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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*.

Visit	Image type required per visit
	Executive Committee Pre-Procedural Review for First 5 Patients:
	 Cardiac CT/TEE: Within 6 months of the date of consent
Screening	 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
	SUC. 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.

Table 1.0



Title:

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.



dies	S	tes	History	
CONFORM Pivotal Rave EDC (SIMT)	i I			
CONFORM Pivotal Medical Imaging Clinical Trials	1			
All studies				

Clicking the **conformalmedical** link will take you to the next page shown below. Next, click on "Conformal CONFORM Pivotal"

::: medidata Medidata Imaging Trials				
	Trials			
	Trial Name	Status	Туре	Info
	Conformal CONFORM Pivotal	Live	Imaging	0
	Conformal EFS	Live	Imaging	0
	Conformal CONFORM Pivotal (UAT)	UAT/Test	Imaging	0
	Conformal EFS (UAT)	UAT/Test	Imaging	0
		(4 results in 1 names)		

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:

conform			Back to Trials Home Documents Tasks	Queries Reporting eCRF Review User Mgmt
Home				
Subjects				View
Subject ID Internal	Site Name 901	Subject Name	Status	C Search Subjects
991777	901	21901-140	~	
991800	901	21901-141	~	
991818	901	21901-142	~	
991828	901	21901-143	~	
991872		21901-144	× 1	
991873	901	21901-145	~	100
992287	901	21901-146	~	
992611	901	21901-147	~	
992755	901	21901-148	~	

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).

	forma	U.		Back to Titals Home Documents Taxlo Gueries Reporting eCRF Review User Mgnt			
Subject: 21	1901-144				Close		
Subject Details					Subject Details		
Subject Name Status	21901-144 Active	Screening Name	Unknown		Subject Name 21 Screening Name Un	901-144 known	
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					Visit/Event Nam	e Complete	Img Reqs
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					Index Procedure	×	0
					Pre-Discharge	×	0
					45 Days	×	0
					473 B.R		

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.

A Medidata Imaging Trials							asmith@conform	naimedical.com Prof
		L [®]		Back to Tria	als Home Documents Tasks Quer	es Reporting eCRF	Review Us	er Mgmt
Subject: 2	21901-144					Close		
Subject Details						Subject Details		
Subject Name Status	21901-144 Active	Screening Name	Unknown			Subject Name 211 Screening Name Uni	901-144 known	
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				Nav	and/or view imaging	Pro-Discharge	č	0
					and/or view imaging	45 Days	x	0
					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.



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a Trials						asmth@cond	ormalmedical.com Profile H
CO	nform	nal		Back to Trials Home Documents Tasks Querie	s Reporting eCRF	Review Us	ar Mgmt
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CI: No	upload supplied.		Ok 🕘 Cancel		Index Procedure	×	0
Start (T Review				Pre-Discharge	×	0
					45 Days	×	0
Start 7	TE Review				12 Months	×	0

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.

CONI THE SHAPE OF	STROKE PREVE				Back to Trials Home Documents Tasks Quer	aeries Reporting eCRF Review User Mgmt		er Mgmt
Subject: 219	901-144					Close		
Baseline Visit/Event	Details					Subject Details		
Visit/Event Name Status	Baseline Active	Visit/Event Date	Unknown 🥜			Subject Name 219 Screening Name Unix Status Act	01-144 nown ve	
Exam upload	Unload					View		
				Refresh Upload Control		 View Subject Audit Log Audit Log Workflow 	n	
				Click the button below to locate your images		Actions	ms Event Visit/Event	
						Visits/Events		
						Visit/Event Name	Complete	Img Reqs
						Baseline	*	0
						Index Procedure	×	0
						Pre-Discharge	×	0
						45 Days	*	U

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



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Subjec	ct: 21901-144			Close		
Baseline Vi	sit/Event Details			Subject Details		
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Baseline Vi	isit/Event Requirements			View		
Туре	Info	Requirement	Commands	View Subject		
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Select the blue box to confirm "Yes, submit now"

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Subject: 21901-144		Close		
Baseline Visit/Event Details		Subject Details		
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EXAM TE Consider A EXAM Vesse Exam Comment		Actions		
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✓ Start CT Review		Baseline .	*	0
		Index Procedure	×	0
✓ Start TTE Review		Pre-Discharge	×	0
You are submitting a Baseline visit/event without including all optional requirements. Would you like to continue anyways?		45 Days 12 Months	×	0

Select the blue box "Click Here to Sign"



Select the green check box "Ok"



CONFORMAL THE SHAPE OF STROKE PREVENTION	Ba	ck to Trials Home Documents Tasks Queries	Reporting eCRF F	teview Use	r Mgmt
Subject: 21901-144			Close		
Baseline Visit/Event Details			Subject Details		
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TTE/TEE Sonographer	Click Here to Sign		Actions		
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Submission Problems (1): Marnings:	your username and password or any other components of your signature (21 CFR Part		Visits/Events		
 ci: no upicad supplied. 			Visit/Event Name	Complete	Img Reqs
Start CT Review	A Cancel		Baseline	8	0
Chart TTE Baulau	Cancer	1	Index Procedure	×	0
Y SLARL THE REVIEW			Pre-Discharge	×	0
You are submitting a Baseline visit/event without including all optional requirements. Would you like to conti	nue anyways?		45 Days	*	0

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

CONTORMO	N N	Back to Trials Home Documents Tasks Queries Reporting eCRF Review User Mgmt
Subject: 21901-144		• Close
Baseline Visit/Event Details		Subject Details
Visit/Event Name Baseline Pass QC Date 09-Dec-2024	VisitEvent Date Unknown / Status Passed QC	Subject Name 21901-144 Streening Name Unknown Status Active
Daseline visit/Event Requirements	- 175m - 193	View
Type Info Required Exam TEE 1 Exam Exam TTE 1 Exam	Upload Exams Comment	► Vew Stelpet ► Audit Log ► Audit Log Wontforms
Document TTE/TEE Sonographer Worksheet 1 Docur Exam CT 1 Exam	Usland Licenset Mobile Device Mobile Uslands Comment Overvide Usland Examp Comment	Actions 0 Realor Detected Items 0 Here Carry 0 Add 9 Mark Valuet
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Queries		Index Procedure 🗙 0 Pro.Discharpe
No queries have been associated with this v	sit/event.	45 Davs ¥ 0

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

CONFORMAL [®] Beck to Trails Home Documents	i Tasks Queries Reporting eCRF Review User Mgmt
Subject: 21901-144	Close
45 Days VisitEvent Details	Subject Details
VadEvent Lanne 45 Days VadEvent Date Unknown /∕ Status Active	Subject Name 21901-144 Screening Name Unknown Status Active
45 Days VisitEvent Requirements	View
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X The 45 Days visit/event has not satisfied all required items. Please provide all required data in order to finalize the visit/event submission and provide your e-signature.	Index Procedure 🗙 0

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.



A Medidata Imaging Trial

Subject	t: 21901-144			Close
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ype Exam	TEE TTE/TEE Sonographe		TEE media corrupted. Imaging not available.	View Subject Addit Log Addit Log Workflows
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				Baseline 🖌 1
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				Pre-Discharge 🗙 0
meries				45 Days 😤 0

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.

ing Trials					asmith@con	formalmedical.co
conformal [®]		Back to Trials Home Doc	uments Tasks Queries	Reporting eCRF	Review Us	ier Mgmt
Subject: 21901-144				Close		
45 Days Visit/Event Details				Subject Details		
VisitEvent Name 45 Days VisitEvent Date Unknown 🎤 Status Active				Subject Name 219 Screening Name Unix Status Act	01-144 nown	
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Visit/Event will be reviewed - thank you!				Visits/Events		
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Queries				Baseline	~	1
No mustles have been accordated with this visit/event				Index Procedure	×	0
The spectrum during process and stress with stress with grants				Pre-Discharge	×	0
Comments				45 Days		

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.

Queries									 Add 6 Months Visit/Ev Add Adverse Event Vi Add Optional TEE at E 	vent isit/Event Baseline Visit/E	vent			
No querie	s have be	een asso	ciated wit	th this visit								Visits/Events		
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TEE	TEE 04-Apr-2022 2:42 PM			OVERRIDE-TEST				koasan@conformalmedical.com		Remove	Index Procedure - Pre-Release	×	0	
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Exam							45 Days	×	1					
Preview	Require	ment	Modality	Study Dat	e Images / Series	Upload Date	Upload By	Jpload By Actions				12 Months	×	1
						_		Preview		1				
÷.	TEE US		US	01-Jan-202 11:30 AM	1 Final: 93 / 1 1 Original: 93 / 1	04-Apr-2022 2:57 PM	koasan@con	formain	medical.com	Remove S Send Stud Download Open In P. Change R Edit DICO	tudy ly Study ACS eq M Headers			
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No files ha	ave been	associat	ed with t	his visit										
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Sonographers Worksheet - 08 pdf TTE/TEE Sonographer Worksheet 4:					04-Apr 4:28 Pt	-2022 M	Open Docum Download Remove Change Req	nent						

No Documents have been associated with this visit



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.



Title:

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".





Title:

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 deidentifying 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".

Subjec	t: 2190	1-229							Close	1		
Baseline Vis	sit/Event Deta	ils							Subject Details			
Visit/Event N Status	ame sit/Event Regi	Baseline Active	Visit/Event Date	Unknown 🥜					Subject Name 219 Screening Name Unk Status Acti	01-229 nown ive		
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🗙 The Ba	seline visit/	event has not satisfied a	ll required items. Pl	ease provide all requ	uired data in order to finali	ize the visit/event submissio	n and provide your e-si	ignature.	Index Procedure Pre-Discharge 45 Days	×××	0	
Queries									12 Months	x	0	
Q ID 340185	0 ⁴	le verdue visit submission		Assigned To	ialmedical.com Refresh	Status V Open	Category	Created All ✓ 07-Mar-2024				

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.

Query History										
Date	<u>User</u>	Action	Query/Response Log	Actions						
07-Mar-2024 01:26 PM GMT	eokeke@conformalmedical.com	Open	Imaging data for 21901-229, Baseline visit is overdue for submission based on the subject's visit calendar. Please submit this visit at your earliest convenience.	<u>Edit</u>						
Actions										

Save
 Send Reminder
 Comment

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