British Society for Rheumatology

Rheumatoid Arthritis Register

Add a New Follow Up:

Adverse Events

Version 6 – 17/01/2024

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**
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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

All Adverse Events for this patient (Clinically Confirmed) SHOW

Suggestion

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:

- 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

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'

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

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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**.

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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')

1 Select **No**

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 | Tutorial | Advance to Next Section

Click **Advance to Next Section**

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.

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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**.

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Adverse Event Details

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

Detailed Description of the event:
[1937/2000 chars left] Pt has fluctuating neutrophils. DMARD temporarily discontinued.

Event Start Date: 01/04/2021 ☐ 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? No

Is it a **S**erious **A**dverse **E**vent? No

Was the patient hospitalised **overnight**? No

Outcome of the event: Resolved

Save

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.

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Adverse Event Details

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

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

Event Start Date: 01/04/2021 ☐ 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? No

Is it a **S**erious **A**dverse **E**vent? Yes

SAE Category Death

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: 01/04/2021

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 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**? Yes

Hospital Admission Date 25/03/2021 ☐ This is an estimated date

Hospital Discharge Date 01/04/2021 ☐ This is an estimated date

Outcome of the event: Death

Save

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.

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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 **S**erious **A**dverse **E**vent? 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.

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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.

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		UTI	01/11/2022 Estimated	No	No	
Open		Covid-19	15/12/2022 Estimated	No	**Yes**	**Remember to add all applicable ESI categories to this event** + Add New ESI Category
Open		Hip replacement	01/01/2023	No	No	

ADD NEW | TUTORIAL | ADVANCE TO NEXT SECTION

Please note only our Serious Infection ESI is available for completion

ESI for Adverse Event

ESI

ESI: Serious infection (Excluding TB)

INSERT | CANCEL

Add the ESI form from the event summary.

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		UTI	01/11/2022 Estimated	No	No	
Open		Covid-19	15/12/2022 Estimated	No	**Yes**	**Serious infection (Excluding TB** Add Form ***[Awaiting ESI Form]*** + Add New ESI Category
Open		Hip replacement	01/01/2023	No	No	

ADD NEW | TUTORIAL | ADVANCE TO NEXT SECTION

Created by:

Date created:

Last updated by:

Date last updated:

INSERT FORM

Please complete the questions and click ‘Insert Form’ when complete.

If the edit window is closed the ESI form can be accessed from the patient summary page. Click on '**Missing ESI Form**' on the menu, click '**upload**' next to the event summary and complete the questions. Click '**Insert**' to submit the ESI form.

Menu

- View All Patients
- Add a New Patient
- View Records in Edit Window
- Currently Due Follow-Ups
- Follow-Ups Due Next Month
- Follow-Ups Due Next 3 Months

This Patient

- Demographics
- RA Details
- Missing ESI Form (1)
- Switch Cohort

Study ID: **Cohort: Inflectra**

Consent Date: **Not Entered** Consented By: **Not Entered** Created by on 30/03/2023

	Follow up	Due date	Follow up status	Date entered	Date last updated	Editable?	Quick Actions
Select	Baseline †	15/03/2023	Verified	30/03/2023	07/09/2023	Edit window closed	
Select	1 †	15/09/2023	Queried	07/09/2023	17/01/2024	Edit window closed	
Edit	2 †	15/03/2024			30/03/2023	Cannot yet be opened	
	3 †	15/09/2024			30/03/2023	Edit window not open	
	4 †	15/03/2025			30/03/2023	Edit window not open	
	5 †	15/09/2025			30/03/2023	Edit window not open	
	6 †	15/03/2026			30/03/2023	Edit window not open	
	7 * †	15/03/2027			30/03/2023	Edit window not open	

Study No	FUp No.	AEUID	Short Description	Long Description	Event Start	Event Stop	SAE Category	ESI	
	2		Covid-19, developed PE whilst inpatient	Admitted with COVID-19. Developed PE three days into admission. Treated with oxygen therapy.	28 Feb 2023		Overnight Hospitalisation (initial or prolonged)	Serious infection (Excluding TB)	UPLOAD

Created by:

Date created:

Last updated by:

Date last updated:

INSERT

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.