British Society for Rheumatology

Rheumatoid Arthritis Register

Add a New Follow Up:

Adverse Events

Version 4 – 08/09/2022

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**
- 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

All Adverse Events for this patient (Clinically Confirmed) SHOW

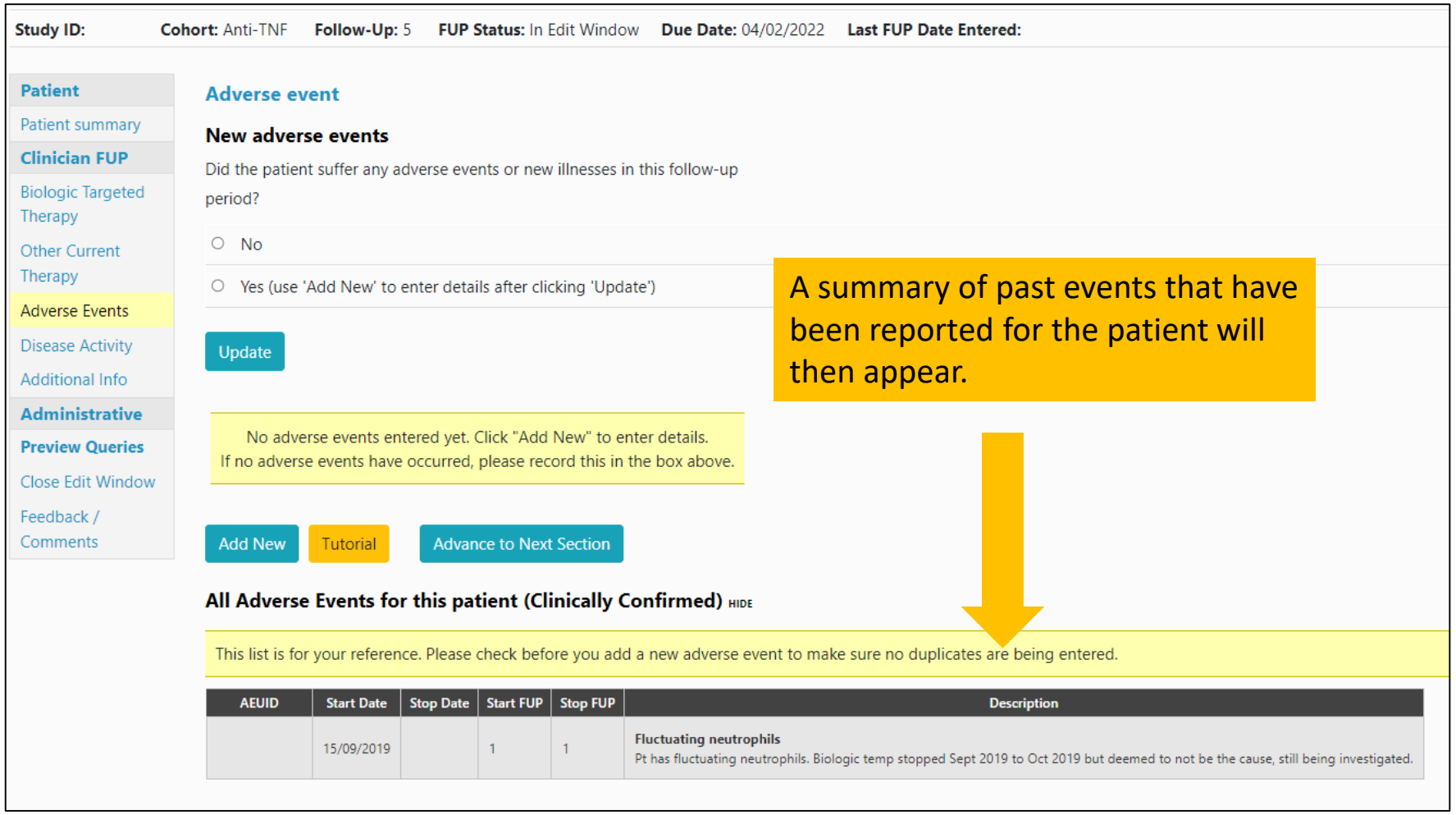
Suggestion

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:

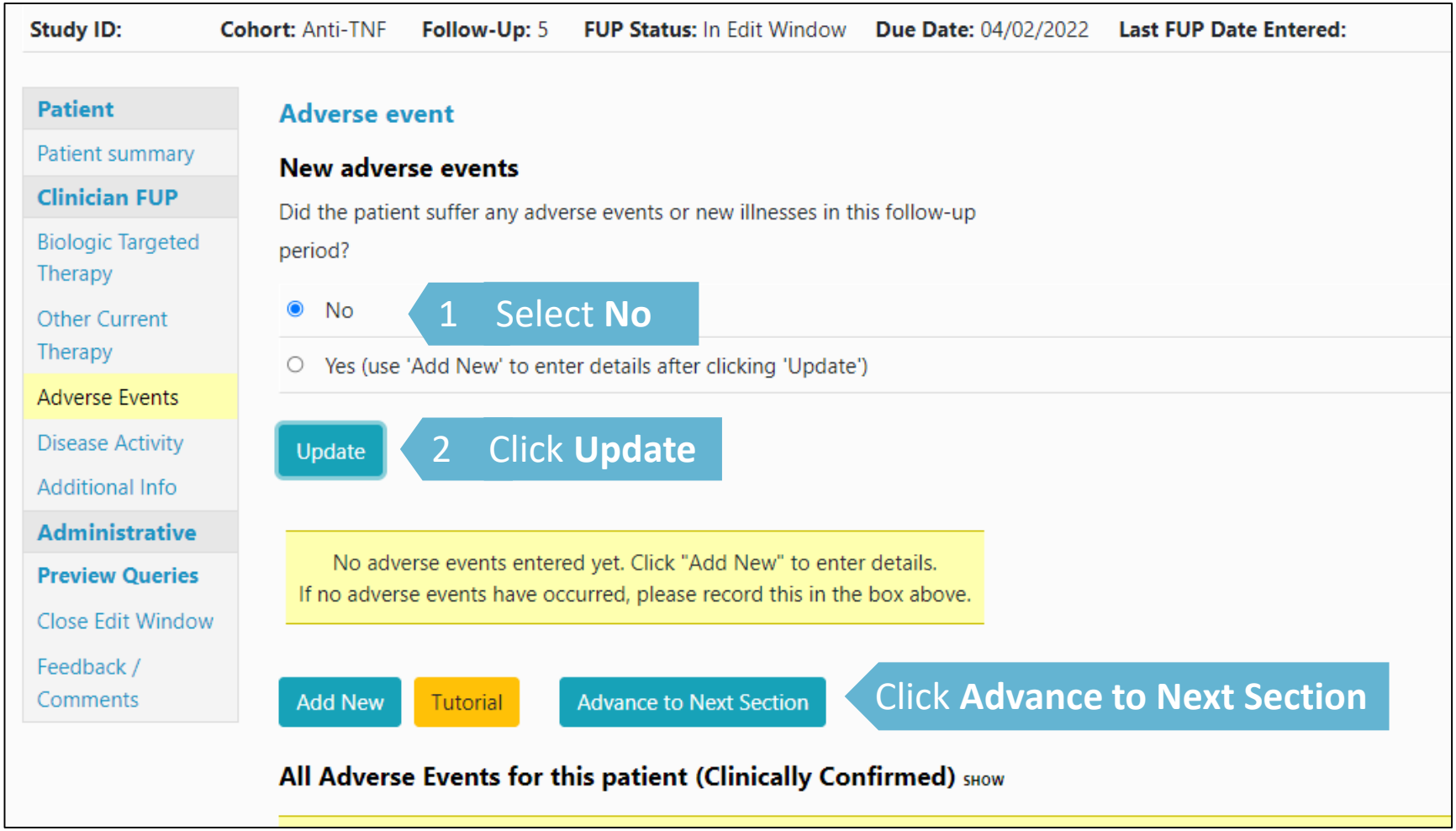
- Any new diagnosis
- Worsening of a pre-existing condition
- **Clinically significant** laboratory results
- Any event that either you or another clinician has considered to be of sufficient importance to document in hospital case notes e.g. nausea, weight gain, headache

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



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] 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

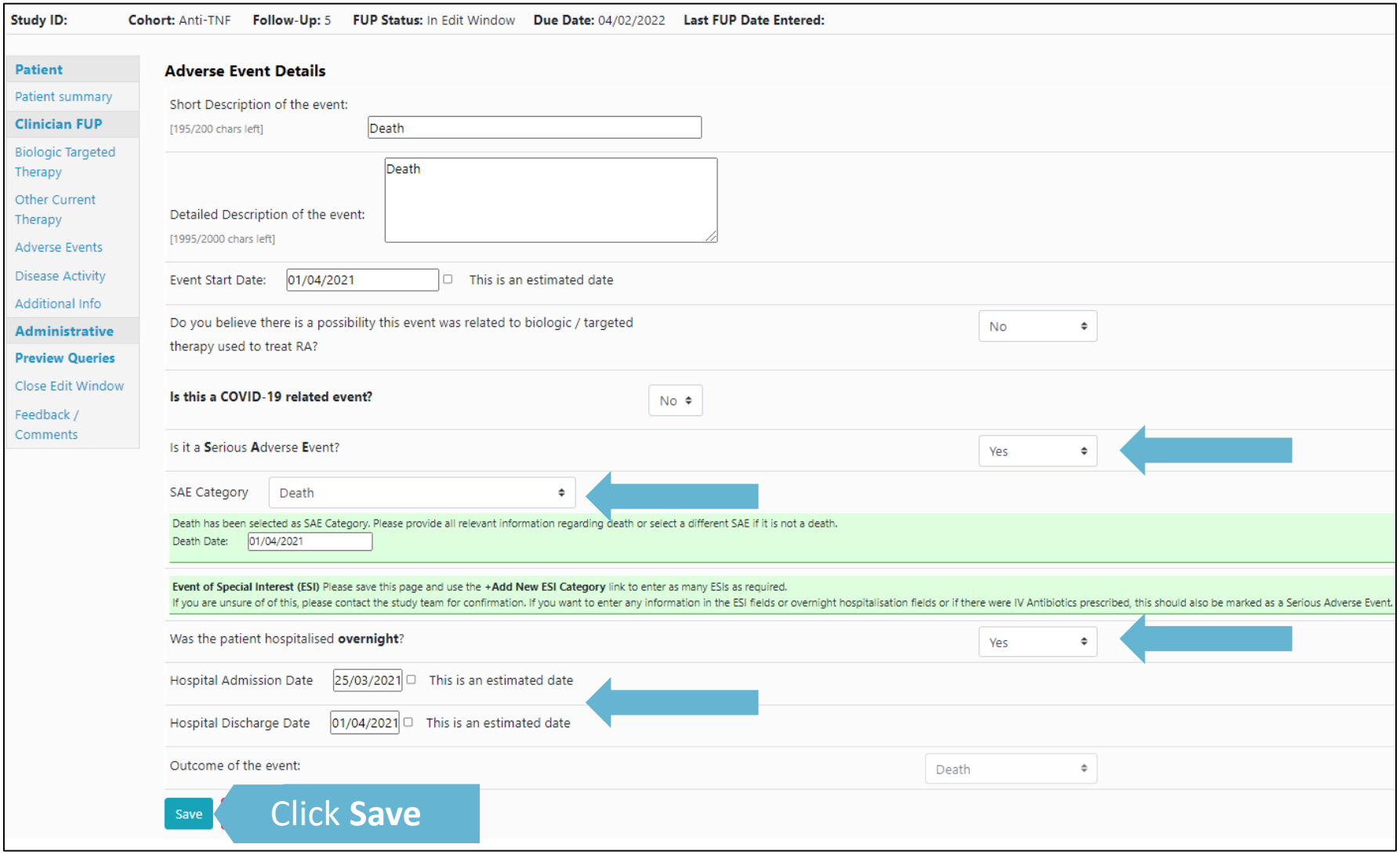
Was the patient hospitalised **overnight**? No

Outcome of the event: Resolved

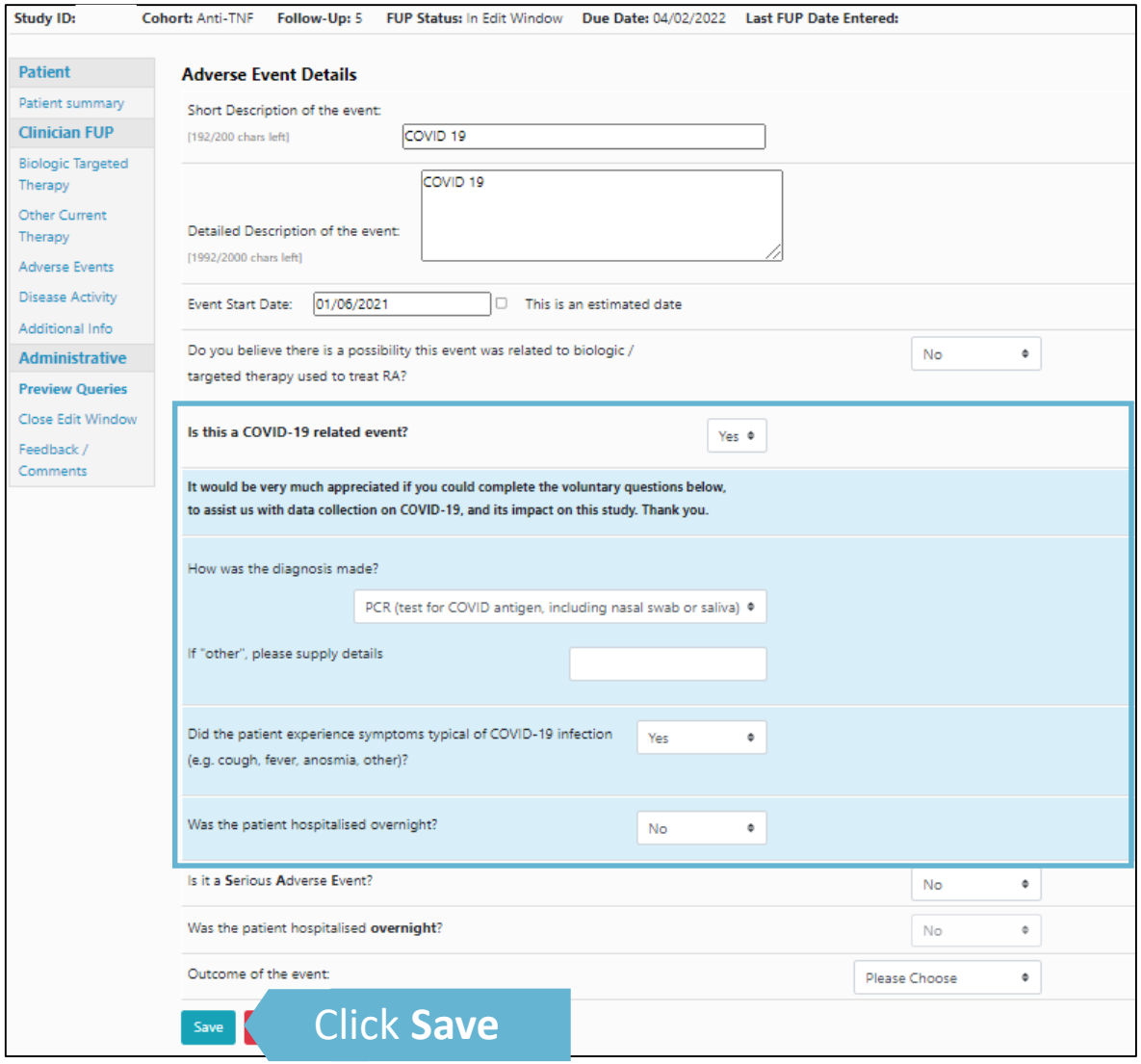
Save Click **Save**

You must complete <u>all</u> fields to be able to save and continue

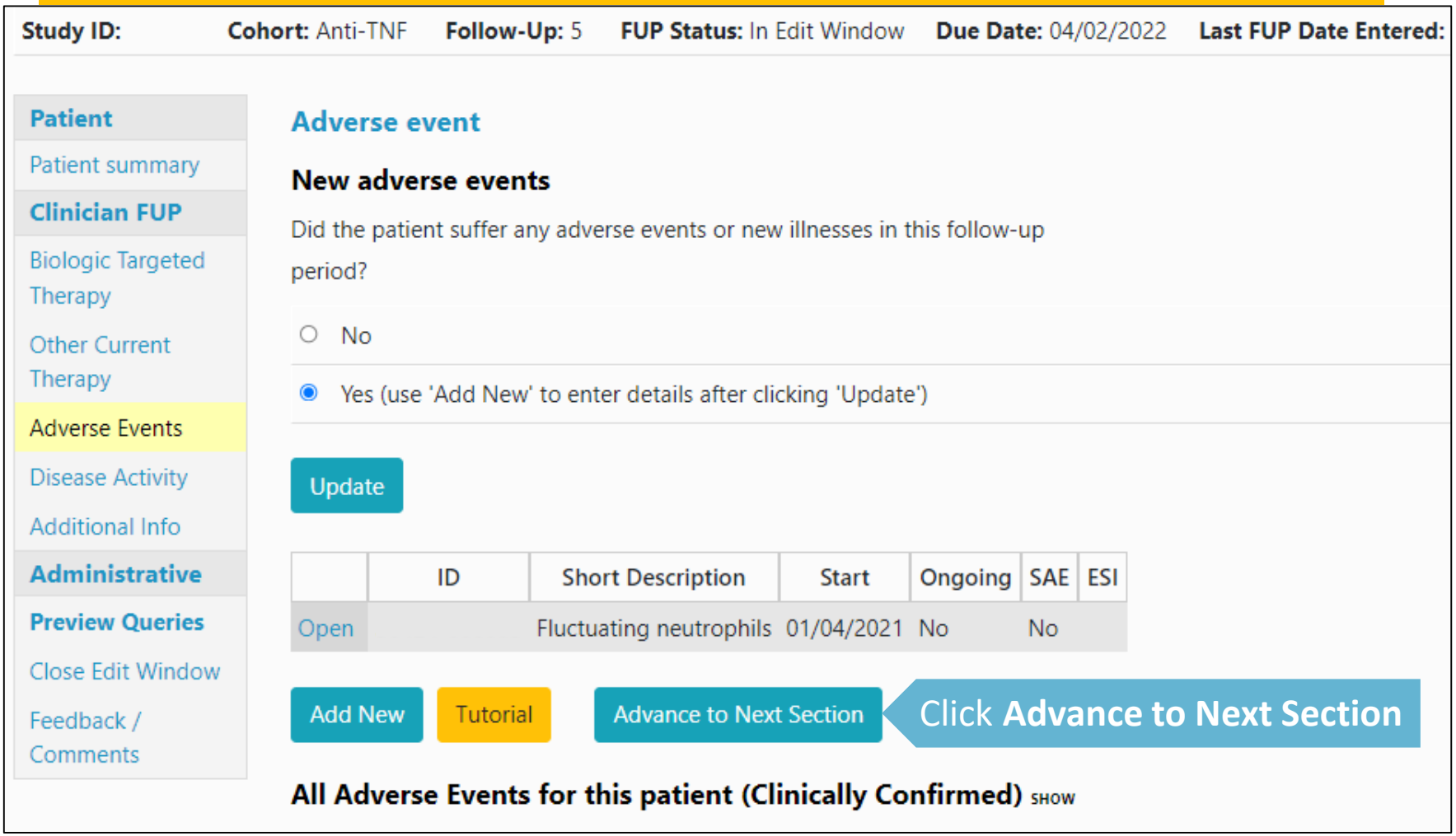
If your event is serious you will get options to add the SAE category, admission/discharge dates (if hospitalised) and date of death where applicable.



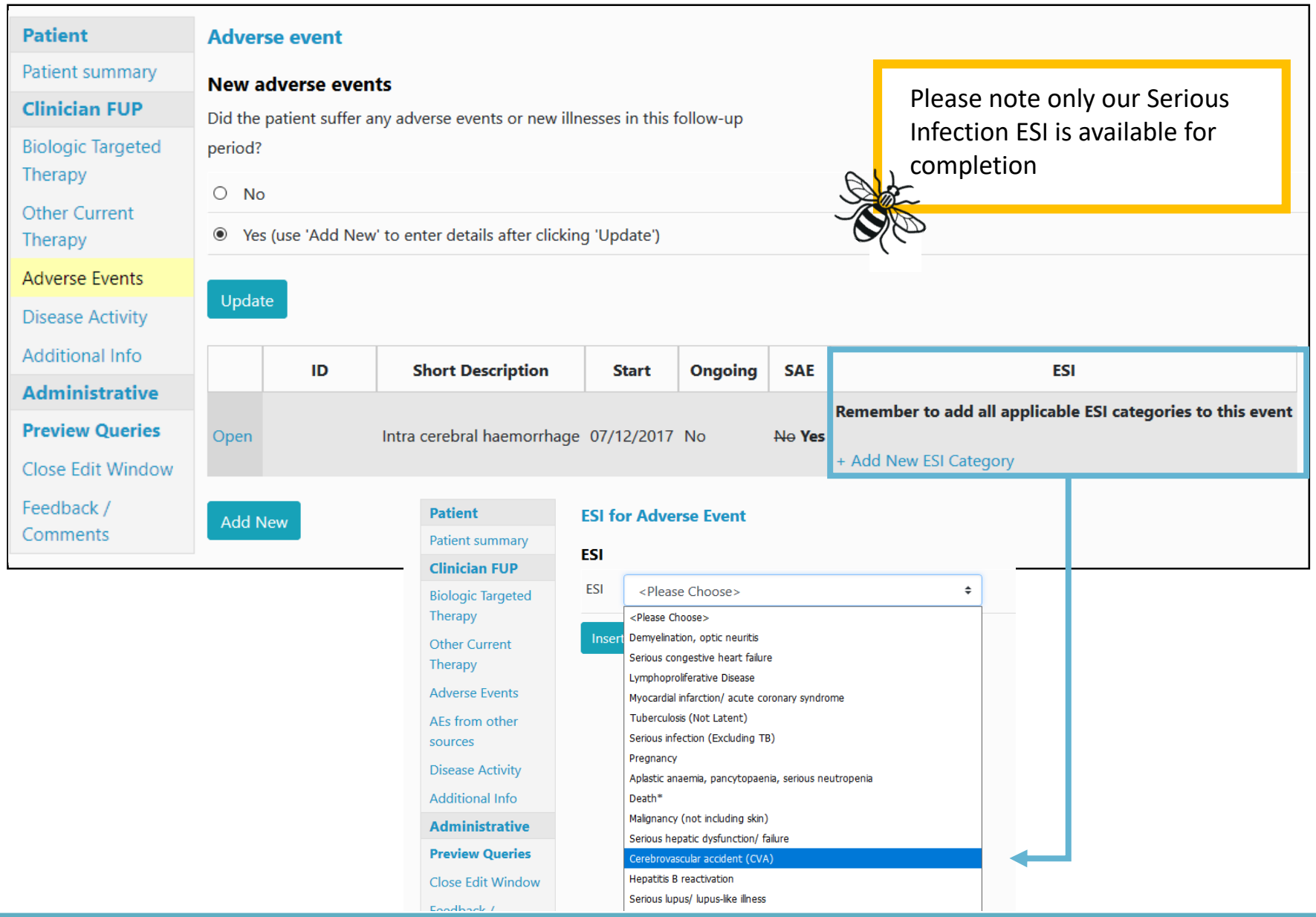
If the event is a COVID-19 related event, please select yes to the 'Is this a COVID-19 related event' question and complete the questions.



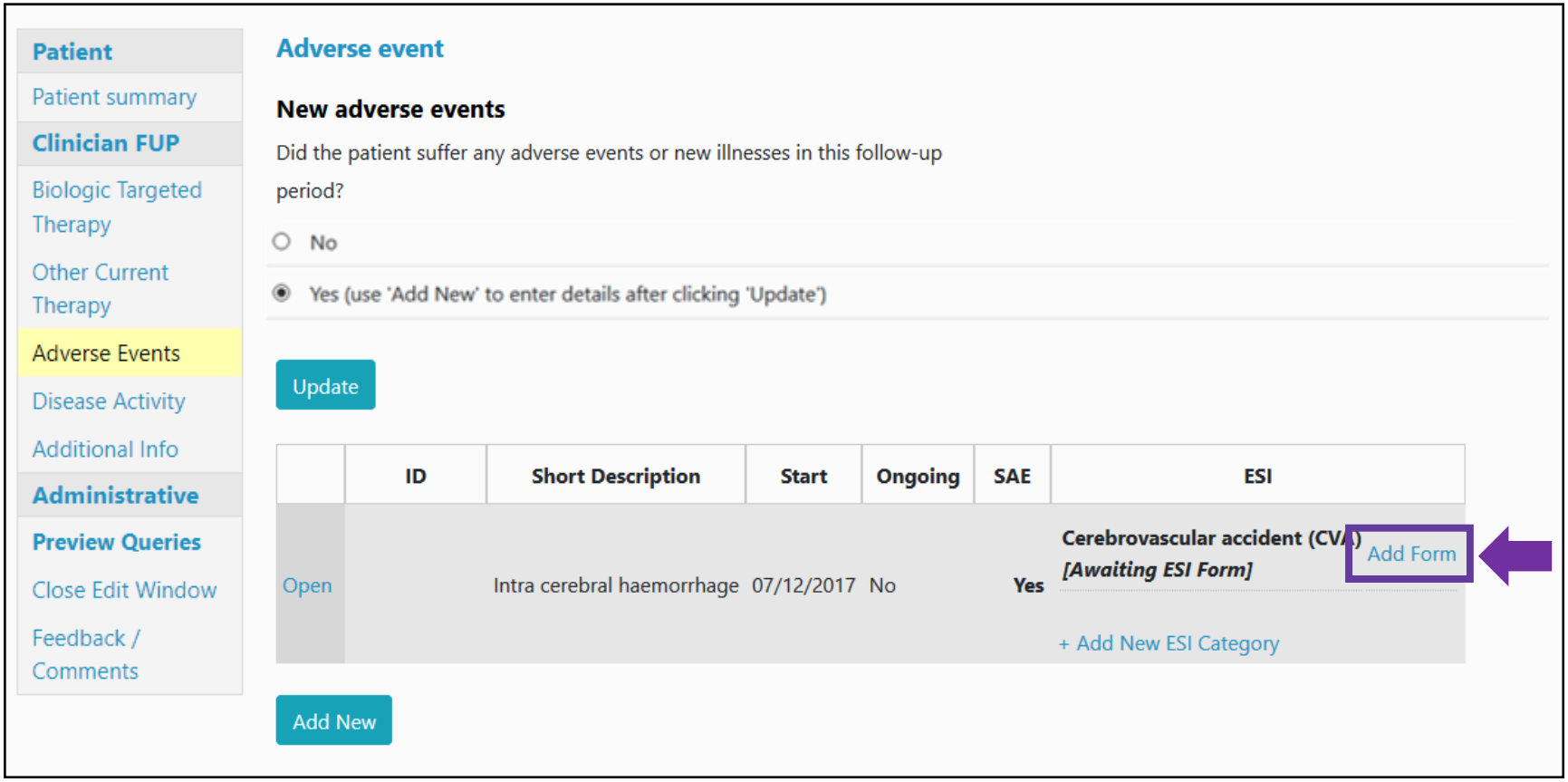
Once saved the event will appear in the summary.
Use the **Add New** button again to enter further events otherwise continue to the next section.



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



Add the ESI form from the event summary.



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.