

CONFORM EDC Updates – Contents

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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.

The diagram illustrates the update to the Adverse Event of Special Interest (AESI) list. On the left, a list of events includes Bleeding Event, Myocardial Infarction, Pericardial Effusion, Neurological Event, Vascular Complication, Systemic Embolization, and Device Embolization. A blue arrow points to the right, where the updated list includes all the previous events plus 'Device Related Thrombus'. Below this, a screenshot of the form shows 'Device Embolization' set to 'No' and 'Device Related Thrombus' highlighted with a red box, also set to 'No'. A 'Verify' button is visible next to each field.

- 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.

The screenshot shows three questions related to the Device Related Thrombus (DRT) event. The first question is 'Device Related Thrombus' with radio buttons for 'Yes' (selected) and 'No'. The second question is 'Was subject treated with an oral anticoagulant?' with radio buttons for 'Yes' and 'No'. The third question is 'Was subject treated with ASA?' with radio buttons for 'Yes' and 'No'.

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.

Primary cause of death	<input type="checkbox"/> Cardiovascular death
	<input type="checkbox"/> Non-Cardiovascular death
	<input type="checkbox"/> Unknown/Not Available



Primary cause of death	<input type="radio"/> Cardiac Death
	<input type="radio"/> Vascular death
	<input type="radio"/> Non-Cardiovascular death
	<input type="radio"/> Unknown/Not Available

Date of Death	11 MAY 2024	<input checked="" type="checkbox"/> Verify
Primary cause of death	Cardiovascular death	<input checked="" type="checkbox"/> Verify
If known, specific primary cause of death (medical term)	CONGESTIVE HEART FAILURE RENAL FAILURE	<input checked="" type="checkbox"/> Verify
Was an autopsy performed?	Unknown	<input checked="" type="checkbox"/> Verify



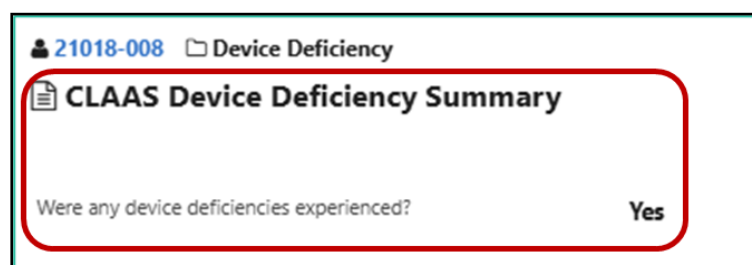
Date of Death	11 MAY 2024	<input checked="" type="checkbox"/> Verify
Primary cause of death		<input type="checkbox"/> Verify
If known, specific primary cause of death (medical term)	CONGESTIVE HEART FAILURE RENAL FAILURE	<input checked="" type="checkbox"/> Verify
Was an autopsy performed?	Unknown	<input checked="" type="checkbox"/> Verify

*~ 20 CRFS
will be impacted*

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.



21018-008 Device Deficiency

CLAAS Device Deficiency Summary

Were any device deficiencies experienced? **Yes**



Device Deficiency Summary

Were any device deficiencies experienced? (please report device deficiencies for CLAAS and Control devices) Yes No

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.

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

Device Deficiency

Device Deficiency, Log Lines

Back To Complete View < Previous Line

Date of Device Deficiency dd -- yyyy

Date Sponsor was notified dd -- yyyy

Component (select one)

- 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
- Delivery Catheter Regular 27mm
- Delivery Catheter Large 35mm
- Watchman - Implant
- Watchman - Delivery Catheter
- Watchman - Access Sheath
- Amulet - Implant
- Amulet - Delivery Catheter
- Amulet - Access Sheath

VS

Action / Outcome of the device deficiency (Check all that apply)

Used another CLAAS product	<input type="checkbox"/>
Continued to use the product	<input type="checkbox"/>
CLAAS device embolized	<input type="checkbox"/>
Procedure terminated	<input type="checkbox"/>
Other	<input type="checkbox"/>

Action / Outcome of the device deficiency (Check all that apply)

Continued to use the product	<input type="checkbox"/>
Procedure terminated	<input type="checkbox"/>
Other	<input type="checkbox"/>

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.

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.

Did an Adverse Event occur due to the deficiency? Yes
If yes, Complete an Adverse Event Form and follow reporting guidelines per protocol. No

If Yes, What is the AE#?

If Yes, was it a Serious Adverse Event? Yes No

- 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.

Did an Adverse Event occur due to the deficiency? Yes No
If yes, Complete an Adverse Event Form and follow reporting guidelines per protocol.

If No, could it have led to a Serious Adverse Device Effect (SADE)? Yes No

- if appropriate action had not been taken
- if intervention had not occurred, or
- if circumstances had been less fortunate

~ 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.

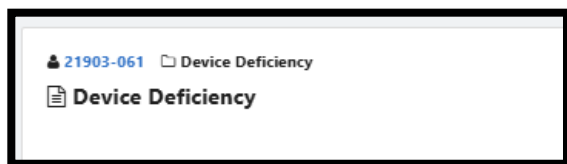
This screenshot shows the 'Location of Device' dropdown menu. The menu is open, displaying the following options: -- (selected), --, Sponsor / Manufacturer, Investigational / Study Site, Remains Implanted, Discarded, Unknown, and Other. The background of the form shows the 'Action / Outcome of the device deficiency (Check all that apply)' section with options 'Continued to use the product' and 'Procedure terminated'.

This screenshot shows the 'Other, specify:' text area. The 'Location of Device' dropdown is set to 'Other'. Below the dropdown is a text input field with a character count of '0 / 200'.

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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

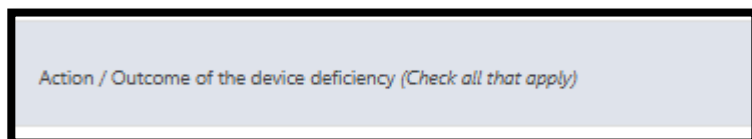


- New Question- “Date of Sponsor Notification”
 - Notify sponsor by reporting data in EDC

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.



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

The screenshot shows the 'CLAAS Delivery System' form interface. At the top, there are two buttons: 'Open Query' (red) and 'Overdue' (orange). Below this is the title 'CLAAS Delivery System, Log Lines' and a link 'Back To Complete View'. The main section is titled 'Access Sheath/Additional Components' and contains a list of radio button options: 'Regular (27MM) Single Curve', 'Regular (27MM) Double Curve', 'Large (35MM) Single Curve', 'Large (35MM) Double Curve', and 'VizaraMed Multiflex Steerable Sheath'. The last option is highlighted with a red rectangular box.

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.

The screenshot shows a web form titled "Study Exit". It contains two main sections. The first section is for the "Date of Study Exit", which includes three input fields: "dd", a dropdown menu with "..." and a downward arrow, and "yyyy", followed by a calendar icon. The second section is for "Subject Classification", which lists five radio button options: "Screen Failure", "No longer meets eligibility criteria", "Withdrawn", "Subject Death", and "Completed Study - Subject implanted and completed 5-year follow-up". At the bottom left of the form are two buttons: "Save" (in blue) and "Cancel".

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

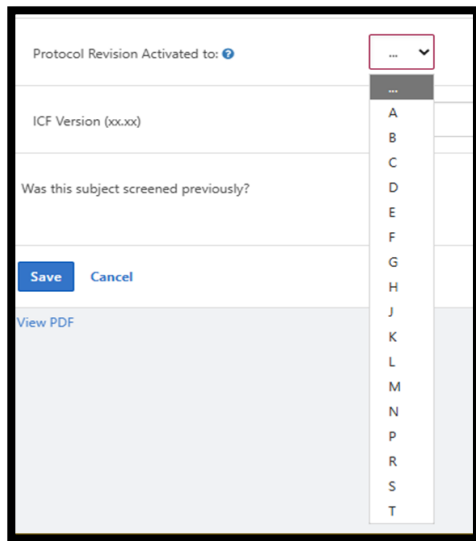
Informed Consent

- 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



Inclusion/Exclusion Criteria

- Added EC21 and EC22 which only applies for France

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

History of procedure to convert atrial fibrillation or atrial flutter?	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
If yes, specify type	<input type="radio"/> Cardioversion <input type="radio"/> Ablation <input type="radio"/> Both Cardioversion & Ablation

Randomization

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

The screenshot shows the 'Randomization' form in the Conformal EDC system. At the top, it displays the subject ID '21002-035' and the form title 'Randomization'. A yellow badge indicates 'Requires Signature'. A blue reminder box states: 'Reminder: Once a subject has been randomized, per protocol there is a 14 day window to treat the patient.' Below this, there is a checkbox labeled 'Check here to randomize subject' which is checked, and a 'Verify' button with a green checkmark. A grey message box below the checkbox says 'Patient successfully randomized.' At the bottom, a red 'CAUTION' message reads: 'CAUTION: Saving this form will result in randomization for this subject.' A red reminder box states: 'Reminder: Prior to randomization, imaging should have been reviewed and approved by Conformal.' At the very bottom, a red note says: 'Please confirm that this is the intended action and all inclusion/exclusion criteria have been met/not met including [echo eligibility criteria](#).'