



CTIMP SAE logging – ReDA

PoDA	Instructions			
Sections	This is logged in the Post Approval tab- SAE section			
Subject ID	Add SAE			
	Subject ID:			
	Eree text field, this information can be found on SAE form			
Sito	Free text field, this information can be found on SAE form.			
Olle	Site: [NOT SET]			
	Choose from drop down list the site in which this event occurred (if not on the list, leave this section as [NOT SET].			
Event	* Event Description:			
Description	Type in the event name as per format below:			
	Type in the event name as per format below.			
	Sub 'Study patient number/ID', SAE 'Event name', JRMO 'date SAE received by JRMO/dd- mm-yy'			
	Example: Sub R055, SAE Portal Vein Thrombosis, JRMO 21-1-21			
SAE type	SAE Type: [NOT SET]			
	Results in death			
	Hospitalisation or prolongation of hospitalisation Persistent or significant disability or incapacity			
	Persistent or significant disability or incapacity Congenital anomaly or birth defect			
	Choose from drop down list the category ticked on the SAE report form.			
Date of Event	Date of Event: Select Date			
	Date of Event is provided on the SAE form			
Date site	Date of Event is provided on the SAE form			
aware	Date site aware: Select Date			
	Date site aware is provided on the SAE form			
Date JRMO	Date JRMO Received: Select Date			
Received	Enter the date in which the valid SAE form was received by JRMO (i.e. date email/fax			
	received)			
Relationship	Relationship(s) to IMP: 1. Relationship: [NOT SET]			
to IMP	Add New Relationship Not Applicable Not Reasonably Possible			
	Reasonably Possible Related & Expected			
	Unrelated & Expected Unrelated & Unexpected			
	 1. IMP: Study IMP name (free text box). 			
	 Relationship: select from the drop down list the option provided by the study team on the SAE resport form. (If the patient was randomised to an arm that includes more than one IMP, click on the 'Add New Relationship' button and type in IMP 2 name, then select Relationship for IMP 2 as per IMP 1. If the patient was randomised to a control arm, type in 'Control Arm' and select 'Not 			
	Applicable' from the Relationship drop down list.			
If the patient was randomised to an arm that includes a NIMP, type in 'NIM 'Net Applicable' from the Relationship drop down list				





Outcome	Outcome: [NOT SET] Recovered with sequale Unknown Not Recovered Recovered Fatal Recovering Choose from drop down list the Outcome ticked on the SAE report form.		
Dept. where event	Dept where event occurred:		
occurred	Type in the name of the reporting site.		
Description	Type in the Event name and any description given on the SAE report form.		
Date reported to REC	Date Reported to REC: Select Date		
Date assessed by	Date Assessed to PI/MA: Select Date		
CI/MA Assessment	CI/MA Assessment:		
	Enter Yes/No and the date CI assessed it.		
Event Closed	Event Closed: Save Cancel		
	Tick only when all documents have been signed by CI and Event is resolved.		





CTIMP SUSAR logging - ReDA

ReDA	Instructions			
Sections	This is logged in the Post Approval tab- SUSAR section			
Subject ID	Add SAE			
	Subject ID:			
Free text field, this information can be found on SAE/SUSAR form.				
Site	Site: [NOT SET]			
	Choose from drop down list the site in which this event occurred (if not on the list, leave this section as [NOT SET].			
Event	* Event Description:			
Description	Type in the event name as per format below:			
	Sub 'Study patient number/ID', SUSAR 'Event name', JRMO 'date SAE received by JRMO/dd-mm-yy'			
	Example: Sub 3445, SUSAR Pneumonia, JRMO 21-3-21			
SAE type	SUSAR Type: [NOT SET]			
	[NOT SET] Results in death Life threatening Hospitalisation or prolongation of hospitalisation Persistent or significant disability or incapacity Congenital anomaly or birth defect Other important medical event			
	Choose from drop down list the category ticked on the SAE/SUSAR report form.			
Date of Event	Date of Event: Select Date			
	Date of Event is provided on the SAE/SUSAR form			
Date site aware	Date site aware: Select Date			
	Date site aware is provided on the SAE/SUSAR form			
Received	Date JRMO Received: Select Date			
	Enter the date in which the valid SAE/SUSAR form was received by JRMO (i.e. date email/fax received)			
Relationship to IMP	Relationship(s) to IMP: 1. Relationship: [NOT SET] IMP: Add New Relationship Not Applicable Not Applicable Not Reasonably Possible Related & Unexpected Related & Unexpected Related & Unexpected Unrelated & Unexpected Unrelated & Unexpected Unrelated & Unexpected			
	 1. IMP: Study IMP name (free text box) Relationship: select Related & Unexpected (SUSAR) from the drop down list. (If the patient was randomised to an arm that includes more than one IMP, click on the 'Add New Relationship' button and type in IMP 2 name, then select Relationship for IMP 2 			
Outcome	Outcome: [NOT SET] Recovered with sequale Unknown Not Recovered Recovered Fatal Recovering Choose from drop down list the Outcome ticked on the SAE report form.			





Dept. where event occurred	Dept where event occurred:			
	Type in the name of the reporting site.			
Description	Description:			
	Type in the Event name and any description given on the SAE report form.			
Date reported to REC	Date Reported to REC: Select Date			
	Enter the date in which CI/study team notified REC about the SUSAR.			
Date reported to MHRA	Date Reported to MHRA: Select Date			
	Enter the date in which the event was logged into eSUSAR system.			
Date assessed by PI/MA	Date Assessed to PI/MA: Select Date			
	Enter the date in which the event was assessed by PI or qualified staff member.			
CI/MA Assessment	CI/MA Assessment:			
	Enter Yes/No and the date CI assessed it.			
Event Closed	Event Closed:			
	Save Cancel			
	Tick only when all documents have been signed by CI and Event is resolved.			

Clinical Investigations – Logging SAEs (other than SADEs and SAEs related to a comparator or investigational procedure)

ReDA	Instructions		
Sections	This is logged in the Post Approval tab- SAE section		
Subject ID	Add SAE		
	Subject ID:		
	Free text field, this information can be found on Device Safety Report form.		
Site	Site: [NOT SET]		
	Choose from drop down list the site in which this event occurred (if not on the list, leave this section as [NOT SET].		
Event Description	* Event Description:		
•	Type in the event name as per format below:		
	Sub 'Study patient number/ID', SAE 'Event name', JRMO 'date SAE received by JRMO/dd- mm-yy'		
	Example: Sub R055, SAE Portal Vein Thrombosis, JRMO 21-1-21		
SAE type	SAE Type: [NOT SET] Results in death Life threatening Hospitalisation or prolongation of hospitalisation Persistent or significant disability or incapacity Congenital anomaly or birth defect Other important medical event Choose from drop down list the category ticked on the Device Safety report form.		





Date of Event	Date of Event: Select Date				
	Date of Event is provided on the Device Safety report form				
Date site aware	Date site aware: Select Date				
D (15140	Date site aware is provided on the Device Safety report form				
Date JRMO Received	Date JRMO Received: Select Date				
	Enter the date in which the valid Device Safety report form was received by JRMO (i.e. date email/fax received)				
Relationship to IMP	Relationship(s) to IMP: 1. Relationship: [NOT SET] * IMP: Not Applicable Not Reasonably Possible Reasonably Possible Related & Unexpected Related & Unexpected Unrelated & Expected Unrelated & Unexpected Unrelated & Unexpected Image: Constraint of the second of the				
	device, comparator or sham that the participant has been exposed to.				
	Relationship: select from the drop down list the option provided by the study team on the Device Safety report form.				
	If the patient was randomised to a control arm in which they do not undergo the investigational proceudre, type in 'Control Arm' and select 'Not Applicable' from the Relationship drop down list.				
Outcome	Outcome: [NOT SET] Image: Not Set in the sequal end of the sequence of				
	Choose from drop down list the Outcome ticked on the Device Safety report form.				
Dept. where event	Dept where event occurred:				
occurred	Type in the name of the reporting site.				
Description	Description:				
	Type in the Event name and any description given on the Device Safety report form. Include type of injury, action taken, current location of device and quantity of devices affected if applicable.				
Date reported	Date Reported to REC: Select Date				
	Leave this blank				
Date assessed by	Date Assessed to PI/MA: Select Date				
	Enter the date in which the event was assessed by PI or qualified staff member.				
Assessment	CI/MA Assessment:				





	Enter Yes/No and the date CI assessed it.
Event Closed	Event Closed:
	Save Cancel Tick only when all documents have been signed by CI and Event is resolved.

Clinical Investigations – Logging device deficiencies (other than those which could have caused a SADE)

ReDA	Instructions		
Sections	This is logged in the Post Approval tab - AE section		
Subject ID	Free text field, this information can be found on Device Safety Report form.		
Site	Site: [NOT SET] •		
	list, leave this section as [NOT SET].		
Event Description	* Event Description:		
	Type in the event name as per format below device deficiency as appropriate :		
	Sub 'Study patient number/ID', Device Deficiency, 'Deficiency name', JRMO 'date SAE received by JRMO/dd-mm-yy'		
	Example: Sub R055, Device Deficiency, material breakage, JRMO 21-1-21		
Event type	Leave this section blank		
Date of Device Deficiency	Date of Event: Select Date		
Denoichey	Date of Event is provided on the Device Safety Event form		
Date site aware	Date site aware: Select Date		
	Date site aware is provided on the Device Safety Event form		
Relationship to IMP,	Leave this section blank		
Outcome	Choose from drop down list the Outcome ticked on the Device Safety report form.		
Date reported to REC	Leave this section blank		





Dept. where event	Dept where event occurred:		
occurred	Type in the name of the reporting site.		
Description	Description:		
	Use this field to add a short summary of the information provided. Include location of device and quantity of devices affected where applicable.		
Date	Date Assessed to PI/MA: Select Date		
assessed by PI/MA	Enter the date in which the event was assessed by PI or qualified staff member.		
CI/MA	CI/MA Assessment:		
Assessment			
	Enter Yes/No and the date CI assessed it.		
Event Closed	Event Closed:		
	Save Cancel		
	Tick only when all documents have been signed by CI and Event is resolved.		

Clinical Investigation – Events Reportable to MHRA (SADE, SAEs related to comparators or investigational procedures, and device deficiencies that could have caused SADEs)

ReDA	Instructions		
Sections	This is logged in the Post Approval tab- SUSAR section		
Subject ID	Add SAE		
	Subject ID:		
	Free text field, this information can be found on Device Safety Report form.		
Site	Site: [NOT SET]		
	Choose from drop down list the site in which this event occurred (if not on the list, leave this section as [NOT SET].		
Event Description	* Event Description:		
	Type in the event name as per format below:		
	Sub 'Study patient number/ID', SAE 'Event name', JRMO 'date SAE received by JRMO/dd- mm-yy'		
	Sub 'Study patient number/ID', SADE 'Event name', JRMO 'date SAE received by JRMO/dd-mm-yy'		
	Sub 'Study patient number/ID', ASADE 'Event name', JRMO 'date SAE received by JRMO/dd-mm-yy'		
	Sub 'Study patient number/ID', USADE 'Event name', JRMO 'date SAE received by JRMO/dd-mm-yy'		
	Sub 'Study patient number/ID', Device Deficiency 'Event name', JRMO 'date SAE received by JRMO/dd-mm-yy'		
	Example: Sub 3445, USADE Haemhorrage, JRMO 21-3-21		





SAE type	SUSAR Type: [NOT SET]			
	[NOT SET]			
	Results in death Life threatening			
	Hospitalisation or prolongation of hospitalisation Persistent or significant disability or incapacity			
	Congenital anomaly or birth defect			
	Other important medical event Choose from grop gown list the category ticked on the Device Safety report form. Leave as			
	[NOT SET] for device deficiencies			
Date of Event				
	Date of Event is provided on the Device Safety Poport form			
Date site				
aware	Date site aware is provided on the Device Sefety Penert form			
Date JRMO	Date site aware is provided on the Device Safety Report form			
Received	Date JRMO Received: Select Date			
	Enter the date in which the valid Device Safety Report form was received by JRMO (i.e. date email/fax received)			
Relationship to	Relationship(s) to IMP: 1. [NOT SET]			
IMP	Add New Relationship Not Applicable Not Pasciple			
	Reasonably Possible Related & Expected			
	Related & Unexpected (SUSAR) Unrelated & Expected Unrelated & Unexpected			
	1. IMP: Enter the investigational device, comparator or sham that the participant has			
	been exposed to. If the event is an SAE related to an investigational procedure, also enter the name of the procedure. Add new rows for each investigational device, comparator or sham.			
	Relationship: select the relationship as specified on the Device Safety Report Form.			
Outcome	Outcome: [NOT SET]			
	[NOT SET]			
	Recovered with sequale			
	Not Recovered			
	Recovered Fatal			
	Recovering			
	Choose from drop down list the Outcome ticked on the Device Safety report form.			
Dept. where event occurred	Dept where event occurred:			
	Type in the name of the reporting site.			
Description	Description:			
	Type in the Event name and any description given on the Device Safety report form.			
	Include type of injury, action taken, suspect device details, and quantity of affected devices			
Data reported	as applicable.			
to REC	Date Reported to REC: Select Date			
Enter the date in which CI/ study team notified REC about the event (USADEs				
	unexpected serious adverse reactions only).			
Date reported to MHRA	Date Reported to MHRA: Select Date			
	Enter the date in which the event was reported to the MHRA.			
Date assessed by PI/MA				





	Date Assessed to PI/MA: Select Date	Enter the date in which the event was assessed by PI or qualified staff member.	
CI/MA Assessment	CI/MA Assessment:		
	Enter Yes/No and the date CI assessed it.		
Event Closed	Event Closed:		
	Save Cancel Tick only when all documents have been signed by CI and Event is resolved.		

Logging Follow ups reports

ReDA Sections	Instructions
Overall	Do not change the event name
All fields	Alter fields as needed in line with Above.
Overall	Add a comment to description box do clearly document follow up information and changes

Logging AESIs and follow up reports

ReDA	Instructions
Sections	This is logged in the Post Approval tab- AE section
Subject ID	Free text field, this information can be found on AESI form.
Site	Site: [NOT SET]
	Choose from drop down list the site in which this event occurred (if not on the list, leave this section as [NOT SET].
Event Description	* Event Description:
	Type in the event name as per format below AESI as appropriate :
	Sub 'Study patient number/ID', AESI, 'Event name', JRMO 'date SAE received by JRMO/dd-mm-yy'
	Example: Sub R055, AESI, Raised LFT , JRMO 21-1-21
Event type	Select AESI
Date of Event	Date of Event: Select Date
	Date of Event is provided on the SAE form
Date site aware	Date site aware: Select Date
	Date site aware is provided on the SAE form





Relationship to IMP,	 1. IMP: Study IMP name (free text box) Relationship: select Related & Unexpected (SUSAR) from the drop down list. (If the patient was randomised to an arm that includes more than one IMP, click on the 'Add New Relationship' button and type in IMP 2 name, then select Relationship for IMP 2
Outcome	Choose from drop down list the Outcome ticked on the AESI report form.
Date reported to REC	Leave these sections blank
Dept. where event	Dept where event occurred:
occurred	Type in the name of the reporting site.
Description	Use this field to add a short summary of information provided. Confirm AESI has been reported to IMP manufacturer if applicable. For follow up reports include date added
Date assessed by PI/MA	Date Assessed to PI/MA: Select Date
	Enter the date in which the event was assessed by PI or qualified staff member.
CI/MA Assessment	CI/MA Assessment:
-	Enter Yes/No and the date CI assessed it.
Event Closed	Event Closed: Cancel
	Tick only when all documents have been signed by CI and Event is resolved.

Logging pregnancy and follow-up reports

ReDA	Instructions
Continuo	This is logged in the Dest Approval tob. AE section
Sections	This is logged in the Post Approval tab- AE section
Subject ID	Free text field, this information can be found on pregnancy form.
Site	Site: [NOT SET]
	site. [NOTSET]
	Choose from drop down list the site in which this event occurred (if not on the list, leave
	Choose from drop down list the site in which this event occurred (in not on the list, leave
	this section as [NOT SET].
Event	* Event Description:
Description	
Description	
	Type in the event name as per format below, specifying. Participant or partner as
	Type in the event name as per format below, specifying Tanticipant of partner as
	appropriate :
	Sub 'Study patient number/ID' Pregnancy Partner, 'Event name', JRMO 'date SAE
	reactived by IDMO/dd mm vi
	received by JRIVIO/dd-mm-yy
SOP 26c AD 1 RoDA	instructions to log safety events v2.0.15.00.2021 EINAL





	Example: Sub R055, Pregnancy Partner, JRMO 21-1-21
Event type	Select pregnancy- closed or pregnancy to be followed up
Date of Event	Date of Event: Select Date
Date site aware	Date site aware is provided on the SAE form
Date JRMO Received	Date JRMO Received: Select Date
Relationship to IMP, Outcome Date reported to REC	Leave these sections blank
Dept. where event occurred	Dept where event occurred: Type in the name of the reporting site.
Description	Use this field to add a short summary of information provided. Include details of the gestational week, any investigations completed to assess the pregnancy and any advice received from the sponsor's expert. Add the outcome of the pregnancy once received. For follow up reports include date added
Date assessed by	Date Assessed to PI/MA: Select Date
CI/MA Assessment	CI/MA Assessment:
Event Closed	Event Closed: Save Cancel Tick only when all documents have been signed by CI and Event is resolved.