

# British Society for Rheumatology

## Biologics Register for Rheumatoid Arthritis



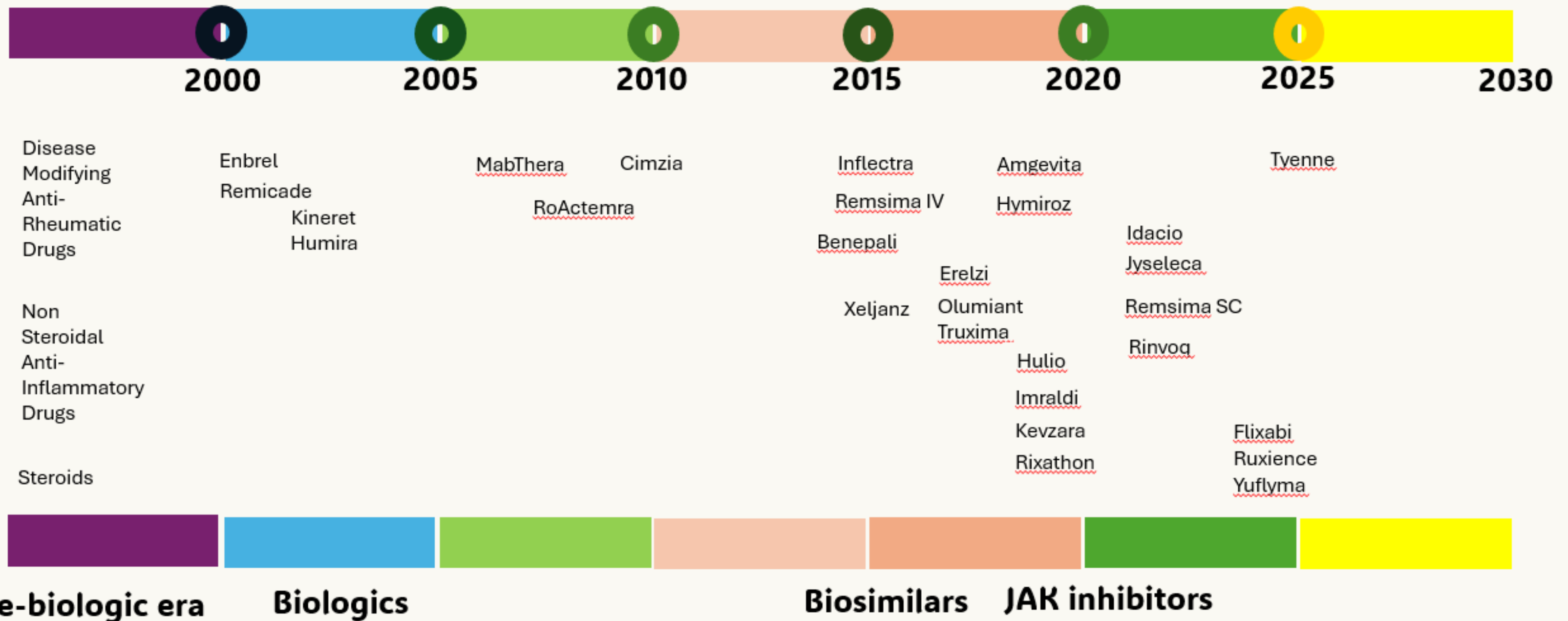
UKRDN ID: 7302

# Primary Aim

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



## Biologic Therapy Timeline



# 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>

# 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://bsrbr.org/hospitals/research-development/research-delivery-network/>

**RDN Portfolio ID:**  
**7302**



# Recruitment Eligibility



**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**

## Drugs we recruit for

### ANTI-TNF COHORT

adalimumab originator\*  
**Humira**

etanercept originator\*  
**Enbrel**

infliximab originator\*  
**Remicade**

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

rituximab originator  
**MabThera**

### 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**  
**Truxima**

tocilizumab  
biosimilars  
**Tyenne**

### OTHER TARGETED THERAPIES

baricitinib  
**Olumiant**

upadacitinib  
**Rinvoq**

tofacitinib  
**Xeljanz**

filgotinib  
**Jyseleca**

tocilizumab  
**RoActemra**

sarilumab  
**Kevzara**

certolizumab  
**Cimzia**

abatacept  
**Orencia**

## 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:

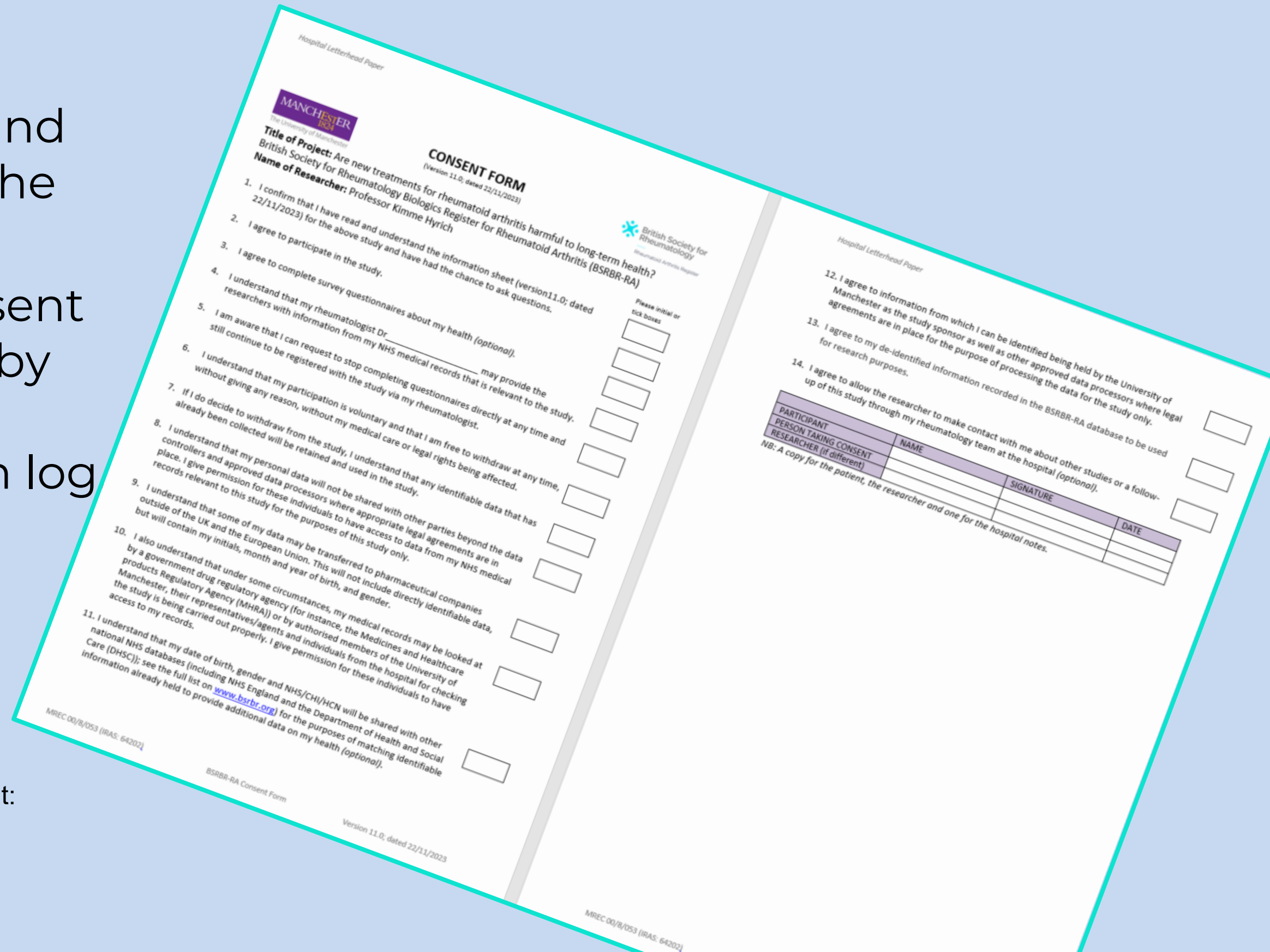
<https://bsrbr.org/hospitals/data-collection/baseline-information/>





# 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.



**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

1. I confirm that I have read and understand the information sheet (version 11.0; 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 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.

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](http://www.bsrbr.org) for the purposes of matching identifiable information already held to provide additional data on my health (optional).

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).

|                           | NAME | SIGNATURE | DATE |
|---------------------------|------|-----------|------|
| PARTICIPANT               |      |           |      |
| PERSON TAKING CONSENT     |      |           |      |
| RESEARCHER (if different) |      |           |      |

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

MREC 00/8/053 (IRAS: 64202)

BSRBR-RA Consent Form

Version 11.0, dated 22/11/2023

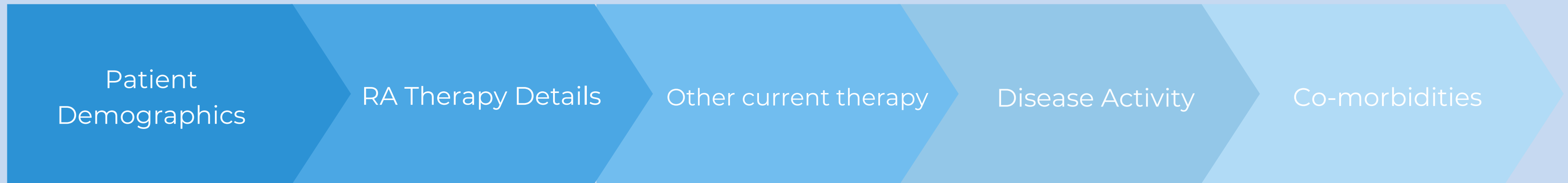
MREC 00/8/053 (IRAS: 64202)

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

# Baseline Data Capture

Completed upon registration of patients

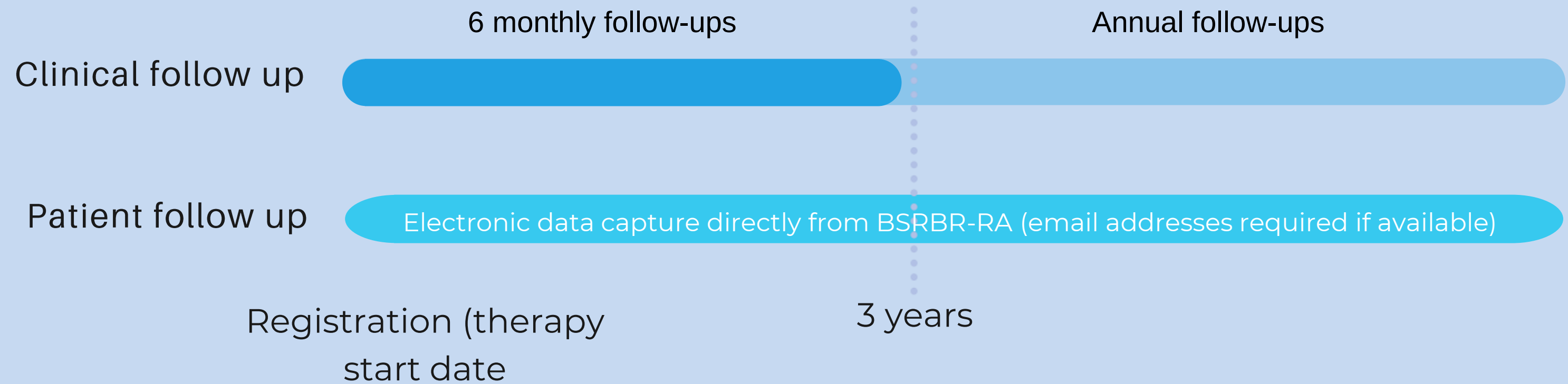
## Clinic



## Patient



# 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.

# 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)



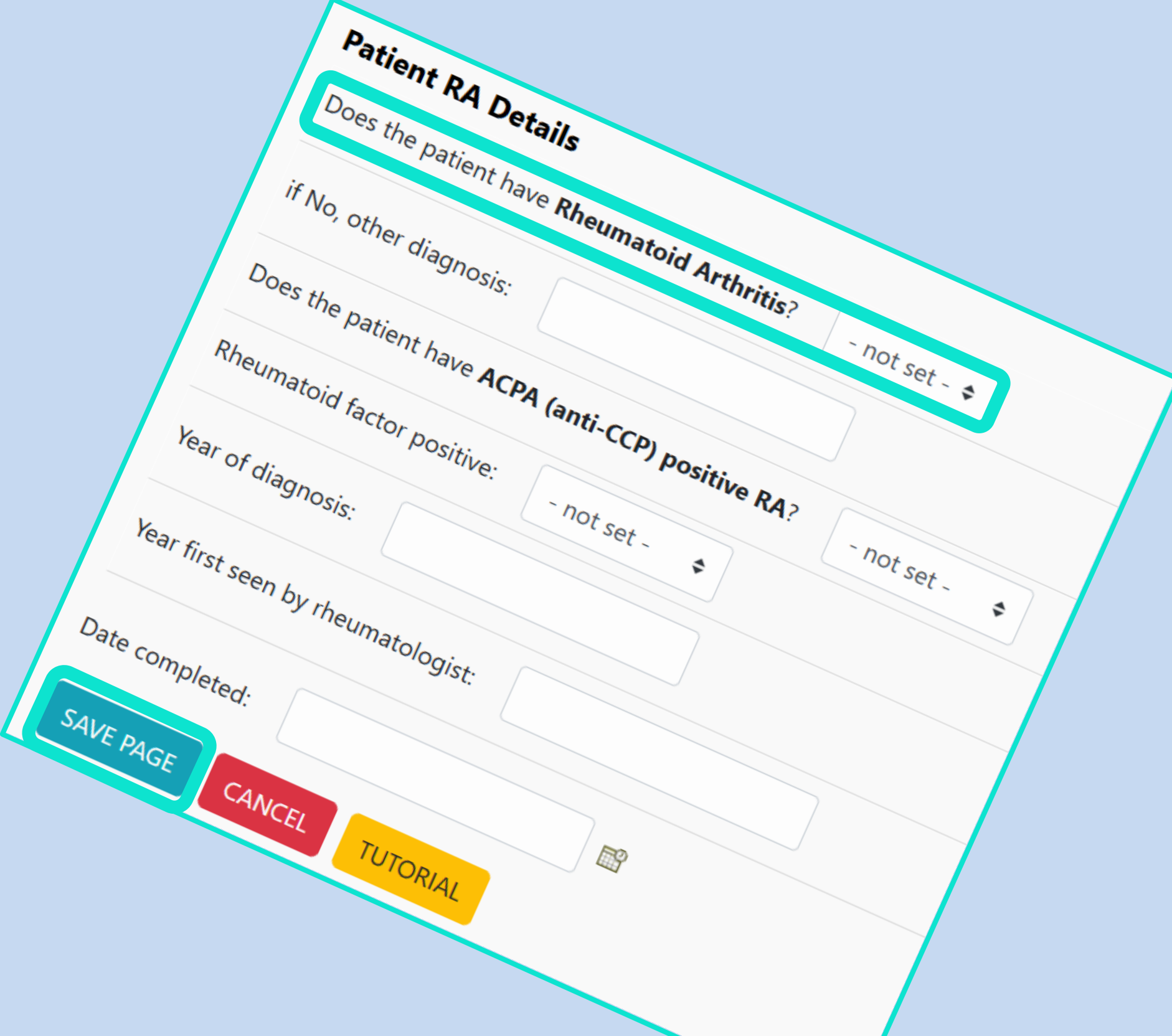
# How to avoid data queries...

**Registrations – p14**

**Follow ups – p16**

# How to avoid queries about registrations!

- ✓ 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.



The screenshot shows a web form titled "Patient RA Details". The form contains several fields and dropdown menus, all of which are highlighted with a red border. The fields include:

- Does the patient have **Rheumatoid Arthritis?** (dropdown menu, currently set to "- not set -")
- if No, other diagnosis: (text input field)
- Does the patient have **ACPA (anti-CCP) positive RA?** (dropdown menu, currently set to "- not set -")
- Rheumatoid factor positive: (dropdown menu, currently set to "- not set -")
- Year of diagnosis: (text input field)
- Year first seen by rheumatologist: (text input field)
- Date completed: (text input field)

At the bottom of the form, there are three buttons: "SAVE PAGE" (red), "CANCEL" (blue), and "TUTORIAL" (green). The "SAVE PAGE" button is highlighted with a red border.

# How to avoid queries about registrations!

- ✓ 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.



**Biologic Targeted Therapy**

If **NOT** first biologic / targeted therapy, please enter details in Previous Biologics / DMARDs / Steroids.

| Drug                             | Start Date | Stop Date | Dose  | Frequency   | Stop Reason | Doses & Batch |
|----------------------------------|------------|-----------|-------|-------------|-------------|---------------|
| Benepali (etanercept biosimilar) | 01/10/2023 |           | 50 mg | Once a week |             | 01/10/2023    |

ADD NEW TUTORIAL ADVANCE TO NEXT SECTION

Benepali (etanercept biosim... 50mg

Oct 2023 Nov Dec Jan 2024 Feb Mar

# How to avoid queries about follow ups!

- ✓ 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,



☐ No

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

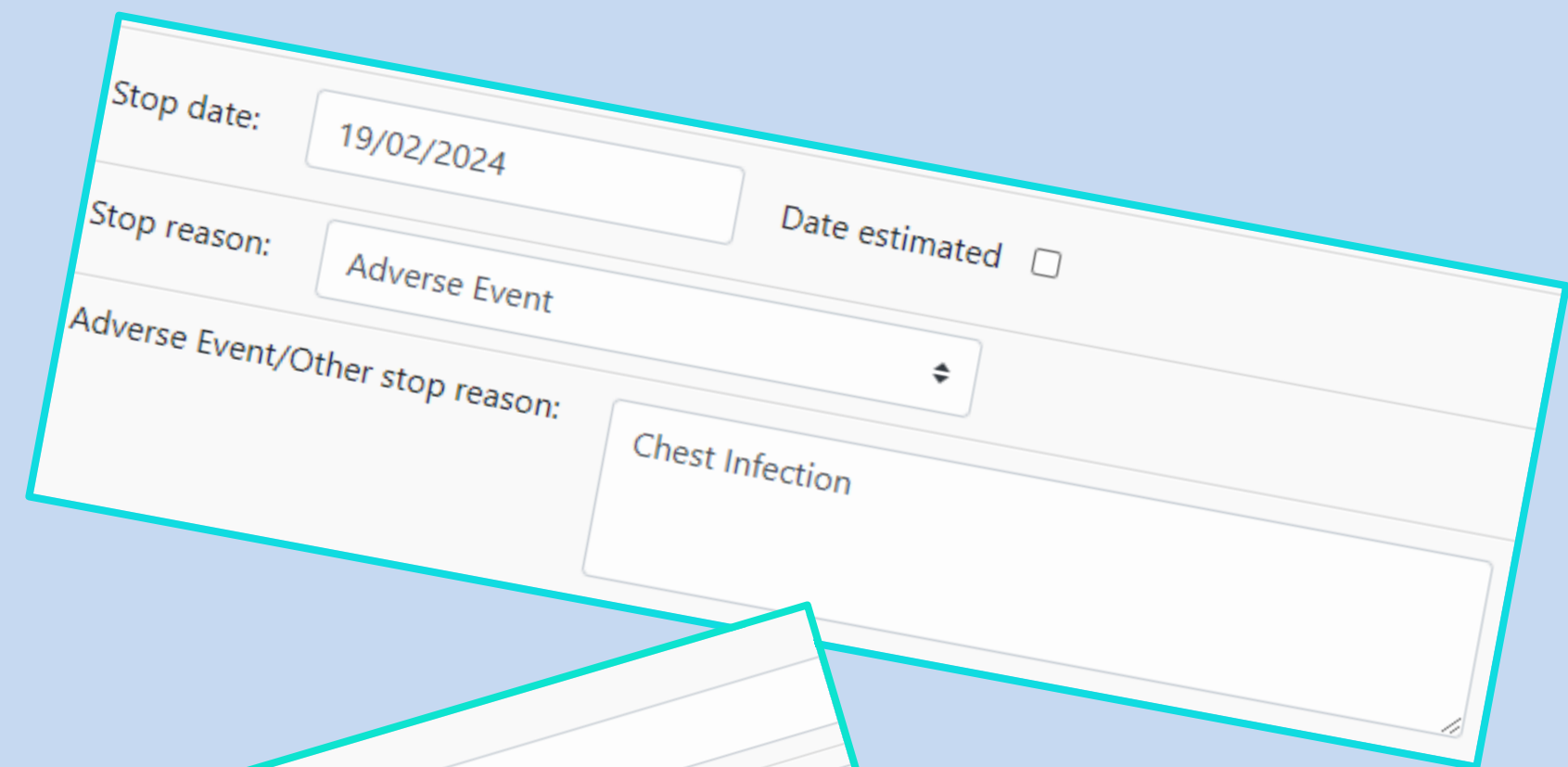
UPDATE



# How to avoid queries about follow ups!

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.



Stop date: 19/02/2024 Date estimated ☐

Stop reason: Adverse Event

Adverse Event/Other stop reason: Chest Infection



Short Description of the event: Chest Infection  
[185/200 chars left]

Detailed Description of the event: Treated with antibiotics.  
[1975/2000 chars left]

# Registering an Account

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

# 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

