



**British Society for
Rheumatology**

Rheumatoid Arthritis Register

Add a New Follow Up: Adverse Events

Version 1 – 11/12/2019

Continue to **Adverse Events** via the menu side bar.
Please provide information from **Last FUP Date Entered**.

Study ID: 30557 Cohort: Benepali Follow-Up: 2 FUP Status: Due Date: 13/10/2019 **Last FUP Date Entered: 13/09/2019**

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

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.



Study ID: 30557 Cohort: Benepali Follow-Up: 2 FUP Status: Due Date: 13/10/2019 Last FUP Date Entered: 13/09/2019

Patient

Patient summary

Clinician FUP

Biologic Targeted Therapy

Other Current Therapy

Adverse Events

Disease Activity

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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

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
	30/11/2017		1	1	Cataracts Cataracts
	20/01/2018		2	2	Undisplaced fracture left radial styloid Slipped on ice subsequently injuring left wrist. Attended A&E, x-ray confirmed fracture left styloid, plaster cast applied.
	16/05/2018		2	2	Urinary tract infection GP px nitrofurantain

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

Patient	Adverse event
Patient summary	New adverse events
Clinician FUP	Did the patient suffer any adverse events or new illnesses in this follow-up period?
Biologic Targeted Therapy	<input checked="" type="radio"/> No 1 Select No
Other Current Therapy	<input type="radio"/> Yes (use 'Add New' to enter details after clicking 'Update')
Adverse Events	Update 2 Click Update
Disease Activity	No adverse events entered yet. Click "Add New" to enter details. If no adverse events have occurred, please record this in the box above.
Additional Info	Add New
Administrative	All Adverse Events for this patient (Clinically Confirmed) <small>SHOW</small>
Preview Queries	Suggestion
Close Edit Window	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:
Feedback / Comments	<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
	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 there are adverse events to record select **Yes** and **Update**.
Then click **Add New** to add an event.

Patient

Patient summary

Clinician FUP

Biologic Targeted Therapy

Other Current Therapy

Adverse Events

Disease Activity

Additional Info

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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 **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.

3 **Click Add New**

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:

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- 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'

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

Adverse Event Details

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

Detailed Description of the event:
[1866/2000 chars]

Event Start Date: This is an estimated date

Is this an ongoing event?

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

Is it a **Serious Adverse Event**?

Was the patient hospitalised **overnight**?

Outcome of the event:

Primary Source:

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.

Adverse Event Details

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

Detailed Description of the event:
[1994/2000 chars]

Event Start Date: This is an estimated date

Is this an ongoing event?

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

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:

Primary Source:

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

Patient

Patient summary

Clinician FUP

Biologic Targeted Therapy

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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	30424-000001	Fluctuating neutrophils	15/09/2019	No	No	

Add New

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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 there are no more Adverse Events to add continue to Disease Activity.

