



**British Society for
Rheumatology**

Rheumatoid Arthritis Register

Add a New Follow Up: Adverse Events

Continue to Adverse Events.

Study ID: **Cohort:** Anti-TNF **Follow-Up:** 5 **FUP Status:** In Edit Window **Due Date:** 04/02/2022 **Last FUP Date Entered:**

Patient	<h3>Adverse event</h3> <h4>New adverse events</h4> <p>Did the patient suffer any adverse events or new illnesses in this follow-up period?</p> <p><input type="radio"/> No</p> <p><input type="radio"/> Yes (use 'Add New' to enter details after clicking 'Update')</p> <p>Update</p> <p>No adverse events entered yet. Click "Add New" to enter details. If no adverse events have occurred, please record this in the box above.</p> <p>Add New Tutorial Advance to Next Section</p> <p>All Adverse Events for this patient (Clinically Confirmed) SHOW</p> <p>Suggestion</p> <p>Please ensure all adverse events are listed. All other current therapies should also be listed in the Other Current Therapy page. Examples of adverse events include, but are not restricted to:</p> <ul style="list-style-type: none">• Any new diagnosis• Worsening of a pre-existing condition• Clinically significant laboratory results• Any event that either you or another clinician has considered to be of sufficient importance to document in hospital case notes e.g. nausea, weight gain, headache <p>Please note that if an event classifies as an event of special interest (ESI), it can also be marked as serious for the reason of 'Medically Important Event'</p>
Patient summary	
Clinician FUP	
Biologic Targeted Therapy	
Other Current Therapy	
Adverse Events	
Disease Activity	
Additional Info	
Administrative	
Preview Queries	

Close Edit Window

Feedback / Comments

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



Study ID: Cohort: Anti-TNF Follow-Up: 5 FUP Status: In Edit Window Due Date: 04/02/2022 Last FUP Date Entered:

Patient

Patient summary

Clinician FUP

Biologic Targeted Therapy

Other Current Therapy

Adverse Events

Disease Activity

Additional Info

Administrative

Preview Queries

Close Edit Window

Feedback / Comments

Adverse event

New adverse events

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

- No
- Yes (use 'Add New' to enter details after clicking 'Update')

Update

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

Advance to Next Section

A summary of past events that have been reported for the patient will then appear.



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	Stop Date	Start FUP	Stop FUP	Description
	15/09/2019		1	1	Fluctuating neutrophils Pt has fluctuating neutrophils. Biologic temp stopped Sept 2019 to Oct 2019 but deemed to not be the cause, still being investigated.

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

Study ID: **Cohort:** Anti-TNF **Follow-Up:** 5 **FUP Status:** In Edit Window **Due Date:** 04/02/2022 **Last FUP Date Entered:**

Patient	Adverse event
Patient summary	
Clinician FUP	New adverse events
Biologic Targeted Therapy	Did the patient suffer any adverse events or new illnesses in this follow-up period?
Other Current Therapy	<input checked="" type="radio"/> No 1 Select No
Adverse Events	<input type="radio"/> Yes (use 'Add New' to enter details after clicking 'Update')
Disease Activity	Update 2 Click Update
Additional Info	
Administrative	No adverse events entered yet. Click "Add New" to enter details. If no adverse events have occurred, please record this in the box above.
Preview Queries	
Close Edit Window	Add New Tutorial Advance to Next Section Click Advance to Next Section
Feedback / Comments	

All Adverse Events for this patient (Clinically Confirmed) SHOW

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

Study ID: Cohort: Anti-TNF Follow-Up: 5 FUP Status: In Edit Window Due Date: 04/02/2022 Last FUP Date Entered:

Patient

Patient summary

Clinician FUP

Biologic Targeted
Therapy

Other Current
Therapy

Adverse Events

Disease Activity

Additional Info

Administrative

Preview Queries

Close Edit Window

Feedback /
Comments

Adverse event

Record of new adverse events updated

New adverse events

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

- No
- Yes (use 'Add New' to enter details after clicking 'Update')

1 Select Yes

Update

2 Click Update

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

3 Click Add New Section

All Adverse Events for this patient (Clinically Confirmed) SHOW

Complete event details and answer the questions and click **Save**.

Study ID: **Cohort:** Anti-TNF **Follow-Up:** 5 **FUP Status:** In Edit Window **Due Date:** 04/02/2022 **Last FUP Date Entered:**

Patient

Patient summary

Clinician FUP

Biologic Targeted Therapy

Other Current Therapy

Adverse Events

Disease Activity

Additional Info

Administrative

Preview Queries

Close Edit Window

Feedback / Comments

Adverse Event Details

Short Description of the event:
[177/200 chars left]

Detailed Description of the event:
[1937/2000 chars left]

Event Start Date: This is an estimated date

Do you believe there is a possibility this event was related to biologic / targeted therapy used to treat RA?

Is this a COVID-19 related event?

Is it a **Serious Adverse Event**?

Was the patient hospitalised **overnight**?

Outcome of the event:

 Click Save

You must complete all fields to be able to save and continue

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.

Study ID: Cohort: Anti-TNF Follow-Up: 5 FUP Status: In Edit Window Due Date: 04/02/2022 Last FUP Date Entered:

Patient

Patient summary

Clinician FUP

Biologic Targeted Therapy

Other Current Therapy

Adverse Events

Disease Activity

Additional Info

Administrative

Preview Queries

Close Edit Window

Feedback / Comments

Adverse Event Details

Short Description of the event:
[195/200 chars left]

Detailed Description of the event:
[1995/2000 chars left]

Event Start Date: This is an estimated date

Do you believe there is a possibility this event was related to biologic / targeted therapy used to treat RA?

Is this a COVID-19 related event?

Is it a **Serious Adverse Event**?

SAE Category

Death has been selected as SAE Category. Please provide all relevant information regarding death or select a different SAE if it is not a death.

Death Date:

Event of Special Interest (ESI) Please save this page and use the **+Add New ESI Category** link to enter as many ESIs as required.
If you are unsure of this, please contact the study team for confirmation. If you want to enter any information in the ESI fields or overnight hospitalisation fields or if there were IV Antibiotics prescribed, this should also be marked as a Serious Adverse Event.

Was the patient hospitalised **overnight**?

Hospital Admission Date This is an estimated date

Hospital Discharge Date This is an estimated date

Outcome of the event:

Click Save

If the event is a COVID-19 related event, please select yes to the 'Is this a COVID-19 related event' question and complete the questions.

Study ID: Cohort: Anti-TNF Follow-Up: 5 FUP Status: In Edit Window Due Date: 04/02/2022 Last FUP Date Entered:

Patient

Patient summary

Clinician FUP

Biologic Targeted Therapy

Other Current Therapy

Adverse Events

Disease Activity

Additional Info

Administrative

Preview Queries

Close Edit Window

Feedback / Comments

Adverse Event Details

Short Description of the event:
(192/200 chars left) COVID 19

Detailed Description of the event:
(1992/2000 chars left) COVID 19

Event Start Date: 01/06/2021 This is an estimated date

Do you believe there is a possibility this event was related to biologic / targeted therapy used to treat RA? No

Is this a COVID-19 related event? Yes

It would be very much appreciated if you could complete the voluntary questions below, to assist us with data collection on COVID-19, and its impact on this study. Thank you.

How was the diagnosis made?
PCR (test for COVID antigen, including nasal swab or saliva)

If "other", please supply details

Did the patient experience symptoms typical of COVID-19 infection (e.g. cough, fever, anosmia, other)? Yes

Was the patient hospitalised overnight? No

Is it a **Serious Adverse Event**? No

Was the patient hospitalised **overnight**? No

Outcome of the event: Please Choose

Save **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.

Study ID: **Cohort:** Anti-TNF **Follow-Up:** 5 **FUP Status:** In Edit Window **Due Date:** 04/02/2022 **Last FUP Date Entered:**

Patient

Patient summary

Clinician FUP

Biologic Targeted Therapy

Other Current Therapy

Adverse Events

Disease Activity

Additional Info

Administrative

Preview Queries

Close Edit Window

Feedback / Comments

Adverse event

New adverse events

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

No

Yes (use 'Add New' to enter details after clicking 'Update')

Update

	ID	Short Description	Start	Ongoing	SAE	ESI
Open		Fluctuating neutrophils	01/04/2021	No	No	

Add New **Tutorial** **Advance to Next Section** **Click Advance to Next Section**

All Adverse Events for this patient (Clinically Confirmed) SHOW

After saving a Serious Adverse Event you will also have the opportunity to add an ESI category.

Patient
Patient summary

Clinician FUP
Biologic Targeted Therapy
Other Current Therapy

Adverse Events

Disease Activity
Additional Info

Administrative

Preview Queries
Close Edit Window
Feedback / Comments

Adverse event

New adverse events

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

No

Yes (use 'Add New' to enter details after clicking 'Update')

Update

	ID	Short Description	Start	Ongoing	SAE	ESI
Open		Intra cerebral haemorrhage	07/12/2017	No	No Yes	Remember to add all applicable ESI categories to this event + Add New ESI Category

Add New

Please note only our Serious Infection ESI is available for completion



ESI for Adverse Event

ESI

ESI <Please Choose>

Insert

- <Please Choose>
- Demyelination, optic neuritis
- Serious congestive heart failure
- Lymphoproliferative Disease
- Myocardial infarction/ acute coronary syndrome
- Tuberculosis (Not Latent)
- Serious infection (Excluding TB)
- Pregnancy
- Aplastic anaemia, pancytopenia, serious neutropenia
- Death*
- Malignancy (not including skin)
- Serious hepatic dysfunction/ failure
- Cerebrovascular accident (CVA)**
- Hepatitis B reactivation
- Serious lupus/ lupus-like illness

Add the ESI form from the event summary.

Patient

Patient summary

Clinician FUP

Biologic Targeted Therapy

Other Current Therapy

Adverse Events

Disease Activity

Additional Info

Administrative

Preview Queries

Close Edit Window

Feedback / Comments

Adverse event

New adverse events

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

No

Yes (use 'Add New' to enter details after clicking 'Update')

[Update](#)

	ID	Short Description	Start	Ongoing	SAE	ESI
Open		Intra cerebral haemorrhage	07/12/2017	No	Yes	Cerebrovascular accident (CVA) [Awaiting ESI Form] Add Form

[+ Add New ESI Category](#)

[Add New](#)

The ESI section of the database is being re-developed, so at the current time we only require ESI forms to be completed for serious infections. If the ESI category is missed from a serious infection event, the PV team will add this and you will be notified that a form requires completion.