

Table of Contents

1. CONFORM Pivotal Medidata Adjudicate.....	1
2. Medidata Adjudicate FAQ.....	1
3. Navigating Medidata Adjudicate.....	3
4. How to upload AE Source Documents in Medidata Adjudicate.....	6
5. How to Redact Documents in Medidata Adjudicate.....	12

1. CONFORM Pivotal Medidata Adjudicate

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

2. Medidata Adjudicate FAQ

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2.6.1. No. If there is a circumstance where multiple AE's entered share the same source documentation, that source documentation only needs to be entered one time under one event visit folder. Communication regarding source documents may come from the 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?

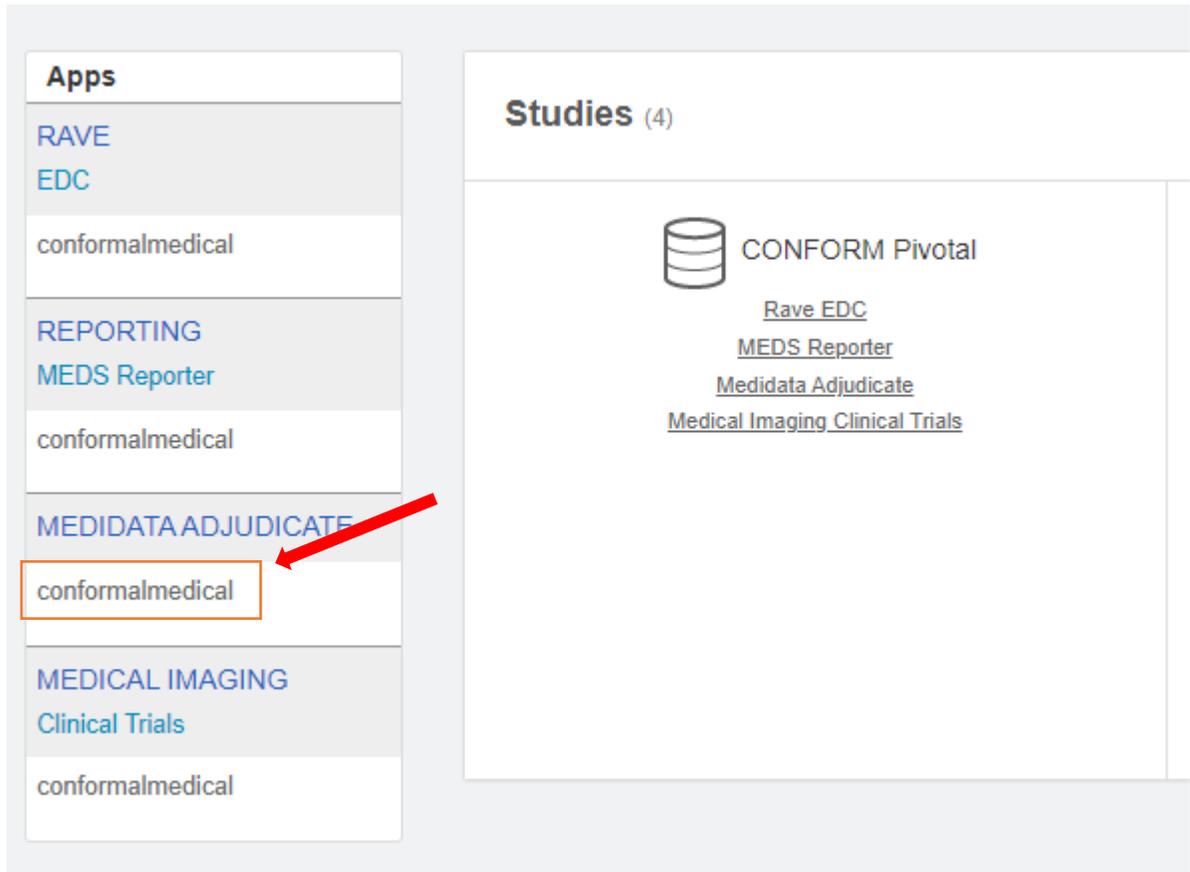
2.7.1. No. All imaging related to an AE is uploaded through Medidata Medical Imaging Portal Refer to **CONFORM Imaging Upload MOP** for more information on uploading imaging.

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

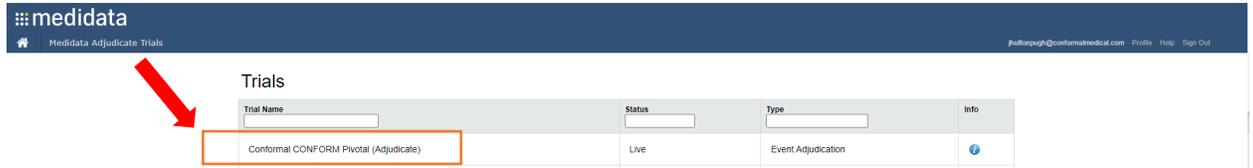
2.8.1. If you have a technical issue related to uploading source documents, redaction etc. please **contact** your Site Manager. For all other questions related to queries, please send a query response within Medidata Adjudicate to the NAMSA Safety Team.

3. Navigating Medidata Adjudicate

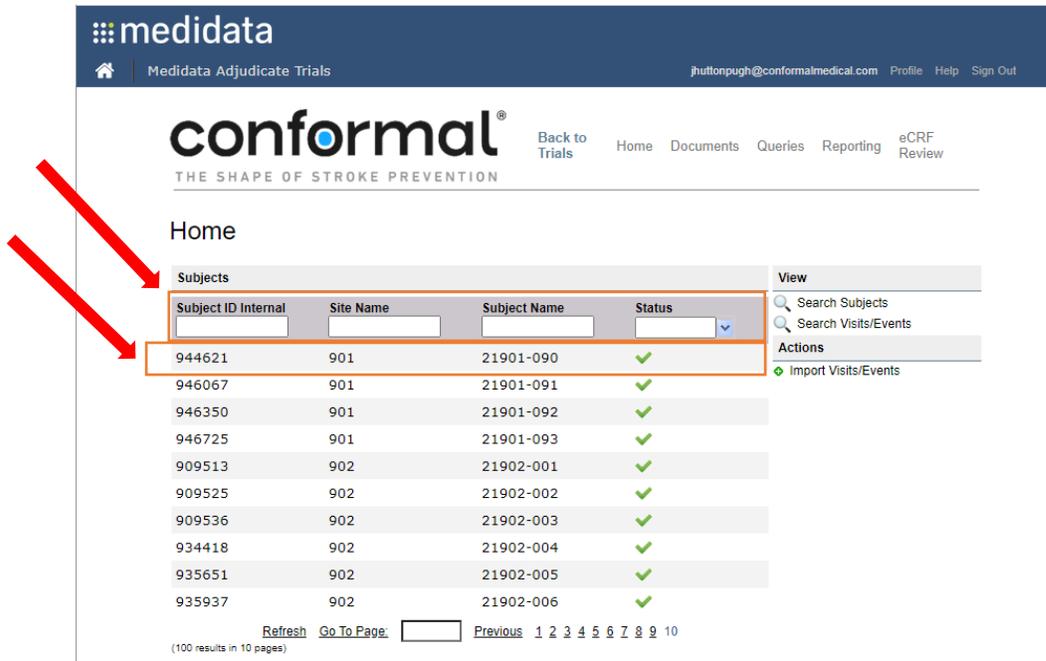
- 3.1.** Log in from the Medidata home page. When on the home page, go to “Apps” on the left side of the screen. Medidata Adjudicate access is available near the bottom of the list. Click the **conformalmedical** link to bring you to the Medidata Adjudicate home page.



- 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".

medidata
j.hultonpugh@conformalmedical.com Profile Help Sign Out

Back to Trials Home Documents Queries Reporting eCRF Review

Subject: 21901-009 Close

Subject Details		Subject Details	
Subject Name	21901-009	Subject Name	21901-009
Date of Procedure	01-Feb-2022	Screening Name	Unknown
		Status	Active

Queries

No queries have been associated with this subject

View

- ▶ Audit Log
- ▶ Workflows (0 / 0)

Actions

- New Query
- Add Adverse Event Visit/Event

Visits/Events

Visit/Event Name	Complete	Img Reqs
Adverse Event 1	✖	0

4. How to Upload AE Source Documents in Medidata Adjudicate

- 4.1. You will be notified by the NAMS 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.

medidata Medidata Adjudicate Trials jhuttonpugh@conformalmedical.com Profile Help Sign Out

conformal[®] THE SHAPE OF STROKE PREVENTION Back to Trials Home Documents Queries Reporting eCRF Review

Subject: 21901-009 Close

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

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

Submission Problems (3):

Errors:

- Documents: Requires an upload

Warnings:

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

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

Queries

No queries have been associated with this visit

Exam

No Exams have been associated with this visit

Files

No files have been associated with this visit

Documents

No Documents have been associated with this visit

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

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

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

The screenshot displays the Medidata Conformal interface for adjudicating an adverse event. The header includes the Medidata logo and user information. The main content area shows the subject ID 21901-009 and details for Adverse Event 1, which is 'PERICARDIAL EFFUSION'. The 'Exam Upload - Details' section is active, showing a grid of document types with checkboxes. Three red arrows highlight the 'Submission Details' section, the 'Documents' section, and the 'Continue' button.

Adverse Event 1 Visit/Event Details		Subject Details	
Visit/Event Name	Adverse Event 1	Adjudication Required?	Unknown
Adverse Event Term	PERICARDIAL EFFUSION	AE Start Date	Unknown
EDC Event Number	1	Status	Active
Exam Upload - Details		View	
Submission Details		<ul style="list-style-type: none"> View Subject Audit Log Audit Log Workflows Workflows (0 / 0) 	
<input checked="" type="checkbox"/> Admission/ER Notes	<input type="checkbox"/> Autopsy Report	Actions	
<input type="checkbox"/> Death Certificate	<input type="checkbox"/> Discharge Summary	<ul style="list-style-type: none"> Restore Deleted Items New Query Add Adverse Event Visit/Event 	
<input type="checkbox"/> Index Admission H&P	<input checked="" type="checkbox"/> Index Procedure Report	Visits/Events	
<input type="checkbox"/> Other	<input checked="" type="checkbox"/> Pre/Post Procedure Labs	Visit/Event Name	Complete
<input type="checkbox"/> Progress Notes	<input type="checkbox"/> Surgery Procedure Report	Adverse Event 1	0
<input type="checkbox"/> Transfusion Records			

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

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

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

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

Below this table is the "Adverse Event 1 File Upload [Documents]" section. It features a "Choose File" button, a table of uploaded files, and "Save Uploads" and "Cancel" buttons. The file upload table is as follows:

File Name	Action
Test for Medidata Adjudicate.pdf	Remove

On the right side of the screen, there is a "Subject Details" panel with the following information:

- Subject Name: 21901-009
- Screening Name: Unknown
- Status: Active

Below the subject details are sections for "View" (with expandable options like View Subject, Audit Log, etc.), "Actions" (with options like Restore Deleted Items, New Query, etc.), and "Visits/Events" (with a table showing Visit/Event Name, Complete status, and Img Reqs).

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.

medidata
Medidata Adjudicate Trials

THE SHAPE OF STROKE PREVENTION

Subject: 21901-009

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

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

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

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

Queries			
No queries have been associated with this visit			

Exam			
No Exams have been associated with this visit			

Files			
No files have been associated with this visit			

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

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”.

The screenshot shows the Medidata Adjudicate Trials interface for subject 21901-009. A red arrow points to a warning message: "You are submitting a Adverse Event 1 visit without including all optional requirements. Would you like to continue anyways?". Below the message are two buttons: "Yes, submit now" and "No - abort".

Subject: 21901-009 Close

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

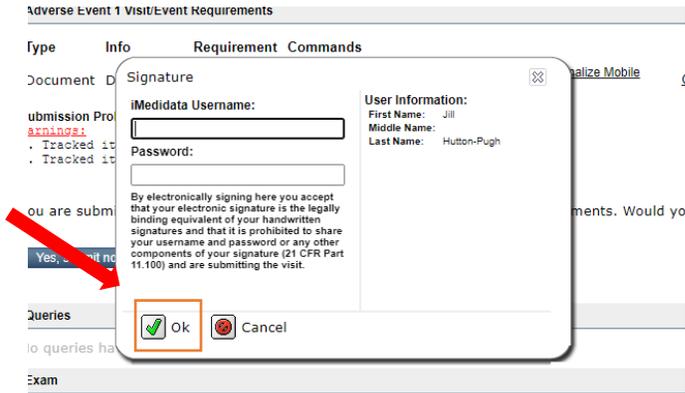
Adverse Event 1 Visit/Event Requirements						
Type	Info	Requirement	Commands			
Document	Documents	1 Document	Upload Document	Upload via Mobile Device	Edit & Finalize Mobile Uploads	Comment

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

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

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

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



5. How to Redact Documents in Medidata Adjudicate

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

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

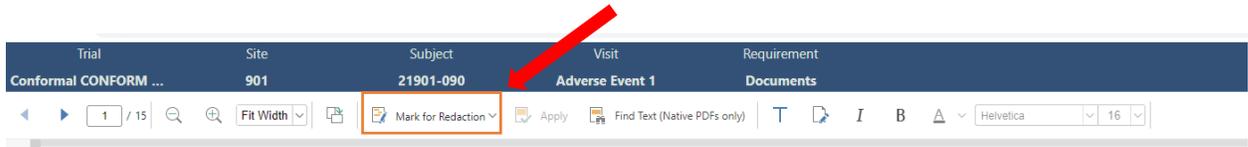
5.1. Simple Redaction: Use when attempting to redact limited mentions of PHI.

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

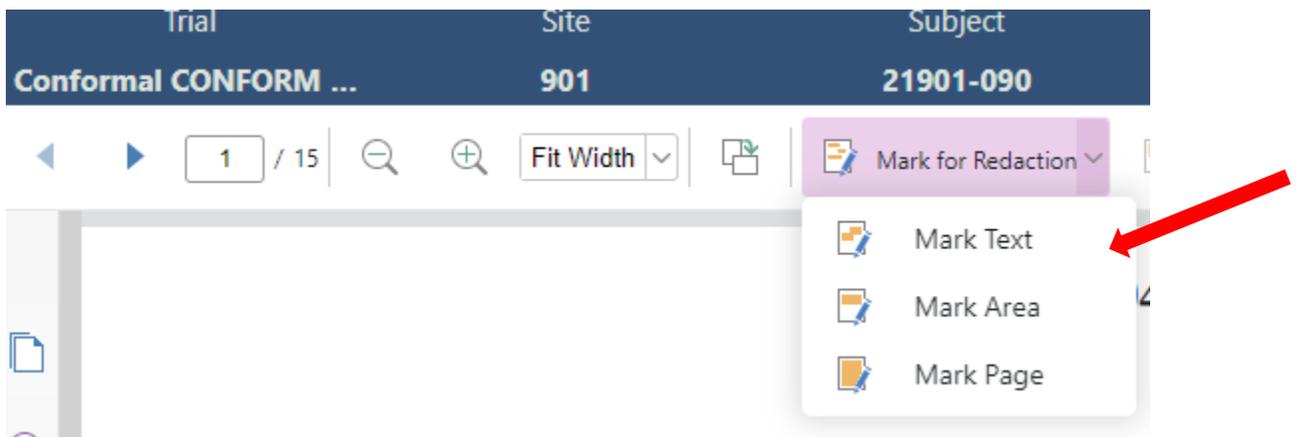
The screenshot displays the Medidata Adjudicate interface for Subject: 21901-090. The main content area is divided into several sections: Adverse Event 1 Visit/Event Details, Adverse Event 1 Visit/Event Requirements, Submission Problems (3), and a list of Documents. The Documents section contains a table with columns for File Name, Requirement, Details, Upload Date, and Actions. A red arrow points to the 'Open Document' button in the Actions column of the first document row.

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

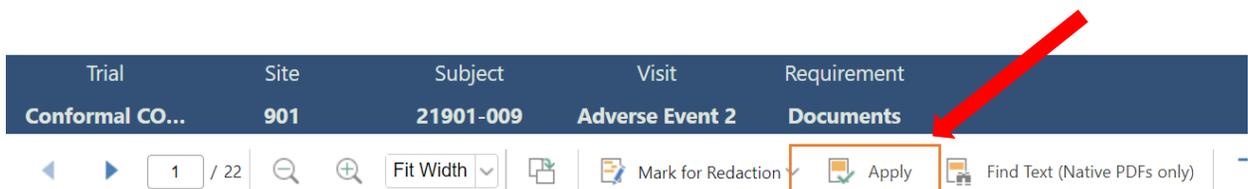
5.1.2. Once the document is opened, click the drop down for “Mark for Redaction” and the redaction tool will appear.



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



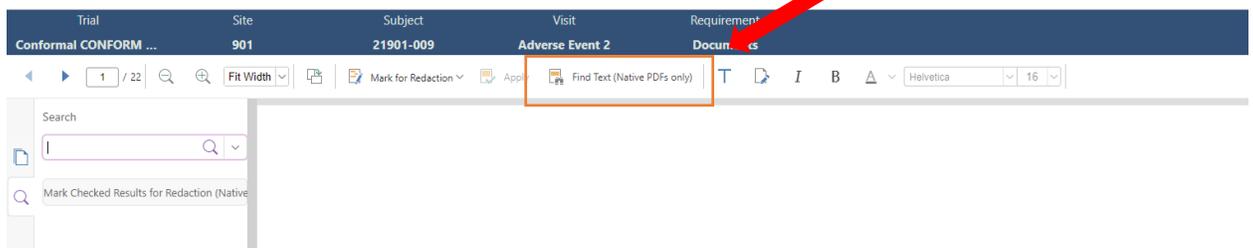
5.1.4. Once you highlight the text/area/page you chose, click “Apply” to redact. **Before leaving the page click “Save” in the upper right corner of the page to ensure your redactions will be saved.**



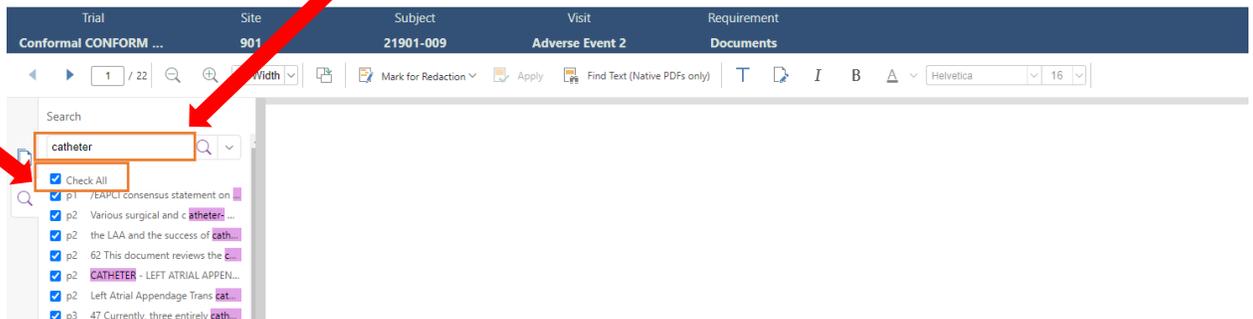
5.2. Find Text redaction feature: This is a Search and Find Redaction tool for rapid redaction. This function allows you to redact multiple mentions of a select term at one time as is described below.

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

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



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



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

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

1 / 22 | Fit Width | Mark for Redac

Search

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

No more

Mark Checked Results for Redaction (Nativ

██████/EAPO
██████ atrial ap

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

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

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

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

