

ReDA instructions to log safety events

Serious Adverse Events

ReDA Sections	Instructions
	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 SAE 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] [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 report form.
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
Date JRMO Received	Date JRMO Received: Select Date ... Enter the date in which the valid SAE 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 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 report 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	Outcome: [NOT SET] [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 ... This is only applicable if logging a SUSAR.
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.

Ensure copies of both the initial and follow up SAE forms are uploaded to ReDA under 'documents'.

Adding documents to ReDA

Documents tab

Browse – download from indemnity pdf only

File name type – initial or follow report SAE

Add File name

Suspected Unexpected Serious Adverse Reactions

ReDA Sections	Instructions
	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 Description	★ 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	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
Date JRMO 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 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] [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.

Ensure copies of both the initial and follow up SUSAR forms are uploaded to ReDA under 'documents'.

Logging follow-up reports

ReDA Sections	Instructions
Overall	Do not change the SAE/SUSAR 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. Upload copies of both the initial and follow up SUSAR forms to ReDA under documents.

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	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 occurred	Dept where event occurred: Type in the name of the reporting site.
Description	Description: Use this field to add a short summary of information provided. 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: ☐ Save Cancel Tick only when all documents have been signed by CI and Event is resolved.

Ensure copies of both the initial and follow up AESI forms are uploaded to ReDA under 'documents'.

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 f 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, 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: 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
Date JRMO Received	Date JRMO Received: Select Date ... 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	Dept where event occurred: Type in the name of the reporting site.
Description	Description: Use this field to add a short summary of information provided. 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: ☐ Save Cancel Tick only when all documents have been signed by CI and Event is resolved.

Ensure copies of both the initial and follow up Pregnancy forms are uploaded to ReDA under 'documents'.