conformal®
THE SHAPE OF STROKE PREVENTION

CONFORM Pivotal Manual of Procedures

Table of Contents

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.

Study Contact List

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Site Personnel
Training Requirements

conformal™ The Shape of Stroke Prevention	Title: MOP 3 - Site Training

Site Personnel Training Requirements

	Principal Investigator	Implanting Sub-Investigator	Non-Implanting Sub-Investigator	Research Coordinator	Regulatory
Training Required to:					
CONFORM Protocol & Amendments	X	X	X	X	
CONFORM TEE Imaging Acquisition Protocol	O	O			
Protocol Synopsis & Amendments					X[3]
CLAAS AcuFORM Instructions for Use	X	X	O	O	
Didactic Device Training	X[1]	X			
Hands on Device Training	X[1]	X			
Device Accountability App				X	
EDC System/ AE Adjudicate / Imaging Module				X	
EDC – Sign Off	X				
Documents Maintained:					
Listed on the DOA	X	X	X	X	O
Financial Disclosure	X	X	X		
Investigator Agreement	X	X	X		
GCP Certification (current at activation)	X	X	X	X	X[3]
CV (signed/dated within past 2 years)	X	X	X	X	X[3]
Active Medical License	X	X	O	O	
NIHSS and mRS[2]				X	
Key:					

X = Required
O = Optional
[1] = Didactic training must be completed by a Conformal FCS team member prior to the first implant.
[2] = Training/certification must be current; at least one member of study team must have NIHSS/mRS certification
[3] = Only required if listed on DOA

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

Imaging Personnel Training Requirements

Role	Imager for Screening Imaging (CT[1], TEE[1], TTE, MRI)	Imager for Procedural TEE	Imager for Pre-Discharge TTE	Imager for Follow-up TEEs (45 D, 6 M[2], 12 M, Unscheduled)	Lead Echo-cardiographer
Training Required to:					
CONFORM Protocol Synopsis & Amendments[4]	O	X	O	X	X
CONFORM TEE Imaging Acquisition Protocol[4]	O	X	O	X	X
Protocol & Amendments[4]	O	O	O	O	O
CLAAS AcuFORM Instructions for Use[4]	O	O	O	O	O
Didactic Device Training	O	O	O	O	O
Hands on Device Training	O	O	O	O	O
Documents Maintained:					
GCP Certification (current at activation)	O	X[3]	X[3]	X[3]	X
CV (signed/dated within past 2 years)	O	X[3]	X[3]	X[3]	X
Active Medical License	O	X[3]	X[3]	X[3]	X
FAQs:					
Does this person need to be listed on the DOA?	No	No	No	No	Yes
Does this person need to be a physician?	No	Yes	No	Yes	Yes
Can the PI also act as this role?	Yes	No	Yes	Yes	No
Can this person be the same as Procedural Implanter?	Yes	No	Yes	Yes	No
Key:					

X = Required
O = Optional
[1] = Required prior to randomization
[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

Contents

1 General Instructions

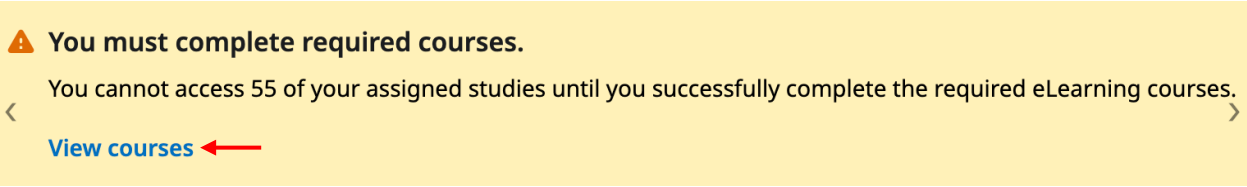
Note: These instructions are specific to the database as applies to patients consented under Protocol Revision K. If you need instructions for patients consented under an earlier Protocol Revision, please ask your site manager for the eCRF Completion Guidelines Version 1.0.

1.1 Database Access and Security

Rave Database Link:

https://login.imedidata.com/login

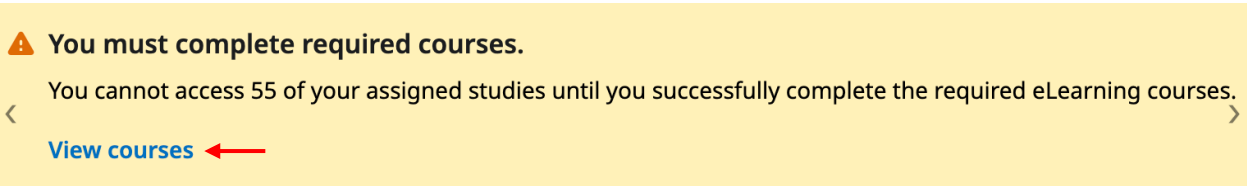
Existing users: You will receive an email from Medidata, informing you of access to the study. Depending on the user's role for the study, additional eLearning may be required prior to gaining access to the study EDC. Pending eLearning will be displayed on the home screen and can be accessed via the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



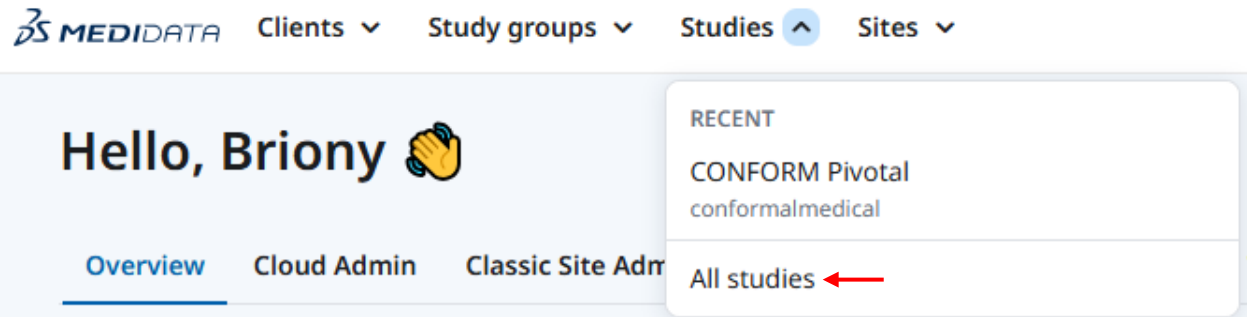
New users:

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.

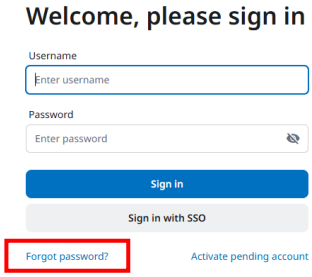


Upon logging into Medidata Rave, the study can be accessed via "Studies" then "All studies."



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



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

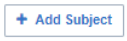
1.3 System Timeout

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

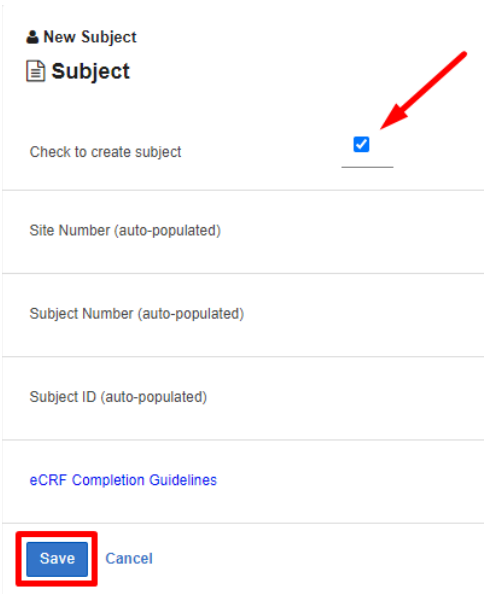
If data is not saved and the system times out, the data will need to be re-entered. Click the Save button at the bottom of the form.

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.



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).

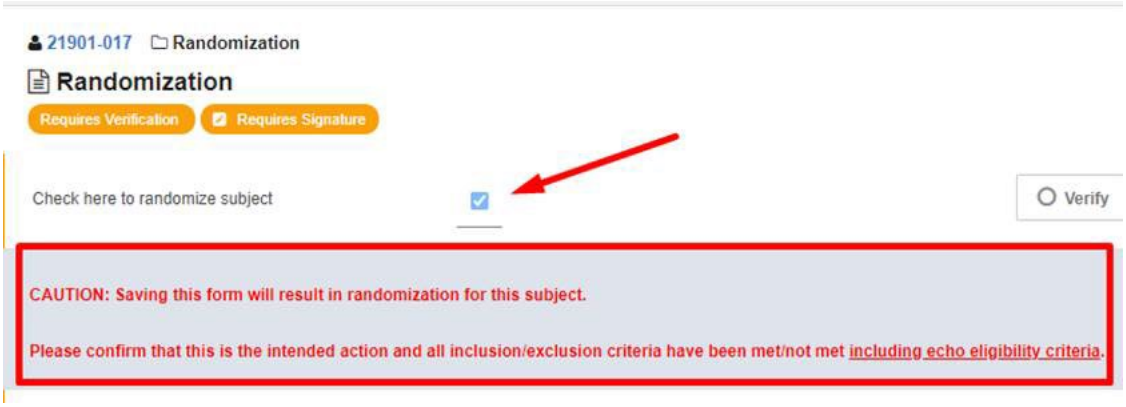
It is important to only add a subject in EDC after the subject has signed the informed consent form, as this action cannot be undone. If a new subject is entered into the database in error, contact your Site Manager immediately.

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.

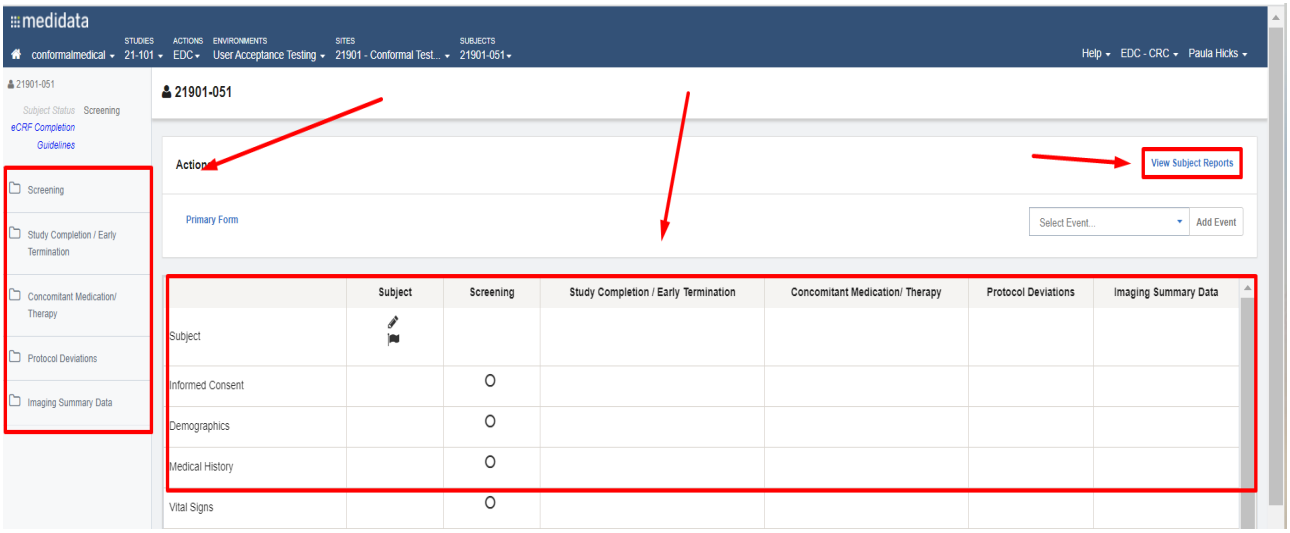


A Protocol Deviation is required if:

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

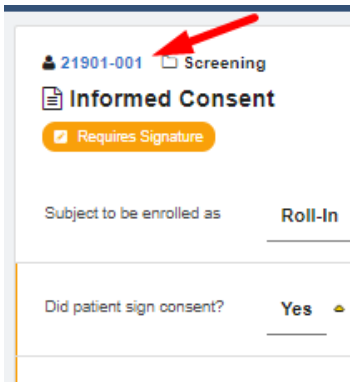
2.3 Subject Record Grid

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.



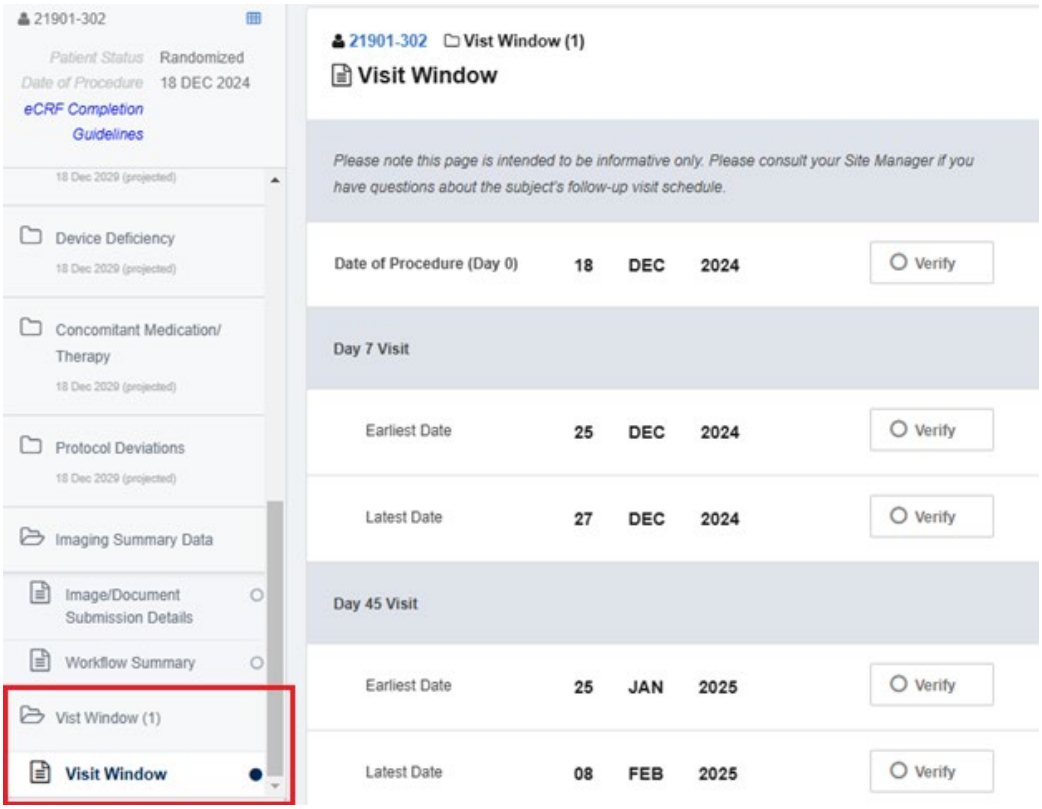
Note: Subject specific reports are also available for use and can be accessed using the link as indicated by the right arrow.

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.



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.



3 Individual CRF Instructions

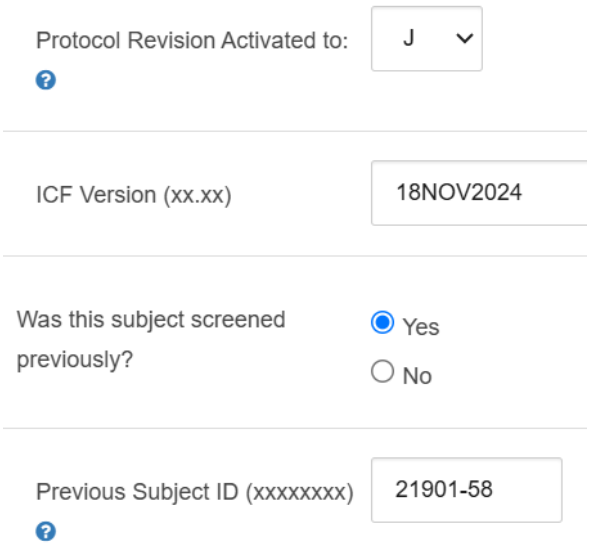
3.1 Screening and Randomization

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.

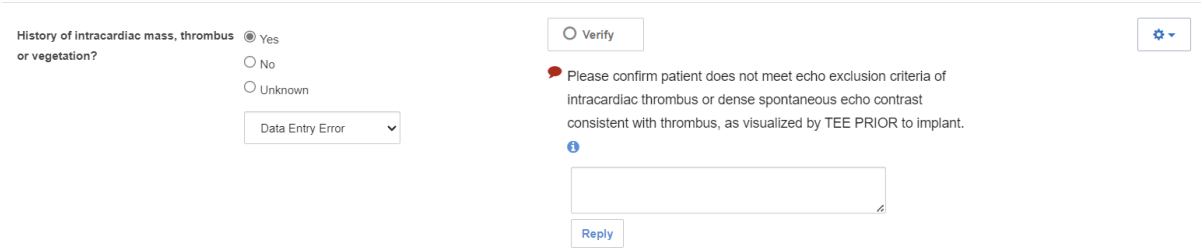


3.1.2 Medical History

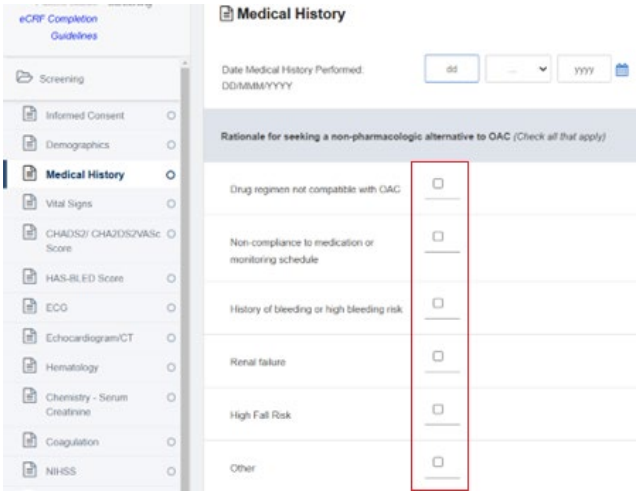
Medical history may be completed up to 30 days prior to consent as part of site standard of care. If it is completed greater than 30 days prior to the date of informed consent, a protocol deviation must be entered.

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.).



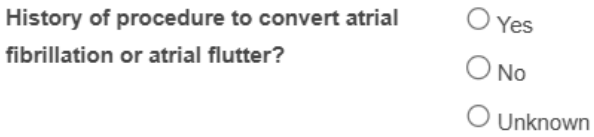
Rationale for seeking a non-pharmacologic alternative to OAC *(Check all that apply)*



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.).

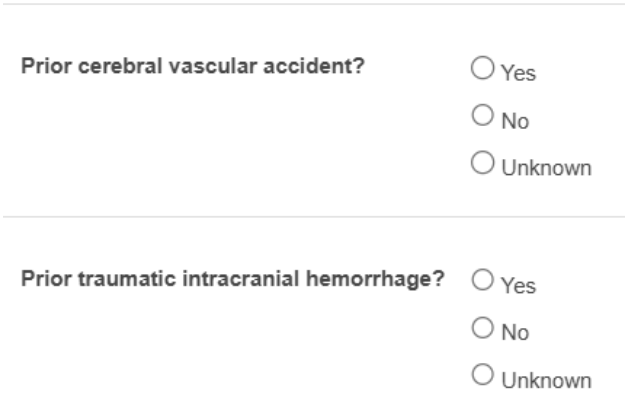
Every effort should be made to collect definitive yes/no responses from the Subject Medical Record. Your response may prompt queries to assess if any inclusion/exclusion criteria has not/has been met in relation to your response.

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.



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?**



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.

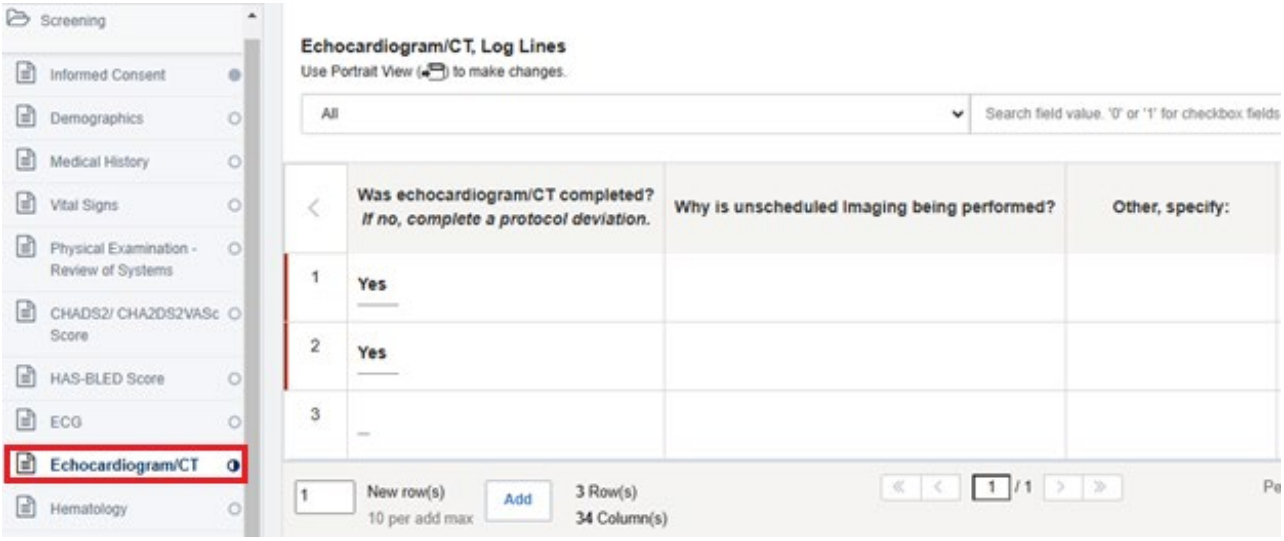
If "*Have all the inclusion criteria and none of the exclusion criteria, as specified by the protocol, been met for this subject?*" is answered "No," each individual Inclusion/Exclusion criteria will become visible.

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.

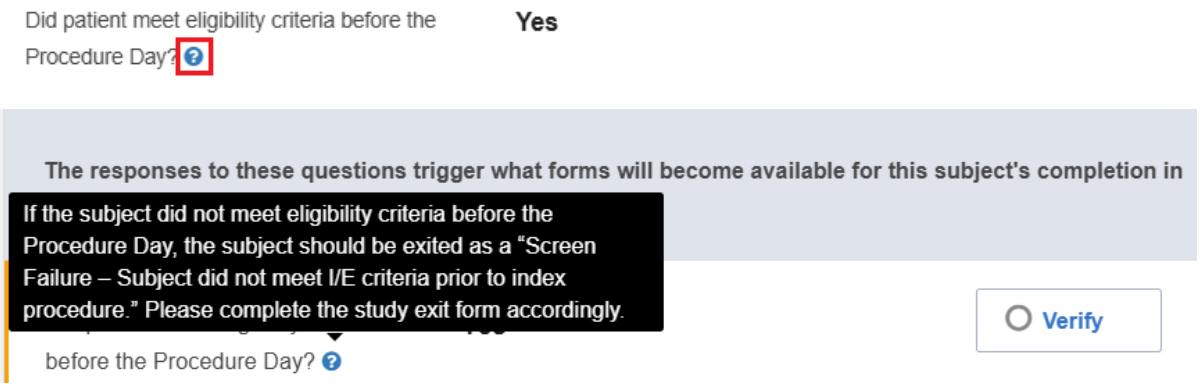
All Imaging Log Lines can be visualized by selecting "Echocardiogram/CT". Please upload all images into the Imaging Module.



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

3.1.6 Patient Population

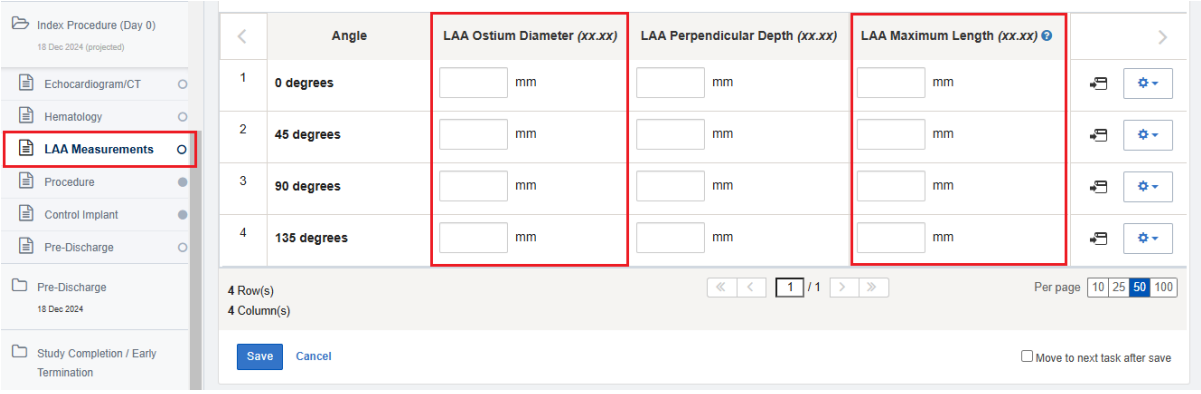
The responses to the questions in the *Patient Population* Form trigger what forms will become available for this subject's completion in EDC. Please hover over the question mark for guidance on the subject's required follow-up visits and patient exit classification.



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.



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.”

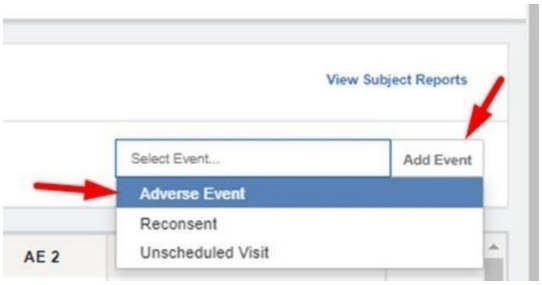
3.2.3 Pre-Discharge

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.



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.

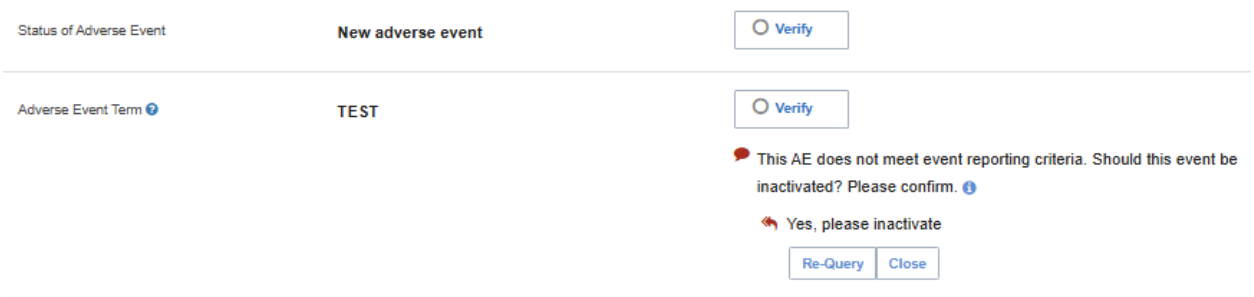
AE entry into the Database is considered the Date Sponsor Notified of AE. If RC does not have access to the database or is not yet sure if a discovered/reported event meets protocol specified reporting criteria, the RC should notify their Site Manager via email or phone call and file a printed copy of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



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

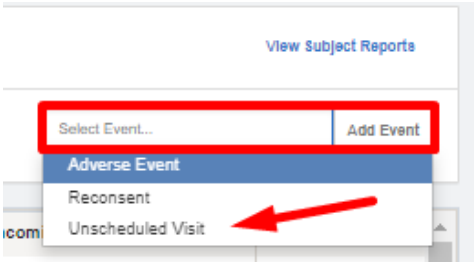
Reason for inactivation (e.g., duplicate of AE X, does not meet reporting requirements per protocol)

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.

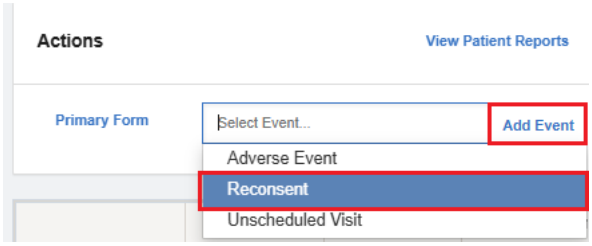
3.4 Unscheduled Visit

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.



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.

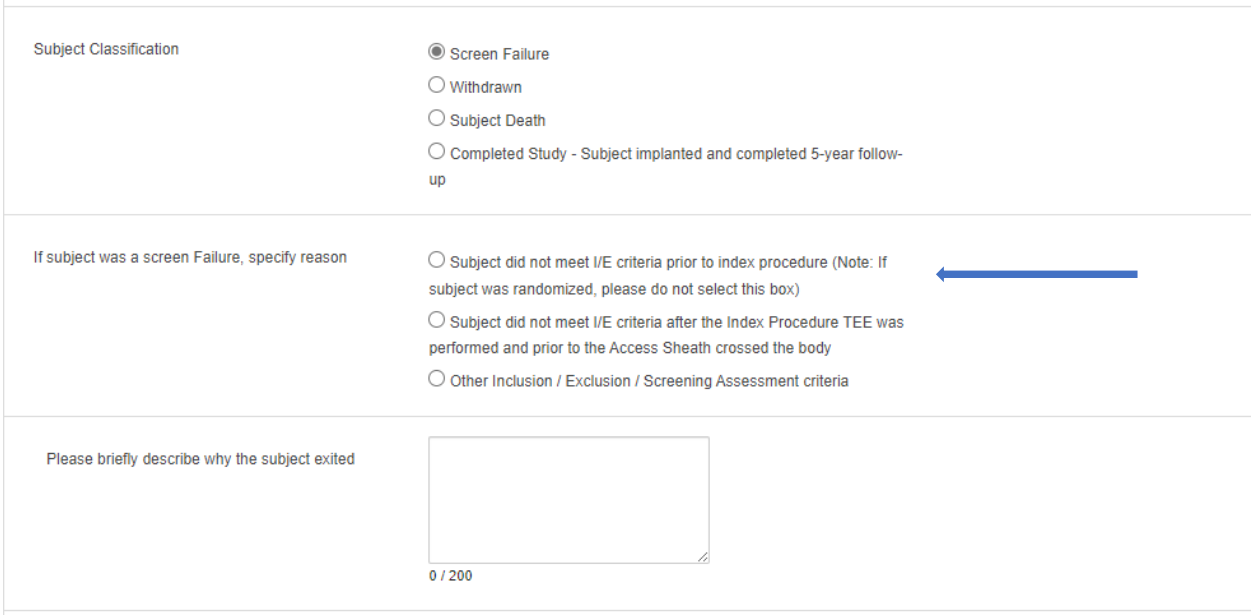
The following four categories of Subject Classification will be tracked as documented in EDC on the Study Exit Form.

- **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).



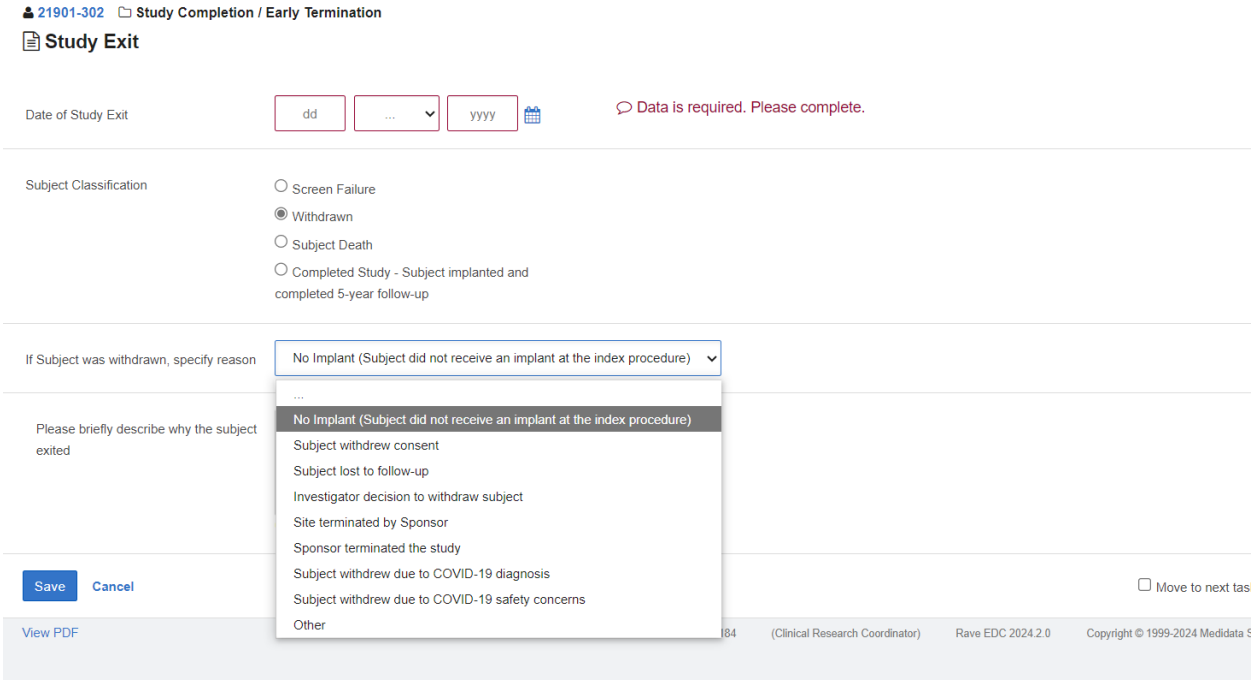
In Brief Description: enter which I/E criteria has not been met.

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."

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.



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.

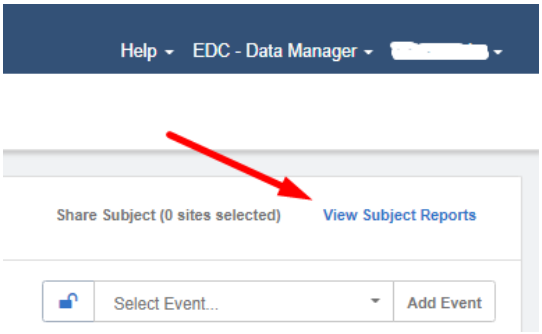
4 Data Management

4.1 Data Queries

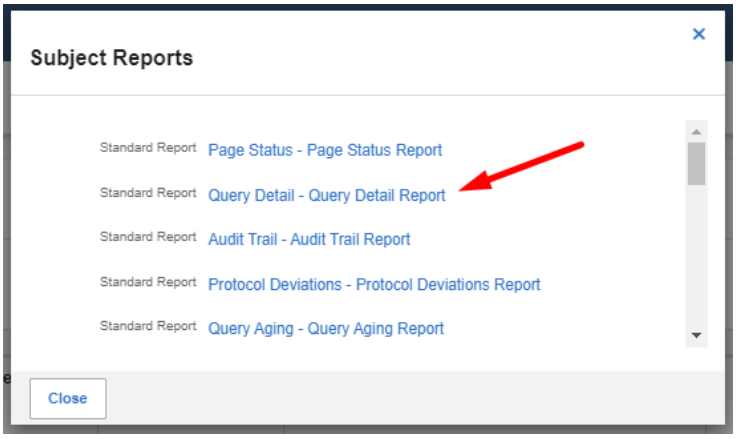
Queries refer to questions or flags raised by the system or study personnel when inconsistencies, missing information, or potential errors are detected within the clinical trial data entered by sites. Queries can be auto generated or created manually by data managers, the safety team, or CRAs.

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.

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

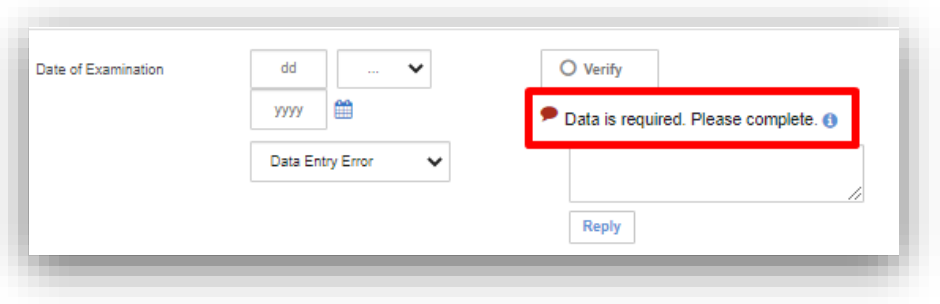


Select the Query Detail - Query Detail Report which shows all the queries for the subject.

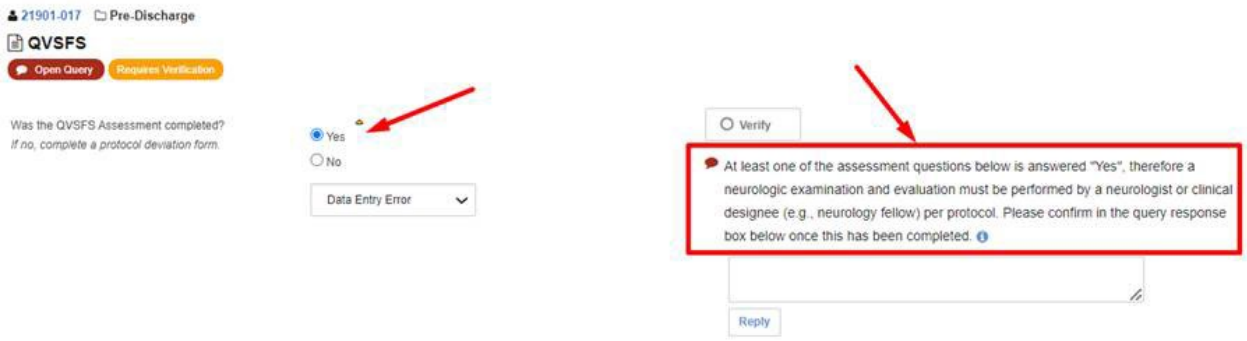


4.2 Mandatory Fields and Edit Checks

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:

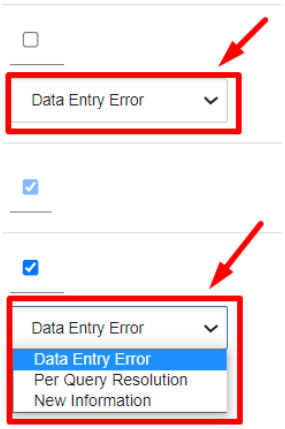


Reminder: Update the data in fields as needed prior to responding to queries. Most queries will automatically close once data is entered and saved. If the query remains open once data is entered, respond to the query.

4.3 Changing Previously Entered Data

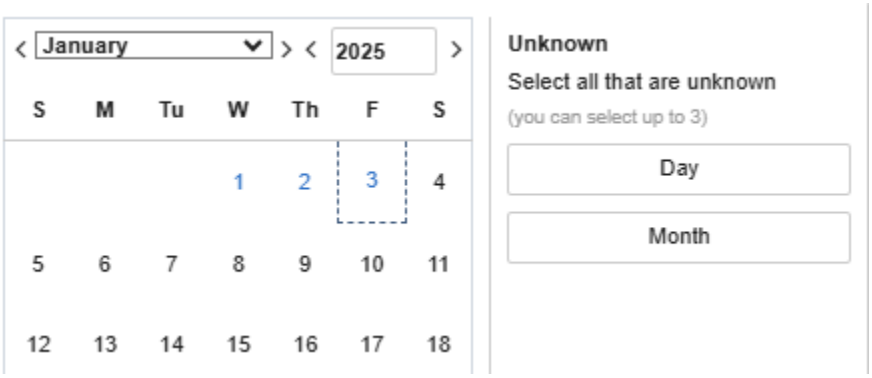
If data is changed for an existing record, the system will require a reason for change.

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.



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:



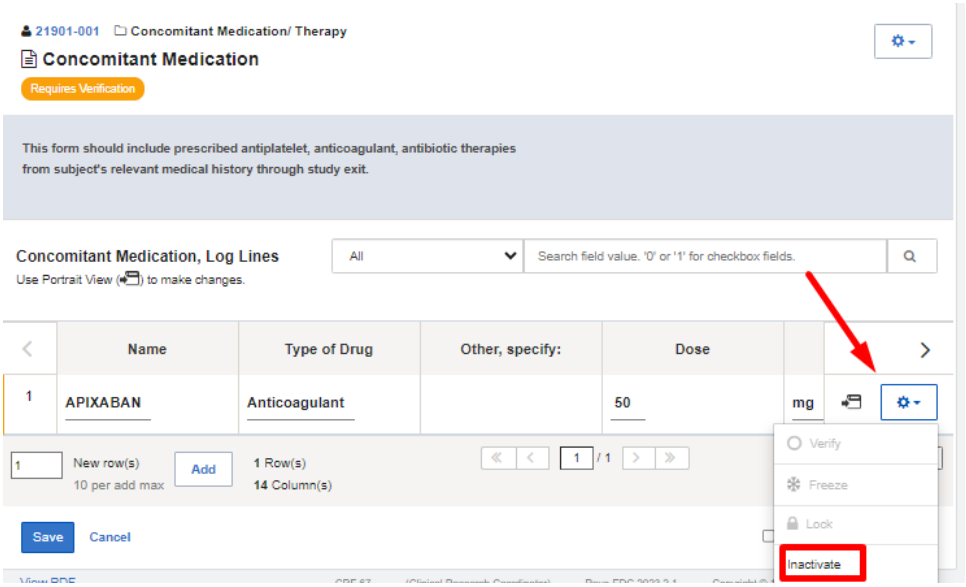
For fields that require a full date where you are unable to determine the day, please record as 01MonYYYY in EDC. If unable to determine day **and** month, please record as 01JanYYYY. Every effort should be made to at least obtain an approximate year. Do not enter "UNK" for unknown fields. If the year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

4.5 Inactivating Log Lines

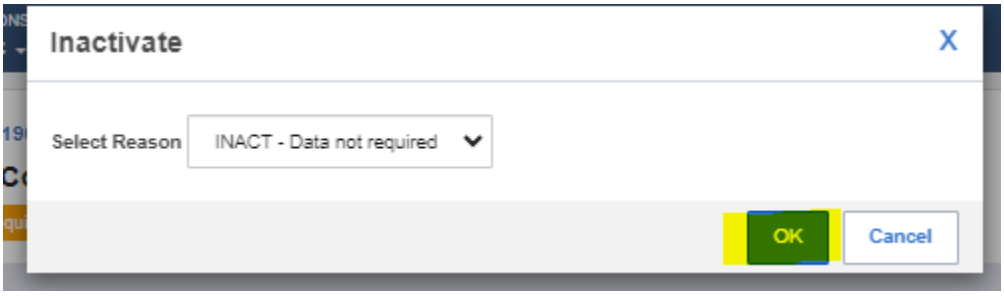
In the event that data has been entered in error (i.e., data entered into the wrong subject, study does not require data, entry error, etc.) sites have the ability to inactivate Con Meds, Imaging, and PDs on their own. Adverse Event inactivation process is detailed in the Adverse Event section of this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

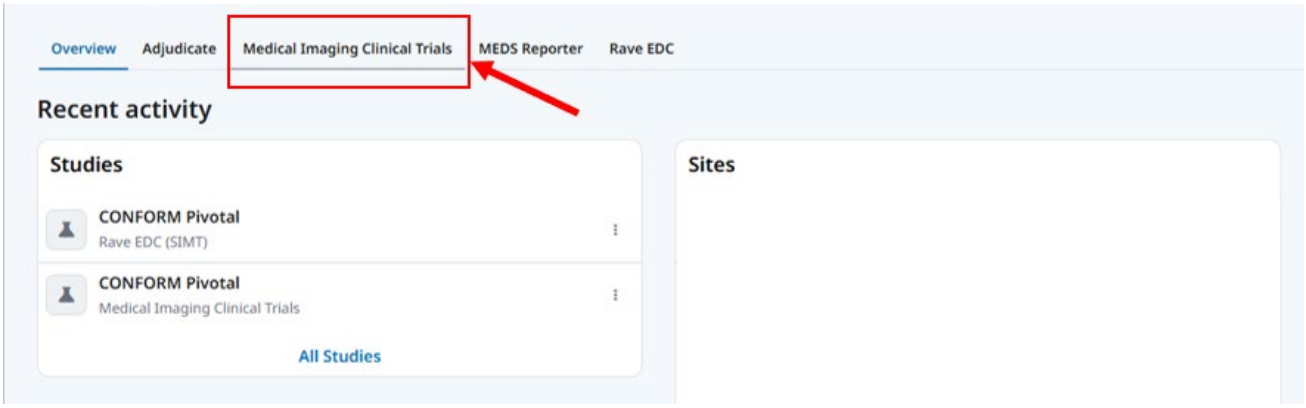


A popup will display, select “OK” and the change is complete. It is not necessary to save the form.

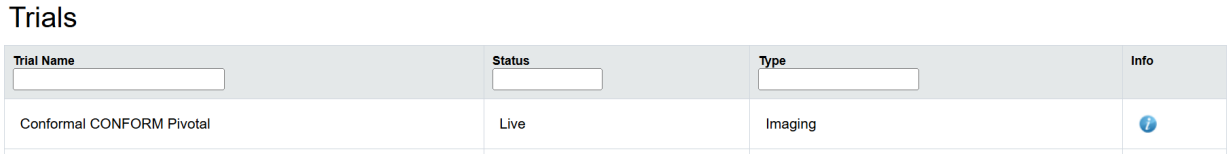


5 Imaging Uploads

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.



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.

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
NAMSA	conformalsupport@namsa.com
Conformal Medical, Inc. (Sponsor)	**Aly Dechert** Manager of Clinical Operations adechert@conformalmedical.com 15 Trafalgar Square, Ste. 101 Nashua, NH 03063 **Michelle Pappas** Associate Director, Clinical Safety mpappas@conformalmedical.com 15 Trafalgar Square, Ste. 101 Nashua, NH 03063

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

conformal™ The Shape of Stroke Prevention	**Title:**
	MOP 05 – Study Schema Table

Protocol Rev M

	Screening	Procedure[0]	Pre-Discharge	7-Day	45-Day	6 Month (180 days)	12 Month (365 days)	18 Month (545 days)	2, 3, 4, 5 Year (730, 1095, 1460, 1825 days)	Stroke/SE Assessment[1]
		Day 0		+2 Days	±7 Days	±30 Days	±30 Days	±30 Days	±60 Days	+14 Days
	Clinic Visit			Telehealth[2]	Clinic Visit/ Telehealth[2]	Telehealth[2]	Clinic Visit/ Telehealth[2]	Clinic Visit	Telehealth[2]	
Informed Consent	X									
Medical and Surgical History	X									X
Physical Exam/Assessment	X									X
Vital Signs	X									
CHA_2DS_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					X		X
QVSFS	X[8]			X	X	X	X	X	X	X
Cardiac CT	X[9]				X[11]		X[11]			
TTE	X[9]		X[10]							
TEE	X[9]	X			X[12]		X[12]			X
Brain Imaging	X[13]									X[14]
AE Assessment	X	X	X	X	X	X	X	X	X	X
Medication Review[15]	X	X	X	X	X	X	X	X	X	X
INR[16]	X	X								
Randomization	X[17]									
LAA Measurements		X								

TABLE FOOTNOTES Protocol Rev M

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

[1] In the event of a suspected stroke or systemic embolism, a clinical assessment is required within 14 days after the site becomes aware of the event. If the patient is unable to travel due to hospitalization or disability, chart review can be performed in lieu of clinic visit.

[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.

[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 LAAO 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 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 suggested 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 only after all clinical assessments and eligibility criteria are confirmed** and shall be performed within 90 days of informed consent.

Randomization

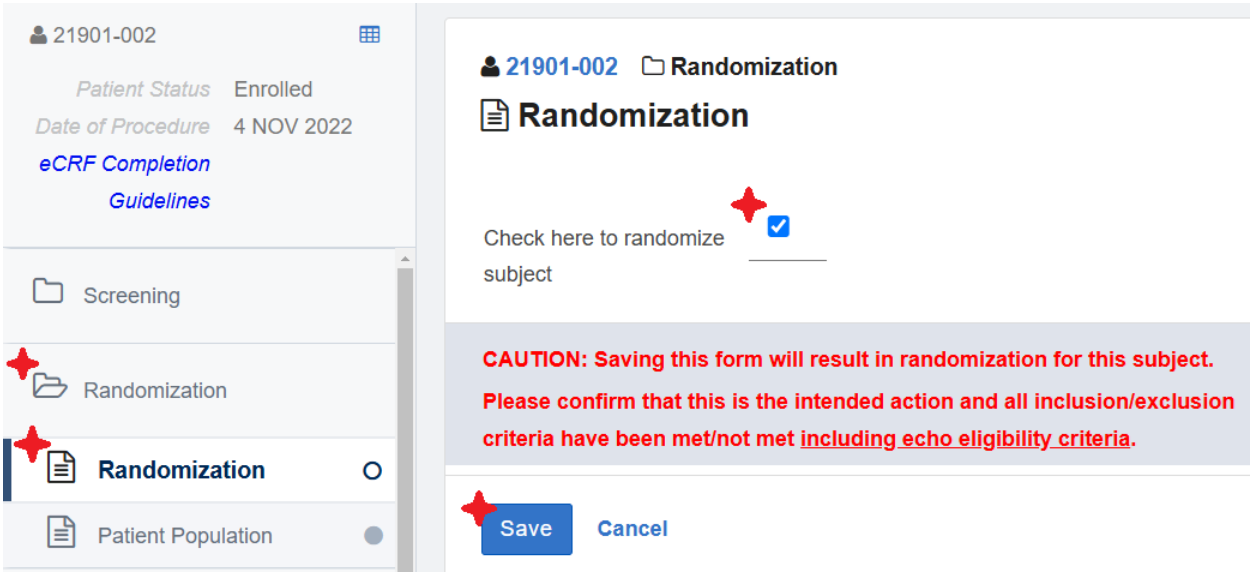
conformal™ The Shape of Stroke Prevention	**Title:** **MOP 6 - Randomization**

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:



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

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

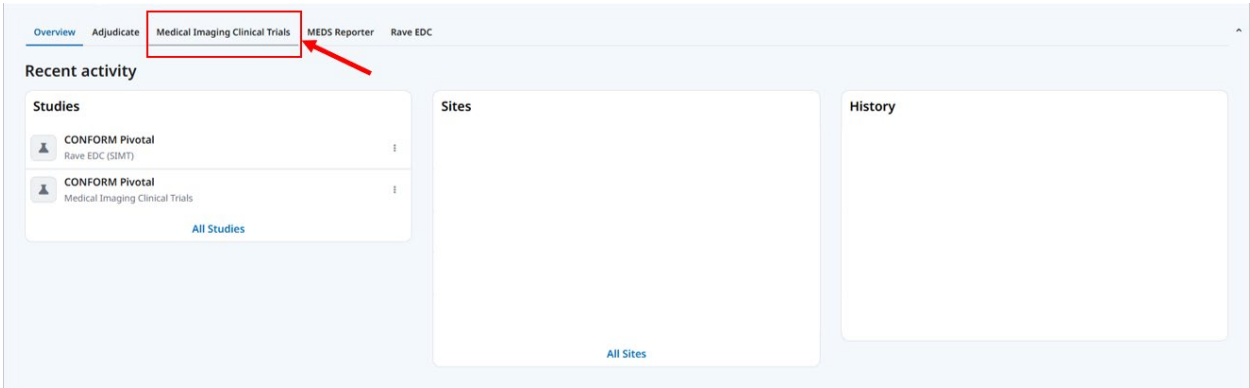
Visit	Image type required per visit
Screening	**Executive Committee Pre-Procedural Review for First 5 Patients**: • Cardiac CT/TEE: Within 6 months of the date of consent **Post-5 Patient Review Imaging Options**: Within 6 months of the date of consent (one of the following must be performed) • TEE • Cardiac CT • TTE* • Cardiac MRI* ** TEE or CT is required prior to randomization to fully evaluate all echo exclusion criteria. Note that TTE and Cardiac MRI can only be completed as screening imaging if site has 3+ procedures on a given day. If there are less than 3 procedures, Conformal requires that a CT or TEE is done as screening imaging.* **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.
Randomization	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. **Note: The subject will undergo TEE during the Index Procedure, and this timepoint will serve as a review of Echo Exclusion Criteria.**

Visit	Image type required per visit
Procedure	• TEE ○ If 3D imaging is acquired, the 3D raw data should be transferred with the uploaded images • Angio
Pre-Discharge	TTE • At least 4 hours post-procedure
45-Day (± 7 Days)	TEE • 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.
6 Month (± 30 days)	**TEE is only required at 6 Months IF**: Subjects at the 45-day visit that had evidence of a non-trivial residual leak (>3mm) or thrombus. The subject will need a repeat TEE at 6 months if there is no TEE imaging documentation of the event resolution.
12 Month (± 30 Days)	TEE • Cardiac CT may be used in lieu of TEE. ○ 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	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. 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. Neurological Event requires a Brain CT/MRI • Brain imaging is not required for patients with systemic embolism without new findings suggestive of TIA/stroke

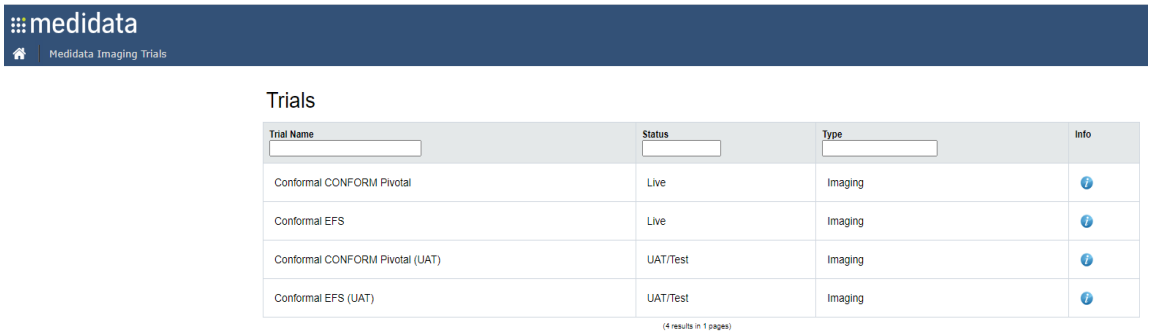
*Table 1.*0

2. Navigating Imaging Uploads in EDC

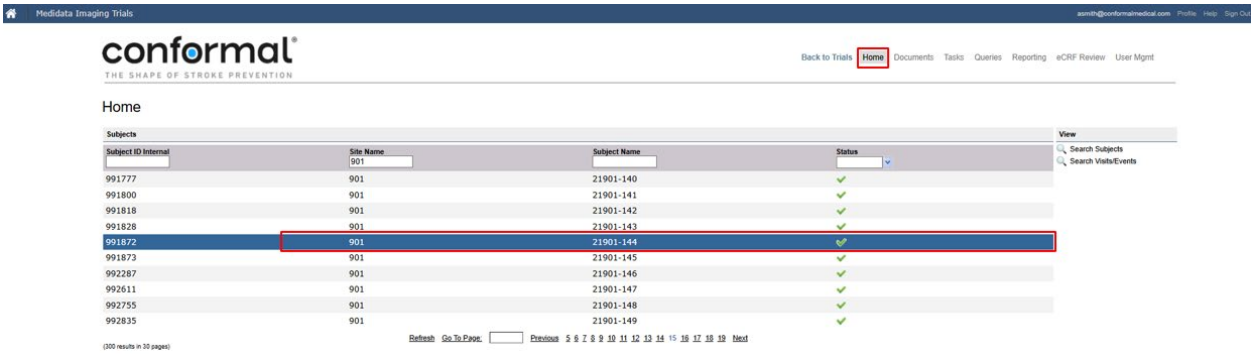
Log in from the Medidata home page. From the home page, go to “Apps” on the left side of the screen. Click the **conformalmedical** link under “Medical Imaging” to bring you to the imaging home page.



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:

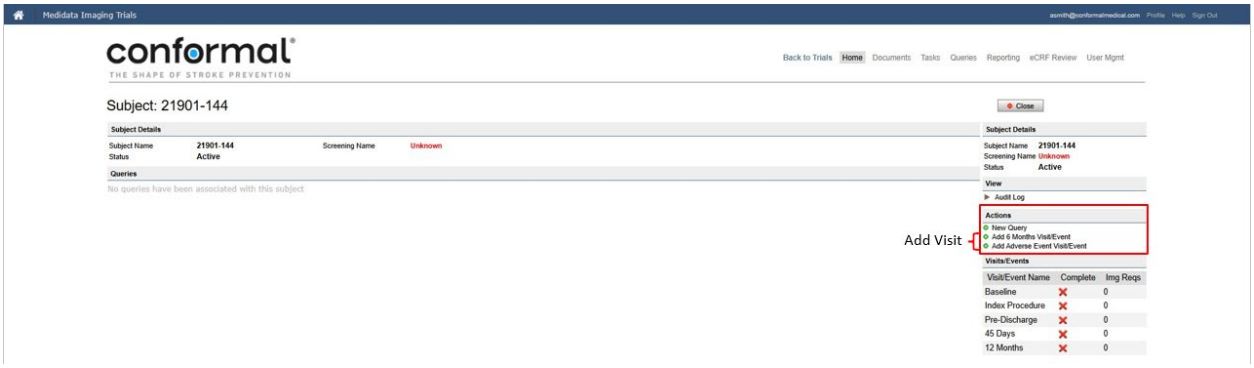


Once you click on a patient (in this case subject 21901-144 has been selected), you will be brought to the patient's repository page (pictured below). In the middle of the page, on the right-hand side of the screen, you can select the Visits/Events, which will open the specific Visit/Event details, Visit/Event

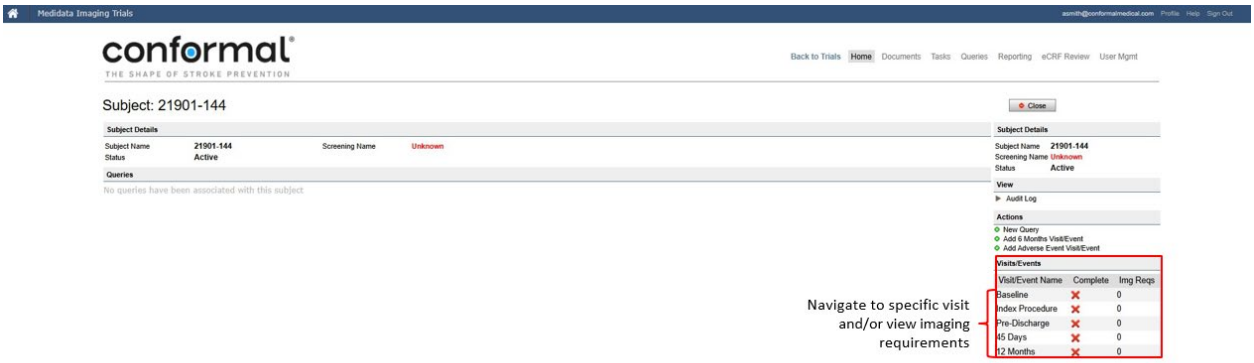
Requirements, and additional sections associated with the patient for that time point including a preview under the Exam Section.

Under the “Actions” section:

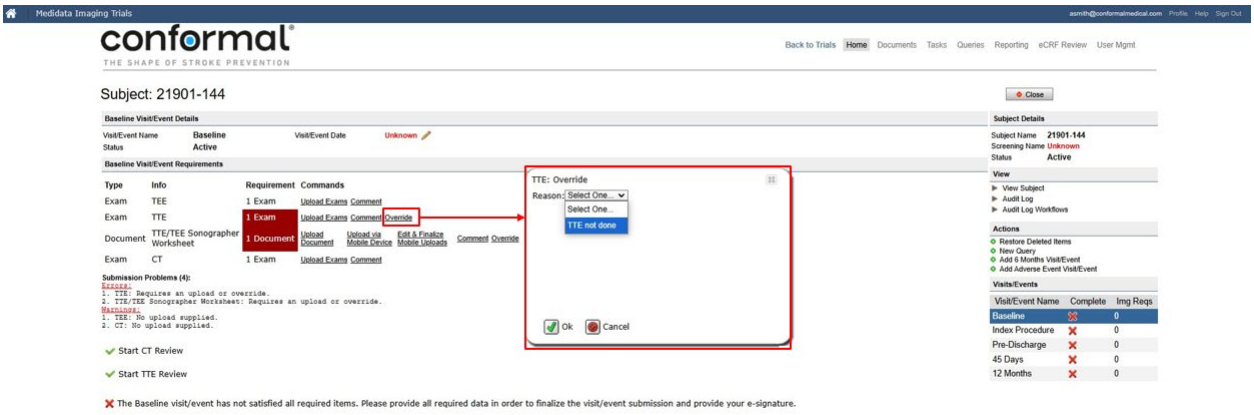
- You will also be able to add another visit for the patient (i.e., the patient has a device-related thrombus detected during their 45-day imaging, and the patient is required to come in for a 6-month TEE or add an adverse event visit for adverse events with associated imaging).



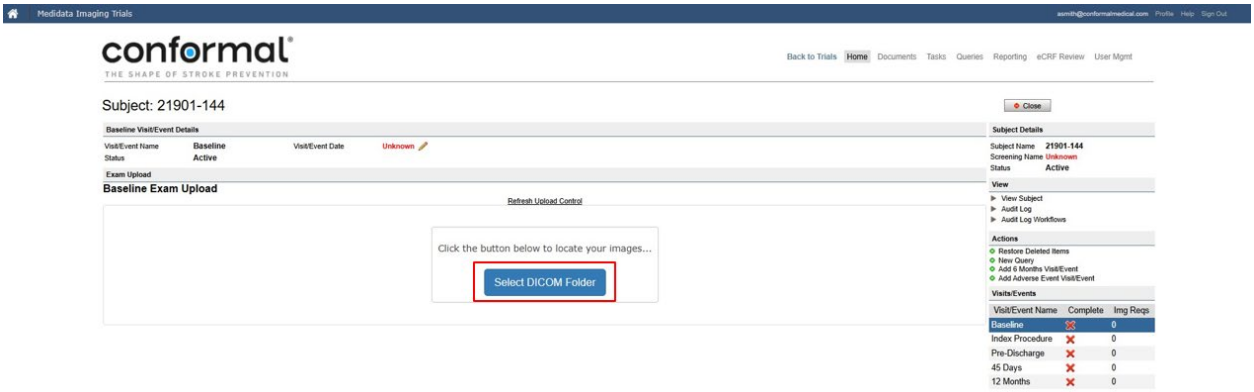
By clicking on any of the visits in the Visits/Events section in the bottom right, you will be able to navigate to that specific visit and view the imaging requirements.



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.



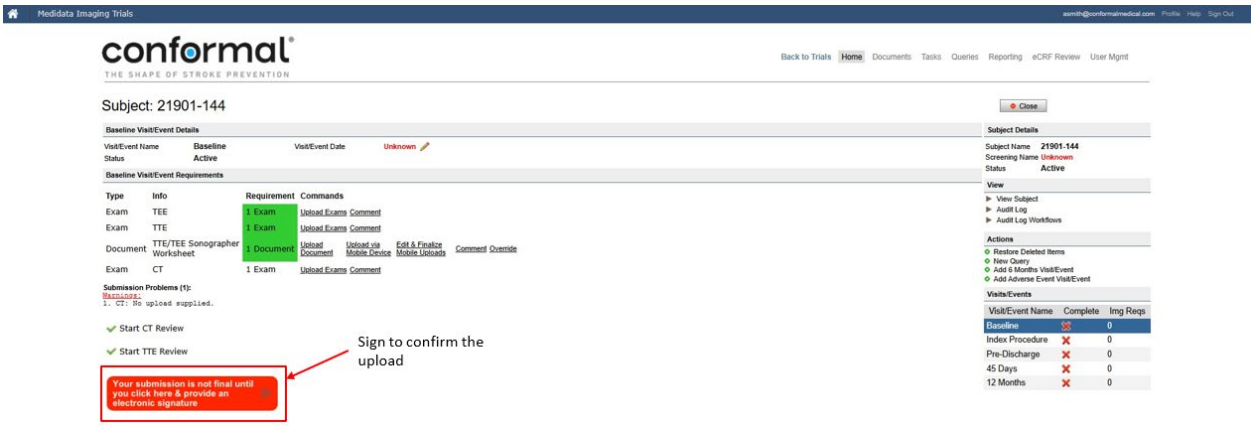
By clicking on the Upload Exams button, you will be taken to this page below, where you can upload the DICOM formatted imaging directly from your computer.



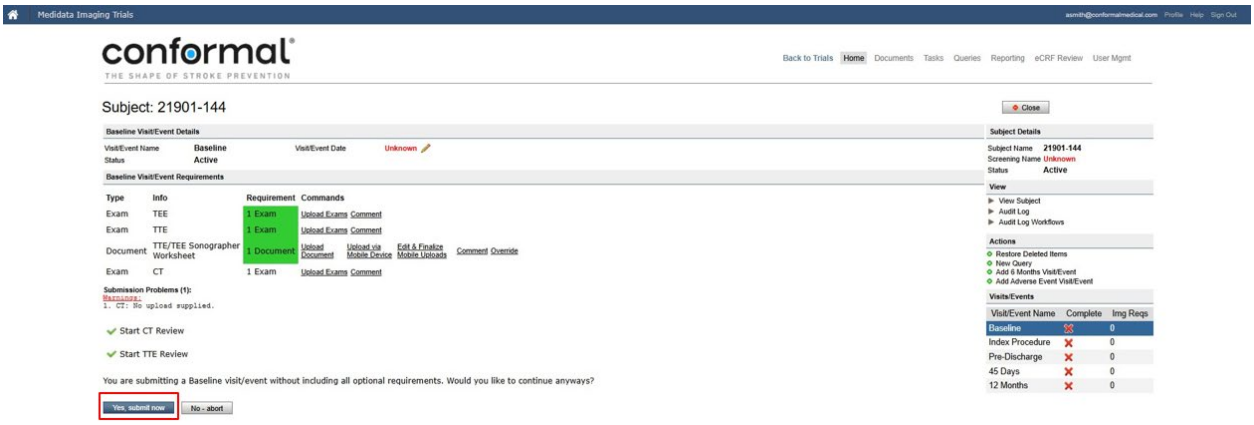
Once you have uploaded the required images, you will need to re-sign to confirm the upload. On this page, you will now see what was uploaded and when the images and/orsonographer worksheets were uploaded.

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

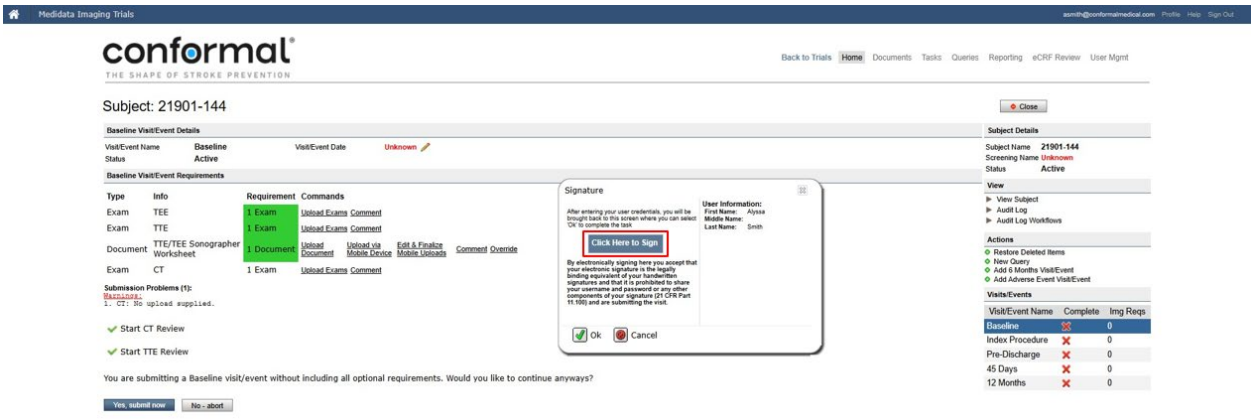
Select the red box to provide your electronic signature



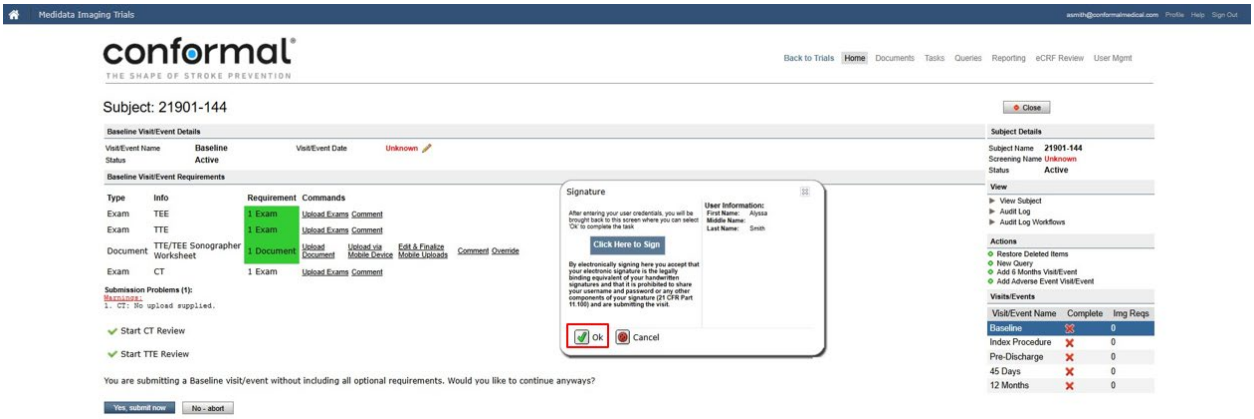
Select the blue box to confirm “Yes, submit now”



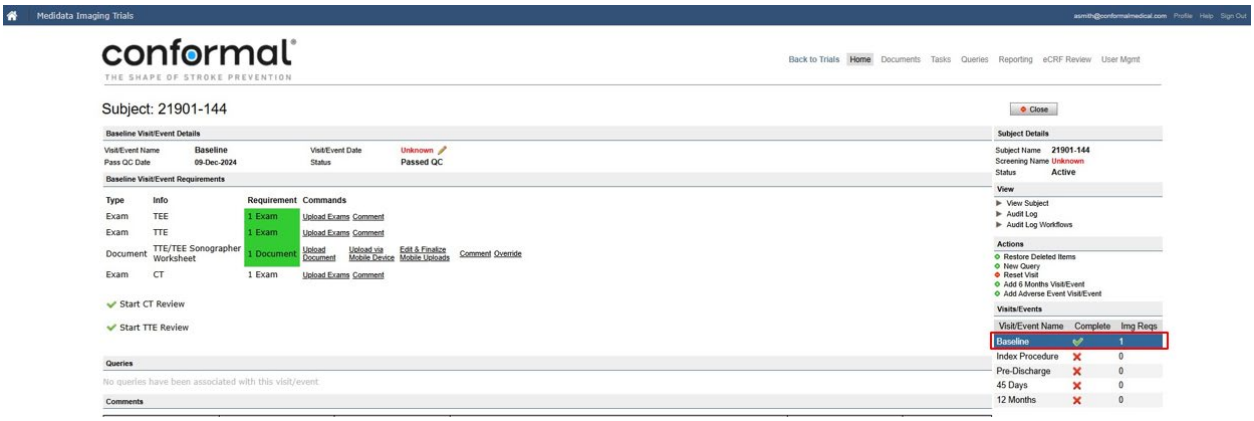
Select the blue box “Click Here to Sign”



Select the green check box “Ok”

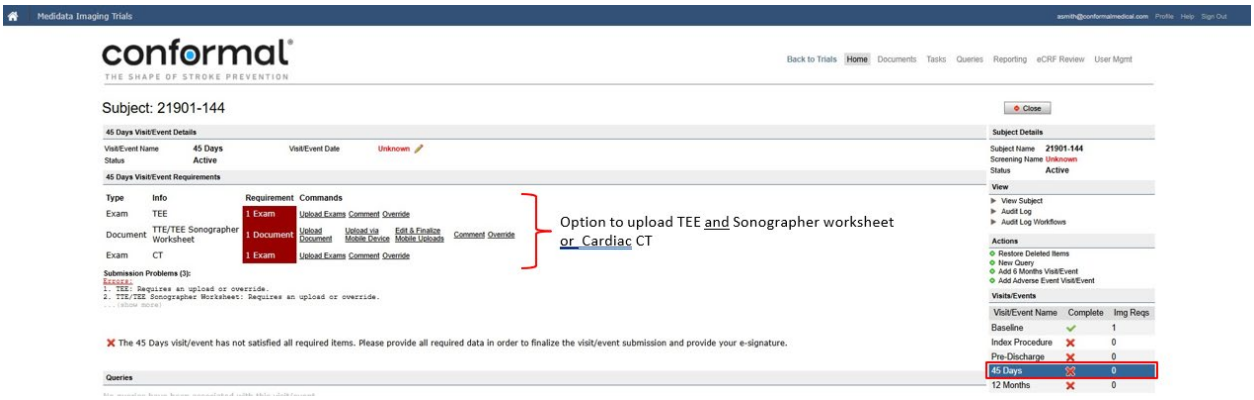


Once the uploaded exams and documents (if required) have passed QC, a green checkmark will appear showing the visit upload requirements are complete.

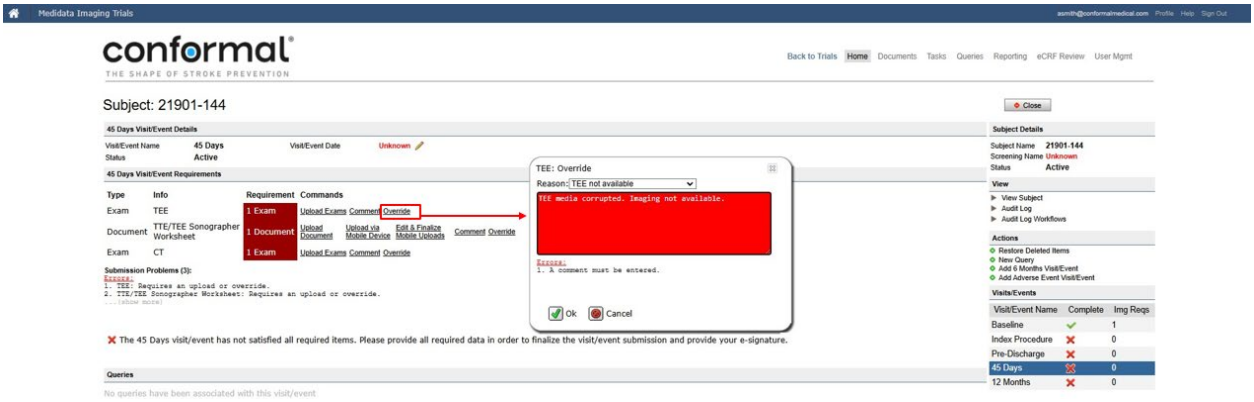


At 45 Days and 12 Months, either a TEE and Sonographer Worksheet or a Cardiac CT may be uploaded.

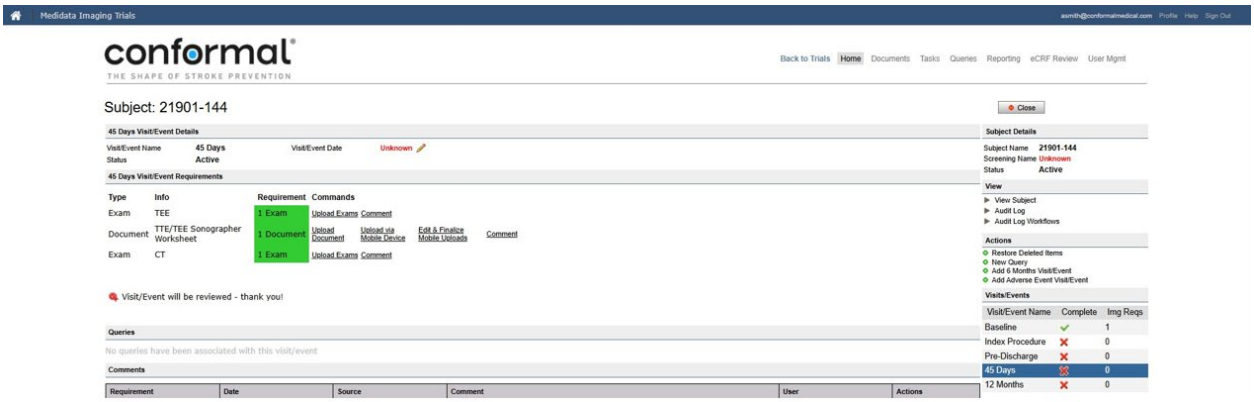
A completed and signed Sonographer Worksheet must accompany any uploaded TEE



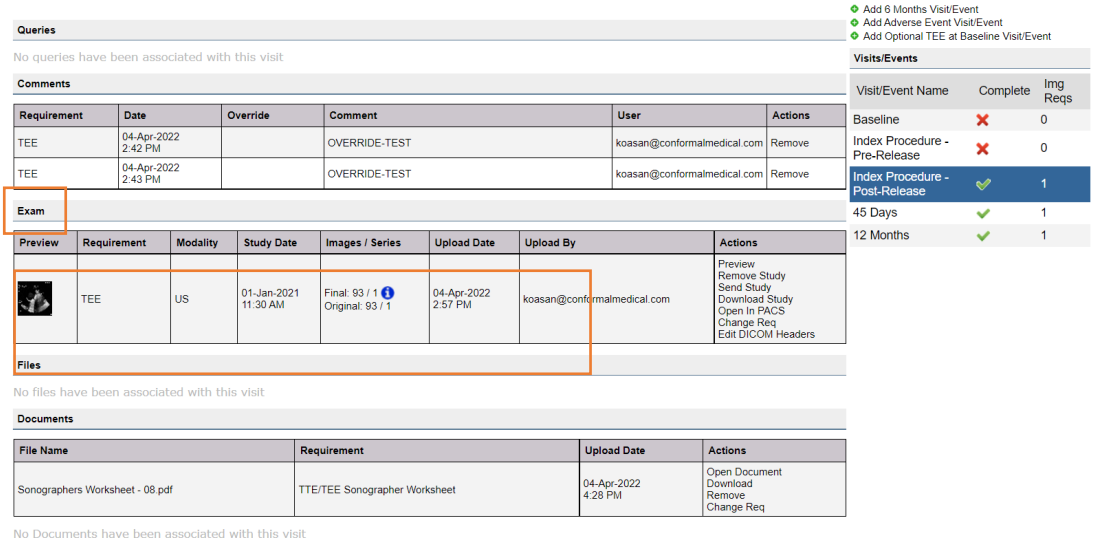
A comment must be provided if imaging type was performed but not available, in order to successfully override.



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.

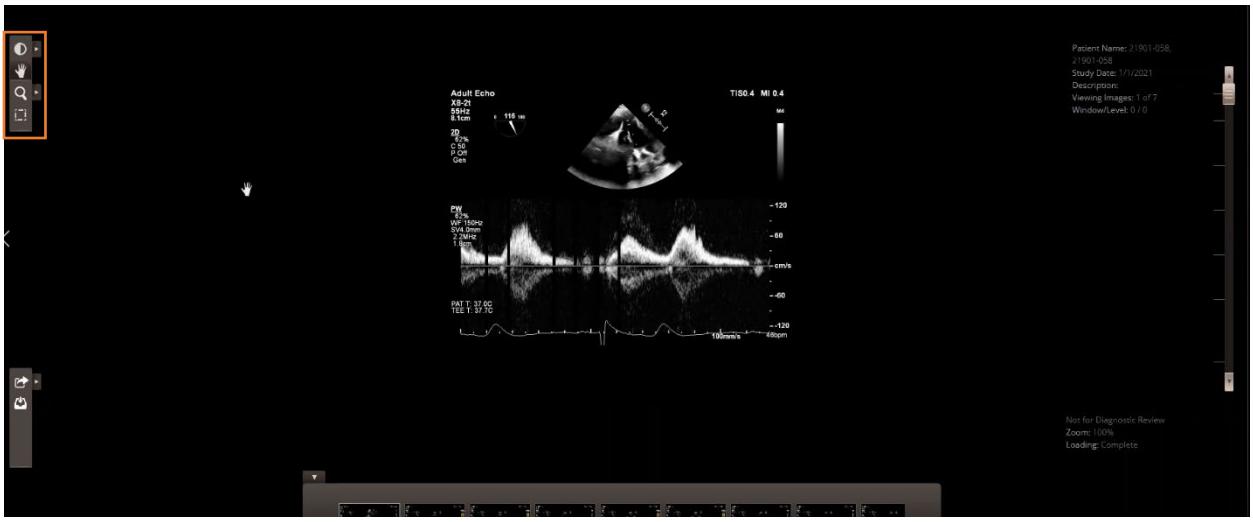


When scrolling further down this page below the comment section, you will see a section labelled “Exam”. This section is where you may preview the imaging, by clicking on the small picture.



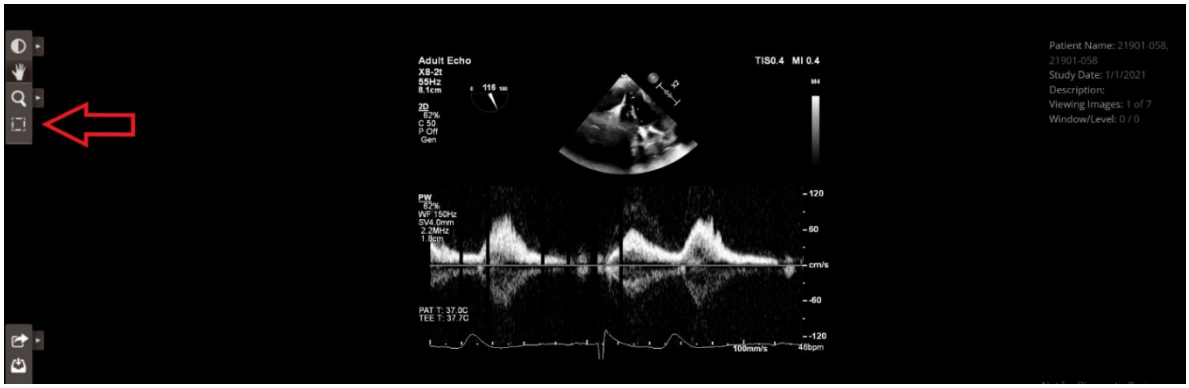
While previewing the images you will be able to see what was uploaded. Intelemage has a feature which assists with deidentifying remaining PHI.

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

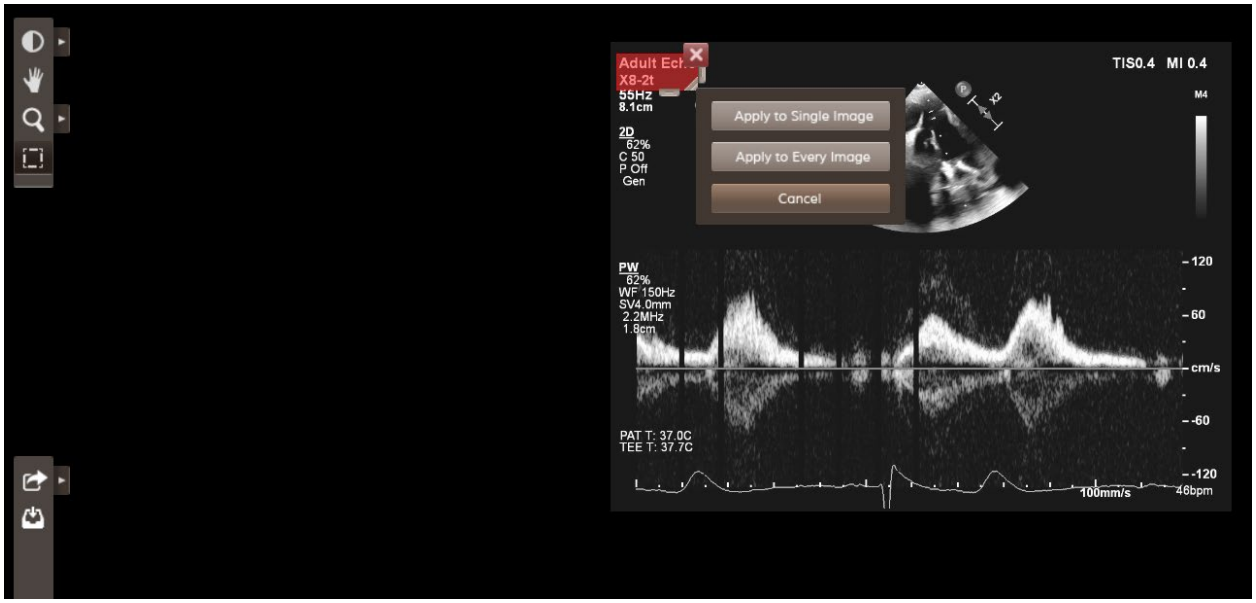
To redact, you will click on the box in the top left in the preview of the image.



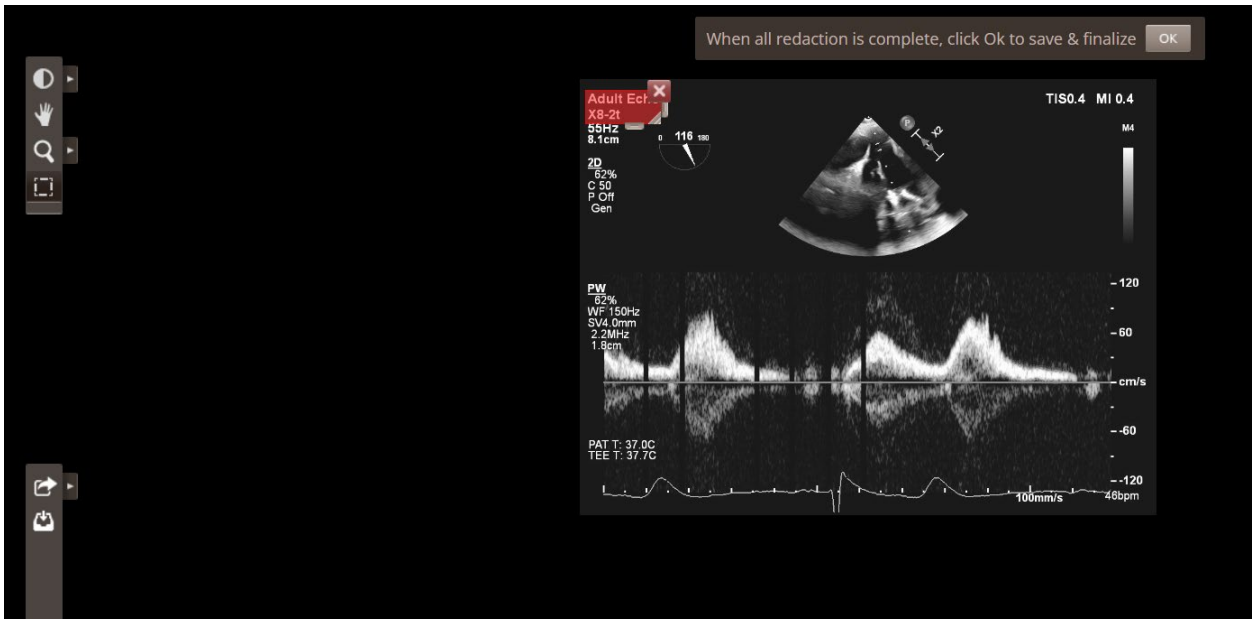
After clicking on the box, you will see a crosshair that appears. You will be able to click and drag your mouse around the area that you would like to de-identify. Once you have created the red shaded area around the PHI, you will see 3 options appear: “Apply to Single Image”, Apply to Every Image”,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

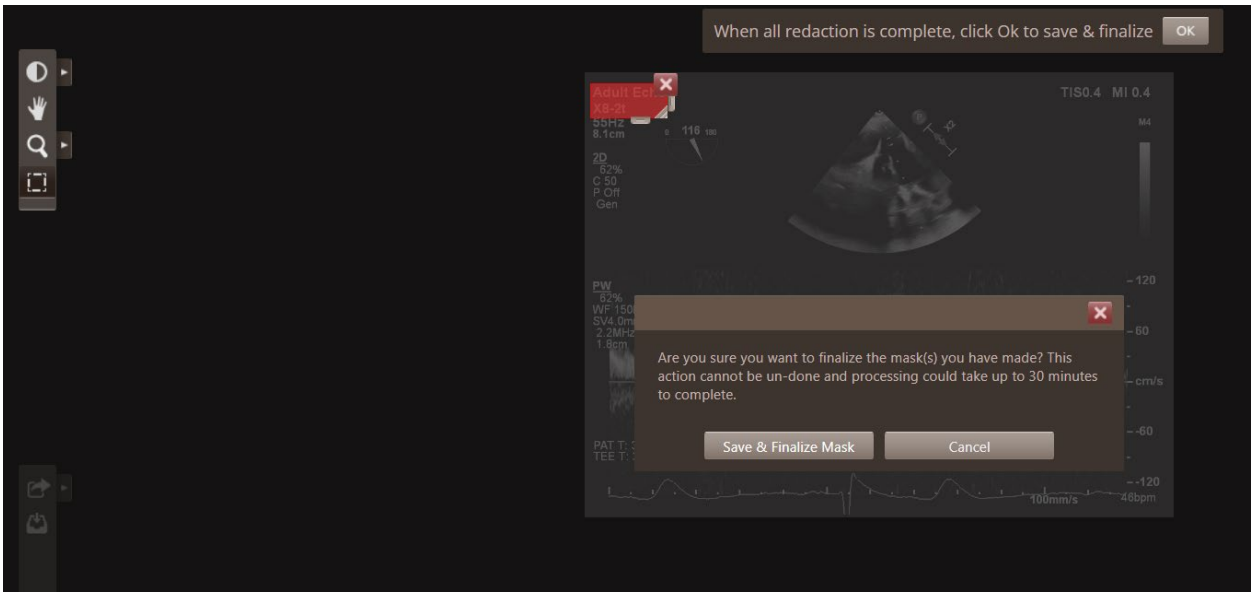


Once you select a masking option, you will see a message pop up that states: “When all redaction is complete, click OK to save & finalize”.

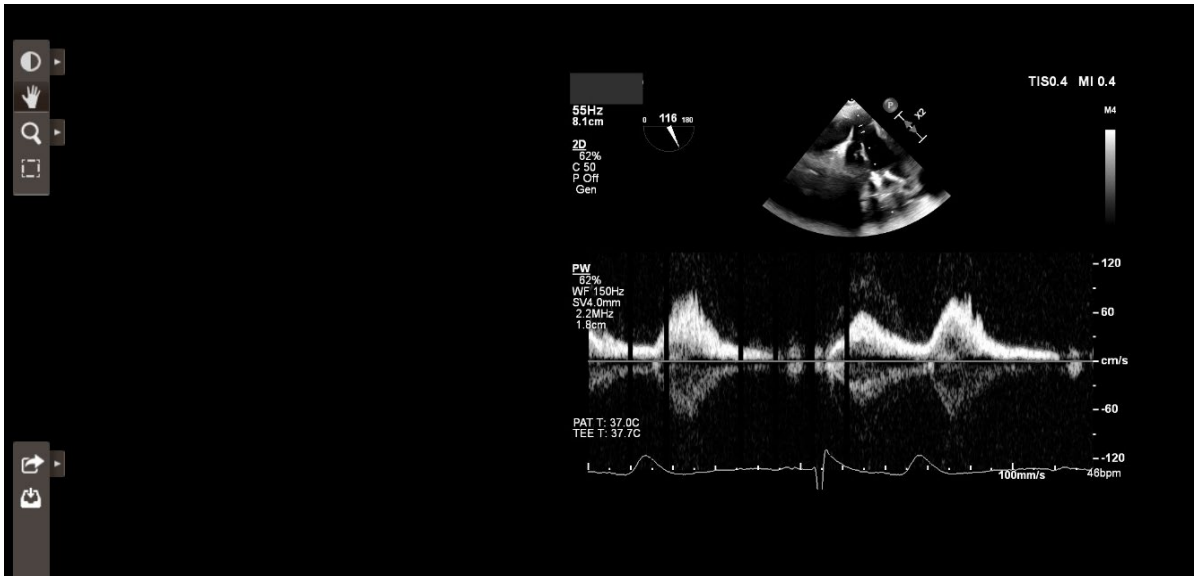


Once you select “Ok”, another message will populate asking if you are sure you would like to finalize. **This action cannot be undone**, so please confirm the masking option and area you are de-identifying are correct.

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

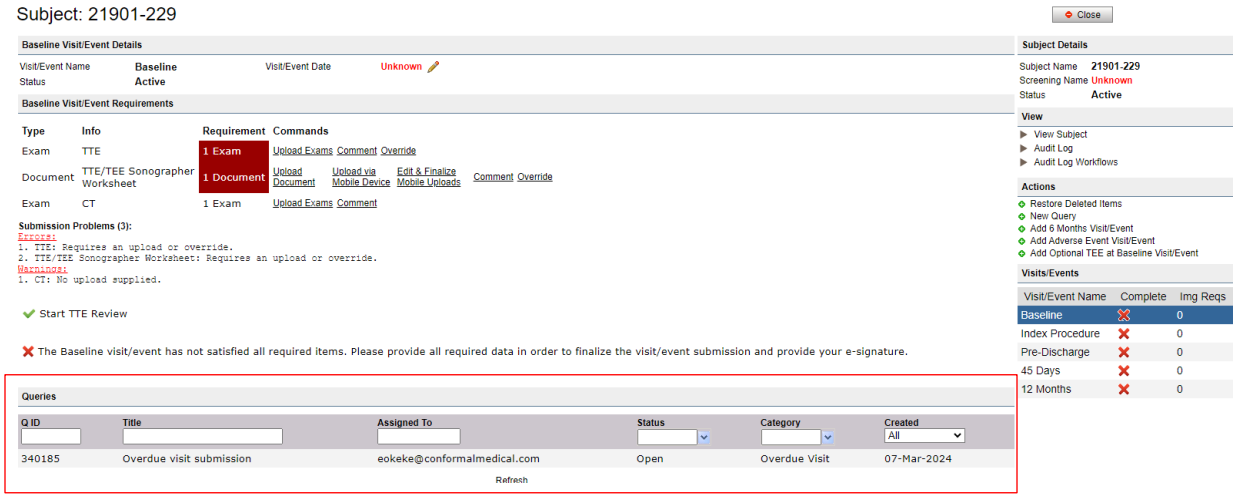


Once you select “Save & Finalize Mask”, the system will begin masking the area you have selected. Below is the result of masking in the top left corner of the image.

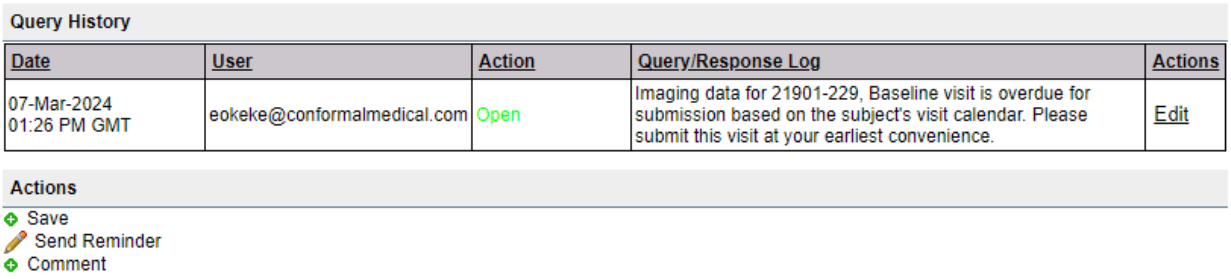


4. Addressing Imaging Queries

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”.



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.



5. 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

Table of Contents

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 (>=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 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!**

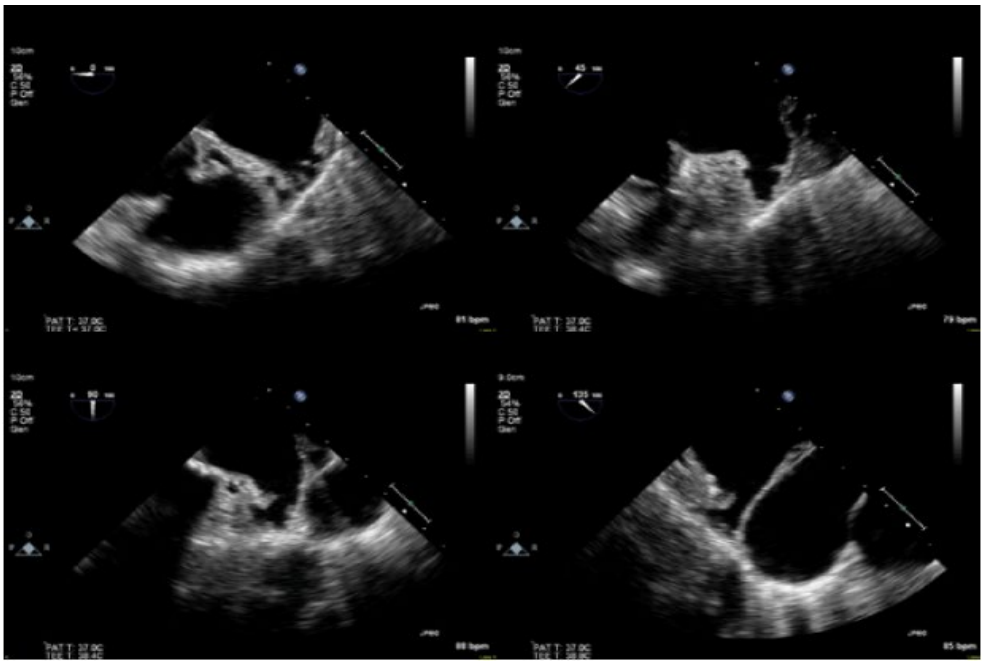
2.0 Two-Dimensional TEE Echocardiography Guide

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.

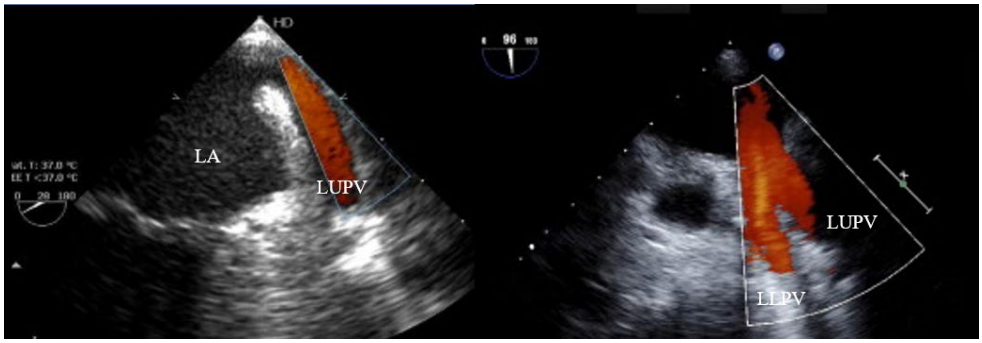
2.1.1 Two-Dimensional Imaging of Left Atrium/Left Atrial Appendage

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 0^0 – 180^0. Images of the LAA are acquired at 0^0, 45^0, 90^0, and 135^0.



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 index[7] for diagnosing pulmonary vein stenosis.

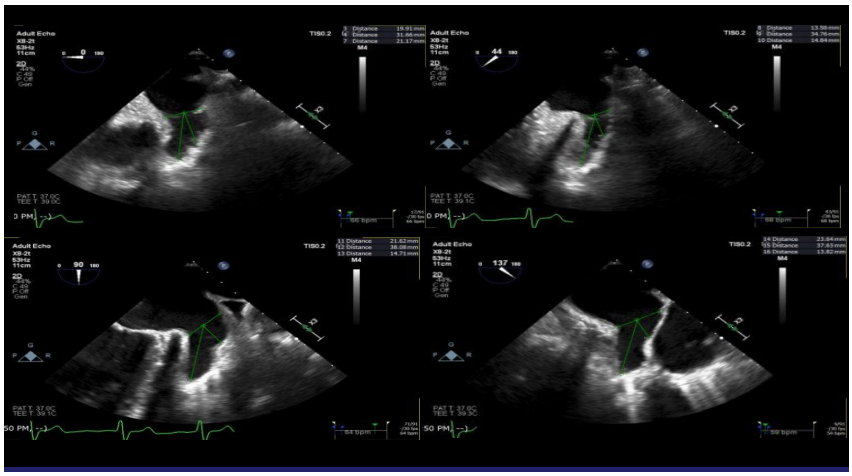


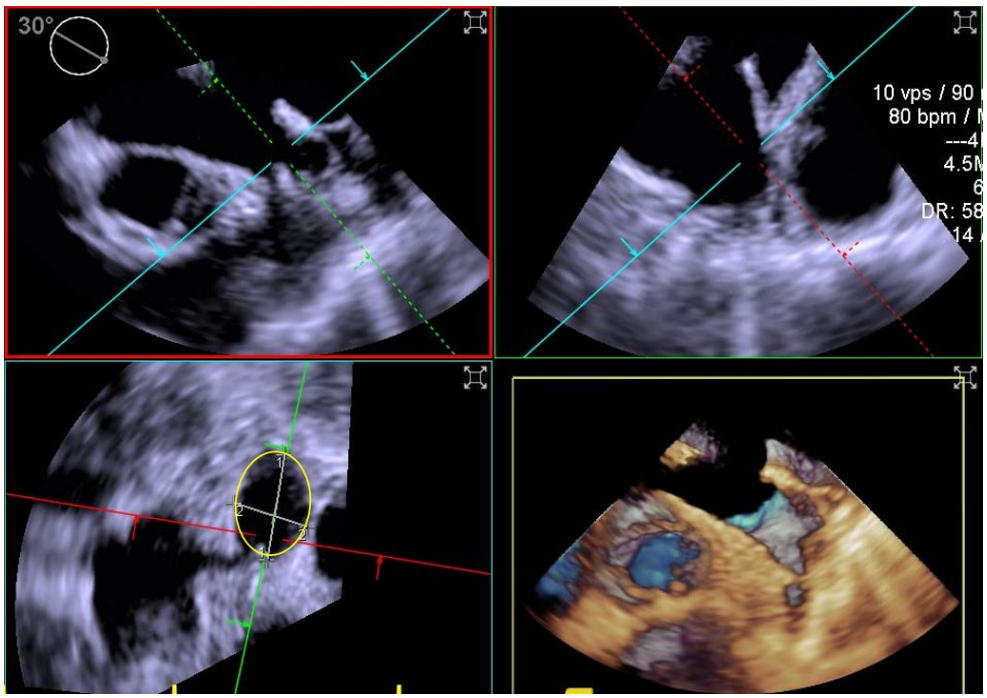
Cartwright, Bruce MBBS, et al Intraoperative Pulmonary Vein Examination by Transesophageal Echocardiography: An Anatomic update and Review of Utility. Journal of Cardiothoracic and Vascular Anesthesia. Volume 27, Issue 1, February 2013, Pages 111-120

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 0^0, 45^0, 90^0, and 135^0. The 3D image of the LAA should be taken from a wide-angled view at 45^0. 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

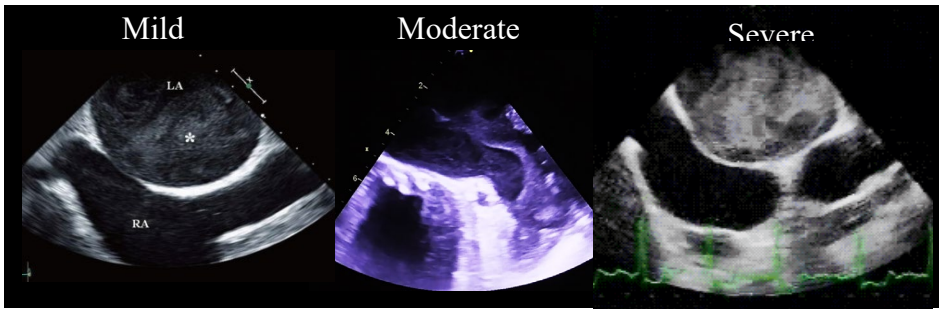




2.1.4 LAA Spontaneous Echocardiographic Contrast (SEC)

Will be assessed from the images acquired. Please optimize gains. The following grading will be used:

a. Absence of echogenicity
b. Mild (minimal echogenicity, only transiently detectable with optimal gain settings during the cardiac cycle)
c. Moderate (dense swirling pattern throughout the cardiac cycle)
d. 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

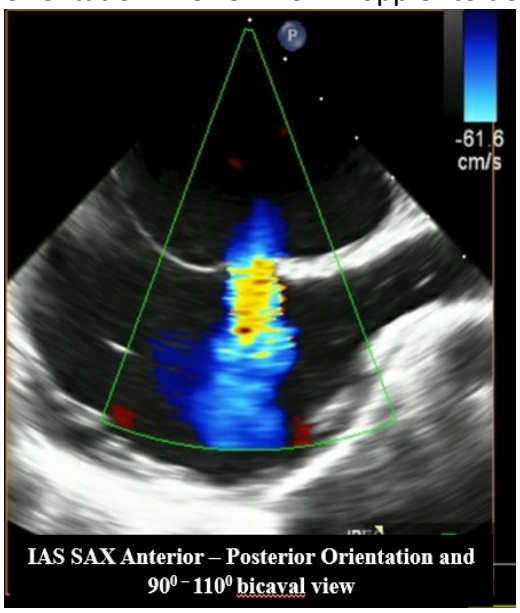
https://drsvenkatesan.com/2011/04/10/a-hurricane-inside-left-atrium/

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 $90^0 - 110^0$ bicaval view inferior to superior orientation. Perform CW Doppler to demonstrate direction of flow.

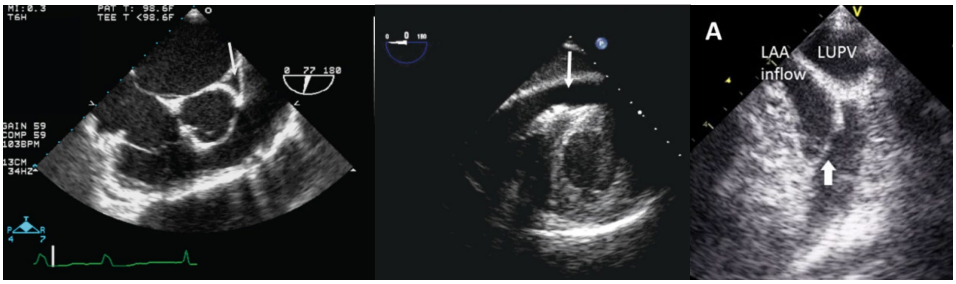


IAS SAX Anterior – Posterior Orientation and $90^0 - 110^0$ bicaval view

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.

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



https://thoracickey.com/wp-content/uploads/2016/06/B9781455707614000232_f23-02-9781455707614.jpg

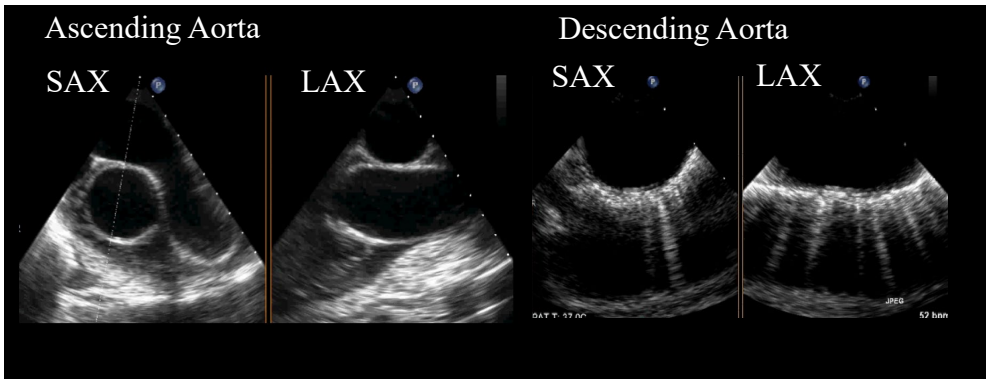
Kamperidis, V et al. "Left Atrial Appendage Pericardial Fluid: Contrast-Enhanced Transesophageal Echocardiography Makes It Visible." Hippokratia20.3 (2016): 235–237. Print.

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



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 0^0-135^0 and acquire clips at 0^0, 45^0, 90^0, 135^0 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.

2.2.1.1 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

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 0^0-135^0 and acquire clips at 0^0, 45^0, 90^0, 135^0 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.

2.3.2.1 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 45^0. 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).

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 $90^0 - 110^0$ 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 0^0-135^0 and acquire clips at 0^0, 45^0, 90^0, 135^0 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).

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 45^0. 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 $90^0 - 110^0$ 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.

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** – Transesophogeal Echocardiography
31. **TG** - Transgastric
32. **UE** – Upper Esophageal
33. **TEE** – Transesophogeal Echocardiography

4.0 References

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5.0 Contacts

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CONFORM TEE
Checklist

conformal™ The Shape of Stroke Prevention	CONFORM Pivotal Trial **TEE Checklist – ALL LAAO cases to be performed by Non-Implanting Physician**

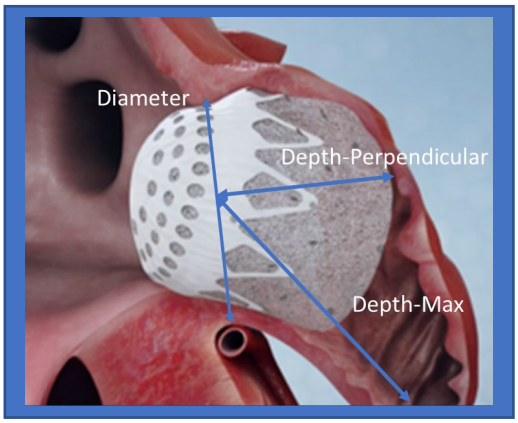
TEE BASELINE

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

conformal™ The Shape of Stroke Prevention	CONFORM Pivotal Trial **TEE Checklist – ALL LAAO cases to be performed by Non-Implanting Physician**

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.
15 Trafalgar Square, Ste. 101
Nashua, NH 03063

Cardiac CT Core Lab:
St. Paul's Hospital/University of British Columbia
1081 Burrard Street
Vancouver, BC
V6Z 1Y6,
Canada

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	DocuSigned by: David Pomfret Signer Name: David Pomfret Signing Reason: I approve this document Signing Time: 15-Jun-2022 | 17:43:29 EDT 1C87BCDC0C294C79BCA0276D6AC3D9CB
Philipp Blanke	Director CT Core Lab	DocuSigned by: Philipp Blanke Signer Name: Philipp Blanke Signing Reason: I am the author of this document Signing Time: 15-Jun-2022 | 06:18:06 PDT FB1A7E95968B408DB92FE4A022C9D797

Table of Contents

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 with in 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, ≤ 1mm; 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

conformal™ The Shape of Stroke Prevention	Title: **MOP 8 – Device Accountability WI**

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

conformal™ The Shape of Stroke Prevention	**Title:**
	MOP 8a – Device Return

Device Return

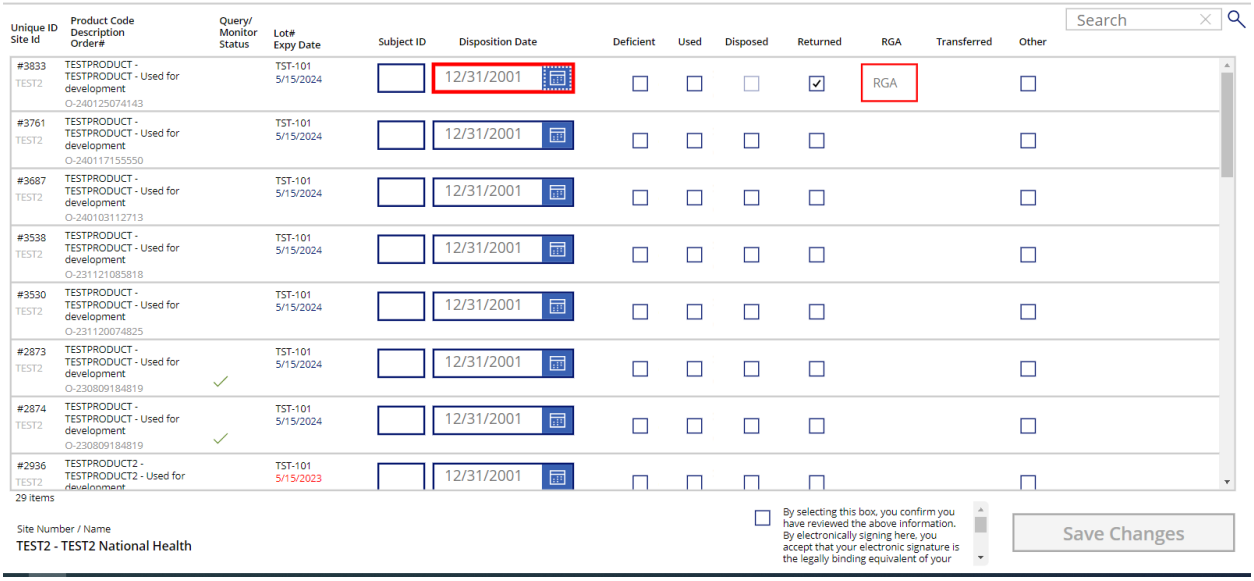
- Devices are returned to the Sponsor for several reasons which include but are not limited to:
  - Product expiration
  - Device malfunction
  - Shipping/ordering error
  - Inventory return/exchange

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



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?

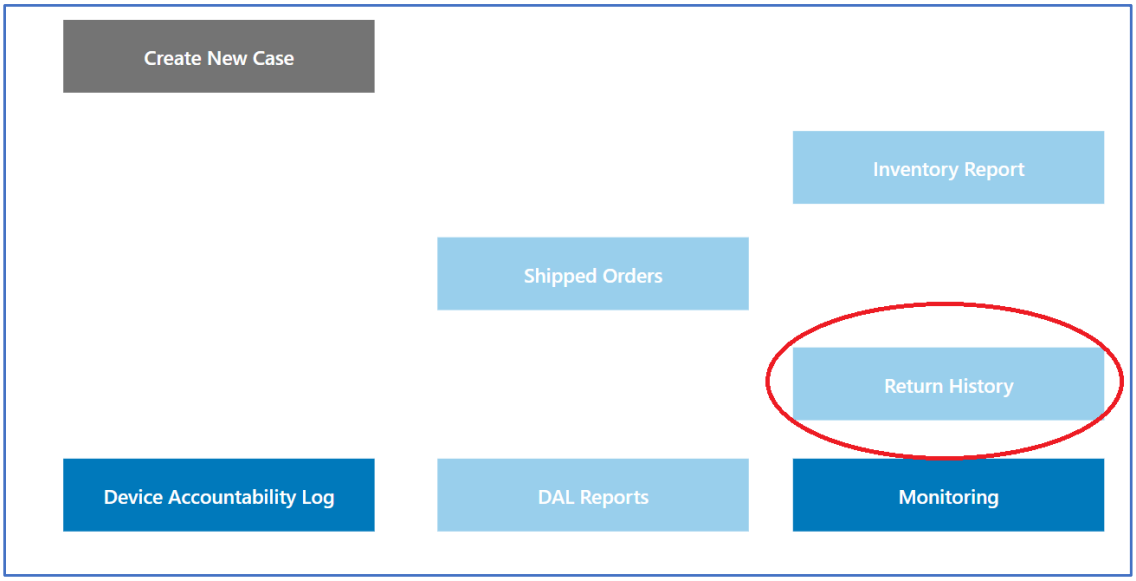
- Check off the appropriate box on the Device Accountability Log

- Note: not all product with a device deficiency needs to be returned.

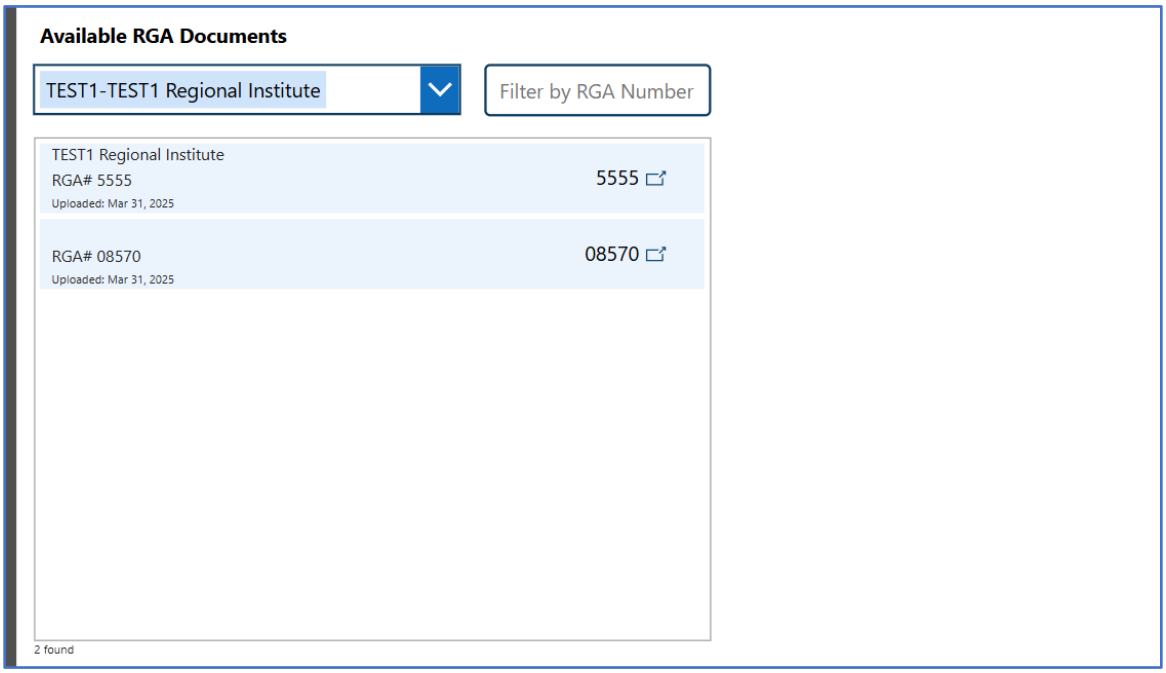
- Record the device deficiency in EDC

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

Contents

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.

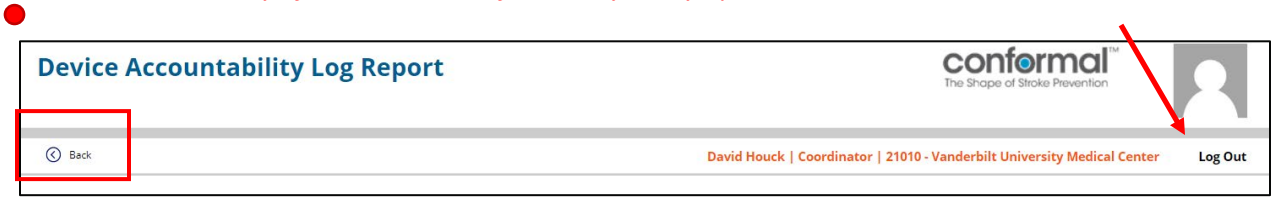
II. GETTING STARTED

- 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*.



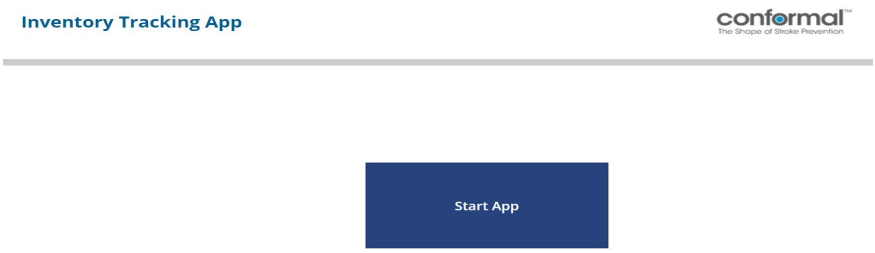
3. Any time you select a date within the application, you will need to press Ok to enter that selection.

IV. LOGIN INSTRUCTIONS

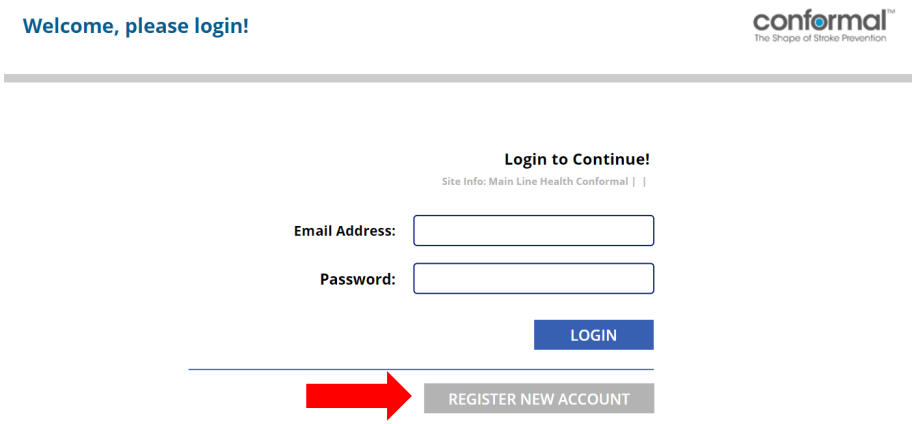
If you are designated for access to the inventory tracking application, you will create a Personal Login for access to the functions within the program and track all activity. Please follow the steps below to create your account.

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.

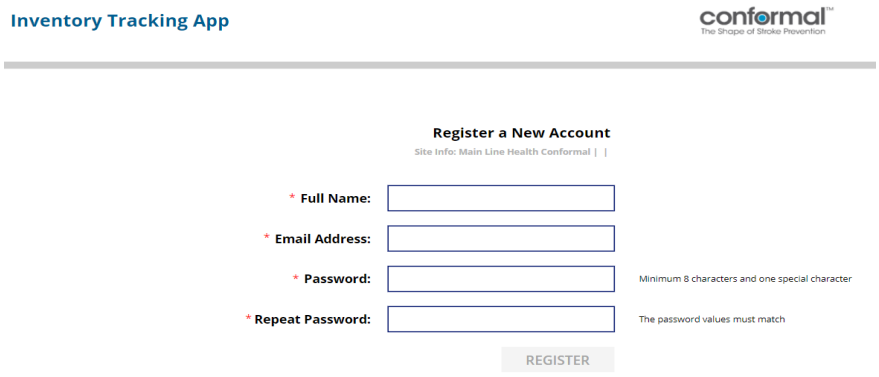
2. Press **Start App**



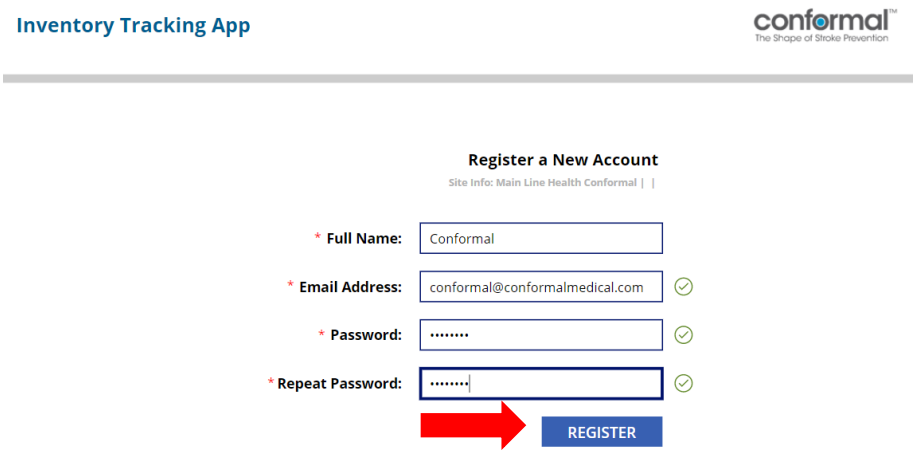
3. If this is your first time using the application, press the **Register New Account** button.
   - If you have already created an account, then skip to step 7.



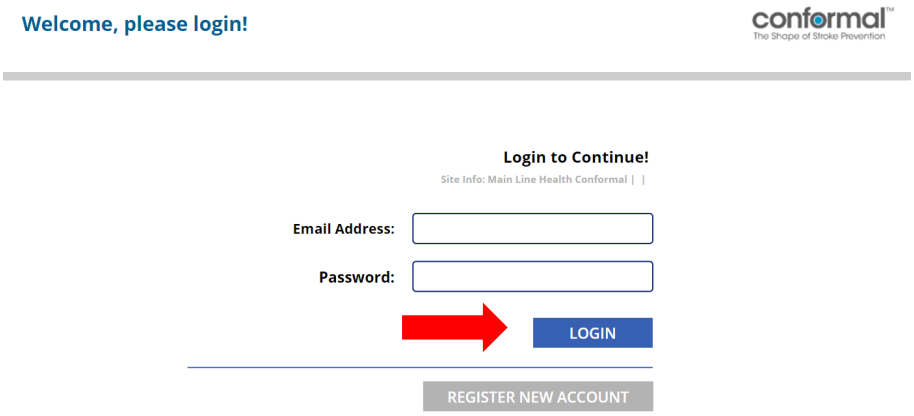
4. Complete the form with your name and email, and create a personal password for your Personal Login.
   - It is recommended to use your work email
   - It is recommended to use a password that is not used anywhere else for security reasons.



Press **Register**



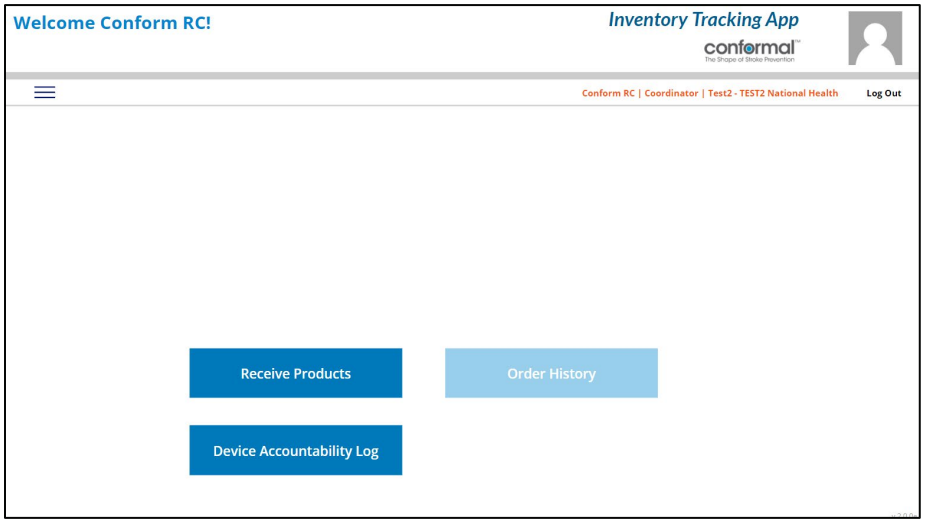
5. **Login** to receive product and update the device accountability log.



V. RECEIVE PRODUCT

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

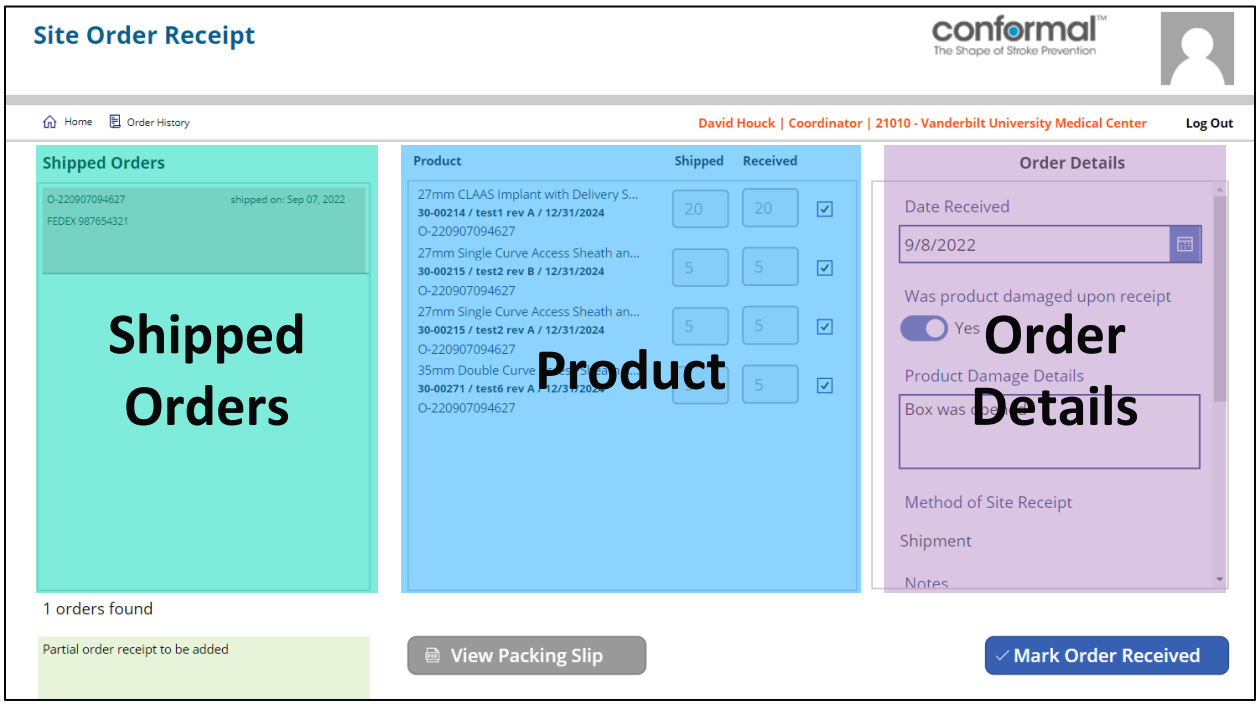
1. This image shows the **Home Screen**



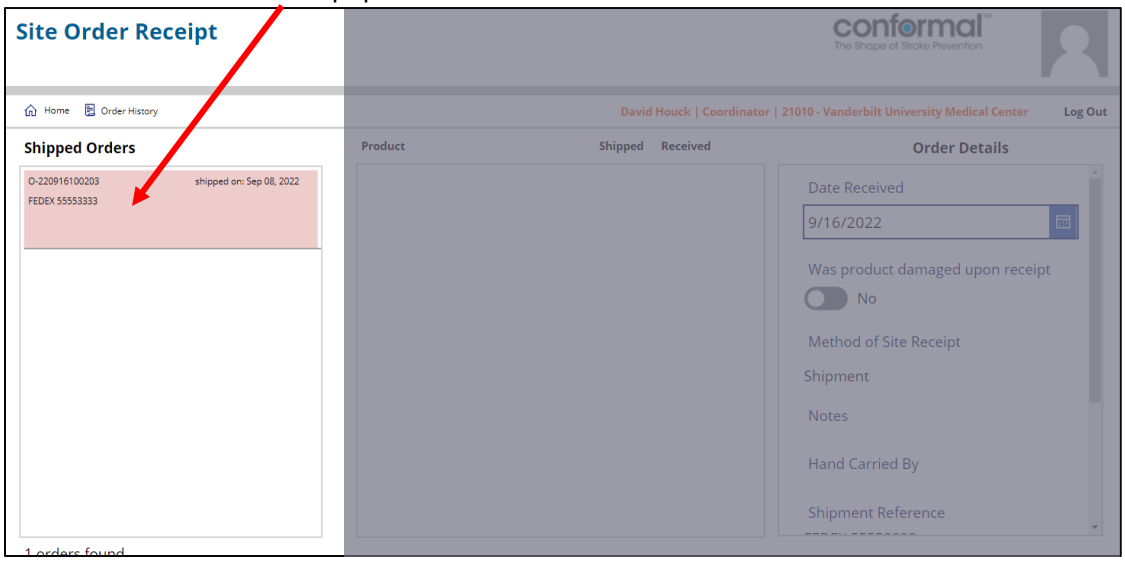
2. Click the button **Receive Products**

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

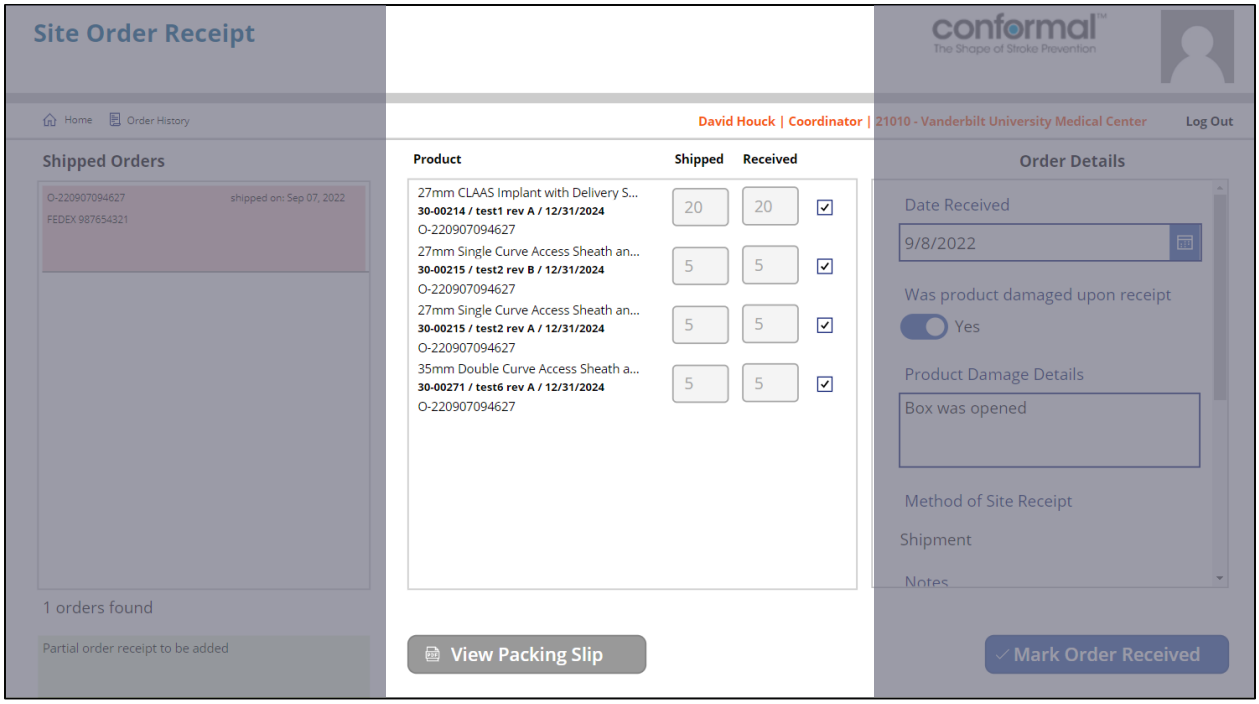
3. You will see the **Site Order Receipt Page**. This page consists of three sections:
   - Left section: **Shipped Orders Panel**
   - Middle section: **Product Panel**
   - Right section: **Order Details Panel**



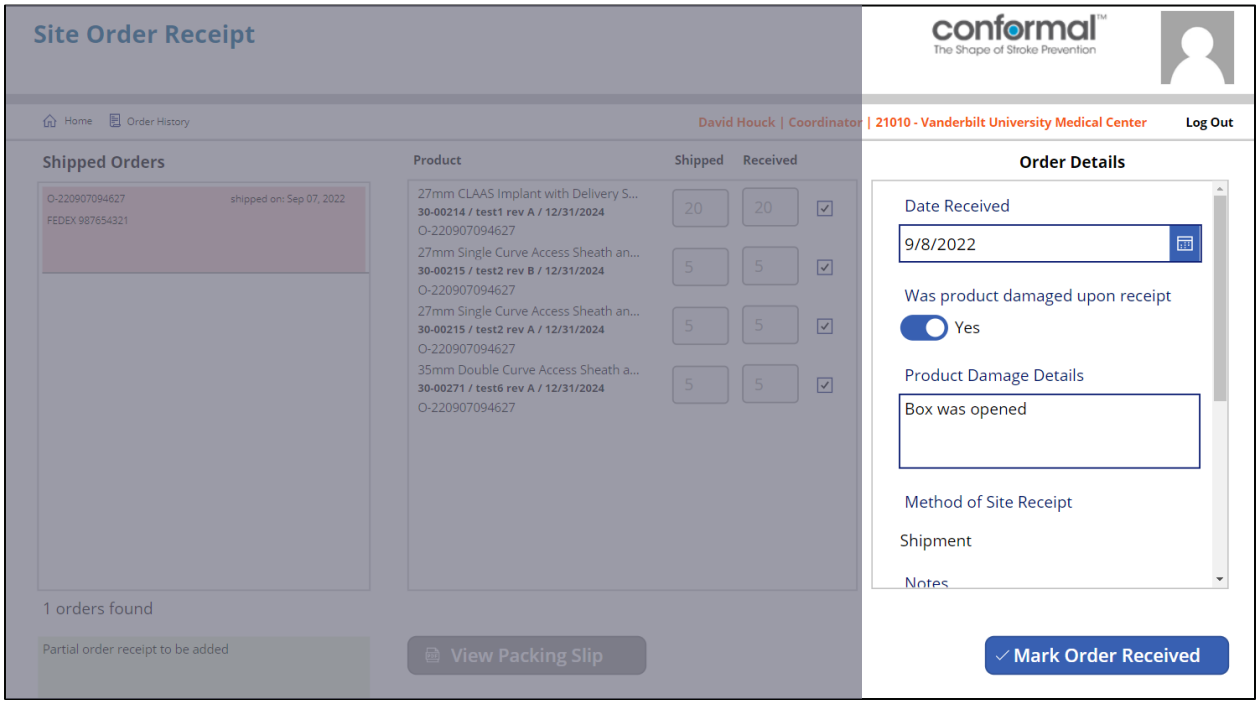
4. Orders that have been shipped to your site will be displayed on the left in the **Shipped Orders Panel**. The **Product Panel** and **Order Details Panel** will appear once you select your order.
   - The O-## number is the Conformal Order#
   - The tracking number and shipping date are displayed.
   - Click on the order to populate the Product Panel.



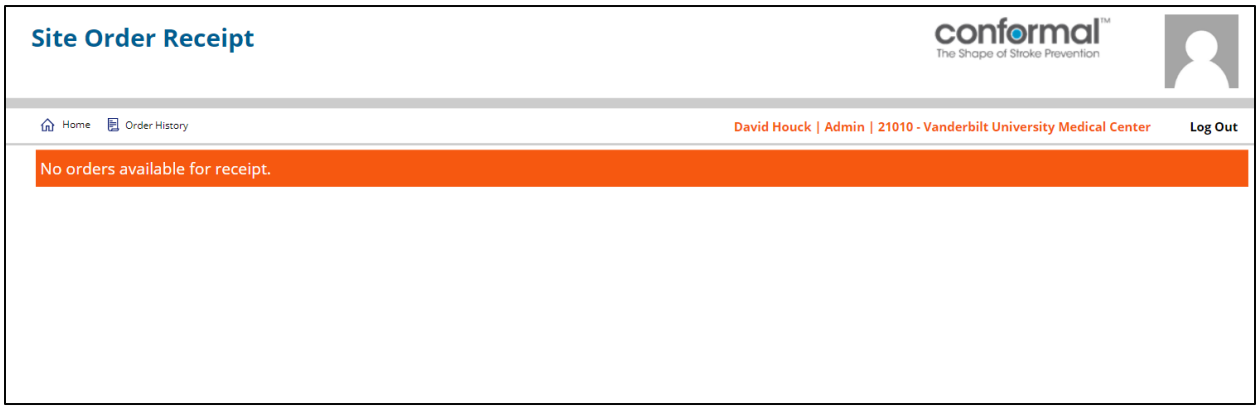
5. The **Product Panel** will populate in the middle section. The **Product Panel** contains information on the device type, lot number, and quantity
    - Confirm all product listed as shipped has been received by checking the boxes next to each line item.
    - Click the button “View Packing Slip” 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.



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.

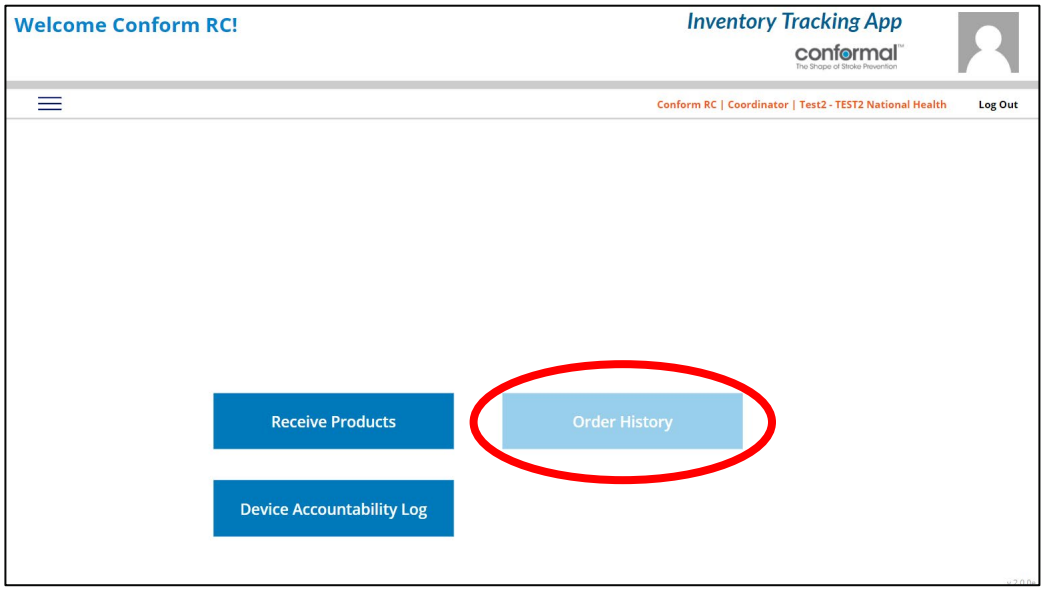


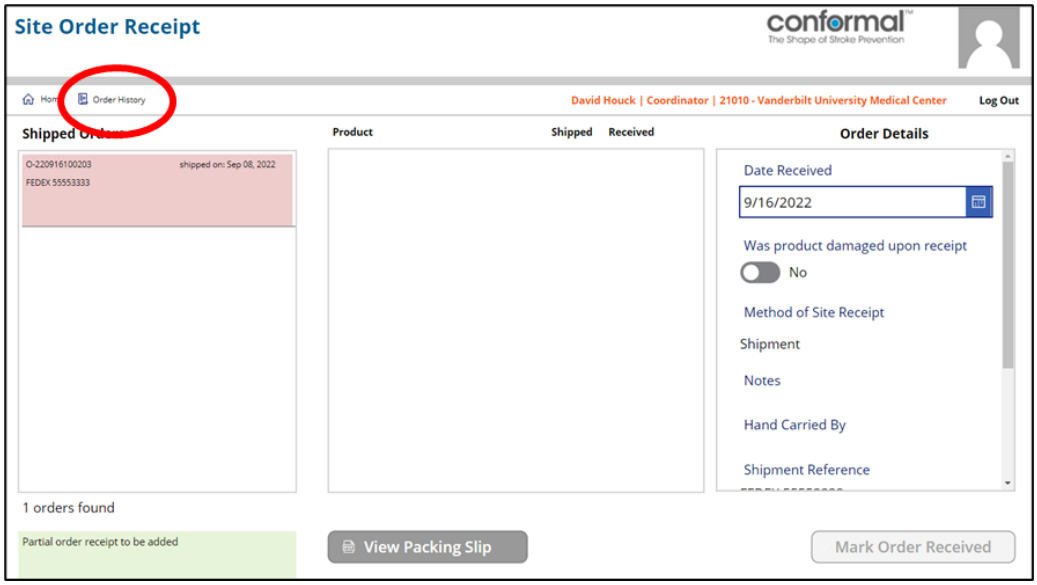
7. After an order has been marked received or if there are no current orders for your site, the following message will be displayed.



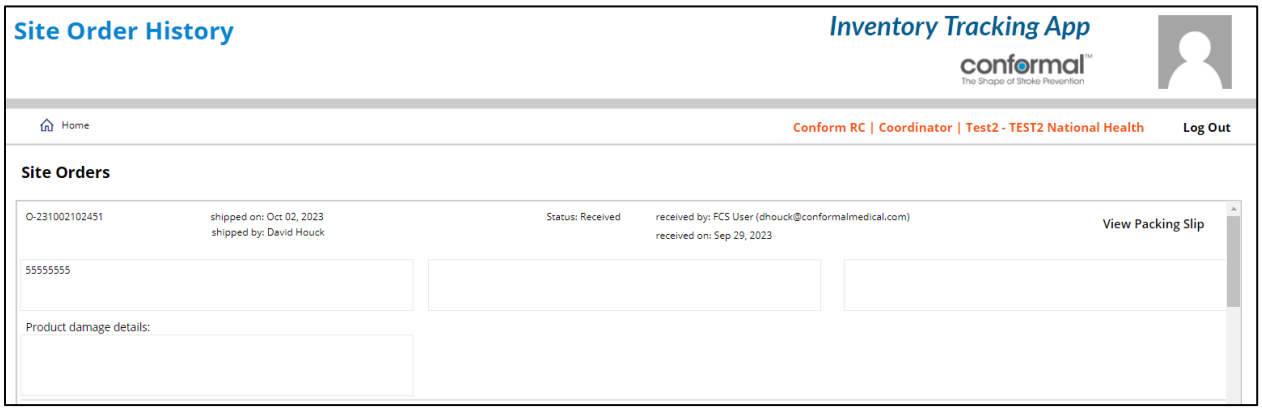
VI. VIEW ORDER HISTORY

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

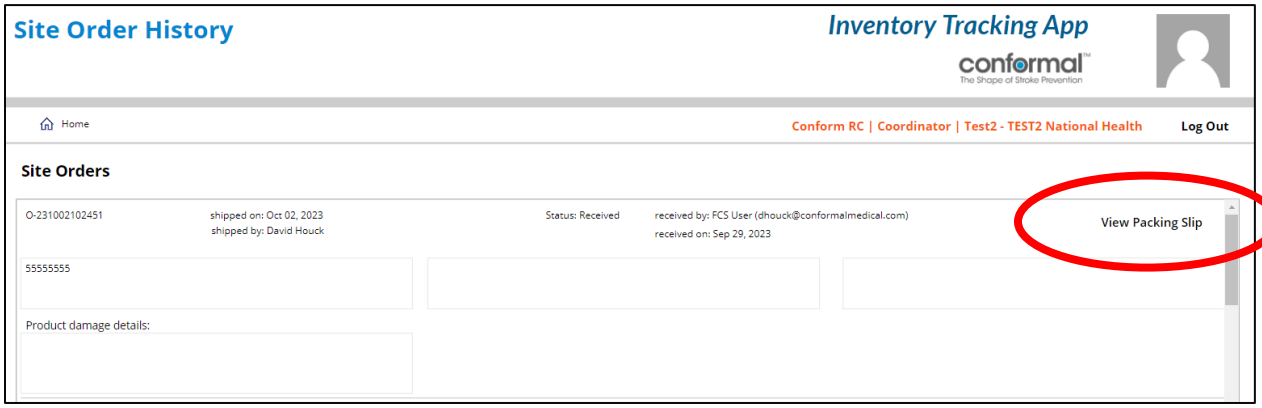




2. Review all orders that have been processed at your site.
    - Order number
    - Shipping date
    - Status
    - Date received
    - Who received the order
    - Additional comments entered at time of receipt

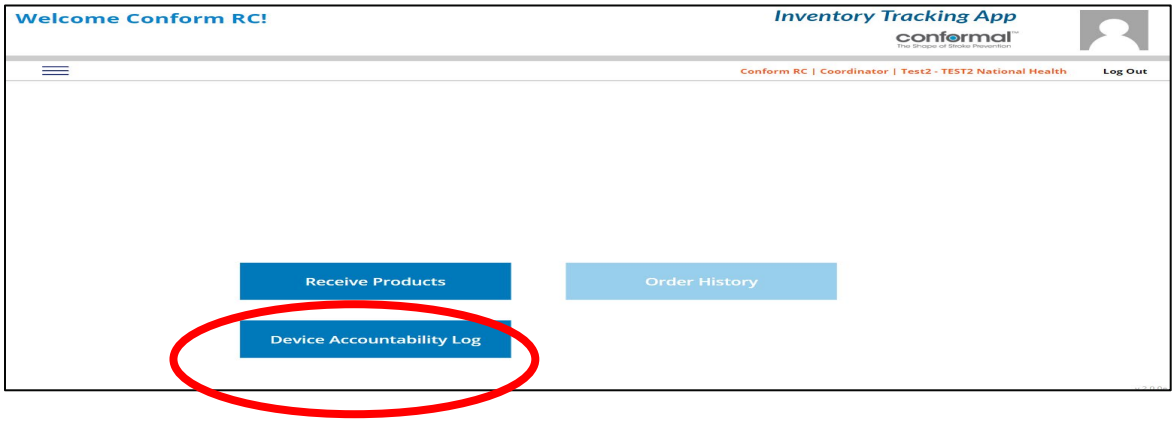


3. View the packing slip associated with the order. You will only be able to view orders associated with your site.

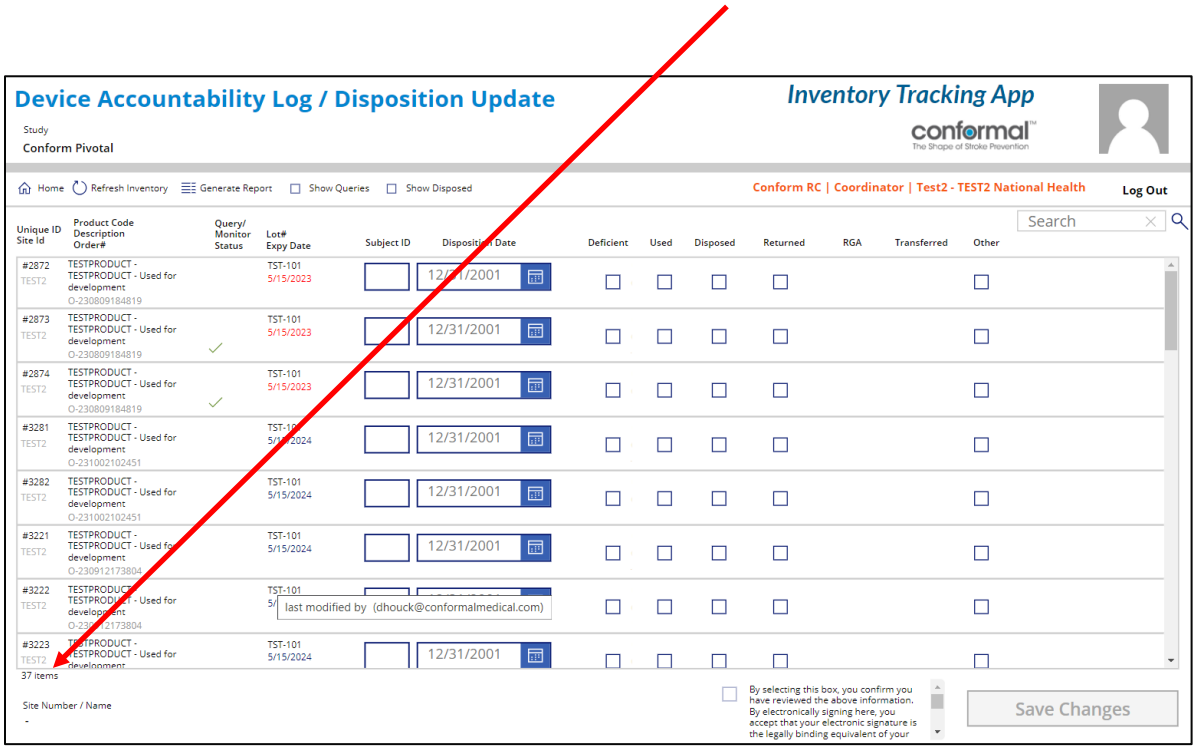


VII. DEVICE ACCOUNTABILITY LOG

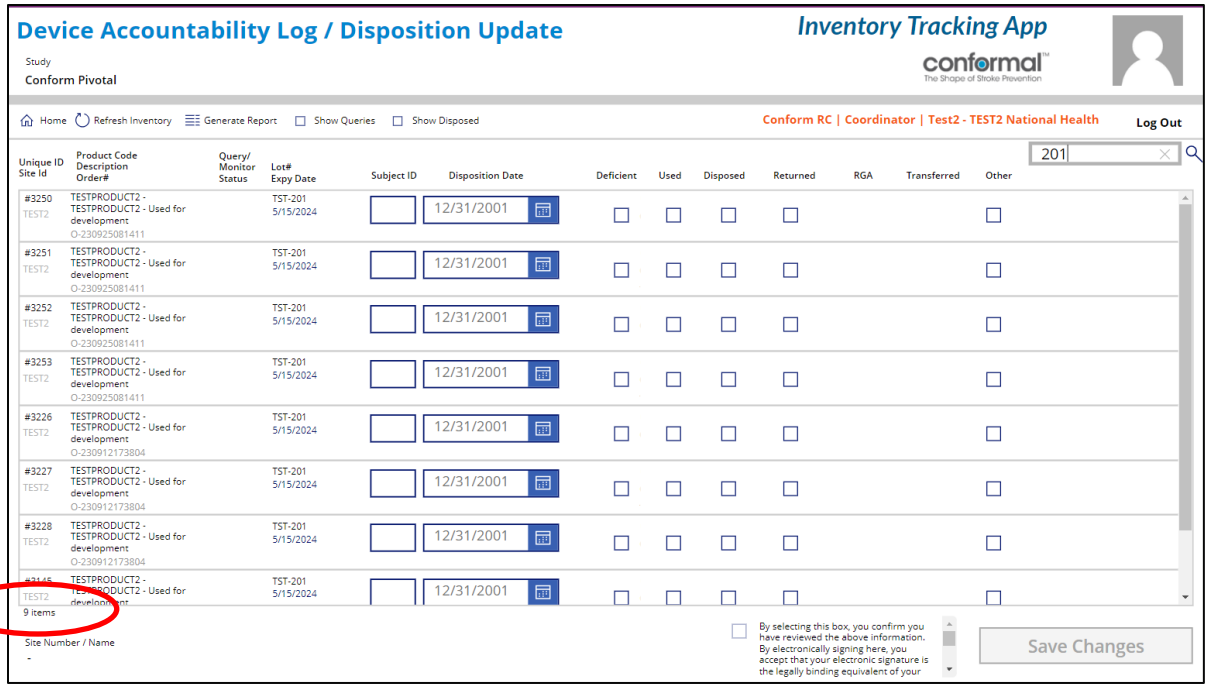
1. From the **Home Screen**, click **Disposition Update** to update the **Device Accountability Log (DAL)**.



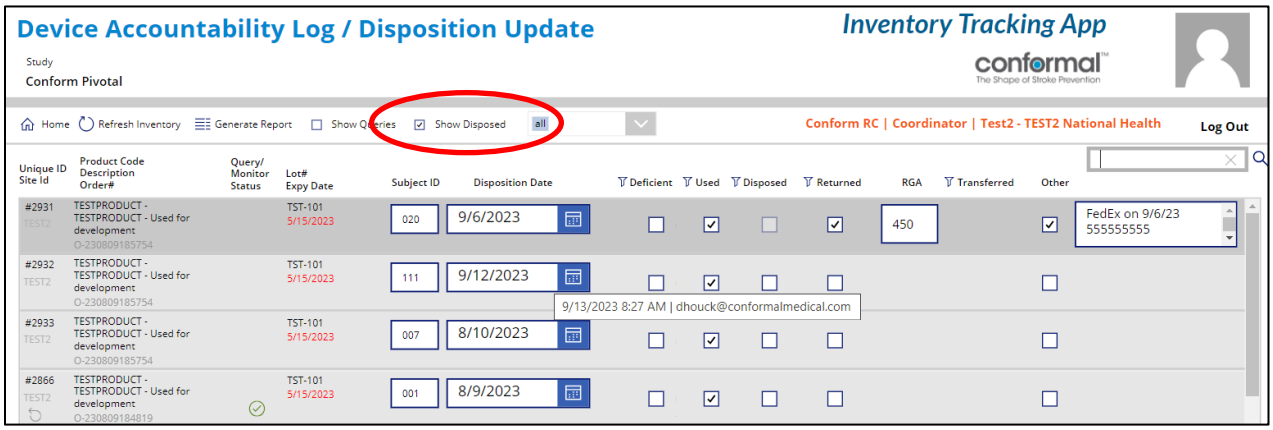
2. The **DAL** is automatically populated after you have marked an order as received. Each product received will be displayed as its own line item. The default view will show <u>only unused</u> product at your site. The total number is listed at the bottom.



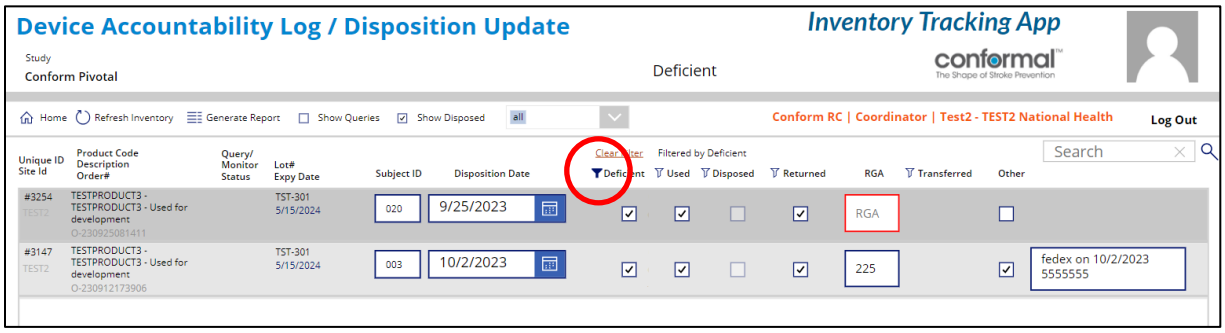
3. Search feature:
   - Use the **Search Feature** at the top right of the screen to search by any terms used in the top line of the first three displayed columns: Product Code, Description, and Lot Number
   * The filter will automatically update as you type in the search term.
   * The number of unused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



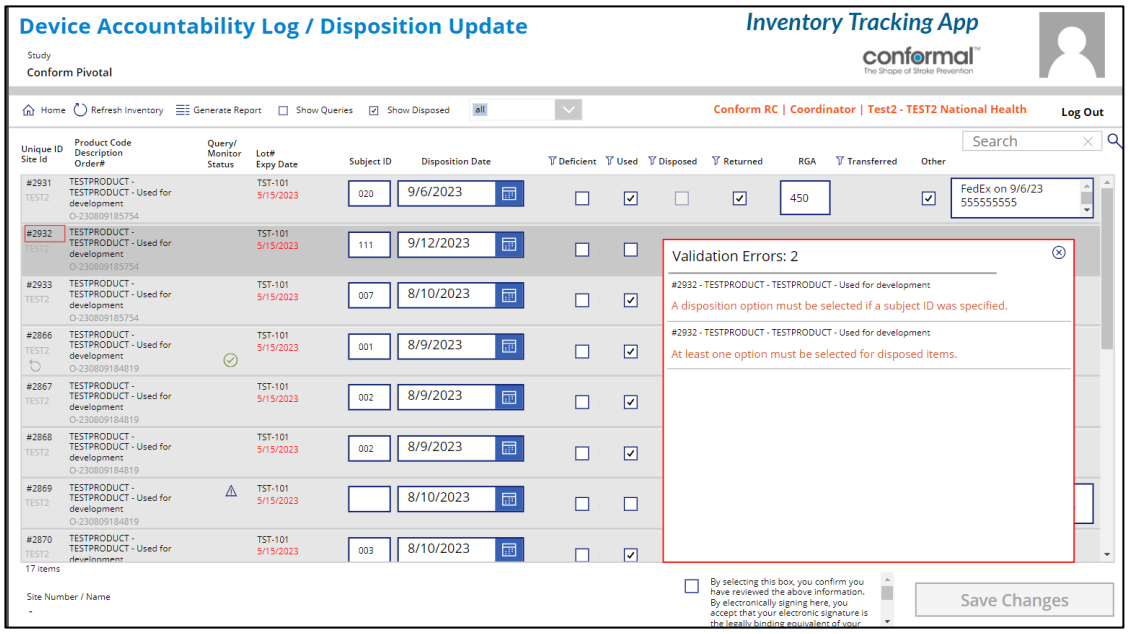
4. Click the **Show Disposed** box to display all product that has already been given a disposition. You can limit the display to products with a disposition date in a defined window:
   a. 30 days
   b. 90 days
   c. 180 days
   d. All



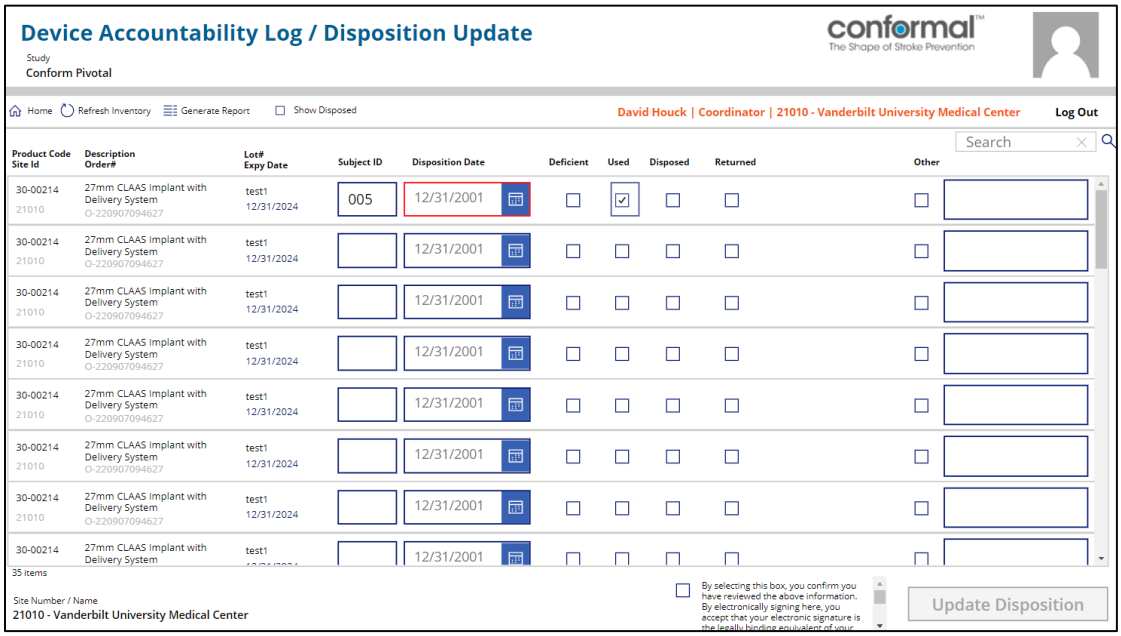
5. Additional filters:
   - Additional filters can be added for type of disposition. Click on the filter icon next to the disposition column.
   - If a disposition of Returned has been selected, you will be required to enter an RGA number.
     * Please reach out to your Site Manager for an RGA number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

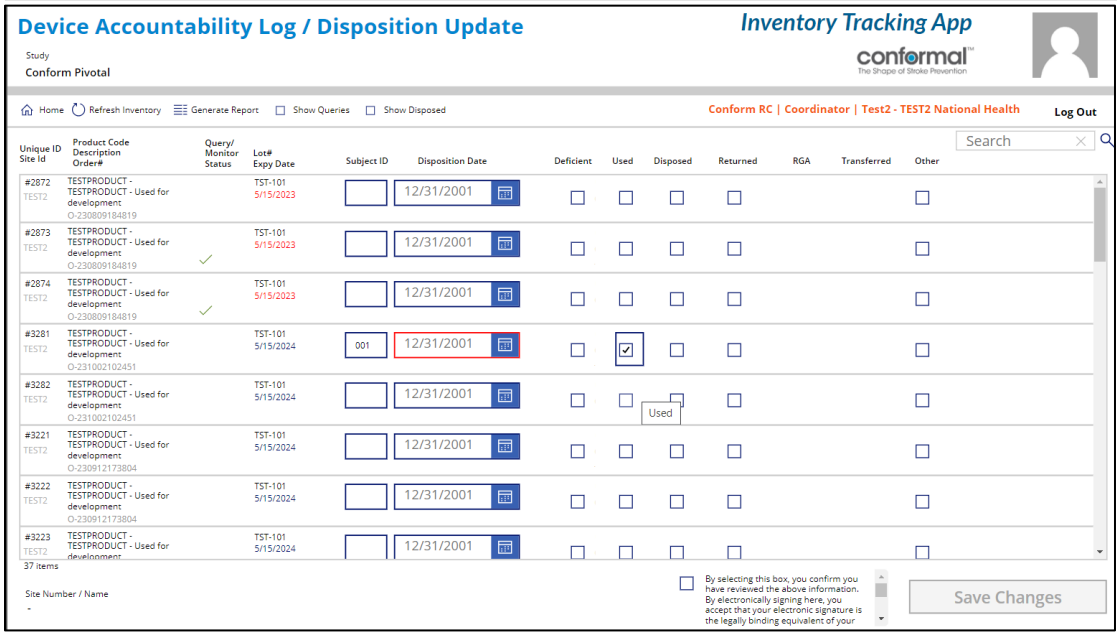


6. If a **Subject ID** is entered, a disposition must be selected to save the record. This error message will appear if no disposition is selected.

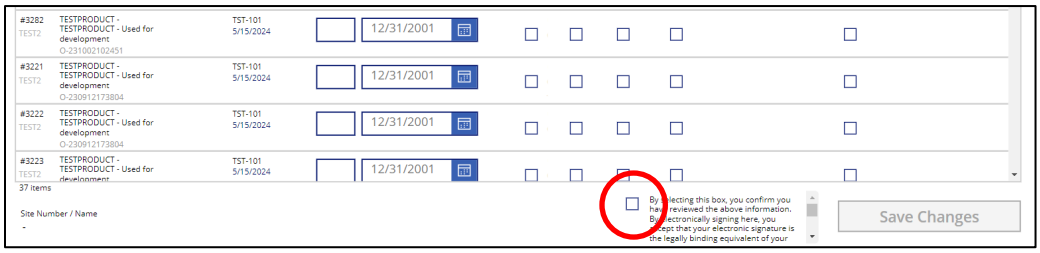


7. Updating Disposition
    a. A **Disposition Date** is required if any disposition is selected
    b. Any dispositions may be selected together (i.e., Used, Disposed)
        i. Exception: You cannot select both “Disposed” and “Returned”

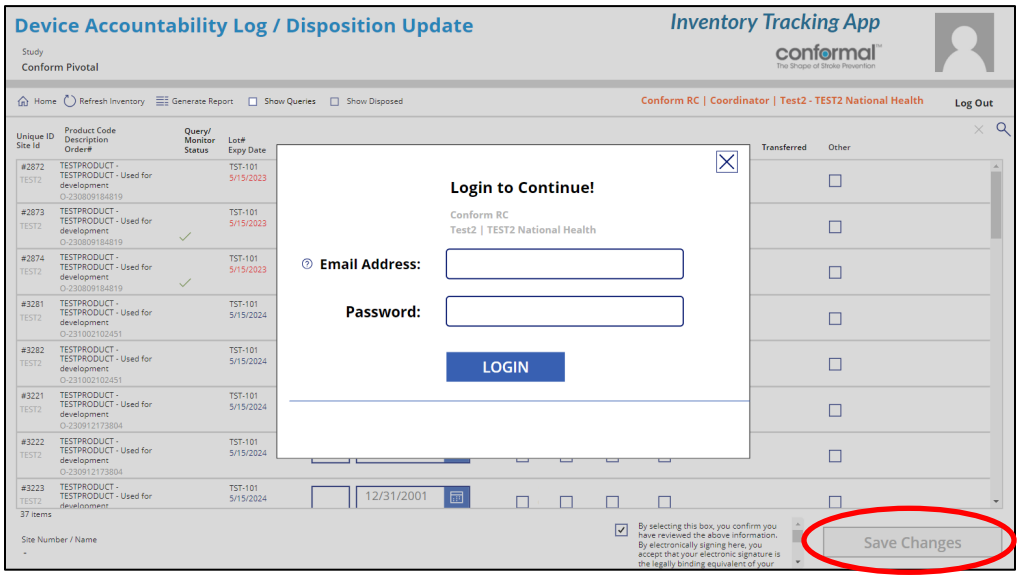




8. Sign Off
    a. Sign off DAL updates by selecting the box at the bottom of the log.
    b. By selecting this box, you confirm you have reviewed the above information. *By electronically signing here, you accept that your electronic signature is the legally binding equivalent of your handwritten signatures 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.*



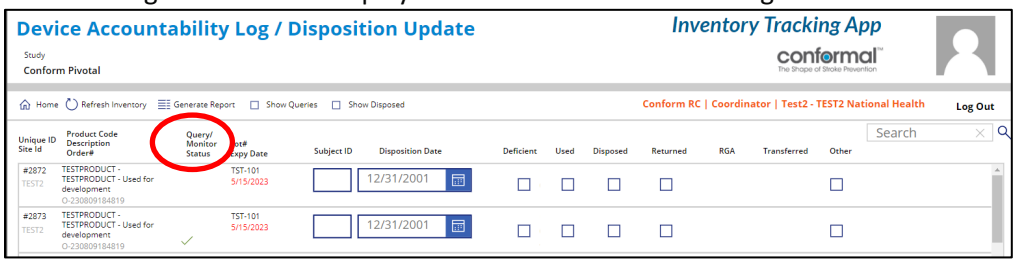
    c. The first time in a session, you will be prompted to login again with your unique user ID to acknowledge acceptance of your electronic signature.



    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.

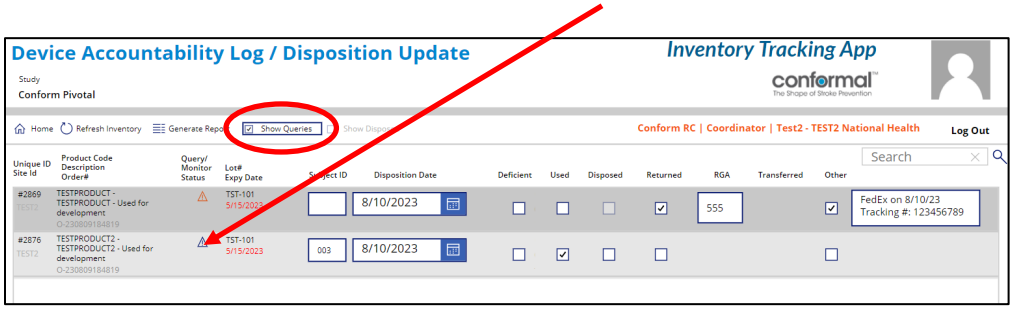
9. Monitoring
   a. A unique ID will be assigned to each inventory line in the Device Accountability Log. This number is used only for reference in the log and will not be found on package labels or packing slips.

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

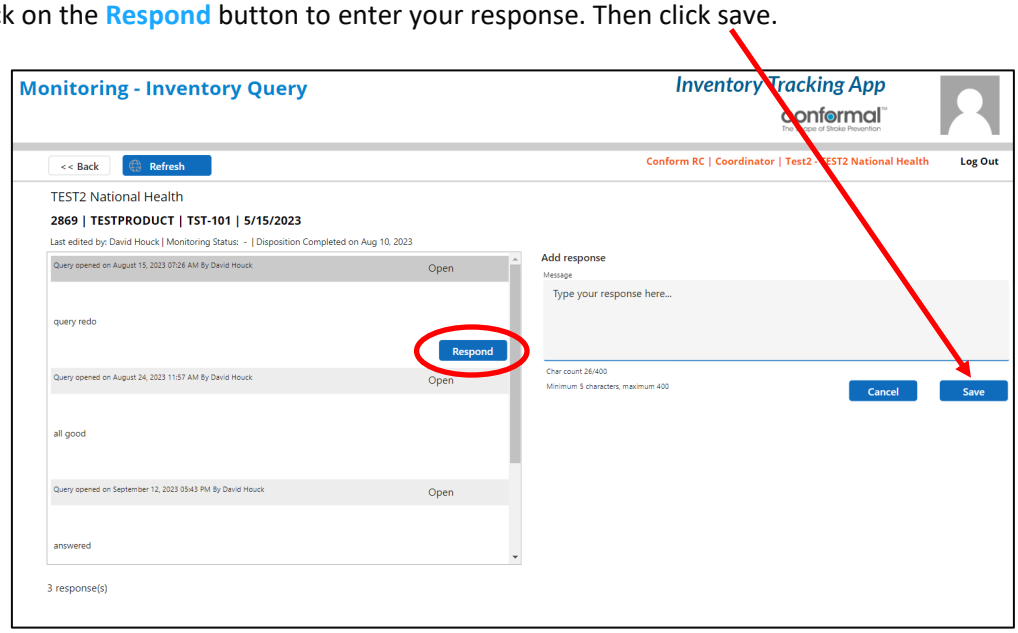


      i. Blank – No status yet
      ii. ✓ - Confirmed status
      iii. ⊘ - Monitored status
      iv. ⚠ - Open Query
      v. ⚠ - Responded to Query

   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.



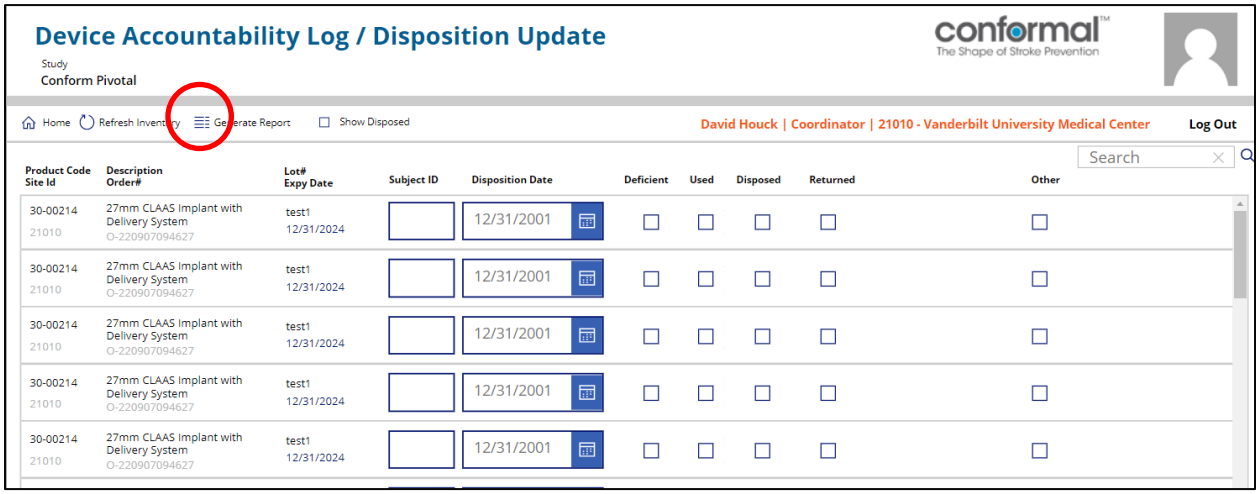
You can click on the **Respond** button to enter your response. Then click save.



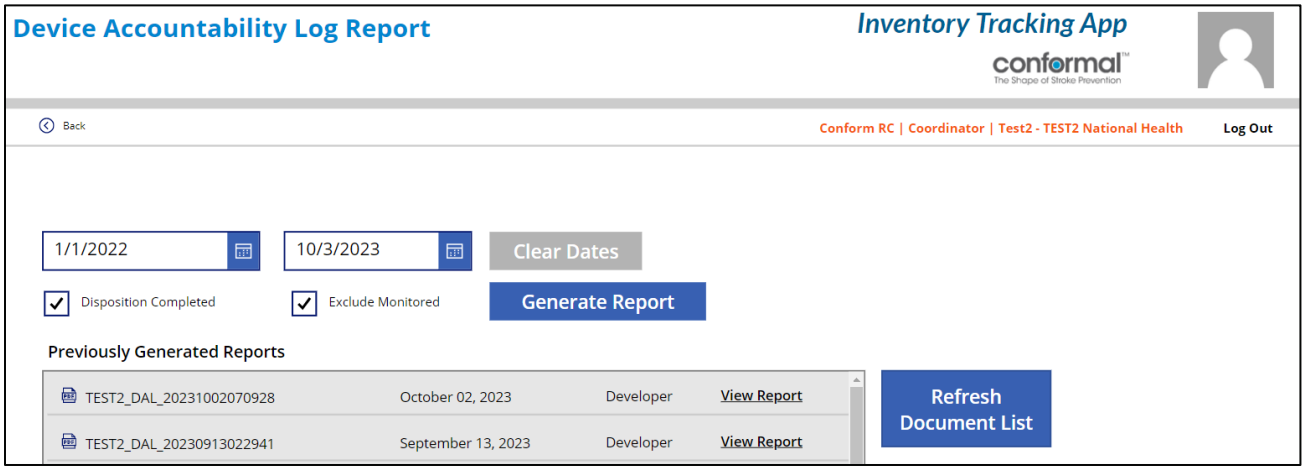
** Note that it may take up to 15 minutes for the query icon to be updated after a response is entered.

VIII. GENERATE REPORTS

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



2. **Device Accountability Log Reports** can be generated at any time.
   a. Reports will default to include all dates, but a date range may be specified to only report updates done in that timeframe.
   b. If the **Disposition Completed** box is not checked then all product, used or unused, will be included in the report.
   c. If the **Disposition Completed** box is checked, then unused product will be excluded from the report.
   d. If the **Exclude Monitored** box is checked, then product that has the "Monitored" status will be excluded from the report.
   e. 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.



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
Follow-Up Visit: • Completed before or after window • Missed entirely	• 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.
Assessments and Laboratory Tests: • Completed before or after window • Not Done	• 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.
Study Assessments • Completed before or after window • Not Done	• 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.
Subject Informed Consent: • Not collected/documented appropriately	• Review signed ICF prior to performing study-specific procedures. • Ensure the most current ICF version clearly labeled and available.

	• If your IRB requires initials/dates on each page, review each page to ensure completed
<u>Study Medications</u> • Dose changed or stopped sooner than 6 months post-procedure, per protocol	• Document reason for medication deviation and store source documentation in patient binder.
<u>Adverse Event (AE) Reporting</u>	• **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. ○ 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

Table of Contents

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 **t**he 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 NAMSA 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 NAMSA 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 hospitilization) 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 NAMSA 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?

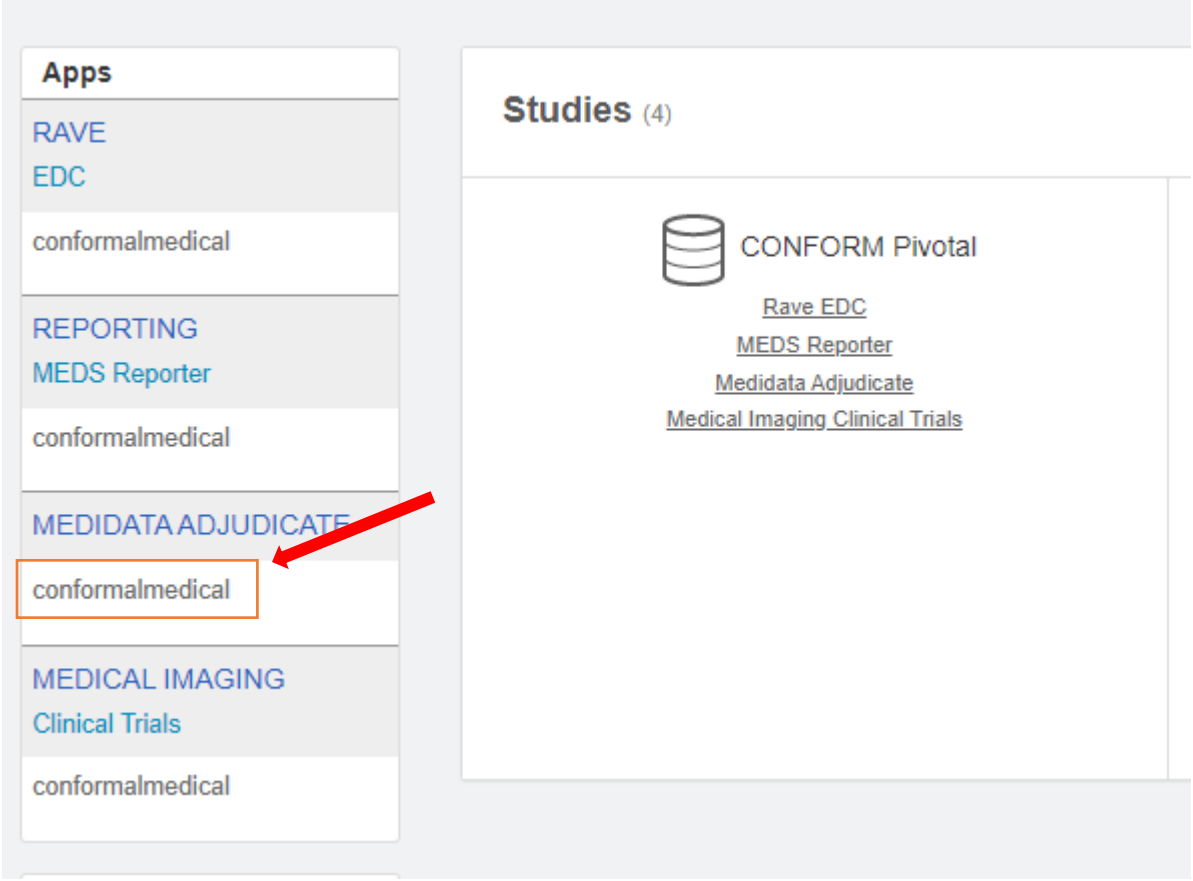
2.7.1. No. All imaging related to an AE is uploaded through Medidate Medical Imaging Portal Refer to **CONFORM Imaging Upload** MOP for more information on uploading imaging.

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

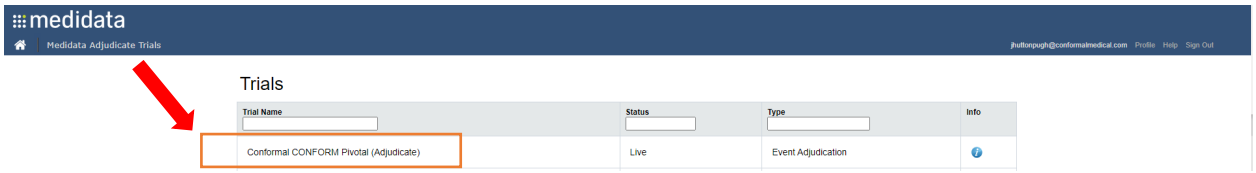
2.8.1. If you have a technical issure related to uploading source documents, redaction etc. please **contact** your Site Manager. For all other questions related to queries, please send a query response within Medidata Adjudicate to the NAMSA Safety Team.

3. Navigating Medidata Adjudicate

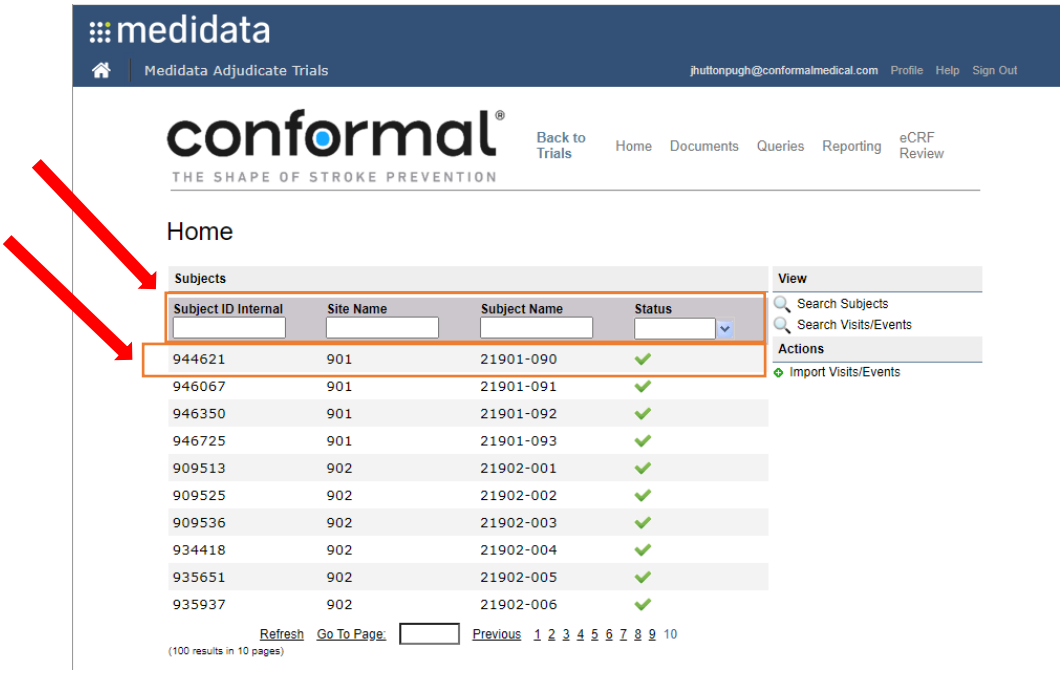
3.1. Log in from the Medidata home page. When on the home page, go to "Apps" on the left side of the screen. Medidata Adjudicate access is available near the bottom of the list. Click the **conformalmedical** link to bring you to the Medidata Adjudicate home page.



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

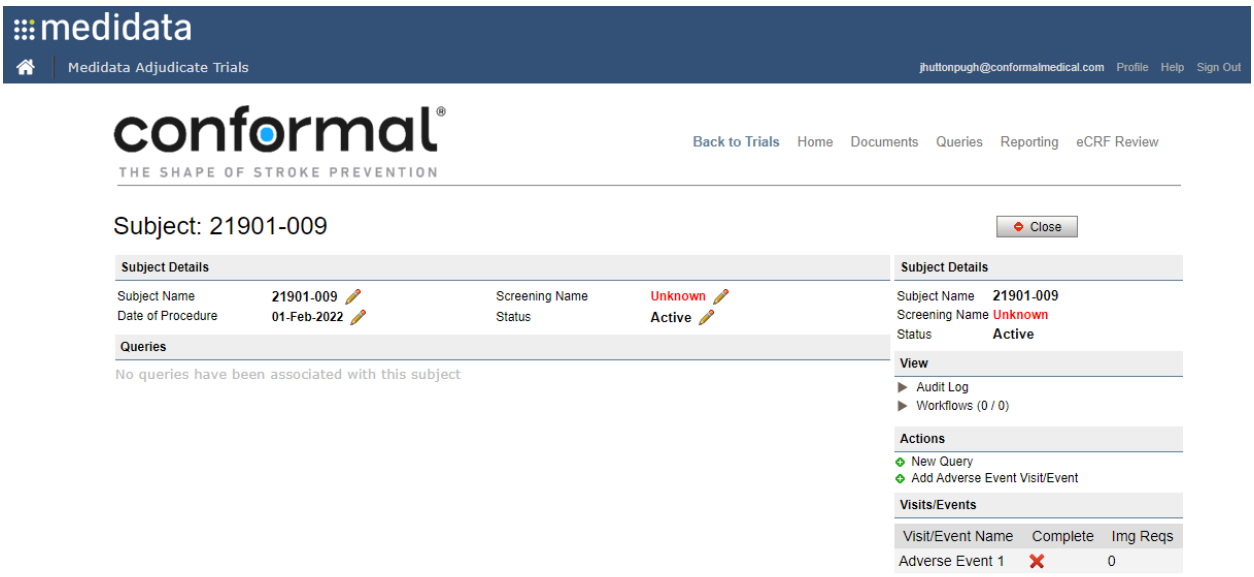


3.3. You will then be directed to the Adjudicate home page, where you can access all subjects who have been entered into Rave EDC by your site.



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".

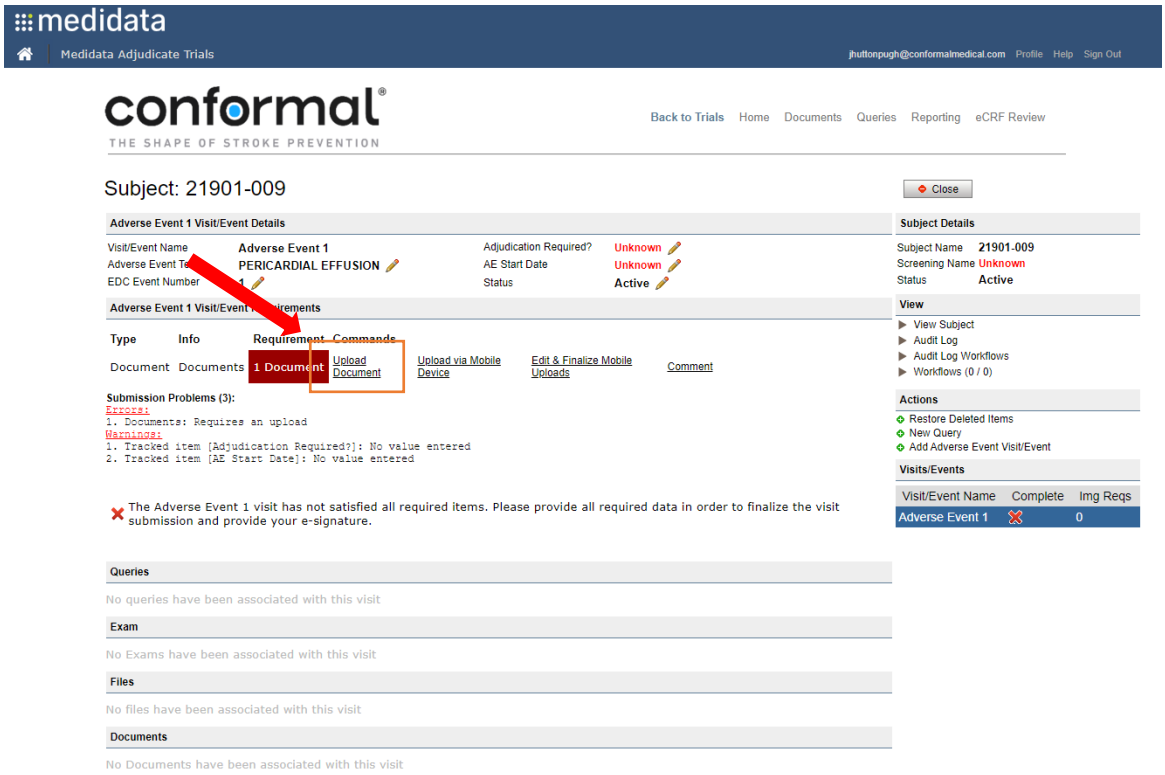


4. How to Upload AE Source Documents in Medidata Adjudicate

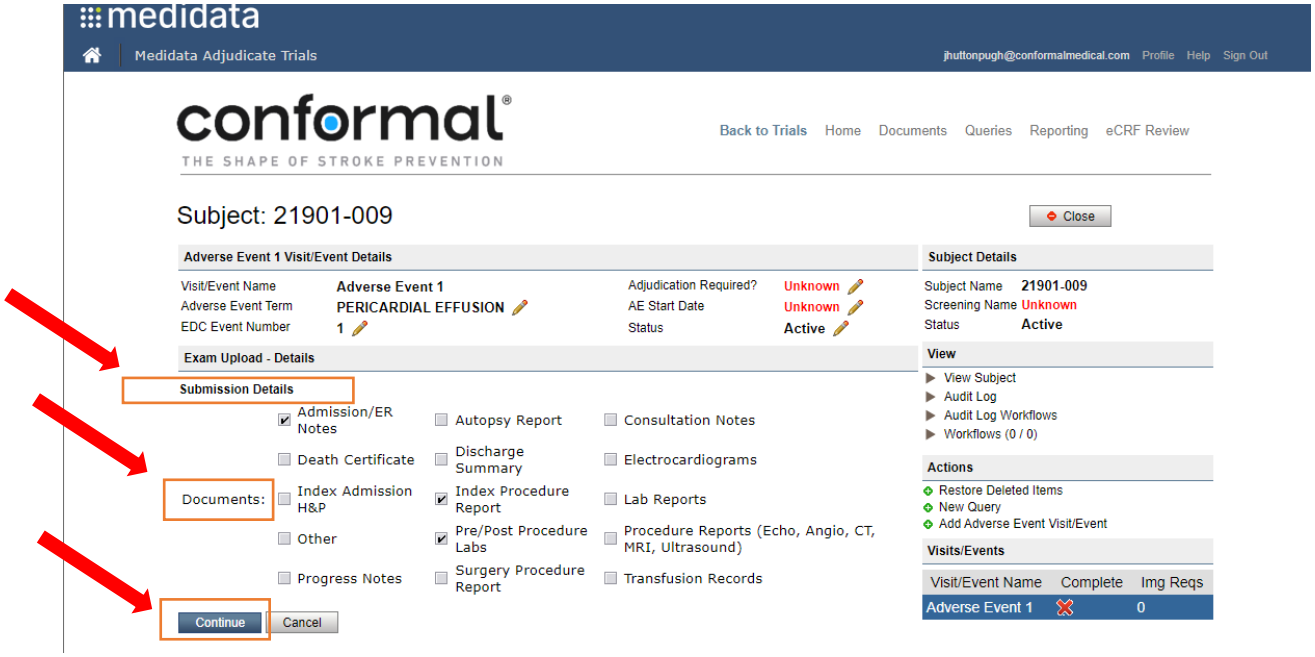
4.1. You will be notified by the NAMSA Safety team via query, and possibly your Site Manager, when the CEC has selected an AE/SAE to be adjudicated and requested source documentation. You will be provided the AE/SAE number and name, as well as a list of source documents the CEC has requested to support 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.

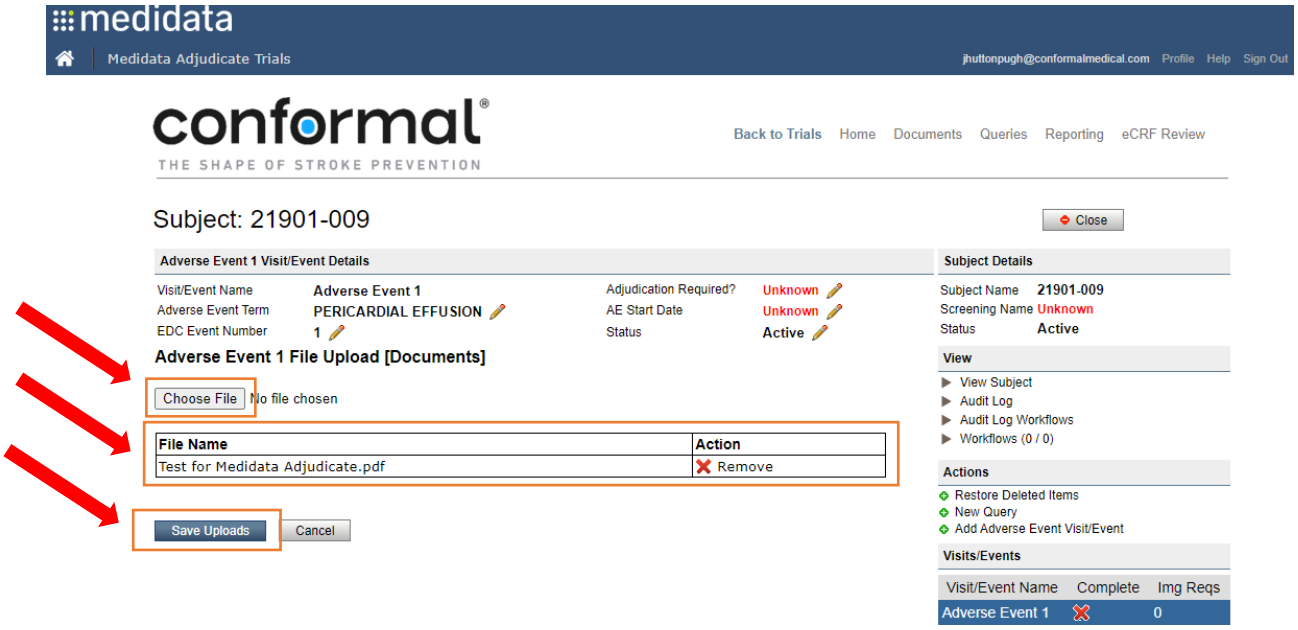


4.4. By clicking on the "Upload Document" you will be taken to the Event Details page shown below. This page allows you to identify the type of source documents included in the upload. You have the ability to click on multiple document types (e.g. Progress Notes, Lab Documents, etc.) for the documents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



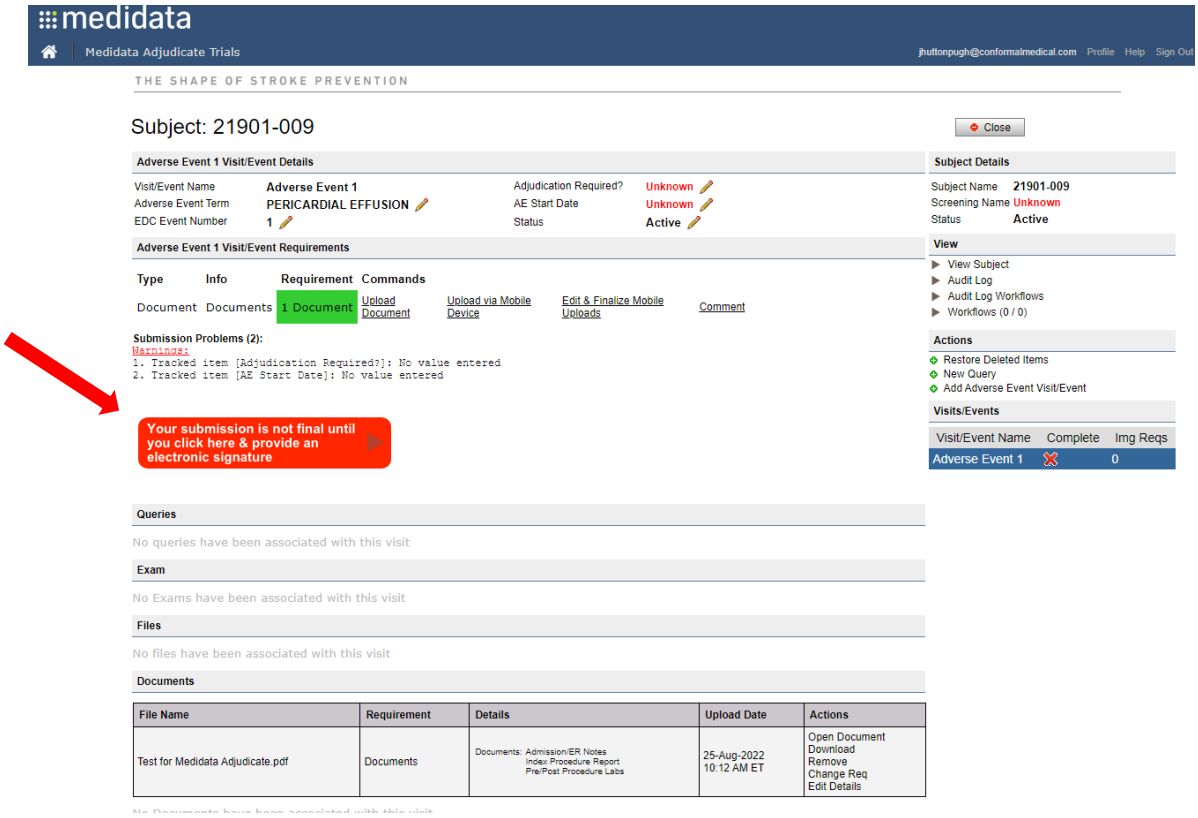
4.5. Once you have finished uploading all document details, click on the blue "Continue" tab and you will be taken to the next screen shown in **section 4.6.**

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.

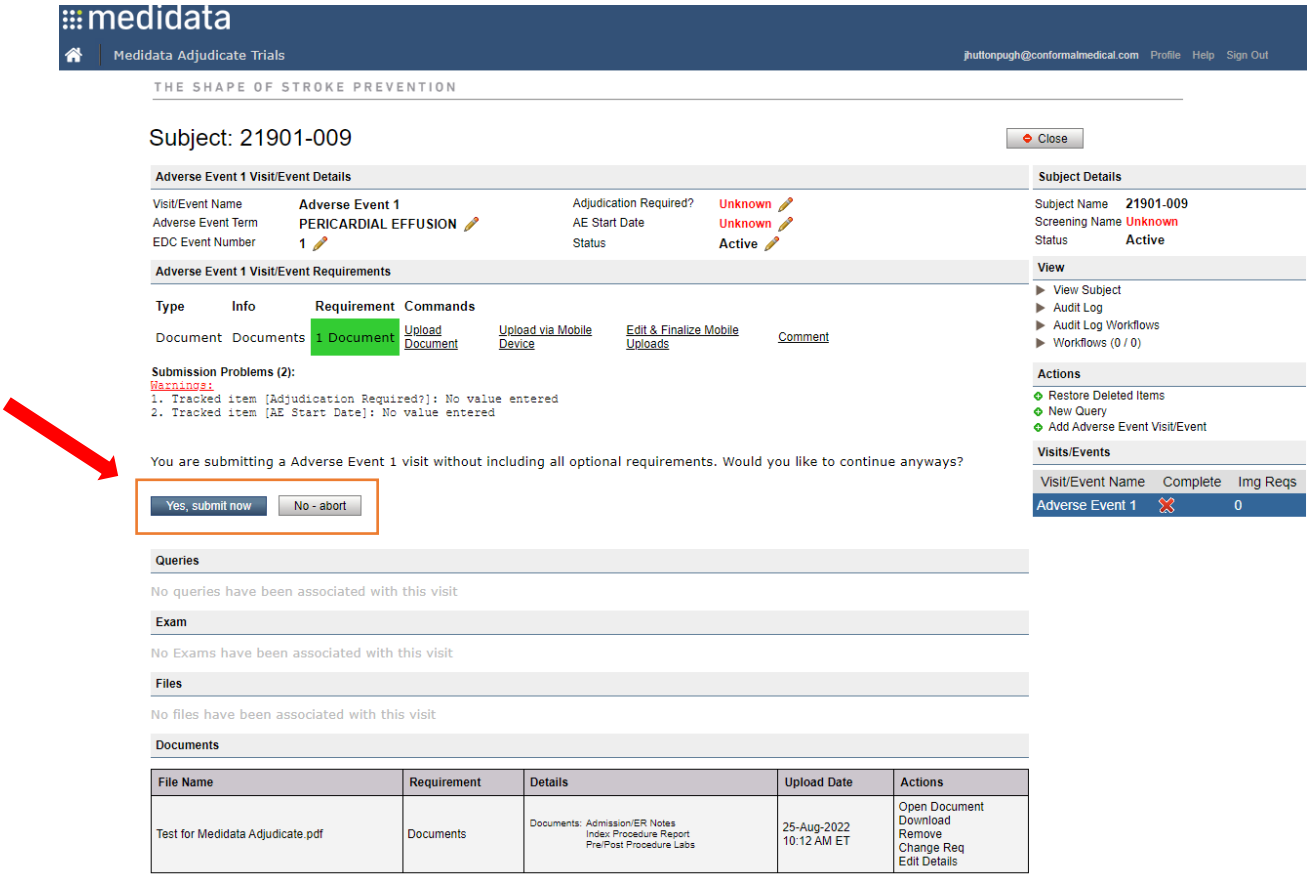


4.7. Once you have uploaded your redacted source documents, click "Save Uploads" in the bottom left corner of the screen, you will be taken to a summary screen in **section 4.8.**

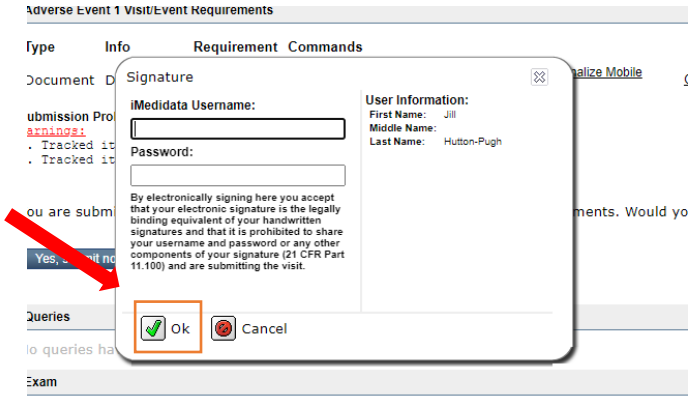
4.8. This summary screen will prompt you for your electronic signature to finalize the submission. By clicking on the red button in the middle of the screen you are verifying that you submitted the redacted source documentation.



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".



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.



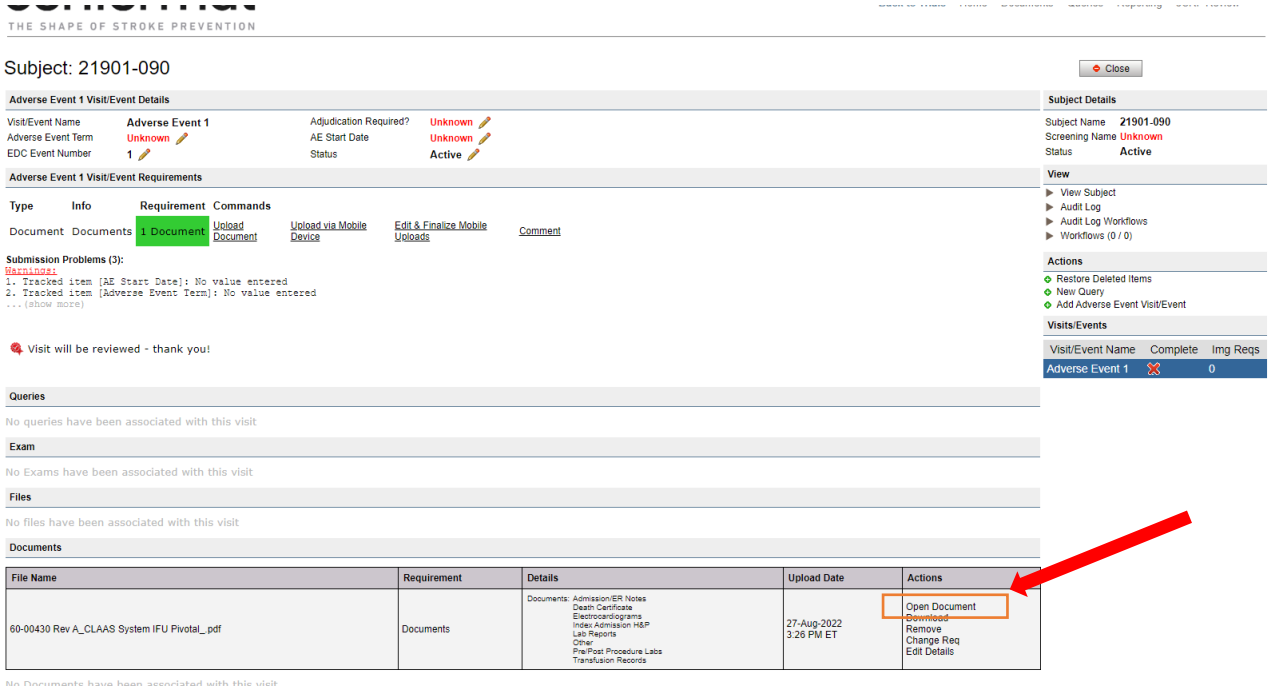
5. How to Redact Documents in Medidata Adjudicate

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

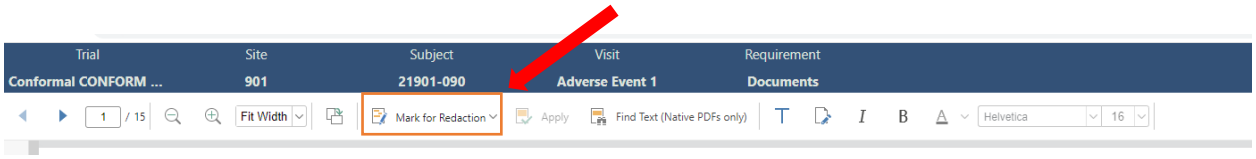
There are two methods you can use to redact within Medidata Adjudicate.

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

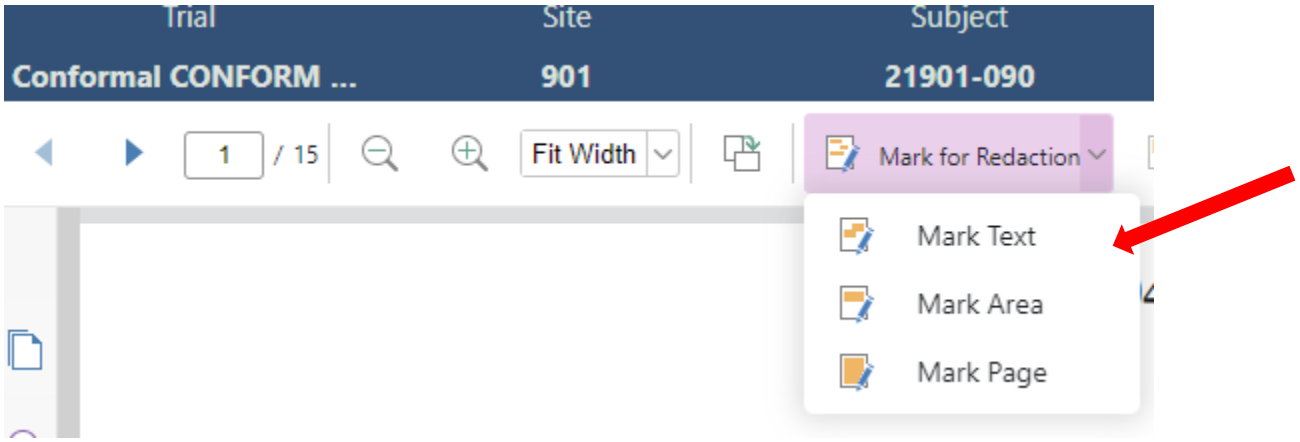
5.1.1. When you are on the source document upload page, click “Open Document” in the lower right corner of the page.



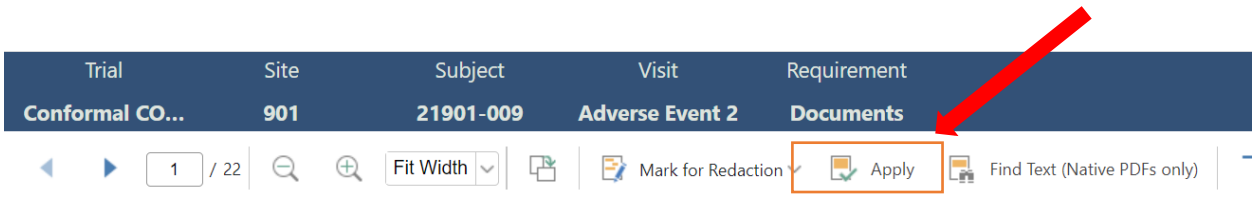
5.1.2. Once the document is opened, click the drop down for “Mark for Redaction” and the redaction tool will appear.



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



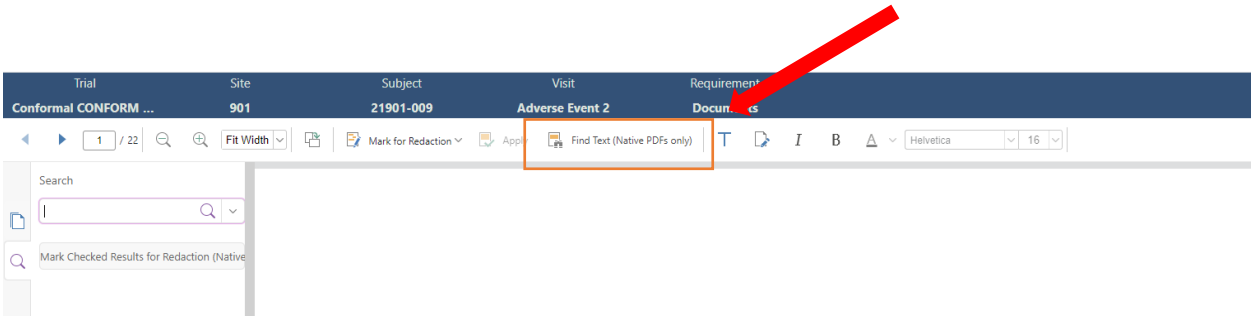
5.1.4. Once you highlight the text/area/page you chose, click “Apply” to redact. **Before leaving the page click “Save” in the upper right corner of the page to ensure your redactions will be saved.**



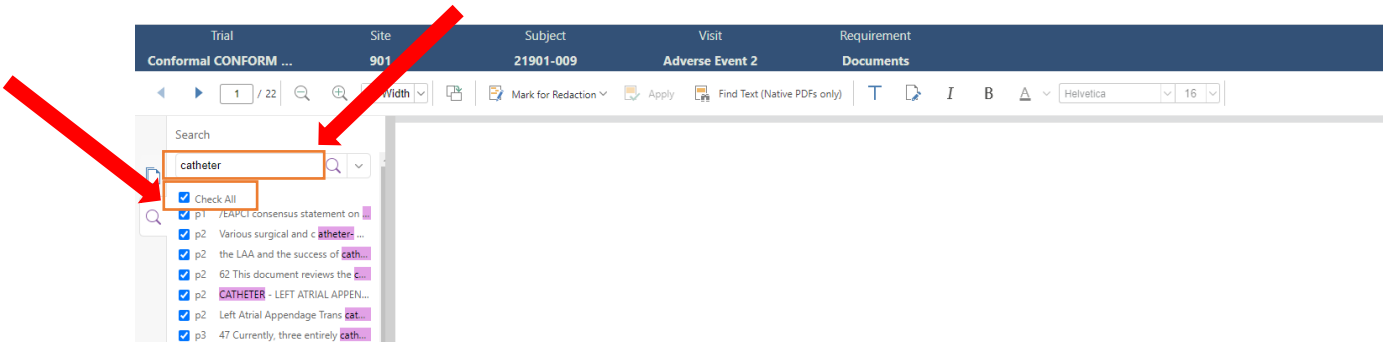
5.2. Find Text redaction feature: This is a Search and Find Redaction tool for rapid redaction.This function allows you to redact multiple mentions of a select term at one time as is described below.

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.

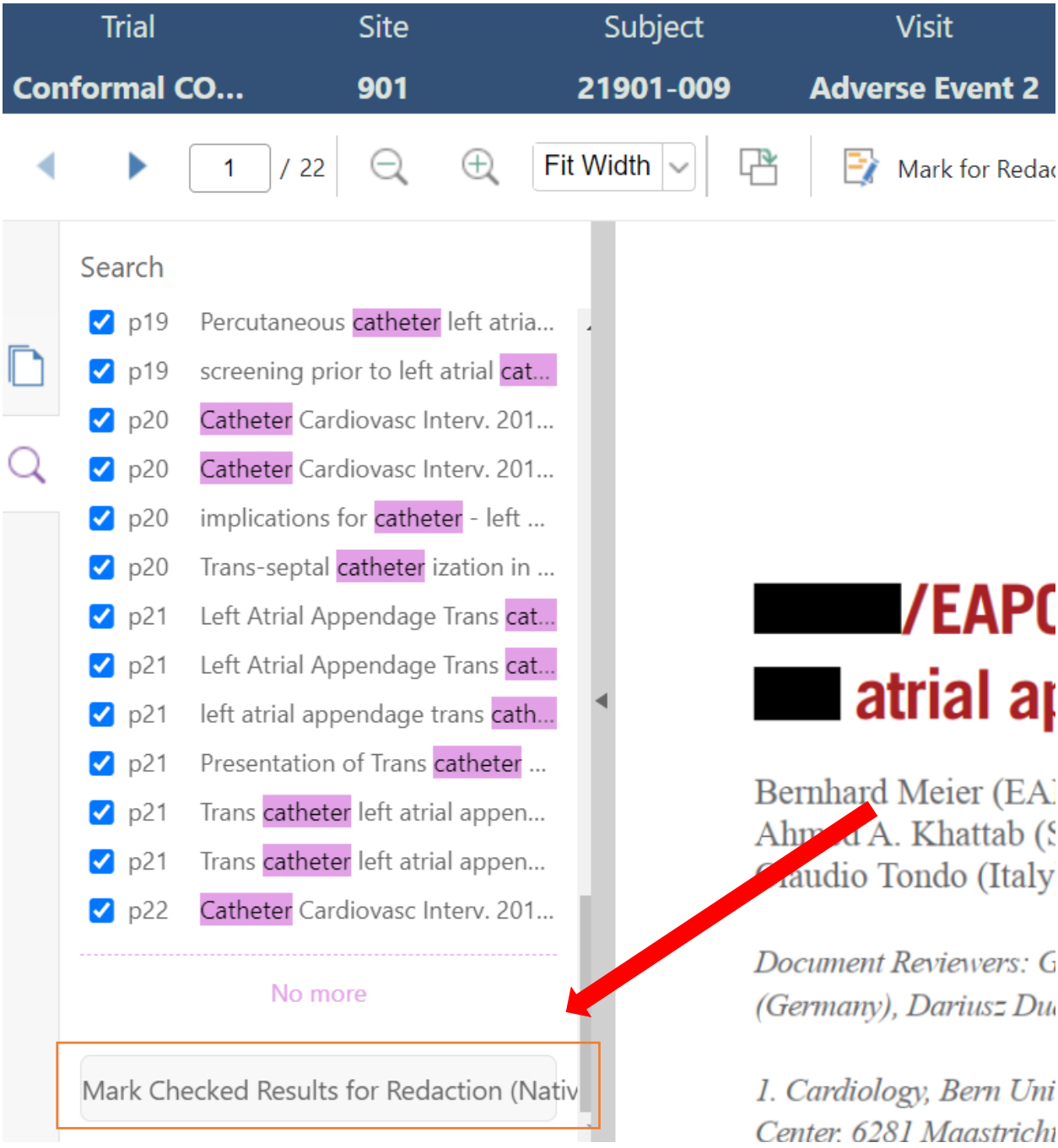
5.2.2. Once the document is open, click “Find Text” in the top tool bar.



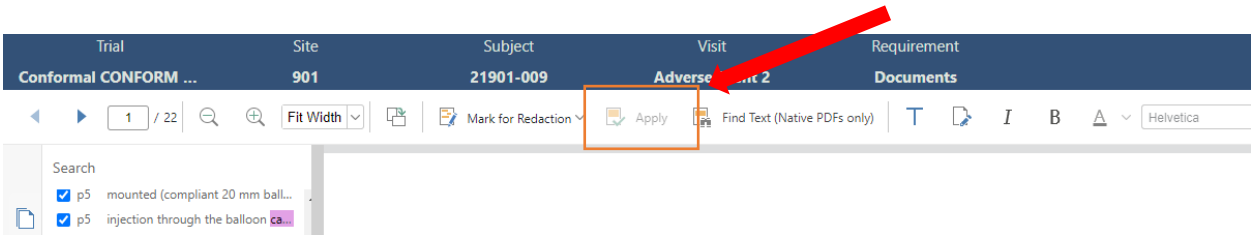
5.2.3. Enter text you would like to find in the “Search” box (i.e. first name, last name, DOB, any ID number for subject), then check the “Check all” box.



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



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

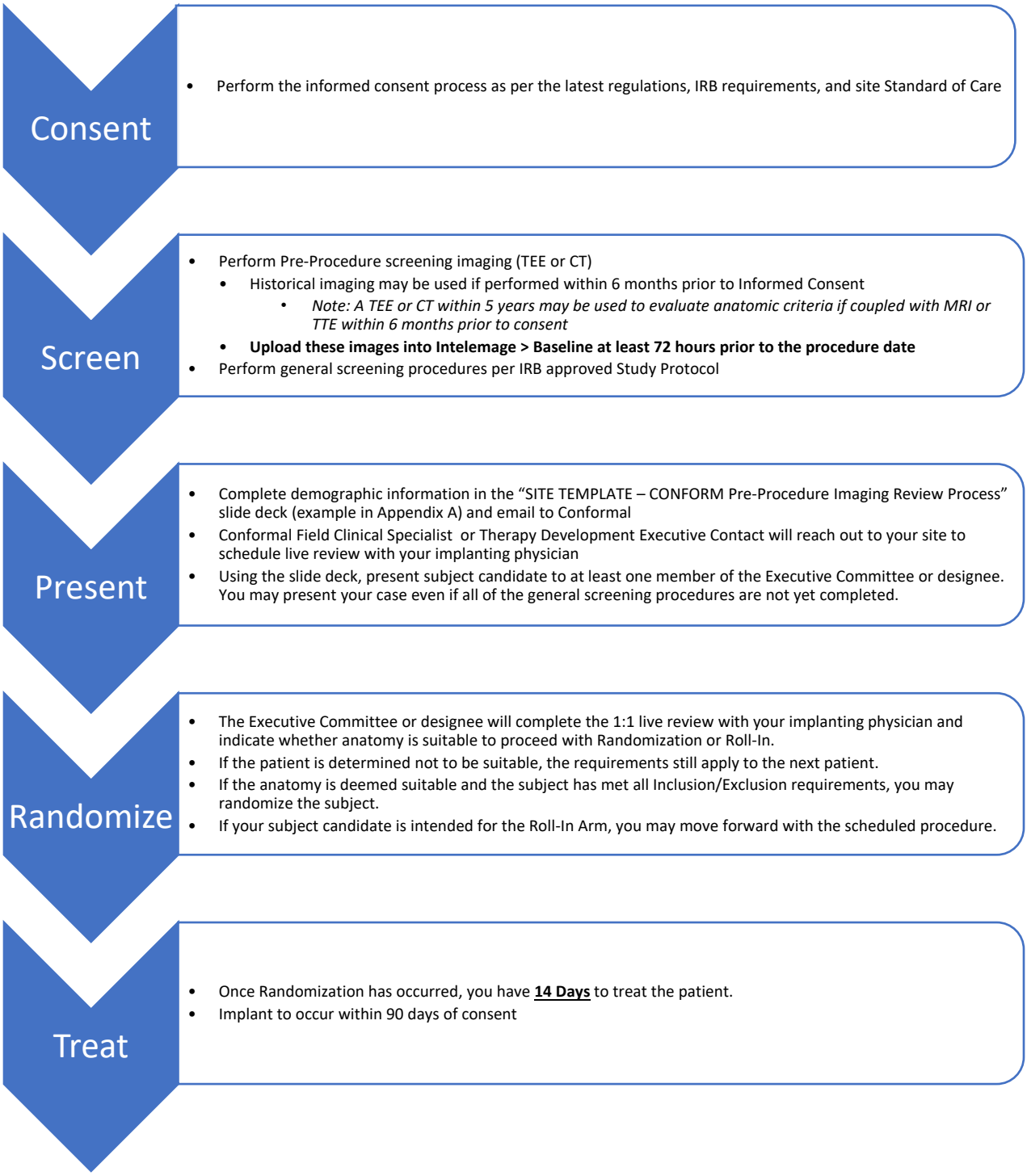
This process is required for each implanting physician's 1st procedure. This applies to Roll-In and Randomized subjects (CLAAS® or Control). The purpose of this Pre-Procedure Review Process is to review the subject candidate's LAA anatomy suitability prior to roll-in or randomization. Once the subject has consented, Implanters will present their site's first subject candidate TEE or CT images to at least one member of the Executive Committee or designee(s), the "Committee."

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

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

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

Figure 1 Pre-Procedure Review Process



Frequently Asked Questions

Q: Does the requirement to screen the first case apply to the site or to each operator?
A: This process is intended to apply to each operator's first case.

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

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

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

Q: Can I use a historical TEE or CT Image within 6 months of consent?
A: Yes. Note: A TEE or CT within 5 years of consent may be used to evaluate anatomic criteria if coupled with MRI or TTE within 6 months prior to consent.

Q: How do I schedule the live Pre-Procedure Review and how long does that review take?
A: Communicate your screening/imaging plans with your Site Manager as soon as your subject is consented, and a possible implant date has been determined. Your Site Manager, Executive Contact, and/or a Conformal Field Clinical Specialist will work with you to schedule a time for the 1:1 live Pre-Procedure Imaging Review. The call will likely take 15 minutes or less.

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

Q: What format will the presentation be in?
A: The presentation will be via video conference or phone call, which Conformal Medical will set up, with video conference link if applicable.

Q: How do I obtain the Sponsor generated PowerPoint template?
A: Your Site Manager will provide the Sponsor generated PowerPoint template that the Implanter will use to present to the Committee.

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

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

Q: How do I document that our site has completed the required Pre-Procedure Review Process:
A: A Conformal Field Clinical Specialist will email your team after the 1:1 live Pre-Procedure Imaging Review. Please file a copy of this correspondence in your Investigator Site File.

Q: After each implanting physician's 1st case, do we still have to wait for Conformal to review baseline imaging prior to randomization?
A: Yes, *for all subjects,* wait for the notification from Conformal of anatomical suitability before randomizing the subject in Medidata.

Appendix A Follows
SITE TEMPLATE - CONFORM Pre-Procedure Imaging Review Process Example V5.0 05MAR2025

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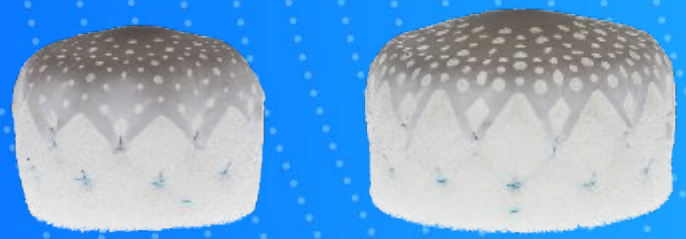
THE SHAPE OF STROKE PREVENTION

CONFORM Pivotal Trial
Pre-Procedure Review Template



V5.0 05MAR2025

Site and Subject Information

SITE TO COMPLETE THE INFORMATION ON THIS PAGE

		Mark “X” for which cohort this subject is intended	
Review Date	**Subject ID**	**Roll – In Cohort**	**Randomized Cohort**
	21000-000		X

Site Name	Example Medical Center
Name of Implanting Physician	Dr. Jane Doe
Name of Procedural Imager	Dr. John Smith
Number of CONFORM procedures to date	1

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Subject Demographics 21000-000

SITE TO COMPLETE THE INFORMATION ON THIS PAGE

Age/Gender	75/Female
Brief Medical History	Persistent Afib, HTN, Hyperlipidemia, DM1
What type of Afib? (permanent/persistent/paryoxysmal)	Paryoxysmal
CHA2DS2VASc (CHF-1, HTN-1, >65-1, DM-1, Stroke-2, Vasc Dz-1, >75-1, F-1)	3
What is the rational to seek non-pharmacologic alternative to OAC?	Bleed risk, Anemia

Echo review - **SITE** to Complete for evaluated criteria

Subject 21000-000

EF per screening imaging	**60%**	
	Mark “x” for response	
	Yes	**No**
Intracardiac thrombus		X
ASD requiring closure		X
High Risk PFO: Atrial septal aneurysm (excursion or length >15mm) / Large shunt (early within 3 beats or substantial passage of bubbles >20)		X
Moderate or severe mitral stenosis (area < 1.5cm^2)		X
Complex atheroma with mobile plaque in aorta (descending/Arch)		X
Evidence of cardiac tumor		X
Inadequate LAA depth		X
Unfavorable LAA configuration		X
LAA size not within device sizing specifications (Control or CLAAS)		X
Circumferential Pericardial Effusion Present?		X
If yes, is the Pericardial effusion >10mm		

Baseline TEE performed at the time of procedure in conjunction with Field Clinical Specialist review will provide final confirmation

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Echo review – Subject 21000-000

NOTE: A Conformal Field Clinical Specialist or Imaging Manager will embed the specified Echo or CT images into this slide deck.

0°

45°

Diameter Min:
Diameter Max:
Diameter Mean:
Functional Depth ≥10mm:

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Echo review – Subject 21000-000

NOTE: A Conformal Field Clinical Specialist of Imaging Manager will embed the specified Echo images into this slide deck.

90°

135°

Diameter Min: 19 mm
Diameter Max: 26 mm
Diameter Mean: 22.5 mm
Functional Depth ≥10mm: 15 mm

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CT review – Subject 21000-000

NOTE: A Conformal Field Clinical Specialist of Imaging Manager will embed the specified CT images into this slide deck.

- LAA Dimensions

Volume Render Image

En Face Ostial Min/Max/Mean

2D Orthogonal Width & Depth

2D Orthogonal Width & Depth

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Suitability for Roll-In
SPONSOR Will Complete
Subject 21000-000

NOTE: Conformal will complete this slide for Roll in Subjects. Please do not fill out this slide. See below for example of sponsor populated slide.

- Executive Committee Member(s)
  - Drs. Aaron Kaplan & Devi Nair
    - ❑ Not Required
- Sponsor Representative(s)
  - Clinical Site Manager: Aly Dechert
  - Field Clinical Specialist: David Houck
- Site Presenter/Implanting physician
  - Dr. Jane Doe

- Roll-In Suitability
  - ☒ Suitable
  - ❑ Not Suitable
    - ❑ Does not meet sizing criteria
    - ❑ Not anatomically suitable
    - ❑ Other (specify)
- Has site completed all required reviews
  - ❑ Yes
  - ☒ No
    - Number of Reviews Remaining: 3
- Additional Notes: Diameter and depth measurements via TEE in 0, 45, 90, and 135 views on day of procedure are required to confirm device size selection and LAA measurements permit CLAAS and commercial devices, per IFU sizing criteria.

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Suitability for Randomization
SPONSOR Will Complete
Subject 21000-000

NOTE: Conformal will complete this slide for Randomized Subjects. Please do not fill out this slide. See below for example of sponsor populated slide.

- Executive Committee Member(s)
  - Drs. Aaron Kaplan & Devi Nair
    - ❑ Not Required
- Sponsor Representative(s)
  - Clinical Site Manager: Aly Dechert
  - Field Clinical Specialist: David Houck
- Site Presenter/Implanting physician
  - Dr. Jane Doe

- Randomization Suitability
  - ☒ Suitable
  - ❑ Not Suitable
    - ❑ Does not meet sizing criteria
    - ❑ Not anatomically suitable
    - ❑ Other (specify)

- Has site completed all required reviews
  - ❑ Yes
  - ☒ No
    - Number of Reviews Remaining: 3

- Additional Notes: Diameter and depth measurements via TEE in 0, 45, 90, and 135 views on day of procedure are required to confirm device size selection and LAA measurements permit CLAAS and commercial devices, per IFU sizing criteria.

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Sizing Criteria

ASP: Release Criteria

1 Anchor

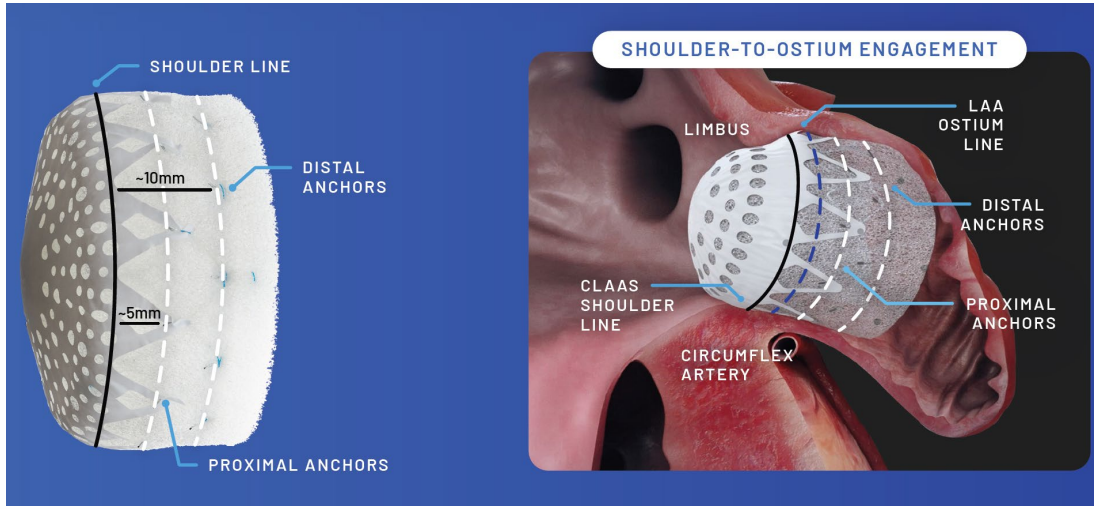
- Observe coincident tissue/implant movement during Tug Test
- Repeat if implant movement is observed from the deployed position

2 Seal

- Target < 3mm leak in all FOUR ultrasound views (0°, 45°, 90°, 135°)

3 Position

- CLAAS Shoulder at or slightly proximal to LAA ostium*
- CLAAS position evaluated in all FOUR ultrasound views (0°, 45°, 90°, 135°)
- Target deployment is for the Shoulder Line to be < 5mm proximal to the LAA ostium and not to exceed 8mm



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CLAAS® AcuFORM Sizing Criteria

A baseline TEE should be performed to verify that a patient's anatomy is appropriate for the CLAAS to be implanted. Perform baseline analysis to confirm appropriate LAA anatomy and absence of LAA thrombus.

1. Assess the following through multiple imaging planes (e.g., 0°, 45°, 90°, 135°).
    a. LAA size/shape, number of lobes in the LAA and location of lobes relative to ostium
    b. Confirm the absence of thrombus (use Color Doppler and echo contrast as necessary)
2. Record the largest (D_{max}) and smallest (D_{min}) LAA ostium diameters and LAA depth (0°, 45°, 90° and 135° sweep).
3. Identify if the CLAAS Implant will fit based on Table 1.

Table 1: CLAAS Implant sizing

CLAAS Size	Mean LAA Ostium Diameter (D_{min} + D_{max}) / 2	LAA Ostium Diameter Ranges (Dmin & Dmax must be within range)	Minimum Landing Zone (Depth)
Regular	≤ 25 mm	10 – 33 mm	10 mm
Large	≤ 32 mm	20 – 40 mm	10 mm

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Watchman FLX IFU Sizing Criteria

7. Confirm LAA size and select appropriate WATCHMAN FLX Device. Transesophageal echocardiography (TEE) and fluoroscopy were used in most WATCHMAN clinical trials for selection of device size and implant guidance. There is limited evidence to support the use of intracardiac echocardiography (ICE) and fluoroscopy to guide LAAC implantation.

   A. Perform the following through multiple imaging views:
      - Measure the LAA length and width at the ostium.
      - Assess LAA size/shape, number of lobes, and location of lobes relative to the ostium.
      - Confirm the absence of thrombus.

Note: TEE imaging recommendations: Measure the LAA ostium at approximately these angles as anatomy permits:
- at 0° measure from coronary artery marker to a point approximately 2 cm from tip of the "limbus."
- at 45° measure from top of the mitral valve annulus to a point approximately 2 cm from tip of the "limbus."
- at 90° measure from top of the mitral valve annulus to a point approximately 2 cm from tip of the "limbus."
- at 135° measure from top of the mitral valve annulus to a point approximately 2 cm from tip of the "limbus."

   B. Choose a Closure Device based on maximum LAA ostium width recorded. Use **Table 45** as a guide. The LAA depth should be approximately half the labeled implant diameter or longer.

Note: LAA anatomy should accommodate a single Closure Device as described in **Table 45**.

Table 45. WATCHMAN FLX Device Selection

Max LAA Ostium Width and/or Deployed Closure Device Diameter (mm)	Closure Device Size (mm)
14.0 – 18.0	20
16.8 – 21.6	24
18.9 – 24.3	27
21.7 – 27.9	31
24.5 – 31.5	35

Note: These values are based on TEE. Other imaging modalities may vary.

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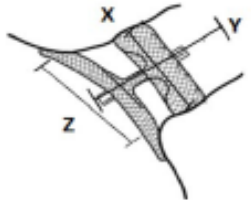
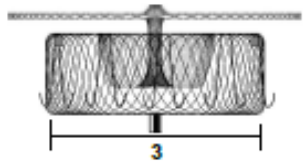
Amulet Sizing Criteria

5. Use angiography, TEE (preferably 3D), or pre-procedural cardiac CT to measure the left atrial appendage, including the depth of the left atrial appendage (shown as Y in Table 2, in Appendix A) and the maximum width of the orifice (shown as Z in Table 2 in Appendix A). Image the left atrial appendage until it is clearly visible.
   - Identify and measure the left atrial appendage at the landing zone (defined as a minimum of 10–12 mm from the orifice) for the device lobe (shown as X in Table 2 in Appendix A: Supplemental Information) to determine the appropriate device size to occlude the left atrial appendage.
   - Consider using two imaging modalities to inform sizing. Use the maximum landing zone measurement if using 2D TEE or angiography and mean landing zone measurement if using 3D TEE or pre-procedural CT. When choosing between two sizes, consider depth and orifice measurements, confirming the orifice measurement (shown as Z in Table 2 of Appendix A: Supplemental Information) is less than the disc size of the selected device and there is sufficient depth. See Table 2 in Appendix A to determine the appropriate device size to occlude the left atrial appendage.

WARNING: Do not implant the device if the measurements of the left atrial appendage do not fall within the sizing chart in Table 2 of Appendix A.

Table 2. Sizing chart





Landing Zone Width X[a]	Distance from Orifice Y	Device Size (Lobe Diameter) 3	Device Order Number
mm	mm	mm	
11.0 - 13.0	≥ 10	16	9-ACP2-007-016
13.0 - 15.0	≥ 10	18	9-ACP2-007-018
15.0 - 17.0	≥ 10	20	9-ACP2-007-020
17.0 - 19.0	≥ 10	22	9-ACP2-007-022
19.0 - 22.0	≥ 12	25	9-ACP2-010-025
22.0 - 25.0	≥ 12	28	9-ACP2-010-028
25.0 - 28.0	≥ 12	31	9-ACP2-010-031
28.0 - 31.0	≥ 12	34	9-ACP2-010-034

a. The landing zone is where the lobe of the device will be placed in the left atrial appendage.

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Study Exit Flowchart

Submitting
Planned/Scheduled Case

Submitting Planned/Scheduled Case

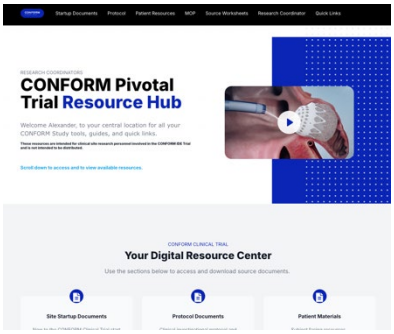
To notify the Conformal Team about a planned or scheduled case in the CONFORM Pivotal Trial, please use one of the two options below to ensure adequate on-site team support.

OPTION 1:

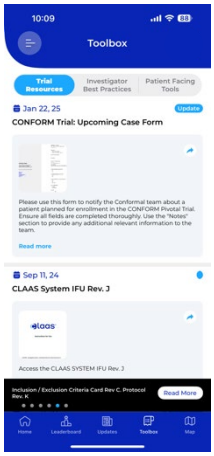
Instructions using the CONFORM Trial**: Upcoming Case online form.** To ensure accurate and timely submission of upcoming CONFORM Pivotal Trial patient cases, please follow the steps below when completing the form.

1. Access the Online Submission Form
   Click the following link (Submit Patient Cases) (https://qrco.de/bfhae8) 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): 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.



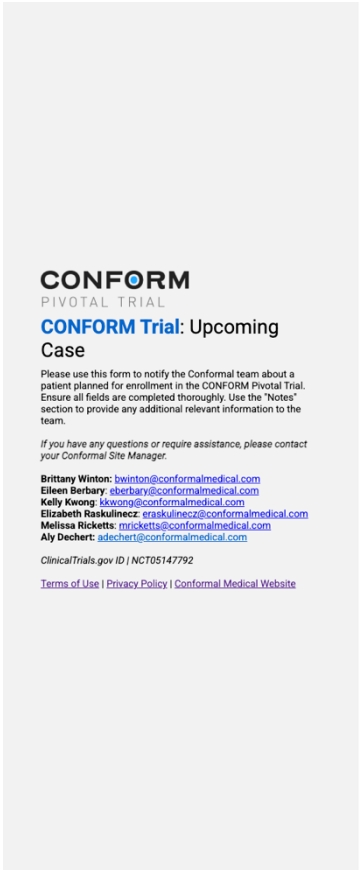
Scan the QR Code: with your mobile device open your camera to scan the code to navigate to the form.

SCAN ME

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
PIVOTAL TRIAL

CONFORM Trial: Upcoming Case

Please use this form to notify the Conformal team about a patient planned for enrollment in the CONFORM Pivotal Trial. Ensure all fields are completed thoroughly. Use the "Notes" section to provide any additional relevant information to the team.

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

Brittany Winton: bwinton@conformalmedical.com
Eileen Berbary: eberbary@conformalmedical.com
Kelly Kwong: kkwong@conformalmedical.com
Elizabeth Raskulinecz: eraskulinecz@conformalmedical.com
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ClinicalTrials.gov ID | NCT05147792

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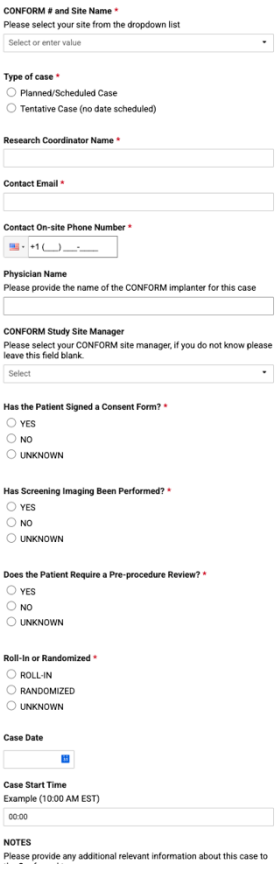
CONFORM # and Site Name *
Please select your site from the dropdown list
Select or enter value

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

Research Coordinator Name *

Contact Email *

Contact On-site Phone Number *
+1 (___) ___-____

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.
Select

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)
00:00

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.