British Society for Rheumatology

Rheumatoid Arthritis Register

The University of Manchester

British Society for Rheumatology

Biologics Register for Rheumatoid Arthritis

UKRDN ID: 7302

Welcome Presentation

Version 10.3: 07/04/2025

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Primary Aim

To monitor the long-term safety of biologic, biosimilar, and other new targeted therapies in the UK

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2001

2018

THERAPEUTIC TIMELINE

Enbrel

Remicade

Kineret

Humira

MabThera

Cimzia

RoActemra

Inflectra

Remsima

Benepali

Flixabi

Olumiant

Kevzara

Erelzi

Rixathon

Xeljanz

Others

Biologics

Biosimilars

JAK inhibitors

2023 and beyond…

JAKi (Jyseleca, Rinvoq) adalimumab biosimilars (Amgevita, Hymiroz, Idacio, Imraldi, Yuflyma), rituximab biosimilars (Ruxience, Truxima), Remsima SC, tocilizumab biosimilar (Tyenne)…

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Where are the data used?

Pharmacovigilance

Used for post-marketing surveillance for pharmaceutical companies for the drug regulators (EMA, FDA)

Independent Study

c. 100 scientific academic study papers have been published using BSRBR-RA data

View related publications: https://bit.ly/2jWtOle

Open Data Access

External parties are encouraged to access and analyse the rich BSRBR-RA data set

Visit the BSR Website to find out more
https://www.rheumatology.org.uk/practice-quality/registers

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Research Delivery Network and Accruals

BSRBR-RA is part of the NIHR Research Delivery Network Portfolio. This means that the study is eligible for consideration for support from the Research Delivery Network in England.

The coordinating centre at The University of Manchester are responsible for uploading recruitment figures to the Central Portfolio Management system (CPMS) on a monthly basis.

Further information on this, including a guide on accessing study support can be found on our website, at the following link:

https://www.bsrbr.org/hospitals/research-development/research-delivery-network/

RDN Portfolio ID:
7302

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Recruitment Eligibility

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- Aged 16 Years or over
- Started eligible biologic treatment
- Diagnosis of Rheumatoid Arthritis
- Registration within 6 months of the therapy start date*

*Patients already registered, and starting a new eligible therapy: cohort switch request needs to be made within 24 months of therapy start

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Drugs we recruit for

ANTI-TNF originators

adalimumab originator*
Humira

etanercept originator*
Enbrel

infliximab originator*
Remicade

*patients must be biologic, biosimilar & targeted therapy naive to be eligible

BIOSIMILARS

adalimumab biosimilars
Amgevita
Hulio
Hyrimoz
Idacio
Imraldi
Yuflyma

infliximab biosimilars
Flixabi
Inflectra
Remsima IV
Remsima SC

etanercept biosimilars
Benepali
Erelzi

rituximab biosimilars
Rixathon
Ruxience

tocilizumab biosimilars
Tyenne

OTHER TARGETED THERAPIES

baricitinib
Olumiant

certolizumab
Cimzia

tofacitinib
Xeljanz

filgotinib
Jyseleca

tocilizumab
RoActemra

sarilumab
Kevzara

upadacitinib
Rinvoq

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Information *required* to register patients

- ✓ Patient Details - Including NHS number (CHI number for Scotland) and HRN
- ✓ DAS28 Assessment / disease activity (originator to biosimilar only) - at the time patient started drug
- ✓ Tradename of biologic / biosimilar/targeted therapy → etanercept biosimilars **Benepali** **Erelzi**
- ✓ Start date of biologic (within 6 months of registration)
- ✓ **Completed and initialled/ticked current version Consent Form***

Registration documents available to download here:
https://bsrbr.org/hospitals/data-collection/baseline-information/

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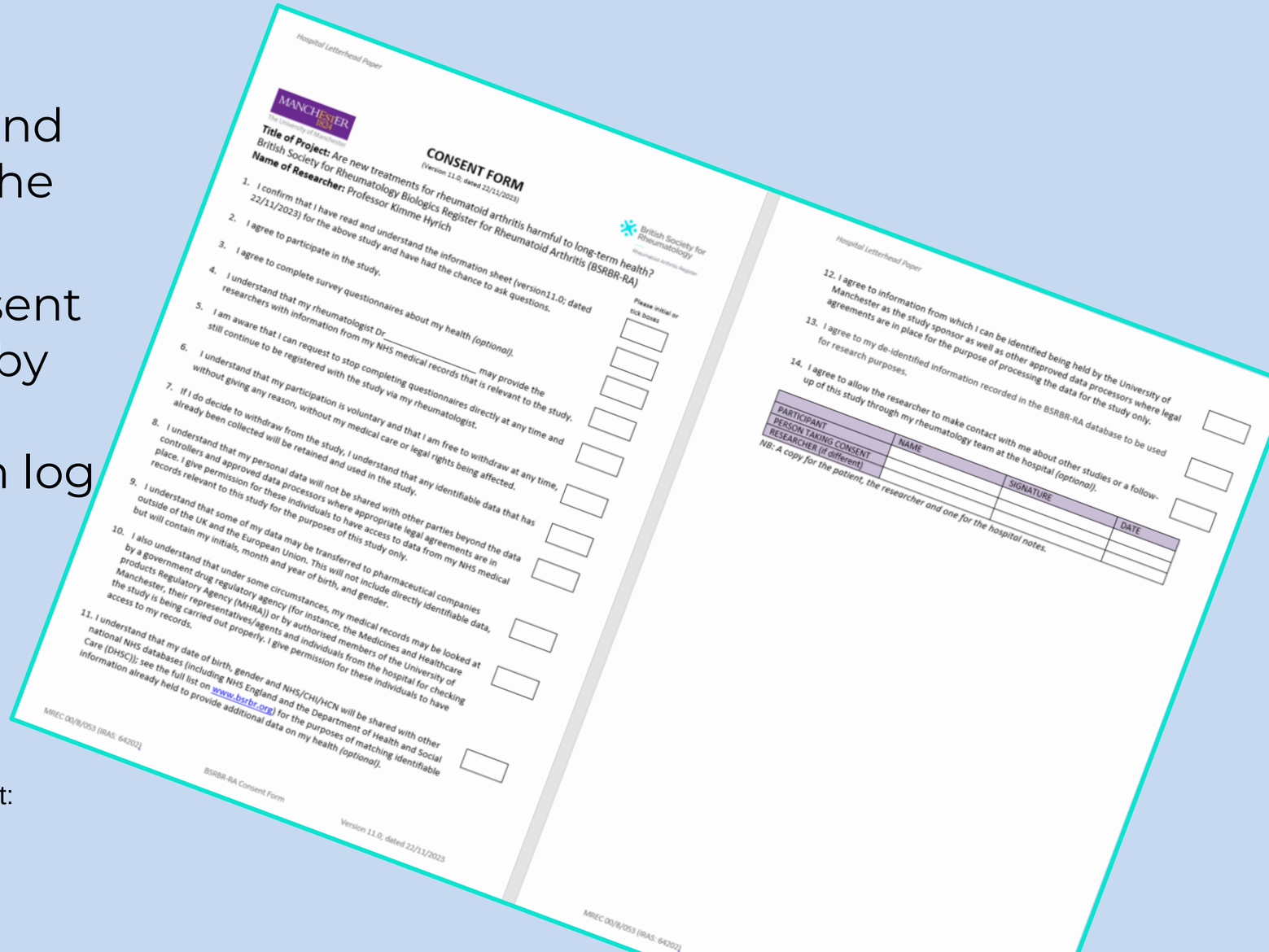
Consent

- ✓ Please make sure **all** boxes are ticked/initialed by the patient and that it is **signed** and **dated** by the patient.
- ✓ Please make sure that the consent form has been **countersigned** by someone at site with that responsibility on the delegation log
- ✓ Please avoid putting PII, such as HRN, on the consent form.



Hospital Letterhead Paper

CONSENT FORM

(Version 11.0; dated 22/11/2023)

Title of Project: Are new treatments for rheumatoid arthritis harmful to long-term health? British Society for Rheumatology Biologics Register for Rheumatoid Arthritis (BSRBR-RA)

Name of Researcher: Professor Kimme Hyrich

Please initial or tick boxes

1. I confirm that I have read and understand the information sheet (version11.0; dated 22/11/2023) for the above study and have had the chance to ask questions.
2. I agree to participate in the study.
3. I agree to complete survey questionnaires about my health *(optional)*.
4. I understand that my rheumatologist Dr _____ may provide the researchers with information from my NHS medical records that is relevant to the study.
5. I am aware that I can request to stop completing questionnaires directly at any time and still continue to be registered with the study via my rheumatologist.
6. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
7. If I do decide to withdraw from the study, I understand that any identifiable data that has already been collected will be retained and used in the study.
8. I understand that my personal data will not be shared with other parties beyond the data controllers and approved data processors where appropriate legal agreements are in place. I give permission for these individuals to have access to data from my NHS medical records relevant to this study for the purposes of this study only.
9. I understand that some of my data may be transferred to pharmaceutical companies outside of the UK and the European Union. This will not include directly identifiable data, but will contain my initials, month and year of birth, and gender.
10. I also understand that under some circumstances, my medical records may be looked at by a government drug regulatory agency (for instance, the Medicines and Healthcare products Regulatory Agency (MHRA)) or by authorised members of the University of Manchester, their representatives/agents and individuals from the hospital for checking the study is being carried out properly. I give permission for these individuals to have access to my records.
11. I understand that my date of birth, gender and NHS/CHI/HCN will be shared with other national NHS databases (including NHS England and the Department of Health and Social Care (DHSC)); see the full list on www.bsrbr.org) for the purposes of matching identifiable information already held to provide additional data on my health *(optional)*.

MREC 00/8/053 (IRAS: 64202)

BSRBR-RA Consent Form

Version 11.0; dated 22/11/2023

Hospital Letterhead Paper

12. I agree to information from which I can be identified being held by the University of Manchester as the study sponsor as well as other approved data processors where legal agreements are in place for the purpose of processing the data for the study only.
13. I agree to my de-identified information recorded in the BSRBR-RA database to be used for research purposes.
14. I agree to allow the researcher to make contact with me about other studies or a follow-up of this study through my rheumatology team at the hospital *(optional)*.

PARTICIPANT	NAME	SIGNATURE	DATE
PERSON TAKING CONSENT			
RESEARCHER (if diherent)			

NB: A copy for the patient, the researcher and one for the hospitol notes.

MREC 00/8/053 (IRAS: 64202)

*For further information on the BSRBR-RA consent process visit: https://www.bsrbr.org/hospitals/eligibility/consent-process/

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Baseline Data Capture

Completed upon registration of patients

Clinic

- Patient Demographics
- RA Therapy Details
- Other current therapy
- Disease Activity
- Co-morbidities

Patient

- HAQ Form
- EQ-5D Form

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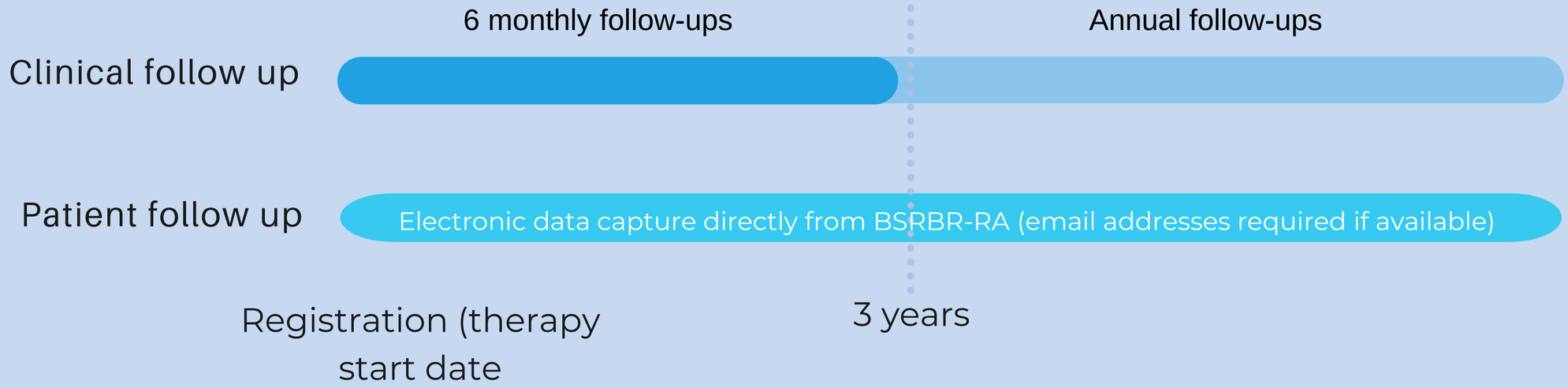
Follow-up Timeline



Clinical follow-up data is collected every 6 months for 3 years (FUPs 1-6), then annually thereafter (FUP7+ onwards).

Patient follow-up data is collected every 6 months.

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Follow-up Data Capture

1) Biologic therapy

Includes any changes to the patient's biologic/biosimilar/JAKi therapy (start & stop dates, dose, route, and reasons for discontinuation; even if temporary)

2) Other RA therapy

Includes any changes to the patient's DMARD therapy (start & stop dates and reasons for discontinuation; even if temporary) and any steroids the patient has had during the follow up period.

3) Adverse Events

Details for any new illnesses or adverse events that have occurred since the last follow up

For more information on how to report adverse events:
https://www.bsrbr.org/hospitals/data-collection/adverse-events/

4)Latest DAS28 score, weight measurement (if available)

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How to avoid data queries…

Registrations – p14

Follow ups – p16

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How to avoid queries about registrations!

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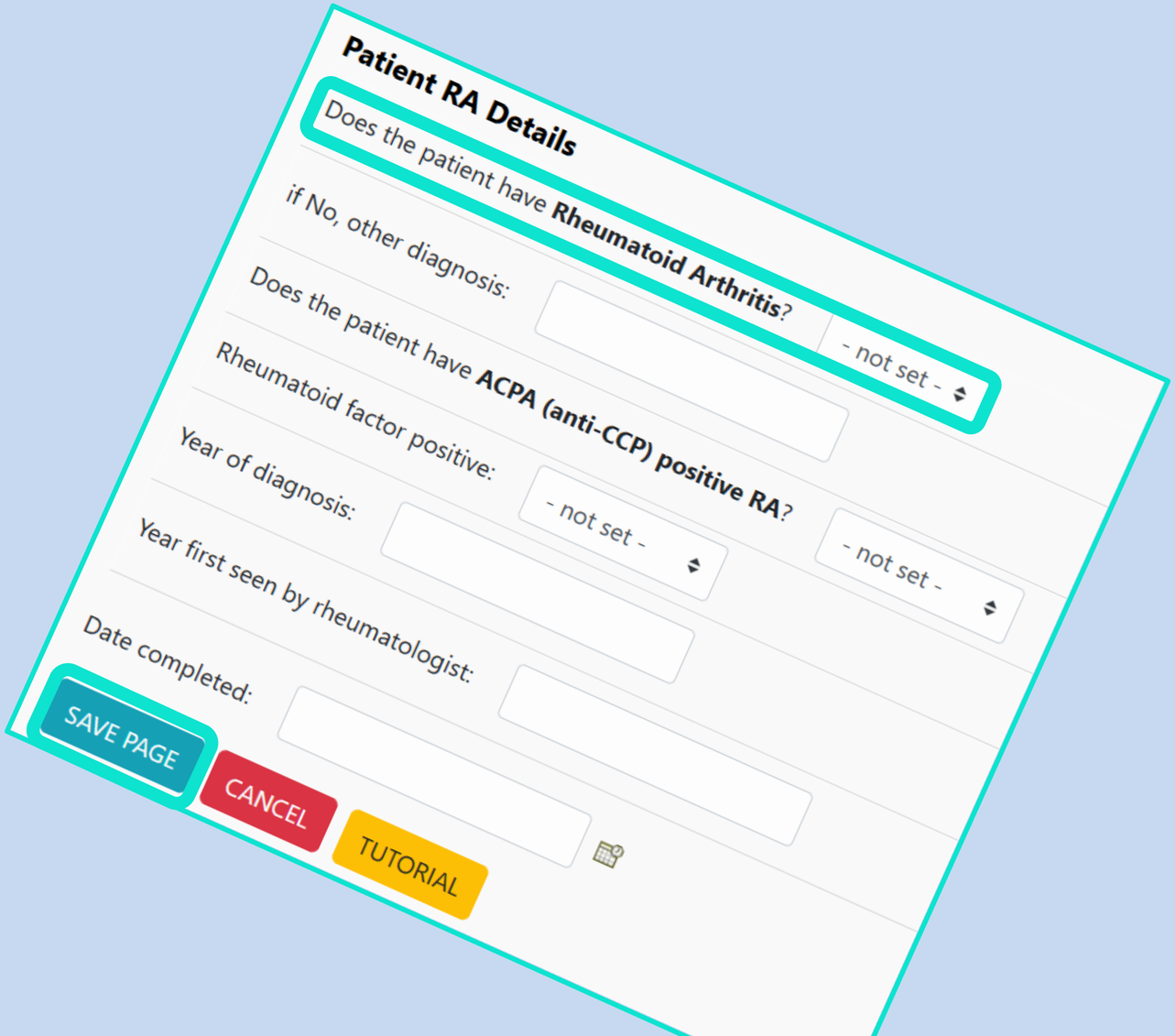
✓Please make sure you Complete the RA details page when registering a patient.

✓Remember to click the ‘SAVE PAGE’ button at the bottom of the page to save your answers.



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How to avoid queries about registrations!

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✓Please remember to complete the biologic targeted therapy section on the baseline.

✓It is important that this section is completed or it might delays in validating the registration.

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How to avoid queries about follow ups!

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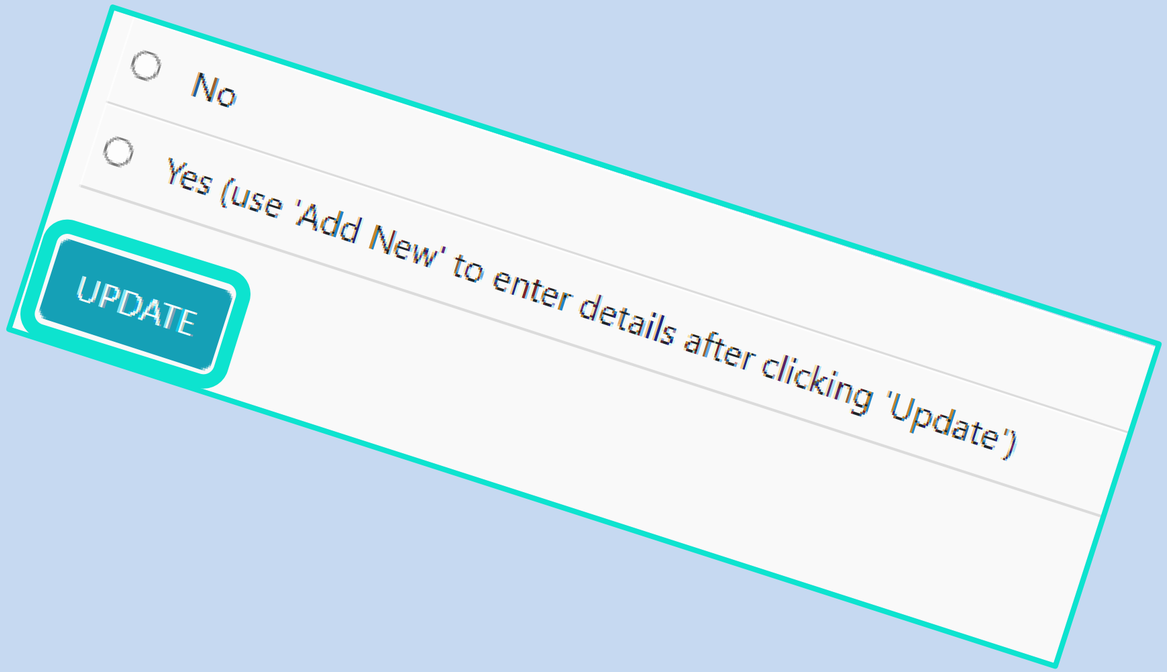
✓Our questions use radio buttons.

✓Remember to select yes or no and press the UPDATE button to save your answer.

✓If you are unable to make a selection, please leave a feedback note,



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How to avoid queries about follow ups!

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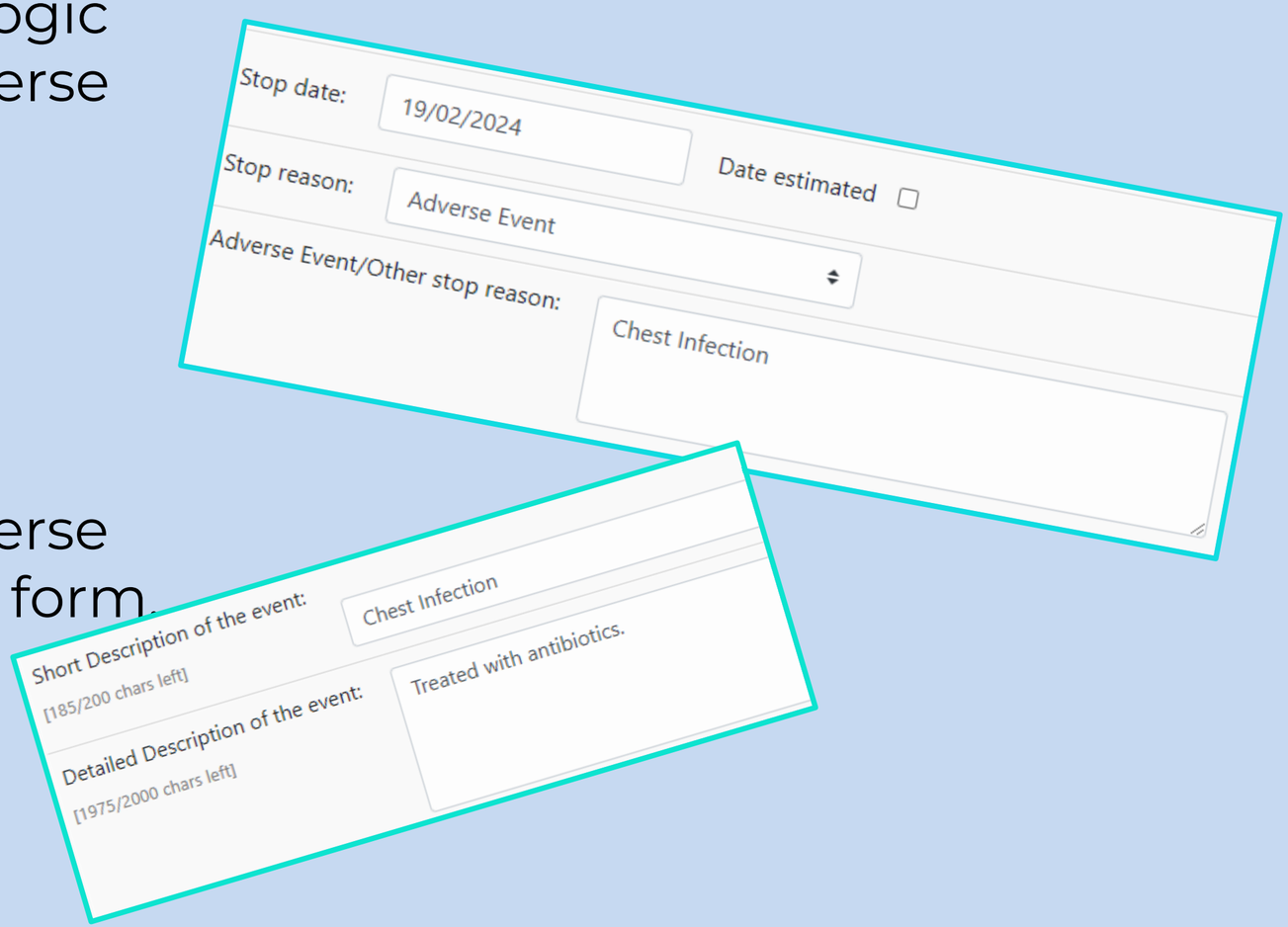
If a patient has stopped their biologic or DMARD therapy due to an adverse event please -

i. make sure to tell us what the adverse event was in the stop reason box.
ii. remember to add it to the adverse events section of the follow up form.



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Registering an Account

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Once your signed CV and GCP certificate has been received by us, you can register for an account

1

Register for an account

https://database.bsrbr.org/Register.aspx.

Once you have set up your account it will be reviewed in the BSRBR-RA office

2

Approval from PI

An email will be sent to the PI at your site to approve your access to the online database

3

Account authorisation

You will be notified when your access to the BSRBR-RA database has been approved

4

Log In

You can log in and enter data. Your name will also be automatically added to your centre's delegation log

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Thank you for completing the BSRBR-RA Database training!

Further information on training and database support can be found here :
https://bsrbr.org/database/training-help/

Getting in touch with us is easy

Please contact the team if you have any questions

BSRBR-RA Team: 0161 275 1652

biologics.register@manchester.ac.uk