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CONFORM Pivotal Trial: EDC Updates Overview
05-11-2026

CONFORM EDC Updates – Contents

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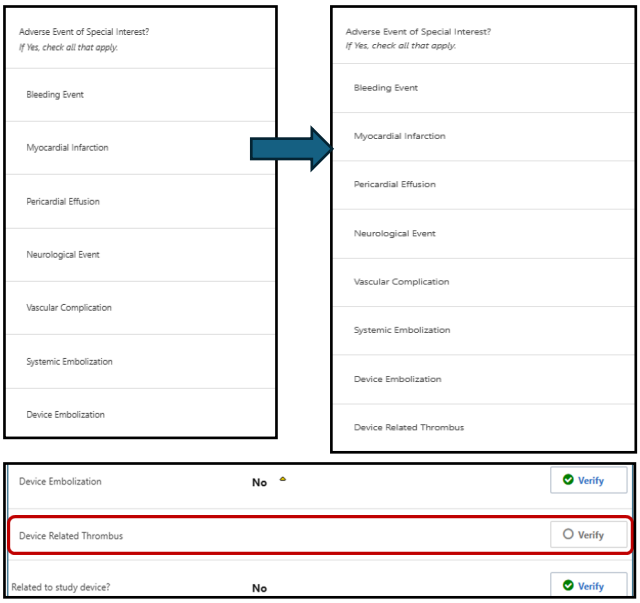
05-11-2026

Adverse Event CRF

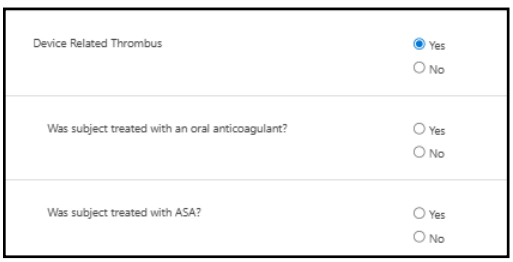
- Adverse Events of Special Interest (AESI)
    - Addition of Device Related Thrombus (DRT)

IMPACT - Changes will be moving forward. No retroactive changes needed.



- If DRT is selected under AESI- 2 medication related questions trigger- New Field
    1. Was subject treated with an oral anticoagulant? = Yes /No
    2. Was subject treated with ASA? = Yes / No

NOTE - This question is to capture medications started as a direct result of the DRT and not the medications already being taken by the subject.



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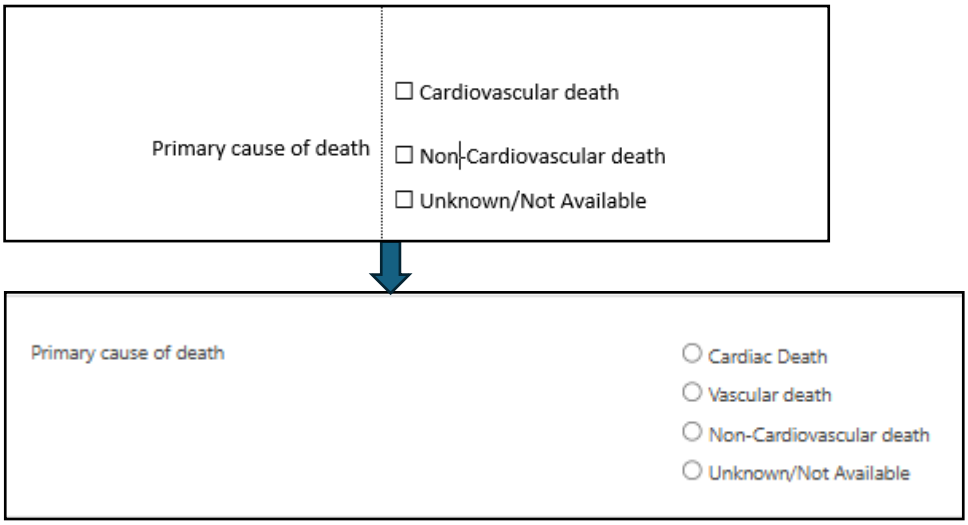
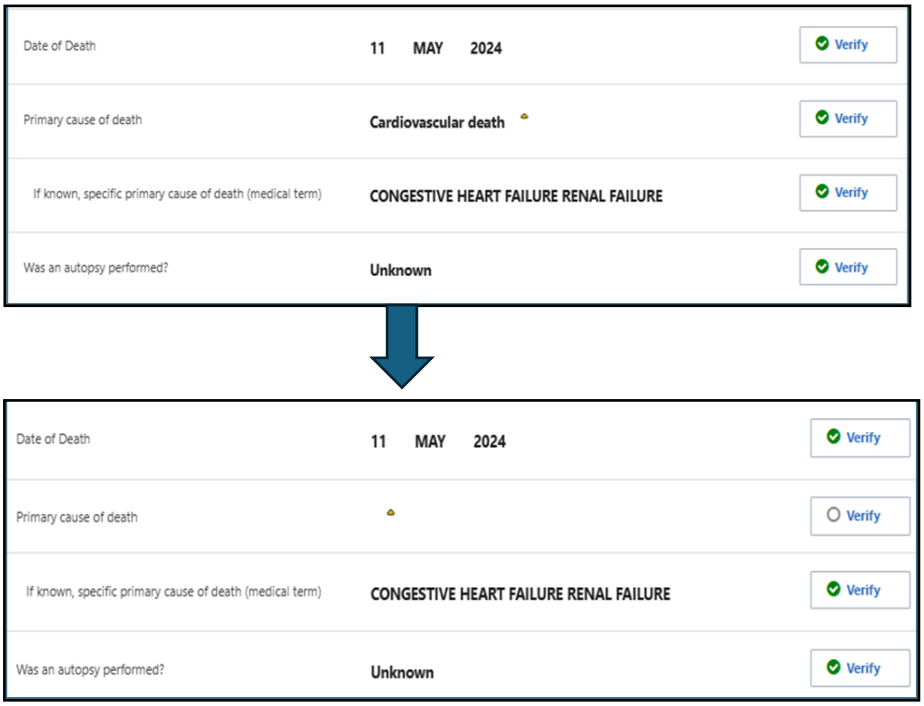
Adverse Event — Death CRF

- Primary Cause of Death
    - Cardiac related vs Vascular related death cause will be reported separately

IMPACT - Updates are required for the existing Death eCRFs reported by sites.





~ 20 CRFS will be impacted

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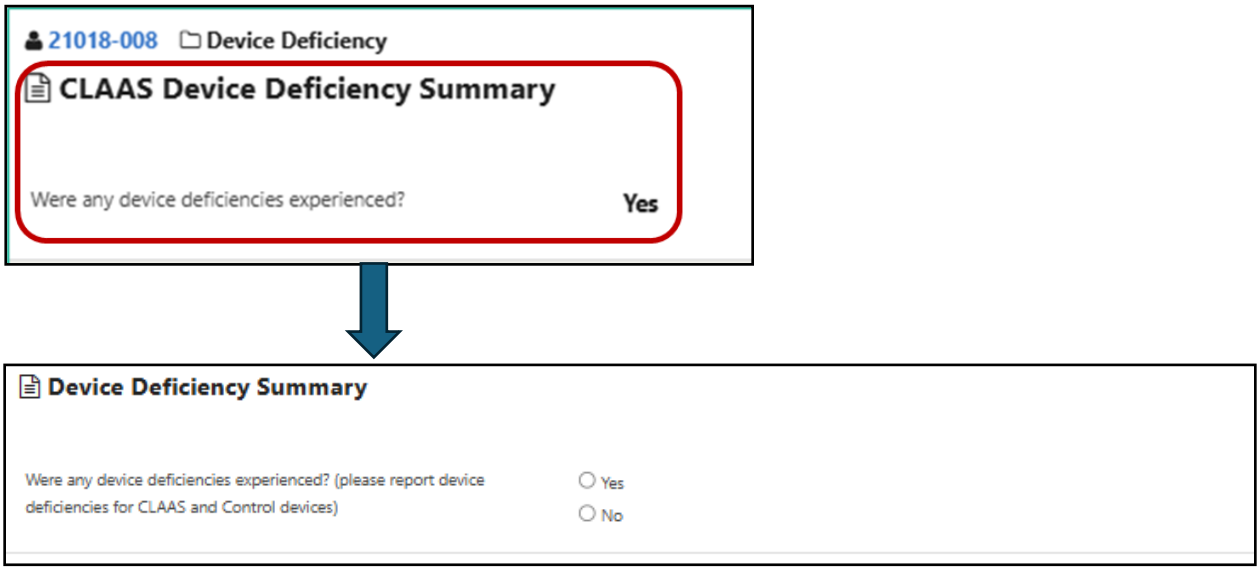
Device Deficiency Summary CRF

- CLASS Device Deficiency Summary CRF will now be updated to Device Deficiency Summary CRF
    - Both CLASS and CONTROL device deficiencies will be reported under the same CRF.

IMPACT - All previously reported Device deficiency CRFs will need to be updated with responses for this question.



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Device Deficiency CRF

Renamed form from CLAAS Device Deficiency to Device Deficiency

- New field for Date Sponsor was notified
- Added VizaraMed, Watchman device components, and Amulet components
- Added a new field for "Could it have led to a Serious Adverse Device Effect (SADE)?"
- Updated field label from "Please confirm which AE Number is related to this device deficiency" to "if yes, what is the AE #?"
- Added a new field for if yes, was it a serious adverse event?
- Added a new field for location of device
- Added a section titled 'Action / Outcome of the device deficiency'
- Enable fields under 'Action / Outcome of the device deficiency' section when condition is met

Note: the sub questions for "Did device deficiency or device malfunction occur have been removed from Control implant CRF due to the device deficiency CRF updates above.

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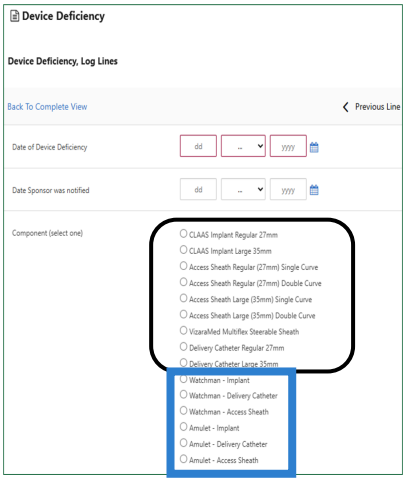
Device Deficiency CRF

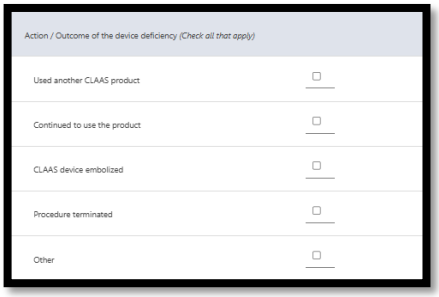
New List of Device Components added

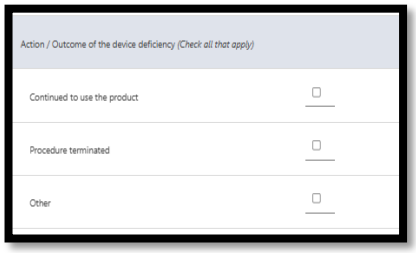
IMPACT - All previously reported Device deficiency CRFs will need to be updated with responses for this question.

- Triggers for 'Action/Outcome of the device deficiency' section
  - Component = checked with any of below option
    - CLASS Implant Regular 27mm
    - CLAAS Implant Large 35mm
    - Access Sheath Regular (27mm) Single Curve
    - Access Sheath Regular (27mm) Double Curve
    - Access Sheath Large (35mm) Single Curve
    - Access Sheath Large (35mm) Double Curve
    - VizaraMed Multiflex Steerable Sheath
    - CLAAS Delivery Catheter Regular 27mm
    - Delivery Catheter Large 35mm
  - Then it will enable below fields under 'Action / Outcome of the device deficiency' section.
    - Used another CLAAS product
    - CLAAS device embolized



VS





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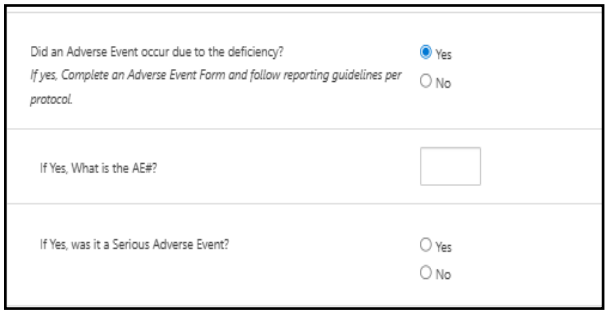
Device Deficiency CRF

Device deficiency CRFs updates are to support regulatory reporting requirements.

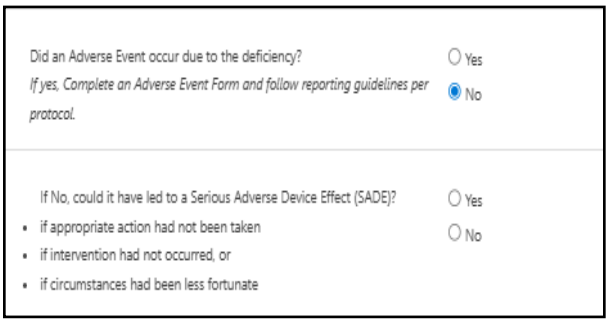
- Trigger fields for 'Did an Adverse Event occur due to the deficiency?'
    - **Scenario 1**- If 'YES' is selected.
        - 2 Additional questions trigger requiring response-
        - If yes, What is the AE#?
        - If yes, Was it an SAE?

IMPACT - All previously reported Device deficiency CRFs will need to be updated with responses for this question.



- Trigger fields for 'Did an Adverse Event occur due to the deficiency?'
    - **Scenario 2**- If 'NO' is selected.
        - 1 Additional question triggers requiring response-
        - If No, Could it have led to a Serious Adverse Device Effect (SADE)#?

IMPACT - All previously reported Device deficiency CRFs will need to be updated with responses for this question.



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~ 60 DD CRFS will be impacted

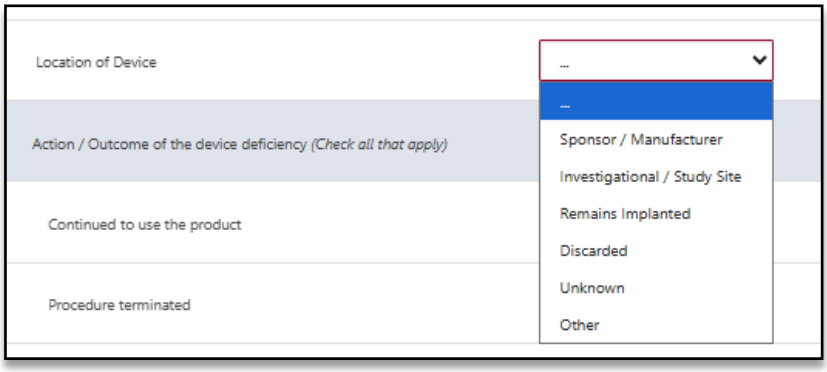
Device Deficiency CRF

Device Location- New Field Added

- All previously reported Device deficiency CRFs will need to be updated with responses for Device location datapoint.
    - Added new field with below options:
    - Sponsor / Manufacturer
    - Investigational / Study Site
    - Remains Implanted
    - Discarded
    - Unknown
    - Other

  If Other is selected, please specify

IMPACT - All previously reported Device deficiency CRFs will need to be updated with responses for this question.



CAUTION: Investigational Device. Limited by federal (or United States) law to investigational use. Outside the United States, the device is intended exclusively for clinical investigation. Not approved for commercial use.

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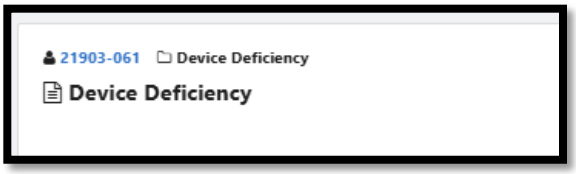
Device Deficiency CRF

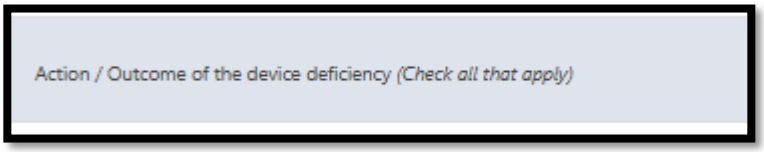
- CLASS Device Deficiency CRF will now be updated to "Device Deficiency CRF"
    - Both CLASS and CONTROL device deficiencies will be reported under the same CRF



- New Question- "Date of Sponsor Notification"
    - Notify sponsor by reporting data in EDC

IMPACT - All previously reported Device deficiency CRFs will need to be updated with the date of sponsor notification.

- Outcome of the device deficiency will now be updated to "Action/Outcome of the device deficiency"
    - Just a change in title, the list of responses will remain same.



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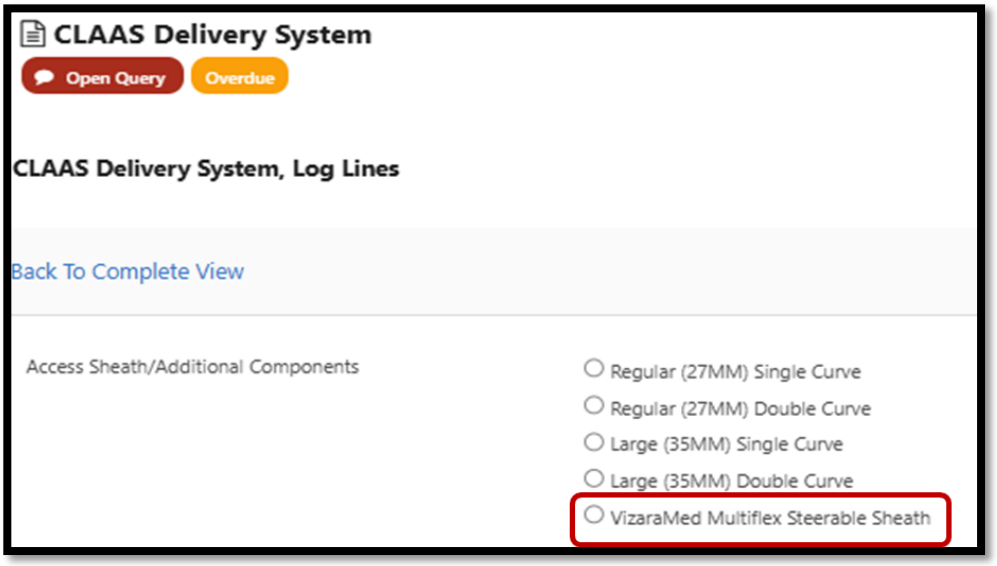
CLAAS Delivery System CRF

- Access sheath/Additional component- *New Field added*
    - Option to report the use of Vizaramed Multiflex Steerable Sheath
    - Site to verify the current response reported and update as applicable.

IMPACT - Retroactive changes



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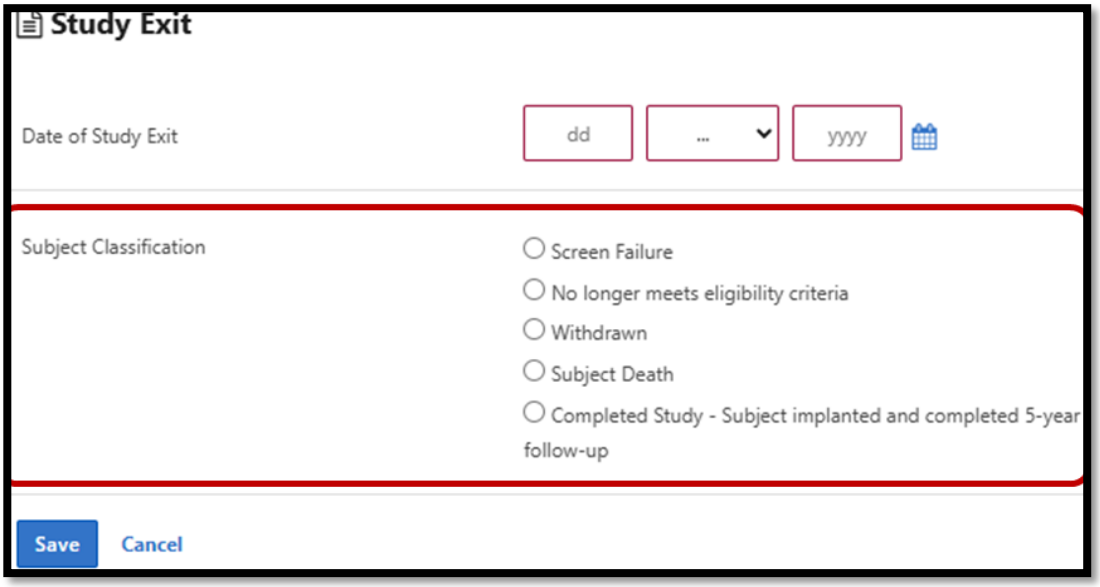
Study Exit CRF

- Subject Classification- *New Field added*
    - Subject Classification - Updated options for this field as below
        - Screen Failure
        - No longer meets eligibility criteria- ***New Field To report subjects that were randomized and a device attempt was made but did not receive implant.***
        - Withdrawn
        - Subject Death
        - Completed Study - Subject implanted and completed 5-year follow-up

IMPACT - Site to verify the current response reported and update responses where applicable.



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Control Implant CRF

- Removed below fields:
    - If yes, please provide brief description of deficiency or malfunction:
    - Did an adverse event occur due to the deficiency?
    - Please confirm which AE Number is related to this device deficiency:
    - Deficiency due to:
    - Other, specify:
- The fields will no longer be available

IMPACT – None to the site

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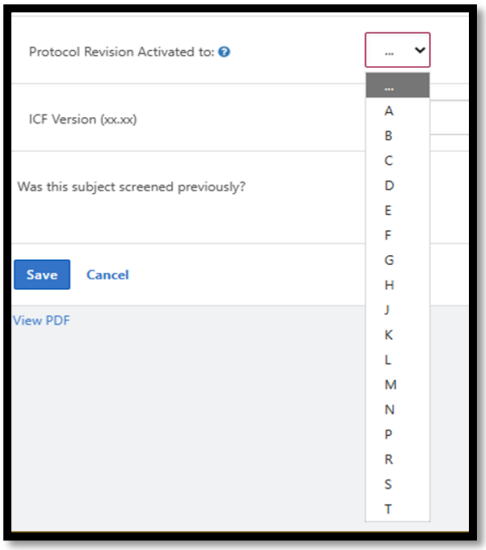
Informed Consent

- Protocol Revision Activated to - Below options added in the dropdown list for this field:
    - R, S, T

Re-consent Log

- Protocol Revision Activated to - Below options added in the dropdown list for this field:
    - R, S, T

IMPACT LOW - Site will have new options available



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Inclusion/Exclusion Criteria

- Added EC21 and EC22 which only applies for France

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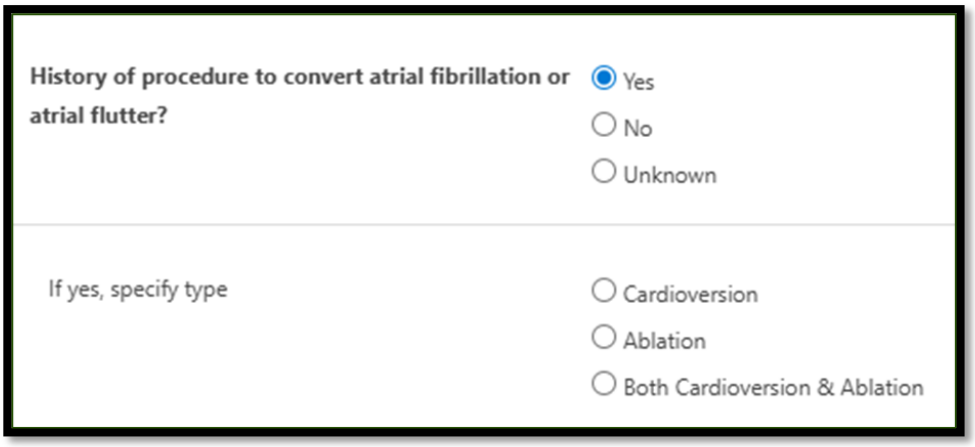
Medical History

- History of procedure to convert Afib or Aflutter? If yes, specify type - Updated options for this field as below:
    - Cardioversion
    - Ablation
    - Both Cardioversion & Ablation

IMPACT - Changes will be moving forward. No retroactive changes needed



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Randomization

- Added reminder: Prior to randomization, must be reviewed and approved by Conformal.