CONFORM Pivotal Trial

eCRF Completion Guidelines

Contents

1 General Instructions

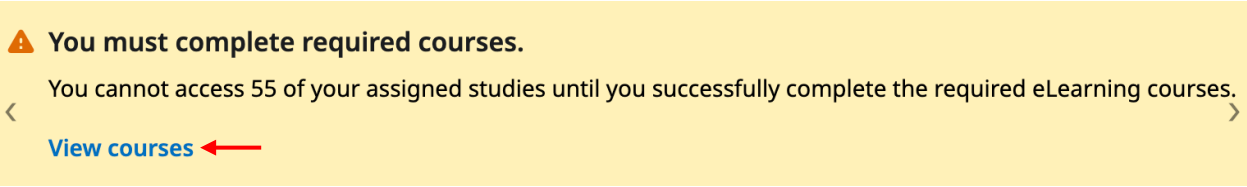
Note: These instructions are specific to the database as applies to patients consented under Protocol Revision K. If you need instructions for patients consented under an earlier Protocol Revision, please ask your site manager for the eCRF Completion Guidelines Version 1.0.

1.1 Database Access and Security

Rave Database Link:

https://login.imedidata.com/login

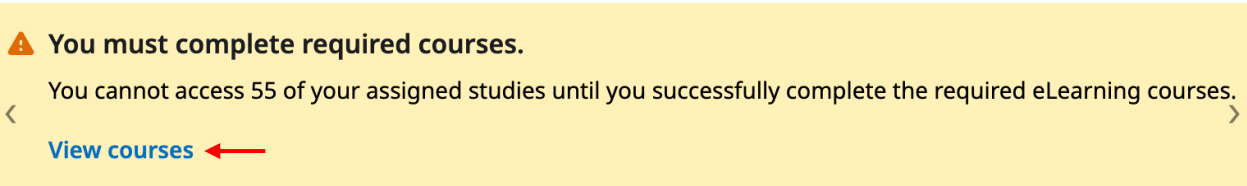
Existing users: You will receive an email from Medidata, informing you of access to the study. Depending on the user's role for the study, additional eLearning may be required prior to gaining access to the study EDC. Pending eLearning will be displayed on the home screen and can be accessed via the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



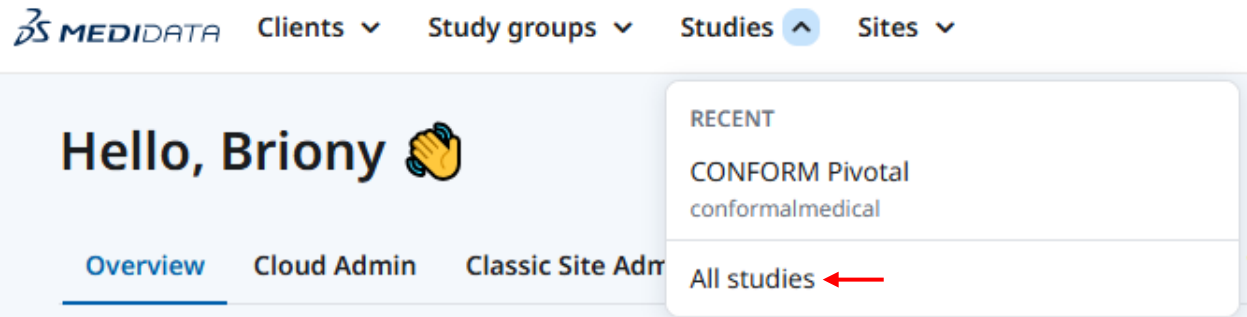
New users:

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.

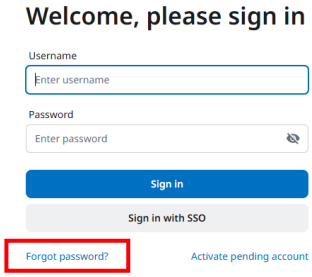


Upon logging into Medidata Rave, the study can be accessed via "Studies" then "All studies."



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

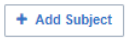
1.3 System Timeout

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

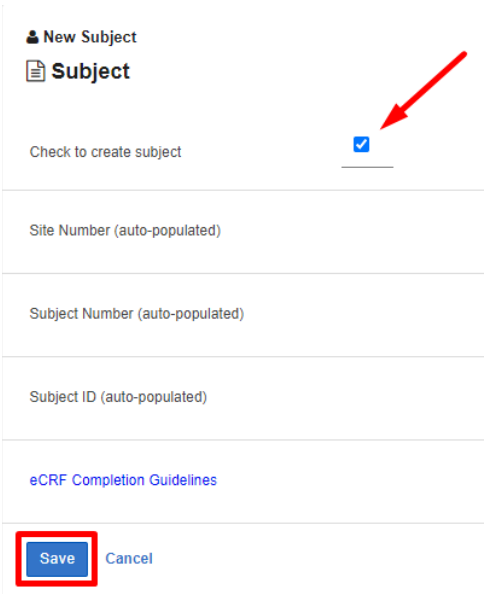
If data is not saved and the system times out, the data will need to be re-entered. Click the Save button at the bottom of the form.

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).

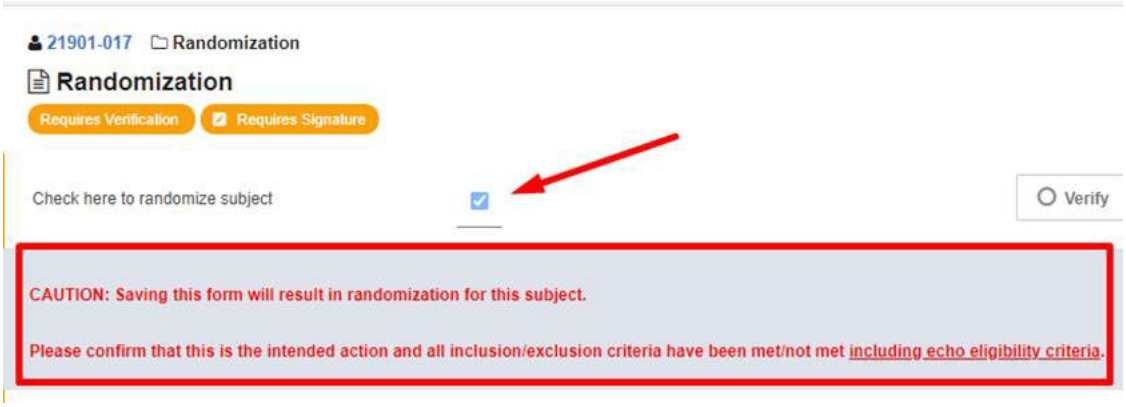
It is important to only add a subject in EDC after the subject has signed the informed consent form, as this action cannot be undone. If a new subject is entered into the database in error, contact your Site Manager immediately.

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.

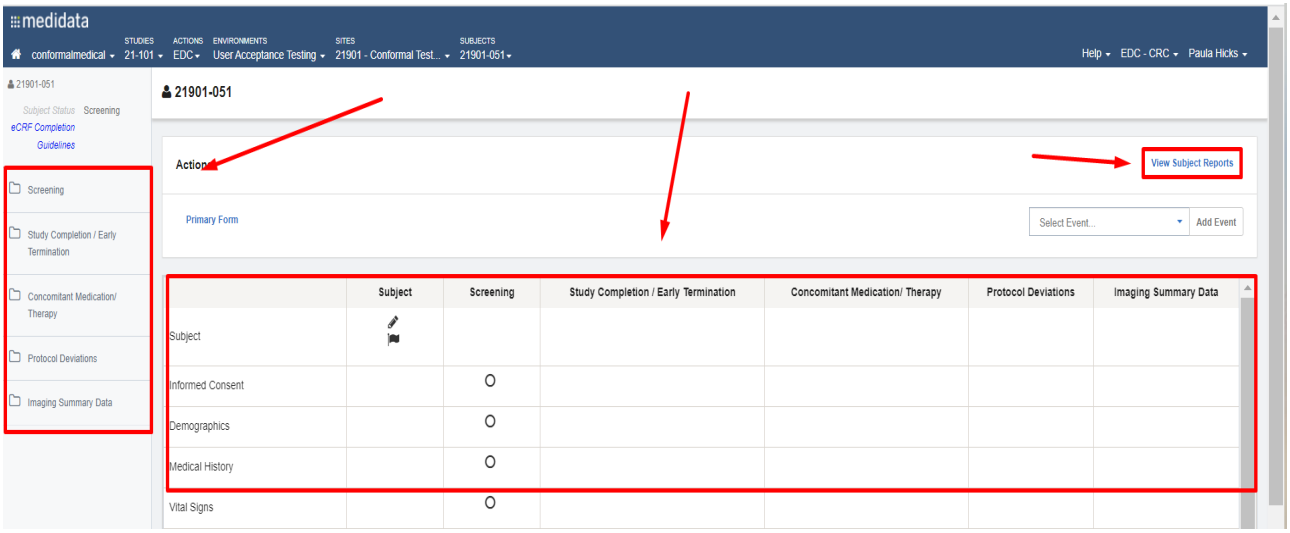


A Protocol Deviation is required if:

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

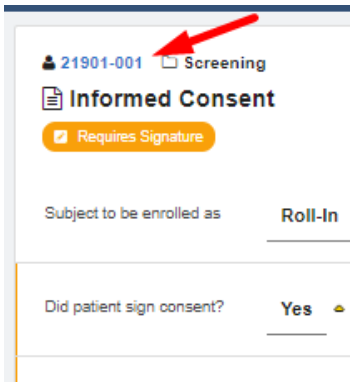
2.3 Subject Record Grid

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.



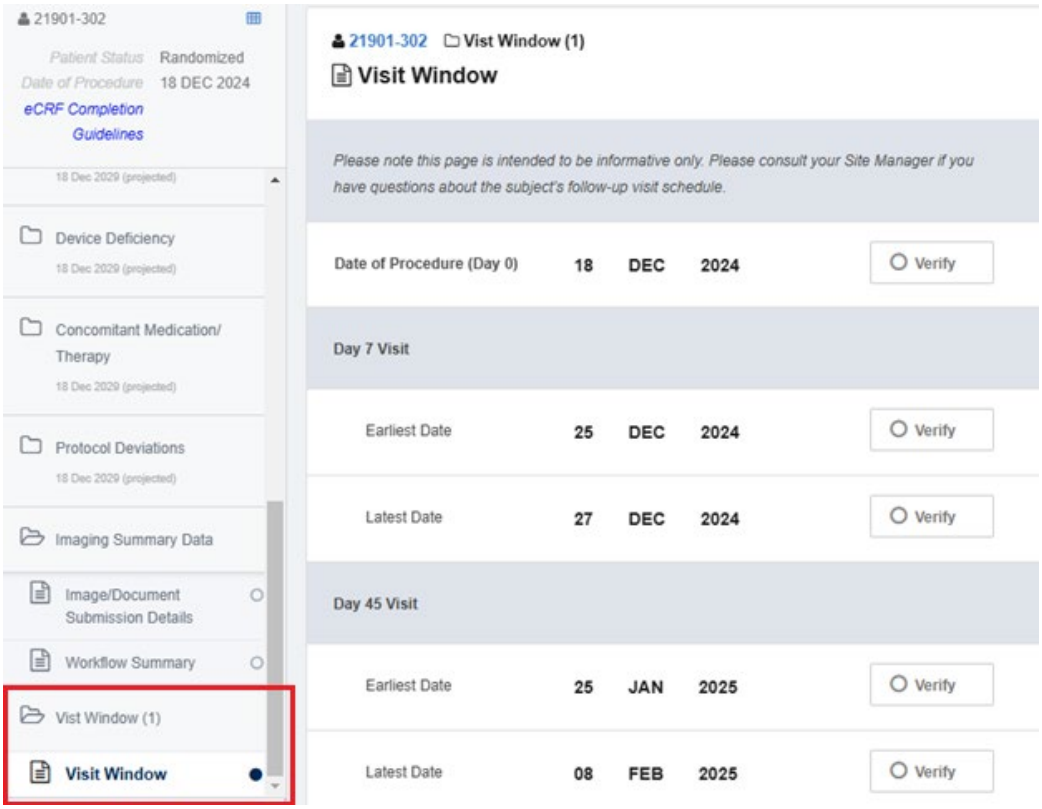
Note: Subject specific reports are also available for use and can be accessed using the link as indicated by the right arrow.

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

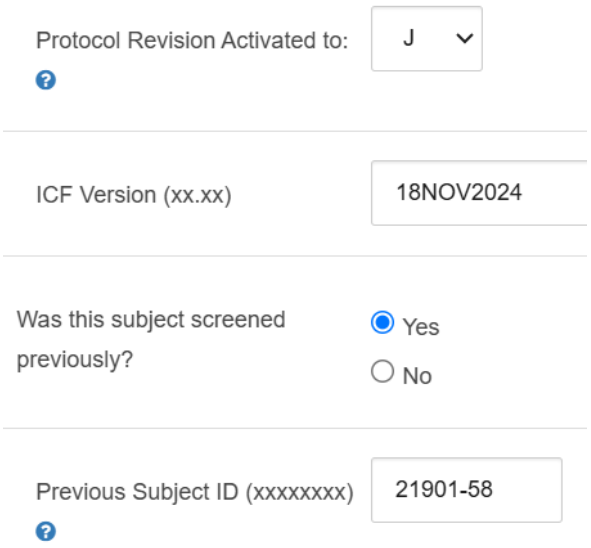
3.1 Screening and Randomization

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.

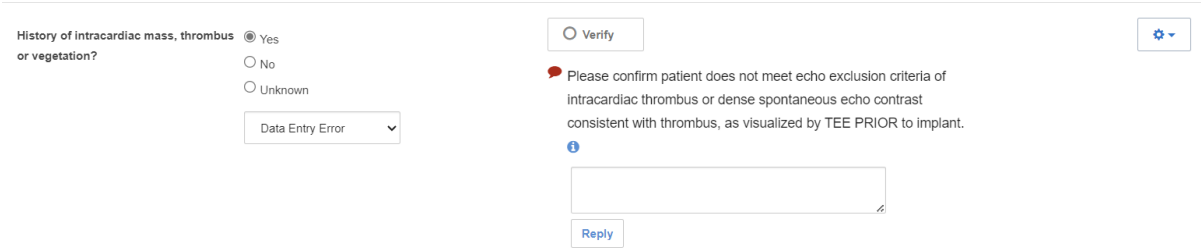


3.1.2 Medical History

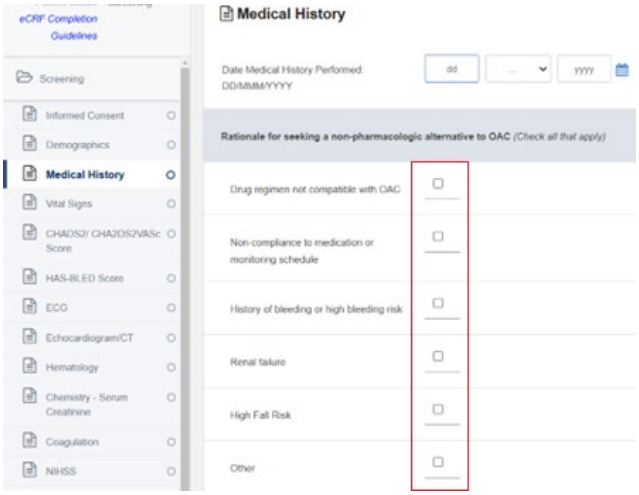
Medical history may be completed up to 30 days prior to consent as part of site standard of care. If it is completed greater than 30 days prior to the date of informed consent, a protocol deviation must be entered.

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.).



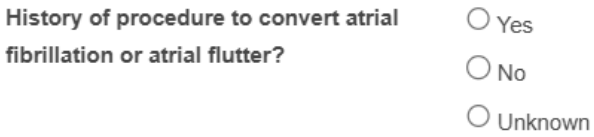
Rationale for seeking a non-pharmacologic alternative to OAC *(Check all that apply)*



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.).

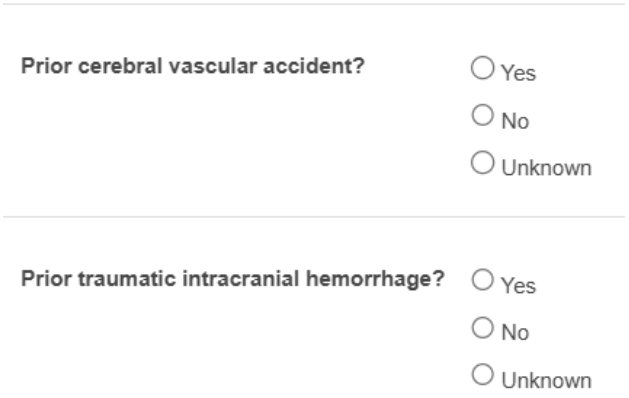
Every effort should be made to collect definitive yes/no responses from the Subject Medical Record. Your response may prompt queries to assess if any inclusion/exclusion criteria has not/has been met in relation to your response.

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.

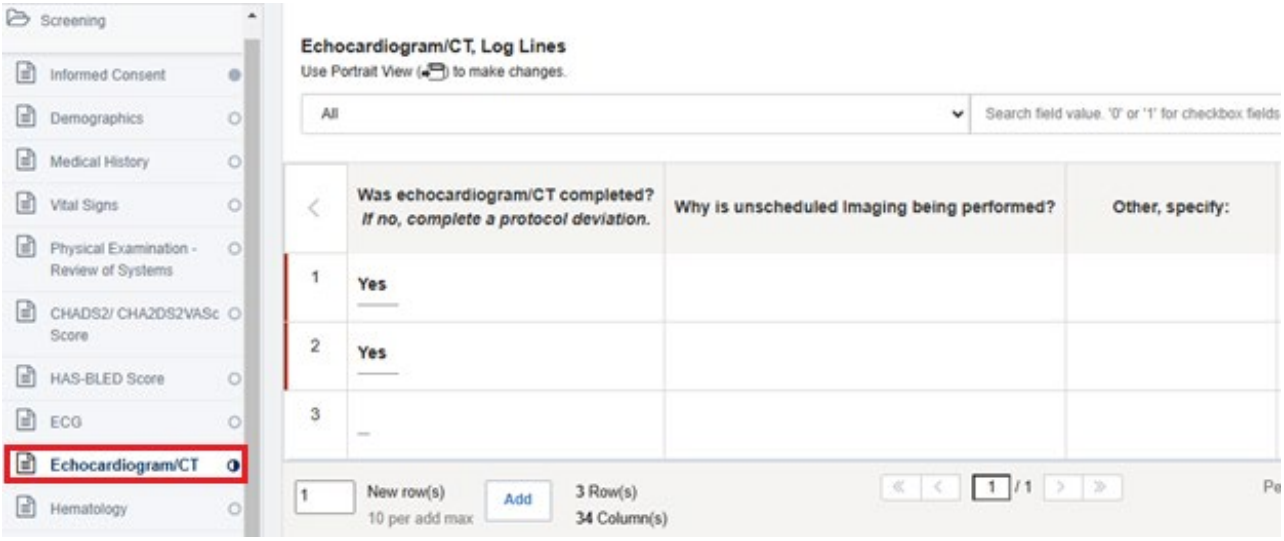
If "*Have all the inclusion criteria and none of the exclusion criteria, as specified by the protocol, been met for this subject?*" is answered "No," each individual Inclusion/Exclusion criteria will become visible.

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.

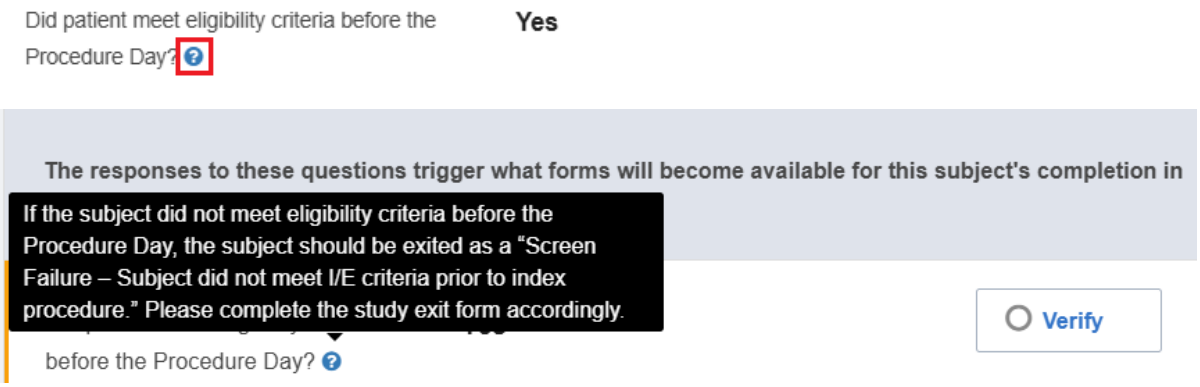
All Imaging Log Lines can be visualized by selecting "Echocardiogram/CT". Please upload all images into the Imaging Module.



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

3.1.6 Patient Population

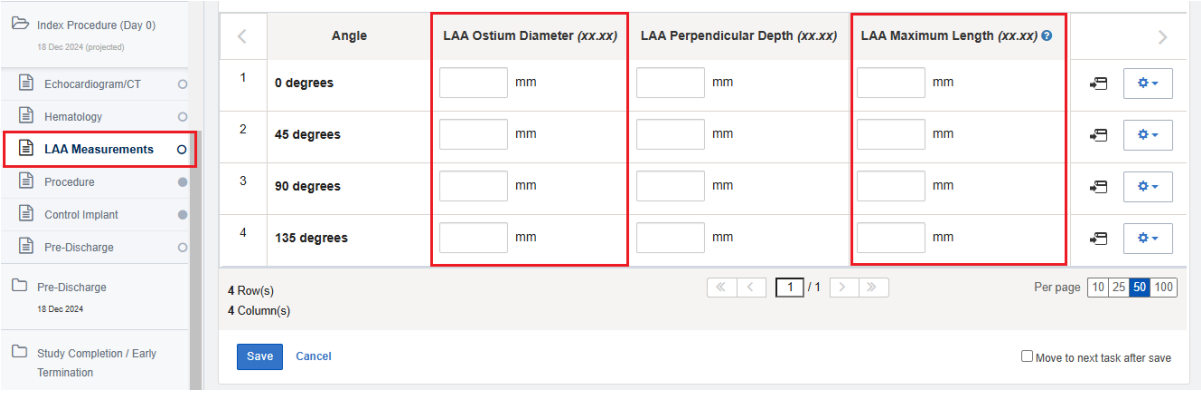
The responses to the questions in the *Patient Population* Form trigger what forms will become available for this subject's completion in EDC. Please hover over the question mark for guidance on the subject's required follow-up visits and patient exit classification.



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.”

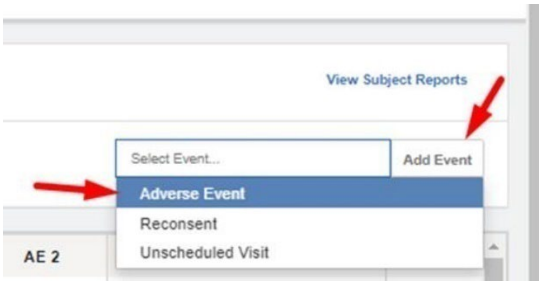
3.2.3 Pre-Discharge

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.

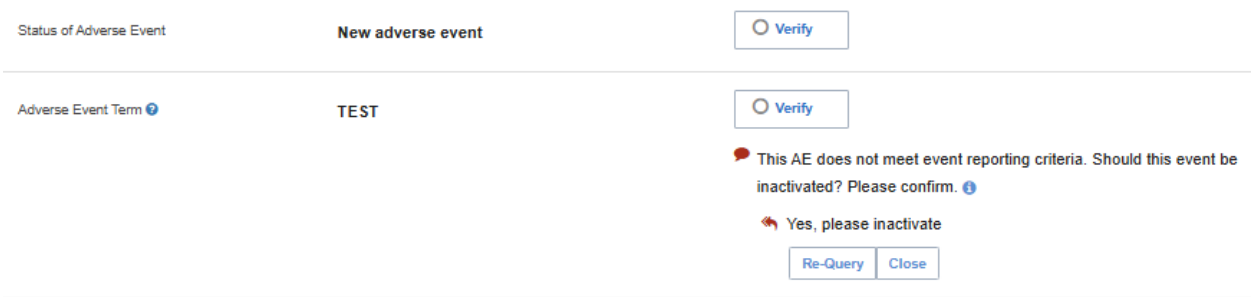
AE entry into the Database is considered the Date Sponsor Notified of AE. If RC does not have access to the database or is not yet sure if a discovered/reported event meets protocol specified reporting criteria, the RC should notify their Site Manager via email or phone call and file a printed copy of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

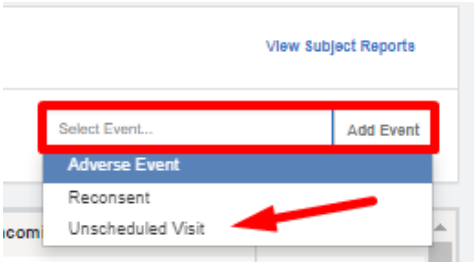
Reason for inactivation (e.g., duplicate of AE X, does not meet reporting requirements per protocol)

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.

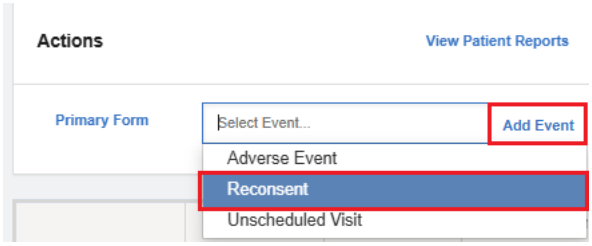
3.4 Unscheduled Visit

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.

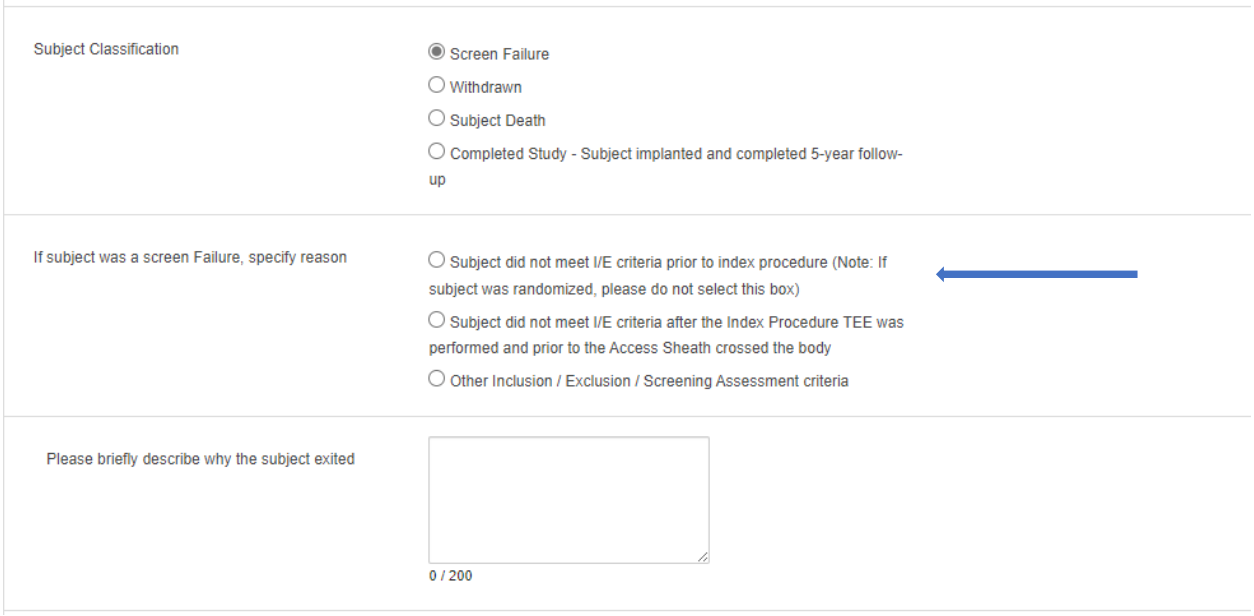
The following four categories of Subject Classification will be tracked as documented in EDC on the Study Exit Form.

- **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).



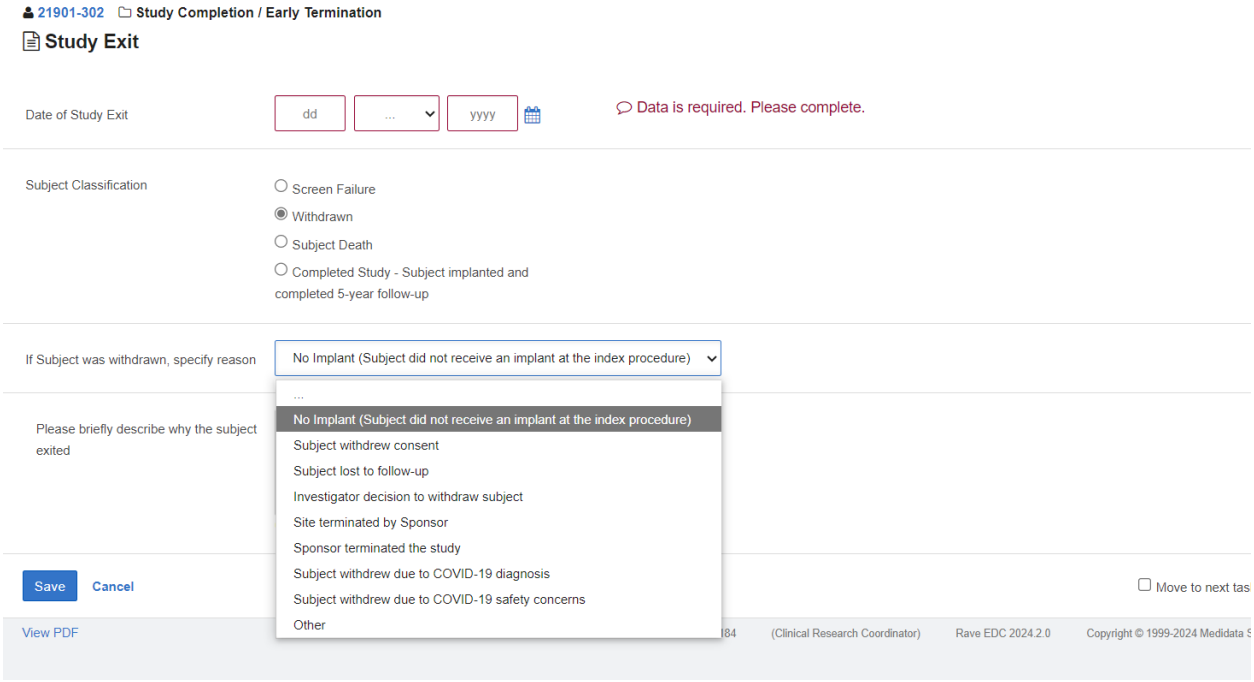
In Brief Description: enter which I/E criteria has not been met.

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.

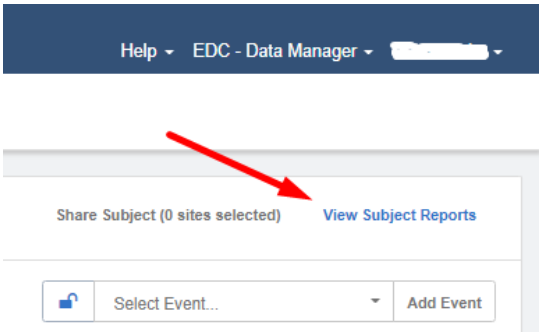
4 Data Management

4.1 Data Queries

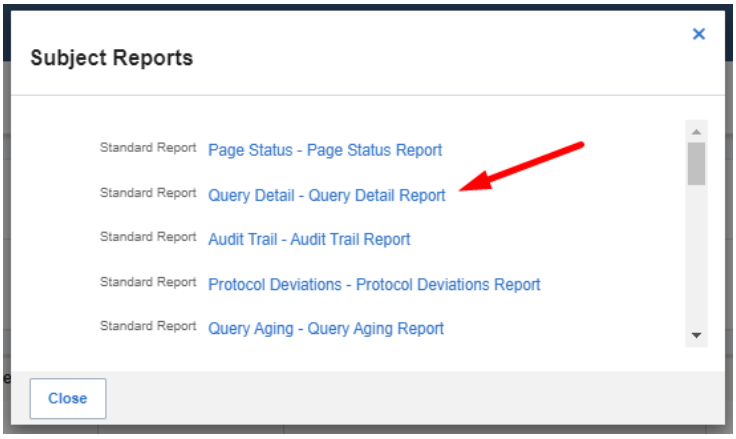
Queries refer to questions or flags raised by the system or study personnel when inconsistencies, missing information, or potential errors are detected within the clinical trial data entered by sites. Queries can be auto generated or created manually by data managers, the safety team, or CRAs.

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.

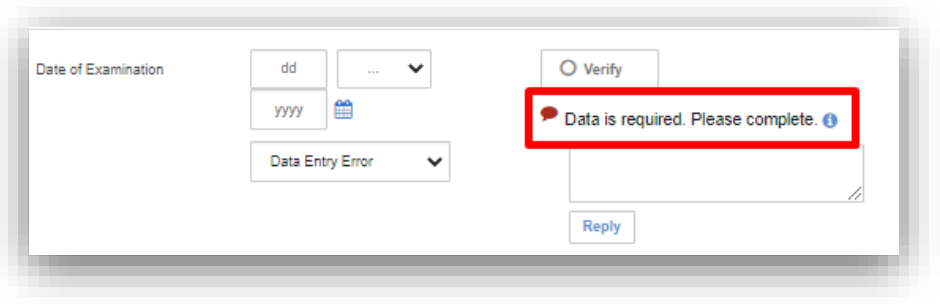


Select the Query Detail - Query Detail Report which shows all the queries for the subject.

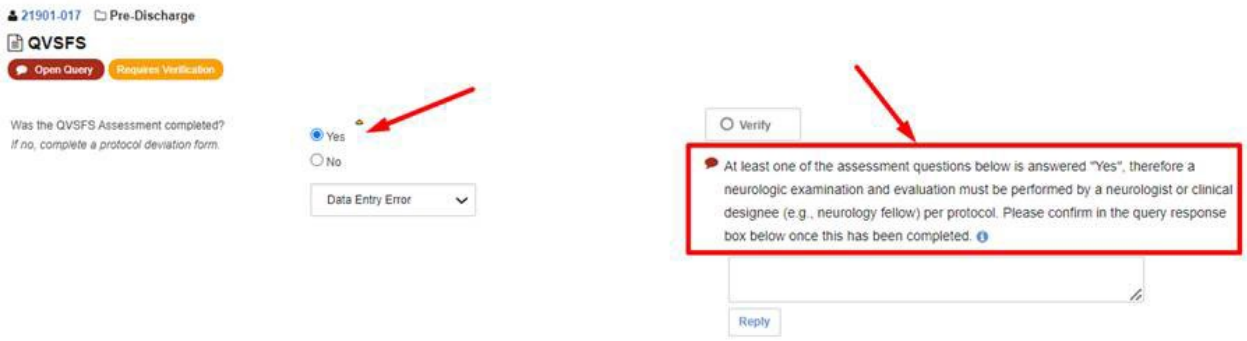


4.2 Mandatory Fields and Edit Checks

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:

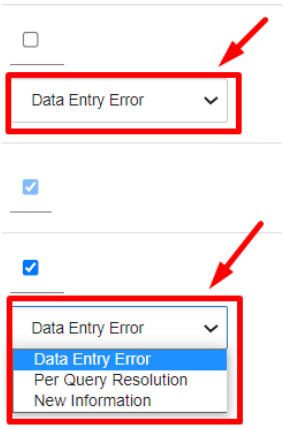


Reminder: Update the data in fields as needed prior to responding to queries. Most queries will automatically close once data is entered and saved. If the query remains open once data is entered, respond to the query.

4.3 Changing Previously Entered Data

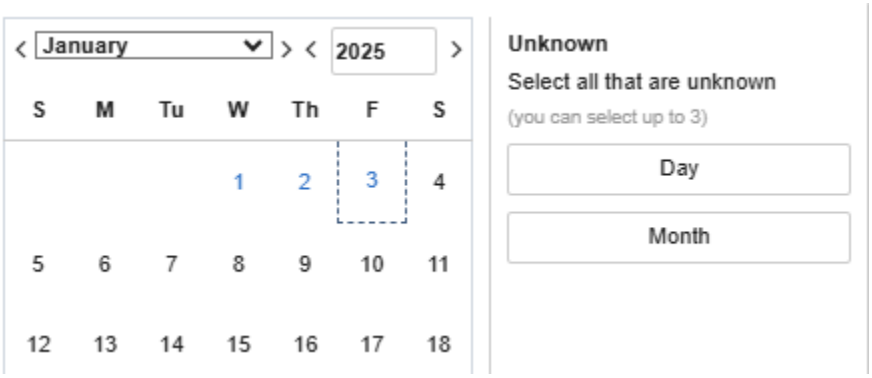
If data is changed for an existing record, the system will require a reason for change.

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:



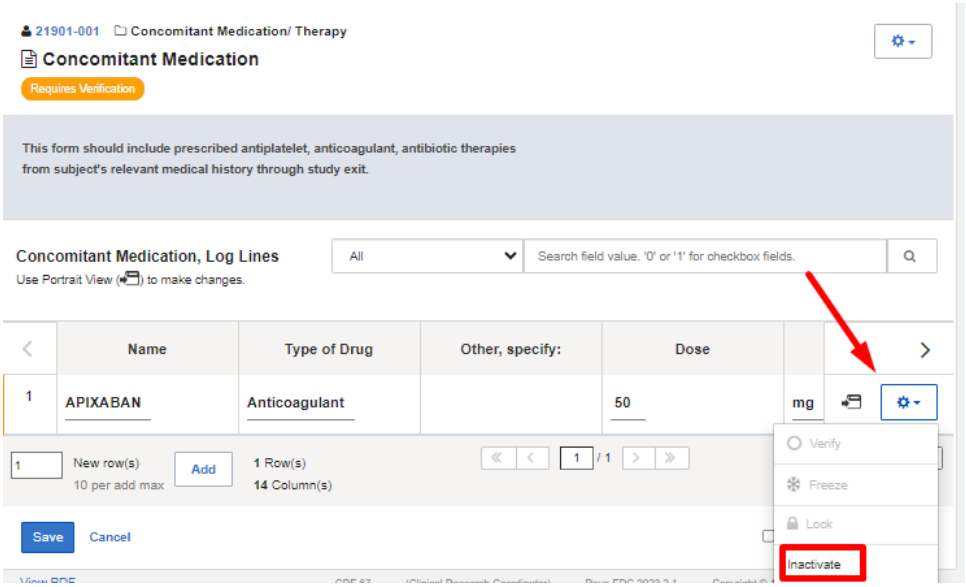
For fields that require a full date where you are unable to determine the day, please record as 01MonYYYY in EDC. If unable to determine day **and** month, please record as 01JanYYYY. Every effort should be made to at least obtain an approximate year. Do not enter "UNK" for unknown fields. If the year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

4.5 Inactivating Log Lines

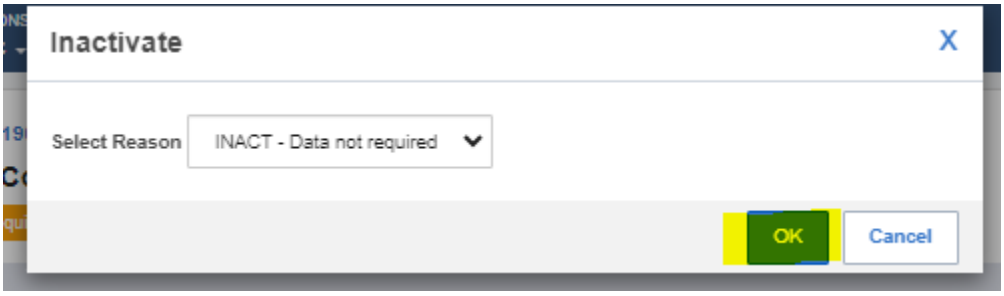
In the event that data has been entered in error (i.e., data entered into the wrong subject, study does not require data, entry error, etc.) sites have the ability to inactivate Con Meds, Imaging, and PDs on their own. Adverse Event inactivation process is detailed in the Adverse Event section of this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

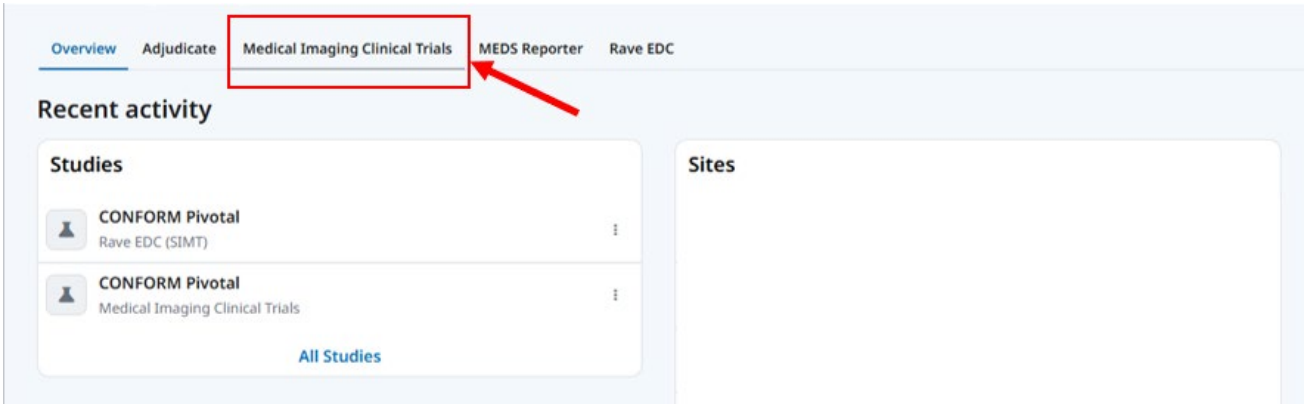


A popup will display, select “OK” and the change is complete. It is not necessary to save the form.

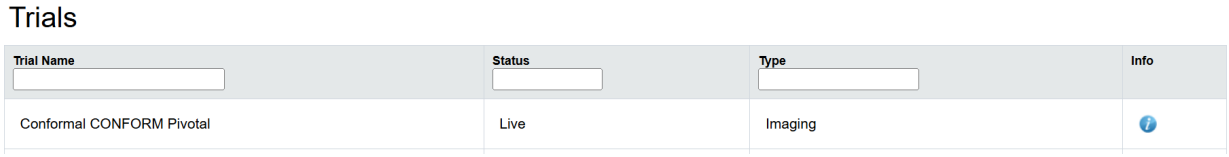


5 Imaging Uploads

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
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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