British Society for Rheumatology

Rheumatoid Arthritis Register

Add a New Follow Up:

Adverse Events

Adverse events

Did the patient suffer any adverse events or new illnesses in this follow-up period? ○ Yes ○

No adverse events entered yet. Click "Add New" to enter details.
If no adverse events have occurred, please record this in the box above.

[Add New] [Tutorial] [Next Section]

Click here to view all Adverse Events for this patient (Clinically Confirmed) [Show]

If you are not sure if you have reported an event you can check by clicking on the **Show** button.

Suggestion Please ensure all adverse events are listed. Examples of adverse events include, but are not restricted to:

- Any new diagnosis
- Worsening of a pre-existing condition
- **Clinically significant** laboratory results
- Any event that has been considered to be of sufficient importance to document in hospital case notes. These may include nausea, weight gain, headaches etc.

While adverse events can be directly attributed to a drug the patient is receiving, they do not have to be. On the other hand, any side effects should be recorded

Click here to view all Adverse Events for this patient (Clinically Confirmed) [Hide]

This list is for your reference. Please check before you add a new adverse event to make sure no duplicates are being entered.

AEUID	Start Date	Reported FUP	Description
	06/09/2024	3	**Low neutrophils** DMARD stopped

A summary of adverse events that have been reported for the patient will be listed.

You will be asked to add any Adverse Events on this page.
If there are no adverse events to record select **No** and the click **Next Section.**

Adverse events

Did the patient suffer any adverse events or new illnesses in this follow-up period? ○ Yes ◉ No

Select **No**

No adverse events entered yet. Click "Add New" to enter details.
If no adverse events have occurred, please record this in the box above.

[Add New] [Tutorial] [Next Section]

Click **Next Section**

Click here to view all Adverse Events for this patient (Clinically Confirmed) [Show]

Suggestion Please ensure all adverse events are listed. Examples of adverse events include, but are not restricted to:
- Any new diagnosis
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While adverse events can be directly attributed to a drug the patient is receiving, they do not have to be. On the other hand, any side effects should be recorded even if they are known to be caused by a drug the patient is receiving.

If there are adverse events to record select **Yes**.
Then click **Add New** to add an event.

Adverse events

Did the patient suffer any adverse events or new illnesses in this follow-up period? ⦿ Yes ○ No

1   Select **Yes**

No adverse events entered yet. Click "Add New" to enter details.
If no adverse events have occurred, please record this in the box above.

[Add New] [Tutorial] [Next Section]

2   Click **Add New**

Click here to view all Adverse Events for this patient (Clinically Confirmed) [Show]

Suggestion Please ensure all adverse events are listed. Examples of adverse events include, but are not restricted to:
- Any new diagnosis
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Complete event details and answer the questions and click **Save**.

New Adverse Event

Short description of the event [200/200 chars left]	
Detailed description of the event [2000/2000 chars left]	

Please avoid entering any sensitive information such as hospital name, patient name, drug name, addresses or date of birth in the descriptions.

Event Start Date	dd/mm/yyyy 🗓 Estimated: ☐
Do you believe there is a possibility this event was related to biologic / targeted therapy used to treat RA?	○ Yes ○ No ○ Don't know ○ Missing
Is it a Serious Adverse Event? ⓘ	○ Yes ○ No
Was the patient hospitalised **overnight**?	○ Yes ○ No

Save   Tutorial   Cancel   ◀ Click **Save**

You must complete <u>all</u> fields to be able to save the adverse event.

Some adverse events are classified as **Serious Adverse Events**.

Is it a Serious Adverse Event? ⓘ ○ Yes
                                ○ No

SAEs are events that result in:

- Death
- Life-threatening (immediately)
- Overnight hospitalisation (initial or prolonged)
- Requires an IV antibiotic/antifungal/antiviral drug
- Significant loss of function or disability
- Congenital malformation/birth defect
- Other medically important event
- Pregnancy

If you are not sure if the adverse event is classified as serious, click on the **I** button to see the definitions.

If your event is serious, you will get options to add the SAE category, admission/discharge dates (if hospitalised) and date of death where applicable.

New Adverse Event

Short description of the event [185/200 chars left]	Chest Infection
Detailed description of the event [1944/2000 chars left]	Hospitalised for 2 nights. Responded well to antibiotics

Please avoid entering any sensitive information such as hospital name, patient name, drug name, addresses or date of birth in the descriptions.

Event Start Date	21/12/2025 Estimated: ☐
Do you believe there is a possibility this event was related to biologic / targeted therapy used to treat RA?	○ Yes ● No ○ Don't know ○ Missing
Is it a Serious Adverse Event? ℹ	● Yes ○ No
SAE category	Overnight Hospitalisation (initial or prolonged) ⌄

Overnight hospitalisation has been selected as SAE Category. Please provide hospitalisation dates or select a different SAE if it is not an overnight hospitalisation.

Event of Special Interest (ESI) (Serious Infections only) Please save this page and use **Add new Serious Infection** to add an ESI form. If you are unsure of of this, please contact the study team for confirmation.

Was the patient hospitalised **overnight**?	● Yes ○ No
Hospital Admission Date	21/12/2025 Estimated: ☐
Hospital Discharge Date	23/12/2025 Estimated: ☐

Save   Tutorial   Cancel

Click **Save**

Once saved the event will appear in the summary.
Use the **Add New** button again to enter further events otherwise continue to the next section.

Adverse events

Did the patient suffer any adverse events or new illnesses in this follow-up period?   ● Yes   ○ No

	ID	Short Description	Start Date	SAE	ESI
Open		Chest Infection	21/12/2025	Yes	No ESIs
					Add New Serious Infection

Add New   Tutorial   Next Section   **Click Next Section**

If you have recorded a Serious Adverse Event that is an infection, please move to the next page to find out how to complete an Event of Special Interest (ESI) form.

After saving a Serious Adverse Event, please complete and ESI form

<u>Please note </u>we only require an ESI form for Infections that have an SAE category.

Adverse events

Did the patient suffer any adverse events or new illnesses in this follow-up period? ● Yes ○ No

ID	Short Description	Start Date	SAE	ESI
Open	Chest Infection	21/12/2025	Yes	No ESIs

Add New Serious Infection

Add New Tutorial Next Section

1. Click **Add New Serious Infection**

ESI

Serious infection (Excluding TB Add Form

Add New Serious Infection

2. Click **Add Form**

Complete the questions with as much information that is available.

Serious Infection (excluding TB)

Please confirm site of infection

Were microbiological/serological tests carried out?   ○ Yes   ○ No   ● Unknown

If yes, specify result or state where nil grown

Were IV - Antibiotics/Antivirals/Antifungals used to treat the serious infection?   ○ Yes   ○ No   ● Unknown

At the time of infection, did the patient have:

An indwelling catheter?   ○ Yes   ○ No   ● Unknown

Intravenous access (e.g. Hickman line)?   ○ Yes   ○ No   ● Unknown

Any wounds or ulcers?   ○ Yes   ○ No   ● Unknown

Medication at time of infection

Scroll down page to complete all questions.

Prior to the infection, what was the patients:

White Cell Count:

Neutrophil Count:

Lymphocyte Count:

Taken on: dd/mm/yyyy

At the time of the infection, what was the patients:

White Cell Count:

Neutrophil Count:

Lymphocyte Count:

Has the patient ever had Felty's?   ○ Yes   ○ No   ● Unknown

Has the patient ever had a splenectomy?   ○ Yes   ○ No   ● Unknown

Save   Tutorial   Back

Please complete the questions and click **Save** when complete.

If the edit window is closed the Pharmacovigilance (PV) team will leave a query requesting that the ESI form is completed. They will advise how this can be done outside of the edit window.