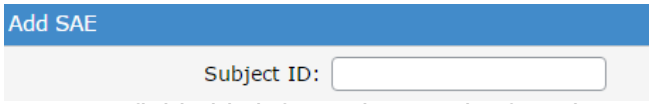
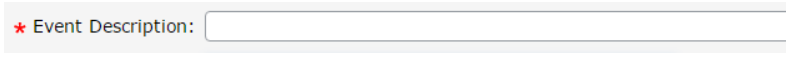
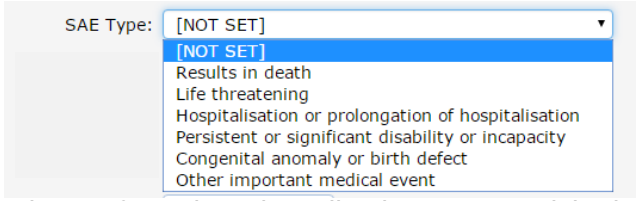
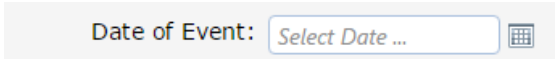
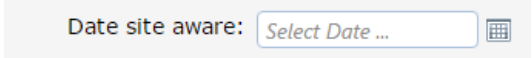
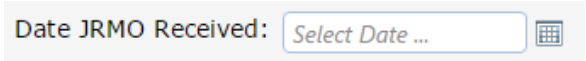
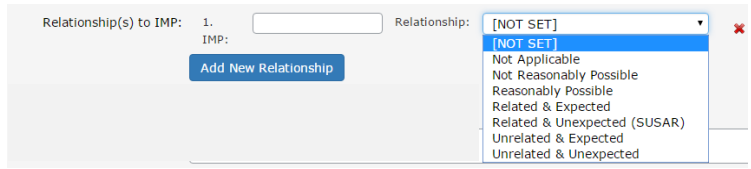
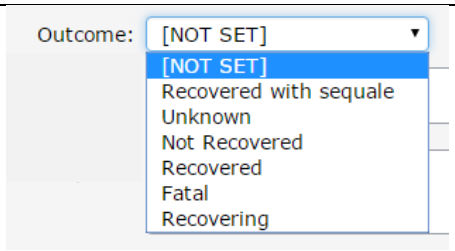
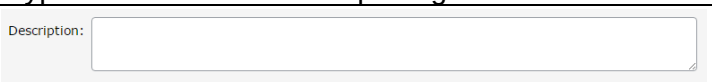
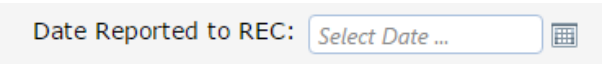
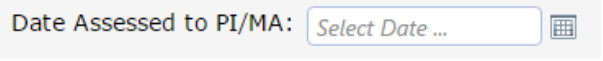
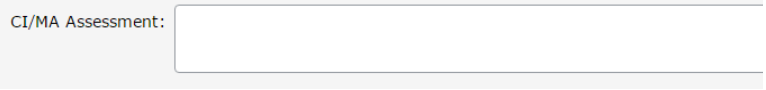
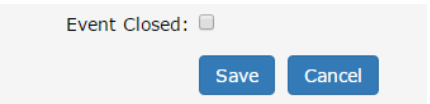
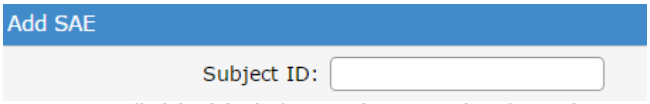
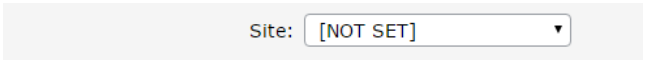
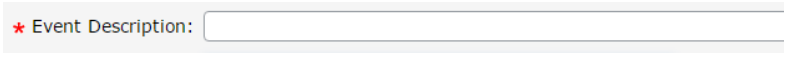
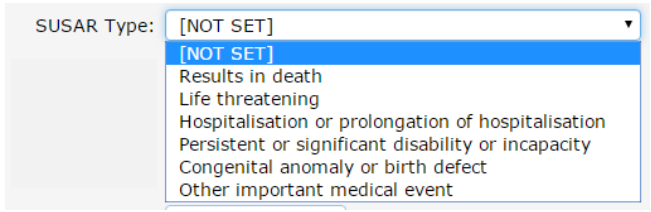
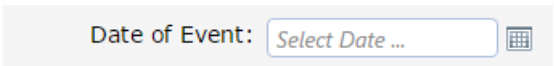
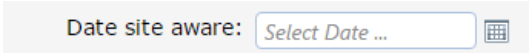
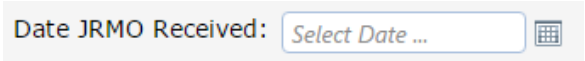
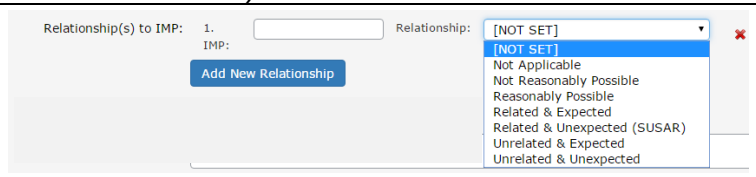
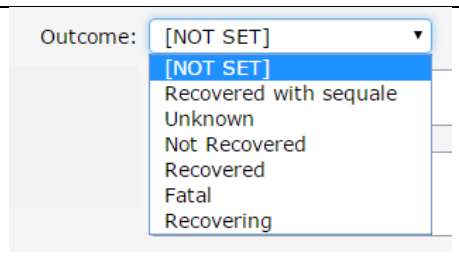
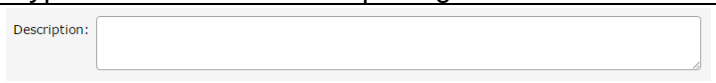
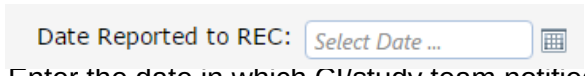
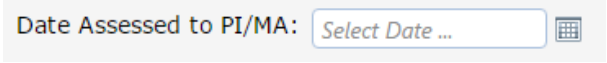
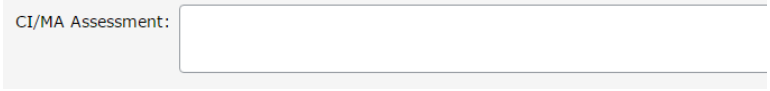
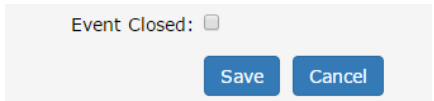
CTIMP SAE logging – ReDA

ReDA Sections	Instructions This is logged in the Post Approval tab- SAE section
Subject ID	 Free text field, this information can be found on SAE form.
Site	 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	 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	 Choose from drop down list the category ticked on the SAE report form.
Date of Event	 Date of Event is provided on the SAE form
Date site aware	 Date site aware is provided on the SAE form
Date JRMO Received	 Enter the date in which the valid SAE form was received by JRMO (i.e. date email/fax received)
Relationship to IMP	 • 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 'NIMP' and select 'Not Applicable' from the Relationship drop down list.

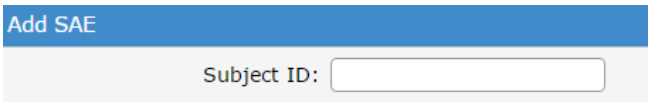
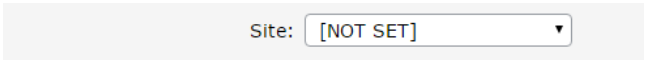
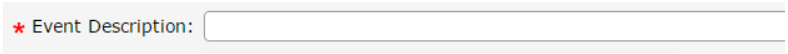
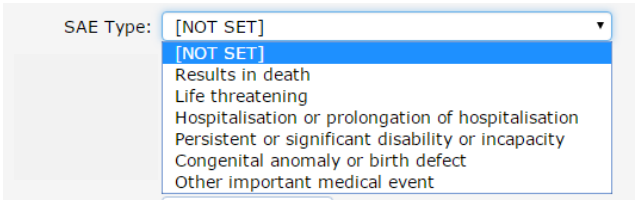
Outcome	 Choose from drop down list the Outcome ticked on the SAE report form.
Dept. where event occurred	 Type in the name of the reporting site.
Description	 Type in the Event name and any description given on the SAE report form.
Date reported to REC	 This is only applicable if logging a SUSAR.
Date assessed by PI/MA	 Enter the date in which the event was assessed by PI or qualified staff member.
CI/MA Assessment	 Enter Yes/No and the date CI assessed it.
Event Closed	 Tick only when all documents have been signed by CI and Event is resolved.

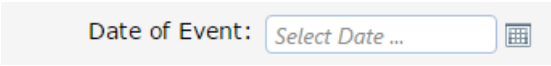
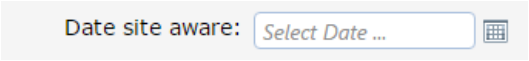
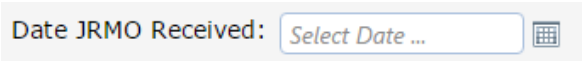
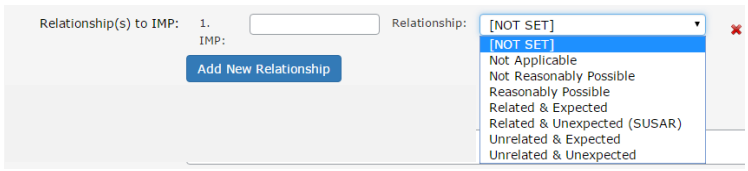
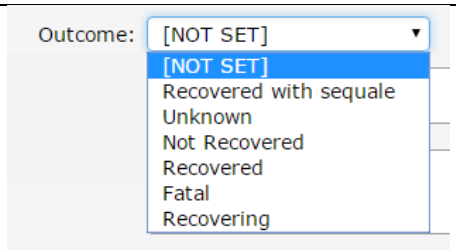
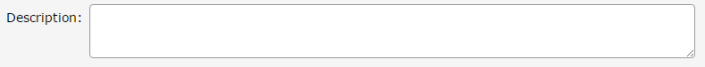
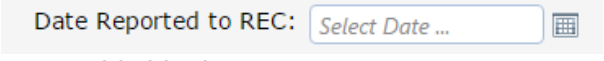
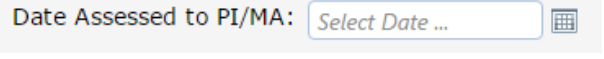
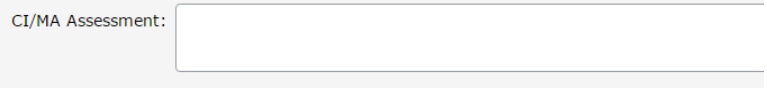
CTIMP SUSAR logging - ReDA

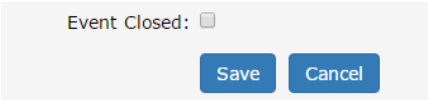
ReDA Sections	Instructions This is logged in the Post Approval tab- SUSAR section
Subject ID	 Free text field, this information can be found on SAE/SUSAR form.
Site	 Choose from drop down list the site in which this event occurred (if not on the list, leave this section as [NOT SET].
Event Description	 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	 Choose from drop down list the category ticked on the SAE/SUSAR report form.
Date of Event	 Date of Event is provided on the SAE/SUSAR form
Date site aware	 Date site aware is provided on the SAE/SUSAR form
Date JRMO Received	 Enter the date in which the valid SAE/SUSAR form was received by JRMO (i.e. date email/fax received)
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 SAE report form.

Dept. where event 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	 Enter the date in which CI/study team notified REC about the SUSAR.
Date reported to MHRA	 Enter the date in which the event was logged into eSUSAR system.
Date assessed by PI/MA	 Enter the date in which the event was assessed by PI or qualified staff member.
CI/MA Assessment	 Enter Yes/No and the date CI assessed it.
Event Closed	 Tick only when all documents have been signed by CI and Event is resolved.

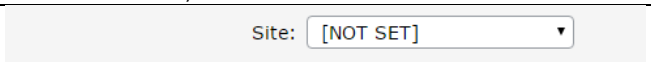
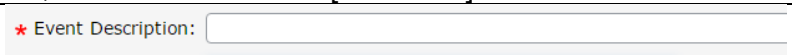
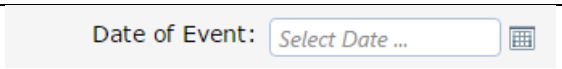
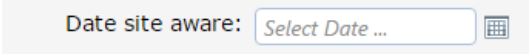
Clinical Investigations – Logging SAEs (other than SADEs and SAEs related to a comparator or investigational procedure)

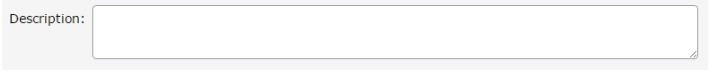
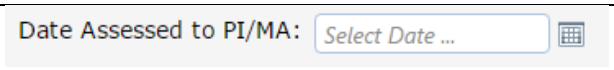
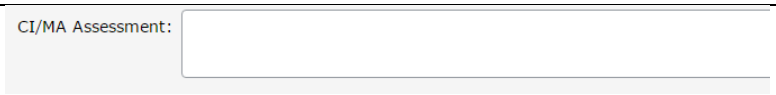
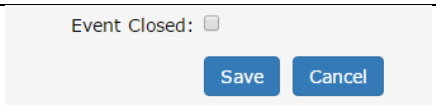
ReDA Sections	Instructions This is logged in the Post Approval tab- SAE section
Subject ID	 Free text field, this information can be found on Device Safety Report form.
Site	 Choose from drop down list the site in which this event occurred (if not on the list, leave this section as [NOT SET].
Event Description	 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	 Choose from drop down list the category ticked on the Device Safety report form.

Date of Event	 Date of Event is provided on the Device Safety report form
Date site aware	 Date site aware is provided on the Device Safety report form
Date JRMO Received	 Enter the date in which the valid Device Safety report form was received by JRMO (i.e. date email/fax received)
Relationship to IMP	 1. IMP: Investigational device name (free text box). Add a new row for each investigational 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	 Choose from drop down list the Outcome ticked on the Device Safety report form.
Dept. where event occurred	 Type in the name of the reporting site.
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 to REC	 Leave this blank
Date assessed by PI/MA	 Enter the date in which the event was assessed by PI or qualified staff member.
CI/MA Assessment	

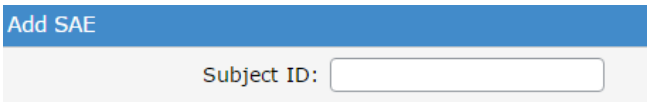
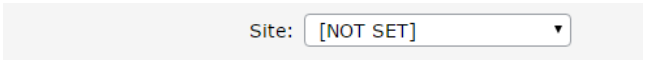
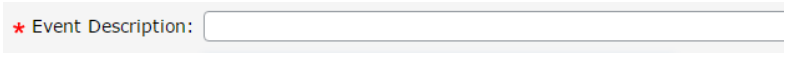
	Enter Yes/No and the date CI assessed it.
Event Closed	 Tick only when all documents have been signed by CI and Event is resolved.

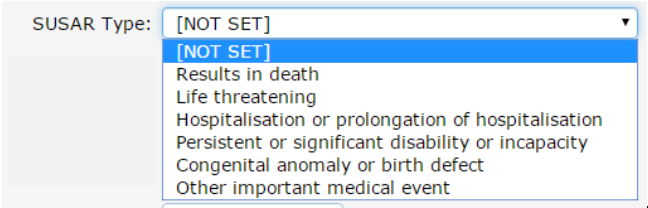
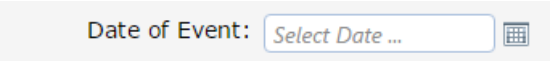
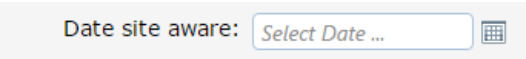
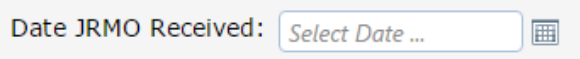
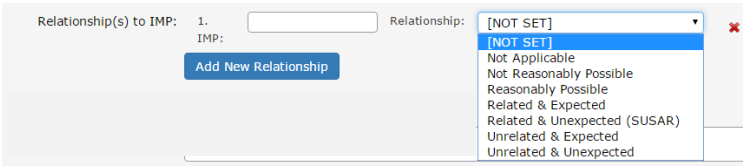
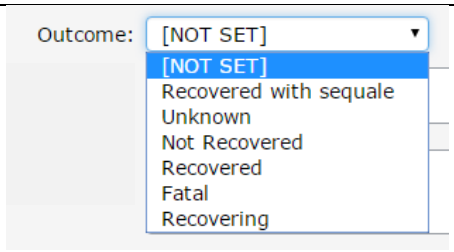
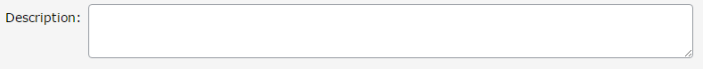
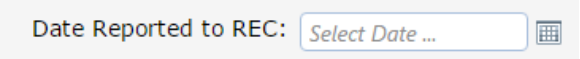
Clinical Investigations – Logging device deficiencies (other than those which could have caused a SADE)

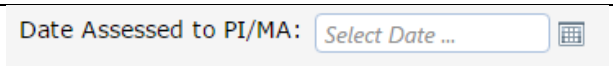
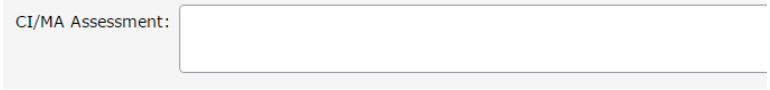
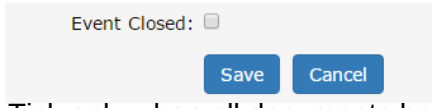
ReDA Sections	Instructions This is logged in the Post Approval tab - AE section
Subject ID	Free text field, this information can be found on Device Safety Report form.
Site	 Choose from drop down list the site in which this device deficiency occurred (if not on the list, leave this section as [NOT SET].
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 is provided on the Device Safety Event form
Date site aware	 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 occurred	 Type in the name of the reporting site.
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 assessed by PI/MA	 Enter the date in which the event was assessed by PI or qualified staff member.
CI/MA Assessment	 Enter Yes/No and the date CI assessed it.
Event Closed	 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 Sections	Instructions This is logged in the Post Approval tab- SUSAR section
Subject ID	 Free text field, this information can be found on Device Safety Report form.
Site	 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	 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

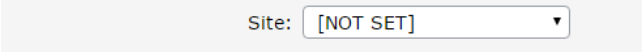
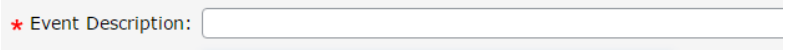
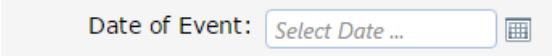
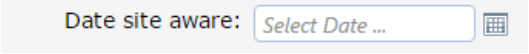
SAE type	 Choose from drop down list the category ticked on the Device Safety report form. Leave as [NOT SET] for device deficiencies
Date of Event	 Date of Event is provided on the Device Safety Report form
Date site aware	 Date site aware is provided on the Device Safety Report form
Date JRMO Received	 Enter the date in which the valid Device Safety Report form was received by JRMO (i.e. date email/fax received)
Relationship to IMP	 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	 Choose from drop down list the Outcome ticked on the Device Safety report form.
Dept. where event occurred	 Type in the name of the reporting site.
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 as applicable.
Date reported to REC	 Enter the date in which CI/ study team notified REC about the event (USADEs and other unexpected serious adverse reactions only).
Date reported to MHRA	 Enter the date in which the event was reported to the MHRA.
Date assessed by PI/MA	

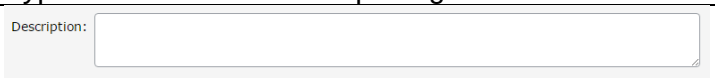
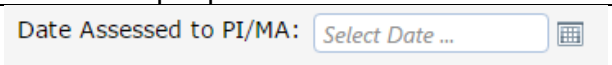
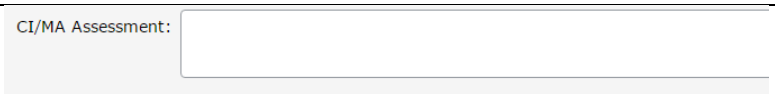
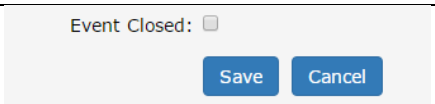
	 Enter the date in which the event was assessed by PI or qualified staff member.
CI/MA Assessment	 Enter Yes/No and the date CI assessed it.
Event Closed	 Tick only when all documents have been signed by CI and Event is resolved.

Logging Follow ups reports

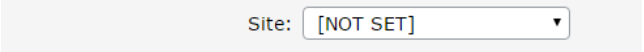
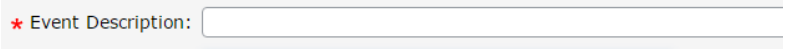
ReDA Sections	Instructions
Overall	Do not change the event name
All fields	Alter fields as needed in line with Above.
Overall	Add a comment to description box do clearly document follow up information and changes

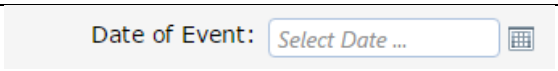
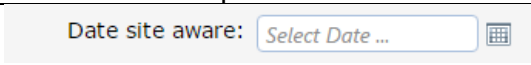
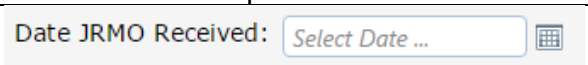
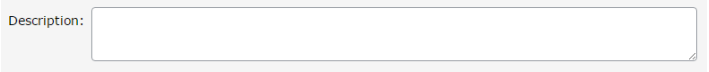
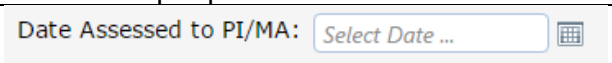
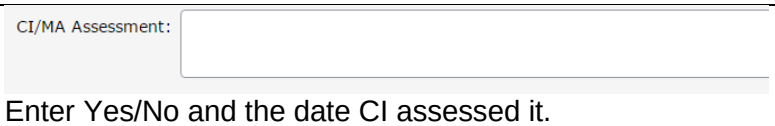
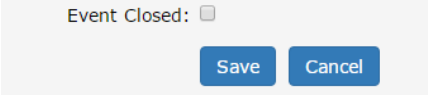
Logging AESIs and follow up reports

ReDA Sections	Instructions This is logged in the Post Approval tab- AE section
Subject ID	Free text field, this information can be found on AESI form.
Site	 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	 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 is provided on the SAE form
Date site aware	 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 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	 Enter the date in which the event was assessed by PI or qualified staff member.
CI/MA Assessment	 Enter Yes/No and the date CI assessed it.
Event Closed	 Tick only when all documents have been signed by CI and Event is resolved.

Logging pregnancy and follow-up reports

ReDA Sections	Instructions This is logged in the Post Approval tab- AE section
Subject ID	Free text field, this information can be found on pregnancy form.
Site	 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	 Type in the event name as per format below, specifying Participant or partner as appropriate : Sub 'Study patient number/ID', Pregnancy Partner, 'Event name', JRMO 'date SAE received by JRMO/dd-mm-yy'

	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 is provided on the SAE form
Date site aware	 Date site aware is provided on the SAE form
Date JRMO Received	 Enter the date in which the valid pregnancy form was received by JRMO (i.e. date email/fax received)
Relationship to IMP, Outcome Date reported to REC	Leave these sections blank
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 PI/MA	 Enter the date in which the event was assessed by PI or qualified staff member.
CI/MA Assessment	 Enter Yes/No and the date CI assessed it.
Event Closed	 Tick only when all documents have been signed by CI and Event is resolved.