a study's conduct and operations. It supplements the study protocol by detailing a study's organization, operational data definitions, recruitment, screening, enrollment, randomization, intervention procedures and follow-up procedures, data collection methods, data flow, case report forms (CRFs), and quality control procedures. Procedures in the MOP should be followed with the same degree of vigor as those documented in the protocol.

The MOP is a dynamic "live" document that tends to be updated more frequently than the protocol. Versioning of each section may differ based on updates to operating procedures of protocol.

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Site Personnel Training Requirements

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	No	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				
O = Optional	² = 6 Month imaging only required if 45 Day TEE has findings of leak or thrombus				
	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.

eCRF Completion Guidelines

CONFORM Pivotal Trial

eCRF Completion Guidelines

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eCRF Completion Guidelines

1 General Instructions

Note: These instructions are specific to the database as applies to patients consented under Protocol Revision K. If you need instructions for patients consented under an earlier Protocol Revision, please ask your site manager for the eCRF Completion Guidelines Version 1.0.

1.1 Database Access and Security

Rave Database Link:

<https://login.imedidata.com/login>

Existing users: You will receive an email from Medidata, informing you of access to the study. Depending on the user's role for the study, additional eLearning may be required prior to gaining access to the study EDC. Pending eLearning will be displayed on the home screen and can be accessed via the "View courses" link.

You must complete required courses.

You cannot access 55 of your assigned studies until you successfully complete the required eLearning courses.

[View courses](#) 

New users:

Request access through your assigned Conformal Site Manager, who will work with you to ensure appropriate training and documentation is in place prior to providing access.

A User Authorization Form will then be sent to you for signature via DocuSign. Once the form is completed and processed by the study team, an email invitation is sent to the end user for account activation. Required training (eLearning) videos in Medidata must be completed to gain access to the study database. The eLearning trainings can be accessed via the "View courses" link in the message displayed on the homepage.

You must complete required courses.


You cannot access 55 of your assigned studies until you successfully complete the required eLearning courses.

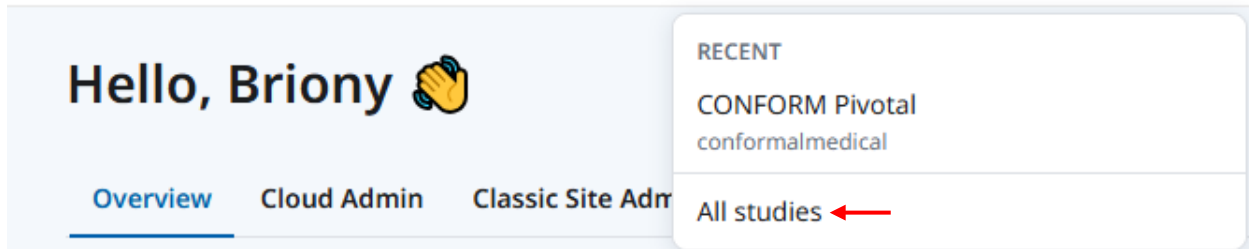
[View courses](#) 

Upon logging into Medidata Rave, the study can be accessed via "Studies" then "All studies."

CONFORM Pivotal Trial

eCRF Completion Guidelines

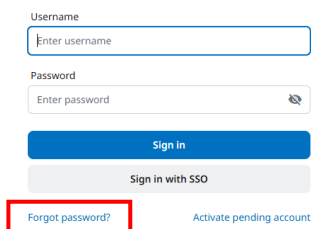
 Clients ▾ Study groups ▾ Studies ▲ Sites ▾



Once accessed, the study will then appear in your Recent Activity menu on the homepage and can also be accessed via “All studies” in that menu.

1.2 Forgotten Password

Welcome, please sign in




1. Open [iMedidata](#)
2. Click the link “I forgot my username or password”
3. Enter your email address and click “send”
4. In a few minutes, **check your email inbox** for an email invite to iMedidata
 - **IMPORTANT: The reset link in this email will only be valid for 4 hours. After 4 hours the link will expire and you will need to repeat the process.**
5. Open the email and click on “reset password”
6. Answer your security question (ie: your birthday date) and click “reset”
7. Type in your new password and confirm.
8. Login to [iMedidata](#) with your username and new password

<https://login.imedidata.com/login>

1.3 System Timeout

The system will time out after 15 minutes of inactivity. Make sure to save your data often.

If data is not saved and the system times out, the data will need to be re-entered. Click the  button at the bottom of the form.

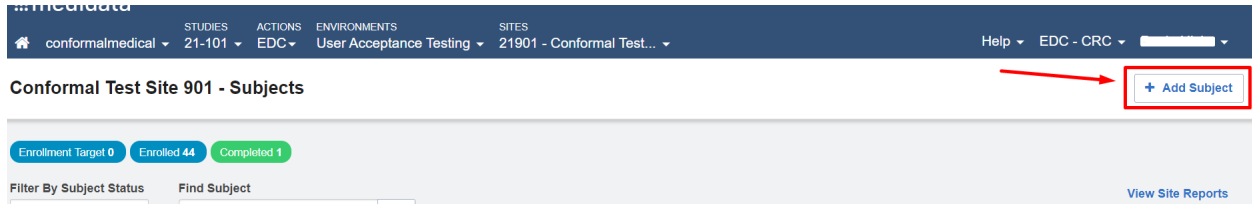
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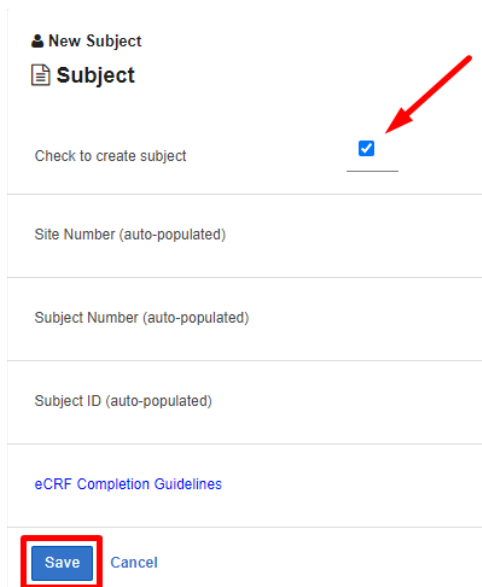
2 Adding and Viewing Subjects

2.1 Add Subject

To add a subject, click the + Add Subject  icon in the upper right corner of the screen, which will take you to the New Subject record.



Check the box next to “Check to create subject.” The subject is added into the system when the record is saved.



The screenshot shows the 'New Subject' form. At the top, there are two tabs: 'New Subject' and 'Subject'. Below the tabs is a checkbox labeled 'Check to create subject' which is checked. A red arrow points to this checkbox. Below the checkbox are several input fields: 'Site Number (auto-populated)', 'Subject Number (auto-populated)', and 'Subject ID (auto-populated)'. At the bottom of the form, there is a link for 'eCRF Completion Guidelines' and two buttons: 'Save' (highlighted with a red box) and 'Cancel'.

After the subject has been added, the subject will be enrolled in one of the following two categories:

ROLL-IN: Up to 3 subjects per site may be implanted with the CLAAS device as part of the roll-in phase of the trial. Sites that implanted 3 subjects with the Initial CLAAS system will be permitted to implant one additional roll-in subject with the Next Generation CLAAS System.

RANDOMIZED: When the subject has met all inclusion criteria and no exclusion criteria (including echocardiographic exclusion criteria), the subject will be randomized to either the CLAAS or Control device.

The category will be entered on the Informed Consent form (see [3.1.1 Informed Consent](#)).

It is important to only add a subject in EDC after the subject has signed the informed consent form, as this action cannot be undone. If a new subject is entered into the database in error, contact your Site Manager immediately.

2.2 Randomization

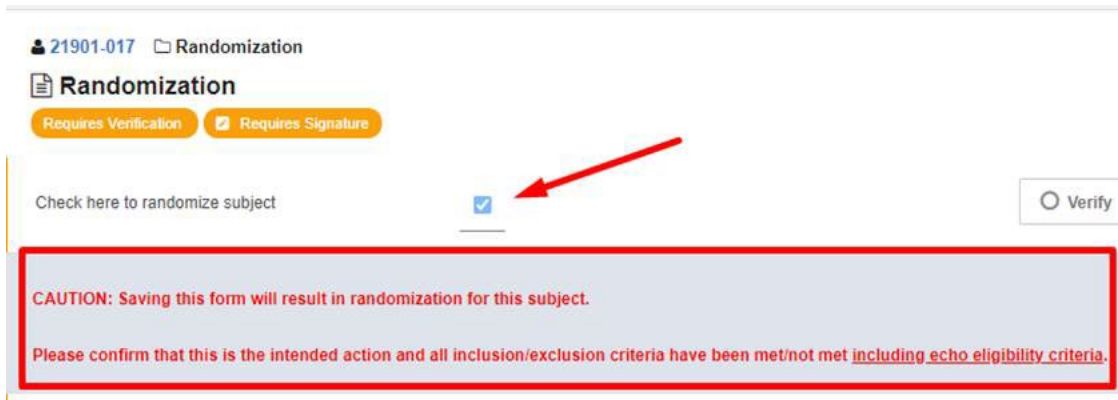
When the subject has met all inclusion criteria and no exclusion criteria (including echocardiographic exclusion criteria), the subject will be randomized to either the CLAAS or Control device.

The LAA occlusion procedure shall take place no later than 14 days from the date of randomization.

Please ensure that more than one Study Personnel listed on your DOA has the ability to randomize subjects within the iMedidata system.

CONFORM Pivotal Trial

eCRF Completion Guidelines



21901-017 Randomization

Randomization

Requires Verification Requires Signature

Check here to randomize subject Verify

CAUTION: Saving this form will result in randomization for this subject.

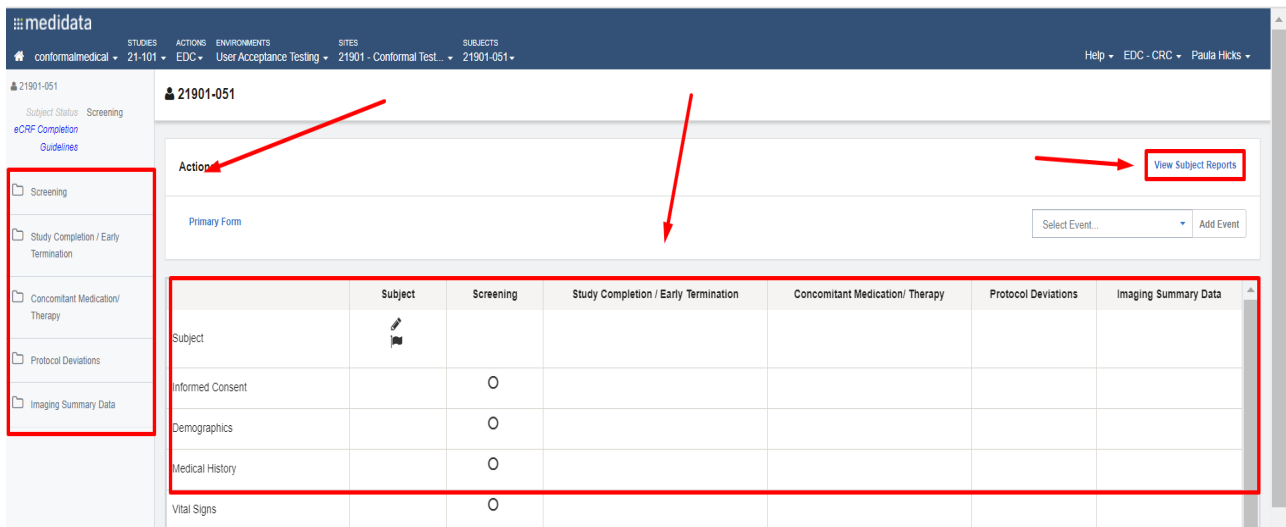
Please confirm that this is the intended action and all inclusion/exclusion criteria have been met/not met including echo eligibility criteria.

A Protocol Deviation is required if:

- Randomization occurs **greater than 90 days** from Original Informed Consent.
- Implant Procedure date is **greater than 14 days** from Randomization date.

2.3 Subject Record Grid

Subject case report forms can be accessed one of two ways – either from the folders on the far-left side of the screen as indicated by the left arrow or from the subject grid as indicated by the middle arrow.



medidata

conformalmedical 21-101 EDC User Acceptance Testing 21901 - Conformal Test... 21901-051 Help EDC - CRC Paula Hicks

21901-051
Subject Status: Screening
eCRF Completion
Guidelines

Screening
Study Completion / Early Termination
Concomitant Medication/ Therapy
Protocol Deviations
Imaging Summary Data

21901-051

Action View Subject Reports

Primary Form Select Event... Add Event

	Subject	Screening	Study Completion / Early Termination	Concomitant Medication/ Therapy	Protocol Deviations	Imaging Summary Data
Subject						
Informed Consent		O				
Demographics		O				
Medical History		O				
Vital Signs		O				

Note: Subject specific reports are also available for use and can be accessed using the link as indicated by the right arrow.

To return to the subject grid while in an individual case report form, click on the **Subject Record ID** link as indicated below, and it will return you to the subject grid. The image below is on the Informed Consent form.

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eCRF Completion Guidelines

21901-001 Screening

Informed Consent

Requires Signature

Subject to be enrolled as **Roll-In**

Did patient sign consent? **Yes**

2.4 Visit Window List

Once the date of procedure has been entered into the Procedure form, the Visit Window list will populate within the Visit Window folder on the left side of the screen. The earliest date and latest date for each study visit are listed on this form, calculated by the system using the protocol-specified visit windows.

21901-302 Vist Window (1)

Visit Window

Please note this page is intended to be informative only. Please consult your Site Manager if you have questions about the subject's follow-up visit schedule.

Date of Procedure (Day 0) **18 DEC 2024**

Day 7 Visit

Earliest Date **25 DEC 2024**

Latest Date **27 DEC 2024**

Day 45 Visit

Earliest Date **25 JAN 2025**

Latest Date **08 FEB 2025**

CONFORM Pivotal Trial

eCRF Completion Guidelines

3 Individual CRF Instructions

3.1 Screening and Randomization

3.1.1 Informed Consent

Please confirm the subject you are randomizing is in the roll-in or randomized category. If subject Randomization occurs **greater than 90 days** from the date of informed consent, a PD must be entered.

ICF Version (xx.xx): Enter the Version of the ICF as recognized by the site and will be recognized for monitoring purposes. Even though the format is listed as (xx.xx), both text and number values can be entered. It is suggested that date of ICF IRB approval be entered here, e.g., 18NOV2024.

If a subject was screen failed previously and is being reconsidered for the study, please enter information regarding prior subject ID on this page.

Protocol Revision Activated to:	J ▼
ICF Version (xx.xx)	18NOV2024
Was this subject screened previously?	<input checked="" type="radio"/> Yes <input type="radio"/> No
Previous Subject ID (xxxxxxx)	21901-58

3.1.2 Medical History

Medical history may be completed up to 30 days prior to consent as part of site standard of care. If it is completed greater than 30 days prior to the date of informed consent, a protocol deviation must be entered.

Medical history must be completed prior to index procedure for roll-in subjects and prior to randomization for randomized subjects.

Auto queries will populate for "Yes" responses as related to Inclusion/Exclusion Criteria (e.g., History of CVA, History of Intracardiac Thrombus, etc.).

CONFORM Pivotal Trial

eCRF Completion Guidelines

History of intracardiac mass, thrombus or vegetation? Yes No Unknown

Data Entry Error

Please confirm patient does not meet echo exclusion criteria of intracardiac thrombus or dense spontaneous echo contrast consistent with thrombus, as visualized by TEE PRIOR to implant.

Rationale for seeking a non-pharmacologic alternative to OAC (Check all that apply)

The screenshot shows the 'Medical History' section of the eCRF. A sidebar on the left lists various data points like Screening, Informed Consent, Demographics, Medical History, Vital Signs, CHADS2/CHA2DS2-VASc Score, HAS-BLED Score, ECG, Echocardiogram/CT, Hematology, Chemistry - Serum Creatinine, Coagulation, and NIHSS. The main content area is titled 'Medical History' and includes a date field for 'Date Medical History Performed'. Below this is a section titled 'Rationale for seeking a non-pharmacologic alternative to OAC (Check all that apply)'. This section contains a list of reasons with checkboxes: 'Drug regimen not compatible with OAC', 'Non-compliance to medication or monitoring schedule', 'History of bleeding or high bleeding risk', 'Renal failure', 'High Fall Risk', and 'Other'. A red box highlights the checkboxes for the first five items.

To meet study inclusion, at least one of the boxes must be checked or “other” should be selected with information entered (i.e., occupational hazard risks, financial issues, etc.).

Every effort should be made to collect definitive yes/no responses from the Subject Medical Record. Your response may prompt queries to assess if any inclusion/exclusion criteria has not/has been met in relation to your response.

History of procedure to convert atrial fibrillation or atrial flutter? If both ablation and cardioversion have been performed for the subject, choose the procedure performed closest to screening data collection.

History of procedure to convert atrial fibrillation or atrial flutter?

Yes

No

Unknown

Prior cerebral vascular accident?

- If subject had a spontaneous brain hemorrhage, please only select “Yes”
- If subject had a brain hemorrhage as a result of a fall or trauma, please select “No” (if no other stroke) and response “Yes” to **Prior traumatic intracranial hemorrhage?**

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eCRF Completion Guidelines

Prior cerebral vascular accident? Yes
 No
 Unknown

Prior traumatic intracranial hemorrhage? Yes
 No
 Unknown

Protocol Deviations are required to be reported for the following:

- Physical Exam and NYHA **greater than 30 days** prior to informed consent
- Lab collection at screening **greater than 60 days** prior to informed consent

3.1.3 Vital Signs

Vital signs are required to be collected and entered in EDC for Screening. Vital signs are not required at any other study visit and do not need to be entered into EDC for other visits.

Screening vital signs may be collected per site standard of care up to 60 days prior to informed consent.

3.1.4 Inclusion/Exclusion Criteria

All patients must have CT or TEE Imaging prior to randomization. Conformal can support same day randomization (using the Procedural TEE) only if you have 3+ cases on any given day.

If “Have all the inclusion criteria and none of the exclusion criteria, as specified by the protocol, been met for this subject?” is answered “No,” each individual Inclusion/Exclusion criteria will become visible.

For Screen Failed subjects, “N/A – Not assessed” may be selected for any criteria not assessed prior to the subject screen failure.

3.1.5 Echocardiogram/CT

Screening imaging (TEE or CT) must be performed prior to randomization. If more than one Imaging was performed, select “Save and Add Another Line” to create a new Echocardiogram/CT Form within the EDC.



All Imaging Log Lines can be visualized by selecting “Echocardiogram/CT”. Please upload all images into the Imaging Module.


CONFORM Pivotal Trial

eCRF Completion Guidelines

A protocol deviation is required for screening imaging performed **greater than 6 months** prior to informed consent.


3.1.6 Patient Population

The responses to the questions in the *Patient Population* Form trigger what forms will become available for this subject's completion in EDC. Please hover over the question mark for guidance on the subject's required follow-up visits and patient exit classification.

Did patient meet eligibility criteria before the Procedure Day? **Yes** 

The responses to these questions trigger what forms will become available for this subject's completion in

If the subject did not meet eligibility criteria before the Procedure Day, the subject should be exited as a "Screen Failure – Subject did not meet I/E criteria prior to index procedure." Please complete the study exit form accordingly.

before the Procedure Day? 

Verify

3.2 Index Procedure and Pre-Discharge

3.2.1 LAA Measurements

The *LAA Measurements* form is located in the Index Procedure folder. If the subject was implanted with the control device, LAA measurements should be collected per the control device's IFU. Only the **LAA Ostium Diameter** and **LAA Maximum length** are required for a control device. A Protocol deviation is *not* required if the LAA Perpendicular Depth was not obtained for a control device.

CONFORM Pivotal Trial

eCRF Completion Guidelines

Angle	LAA Ostium Diameter (xx.xx)	LAA Perpendicular Depth (xx.xx)	LAA Maximum Length (xx.xx)
1 0 degrees	mm	mm	mm
2 45 degrees	mm	mm	mm
3 90 degrees	mm	mm	mm
4 135 degrees	mm	mm	mm

3.2.2 CLAAS Implant/Control Implant

Either the *CLAAS Implant* form or *Control Implant* form will populate in the Index Procedure folder, depending on the device assigned to the subject in EDC. These forms are log line style forms, allowing for more than one device to be entered. All devices that are used or opened for this subject should be entered, including any that are opened but not used.

If needed, additional log lines can be added by clicking “Save and Add Another Line.”

21901-303 Index Procedure (Day 0)

Control Implant

Control Implant, Log Lines

Back To Complete View < Previous Line Line 1 of 1 Next Line > Save and Add Another Line

Control Product

- Amulet
- WATCHMAN FLX
- WATCHMAN FLX PRO

3.2.3 Pre-Discharge

On the *Visit Information* form, the duration between the Pre-discharge TTE and the time of access sheath removal will be automatically calculated by EDC using the time of the pre-discharge TTE entered in this form and the time of access sheath removal in the *Procedure* form.

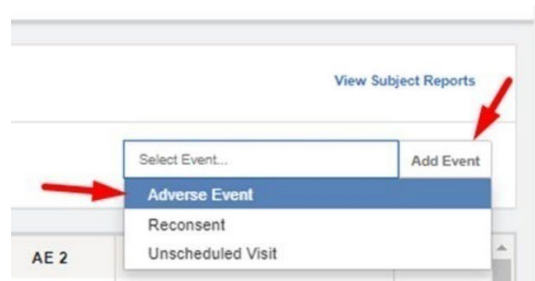
A protocol deviation must be entered if the time between access sheath removal and pre-discharge TTE is **less than four hours**.

3.3 Adverse Events

To enter Adverse Events, select “Adverse Event” in the dropdown on the upper right-hand corner of the EDC page. Click on Add Event. Then, the Adverse Event CRF will populate in the grid.

CONFORM Pivotal Trial

eCRF Completion Guidelines



The adverse events will populate towards the far right of the grid as individual events. They can be accessed by clicking on the radio button associated with the event.

Responses marked “Yes” under “Adverse Events with special interest?” may generate additional forms. For example, if Bleeding Event is marked “Yes,” a Bleeding Event form will populate for completion.

The CONFORM Pivotal Trial does not collect ALL AEs. Site Personnel should refer to the most current version of the CONFORM Pivotal Trial Protocol with attention to Section 12 Safety Reporting: Reportable Events by Investigational Sites and Safety Event Definitions.

AE entry into the Database is considered the Date Sponsor Notified of AE. If RC does not have access to the database or is not yet sure if a discovered/reported event meets protocol specified reporting criteria, the RC should notify their Site Manager via email or phone call and file a printed copy of this notification in the Subject Binder. Alternatively, the site may notify the Sponsor via email at:

Safety@conformalmedical.com

Event Reporting emails should include the following: Subject ID, date of awareness, start date, and suspected AE Term.

3.3.1 Inactivating Adverse Event Forms

If an AE has been entered in error, has been reviewed to be not reportable per protocol, or can be combined with another AE, it may be necessary to inactivate the AE Form. AE form inactivation requests will be documented via query, which will be added by the Site Manager, Safety or Clinical Data Manager to confirm the site agrees with the inactivation. The Research Coordinator (RC) should respond to the query with clear confirmation that the form is to be inactivated.

Status of Adverse Event	New adverse event	<input type="radio"/> Verify
Adverse Event Term	TEST	<input type="radio"/> Verify
<p> This AE does not meet event reporting criteria. Should this event be inactivated? Please confirm. </p> <p> Yes, please inactivate</p> <p><input type="button" value="Re-Query"/> <input type="button" value="Close"/></p>		

CONFORM Pivotal Trial

eCRF Completion Guidelines

If the **site** identifies an AE form that needs to be inactivated, an email should be sent to the site CRA confirming the following information:

Subject Line of email: CONFORM [Site #] AE Inactivation Request

Body of email:

Please inactivate the following Adverse Event(s) from the EDC:

Subject #:

AE # / AE Term

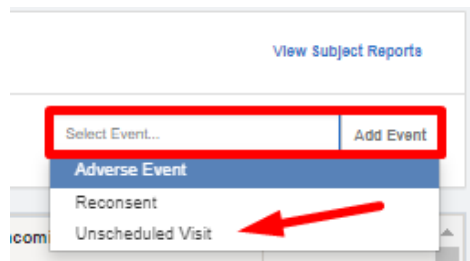
Reason for inactivation (e.g., duplicate of AE X, does not meet reporting requirements per protocol)

Once the email is received, the CRA will open a query to the DM (so no response is required from the site) confirming the form is to be inactivated.

Please contact your assigned Site Manager if you have any questions regarding AE data entry.

3.4 Unscheduled Visit

To enter an unscheduled visit, select “Unscheduled Visit” in the dropdown on the upper right-hand corner of the EDC page. Click on Add Event. The Unscheduled Visit CRF will populate in the grid. For example, per protocol, subjects with a suspected stroke shall be documented as an Unscheduled Visit in the Electronic Database System.



3.5 Reconsent

To enter a reconsent, select “Reconsent” in the dropdown on the upper right-hand corner of the EDC page. Click on Add Event. The Reconsent CRF will populate in the grid.

CONFORM Pivotal Trial

eCRF Completion Guidelines

The screenshot shows the 'Actions' section of the eCRF. On the left, there is a 'Primary Form' dropdown menu. To its right is a text input field labeled 'Select Event...' and an 'Add Event' button. Below the input field, a list of event types is displayed: 'Adverse Event', 'Reconsent', and 'Unscheduled Visit'. The 'Reconsent' option is highlighted with a blue background. A red rectangular box highlights the 'Add Event' button.

3.6 Study Exit

The CONFORM Pivotal Trial has provided a Study Exit Flowchart in MOP-13. Refer to this Flowchart in determining Study Exit timepoints for your subject. Note that responses entered on the [Patient Population](#) form directly impact the Study Exit form.

The following four categories of Subject Classification will be tracked as documented in EDC on the Study Exit Form.

- **Screen Failure**
- **Withdrawn**
- **Subject Death**
- **Completed Study**

3.6.1 Screen Failure

The following three categories of Screen Failure will be tracked on the Study Exit form. Specific reasons for the screen failure must also be documented.

1. Subject did not meet I/E criteria prior to index procedure (Note: if subject was randomized, please do not select this box)
2. Subject did not meet I/E criteria after the Index Procedure TEE was performed and prior to the Access Sheath crossing the body
3. Other Inclusion/Exclusion / Screening Assessment criteria (Note: This should only be chosen if a patient was randomized, but never had the Procedural TEE, and did not meet I/E criteria).

CONFORM Pivotal Trial

eCRF Completion Guidelines

Subject Classification	<input checked="" type="radio"/> Screen Failure <input type="radio"/> Withdrawn <input type="radio"/> Subject Death <input type="radio"/> Completed Study - Subject implanted and completed 5-year follow-up
If subject was a screen Failure, specify reason	<input type="radio"/> Subject did not meet I/E criteria prior to index procedure (Note: If subject was randomized, please do not select this box) ← <input type="radio"/> Subject did not meet I/E criteria after the Index Procedure TEE was performed and prior to the Access Sheath crossed the body <input type="radio"/> Other Inclusion / Exclusion / Screening Assessment criteria
Please briefly describe why the subject exited	<div style="border: 1px solid #ccc; height: 60px; width: 100%;"></div> <p>0 / 200</p>

In Brief Description: enter which I/E criteria has not been met.

For Screen Failures after Procedure TEE performed but prior to Access Sheath (2): it would be expected that the subject has met an Echo Exclusion Criteria, in the Randomization Folder Echocardiographic Exclusion Criteria eCRF: ***Did the subject meet any echo exclusion Criteria per the procedural TEE?*** would be expected to be “Yes.”

Echocardiographic Exclusion Criteria

Requires Verification

Did the patient meet any echo exclusion criteria per the procedural TEE? Yes

Verify

3.6.2 Withdrawn

If a subject has been randomized and Study Exit is not related to Death or Completed Study, *Withdrawn* should be selected for data entry.


At any time point of the study, whether a subject has been randomized or not, if a subject decides to withdraw consent or the Investigator decides to withdraw the subject, *Withdrawn* should also be selected for data entry.

CONFORM Pivotal Trial

eCRF Completion Guidelines

21901-302 Study Completion / Early Termination

Study Exit

Date of Study Exit  Data is required. Please complete.

Subject Classification

- Screen Failure
- Withdrawn
- Subject Death
- Completed Study - Subject implanted and completed 5-year follow-up

If Subject was withdrawn, specify reason

Please briefly describe why the subject exited

...

No Implant (Subject did not receive an implant at the index procedure)

Subject withdrew consent

Subject lost to follow-up

Investigator decision to withdraw subject

Site terminated by Sponsor

Sponsor terminated the study

Subject withdrew due to COVID-19 diagnosis

Subject withdrew due to COVID-19 safety concerns

Other

Move to next task

[View PDF](#) 84 (Clinical Research Coordinator) Rave EDC 2024.2.0 Copyright © 1999-2024 Medidata S

If a randomized subject meets all I/E Criteria at Screening and at Procedure TEE, but does not receive an implant, enter the subject classification as *Withdrawn* and the reason as *No Implant* (as pictured above).

If subject is **lost to follow-up** (subject is unreachable, missed visit has occurred, and site personnel made all reasonable efforts to locate and communicate with subject per protocol requirements), enter the subject classification as *Withdrawn* and the reason as *Subject Lost to Follow-up*.

3.6.3 Subject Death

If Subject Death is chosen the following query will populate: ***Please complete the Adverse Event and Death Form.*** Ensure only one AE has an outcome of Death.

Date of Study Exit and Date of Death should be the same.

Conform Study Appendix A: Definitions: ***Mortality*** should be referenced for determination of Primary cause of death for data entry. Source documentation should be available to monitoring for determination of Cardiovascular/Non-Cardiovascular death. AE Event Term may be updated per Certificate of Death or Autopsy as assessed. Every effort should be made by site research staff to obtain any source related to subject's death and provided to Safety as required.

CONFORM Pivotal Trial

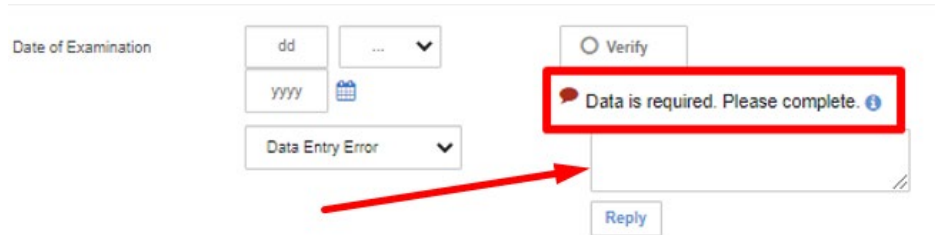
eCRF Completion Guidelines

4 Data Management

4.1 Data Queries

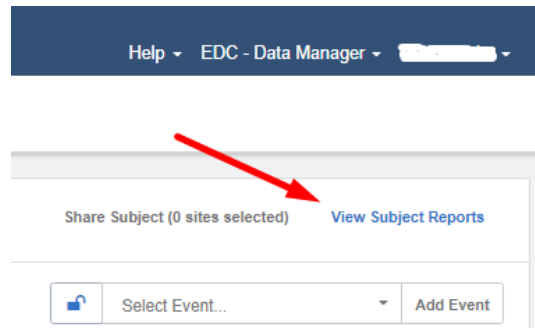
Queries refer to questions or flags raised by the system or study personnel when inconsistencies, missing information, or potential errors are detected within the clinical trial data entered by sites. Queries can be auto generated or created manually by data managers, the safety team, or CRAs.

To reply to a query, enter a response in the field below the query and click “Reply”. If query resolution requires data to be added/updated, please complete/update the field first as you may find the query closes automatically without requiring a response.

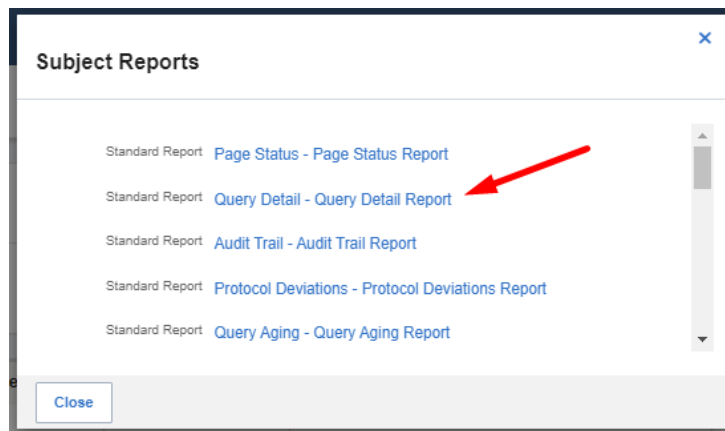


The screenshot shows a form for 'Date of Examination'. It includes input fields for 'dd' and 'yyyy', a 'Verify' button, and a 'Data Entry Error' dropdown menu. A red box highlights an error message: 'Data is required. Please complete.' with an information icon. A red arrow points from the error message to a text input field below it, which has a 'Reply' button underneath.

A list of each subject’s queries can be accessed through View Subject Reports on the subject page.



Select the Query Detail - Query Detail Report which shows all the queries for the subject.

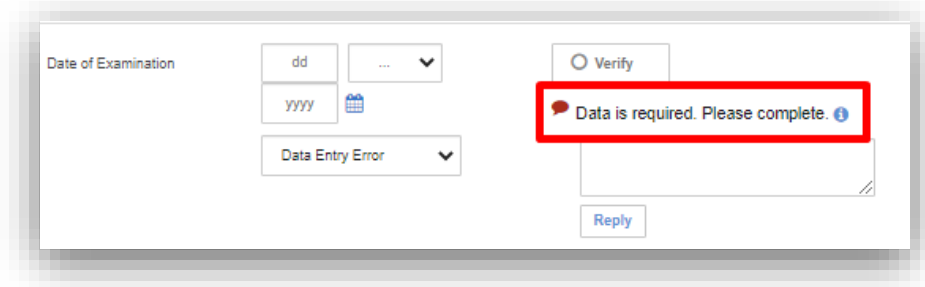


CONFORM Pivotal Trial

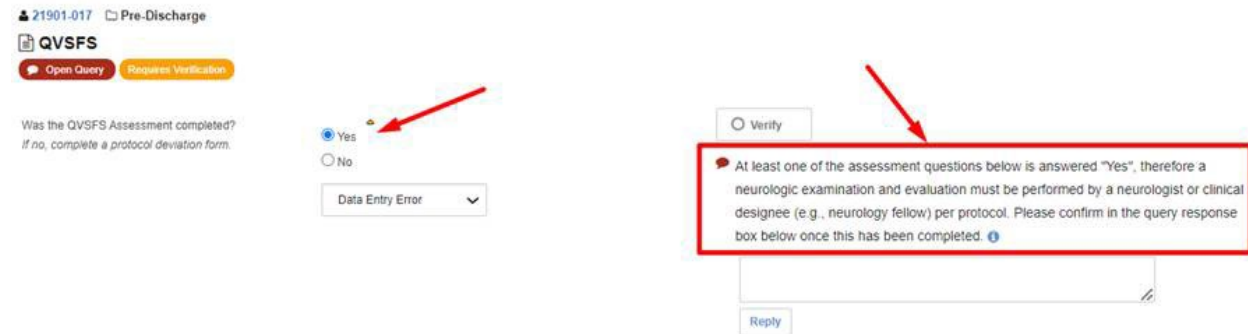
eCRF Completion Guidelines

4.2 Mandatory Fields and Edit Checks

If a required question is not answered, a query will generate stating “Data is required. Please complete.” The query will automatically close when data is entered.



Depending on the response to each field, additional fields may display as needed. Queries may generate based on the data entered such as values or dates or values out of range. Another query example is below:

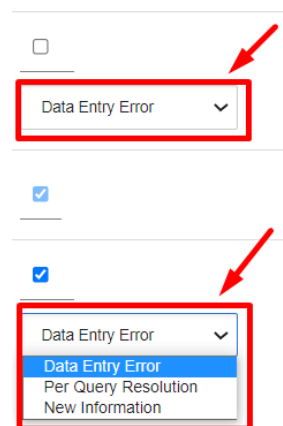


Reminder: Update the data in fields as needed prior to responding to queries. Most queries will automatically close once data is entered and saved. If the query remains open once data is entered, respond to the query.

4.3 Changing Previously Entered Data

If data is changed for an existing record, the system will require a reason for change.

When a saved response is changed, a box will display below the field with a reason for change. The default reason is “Data Entry Error.” There are three options to choose from on the dropdown list (see image to the right). Select the response that applies. Do this for each field that is changed. Click SAVE at the bottom of the screen when done to save the changes.



CONFORM Pivotal Trial

eCRF Completion Guidelines

4.4 Unknown Date Entry

Date fields occur throughout the forms in the EDC. Some fields will allow a partial date to be entered (but the year will always be required). Date fields that allow a partial date will display the “unknown” options when you click on the calendar next to the date field:

The screenshot shows a date selection interface. On the left is a calendar for January 2025. The days of the week are labeled S, M, Tu, W, Th, F, S. The dates 1 through 18 are visible. The date 3 is highlighted with a dashed blue border. On the right is an 'Unknown' selection panel. It has the title 'Unknown' and the instruction 'Select all that are unknown (you can select up to 3)'. There are two checkboxes: 'Day' and 'Month', both of which are currently unchecked.

For fields that require a full date where you are unable to determine the day, please record as 01MonYYYY in EDC. If unable to determine day **and** month, please record as 01JanYYYY. Every effort should be made to at least obtain an approximate year. Do not enter “UNK” for unknown fields. If the year definitely cannot be determined, this should be recorded as 1901.

4.5 Inactivating Log Lines

In the event that data has been entered in error (i.e., data entered into the wrong subject, study does not require data, entry error, etc.) sites have the ability to inactivate Con Meds, Imaging, and PDs on their own. Adverse Event inactivation process is detailed in the Adverse Event section of this document.

Reminder: Medication assessment data collection includes the use of antiplatelet, anticoagulation and endocarditis prophylactic antibiotic medication only.

Log lines can be inactivated by the site. Click the gear icon at the end of the log line and select “Inactivate.”

CONFORM Pivotal Trial

eCRF Completion Guidelines

21901-001 Concomitant Medication/ Therapy

Concomitant Medication

Requires Verification

This form should include prescribed antiplatelet, anticoagulant, antibiotic therapies from subject's relevant medical history through study exit.

Concomitant Medication, Log Lines

All Search field value. '0' or '1' for checkbox fields.

Name	Type of Drug	Other, specify:	Dose	mg
1 APIXABAN	Anticoagulant		50	mg

1 New row(s) 10 per add max Add 1 Row(s) 14 Column(s)

Save Cancel

Verify Freeze Lock Inactivate

A popup will display, select “OK” and the change is complete. It is not necessary to save the form.

Inactivate

Select Reason INACT - Data not required

OK Cancel

5 Imaging Uploads

Imaging is uploaded in a separate app within Medidata. To access the app, click “Medical Imaging Clinical Trials” along the top of the Medidata home page.

Overview Adjudicate **Medical Imaging Clinical Trials** MEDS Reporter Rave EDC

Recent activity

Studies

- CONFORM Pivotal Rave EDC (SIMT)
- CONFORM Pivotal Medical Imaging Clinical Trials


All Studies

CONFORM Pivotal Trial

eCRF Completion Guidelines

Clicking the **conformalmedical** link will take you to the next page shown below. Next, click on “Conformal CONFORM Pivotal.”

Trials

Trial Name	Status	Type	Info
Conformal CONFORM Pivotal	Live	Imaging	

You will be directed to the imaging home page, where you can see all patients who are currently in the trial at your site.

Note: there is a folder in EDC called “Imaging Summary Data.” Information will automatically be pulled from the Medidata imaging app into a form in this folder, called “Image/Document Submission Details.” The information in this form cannot be edited in EDC and must be edited within the separate imaging app.

For detailed instructions on navigating the imaging app and uploading images, see the Imaging Upload section of the Manual of Procedures, section 7.

6 Conclusion

If you need additional support with eCRF Completion Guidelines, or if you encounter issues, please reach out to your assigned Site Manager. Further contact information is available on the next page.

CONFORM Pivotal Trial

eCRF Completion Guidelines

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

Revision History			
Version	Description	Name	Date
1.0	New Document	Paula Hicks	22JUN2022
2.0	Updated all sections to clarify general guidance and form-specific guidance	Briony Macdonald-McMillan	14JAN2025

Study Schema Table

Title:

MOP 05 – Study Schema Table

Protocol Rev R

	Screening	Procedure ⁰	Pre-Discharge	7-Day	45-Day	6 Month	12 Month	18 Month	2, 3, 4, 5 Year	Stroke/SE
		Day 0		+2 Days	±7 Days	±30 Days	±30 Days	±30 Days	±60 Days	Assessment ¹
				Telehealth ²	Clinic Visit/ Telehealth ²	Telehealth ²	Clinic Visit/ Telehealth ²	Clinic Visit	Telehealth ²	
Informed Consent	Clinic Visit									
Medical and Surgical History	X									
Physical Exam/Assessment	X									
Vital Signs	X									
CHA ₂ DS ₂ -VASc	X									
HAS-BLED	X									
Serum Creatinine or GFR/eGFR	X ³									
CBC, Platelet count and Hgb/Hct	X ³	X ⁴								
ECG 12 Lead	X ⁵									
Pregnancy Test	X ⁶									
Neuro Assessment	X ⁷		X ⁷					X		X ²⁰
QVSFS	X ⁸			X	X	X	X	X	X	X
Cardiac CT	X ⁹				X ¹¹		X ¹¹			X ¹⁸
TTE	X ⁹		X ¹⁰							
TEE	X ⁹	X ¹⁹			X ¹²		X ¹²			X ¹⁸
Brain Imaging	X ¹³									X ¹⁴
AE Assessment	X	X	X	X	X	X	X	X	X	
Medication Review ¹⁵	X	X	X	X	X	X	X	X	X	
INR ¹⁶	X	X								
Randomization	X ¹⁷									
LAA Measurements		X								

TABLE FOOTNOTES Protocol Rev R

For more in-depth information regarding the Schedule of Assessments, see **Section 9 Study Procedures and Assessments of Protocol**

⁰ Procedure must occur within 14 days from the date of randomization.

¹ In the event of a suspected stroke or systemic embolism, an Adverse Event of Special Interest CRF should be completed.

² Tele-Health Visit: Clinical evaluation can be performed via phone call, video link or clinic visit.

³ May be performed as part of standard of care up to 60 days prior to consent.

⁴ Performed within 48 hours of index procedure.

⁵ Performed within 30 days prior to the index procedure may be used as the baseline ECG, provided there have been no signs or symptoms of myocardial ischemia between the time of the ECG and the screening assessment (in which case the ECG should be performed within 24 hours prior to the index procedure).

⁶ Required for females of childbearing potential within 7 days of index procedure (by site standard, either serum or urine).

⁷ Neuro Assessment to include National Institute of Health Stroke Scale (NIHSS) and Modified Rankin Scale for Neurologic Disability (MRS) within 30 days of index procedure. The pre-discharge stroke assessment must be done after the effects of anesthesia have resolved.

⁸ QVSFS: Questionnaire for Verifying Stroke-Free Status within 30 days of index procedure.

⁹ **Screening imaging (TEE or CT) must be performed prior to randomization.** Imaging is required to assess the anatomic screening criteria. Cardiac CT or TEE can be used to assess all Echocardiographic Eligibility Criteria. TTE and MRI studies are limited to the assessment of Left ventricular ejection fraction and for detection of pericardial effusions. TTE and MRI cannot be used to assess other Echocardiographic Eligibility Criteria.

¹⁰ Implanted subjects only (does not include patients who did not receive a LAO device). TTE is required to surveil for pericardial effusion. The study must be performed at a minimum of 4 hours from the end of the procedure (removal of the access sheath).

¹¹ Cardiac CT may be used in lieu of TEE to screen for end point findings, e.g., DRT or >3mm peri-device Leak.

- If a Device Related Thrombus is detected, a TEE is required to confirm the finding as soon as possible (recommended assessment within 2 weeks; at latest, 4-6 weeks from date of original study or at the patient's next follow up visit, whichever is first). If a thrombus can be classified as a large thrombus (defined as protruding and >10 mm), a confirmatory TEE is not mandated.
- If a non-trivial peri-device leak is noted on CT, a TEE is required to confirm the finding, as soon as possible (ideally within 2 weeks; at latest, 4-6 weeks from date of original study or at the patient's next follow up visit, whichever is first).

Note: A non-trivial peri-device leak found on CT is one in which the site investigator determination indicates a likely finding of leak >3mm if measured by TEE.

- If a Pericardial Effusion measuring >10mm is detected on Cardiac CT, TTE evaluation is required for quantification.

¹² If TEE demonstrates a pericardial effusion measuring >10 mm, a TTE is required.

¹³ Brain Imaging: For subjects with documented history of TIA/Stroke in the 24-month period prior to enrollment, the most recent brain imaging (CT/MRI) report is required at baseline. If there is no available imaging report or there has been a suspected neuro event, brain imaging may be requested by the Sponsor as a baseline reference.

¹⁴ Brain Imaging is ONLY required for patients with Systemic Embolism (SE) if there are new findings suggestive of TIA/Stroke.

¹⁵ Medication assessment data collection includes the use of antiplatelet, anticoagulation and prophylactic antibiotic medication only.

¹⁶ INR levels required only for patients taking Warfarin, or in accordance with standard of care.

¹⁷ **Randomization after all clinical assessments and eligibility criteria are confirmed** and shall be performed within 90 days of informed consent.

¹⁸ For embolic stroke, imaging of LAA is required. TEE is preferred, however Cardiac CT is acceptable

¹⁹ The procedure TEE can serve as both the screening and procedure TEE if done prior to randomization.

²⁰ NIHSS and mRS should be collected at time of event (or as soon as clinically feasible). For all stroke subjects a 90-day mRS is also required to assess disability status

Randomization

Randomization in EDC

- Patients in the CONFORM Study are randomized in Medidata Rave. If you do not have access to Medidata, please contact your Site Manager.
- Please read this entire form carefully before randomizing a subject. Randomization cannot be undone and must follow specific requirements per protocol.

1. How do I randomize a subject?

To create a subject, select 'Add Subject' in the top right corner. Once a subject has been created in the EDC, go to the "Informed Consent" form in the Screening Visit folder. In the form, assign the patient to the 'Roll-In' or 'Randomize' cohort. If subject is to be randomized, select Randomize.

Note: The following two pages must be completed in EDC in order to open the **Randomization folder: Informed Consent and Inclusion/Exclusion Criteria**. Once these two forms are complete, the Randomization folder will open. In the Randomization folder, there is a form called Randomization. Check the box in this form and save the form to randomize the patient. See screenshot below:

The screenshot displays the EDC interface for subject 21901-002. On the left, a sidebar shows the patient's status (Enrolled), date of procedure (4 NOV 2022), and a list of folders: Screening, Randomization, and Patient Population. The 'Randomization' folder is selected. The main content area shows the 'Randomization' form with a checkbox labeled 'Check here to randomize subject' which is checked. A red star icon is next to the checkbox. Below the checkbox is a red 'CAUTION' warning: 'CAUTION: Saving this form will result in randomization for this subject. Please confirm that this is the intended action and all inclusion/exclusion criteria have been met/not met including echo eligibility criteria.' At the bottom, there are 'Save' and 'Cancel' buttons, both with red star icons.

2. What is required before randomization?

At a minimum, the following must be completed before randomization:

- Informed Consent
- All assessments pertaining to Inclusion/Exclusion Criteria
 - CHA2DS2-VASc
 - Medical history
 - Concomitant medications
 - Pregnancy test
 - Hematology, Chemistry - Serum Creatinine, and Coagulation
 - CT/TEE Imaging evaluating all Echocardiographic Exclusion Criteria

3. What is the expected timeline to randomize a subject?

Randomization should be done no more than 14 days prior to the procedure date. The ideal time to randomize is 10-14 days prior to the scheduled procedure. This allows for the Sponsor Field Clinical Specialist team to provide case support for the CLAAS[®] procedure.

Additionally, Randomization must occur no later than 90 days after informed consent is signed. Randomizations which occur more than 14 days prior to Procedure or more than 90 days after consent will require protocol deviation reports.

4. Can I randomize a subject on the table?

Yes - Conformal can support same day-randomization. At the time of the procedural TEE, on-site Conformal Field Clinical Specialists will collaborate with the site PI to determine if subject has met imaging eligibility criteria. Once deemed eligible, randomization can occur via EDC.

5. What do I do if I need to randomize a subject on the table and I can't access the EDC?

Call the phone number 1-866-633-4328 and select option 5 for US. The Medidata Helpdesk team will verify your credentials and can perform emergency randomization. In order to randomize, Informed Consent and Inclusion/Exclusion forms must already be completed. The Helpdesk will need the Site Number and Subject ID Number for the subject.

You may be asked to fill out an emergency randomization form and return it to Helpdesk via fax or email.

Please note that emergency randomization should be used in emergency situations (e.g., power outage or internet outage) and takes some time to complete.

6. What happens if I randomized a subject by mistake?

If you have accidentally randomized a patient, please contact your Site Manager.

Imaging Upload

Contents

1. CONFORM Pivotal Imaging	1
2. Navigating Imaging Uploads in EDC	2
3. Redaction/Masking Tool – How to De-Identify PHI	9
4. Addressing Imaging Queries	12
5. Addressing Site Tasks	12
6. Imaging Protocol Resources.....	13

1. CONFORM Pivotal Imaging

Imaging will be submitted through the EDC system, Medidata Rave, for the applicable time points and events located in *Table 1.0*.

Table 1.0

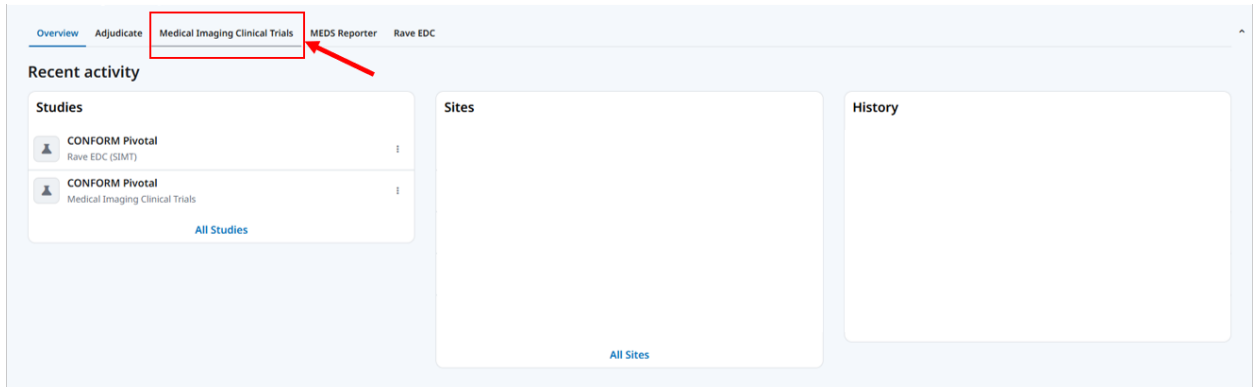
Visit	Image type required per visit
Screening	<p>Within 6 months of the date of consent (one of the following must be performed)</p> <ul style="list-style-type: none"> • TEE • Cardiac CT • TTE* • Cardiac MRI* <p><i>* TEE or CT is required prior to randomization to fully evaluate all echo exclusion criteria. A TEE or CT within 5 years may be used to evaluate anatomic criteria if coupled with MRI or TTE within 6 months prior to consent.</i></p> <p>For patients with a documented history (within 24 months prior to enrollment) of stroke or TIA: Brain Scan with MRI/CT: Historical Imaging post-neurological event per SOC. Otherwise, new imaging is to be taken after consent.</p>
Randomization	<p>Randomization cannot occur until all imaging inclusion/exclusion criteria (as per the imaging modality) have been satisfied by baseline imaging. All patients must have CT or TEE imaging prior to Randomization.</p> <p>Note: The subject will undergo TEE during the Index Procedure, and this timepoint will serve as a review of Echo Exclusion Criteria.</p>
Procedure	<ul style="list-style-type: none"> • TEE <ul style="list-style-type: none"> ○ If 3D imaging is acquired, the 3D raw data should be transferred with the uploaded images

Visit	Image type required per visit
	<ul style="list-style-type: none"> • Angio
Pre-Discharge	TTE <ul style="list-style-type: none"> • At least 4 hours post-procedure
45-Day (± 7 Days)	TEE <ul style="list-style-type: none"> • Cardiac CT may be used in lieu of TEE • If there is a finding of a non-trivial leak (>3mm) or device-related thrombus, a TEE will need to be performed as soon as possible. Refer to Protocol for recommended timing.
12 Month (± 30 Days)	TEE <ul style="list-style-type: none"> • Cardiac CT may be used in lieu of TEE. <ul style="list-style-type: none"> ○ If Pericardial Effusion >10mm is detected on CT, TTE evaluation suggested for quantification. • If there is a finding of a DRT or inadequate seal (leak >3mm) is detected on the CT, a TEE is required to be performed as soon as possible. Refer to Protocol for recommended timing. • If a non-trivial leak is noted, a TEE is required to confirm the finding, as soon as possible. Refer to the Protocol for recommended timing.
Unscheduled/Adverse Event	<p>At any time point, if a Subject has evidence of a significant residual leak (>5mm on TEE) or thrombus, subject should be evaluated for treatment with OAC (Warfarin or DOAC), and ASA for 4-6 weeks followed by repeat imaging.</p> <p>Note: If at any time point a CT has a finding of peri-device leak >3 mm, a TEE must be performed for confirmation and evaluation of the leak.</p> <p>Neurological Event requires a Brain CT/MRI</p> <ul style="list-style-type: none"> • Brain imaging is not required for patients with systemic embolism without new findings suggestive of TIA/stroke

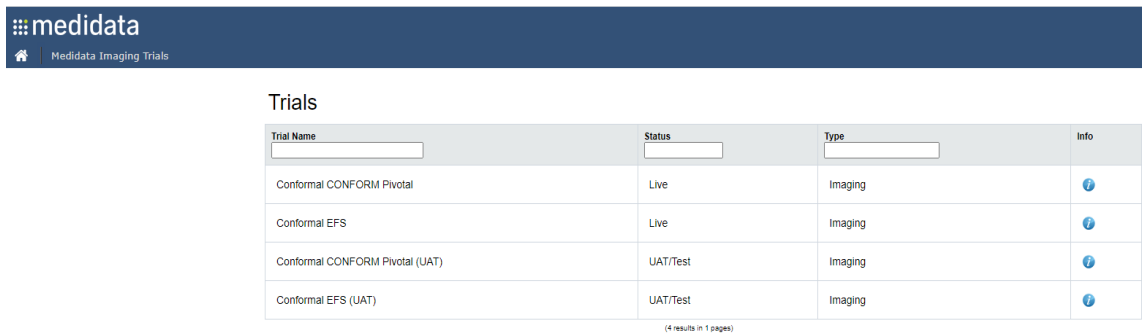
Table 1.0

2. Navigating Imaging Uploads in EDC

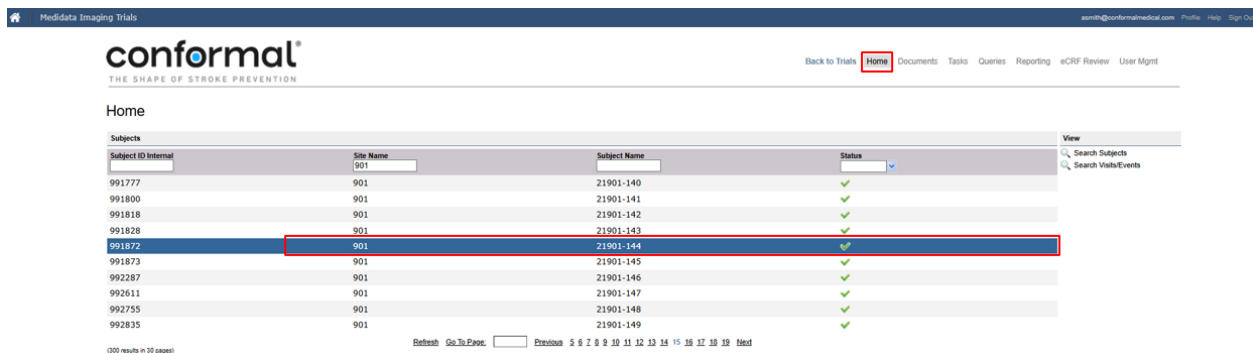
Log in from the Medidata home page. From the home page, go to “Apps” on the left side of the screen. Click the **conformalmedical** link under “Medical Imaging” to bring you to the imaging home page.



Clicking the **conformalmedical** link will take you to the next page shown below. Next, click on “Conformal CONFORM Pivotal”



You will be directed to the imaging home page, where you can see all patients who are currently in the trial at your site. Please note that once you have completed the informed consent and inclusion and exclusion criteria eCRFs and saved complete, these patients will populate in the imaging module:



Once you click on a patient (in this case subject 21901-144 has been selected), you will be brought to the patient’s repository page (pictured below). In the middle of the page, on the right-hand side of the screen, you can select the Visits/Events, which will open the specific Visit/Event details, Visit/Event

Requirements, and additional sections associated with the patient for that time point including a preview under the Exam Section.

Under the “Actions” section:

- You will also be able to add another visit for the patient (i.e., the patient has a device-related thrombus detected during their 45-day imaging, and the patient is required to come in for a 6-month TEE or add an adverse event visit for adverse events with associated imaging).

The screenshot shows the 'conformal' web application interface for subject 21901-144. The 'Add Visit' dropdown menu is open, showing options: 'New Query', 'Add 6 Months Visit/Event', and 'Add Adverse Event Visit/Event'. Below this is a 'Visits/Events' table with columns for 'Visit/Event Name', 'Complete', and 'Img Reqs'.

Visit/Event Name	Complete	Img Reqs
Baseline	X	0
Index Procedure	X	0
Pre-Discharge	X	0
45 Days	X	0
12 Months	X	0

By clicking on any of the visits in the Visits/Events section in the bottom right, you will be able to navigate to that specific visit and view the imaging requirements.

The screenshot shows the same 'conformal' web application interface. A red box highlights the '45 Days' row in the 'Visits/Events' table. A text label points to this row: 'Navigate to specific visit and/or view imaging requirements'.

Visit/Event Name	Complete	Img Reqs
Baseline	X	0
Index Procedure	X	0
Pre-Discharge	X	0
45 Days	X	0
12 Months	X	0

If the required imaging exam is not uploaded/has not met the submission requirement, then the box will be highlighted red (as seen for the TTE, and Sonographer Worksheets). Use the Override buttons to overrule the request for a requirement not fulfilled (i.e., CT is uploaded for the baseline visit). By clicking the override button on the TTE and Sonographer’s worksheet, you’re able to confirm the document and exam were not done. This will allow you to complete submission for the visit.

Subject: 21901-144

Baseline Visit/Event Details

Visit/Event Name	Baseline	Visit/Event Date	Unknown
Status	Active		

Baseline Visit/Event Requirements

Type	Info	Requirement	Commands
Exam	TTE	1 Exam	Upload Exams Comment
Exam	TTE	1 Exam	Upload Exams Comment Override
Document	TTE/TTE Sonographer Worksheet	1 Document	Upload Document Upload via Mobile Device Edit & Finalize Comment Override
Exam	CT	1 Exam	Upload Exams Comment

Submission Problems (4):

1. TTE: Requires an upload of override.
2. TTE/TTE Sonographer Worksheet: Requires an upload of override.

Messages:

1. TTE: No upload supplied.
2. CT: No upload supplied.

Start CT Review
 Start TTE Review

✗ The Baseline visit/event has not satisfied all required items. Please provide all required data in order to finalize the visit/event submission and provide your e-signature.

By clicking on the Upload Exams button, you will be taken to this page below, where you can upload the DICOM formatted imaging directly from your computer.

Subject: 21901-144

Baseline Visit/Event Details

Visit/Event Name	Baseline	Visit/Event Date	Unknown
Status	Active		

Exam Upload

Baseline Exam Upload

Refresh Upload Control

Click the button below to locate your images...

Select DICOM Folder

View

- View Subject
- Audit Log
- Audit Log Workflows

Actions

- Restore Deleted Items
- New Query
- Add 6 Months Visit/Event
- Add Adverse Event Visit/Event

Visit/Event Name	Complete	Img Reqs
Baseline	✗	0
Index Procedure	✗	0
Pre-Discharge	✗	0
45 Days	✗	0
12 Months	✗	0

Once you have uploaded the required images, you will need to re-sign to confirm the upload. On this page, you will now see what was uploaded and when the images and/or sonographer worksheets were uploaded.

Note: if issues uploading DICOM images are encountered, you may need to contact your institution's IT support.

Select the red box to provide your electronic signature

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THE SHAPE OF STROKE PREVENTION

Subject: 21901-144

Baseline Visit/Event Details

Visit/Event Name	Baseline Status	Visit/Event Date	Unknown
	Active		

Baseline Visit/Event Requirements

Type	Info	Requirement	Commands
Exam	TEE	1 Exam	Upload Exams Comment
Exam	TTE	1 Exam	Upload Exams Comment
Document	TTE/TEE Sonographer Worksheet	1 Document	Upload Document Upload via Mobile Device Edit & Finalize Mobile Uploads Comment Queue
Exam	CT	1 Exam	Upload Exams Comment

Submission Problems (1):
Reasons:
1. CT: No upload supplied.

Start CT Review
Start TTE Review

Your submission is not final until you click here & provide an electronic signature

Sign to confirm the upload

Select the blue box to confirm “Yes, submit now”

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THE SHAPE OF STROKE PREVENTION

Subject: 21901-144

Baseline Visit/Event Details

Visit/Event Name	Baseline Status	Visit/Event Date	Unknown
	Active		

Baseline Visit/Event Requirements

Type	Info	Requirement	Commands
Exam	TEE	1 Exam	Upload Exams Comment
Exam	TTE	1 Exam	Upload Exams Comment
Document	TTE/TEE Sonographer Worksheet	1 Document	Upload Document Upload via Mobile Device Edit & Finalize Mobile Uploads Comment Queue
Exam	CT	1 Exam	Upload Exams Comment

Submission Problems (1):
Reasons:
1. CT: No upload supplied.

Start CT Review
Start TTE Review

You are submitting a Baseline visit/event without including all optional requirements. Would you like to continue anyways?

Yes, submit now No, abort

Signature

Click Here to Sign

Select the blue box “Click Here to Sign”

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THE SHAPE OF STROKE PREVENTION

Subject: 21901-144

Baseline Visit/Event Details

Visit/Event Name	Baseline Status	Visit/Event Date	Unknown
	Active		

Baseline Visit/Event Requirements

Type	Info	Requirement	Commands
Exam	TEE	1 Exam	Upload Exams Comment
Exam	TTE	1 Exam	Upload Exams Comment
Document	TTE/TEE Sonographer Worksheet	1 Document	Upload Document Upload via Mobile Device Edit & Finalize Mobile Uploads Comment Queue
Exam	CT	1 Exam	Upload Exams Comment

Submission Problems (1):
Reasons:
1. CT: No upload supplied.

Start CT Review
Start TTE Review

You are submitting a Baseline visit/event without including all optional requirements. Would you like to continue anyways?

Yes, submit now No, abort

Signature

Ok Cancel

Select the green check box “Ok”

Subject: 21901-144

Baseline Visit/Event Details

Visit/Event Name	Baseline	Visit/Event Date	Unknown
Baseline	Active		Unknown

Baseline Visit/Event Requirements

Type	Info	Requirement	Commands
Exam	TEE	1 Exam	Upload Exams Comment
Exam	TTE	1 Exam	Upload Exams Comment
Document	TTE/TEE Sonographer Worksheet	1 Document	Upload Document Upload via Mobile Device Edit & Finalize Mobile Uploads Comment Override
Exam	CT	1 Exam	Upload Exams Comment

Submission Problems (0):

- 1. CT: No upload supplied.

Start CT Review

Start TTE Review

You are submitting a baseline visit/event without including all optional requirements. Would you like to continue anyways?

Yes, submit now No, abort

Signature dialog box:

Click Here to Sign

By electronically signing here you accept that your electronic signature is the legally binding equivalent of your handwritten signature and that it is prohibited to alter your signature and associated or any other components of your signature (21 CFR Part 11.101) and are submitting the visit.

User Information: First Name: Alysa, Middle Name: , Last Name: Smith

Visit/Event Details Table:

Visit/Event Name	Complete	Img Reqs
Baseline	✓	0
Index Procedure	✗	0
Pre-Discharge	✗	0
45 Days	✗	0
12 Months	✗	0

Once the uploaded exams and documents (if required) have passed QC, a green checkmark will appear showing the visit upload requirements are complete.

Subject: 21901-144

45 Days Visit/Event Details

Visit/Event Name	Baseline	Visit/Event Date	Unknown
45 Days	Active	09-Dec-2024	Passed QC

Baseline Visit/Event Requirements

Type	Info	Requirement	Commands
Exam	TEE	1 Exam	Upload Exams Comment
Exam	TTE	1 Exam	Upload Exams Comment
Document	TTE/TEE Sonographer Worksheet	1 Document	Upload Document Upload via Mobile Device Edit & Finalize Mobile Uploads Comment Override
Exam	CT	1 Exam	Upload Exams Comment

Submission Problems (0):

- 1. TEE: Requires an upload or override.
- 2. TTE/TEE Sonographer Worksheet: Requires an upload or override.

Start CT Review

Start TTE Review

Queries: No queries have been associated with this visit/event.

Comments

Visit/Event Details Table:

Visit/Event Name	Complete	Img Reqs
Baseline	✓	1
Index Procedure	✗	0
Pre-Discharge	✗	0
45 Days	✗	0
12 Months	✗	0

At 45 Days and 12 Months, either a TEE and Sonographer Worksheet or a Cardiac CT may be uploaded. A completed and signed Sonographer Worksheet must accompany any uploaded TEE

Subject: 21901-144

45 Days Visit/Event Details

Visit/Event Name	Baseline	Visit/Event Date	Unknown
45 Days	Active		Unknown

45 Days Visit/Event Requirements

Type	Info	Requirement	Commands
Exam	TEE	1 Exam	Upload Exams Comment Override
Document	TTE/TEE Sonographer Worksheet	1 Document	Upload Document Upload via Mobile Device Edit & Finalize Mobile Uploads Comment Override
Exam	CT	1 Exam	Upload Exams Comment Override

Submission Problems (0):

- 1. TEE: Requires an upload or override.
- 2. TTE/TEE Sonographer Worksheet: Requires an upload or override.

✗ The 45 Days visit/event has not satisfied all required items. Please provide all required data in order to finalize the visit/event submission and provide your e-signature.

Queries

Comments

Visit/Event Details Table:

Visit/Event Name	Complete	Img Reqs
Baseline	✓	1
Index Procedure	✗	0
Pre-Discharge	✗	0
45 Days	✗	0
12 Months	✗	0

Option to upload TEE and Sonographer worksheet or Cardiac CT

A comment must be provided if imaging type was performed but not available, in order to successfully override.

Subject: 21901-144

45 Days Visit/Event Details

Visit/Event Name: 45 Days
Status: Active

45 Days Visit/Event Requirements

Type	Info	Requirement	Commands
Exam	TEE	1 Exam	Upload Exams Comment Override
Document	TTE/TEE Sonographer Worksheet	1 Document	Upload Document Upload via Mobile Device Edit & Finalize Mobile Uploads Comment Override
Exam	CT	1 Exam	Upload Exams Comment Override

Submission Problems (2):

1. TEE: Requires an upload or override.
2. TTE/TEE Sonographer Worksheet: Requires an upload or override.

Reason: TEE not available
TEE media corrupted. Imaging not available.

Buttons: Ok, Cancel

Visits/Events

Visit/Event Name	Complete	Img Reqs
Baseline	✓	1
Index Procedure	✗	0
Pre-Discharge	✗	0
45 Days	✗	0
12 Months	✗	0

Once imaging is uploaded or override is complete, this will move through to QC. The red x will remain until exams pass the QC process.

Subject: 21901-144

45 Days Visit/Event Details

Visit/Event Name: 45 Days
Status: Active

45 Days Visit/Event Requirements

Type	Info	Requirement	Commands
Exam	TEE	1 Exam	Upload Exams Comment
Document	TTE/TEE Sonographer Worksheet	1 Document	Upload Document Upload via Mobile Device Edit & Finalize Mobile Uploads Comment
Exam	CT	2 Exams	Upload Exams Comment

Visit/Event will be reviewed - thank you!

Visits/Events

Visit/Event Name	Complete	Img Reqs
Baseline	✓	1
Index Procedure	✗	0
Pre-Discharge	✗	0
45 Days	✓	1
12 Months	✗	0

When scrolling further down this page below the comment section, you will see a section labelled "Exam". This section is where you may preview the imaging, by clicking on the small picture.

Queries

No queries have been associated with this visit

Comments

Requirement	Date	Override	Comment	User	Actions
TEE	04-Apr-2022 2:42 PM		VERRIDE-TEST	koasan@conformalmedical.com	Remove
TEE	04-Apr-2022 2:43 PM		VERRIDE-TEST	koasan@conformalmedical.com	Remove

Exam

Preview	Requirement	Modality	Study Date	Images / Series	Upload Date	Upload By	Actions
	TEE	US	01-Jan-2021 11:30 AM	Final: 93 / 1 Original: 93 / 1	04-Apr-2022 2:57 PM	koasan@conformalmedical.com	Preview Remove Study Send Study Download Study Open In PACS Change Req Edit DICOM Headers

Files

No files have been associated with this visit

Documents

File Name	Requirement	Upload Date	Actions
Sonographers Worksheet - 08.pdf	TTE/TEE Sonographer Worksheet	04-Apr-2022 4:28 PM	Open Document Download Remove Change Req

No Documents have been associated with this visit

Visits/Events

Visit/Event Name	Complete	Img Reqs
Baseline	✗	0
Index Procedure - Pre-Release	✗	0
Index Procedure - Post-Release	✓	1
45 Days	✓	1
12 Months	✓	1

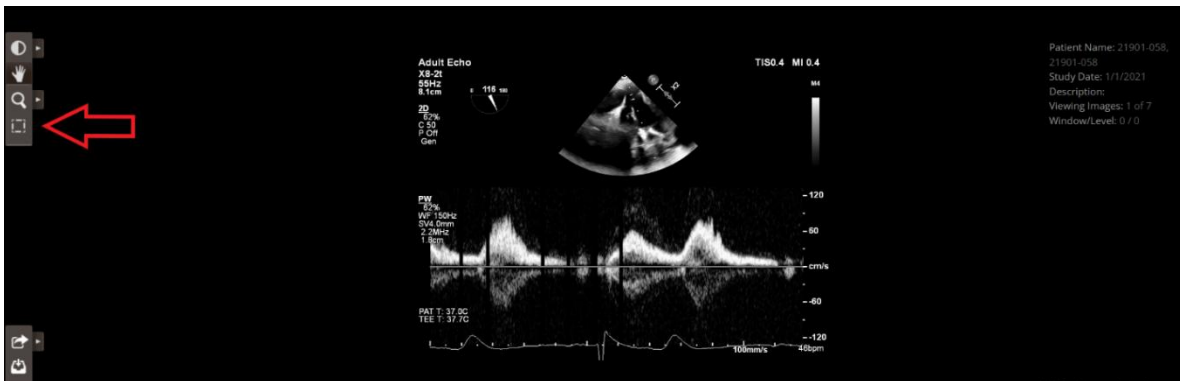
While previewing the images you will be able to see what was uploaded. Rave Inteleimage automatically detects and deidentifies DICOM header fields containing PHI during upload.

If needed, you can manually redact information using the box icon at the bottom on the left panel (see red box below) when previewing an image:



3. Redaction/Masking Tool – How to De-Identify PHI

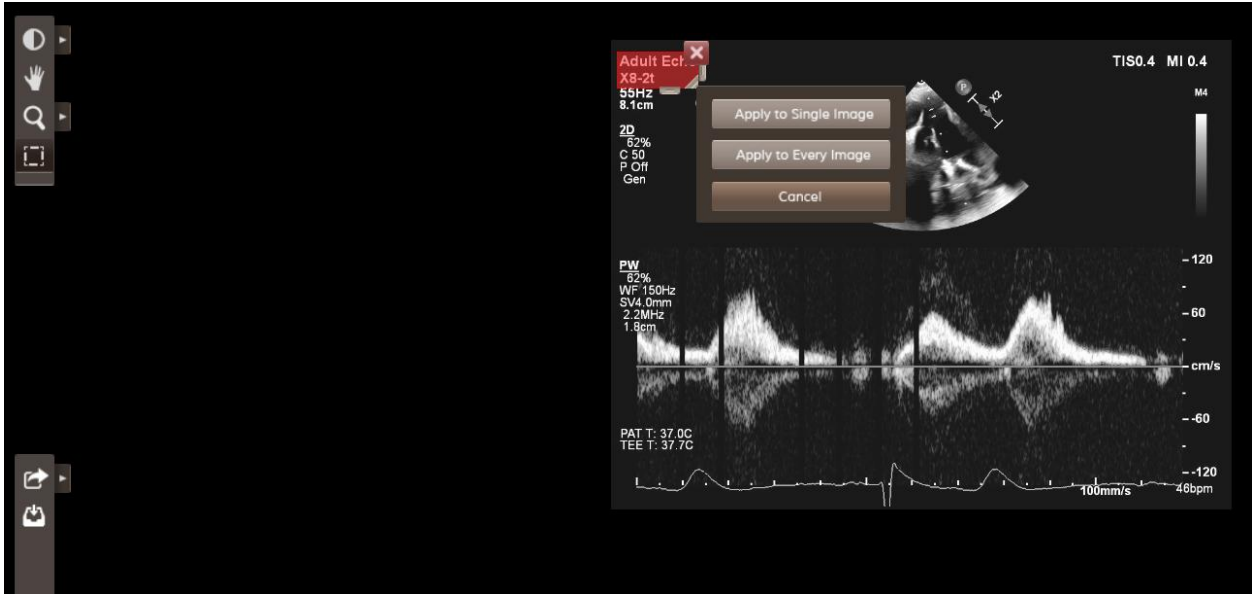
To redact, you will click on the box in the top left in the preview of the image.



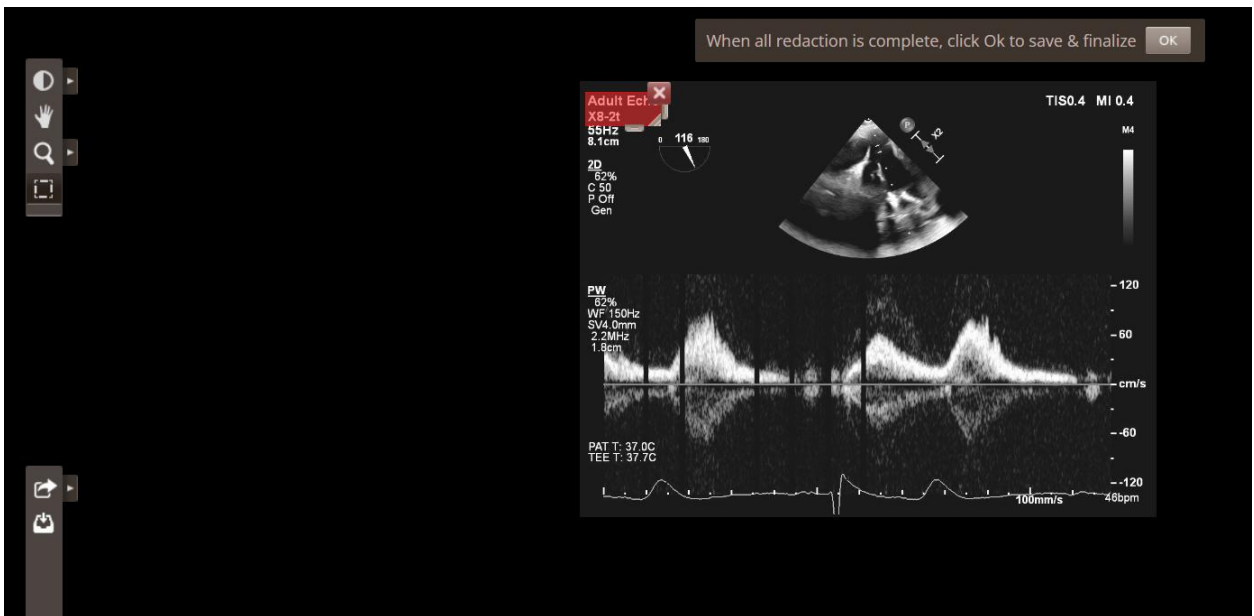
After clicking on the box, you will see a crosshair that appears. You will be able to click and drag your mouse around the area that you would like to de-identify. Once you have created the red shaded area around the PHI, you will see 3 options appear: “Apply to Single Image”, Apply to Every Image”, and “Cancel”.

By clicking on “Apply to Single Image” the mask will only apply to that image.

By clicking on “Apply to Every Image” the mask will apply to all images in upload in the same location. BEWARE: If all PHI is not located in the same area and this is implemented, imaging may get redacted requiring a re-upload.

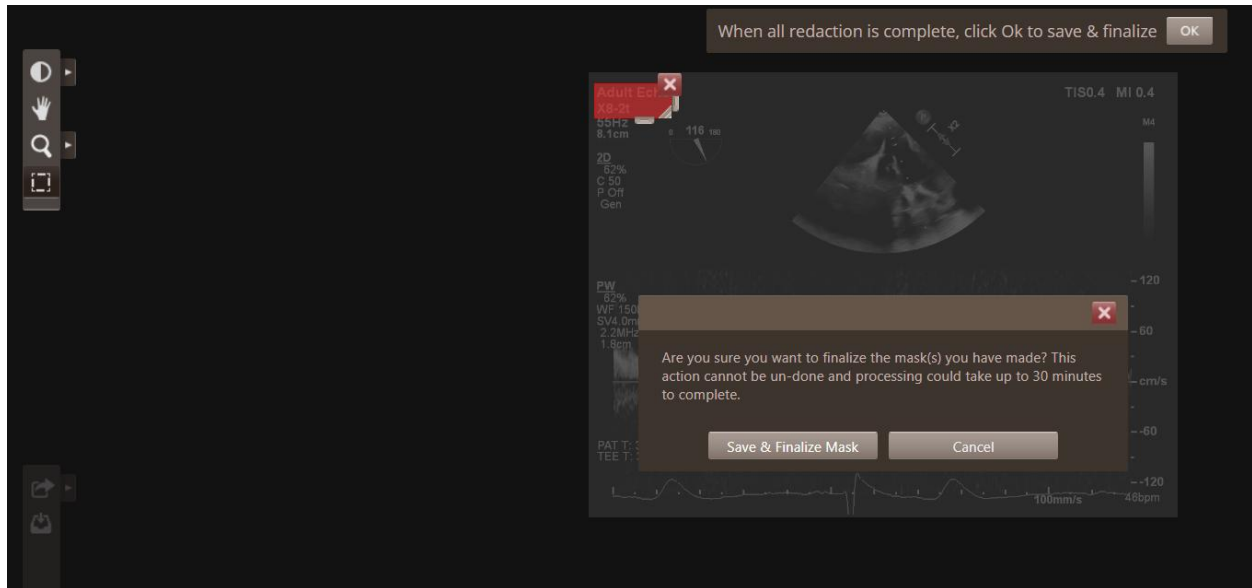


Once you select a masking option, you will see a message pop up that states: “When all redaction is complete, click OK to save & finalize” .

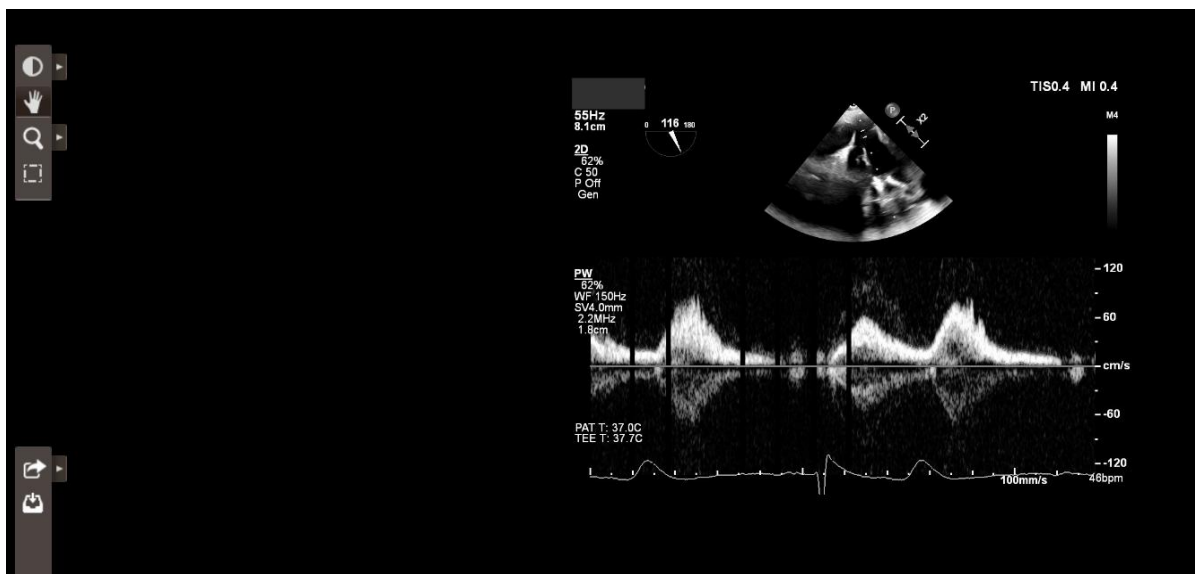


Once you select “Ok”, another message will populate asking if you are sure you would like to finalize. **This action cannot be undone**, so please confirm the masking option and area you are de-identifying are correct.

This process may take up to 30 minutes if you are de-identifying multiple images.



Once you select “Save & Finalize Mask”, the system will begin masking the area you have selected. Below is the result of masking in the top left corner of the image.



4. Addressing Imaging Queries

You will receive an email notification once a query has been assigned to you regarding a visit. Once you log into the portal, the query can be seen under “Queries”.

Subject: 21901-229

Baseline Visit/Event Details

Visit/Event Name: Baseline Status: Active Visit/Event Date: Unknown ✎

Baseline Visit/Event Requirements

Type	Info	Requirement	Commands
Exam	TTE	1 Exam	Upload Exams Comment Override
Document	TTE/TEE Sonographer Worksheet	1 Document	Upload Document Upload via Mobile Device Edit & Finalize Mobile Uploads Comment Override
Exam	CT	1 Exam	Upload Exams Comment

Submission Problems (3):
#20225
 1. TTE: Requires an upload or override.
 2. TTE/TEE Sonographer Worksheet: Requires an upload or override.
#20226
 1. CT: No upload supplied.

✔ Start TTE Review

✘ The Baseline visit/event has not satisfied all required items. Please provide all required data in order to finalize the visit/event submission and provide your e-signature.

Subject Details

Subject Name: 21901-229
 Screening Name: Unknown
 Status: Active

View

- ▶ View Subject
- ▶ Audit Log
- ▶ Audit Log Workflows

Actions

- ◆ Restore Deleted Items
- ◆ New Query
- ◆ Add 6 Months Visit/Event
- ◆ Add Adverse Event Visit/Event
- ◆ Add Optional TEE at Baseline Visit/Event

Visits/Events

Visit/Event Name	Complete	Img Reqs
Baseline	✘ 0	0
Index Procedure	✘ 0	0
Pre-Discharge	✘ 0	0
45 Days	✘ 0	0
12 Months	✘ 0	0

Queries

QID	Title	Assigned To	Status	Category	Created
340185	Overdue visit submission	eokeke@conformalmedical.com	Open	Overdue Visit	07-Mar-2024

Refresh

Queries can be for reasons including but not limited to an overdue visit, missing sonographer’s worksheet, incomplete upload, etc. Click into the query for information on the request. Once the query has been addressed, reply to it for verification that it has been addressed for faster resolution.

Query History

Date	User	Action	Query/Response Log	Actions
07-Mar-2024 01:26 PM GMT	eokeke@conformalmedical.com	Open	Imaging data for 21901-229, Baseline visit is overdue for submission based on the subject’s visit calendar. Please submit this visit at your earliest convenience.	Edit

Actions

- ◆ Save
- ✎ Send Reminder
- ◆ Comment

5. Addressing Site Tasks

Site tasks will populate when the Echo Core Lab has completed a Feedback Form for the imaging submitted.

Home

Subject ID Internal	Site Name	Subject Name	Status	View
902850	901	21901-001	✔	Search Subjects
902851	901	21901-002	✔	Search Visits/Events

[Site Tasks \(3\)](#)

1. Select **Site Tasks** under the View column to the right of your home screen to navigate to the listing of pending tasks for completion.

Home

Site Name	Subject Name	Visit/Event Name	Task Name	Task Type	Due Date	Create Date
901	21901-362	12 Months	TEE Feedback	File Download	N/A	28-Sep-2025
901	21901-360	Index Procedure	TEE Feedback	File Download	N/A	29-Sep-2025
901	21901-365	12 Months	TEE Feedback	File Download	N/A	15-Jan-2026

(3 results in 1 pages) [Refresh](#)

2. Select a row to navigate to the **Site Task Details** window.

Site Task ☐ ✕

Site Task Details

In order to complete this task, you must click the 'Download' button on the right.

Commands

Download

Close

3. Click the **Download** icon under the Commands column to retrieve the Echo Core Lab Feedback report. Once downloaded, the Site Task Details notification will indicate task completion.

Complete these steps for all remaining tasks.

Site Task ☐ ✕

Site Task Details

The task has been completed now.

Commands

Download

Close

6. Imaging Protocol Resources

Please refer to the documents listed below for additional information:

1. CONFORM TEE Image Acquisition Protocol
2. CONFORM CT Acquisition Protocol
3. CONFORM Sonographer Worksheet

CONFORM TEE Imaging Acquisition Protocol



**Yale Cardiovascular Research Group
Yale Echocardiographic Core Lab**

**Transesophageal Echocardiography (TEE)
Image Acquisition Protocol Guidelines**

The CONFORM Pivotal Trial

**An Evaluation of the Safety and Effectiveness of the
Conformal Left Atrial Appendage Seal for Left Atrial
Appendage Occlusion**

Sponsor: Conformal Medical, Inc.
15 Trafalgar Square, Ste.101
Nashua, NH 03063



Yale Cardiovascular Research Group Yale Echocardiographic Core Lab

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Yale Cardiovascular Research Group Yale Echocardiographic Core Lab

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Yale Cardiovascular Research Group Yale Echocardiographic Core Lab

1.0 General Instructions to Site

The following TEE Imaging Protocol is guidance from the Yale Echocardiographic Core Lab that was written specifically for the CONFORM Trial to visualize the CLAAS device and control devices using transesophageal echocardiography (TEE). In order to obtain complete imaging of the device for patients in this trial, all efforts should be made to obtain images at every angle (0, 45, 90 & 135-degrees), as specified in this protocol.

- Confirm 3-beat loops for subjects in sinus rhythm. 3-second loops for arrhythmias and tachycardia.
- Color Flow Doppler: Optimize frame rate (≥ 20 fps) for temporal resolution. Ensure gain setting is appropriate.
- Spectral Doppler: Sweep speed should be 75-100mm/s. 3-beat spectral acquisition for subjects in sinus rhythm, 5-beat acquisition for arrhythmias.
- Nyquist limit of LAA at 40cm/sec and valvular assessment at 60cm/sec.
- All images for the core lab should be recorded in single-plane, unless otherwise specified.
- **DICOM images AND Sonographer Worksheets for Index Procedure and Follow-Up should be uploaded to the EDC.**
- **PLEASE ENSURE ALL PHI HAS BEEN REMOVED FROM IMAGES PRIOR TO UPLOAD!**



Yale Cardiovascular Research Group Yale Echocardiographic Core Lab

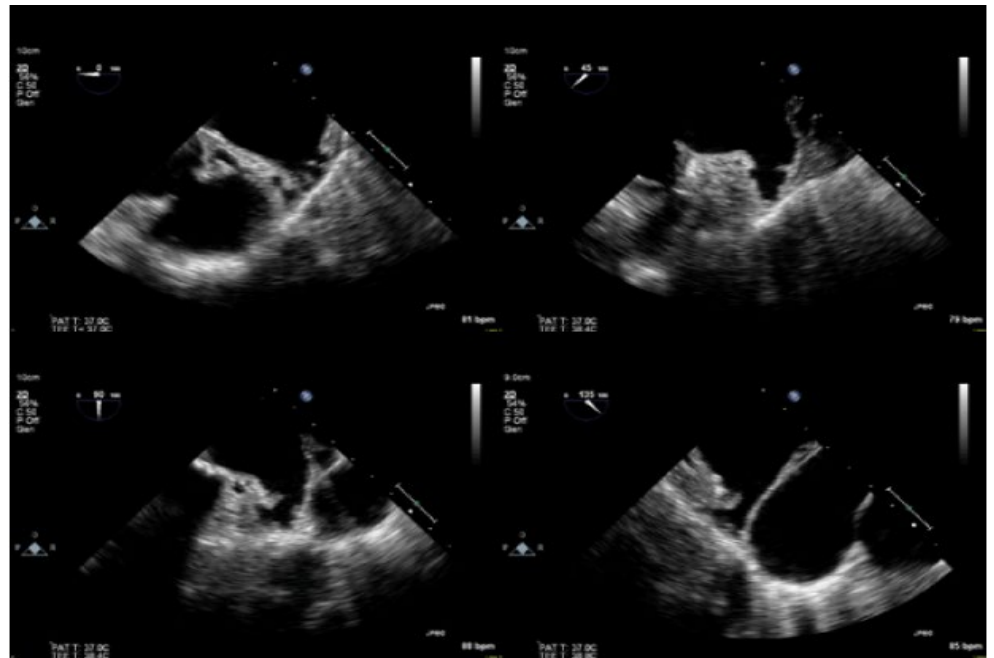
2.0 Two-Dimensional TEE Echocardiography Guide

2.1 Pre-Procedural Imaging (TEE 1: Baseline)

Note: In order to obtain complete imaging, all efforts should be made to obtain images at 0, 45, 90 & 135-degrees.

2.1.1 Two-Dimensional Imaging of Left Atrium/Left Atrial Appendage

Two-dimensional imaging of the left atrial appendage is at the level of the aortic valve (AoV). Once the AoV is visualized, anteflexion of the transducer is performed to obtain the LAA and evaluation is done from 0° – 180°. Images of the LAA are acquired at 0°, 45°, 90°, and 135°.



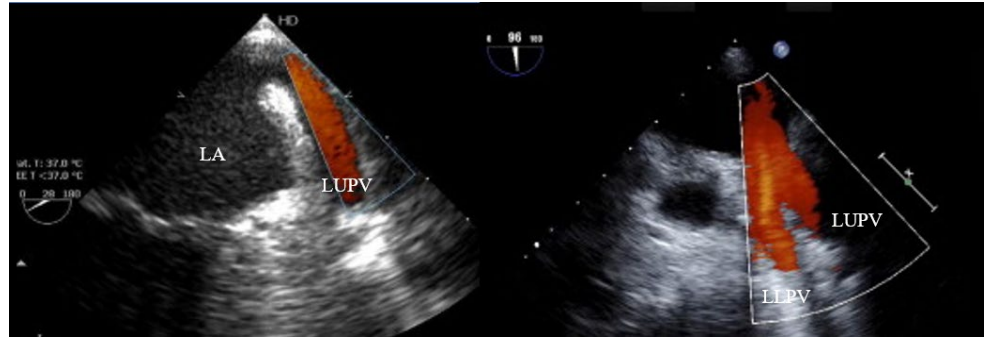
2.1.2 Pulsed-Wave (PW) and Color Flow Doppler of Left Pulmonary Veins

Assess Left Upper Pulmonary Vein (LUPV) and Left Lower Pulmonary Vein (LLPV).

Increased maximum PV Doppler flow velocity (>1.1m/s) combined with color flow Doppler turbulence may be a reliable index⁷ for diagnosing pulmonary vein stenosis.



Yale Cardiovascular Research Group Yale Echocardiographic Core Lab

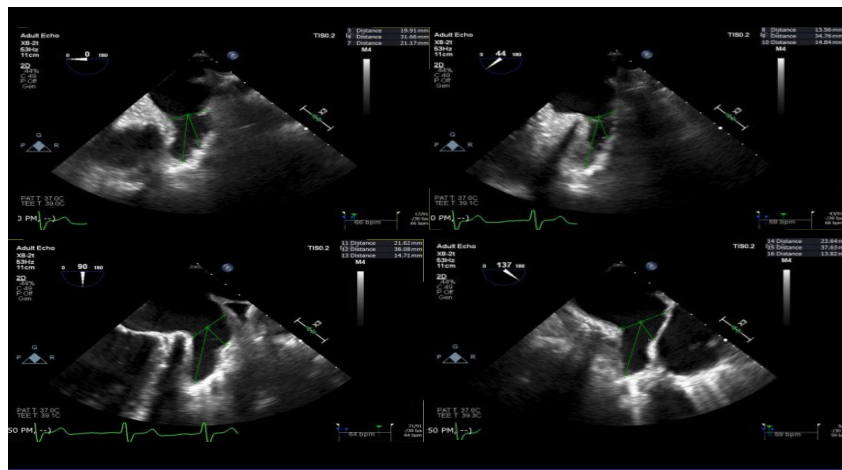


Cartwright, Bruce MBBS, et al Intraoperative Pulmonary Vein Examination by Transesophageal Echocardiography: An Anatomic update and Review of Utility. Journal of Cardiothoracic and Vascular Anesthesia. Volume 27, Issue 1, February 2013, Pages 111-120

2.1.3 LAA Ostium Diameter and LAA Depth

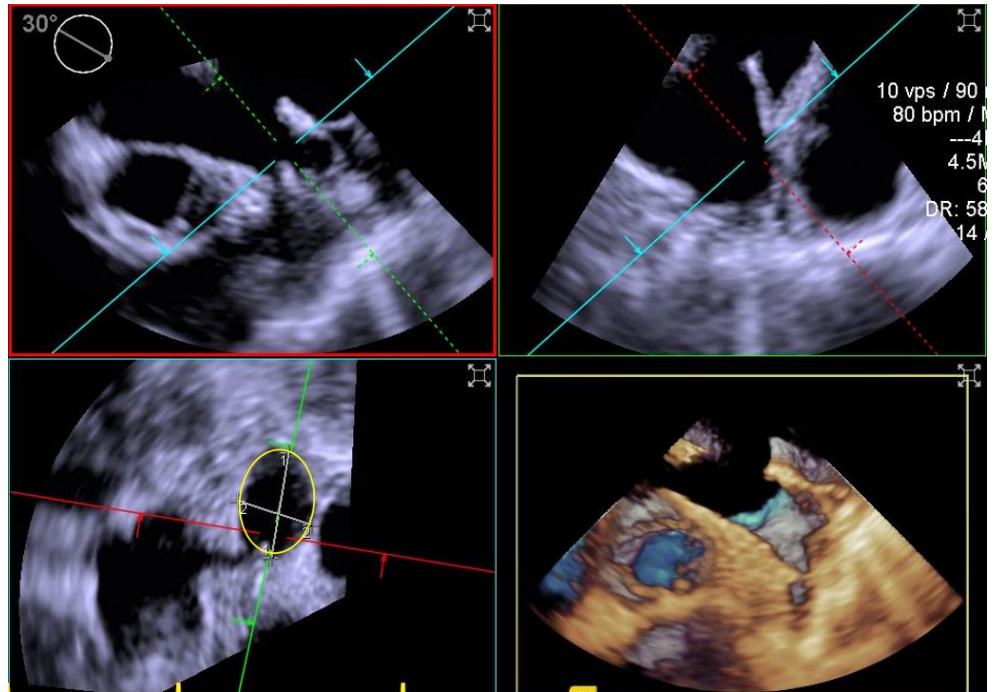
Sweep through LAA views to ascertain the largest diameter and longest depth of the LAA. Measurements are documented at 0°, 45°, 90°, and 135°. The 3D image of the LAA should be taken from a wide-angled view at 45°. The perpendicular depth measurement should be made from the ostial plane to the shortest distance to any anatomic structure. The maximal depth is measured from the ostial plane to the most distal aspect of the LAA.

Implant Size	Mean LAA Ostium Diameter (D _{max} + D _{min}) / 2	LAA Ostium Diameter Range	Minimum Landing Zone
Regular	≤ 25mm	10 – 33mm	10mm
Large	≤ 32mm	20 – 40mm	10mm





Yale Cardiovascular Research Group Yale Echocardiographic Core Lab

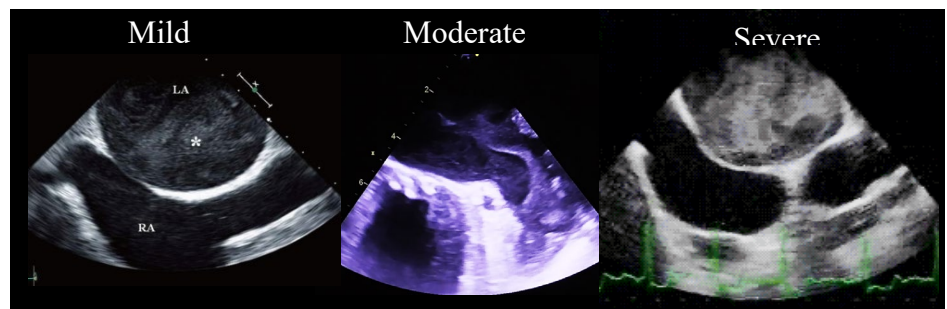


2.1.4 LAA Spontaneous Echocardiographic Contrast (SEC)

Will be assessed from the images acquired. Please optimize gains.

The following grading will be used:

- Absence of echogenicity
- Mild (minimal echogenicity, only transiently detectable with optimal gain settings during the cardiac cycle)
- Moderate (dense swirling pattern throughout the cardiac cycle)
- Severe (intense echo density and very slow swirling patterns in the left atrial appendage, usually with similar density in the left atrium)⁶



Kim, Tae-Seok, MD Role of Echocardiography in Atrial Fibrillation J Cardiovasc Ultrasound. 2011 Jun; 19(2): 51-61.

[Echocardiography step by step](#)

<https://drsvenkatesan.com/2011/04/10/a-hurricane-inside-left-atrium/>



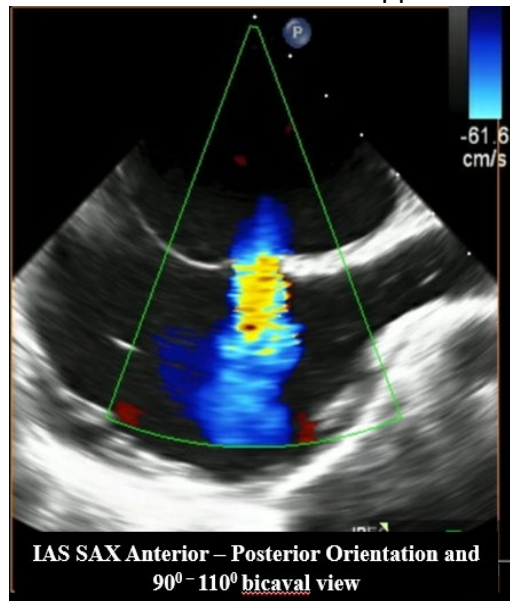
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2.1.5 Intracardiac Thrombus/Vegetation/Mass

A thorough investigation of all cardiac chambers, valves, structures with specific attention to LAA should be performed to rule out intracardiac thrombus, vegetation, or mass.

2.1.6 Atrial Septum

Image atrial septum in both LAX and SAX sweeping through planes. Document atrial septum with color flow Doppler and PW Doppler for atrial level shunting in 90° - 110° bicaval view inferior to superior orientation. Perform CW Doppler to demonstrate direction of flow.



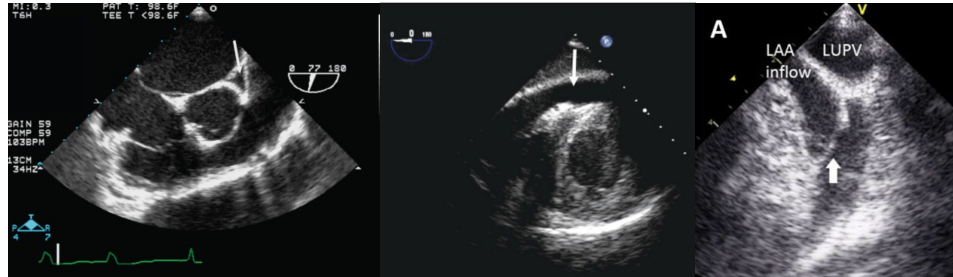
2.1.7 Pericardial Effusion

Image the pericardial space (transverse sinus, oblique sinus around the LAA) for effusion. The largest diameter in diastole will be documented and the degree of pericardial effusion will be decided.

- Absent
- Small (localized and <1 cm width)
- Moderate (circumferential and 1-2cm width)
- Large (circumferential and >2 cm width)



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https://thoracickey.com/wp-content/uploads/2016/06/B9781455707614000232_02-9781455707614.jpg

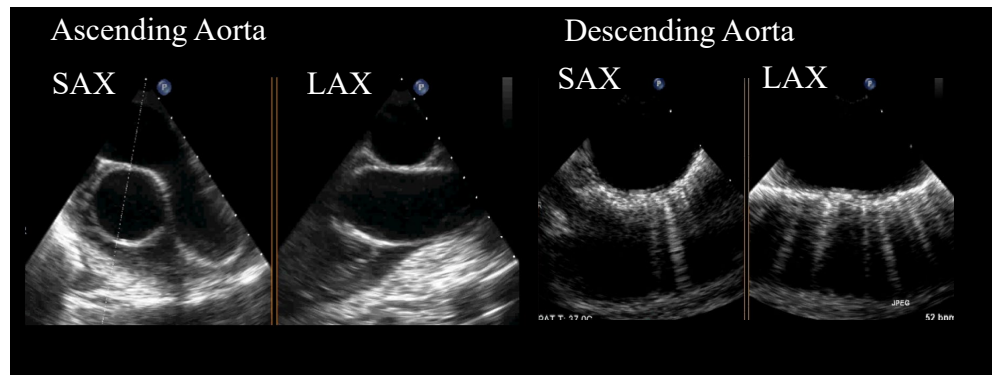
Kamperidis, V et al. "Left Atrial Appendage Pericardial Fluid: Contrast-Enhanced Transesophageal Echocardiography Makes It Visible." *Hippokratia*20.3 (2016): 235-237. Print.

2.1.8 Mitral Valve

Perform color flow Doppler and CW Doppler for quantitative assessment of the mitral valve. Image from ME4, ME3, and ME2.

2.1.9 Aortic Atheroma/Plaque

Image UE 120-150° to assess ascending Ao LAX, UE 0° ascending Ao SAX, ME 0° descending Ao SAX, ME 90° descending Ao LAX
Document location and extent of atheroma if present.





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2.2 Pre-Release Device Assessment (TEE 2: Pre-Release)

Note: In order to obtain complete imaging, all efforts should be made to obtain images at 0, 45, 90 & 135-degrees.

2.2.1 Assess Device

Scan ME 0⁰-135⁰ and acquire clips at 0⁰, 45⁰, 90⁰, 135⁰ with and without color flow Doppler over the device to determine whether there is residual flow through or around the LAAO device. For periodic follow up comparisons, leave the color flow settings at general/medium with color scale set at 30-40cm/s. Keep frame rates \geq 20fps. Ensure to place the color flow region of interest over the device/LAA border.

2.2.1.1 Position

Identify and document the position of the LAAO device, prior to tug test.

Tug Test: Annotate "TUG". Acquire dynamic clip(s) during the tug test showing tether insertion (device apex), in a dedicated viewing angle. Reassess the position of the LAAO device at the conclusion of the tug test.

2.2.1.2 Seal

Identify and document peri-device leaks if present. Demonstrate the vena contracta of the jet(s).

2.2.1.3 Thrombus

Perform a full cardiac scan to investigate for SEC and/or thrombus with specific attention to the implanted device. If thrombus is suspected, optimize imaging and zoom in when acquiring clip so an accurate evaluation of size can be performed. Utilize color flow and PW Doppler for further support.

2.3 Post-Release Device Assessment (TEE 3: Post-Release)

Note: In order to obtain complete imaging, all efforts should be made to obtain images at 0, 45, 90 & 135-degrees.

2.3.1 Assess for Pericardial Effusion

Image the pericardial space (transverse sinus, oblique sinus around the LAA) for effusion. The largest diameter in diastole will



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be documented and the degree of pericardial effusion will be decided.

- a. Absent
- b. Small (localized and < 1cm width)
- c. Moderate (circumferential and 1-2cm width)
- d. Large (circumferential and >2cm width)

2.3.2 Assess Device

Annotate “POST-RELEASE”. Scan ME 0°-135° and acquire clips at 0°, 45°, 90°, 135° with and without color flow Doppler over the device to determine whether there is residual flow through or around the LAAO device. For periodic follow up comparisons, leave the color flow settings at general/medium with color scale set at 30-40cm/s. Keep frame rates ≥ 20 fps. Ensure to place the color flow region of interest over the device/LAA border.

2.3.2.1 Position

Identify and document the position of the LAAO device.

2.3.2.2 Seal

Identify and document peri-device leaks if present. Demonstrate the vena contracta of the jet(s).

2.3.2.3 Thrombus

Perform a full cardiac scan to investigate for SEC and / or thrombus, with specific attention to the implanted device. If thrombus is suspected, optimize imaging, and zoom in when acquiring clip so an accurate evaluation of size can be performed. Utilize color flow and PW Doppler for further support.

2.3.2.4 Assess Device for 3D

The 3D image of the LAAO device should be taken from a wide-angled view at 45°. If performed per SOC, please provide the 3D raw image file for Core Lab assessment.

2.3.3 Left Pulmonary Vein Assessment

Acquire loops of 2D and color flow Doppler of the LUPV and LLPV. Acquire PW spectral Doppler in the pulmonary vein (1cm inside the PV).



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2.3.4 Assess Atrial Septum

Image Atrial Septum in both LAX and SAX sweeping through planes. Document atrial septum with color flow Doppler and PW Doppler for atrial level shunting in 90⁰-110⁰ bicaval view inferior to superior orientation. Perform CW Doppler to demonstrate direction of flow.

2.3.5 Mitral Valve Assessment

Perform color flow Doppler and CW Doppler for quantitative assessment of the mitral valve.
Image from ME4, ME3, and ME2.

2.4 Follow-Up TEE:

2.4.1 Assess for Pericardial Effusion

Image the pericardial space (transverse sinus, oblique sinus around the LAA) for effusion. The largest diameter in diastole will be documented and the degree of pericardial effusion will be decided.

- a. Absent
- b. Small (localized and < 1cm width)
- c. Moderate (circumferential and 1-2cm width)
- d. Large (circumferential and >2cm width)

2.4.2 Assess Device

Scan ME 0⁰-135⁰ and acquire clips at 0⁰, 45⁰, 90⁰, 135⁰ with and without color flow Doppler over the device to determine whether there is residual flow through or around the LAAO device. For periodic follow up comparisons, leave the color flow settings at general/medium with color scale set at 30-40cm/s. Keep frame rates ≥20fps. Ensure to place the color flow region of interest over the device/LAA border.

2.4.2.1 Position

Identify and document the position of the LAAO device.

2.4.2.2 Seal

Identify and document peri-device leaks if present. Demonstrate the vena contracta of the jet(s).



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2.4.2.3 Thrombus

Perform a full cardiac scan to investigate for SEC and/or thrombus, with specific attention to the implanted device. If thrombus is suspected, optimize imaging and zoom in when acquiring clip so an accurate evaluation of size can be performed. Utilize color flow and PW Doppler for further support.

2.4.2.4 Assess Device for 3D

The 3D image of the LAAO device should be taken from a wide-angled view at 45°. If performed per SOC, please provide the 3D raw image file for Core Lab assessment.

2.4.3 Left Pulmonary Vein Assessment

Acquire loops of 2D and color flow Doppler of the LUPV and LLPV. Acquire PW spectral Doppler in the pulmonary vein (1cm inside the PV).

2.4.4 Assess Atrial Septum

Image atrial septum in both LAX and SAX sweeping through planes. Document atrial septum with color flow Doppler and PW Doppler for atrial level shunting (ASD or PFO) in 90°–110° bicaval view inferior to superior orientation. Perform CW Doppler to demonstrate direction of flow.

2.4.5 Mitral Valve Assessment

Perform color flow Doppler and CW Doppler for quantitative assessment of the mitral valve. Image from ME4, ME3, and ME2.



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3.0 Abbreviations

1. **2DE or 2D** - Two-Dimensional Echocardiography
2. **Ao** - Aorta
3. **AoV** - Aortic Valve
4. **ASD** – Atrial Septal Defect
5. **ASE** - American Society of Echocardiography
6. **CLAAS™** - Conformal Left Atrial Appendage Seal
7. **cm** – centimeter
8. **cm/s** – centimeters per second
9. **CW**- Continuous Wave Doppler
10. **DTG** – Deep Transgastric
11. **ePTFE** - expanded polytetrafluoroethylene
12. **fps** – frames per second
13. **IAS** - Interatrial Septum
14. **LA** - Left Atrium
15. **LAA** – Left Atrial Appendage
16. **LAAO** – left Atrial Appendage Occlusion
17. **LAX** – Long Axis
18. **LE** – Lower Esophageal
19. **LLPV** – Left Lower Pulmonary Vein
20. **LUPV** – Left Upper Pulmonary Vein
21. **LV** - Left Ventricle
22. **ME** – Mid Esophageal
23. **mm** – millimeter
24. **m/s** – meters per second
25. **PFO** – Patent Foramen Ovale
26. **PW** - Pulsed Wave Doppler
27. **s** - seconds
28. **SAX** – Short Axis
29. **SEC** – Spontaneous Echocardiographic Contrast
30. **TEE** – Transesophageal Echocardiography
31. **TG** - Transgastric
32. **UE** – Upper Esophageal
33. **TEE** – Transesophageal Echocardiography



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5.0 Contacts

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CONFORM TEE Checklist

TEE BASELINE

General

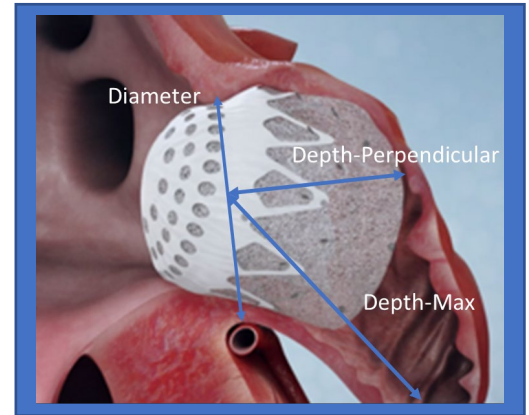
- Confirm 3-beat loops for subjects in sinus rhythm. 3-second loops for arrhythmias and tachycardia
- Color Flow Doppler: Optimize frame rate (>=20fps) for temporal resolution. Ensure gain setting is appropriate
- Spectral Doppler: Sweep speed should be 75-100mm/S. 3-beat spectral acquisition for subjects in sinus rhythm, 5-beat acquisition for arrhythmias
- Nyquist limit of LAA at 40 cm/sec and valvular assessment at 60 cm/sec
- DICOM images AND Sonographer Worksheets should be uploaded to the EDC
- All images required for the core lab, should be recorded in single-plane unless otherwise specified
- PLEASE ENSURE ALL PHI HAS BEEN REMOVED FROM IMAGES PRIOR TO UPLOAD!**

2D LAA

- 0°
- 45°
- 90° PW Doppler inside the LAA at 90°
- 135°

2D LAA Ostial and Depth Measurements (perpendicular to ostial plane and max depth, for both Treatment and Control cases)

- 0°
- 45°
- 90°
- 135°



3D Image of LAA

- Wide-angled acquisition at 45°

Left Pulmonary Veins (PW) and Color Flow Doppler

- 0-90° Assess LUPV by placing PW 1cm in the LUPV (adjust to scale)
- 90-110° Assess LLPV by placing PW 1cm in the LLPV (adjust to scale)

ASD/PFO

- 90-110° Bicaval view with and without color

Pericardial Effusion (Thorough evaluation at baseline is necessary)

- Trans gastric LV (biplane if possible)
- 4-Chamber LV biplane

Mitral Valve

- Biplane imaging of the mitral valve with and without color
- If suspicion of stenosis, formal evaluation with gradient is needed

Aortic Atheroma

- Upper-esophageal 120-150°
- Upper-esophageal 0°
- Mid-esophageal 0°
- Mid-esophageal 90°

IMPORTANT REMINDERS

- Imaging **MUST** be performed at 0, 45, 90 and 135 degrees
- Imaging **MUST** be performed at 0, 45, 90 and 135 degrees at PRE- and POST-Release with and without color
- Color sector must encompass the whole device
- Acquisition should be at least 3 seconds IF in AF

TEE PRE-RELEASE

Tug Test

- Annotate “TUG”
- Acquire dynamic clip in view of tether insertion (device apex)

2D LAAO Device Assessment

- 0° Acquire clip with and without Color Flow Doppler
- 45° Acquire clip with and without Color Flow Doppler
- 90° Acquire clip with and without Color Flow Doppler
- 135° Acquire clip with and without Color flow Doppler

TEE POST-RELEASE AND FOLLOW-UP

General

- Confirm 3-beat loops for subjects in sinus rhythm. 3-second loops for arrhythmias and tachycardia
- Color Flow Doppler: Optimize frame rate (>=20fps) for temporal resolution. Ensure gain setting is appropriate
- Spectral Doppler: Sweep speed should be 75-100mm/s. 3-beat spectral acquisition for subjects in sinus rhythm, 5-beat acquisition for arrhythmias.
- Nyquist limit of LAAO at 40 cm/sec and valvular assessment at 60 cm/sec
- DICOM images AND Sonographer Worksheets should be uploaded to the EDC
- All images required for the core lab, should be recorded in single-plane, unless otherwise specified
- PLEASE ENSURE ALL PHI HAS BEEN REMOVED FROM IMAGES PRIOR TO UPLOAD!**

Pericardial Effusion (if Pericardial effusion observed at baseline obtain similar images)

- Transgastric LV (biplane if possible)
- 4-Chamber LV biplane

2D LAAO Device Assessment

- Annotate “POST RELEASE”
- 0° Acquire clip with/without Color Flow Doppler
- 45° Acquire clip with/without Color Flow Doppler
- 90° Acquire clip with/without Color Flow Doppler
- 135° Acquire clip with/without Color Flow Doppler

ASD/PFO

- 90-110° Bicaval view with and without color

3D Image of LAAO Device

- Wide-angled acquisition (at 45°), 1-beat acquisition, 3-beat loop

Left Pulmonary Veins (PW) and Color Flow Doppler

- 0-90° Assess LUPV by placing PW 1cm in the LUPV (adjust to scale)
- 90-110° Assess LLPV by placing PW 1cm in the LLPV (adjust to scale)

Mitral Valve

- Biplane imaging of the mitral valve with and without color
- Confirm severity of MR has not changed

IMPORTANT REMINDERS

- Imaging MUST be performed at 0, 45, 90 and 135 degrees
- Imaging MUST be performed at 0, 45, 90 and 135 degrees at PRE- and POST-Release with and without color
- Color sector must encompass the whole device
- Acquisition should be at least 3 seconds IF in AF

Please upload the TEE images into the CONFORM Imaging Platform

Questions about Imaging? Please reach out to your Site Manager or Field Clinical Specialist or refer to the CONFORM Manual of Procedures Binder!

CONFORM CT Acquisition Protocol



**THE CONFORM PIVOTAL TRIAL -
AN EVALUATION OF THE SAFETY AND EFFECTIVENESS OF THE
CONFORMAL CLAAS SYSTEM FOR LEFT ATRIAL APPENDAGE
OCCLUSION**

CT ACQUISITION PROTOCOL

Revision A

Study Sponsor:

Conformal Medical, Inc.
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APPROVAL SIGNATURE

Signature Page

The undersigned hereby jointly declare that they have reviewed the CT Acquisition Protocol, understand the impacts associated with approving this Protocol, and agree to its form and content.

Name	Function	Signature & Date
David Pomfret	VP Clinical Affairs	<p>DocuSigned by: <i>David Pomfret</i></p> <p>Signer Name: David Pomfret Signing Reason: I approve this document Signing Time: 15-Jun-2022 17:43:29 EDT 1C87BCDC0C294C79BCA0276D6AC3D9CB</p>
Philipp Blanke	Director CT Core Lab	<p>DocuSigned by: <i>Philipp Blanke</i></p> <p>Signer Name: Philipp Blanke Signing Reason: I am the author of this document Signing Time: 15-Jun-2022 06:18:06 PDT FB1A7E95968B408DB92FE4A022C9D797</p>

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1 Purpose

The purpose of this protocol is to provide recommendations on CT data acquisition and reconstruction for the cardiac CT performed for the CONFORM Pivotal Trial sponsored by Conformal Medical Inc. The CT data may be used in the screening process to assess inclusion / exclusion criteria and subject suitability for enrollment. CT follow-up imaging provides information on device positioning, residual LAA perfusion and thrombotic appositions.

2 Scope

This protocol is limited to the aspects of the CT data acquisition.

3 Scanner Requirements

The CT exam must be performed using a multi-detector scanner with at least 64-detector rows.

4 CT Data Acquisition/Protocol Fundamentals

The CT examination should be comprised of two main elements. An ECG-assisted contrast enhanced cardiac CT scan covering the entire heart and including the entire LAA and a delayed phase ECG-assisted acquisition limited to the LAA. The latter serves the purpose to increase the specificity for LAA thrombus detection, in particular by decreasing false positive findings.

The following lists the main components to create a default protocol.

4.1 Preparation

- Placement of an IV access in an antecubital vein (an 18-gauge IV typically provides the highest safety).
- Positioning of the patient on the scanner table in supine position; positioning should be similar to patient positioning on the cath lab/hybrid OR table, although arms are routinely elevated above the head to reduce radiation absorption at the level of the cardiac structures.
- Placement of ECG-electrodes for subsequent ECG-assisted data acquisition
- Patient instruction on breath-holding to improve patient compliance

Beta-blockers can be considered in patients with a resting heart rate >75 beats per minute. Administration of beta-blockers must be in accordance with the institutional local guidelines. Contraindications to beta-blockers have to be considered. In patients with contraindications to beta-blockers alternative rate controlling medications may be used

4.2 Scouts (Topogram, Scanogram)

- Standard AP, plus lateral scouts (depending on the scanner system) of the thorax

4.3 Contrast administration

Contrast administration protocols should allow for sufficient contrast opacification of the left atrium and left atrial appendage. The delayed phase acquisition does require an additional contrast administration.

- **Bolus tracking:** In general, ‘bolus tracking’ is recommended to trigger data acquisition. The region of interest (ROI) for bolus tracking should be placed within the ascending aorta for 64/128/192 detector row scanners (all scanners except GE Revolution and Toshiba Aquilion One) or in the left atrium for volume scanners (GE Revolution and Canon/Toshiba Aquilion One). The threshold to trigger data acquisition has to be selected while taking into account the time needed for automated breathing instructions and a potential pre-scan delay, with the aim to achieve sufficient contrast enhancement in the left atrium.
- **Contrast injection:** Contrast administration requires the use of a dual-head injector and is performed as a biphasic protocol, i.e. injection of non-diluted contrast followed by a saline chaser. The amount of contrast and injection time should be adjusted to the patient’s body habitus and the scanner system and scan time. Iodine delivery rate (mg/sec) has to be increased in patients with larger body habitus. This can be achieved using higher flow rates. Commonly used rates are 60-90ml contrast media at 3.5-4cc/sec (depending on iodine concentration and body habitus), followed by 50cc saline at the same injection rate.

4.4 First-pass ECG-assisted contrast enhanced cardiac CT data acquisition (‘ First-pass Cardiac CT’)

An ECG-assisted contrast enhanced CT data acquisition of the entire heart including the entire LAA is required in all patients in order to assess the cardiac structures.

- **Acquisition modes:** With all scanner types/vendors, data acquisition should be performed using axial/sequential, prospective ECG-triggering. Depending on the scanner geometry, data acquisition is either performed as a ‘step&shoot’ acquisition or as a gated ‘one beat whole heart’ acquisition (volume scanners).

Manufacturer	Scanner Geometry	Acquisition mode
GE	64-row family (750HD, Discovery)	Step&Shoot (prospective ECG-triggering; axial/sequential)

	Revolution (256 row)	Gated one beat acquisition (prospective ECG-triggering; axial/sequential)
Philips	All scanners	Step&Shoot (prospective ECG-triggering; axial/sequential)
Siemens	All scanners	Step&Shoot (prospective ECG-triggering; axial/sequential) Dual Source scanners: High-pitch helical
Canon/Toshiba	64/80-row family	Step&Shoot (prospective ECG-triggering; axial/sequential)
	Aquilion One	Gated one beat acquisition(prospective ECG-triggering; axial/sequential)

- **Tube and detector settings:** Tube voltage and tube current settings should reflect settings of routine cardiac CT protocols and should follow institutional guidelines. For LAA imaging, higher image noise and thus lower mAs/mA levels are acceptable compared to coronary cardiac CT. Tube voltage should be BMI adjusted.
- **Scan length:** The scan range should extend from the tracheal bifurcation to at least 2cm below the left ventricular apex and has to include the entire LAA. CAVEAT: The routine approach of starting 2cm below the carina for coronary cardiac CT may sometimes lead to incomplete imaging of the LAA.
- Axial/sequential data acquisition (Step&Shoot) should be performed in cranial to caudal direction. Data should be acquired at the smallest available collimation (ideally <0.75mm), based on individual system capabilities.
- **Cardiac cycle coverage:** The target phase for ECG-assisted imaging is end-systole. Common approaches for end-systolic imaging included target phases of e.g. 35% of the RR-interval or 300msec past R-peak.

4.5 Delayed phase ECG-assisted CT data acquisition of the LAA

An ECG-assisted delayed phase CT data acquisition, limited to the LAA should be performed in all patients immediately following the cardiac data acquisition to provide further image data for evaluation of LAA. This data acquisition does not involve additional contrast media administration.

- **Scan mode:** Identical scan mode as use for first-pass cardiac CT.
- **Scan length:** The scan length should cover the LAA but does not have to cover the entire left ventricle.

- **Cardiac cycle coverage:** Identical target phase as for the first-pass cardiac CT.

5 CT Data reconstruction

The first-pass and delayed phase ECG-assisted cardiac CT data sets should be reconstructed as follows

- Axial, thin sliced reconstructions, $\leq 1\text{mm}$; e.g. 0.6mm, 0/4mm increment
- Field of View (FoV) limited to the heart.
- Filtered-back projections or iterative reconstructions using a soft tissue convolution kernel/filter

Device Accountability Work Instruction

These instructions are for the Device Accountability Log to be completed in the Device Accountability App.

1. Why is the Device Accountability Log (DAL) Important?

- The DAL is the 21 CFR Part 812 compliant documentation to capture record of device disposition, batch codes/lot numbers/reference numbers of disposition devices and devices used with subjects.
- Investigational sites must also keep this as record of type/quantity of device, date of receipt, name of person that received/used/disposed of device, batch number/lot number/reference number, etc.

2. Device Receipt

2.1. How Many Devices Can I Record Per Line?

- Record one device per line even if they have the same lot number and/or reference number.

2.2. Where Can I Find the Information Required on the log (Ref #, Lot #, etc.)?

- Reference numbers, lot numbers and expiration dates can be found on the labeling or packaging of each device and on the Shipment Record.

3. Device Disposition

3.1. What Does 'Disposition' Mean?

- Disposition refers to the outcome of the device. i.e., whether it was used, disposed, returned, or opened but not used. For devices that are returned, please refer to the Device Return section for the Returned Goods Authorization (RGA) process.

3.2. When Would the Subject ID be Applicable?

- Complete this column if a device was used or opened with the intent to be used on a subject.

3.3. What is the Date of Disposition?

- This is the date that the device was used, disposed, returned, or opened and not used.
- Select yes or no whether the device had a deficiency or malfunction
 - If yes, record the deficiency in EDC

4. FAQs

- Why do I need to list each product separately rather than write a quantity next to a device?
 - **Answer:** Products must be written one per line so that they can be associated with the correct disposition and/or subject information e.g., perhaps you received 5 Regular Delivery systems for case day, used 2, but returned 3.
- Does subject ID need to be captured for each device?
 - **Answer:** Only if the device was used or was attempted to be used on a subject.
- What devices need an RGA number?
 - **Answer:** Only Sponsor devices that are being sent back to Conformal Medical. If product used during a case needs to be sent back to the Sponsor, your Field Clinical Specialist will generate the RGA number for you. Otherwise, reach out to your Site Manager to obtain an RGA number.
- Should the VizaraMed steerable sheaths be entered in the Device Accountability Log?
 - **Answer:** No, the VizaraMed steerable sheath is not an Investigational Product and should not be entered in the Device Accountability Log.

Return Devices

Device Return

- Devices are returned to the Sponsor for several reasons which include but are not limited to:
 - Product expiration
 - Device malfunction
 - Shipping/ordering error
 - Inventory return/exchange

1. What Do I Do if I Need to Return a Device/Devices?

- All returned devices must have an RGA (Returned Goods Authorization) number. Please ask your **Field Clinical Specialist** to create one on case day or reach out to your **Site Manager**.
 - **Note: product may be returned for many reasons (device deficiency, expiration, site transfer, etc.).**

2. Where Do I Record the RGA Number?

- In the appropriate column of the Device Accountability Application (screenshot below)
- **AND** somewhere visible on the packaging of the return devices

Unique ID Site Id	Product Code Description Order#	Query/Monitor Status	Lot# Expy Date	Subject ID	Disposition Date	Deficient	Used	Disposed	Returned	RGAs	Transferred	Other
#3833 TEST2	TESTPRODUCT - Used for development O-240125074143		TST-101 5/15/2024	<input type="text"/>	12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	RGAs	<input type="checkbox"/>	<input type="checkbox"/>
#3761 TEST2	TESTPRODUCT - Used for development O-240117155550		TST-101 5/15/2024	<input type="text"/>	12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
#3687 TEST2	TESTPRODUCT - Used for development O-240103112713		TST-101 5/15/2024	<input type="text"/>	12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
#3538 TEST2	TESTPRODUCT - Used for development O-231121083818		TST-101 5/15/2024	<input type="text"/>	12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
#3530 TEST2	TESTPRODUCT - Used for development O-231120074825		TST-101 5/15/2024	<input type="text"/>	12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
#2873 TEST2	TESTPRODUCT - Used for development O-230809184819	✓	TST-101 5/15/2024	<input type="text"/>	12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
#2874 TEST2	TESTPRODUCT - Used for development O-230809184819	✓	TST-101 5/15/2024	<input type="text"/>	12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
#2936 TEST2	TESTPRODUCT2 - Used for development		TST-101 5/15/2023	<input type="text"/>	12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>

29 items

Site Number / Name
TEST2 - TEST2 National Health

By selecting this box, you confirm you have reviewed the above information. By electronically signing here, you accept that your electronic signature is the legally binding equivalent of your

Save Changes

3. How do I get a return shipping label?

- Use return labels included with original product shipment OR
- Reach out to the Site Manager or **Field Clinical Specialist**
 - **Site Manager** or **FCS** will generate the return shipping label with FedEx and send it to the site contact via email
- Print the shipping label and place it on the original device packaging
 - Write RGA number somewhere visible on the device packaging
- Use the Other box to enter a return date and tracking number for all returned product

4. What Do I Do if There was a Device Deficiency?

- Check off the appropriate box on the Device Accountability Log

- Note: not all product with a device deficiency needs to be returned.
- Record the device deficiency in EDC

Unique ID Site Id	Product Code Description Order#	Query/ Monitor Status	Lot# Expy Date	Subject ID	Disposition Date	Deficient	Used	Disposed	Returned	RGA	Transferred	Other
#3833 TEST2	TESTPRODUCT - Used for development O-240125074143		TST-101 5/15/2024		12/31/2001	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	RGA	<input type="checkbox"/>	<input type="checkbox"/>
#3761 TEST2	TESTPRODUCT - Used for development O-240117155550		TST-101 5/15/2024		12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
#3687 TEST2	TESTPRODUCT - Used for development O-240103112713		TST-101 5/15/2024		12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
#3538 TEST2	TESTPRODUCT - Used for development O-231121085818		TST-101 5/15/2024		12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
#3530 TEST2	TESTPRODUCT - Used for development O-231120074825		TST-101 5/15/2024		12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
#2873 TEST2	TESTPRODUCT - Used for development O-230809184819	✓	TST-101 5/15/2024		12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
#2874 TEST2	TESTPRODUCT - Used for development O-230809184819	✓	TST-101 5/15/2024		12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
#2936 TEST2	TESTPRODUCT2 - Used for development		TST-101 5/15/2023		12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>

29 items

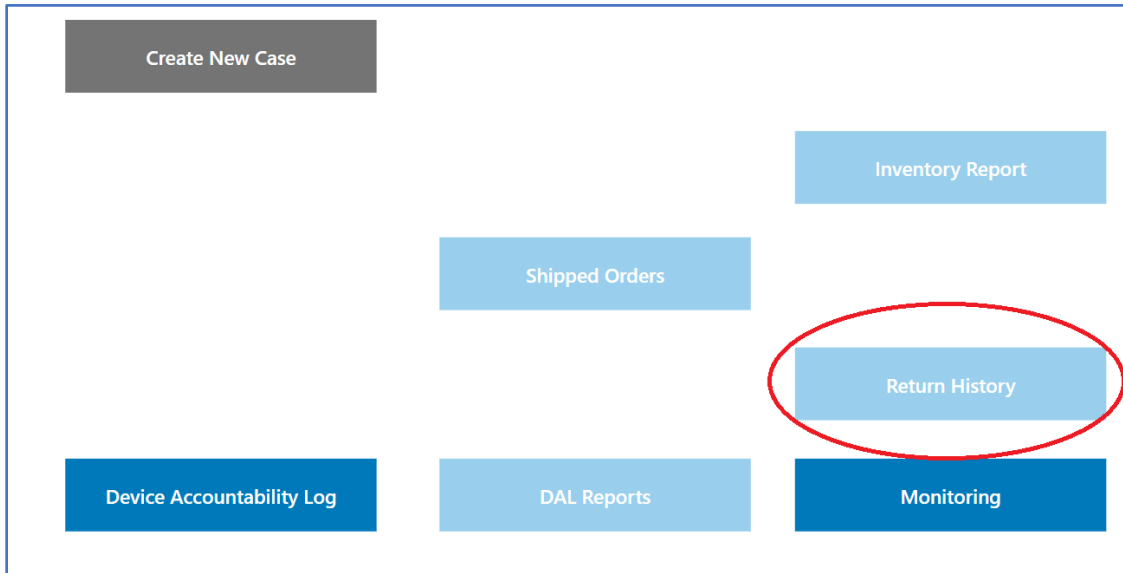
Site Number / Name
TEST2 - TEST2 National Health

By selecting this box, you confirm you have reviewed the above information. By electronically signing here, you accept that your electronic signature is the legally binding equivalent of your

Save Changes

5. How do I generate a report for returned products?

- Once Conformal Medical has confirmed receipt of the returned product, a RGA slip will be uploaded into the Device Accountability App that is available to download.
- Click “Return History” to view



You will be shown a list of available RGAs for viewing and download.

Note: RGAs initiated prior to August 2025 will not be available for download in the IP App.

Available RGA Documents

TEST1-TEST1 Regional Institute



Filter by RGA Number

TEST1 Regional Institute

RGA# 5555

Uploaded: Mar 31, 2025

5555

RGA# 08570

Uploaded: Mar 31, 2025

08570

2 found

Device Accountability App

Device Accountability Application

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I. PURPOSE

- The Device Accountability Application (“App”) serves as a platform to replace the paper Device Accountability. Through the App, sites can:
 - Request product
 - Confirm receipt of product
 - Update disposition of products
 - View reports for all orders, packing slips, and product returns
 - Generate and print device accountability log on demand
- Devices are requested from the Sponsor when there are upcoming CONFORM cases for patients who have been randomized to receive the CLAAS device.

II. GETTING STARTED

- To access the app, you will receive an email containing a link to the inventory tracking application
 - Each individual will create a unique Personal Login
- *Notes* on your unique Personal Login
 - Use your work email to receive App email notifications
 - For security reasons, your password should be different than your other accounts and sufficiently long using a combination of characters.
 - Do not share this password with others
 - Your unique Personal Login for the App is only accessible by you.
- ★ *Recommendation:* Though the app can be accessed via a Smartphone, it functions best in an internet browser on a computer. Any browser (Chrome, Safari, Explorer, etc.) will work.

III. GENERAL NAVIGATION

1. Only use navigation icons within the app. Do **NOT** use the back, home, undo, etc. buttons in your Internet browser.



2. Please remember to log out when you have completed all your work. *You will be logged out automatically after 20 minutes of inactivity -- any updates that have not been saved will be lost.*



3. Any time you select a date within the application, you will need to press Ok to enter that selection.

IV. LOGIN INSTRUCTIONS

If you are designated for access to the inventory tracking application, you will create a Personal Login for access to the functions within the program and track all activity. Please follow the steps below to create your account.

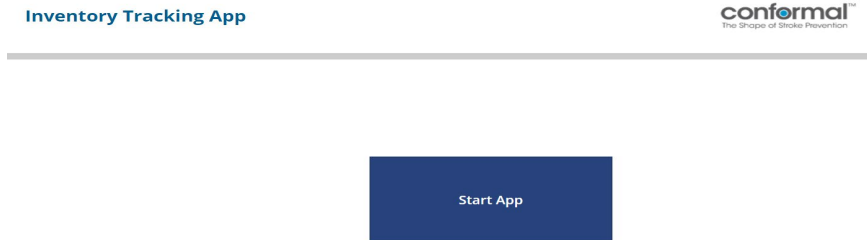
1. Access the link for the Conformal Device Accountability Application:

<https://apps.powerapps.com/play/9cf82348-8866-4c84-a989-02f032c8a64c?tenantId=17f64322-521f-4528-8001-aba3f775f131>

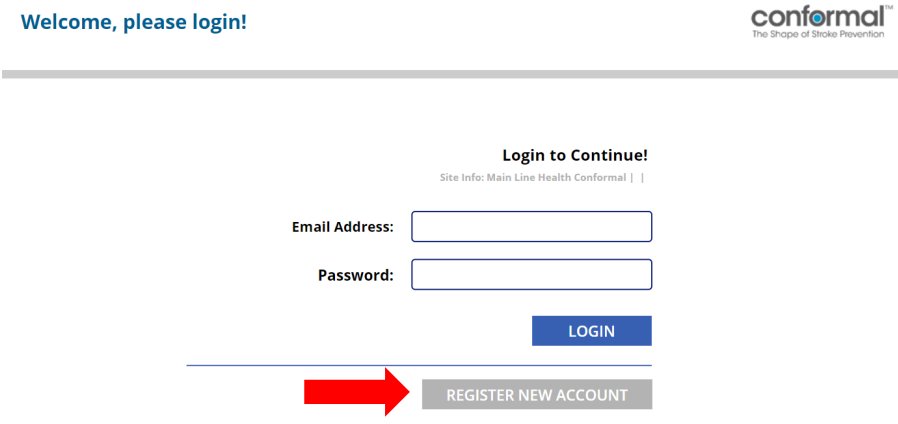


- *Recommendation:* Bookmark this page in your browser as “CONFORM Device Accountability App” for future use.

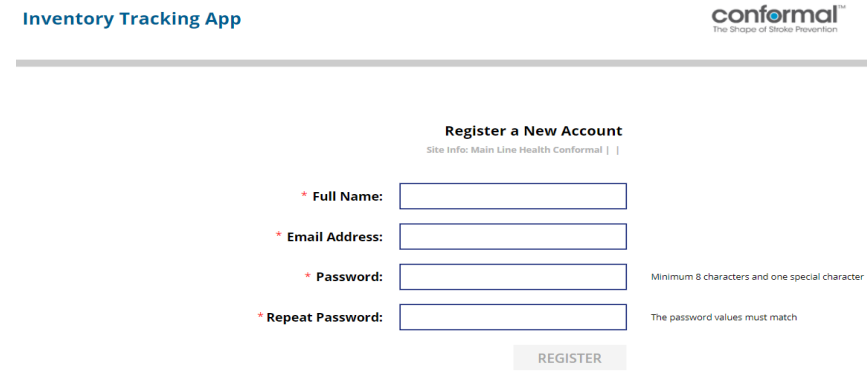
2. Press **Start App**



3. If this is your first time using the application, press the **Register New Account** button.
- If you have already created an account, then skip to step 7.



4. Complete the form with your name and email, and create a personal password for your Personal Login.
- It is recommended to use your work email
 - It is recommended to use a password that is not used anywhere else for security reasons.



Press [Register](#)

Inventory Tracking App

Register a New Account

Site Info: Main Line Health Conformal | |

* Full Name:

* Email Address: ✓

* Password: ✓

* Repeat Password: ✓



REGISTER

5. [Login](#) to receive product and update the device accountability log.

Welcome, please login!

Login to Continue!

Site Info: Main Line Health Conformal | |

Email Address:

Password:



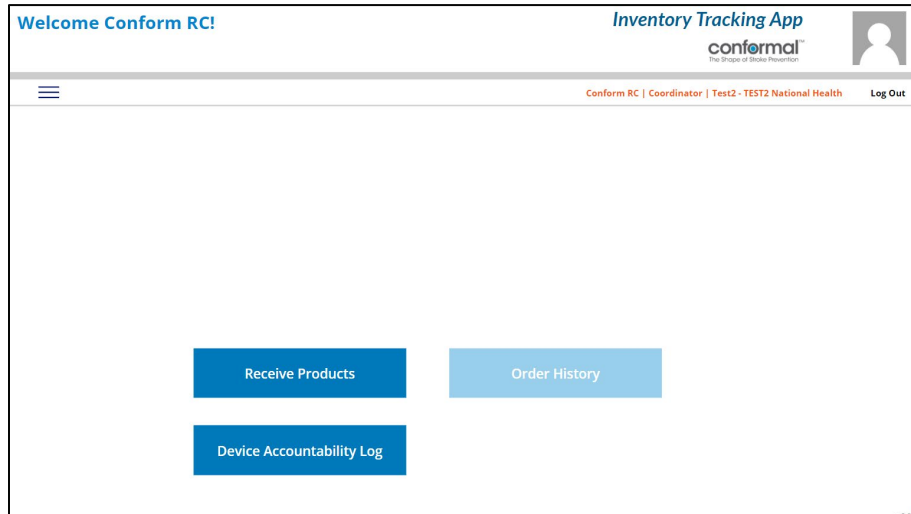
LOGIN

REGISTER NEW ACCOUNT

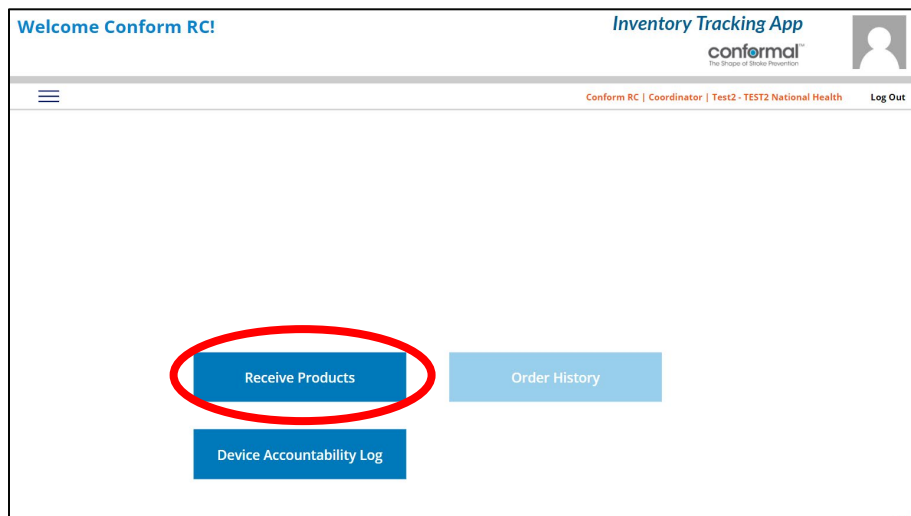
V. RECEIVE PRODUCT

Once logged into your account, follow these instructions to receive product.

1. This image shows the **Home Screen**



2. Click the button **Receive Products**



! *Note: Do NOT acknowledge receipt of order until ALL product is received on site.*

3. You will see the **Site Order Receipt Page**. This page consists of three sections:

- Left section: **Shipped Orders Panel**
- Middle section: **Product Panel**
- Right section: **Order Details Panel**

The screenshot shows the 'Site Order Receipt' page. The top navigation bar includes the 'conformal' logo, the user name 'David Houck | Coordinator | 21010 - Vanderbilt University Medical Center', and a 'Log Out' button. The main content area is divided into three panels:

- Shipped Orders Panel (Left):** Displays a list of shipped orders. One order is visible with details: O-220907094627, shipped on Sep 07, 2022, FEDEX 987654321. A large 'Shipped Orders' text overlay is present.
- Product Panel (Middle):** A table showing product details for the selected order. It has columns for 'Product', 'Shipped', and 'Received'.

Product	Shipped	Received	
27mm CLAAS Implant with Delivery S... 30-00214 / test1 rev A / 12/31/2024 O-220907094627	20	20	<input checked="" type="checkbox"/>
27mm Single Curve Access Sheath an... 30-00215 / test2 rev B / 12/31/2024 O-220907094627	5	5	<input checked="" type="checkbox"/>
27mm Single Curve Access Sheath an... 30-00215 / test2 rev A / 12/31/2024 O-220907094627	5	5	<input checked="" type="checkbox"/>
35mm Double Curve Access Sheath an... 30-00271 / test6 rev A / 12/31/2024 O-220907094627	5		<input checked="" type="checkbox"/>
- Order Details Panel (Right):** Shows details for the selected order, including 'Date Received' (9/8/2022), a toggle for 'Was product damaged upon receipt' (set to 'Yes'), and a section for 'Product Damage Details'. A large 'Order Details' text overlay is present.

At the bottom, there is a 'View Packing Slip' button and a 'Mark Order Received' button.

4. Orders that have been shipped to your site will be displayed on the left in the **Shipped Orders Panel**. The **Product Panel** and **Order Details Panel** will appear once you select your order.

- The O-## number is the Conformal Order#
- The tracking number and shipping date are displayed.
- Click on the order to populate the Product Panel.

This screenshot shows the 'Site Order Receipt' page with a red arrow pointing to an order in the 'Shipped Orders' panel. The order details are: O-220916100203, shipped on Sep 08, 2022, FEDEX 55553333. The 'Product Panel' and 'Order Details Panel' are currently empty, indicating that the selected order has not yet been expanded.

5. The **Product Panel** will populate in the middle section. The **Product Panel** contains information on the device type, lot number, and quantity
 - Confirm all product listed as shipped has been received by checking the boxes next to each line item.
 - Click the button “View Packing Slip” to view or print the packing slip for the order. Note that signatures should be completed electronically within the app. Electronic signature with the Device Accountability App is 21 CFR Part 11 compliant and can be used in place of wet signature of the paper Device Packing Slip (F-50) form upon product receipt.

The screenshot displays the 'Site Order Receipt' interface. At the top, the Conformal logo and user information 'David Houck | Coordinator | 21010 - Vanderbilt University Medical Center' are visible. The main content is divided into three sections:

- Shipped Orders:** Shows a list of orders with details like 'O-220907094627' and 'shipped on: Sep 07, 2022'. A 'View Packing Slip' button is located below this section.
- Product Panel:** A table listing products with columns for 'Product', 'Shipped', and 'Received'. Each row includes a checkbox for marking the order as received.


Product	Shipped	Received	Action
27mm CLAAS Implant with Delivery S... 30-00214 / test1 rev A / 12/31/2024 O-220907094627	20	20	<input checked="" type="checkbox"/>
27mm Single Curve Access Sheath an... 30-00215 / test2 rev B / 12/31/2024 O-220907094627	5	5	<input checked="" type="checkbox"/>
27mm Single Curve Access Sheath an... 30-00215 / test2 rev A / 12/31/2024 O-220907094627	5	5	<input checked="" type="checkbox"/>
35mm Double Curve Access Sheath a... 30-00271 / test6 rev A / 12/31/2024 O-220907094627	5	5	<input checked="" type="checkbox"/>
- Order Details:** Includes fields for 'Date Received' (9/8/2022), a toggle for 'Was product damaged upon receipt' (set to Yes), and a text area for 'Product Damage Details' containing 'Box was opened'. A 'Mark Order Received' button is at the bottom right.

6. The **Order Details Panel** will populate in the right section. The **Order Details Panel** contains the date of receipt, an option to select if any product was damaged, and the option to mark order as received.
 - Confirm the correct date that product is received.
 - * Default value will always be the current date.
 - Check if any product box was damaged. Default value is No.
 - * Toggle to Yes if damaged and enter details in the box below.
 - **IF ALL PRODUCT** in the order has been received, then click on the **Mark Order Received** button.
 - **IF PARTIAL PRODUCT** has been received (i.e., half the order has been received on site), please do not click on Mark Order Reviewed. Wait until all packages have arrived. If part of the shipment is delayed or missing, please contact your Site Manager.

The screenshot displays the 'Site Order Receipt' interface. On the left, a table lists 'Shipped Orders' with columns for 'Product', 'Shipped', and 'Received'. The table contains three rows of product information, each with input fields for quantity and a checkbox for receipt status. On the right, the 'Order Details' panel is visible, featuring a 'Date Received' field set to '9/8/2022', a toggle for 'Was product damaged upon receipt' set to 'Yes', and a text area for 'Product Damage Details' containing the text 'Box was opened'. At the bottom right of the details panel is a blue button labeled 'Mark Order Received'.

Product	Shipped	Received	Receipt Status
27mm CLAAS Implant with Delivery S... 30-00214 / test1 rev A / 12/31/2024 O-220907094627	20	20	<input checked="" type="checkbox"/>
27mm Single Curve Access Sheath an... 30-00215 / test2 rev B / 12/31/2024 O-220907094627	5	5	<input checked="" type="checkbox"/>
27mm Single Curve Access Sheath an... 30-00215 / test2 rev A / 12/31/2024 O-220907094627	5	5	<input checked="" type="checkbox"/>
35mm Double Curve Access Sheath a... 30-00271 / test6 rev A / 12/31/2024 O-220907094627	5	5	<input checked="" type="checkbox"/>

7. After an order has been marked received or if there are no current orders for your site, the following message will be displayed.

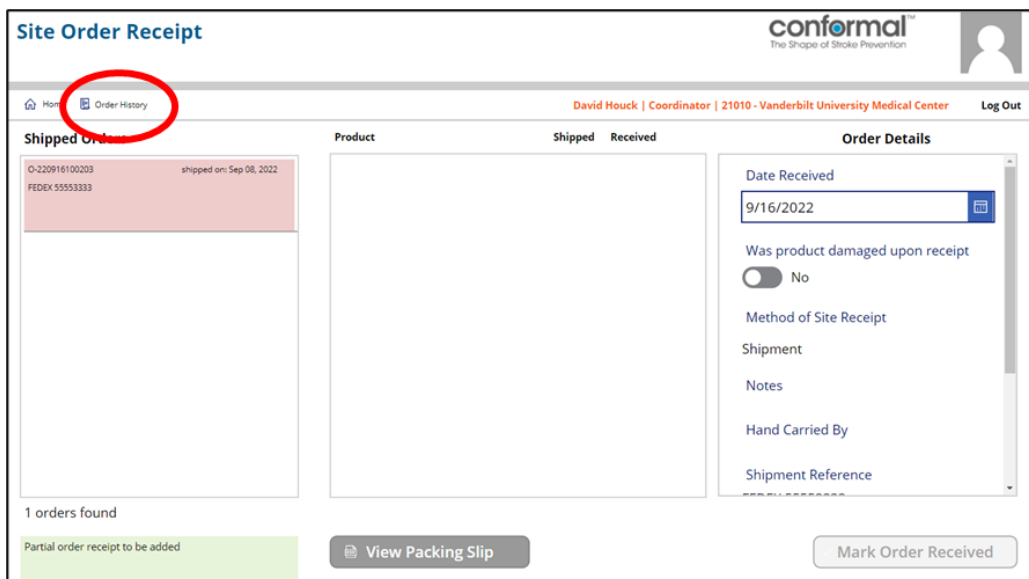
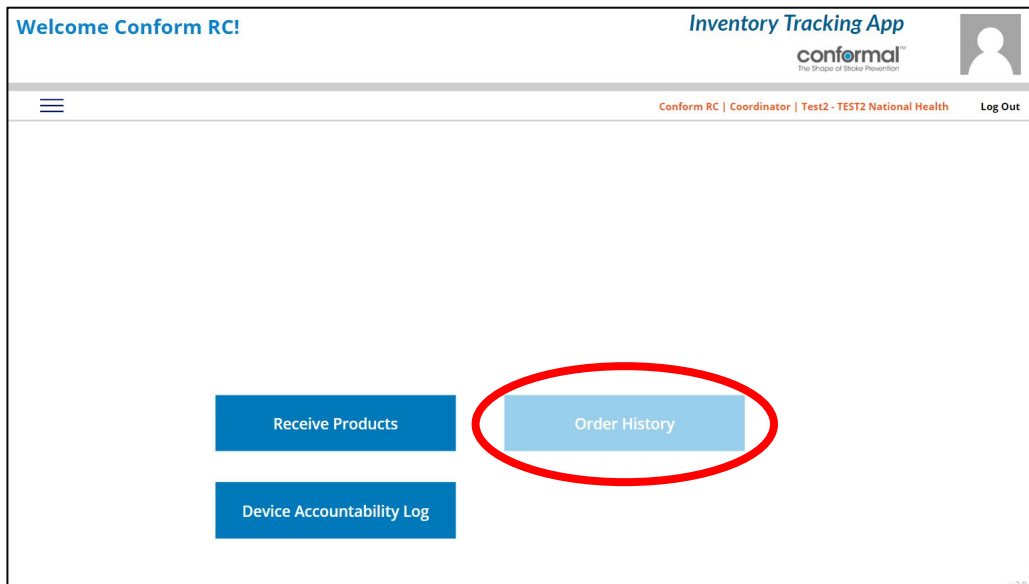
Site Order Receipt **conformal**TM
The Shape of Stroke Prevention 

[Home](#) [Order History](#) David Houck | Admin | 21010 - Vanderbilt University Medical Center [Log Out](#)

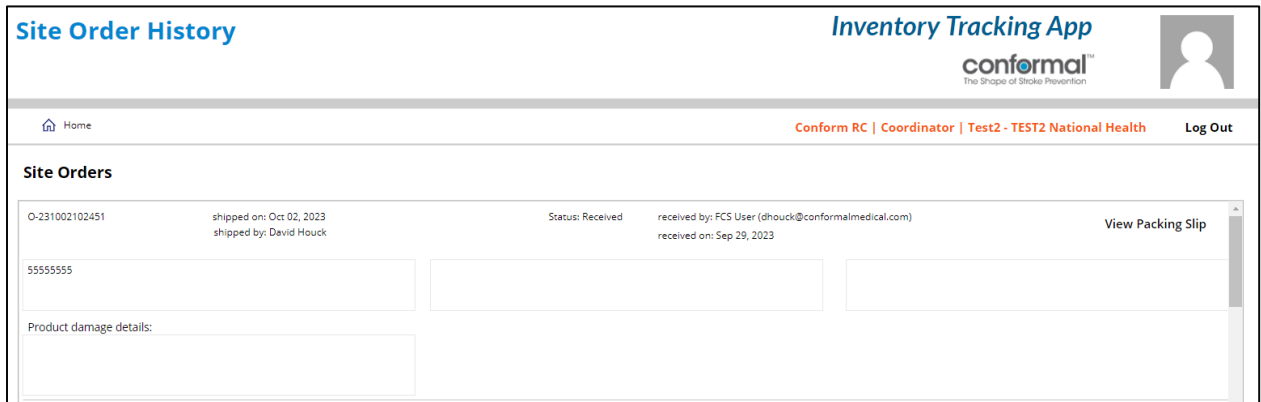
No orders available for receipt.

VI. VIEW ORDER HISTORY

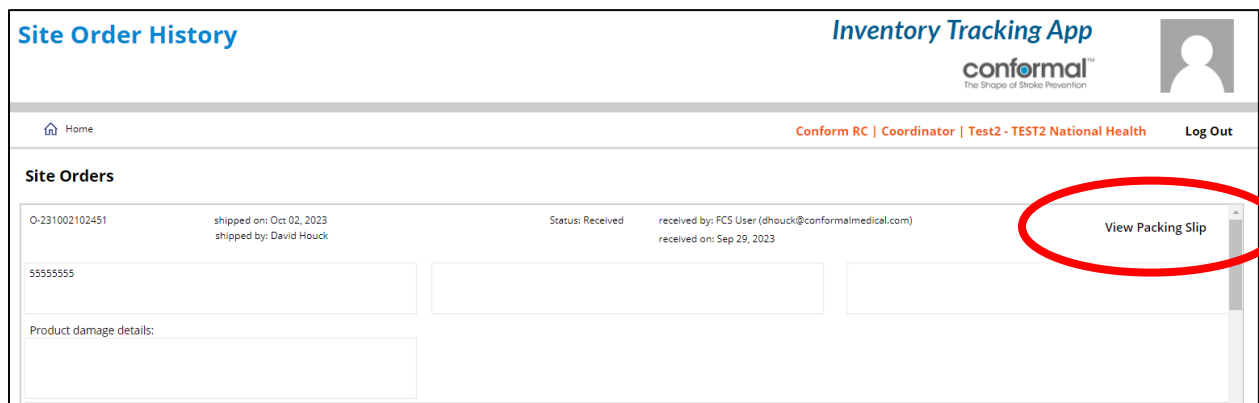
1. From the **Home Screen**, Select the button **Order History** OR from the **Site Order Receipt Screen**, Select the button **Order History**



2. Review all orders that have been processed at your site.
 - Order number
 - Shipping date
 - Status
 - Date received
 - Who received the order
 - Additional comments entered at time of receipt

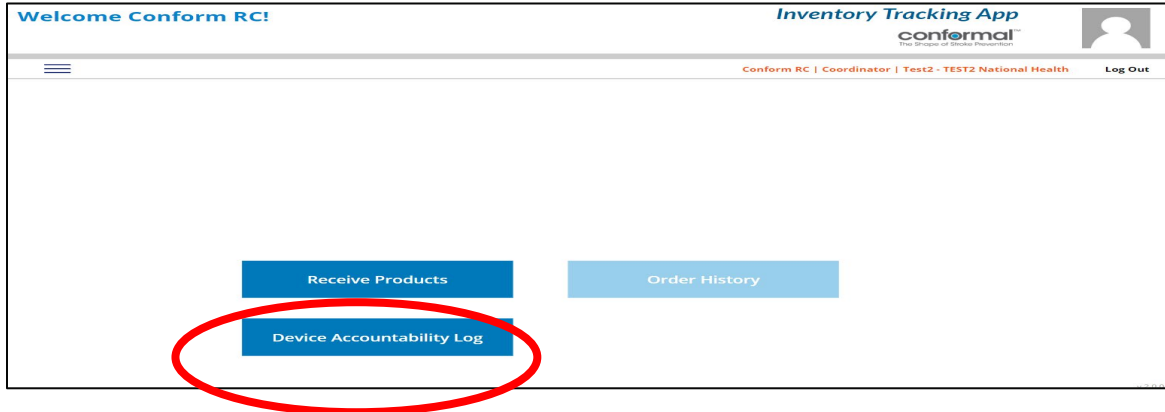


3. View the packing slip associated with the order. You will only be able to view orders associated with your site.



VII. DEVICE ACCOUNTABILITY LOG

- From the **Home Screen**, click **Disposition Update** to update the **Device Accountability Log (DAL)**.



- The **DAL** is automatically populated after you have marked an order as received. Each product received will be displayed as its own line item. The default view will show only unused product at your site. The total number is listed at the bottom.

The screenshot shows the 'Device Accountability Log / Disposition Update' screen. It features a table with columns for Unique ID, Product Code, Query/Monitor Status, Lot#, Expiry Date, Subject ID, Disposition, Date, Deficient, Used, Disposed, Returned, RGA, Transferred, and Other. A red arrow points to the 'Disposition' column. At the bottom, there is a 'Save Changes' button and a confirmation checkbox.

Unique ID Site Id	Product Code Description Order#	Query/Monitor Status	Lot# Expiry Date	Subject ID	Disposition	Date	Deficient	Used	Disposed	Returned	RGA	Transferred	Other
#2872 TEST2	TESTPRODUCT - Used for development O-230809184819		TST-101 5/15/2023			12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>
#2873 TEST2	TESTPRODUCT - Used for development O-230809184819	✓	TST-101 5/15/2023			12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>
#2874 TEST2	TESTPRODUCT - Used for development O-230809184819	✓	TST-101 5/15/2023			12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>
#3281 TEST2	TESTPRODUCT - Used for development O-231002102451		TST-101 5/15/2024			12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>
#3282 TEST2	TESTPRODUCT - Used for development O-231002102451		TST-101 5/15/2024			12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>
#3221 TEST2	TESTPRODUCT - Used for development O-230912173804		TST-101 5/15/2024			12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>
#3222 TEST2	TESTPRODUCT - Used for development O-230912173804		TST-101 5/15/2024			12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>
#3223 TEST2	TESTPRODUCT - Used for development		TST-101 5/15/2024			12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>

Site Number / Name: -

By selecting this box, you confirm you have reviewed the above information. By electronically signing here, you accept that your electronic signature is the legally binding equivalent of your signature.

Save Changes

3. Search feature:

- Use the **Search Feature** at the top right of the screen to search by any terms used in the top line of the first three displayed columns: Product Code, Description, and Lot Number
- * The filter will automatically update as you type in the search term.
- * The number of unused items for that term will be displayed at the bottom of the table

Device Accountability Log / Disposition Update *Inventory Tracking App*

Study: Conform Pivotal **conformal**TM
The Shape of Stroke Prevention

Home Refresh Inventory Generate Report Show Queries Show Disposed Conform RC | Coordinator | Test2 - TEST2 National Health Log Out

Unique ID Site Id	Product Code Description Order#	Query/Monitor Status	Lot# Expiry Date	Subject ID	Disposition Date	Deficient	Used	Disposed	Returned	RGA	Transferred	Other
#3250 TEST2	TESTPRODUCT2 - Used for development O-230925081411		TST-201 5/15/2024		12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>
#3251 TEST2	TESTPRODUCT2 - Used for development O-230925081411		TST-201 5/15/2024		12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>
#3252 TEST2	TESTPRODUCT2 - Used for development O-230925081411		TST-201 5/15/2024		12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>
#3253 TEST2	TESTPRODUCT2 - Used for development O-230925081411		TST-201 5/15/2024		12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>
#3226 TEST2	TESTPRODUCT2 - Used for development O-230912173804		TST-201 5/15/2024		12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>
#3227 TEST2	TESTPRODUCT2 - Used for development O-230912173804		TST-201 5/15/2024		12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>
#3228 TEST2	TESTPRODUCT2 - Used for development O-230912173804		TST-201 5/15/2024		12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>
#3245 TEST2	TESTPRODUCT2 - Used for development		TST-201 5/15/2024		12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>

9 items

Site Number / Name

By selecting this box, you confirm you have reviewed the above information. By electronically signing here, you accept that your electronic signature is the legally binding equivalent of your

Save Changes

4. Click the **Show Disposed** box to display all product that has already been given a disposition. You can limit the display to products with a disposition date in a defined window:

- 30 days
- 90 days
- 180 days
- All

Device Accountability Log / Disposition Update *Inventory Tracking App*

Study: Conform Pivotal **conformal**TM
The Shape of Stroke Prevention

Home Refresh Inventory Generate Report Show Queries **Show Disposed** all Conform RC | Coordinator | Test2 - TEST2 National Health Log Out

Unique ID Site Id	Product Code Description Order#	Query/Monitor Status	Lot# Expiry Date	Subject ID	Disposition Date	Deficient	Used	Disposed	Returned	RGA	Transferred	Other
#2931 TEST2	TESTPRODUCT - Used for development O-230809185754		TST-101 5/15/2023	020	9/6/2023	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	450		FedEx on 9/6/23 55555555
#2932 TEST2	TESTPRODUCT - Used for development O-230809185754		TST-101 5/15/2023	111	9/12/2023	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
#2933 TEST2	TESTPRODUCT - Used for development O-230809185754		TST-101 5/15/2023	007	8/10/2023	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
#2866 TEST2	TESTPRODUCT - Used for development O-230809184819		TST-101 5/15/2023	001	8/9/2023	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			

5. Additional filters:

- Additional filters can be added for type of disposition. Click on the filter icon next to the disposition column.
- If a disposition of Returned has been selected, you will be required to enter an RGA number.
 - * Please reach out to your Site Manager for an RGA number
- ★ *Tip:* Use the Other box to enter a return date and tracking number for all returned product.

The screenshot shows the 'Device Accountability Log / Disposition Update' interface. The table contains the following data:

Unique ID Site Id	Product Code Description Order#	Query/ Monitor Status	Lot# Expy Date	Subject ID	Disposition Date	Deficient	Used	Disposed	Returned	RGA	Transferred	Other
#3254 TEST2	TESTPRODUCT3 - Used for development O-230925081411		TST-301 5/15/2024	020	9/25/2023	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	RGAs	<input type="checkbox"/>	
#3147 TEST2	TESTPRODUCT3 - Used for development O-230912173906		TST-301 5/15/2024	003	10/2/2023	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	225	<input type="checkbox"/>	fedex on 10/2/2023 5555555

6. If a **Subject ID** is entered, a disposition must be selected to save the record. This error message will appear if no disposition is selected.

The screenshot shows the same interface as above, but with a validation error message box overlaid on the table. The error message reads:

Validation Errors: 2

- #2932 - TESTPRODUCT - TESTPRODUCT - Used for development
A disposition option must be selected if a subject ID was specified.
- #2932 - TESTPRODUCT - TESTPRODUCT - Used for development
At least one option must be selected for disposed items.

The table data is partially obscured by the error box, but the following records are visible:

Unique ID Site Id	Product Code Description Order#	Query/ Monitor Status	Lot# Expy Date	Subject ID	Disposition Date	Deficient	Used	Disposed	Returned	RGA	Transferred	Other
#2931 TEST2	TESTPRODUCT - Used for development O-230809185754		TST-101 9/15/2023	020	9/6/2023	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	450	<input type="checkbox"/>	FedEx on 9/6/23 55555555
#2932 TEST2	TESTPRODUCT - Used for development O-230809185754		TST-101 9/15/2023	111	9/12/2023	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	
#2933 TEST2	TESTPRODUCT - Used for development O-230809185754		TST-101 9/15/2023	007	8/10/2023	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	
#2866 TEST2	TESTPRODUCT - Used for development O-230809184819	<input checked="" type="checkbox"/>	TST-101 9/15/2023	001	8/9/2023	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	
#2867 TEST2	TESTPRODUCT - Used for development O-230809184819		TST-101 9/15/2023	002	8/9/2023	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	
#2868 TEST2	TESTPRODUCT - Used for development O-230809184819		TST-101 9/15/2023	002	8/9/2023	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	
#2869 TEST2	TESTPRODUCT - Used for development O-230809184819	<input type="checkbox"/>	TST-101 9/15/2023		8/10/2023	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	
#2870 TEST2	TESTPRODUCT - Used for development		TST-101 9/15/2023	003	8/10/2023	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	

7. Updating Disposition

- a. A **Disposition Date** is required if any disposition is selected
- b. Any dispositions may be selected together (i.e., Used, Disposed)
 - i. Exception: You cannot select both “Disposed” and “Returned”

Device Accountability Log / Disposition Update

Study: Conform Pivotal

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Product Code Site Id	Description Order#	Lot# Expy Date	Subject ID	Disposition Date	Deficient	Used	Disposed	Returned	Other
30-00214 21010	27mm CLAAS Implant with Delivery System O-220907094627	test1 12/31/2024	005	12/31/2001	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30-00214 21010	27mm CLAAS Implant with Delivery System O-220907094627	test1 12/31/2024		12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30-00214 21010	27mm CLAAS Implant with Delivery System O-220907094627	test1 12/31/2024		12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30-00214 21010	27mm CLAAS Implant with Delivery System O-220907094627	test1 12/31/2024		12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30-00214 21010	27mm CLAAS Implant with Delivery System O-220907094627	test1 12/31/2024		12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30-00214 21010	27mm CLAAS Implant with Delivery System O-220907094627	test1 12/31/2024		12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30-00214 21010	27mm CLAAS Implant with Delivery System O-220907094627	test1 12/31/2024		12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30-00214 21010	27mm CLAAS Implant with Delivery System O-220907094627	test1 12/31/2024		12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

35 items

Site Number / Name: 21010 - Vanderbilt University Medical Center

By selecting this box, you confirm you have reviewed the above information. By electronically signing here, you accept that your electronic signature is the legally binding equivalent of your signature.

Update Disposition

Device Accountability Log / Disposition Update

Study: Conform Pivotal

Conform RC | Coordinator | Test2 - TEST2 National Health

Unique ID Site Id	Product Code Description Order#	Query/Monitor Status	Lot# Expy Date	Subject ID	Disposition Date	Deficient	Used	Disposed	Returned	RGA	Transferred	Other
#2872 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-230809184819		TST-101 5/15/2023		12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>
#2873 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-230809184819	✓	TST-101 5/15/2023		12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>
#2874 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-230809184819	✓	TST-101 5/15/2023		12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>
#3201 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-231002102451		TST-101 5/15/2024	001	12/31/2001	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>
#3202 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-231002102451		TST-101 5/15/2024		12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>
#3221 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-230912173804		TST-101 5/15/2024		12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>
#3222 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-230912173804		TST-101 5/15/2024		12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>
#3223 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development		TST-101 5/15/2024		12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>

37 items

Site Number / Name: -

By selecting this box, you confirm you have reviewed the above information. By electronically signing here, you accept that your electronic signature is the legally binding equivalent of your signature.

Save Changes

8. Sign Off

- a. Sign off DAL updates by selecting the box at the bottom of the log.
- b. By selecting this box, you confirm you have reviewed the above information. *By electronically signing here, you accept that your electronic signature is the legally binding equivalent of your handwritten signatures and recognize that it is prohibited to share your username and password or any other components of your signature (21CFR11.100) and are submitting this information.*



#3282 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-231002102451	TST-101 5/15/2024	<input type="text" value="12/31/2001"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
#3221 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-230912173804	TST-101 5/15/2024	<input type="text" value="12/31/2001"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
#3222 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-230912173804	TST-101 5/15/2024	<input type="text" value="12/31/2001"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
#3223 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-230912173804	TST-101 5/15/2024	<input type="text" value="12/31/2001"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

37 items

Site Number / Name

By selecting this box, you confirm you have reviewed the above information. By electronically signing here, you accept that your electronic signature is the legally binding equivalent of your

Save Changes

- c. The first time in a session, you will be prompted to login again with your unique user ID to acknowledge acceptance of your electronic signature.

Device Accountability Log / Disposition Update Inventory Tracking App

Study: Conform Pivotal conformalTM
The Shape of Stroke Prevention

Home Refresh Inventory Generate Report Show Queries Show Disposed Conform RC | Coordinator | Test2 - TEST2 National Health Log Out

Unique ID Site Id	Product Code Description Order#	Query/ Monitor Status	Lot# Expy Date	Transferred	Other
#2872 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-230809184819		TST-101 5/15/2023	<input type="checkbox"/>	<input type="checkbox"/>
#2873 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-230809184819	✓	TST-101 5/15/2023	<input type="checkbox"/>	<input type="checkbox"/>
#2874 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-230809184819	✓	TST-101 5/15/2023	<input type="checkbox"/>	<input type="checkbox"/>
#3281 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-231002102451		TST-101 5/15/2024	<input type="checkbox"/>	<input type="checkbox"/>
#3282 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-231002102451		TST-101 5/15/2024	<input type="checkbox"/>	<input type="checkbox"/>
#3221 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-230912173804		TST-101 5/15/2024	<input type="checkbox"/>	<input type="checkbox"/>
#3222 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-230912173804		TST-101 5/15/2024	<input type="checkbox"/>	<input type="checkbox"/>
#3223 TEST2	TESTPRODUCT - TESTPRODUCT - Used for development O-230912173804		TST-101 5/15/2024	<input type="checkbox"/>	<input type="checkbox"/>

37 items

Site Number / Name

Login to Continue!

Conform RC
Test2 | TEST2 National Health

Email Address:

Password:

LOGIN

By selecting this box, you confirm you have reviewed the above information. By electronically signing here, you accept that your electronic signature is the legally binding equivalent of your

Save Changes

- d. You will only be asked for the additional login once per session. Additional changes will only require you to check the box and press the **Save Changes** button.
- e. After checking the box and/or completing login, the **Save Changes** button will become active to submit the updates.

9. Monitoring

- a. A unique ID will be assigned to each inventory line in the Device Accountability Log. This number is used only for reference in the log and will not be found on package labels or packing slips.

#2873 TEST2	TESTPRODUCT - Used for development O-230809184819	TST-101 5/15/2023	<input type="text" value="12/31/2001"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
#2874 TEST2	TESTPRODUCT - Used for development O-230809184819	TST-101 5/15/2023	<input type="text" value="12/31/2001"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
#2871 TEST2	TESTPRODUCT - Used for development O-231002102451	TST-101 5/15/2023	<input type="text" value="last modified by (dhouck@conformalmedical.com)"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- b. A monitoring status will be displayed for each line item in the log.

Device Accountability Log / Disposition Update Inventory Tracking App

Study: Conform Pivotal conformal™
The Shape of Stroke Prevention

Home Refresh Inventory Generate Report Show Queries Show Disposed Conform RC | Coordinator | Test2 - TEST2 National Health Log Out

Unique ID Site Id	Product Code Description Order#	Query/ Monitor Status	Lot# Expiry Date	Subject ID	Disposition Date	Deficient	Used	Disposed	Returned	RGA	Transferred	Other
#2872 TEST2	TESTPRODUCT - Used for development O-230809184819	<input checked="" type="checkbox"/>	TST-101 5/15/2023	<input type="text" value=""/>	<input type="text" value="12/31/2001"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
#2873 TEST2	TESTPRODUCT - Used for development O-230809184819	<input checked="" type="checkbox"/>	TST-101 5/15/2023	<input type="text" value=""/>	<input type="text" value="12/31/2001"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- i. Blank – No status yet
- ii. - Confirmed status
- iii. - Monitored status
- iv. - Open Query
- v. - Responded to Query

- c. Queries – queries can be opened by a site monitor. You will be able to filter inventory items by open queries. Click on the query icon to access the query and respond.

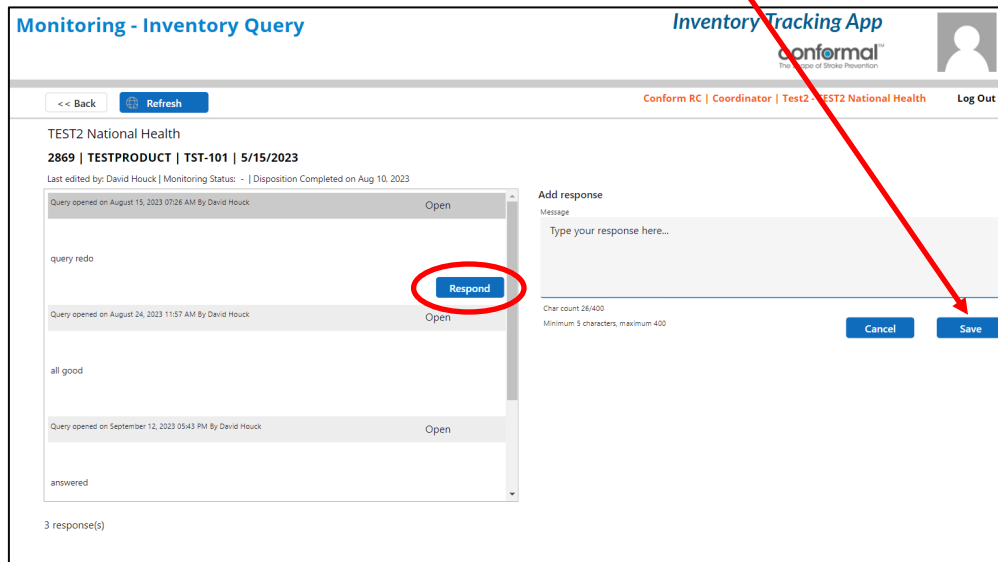
Device Accountability Log / Disposition Update Inventory Tracking App

Study: Conform Pivotal conformal™
The Shape of Stroke Prevention

Home Refresh Inventory Generate Report **Show Queries** Show Disposed Conform RC | Coordinator | Test2 - TEST2 National Health Log Out

Unique ID Site Id	Product Code Description Order#	Query/ Monitor Status	Lot# Expiry Date	Subject ID	Disposition Date	Deficient	Used	Disposed	Returned	RGA	Transferred	Other
#2869 TEST2	TESTPRODUCT - Used for development O-230809184819	<input type="checkbox"/>	TST-101 5/15/2023	<input type="text" value=""/>	<input type="text" value="8/10/2023"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="text" value="555"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
#2876 TEST2	TESTPRODUCT2 - Used for development O-230809184819	<input type="checkbox"/>	TST-101 5/15/2023	<input type="text" value="003"/>	<input type="text" value="8/10/2023"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

You can click on the **Respond** button to enter your response. Then click save.



**** Note that it may take up to 15 minutes for the query icon to be updated after a response is entered.**

VIII. GENERATE REPORTS

- To generate or print a **Device Accountability Log Report**, press the Generate Report icon in the menu bar.

Device Accountability Log / Disposition Update

Study: Conform Pivotal

Home Refresh Inventory **Generate Report** Show Disposed

David Houck | Coordinator | 21010 - Vanderbilt University Medical Center Log Out

Product Code Site Id	Description Order#	Lot# Expy Date	Subject ID	Disposition Date	Deficient	Used	Disposed	Returned	Other
30-00214 21010	27mm CLAA5 Implant with Delivery System O-220907094627	test1 12/31/2024	<input type="text"/>	12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30-00214 21010	27mm CLAA5 Implant with Delivery System O-220907094627	test1 12/31/2024	<input type="text"/>	12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30-00214 21010	27mm CLAA5 Implant with Delivery System O-220907094627	test1 12/31/2024	<input type="text"/>	12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30-00214 21010	27mm CLAA5 Implant with Delivery System O-220907094627	test1 12/31/2024	<input type="text"/>	12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30-00214 21010	27mm CLAA5 Implant with Delivery System O-220907094627	test1 12/31/2024	<input type="text"/>	12/31/2001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- Device Accountability Log Reports** can be generated at any time.
 - Reports will default to include all dates, but a date range may be specified to only report updates done in that timeframe.
 - If the **Disposition Completed** box is not checked then all product, used or unused, will be included in the report.
 - If the **Disposition Completed** box is checked, then unused product will be excluded from the report.
 - If the **Exclude Monitored** box is checked, then product that has the “Monitored” status will be excluded from the report.
 - All generated reports will be saved in the list and may be viewed by clicking on the **View Report** link. Reports will be organized from most recent on top to oldest.

Device Accountability Log Report

Inventory Tracking App

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Back Conform RC | Coordinator | Test2 - TEST2 National Health Log Out

1/1/2022 10/3/2023 Clear Dates

Disposition Completed Exclude Monitored **Generate Report**

Previously Generated Reports

TEST2_DAL_20231002070928	October 02, 2023	Developer	View Report
TEST2_DAL_20230913022941	September 13, 2023	Developer	View Report

Refresh Document List

Patient Implant Card

Patient Implant Card

The current version of the Patient Implant Card is located in the front pocket of every Subject Binder shipped to your site. If you cannot locate, please contact your Site Manager.

1.1 Does every patient need a patient implant card?

- Any patient who receives the CLAAS® implant index procedure should receive a patient implant card. For patients who receive the CONTROL procedure, please follow the instructions per the Manufacturer.

2.1 When do I provide the patient with their patient implant card?

- The patient implant card should be provided to the subject after the procedure and prior to discharge.

3.1 Do I need to fill out the patient implant card before I give it to the subject?

- Yes. All fields should be completed prior to providing to implant card to the subject. Be sure to clearly note the Lot Number of the implant.

4.1 Who do I ask for more patient implant cards?

- If you need more patient implant cards, your visiting Field Clinical Specialist may have more. Otherwise, please reach out to your Site Manager.

5.1 If the subject was an intent to treat for CLAAS® but did not receive an implant, do they still require a Patient Implant Card?

- If the patient did not receive an implant, they do not need a patient implant card.

Protocol Deviations

1. Documenting and Recording Protocol Deviations

Subject Related Protocol Deviations:

- Should be recorded in the visit notes in the medical records or documented on the Protocol Deviation Source Worksheet.
 - If utilizing the source worksheet, capture one deviation per form.
- Deviation-related source documents should be filed in the subject binder, as applicable.
- Enter deviation(s) into the EDC System.

2. Reporting Protocol Deviations – Site Responsibility

2.1 How do I Report Protocol Deviations to the Sponsor?

- Should a protocol deviation occur during the study, Site should report the protocol deviation to the following:

eCRF in EDC (Medidata)

IRB, if applicable

- Please refer to both your site’s IRB Guidelines and your site’s SOPs for reporting protocol deviations.
- If uncertain, please discuss with the IRB and Sponsor.

3. Common Protocol Deviations

Protocol Deviation	Recommendation to Avoid Future Deviations
<u>Follow-Up Visit:</u> <ul style="list-style-type: none"> • Completed before or after window • Missed entirely 	<ul style="list-style-type: none"> • Work with your site manager to review scheduled visits. • Try to schedule visits at the beginning of the follow-up window. In the event subject calls to reschedule or misses the visit, this will give time to reschedule a new visit within window.
<u>Assessments and Laboratory Tests:</u> <ul style="list-style-type: none"> • Completed before or after window • Not Done 	<ul style="list-style-type: none"> • Review the testing required for that visit. If a clinic nurse or separate lab is performing the test, ensure they are aware of the requirements.
<u>Study Assessments</u> <ul style="list-style-type: none"> • Completed before or after window • Not Done 	<ul style="list-style-type: none"> • Make every attempt to perform study assessments in window via an in-office visit or by phone as required. • If for some reason an office visit is required but not possible, proceed with a telehealth or phone visit.
<u>Subject Informed Consent:</u> <ul style="list-style-type: none"> • Not collected/documentated appropriately 	<ul style="list-style-type: none"> • Review signed ICF prior to performing study-specific procedures. • Ensure the most current ICF version clearly labeled and available.

	<ul style="list-style-type: none"> If your IRB requires initials/dates on each page, review each page to ensure completed
<p><u>Study Medications</u></p> <ul style="list-style-type: none"> Dose changed or stopped sooner than 6 months post-procedure, per protocol 	<ul style="list-style-type: none"> Document reason for medication deviation and store source documentation in patient binder.
<p><u>Adverse Event (AE) Reporting</u></p>	<ul style="list-style-type: none"> AE: Enter in EDC (and optionally, complete source worksheet) as soon as possible, but no later than 10 working days from the date of awareness. <ul style="list-style-type: none"> Note: adverse event source should be signed off by PI. SAE: Notify Sponsor within 2 working days in EDC UADE: Notify Sponsor within 2 working days in EDC

4. Deviation from Protocol Deemed Necessary by PI

- PIs may deem a deviation from the protocol to be necessary to protect the safety and/or physical well-being of a subject.
- PI is requested to notify Sponsor as soon as possible and IRB/REB if required.
- This deviation is still required to be reported through the EDC

AE Adjudication Module

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1. CONFORM Pivotal Medidata Adjudicate

- 1.1.** All Source documentation required to support review of an AE/SAE will be uploaded via Medidata Adjudicate.

2. Medidata Adjudicate FAQ

2.1. Do I have to submit source documentation for every AE/SAE that occurs?

- 2.1.1.** No. You only need to upload source documentation for events that are selected by the CONFORM Pivotal Clinical Events Committee (CEC).

2.2. How will I be notified when source document upload is required?

- 2.2.1.** You will be notified directly by the NAMSAs Safety team via query in EDC. Your Site Manager may also do some follow up with you if needed.

2.3. Do I need to create an Adjudication “Visit/Event” (Visit) for each AE I enter?

- 2.3.1.** No. Medidata Adjudicate will **automatically** create a Visit homepage for each AE entered into Medidata Rave.

- 2.3.1.1.** The Visit number created will correlate directly to the AE number from the AE/SAE created in Medidata Rave.

- 2.3.1.2.** It is important that you **do not create a Visit in Medidata Adjudicate** unless instructed to do so.

2.4. Do I have to redact all Protected Health Information (PHI) from source data?

- 2.4.1.** Yes. All subject PHI should be removed from all source documents. You can redact PHI by hand, or you can use the redaction tools in Medidata Adjudicate after each source document is uploaded (procedure is reviewed in **section 5**).

- 2.4.2.** If PHI is accidentally included in the uploaded source documentation, the documentation will be removed from Medidata Adjudicate and you will be contacted by the NAMSAs Safety team to remove the PHI and upload the documents again. See section 5 for instructions on using the redaction tools within Medidata.

2.5. If subject has multiple AE/SAE's, do I have to resend all baseline and procedural source documentaion?

2.5.1. No. If a subject has multiple events, you only need to submit the baseline and procedural source documentation with the first event. For all subsequent events, you will only need to submit documentation specific to that event. Communication regarding source documents may come from your site manager, your monitor or from conformalsupport@namsa.com.

2.6. If a subject has multiple AE/SAE's that share source documentation (for example all AE/SAE's occur during the same hospitalization) does source documentation have to be entered into all correlating Visits listed individually on the Medidata Adjudicate page?

2.6.1. No. If there is a circumstance where multiple AE's entered share the same source documentation, that source documentation only needs to be entered one time under one event visit folder. Communication regarding source documents may come from the NAMSAs Safety Team via query in Medidata Adjudicate or email (conformalsupport@namsa.com).

2.7. Do I submit requested imaging related to an AE in the Medidata Adjudication portal?

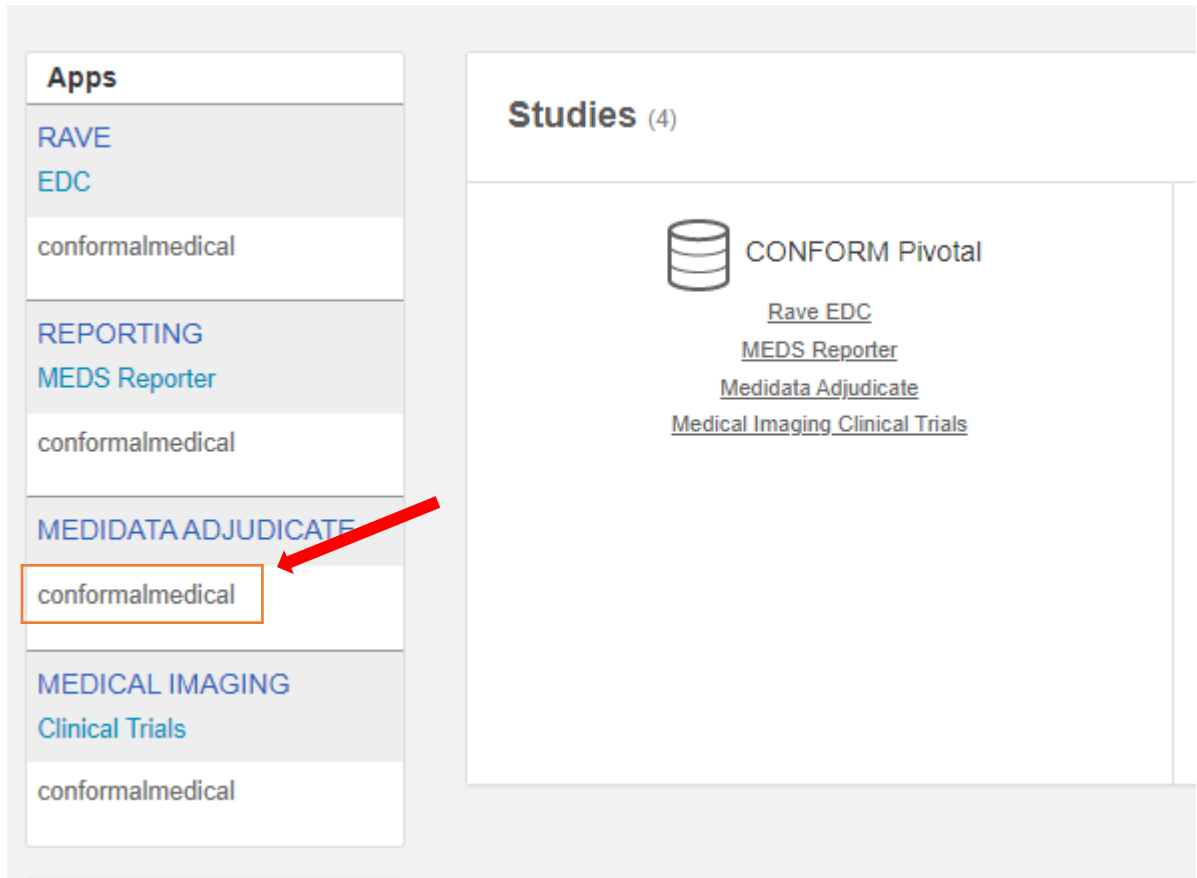
2.7.1. No. All imaging related to an AE is uploaded through Medidata Medical Imaging Portal Refer to **CONFORM Imaging Upload MOP** for more information on uploading imaging.

2.8. Who do I contact if I have any issues or questions regarding Medidata AE adjudication entry and query resolution ?

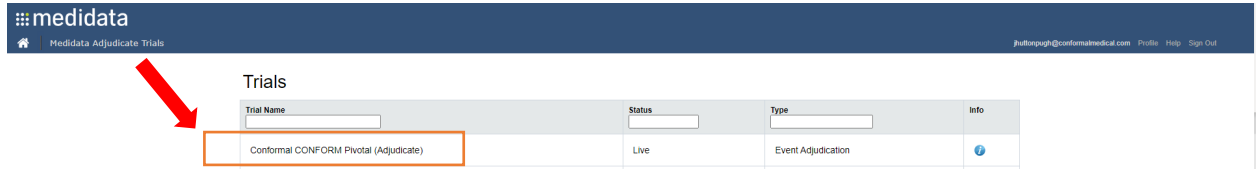
2.8.1. If you have a technical issue related to uploading source documents, redaction etc. please **contact** your Site Manager. For all other questions related to queries, please send a query response within Medidata Adjudicate to the NAMSAs Safety Team.

3. Navigating Medidata Adjudicate

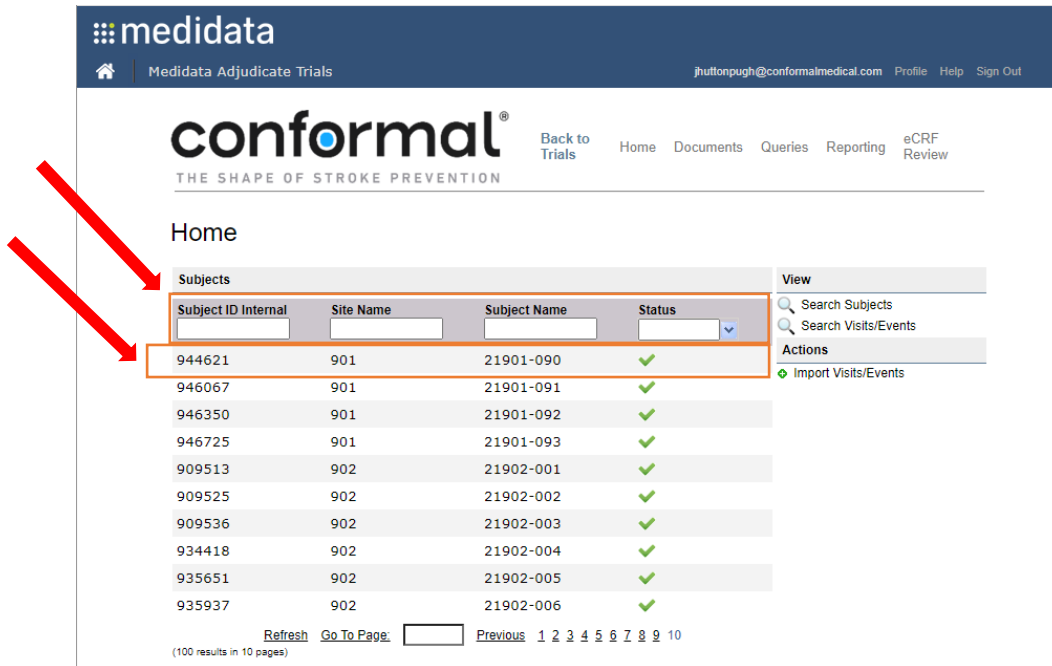
- 3.1.** Log in from the Medidata home page. When on the home page, go to “Apps” on the left side of the screen. Medidata Adjudicate access is available near the bottom of the list. Click the **conformalmedical** link to bring you to the Medidata Adjudicate home page.



- 3.2. Clicking the conformalmedical link will take you to the page shown below. From this page, click “Conformal CONFORM Pivotal (Adjudicate)”.



- 3.3. You will then be directed to the Adjudicate home page, where you can access all subjects who have been entered into Rave EDC by your site.



- 3.4. You can look for a subject by either scrolling through pages, or search by Subject ID, Site Name (Use site number), Subject name (Subject number), or Status of the Medidata Adjudicate submission of source materials.

- 3.5. Select the subject number you are entering source documentation for, and you will be directed to the subject's Medidata Adjudicate Visit page. This page will list all AE/SAE's that were entered into Rave EDC for a subject separately, and in sequential order. The subject's identifying number, status, and a listing of all AE/SAE's are displayed. If there are no AE/SAE's entered for a subject, there will be no events listed in "Visit/Events".

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j.hultonpugh@conformalmedical.com Profile Help Sign Out

Back to Trials Home Documents Queries Reporting eCRF Review

Subject: 21901-009 Close

Subject Details		Subject Details	
Subject Name	21901-009	Screening Name	Unknown
Date of Procedure	01-Feb-2022	Status	Active
Queries			
No queries have been associated with this subject			
View			
▶ Audit Log			
▶ Workflows (0 / 0)			
Actions			
◆ New Query			
◆ Add Adverse Event Visit/Event			
Visits/Events			
Visit/Event Name	Complete	Img Reqs	
Adverse Event 1	✖	0	

4. How to Upload AE Source Documents in Medidata Adjudicate

- 4.1. You will be notified by the NAMSA Safety team via query, and possibly your Site Manager, when the CEC has selected an AE/SAE to be adjudicated and requested source documentation. You will be provided the AE/SAE number and name, as well as a list of source documents the CEC has requested to support review of the event.
- 4.2. When you select the subject number, you will be brought to the patient specific Medidata Adjudicate page as shown in **section 3.5**.
- 4.3. Select the requested Adverse Event to open the folder that correlates to the requested AE/SAE. Once you have selected the requested Adverse Event listed in the bottom right corner of the screen, you will be taken to the page below which relates only to that specific Adverse Event (In this example, Adverse Event 1). From here, click on "Upload Document" to upload your source documents for the correct Adverse Event.

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Back to Trials Home Documents Queries Reporting eCRF Review

Subject: 21901-009 Close

Adverse Event 1 Visit/Event Details				Subject Details	
Visit/Event Name	Adverse Event 1	Adjudication Required?	Unknown	Subject Name	21901-009
Adverse Event Text	PERICARDIAL EFFUSION	AE Start Date	Unknown	Screening Name	Unknown
EDC Event Number	1	Status	Active	Status	Active

Adverse Event 1 Visit/Event Requirements				View	
Type	Info	Requirement	Commands		
Document	Documents	1 Document	Upload Document	View Subject Audit Log Audit Log Workflows Workflows (0 / 0)	

Submission Problems (3):

Errors:

- Documents: Requires an upload

Warnings:

- Tracked item [Adjudication Required?]: No value entered
- Tracked item [AE Start Date]: No value entered

✖ The Adverse Event 1 visit has not satisfied all required items. Please provide all required data in order to finalize the visit submission and provide your e-signature.

Queries

No queries have been associated with this visit

Exam

No Exams have been associated with this visit

Files

No files have been associated with this visit

Documents

No Documents have been associated with this visit

Actions		
<input checked="" type="checkbox"/>	Restore Deleted Items	
<input checked="" type="checkbox"/>	New Query	
<input checked="" type="checkbox"/>	Add Adverse Event Visit/Event	

Visits/Events		
Visit/Event Name	Complete	Img Reqs
Adverse Event 1	<input checked="" type="checkbox"/>	0

- 4.4. By clicking on the “Upload Document” you will be taken to the Event Details page shown below. This page allows you to identify the type of source documents included in the upload. You have the ability to click on multiple document types (e.g. Progress Notes, Lab Documents, etc.) for the documents being loaded under the categories “Submission Details” and “Documents”. You will then be directed to upload documents from your own folders.

The screenshot displays the Medidata Conformal interface for adjudicating an adverse event. The header includes the Medidata logo and user information. The main content area shows the subject ID 21901-009 and details for Adverse Event 1, which is 'PERICARDIAL EFFUSION'. The 'Exam Upload - Details' section is active, showing a grid of document types with checkboxes. Three red arrows point to the 'Submission Details' section, the 'Documents' section, and the 'Continue' button. The 'Documents' section includes options like 'Index Admission H&P', 'Other', and 'Progress Notes'. The 'Continue' button is highlighted in blue.

- 4.5. Once you have finished uploading all document details, click on the blue “Continue” tab and you will be taken to the next screen shown in **section 4.6**.

4.6. From this screen, you click on “Choose File” and upload the redacted source documents. All documents uploaded will be itemized in the “File Name” table. You also have the ability to remove a document if you have loaded it in error by clicking on the red X “Remove” section.

The screenshot shows the Medidata Conformal interface for subject 21901-009. The main content area is titled "Adverse Event 1 Visit/Event Details". It includes a table with the following information:

Visit/Event Name	Adverse Event 1	Adjudication Required?	Unknown
Adverse Event Term	PERICARDIAL EFFUSION	AE Start Date	Unknown
EDC Event Number	1	Status	Active

Below this is the "Adverse Event 1 File Upload [Documents]" section. It features a "Choose File" button (highlighted with a red arrow) and a table of uploaded files:

File Name	Action
Test for Medidata Adjudicate.pdf	Remove

At the bottom left, there is a "Save Uploads" button (highlighted with a red arrow) and a "Cancel" button. On the right side, there is a "Subject Details" panel with information such as Subject Name (21901-009), Screening Name (Unknown), and Status (Active). There is also a "View" section with expandable options like "View Subject", "Audit Log", and "Workflows".

4.7. Once you have uploaded your redacted source documents, click “Save Uploads” in the bottom left corner of the screen, you will be taken to a summary screen in **section 4.8**.

4.8. This summary screen will prompt you for your electronic signature to finalize the submission. By clicking on the red button in the middle of the screen you are verifying that you submitted the redacted source documentation.

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Subject: 21901-009 Close

Adverse Event 1 Visit/Event Details				Subject Details	
Visit/Event Name	Adverse Event 1	Adjudication Required?	Unknown	Subject Name	21901-009
Adverse Event Term	PERICARDIAL EFFUSION	AE Start Date	Unknown	Screening Name	Unknown
EDC Event Number	1	Status	Active	Status	Active

Adverse Event 1 Visit/Event Requirements				View	
Type	Info	Requirement	Commands	View Subject	
Document	Documents	Document	Upload Document	Audit Log	
			Upload via Mobile Device	Audit Log Workflows	
			Edit & Finalize Mobile Uploads	Workflows (0 / 0)	
			Comment	Actions	

Submission Problems (2):
Warnings:
1. Tracked item [Adjudication Required]: No value entered
2. Tracked item [AE Start Date]: No value entered

Your submission is not final until you click here & provide an electronic signature

Queries					
No queries have been associated with this visit					

Exam					
No Exams have been associated with this visit					

Files					
No files have been associated with this visit					

Documents					
File Name	Requirement	Details	Upload Date	Actions	
Test for Medidata Adjudicate.pdf	Documents	Documents: Admission/ER Notes Index Procedure Report Pre/Post Procedure Labs	25-Aug-2022 10:12 AM ET	Open Document Download Remove Change Req Edit Details	

No Documents have been associated with this visit

4.9. Once you have clicked the red button you are taken to the following screen where you are required to click on the “Yes, submit now” button, OR you are given the opportunity to abort the submission “No- abort”.

medidata | Medidata Adjudicate Trials | [j.huttonpugh@conformalmedical.com](#) | Profile | Help | Sign Out

THE SHAPE OF STROKE PREVENTION

Subject: 21901-009 Close

Adverse Event 1 Visit/Event Details				Subject Details	
Visit/Event Name	Adverse Event 1	Adjudication Required?	Unknown	Subject Name	21901-009
Adverse Event Term	PERICARDIAL EFFUSION	AE Start Date	Unknown	Screening Name	Unknown
EDC Event Number	1	Status	Active	Status	Active

Adverse Event 1 Visit/Event Requirements						
Type	Info	Requirement	Commands			
Document	Documents	1 Document	Upload Document	Upload via Mobile Device	Edit & Finalize Mobile Uploads	Comment

Submission Problems (2):
Warnings:

- Tracked item [Adjudication Required?]: No value entered
- Tracked item [AE Start Date]: No value entered

You are submitting a Adverse Event 1 visit without including all optional requirements. Would you like to continue anyways?

Queries		
No queries have been associated with this visit		

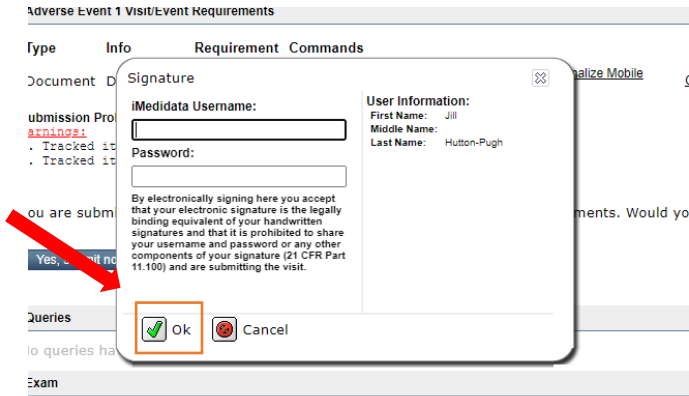
Exam		
No Exams have been associated with this visit		

Files		
No files have been associated with this visit		

Documents				
File Name	Requirement	Details	Upload Date	Actions
Test for Medidata Adjudicate.pdf	Documents	Documents: Admission/ER Notes Index Procedure Report Pre/Post Procedure Labs	25-Aug-2022 10:12 AM ET	Open Document Download Remove Change Req Edit Details

Visits/Events		
Visit/Event Name	Complete	Img Reqs
Adverse Event 1	✘	0

4.10. Once you click the “Yes, submit now” button, a prompt will appear requiring you to enter your Medidata username and password, one more time, to verify your identity related to the submission. When you have added your username and password, click the green “Ok” button. Your submission is now complete and ready for Safety review.



5. How to Redact Documents in Medidata Adjudicate

Medidata Adjudication has a redaction tool if you wish to redact your source documents within Medidata Adjudicate versus manually prior to uploading the documents

There are two methods you can use to redact within Medidata Adjudicate.

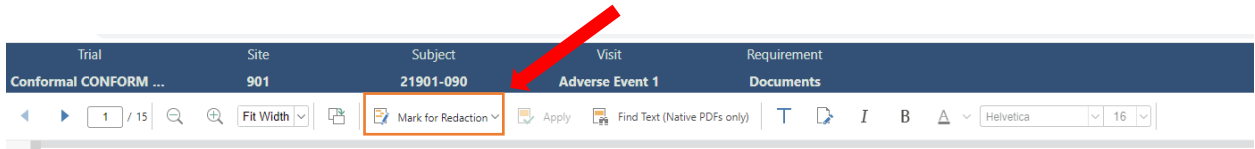
5.1. Simple Redaction: Use when attempting to redact limited mentions of PHI.

5.1.1. When you are on the source document upload page, click “Open Document” in the lower right corner of the page.

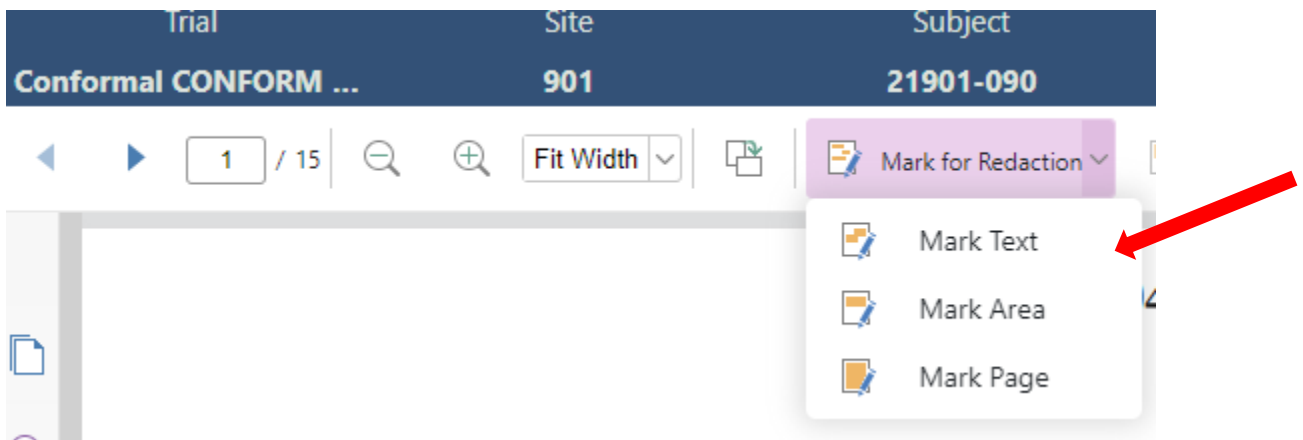
The screenshot displays the Medidata Adjudicate interface for Subject: 21901-090. It includes sections for Adverse Event 1 details, requirements, submission problems, and a list of documents. A red arrow points to the 'Open Document' button in the 'Actions' column of the document list.

File Name	Requirement	Details	Upload Date	Actions
60-00430 Rev_A_CLAAS System IFU Pivotal_.pdf	Documents	Documents: Admission/ER Notes Death Certificate Electrocardiograms Index Admission H&P Lab Reports Other Pre/Post Procedure Labs Transfusion Records	27-Aug-2022 3:26 PM ET	Open Document Download Remove Change Req Edit Details

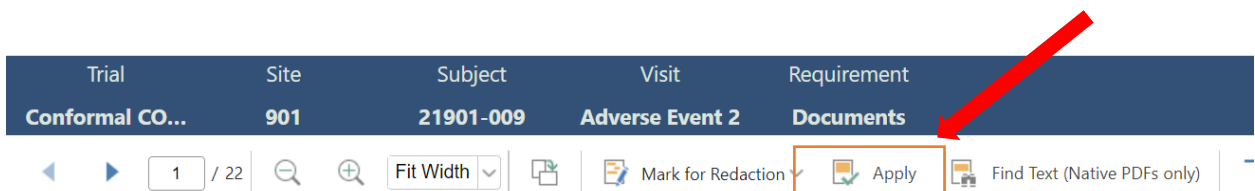
5.1.2. Once the document is opened, click the drop down for “Mark for Redaction” and the redaction tool will appear.



5.1.3. You now have the option to mark text, mark area, or mark page.



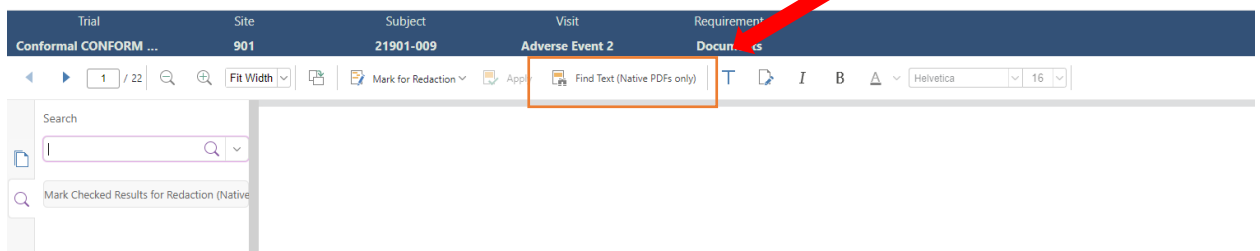
5.1.4. Once you highlight the text/area/page you chose, click “Apply” to redact. **Before leaving the page click “Save” in the upper right corner of the page to ensure your redactions will be saved.**



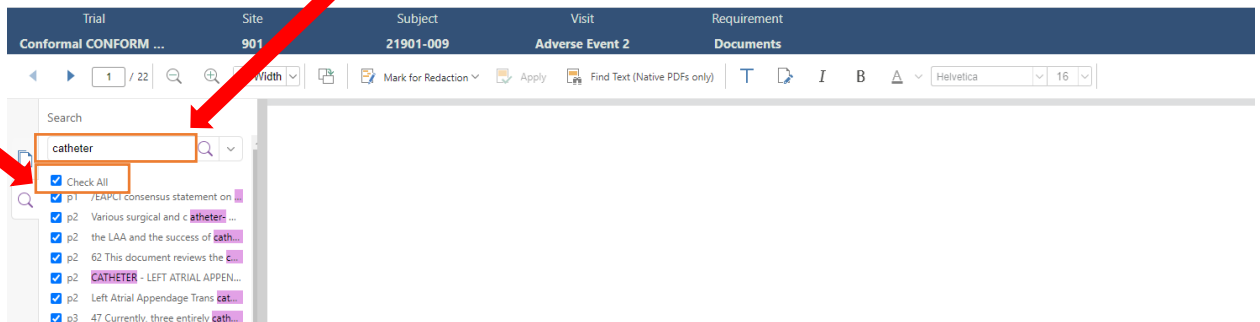
5.2. Find Text redaction feature: This is a Search and Find Redaction tool for rapid redaction. This function allows you to redact multiple mentions of a select term at one time as is described below.

5.2.1. Upload selected source document into Medidata Adjudicate and once you are on the source document upload page, click “Open Document” in the lower right corner of the page.

5.2.2. Once the document is open, click “Find Text” in the top tool bar.



5.2.3. Enter text you would like to find in the “Search” box (i.e. first name, last name, DOB, any ID number for subject), then check the “Check all” box.



5.2.4. Next, scroll to the bottom of the search/find column to find “Mark Checked Results for Redaction”.

Trial	Site	Subject	Visit
Conformal CO...	901	21901-009	Adverse Event 2

1 / 22 | Fit Width | Mark for Redac

Search

- p19 Percutaneous catheter left atria...
- p19 screening prior to left atrial cat...
- p20 Catheter Cardiovasc Interv. 201...
- p20 Catheter Cardiovasc Interv. 201...
- p20 implications for catheter - left ...
- p20 Trans-septal catheter ization in ...
- p21 Left Atrial Appendage Trans cat...
- p21 Left Atrial Appendage Trans cat...
- p21 left atrial appendage trans cath...
- p21 Presentation of Trans catheter ...
- p21 Trans catheter left atrial appen...
- p21 Trans catheter left atrial appen...
- p22 Catheter Cardiovasc Interv. 201...

No more

Mark Checked Results for Redaction (Nativ

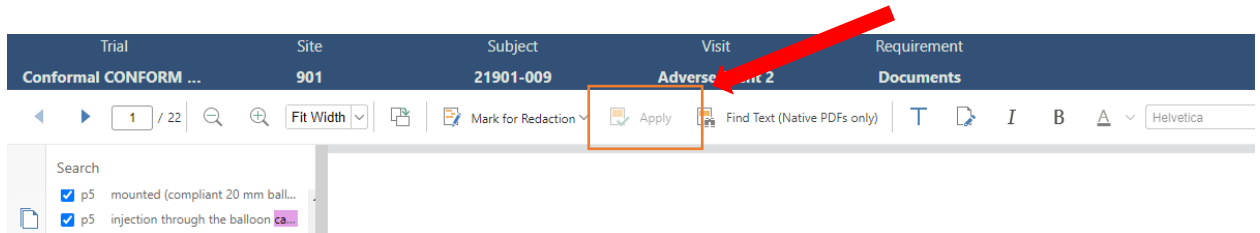
██████/EAPO
██████ atrial ap

Bernhard Meier (EA)
Ahmed A. Khattab (S)
Claudio Tondo (Italy)

*Document Reviewers: G
(Germany), Dariusz Du*

*I. Cardiology, Bern Uni
Center: 6281 Maastricht*

5.2.5. Last, click the “Apply” button on the top tool bar. That should delete all mention of the searchtext entered.



Pre-Procedure Imaging Process

Appendix A Pre-procedure Review Slide Template

Pre-Procedure Review Process

This process is required for each implanting physician’s 1st 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.



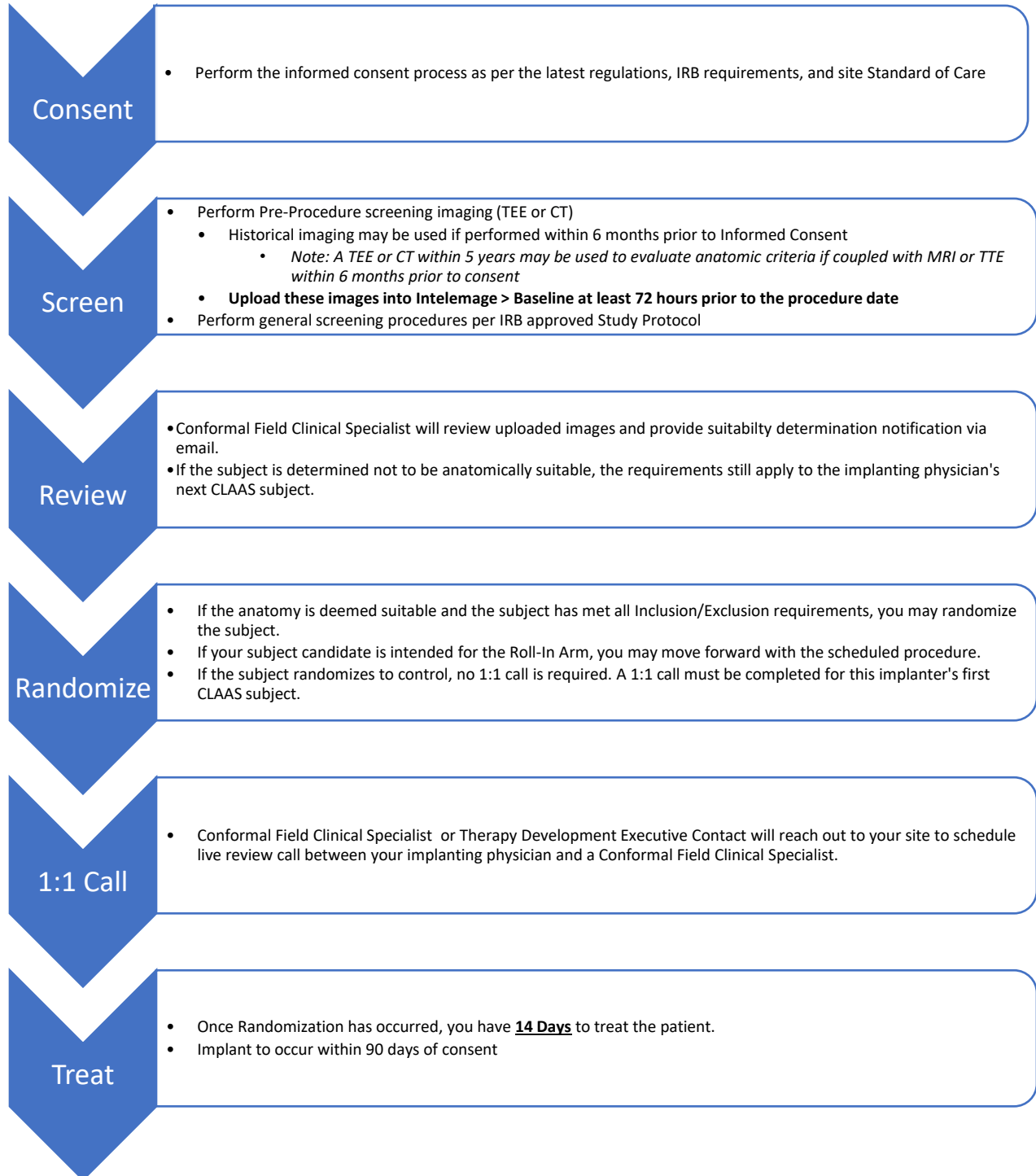
For all subjects at all sites, screening imaging must be uploaded to Medidata Inteleimage and reviewed by Conformal prior to randomizing a subject or confirming a roll-in case.

	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 prior to randomization	✓	✓

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.

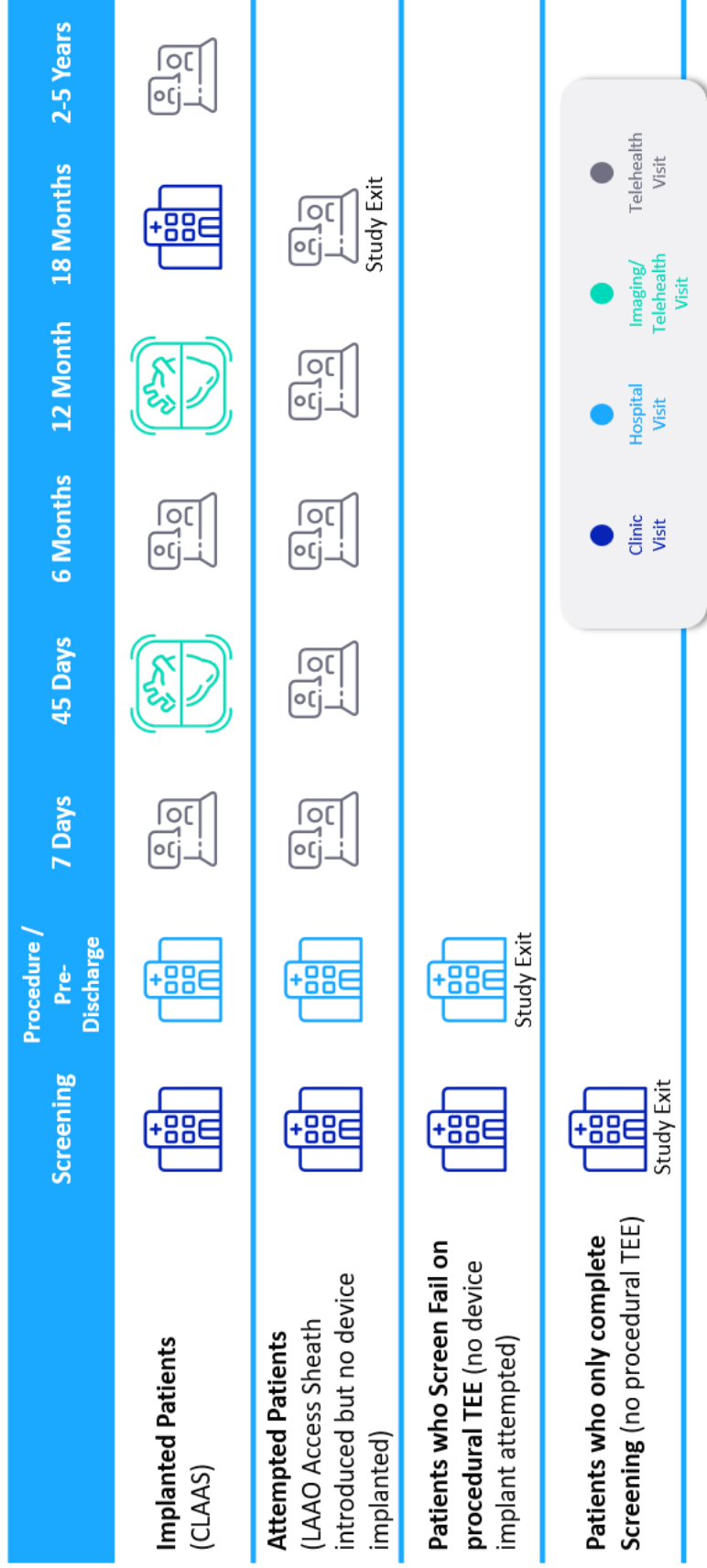
Q: After each implanting physician's 1st case, do we still have to wait for Conformal to review baseline imaging prior to randomization?

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

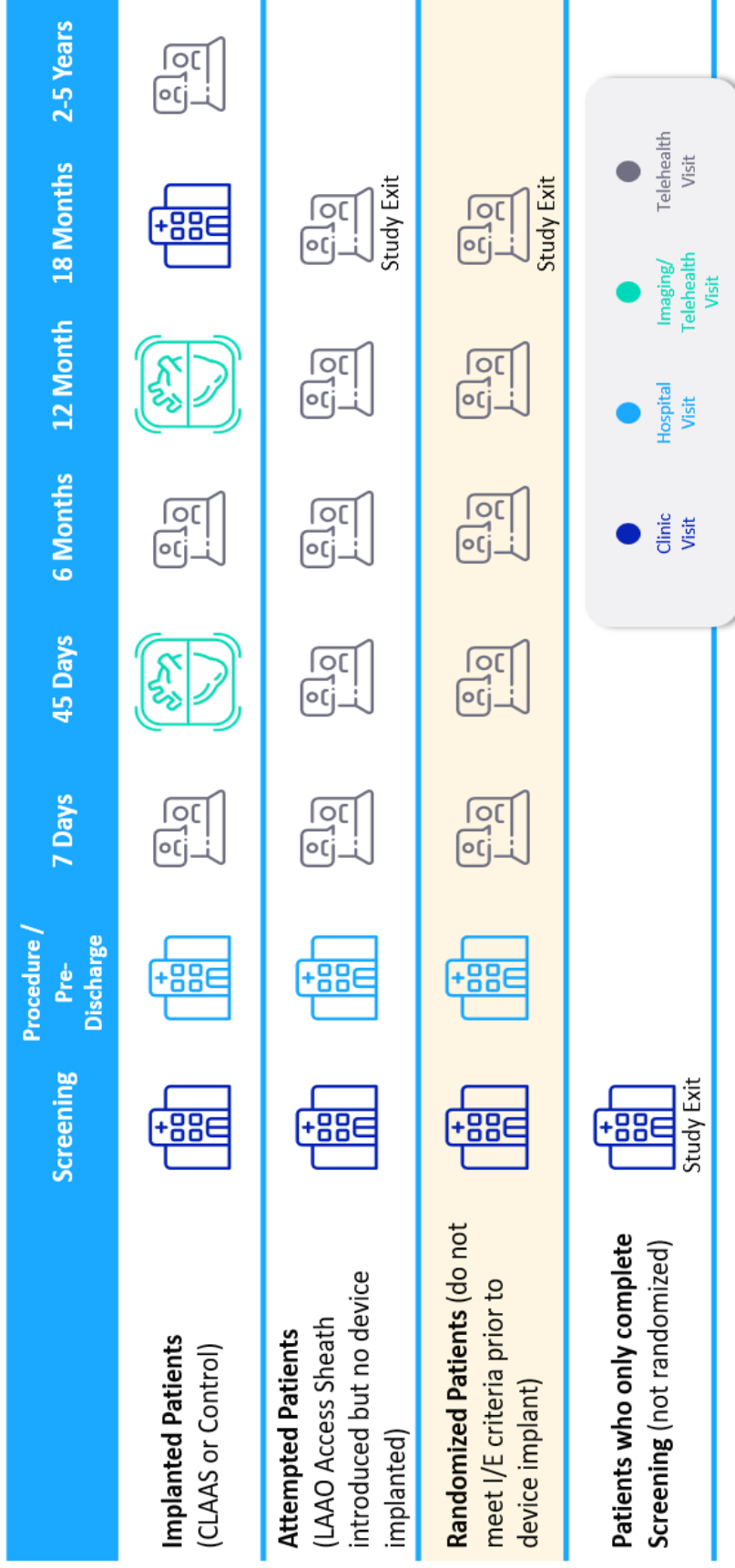
Study Exit Flowchart

Instructions: Please refer to the table below to determine subject's required follow-up visits and patient exit classification for Roll-on vs Randomized Subjects.

Patient Follow Up – Roll-in Subjects



Patient Follow Up – Randomized Subjects



Note: If a subject is screened on the table and no longer meets Eligibility Criteria during the Procedural TEE, the subject should be exited immediately and no further follow-up visits are required.

Submitting Planned/Scheduled Case

Submitting Planned/Scheduled Case

To notify the Conformal Team about a planned or scheduled case in the CONFORM Pivotal Trial, please use one of the two options below to ensure adequate on-site team support.

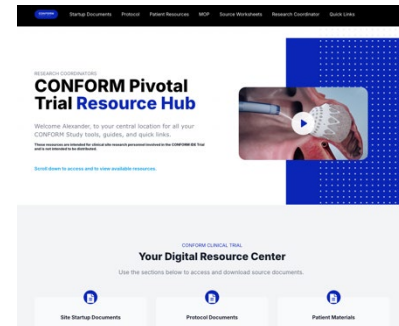
OPTION 1:

Instructions using the CONFORM Trial: Upcoming Case online form. To ensure accurate and timely submission of upcoming CONFORM Pivotal Trial patient cases, please follow the steps below when completing the form.

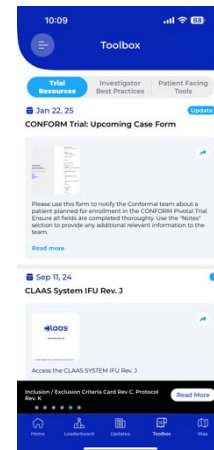
1. Access the Online Submission Form

Click the following link ([Submit Patient Cases](https://qrco.de/bfhae8)) (<https://qrco.de/bfhae8>) to open the form or use the following resources to access the online form via a computer or mobile device:

Access via the [Research Coordinator Portal](https://info.conformalmedical.com/conform-trial-portal) (<https://info.conformalmedical.com/conform-trial-portal>): from the homepage scroll down to access the form



Access using the **CONFORM APP**:
Select Toolbox tab > Trial Resources >
Select the CONFORM Trial: Upcoming Case Form.



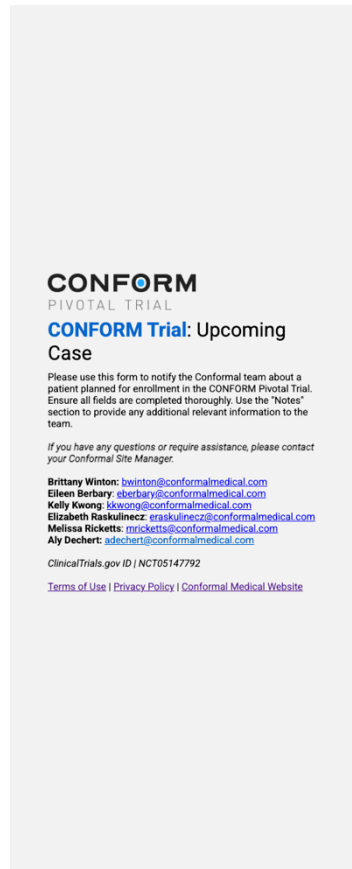
Scan the QR Code: with your mobile device open your camera to scan the code to navigate to the form.



2. Complete All Required Fields on the Form

Fill out each section of the form with accurate case details. This form uses Logic, depending on your answer you will be asked to provide specific information before your submission can be sent. Below are some examples of the form questions:

- **Facility Name:** Enter the name of the hospital, clinic, or center where the procedure will take place.
- **Physician Name:** Provide the name of the physician performing the procedure.
- **Procedure Date & Time:** Select the scheduled date and time of the procedure.
- **Patient Case Details:** Add any relevant patient identifiers or case-specific details as required.
- **Additional Notes (if applicable):** Include any special considerations, such as equipment needs or scheduling constraints.



CONFORM # and Site Name *
Please select your site from the dropdown list
Select or enter value

Type of case *
 Planned/Scheduled Case
 Tentative Case (no date scheduled)

Research Coordinator Name *

Contact Email *

Contact On-site Phone Number *

Physician Name
Please provide the name of the CONFORM implanter for this case

CONFORM Study Site Manager
Please select your CONFORM site manager; if you do not know please leave this field blank.

Has the Patient Signed a Consent Form? *
 YES
 NO
 UNKNOWN

Has Screening Imaging Been Performed? *
 YES
 NO
 UNKNOWN

Does the Patient Require a Pre-procedure Review? *
 YES
 NO
 UNKNOWN

Roll-in or Randomized *
 ROLL-IN
 RANDOMIZED
 UNKNOWN

Case Date

Case Start Time
Example (10:00 AM EST)

NOTES
Please provide any additional relevant information about this case to

3. Review Your Submission

Before submitting, double-check the details to ensure accuracy. Incorrect information could lead to delays or miscommunication. Additionally, the more details you have about the intended case, the better. Once the form is submitted, any “unknown” details you’ve entered cannot be updated. You will need to work with your Site Manager to provide any necessary updates.

In order to receive a copy of your submission, check “Send me a copy of my responses”, and provide your email address.

4. Submit the Form

Once all required fields are completed, click the "**Submit**" button at the bottom of the form.

5. Confirmation & Follow-Up

- If you requested a copy of your responses, you will receive an email after submission containing all the information that was entered in the form for your records.
- If additional details are needed, your CONFORM Site Manager may contact you for clarification.

For any questions or issues with the submission process, please reach out to your CONFORM Trial Site Manager or email Clinical Operations team at: clinops@conformalmedical.com.

OPTION 2:

Call or Send an email to your CONFORM Site Manager. Once you have a planned patient enrolled in the CONFORM Pivotal Trial, you can email the information to your assigned CONFORM Trail Site Manager with all the information necessary to notify them of the upcoming case.

Please be sure to provide as much detail as possible to help us schedule the appropriate onsite team. If additional details are needed, your CONFORM Site Manager may contact you for clarification.