

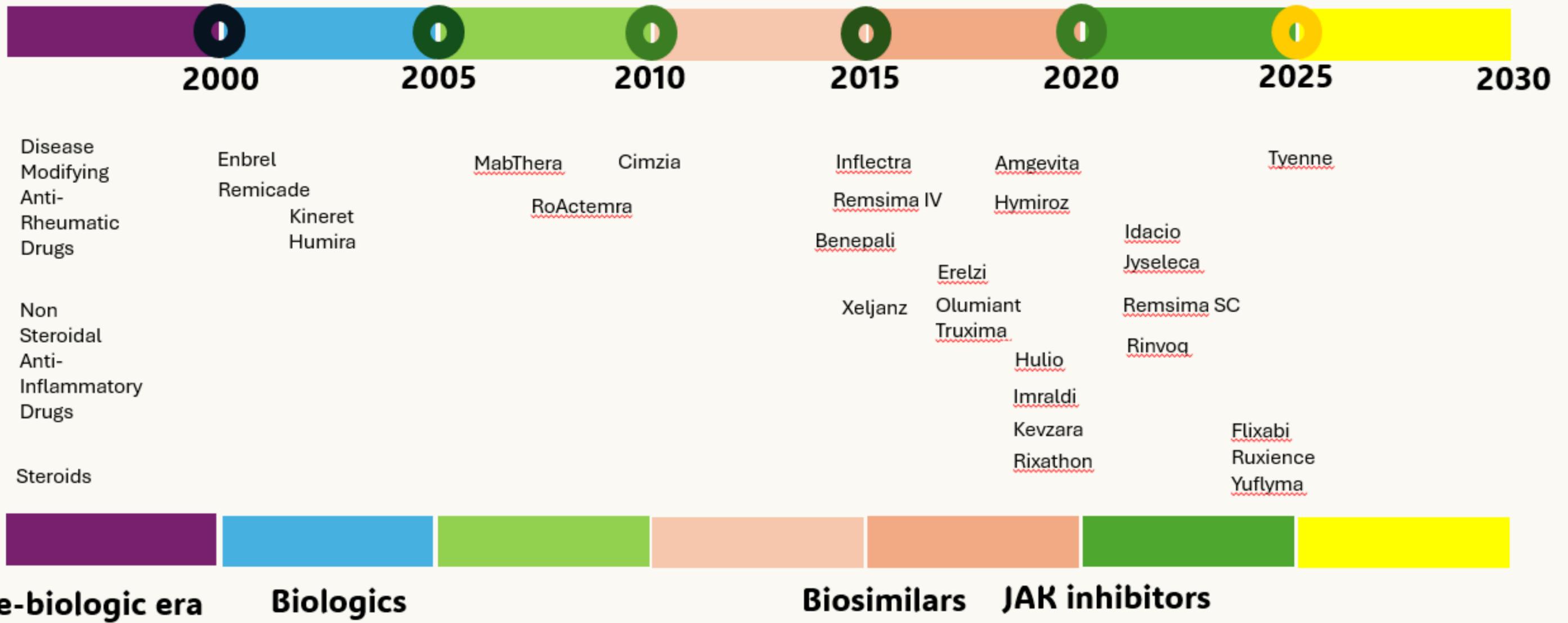
British Society for Rheumatology Biologics Register for Rheumatoid Arthritis

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. 110 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

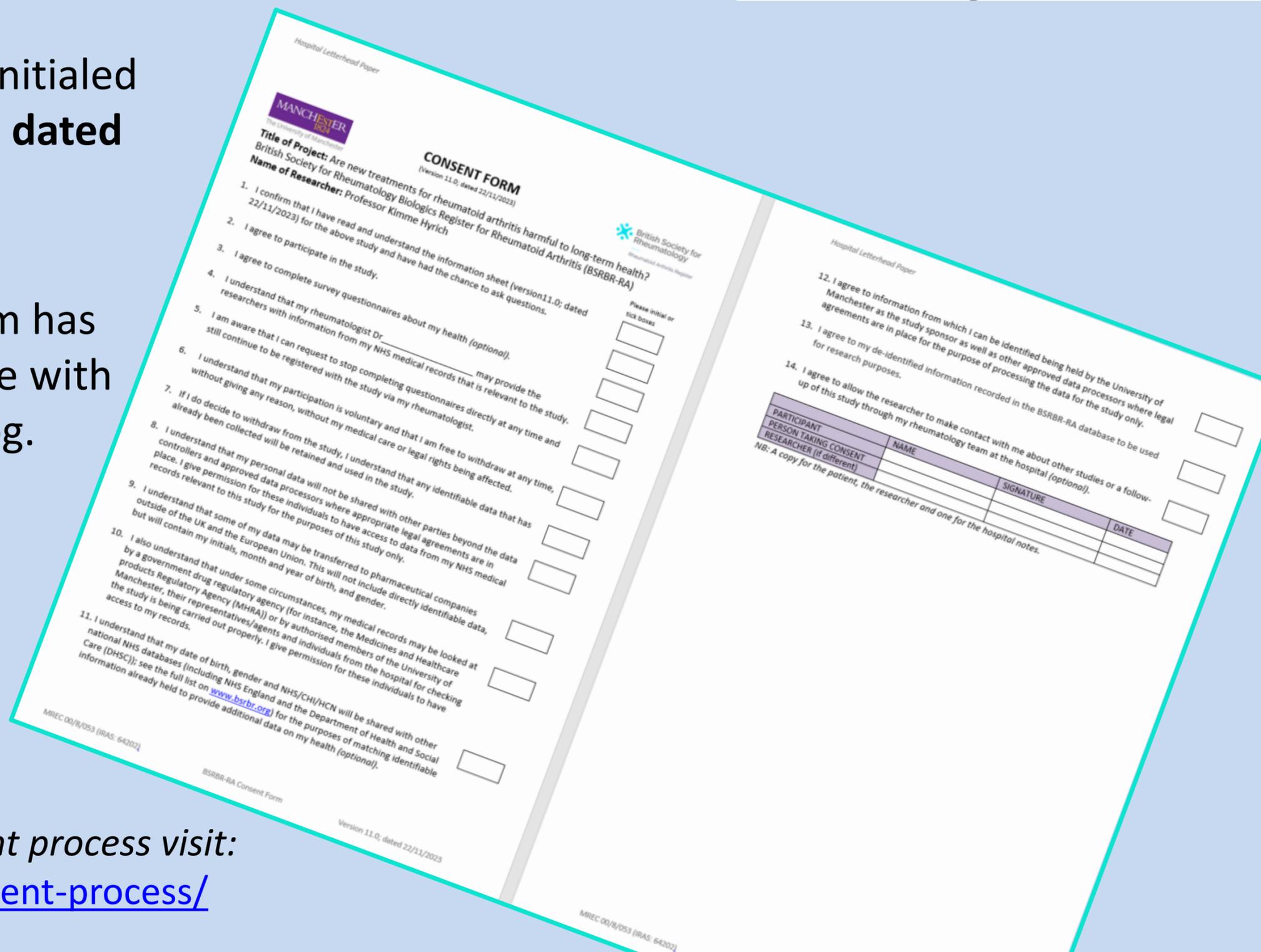
- ✓ Patient Details - Including NHS number (CHI number for Scotland) and HRN
- ✓ Tradename of biologic / biosimilar/targeted therapy → etanercept biosimilars **Benepali** **Erelzi**
- ✓ Start date of biologic (within 6 months of registration)
- ✓ Completed and initialled/ticked current version Consent 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?
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. 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.

5. I understand that my participation is voluntary and that I am free to withdraw at any time and without giving any reason, without my medical care or legal rights being affected.

6. 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.

7. 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.

8. 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.

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).

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

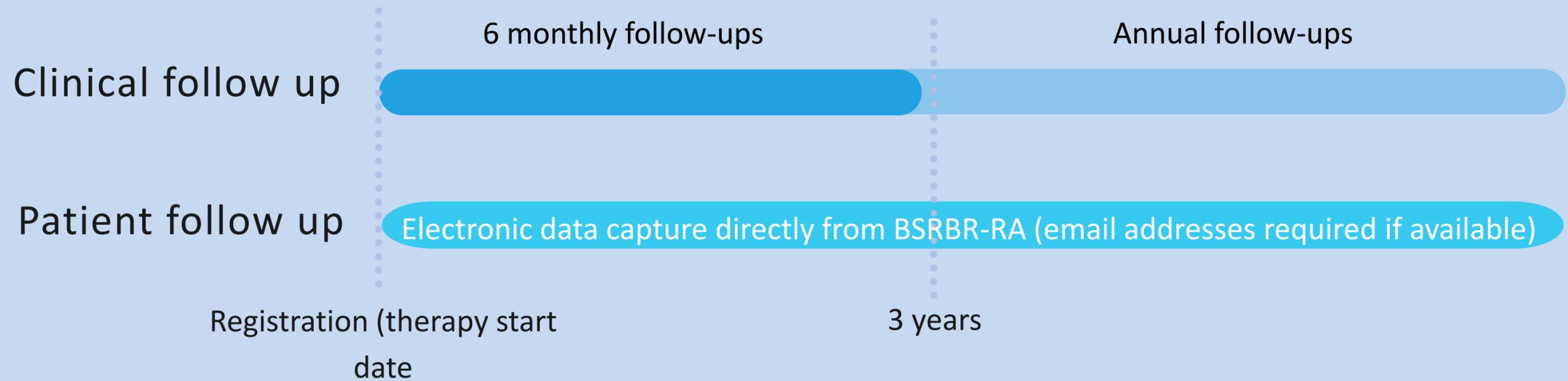
Information from hospital notes (Observational Study):



Patient (usually collected at the point of consent):



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 follows the same pattern.

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)

Registering an Account

1

CV and GCP

Send your hand-signed research CV and GCP to-
biologics.register@manchester.ac.uk

2

Register for an account

<https://database.bsrbr.org/Register>

Once you have set up your account it will be processed by the BSRBR-RA team

3

Approval from PI

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

4

Account authorisation

You will be notified when your access to the BSRBR-RA database has been approved and will be able to log in.

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/>

Please contact the team if you have any
questions

BSRBR-RA Team

0161 275 1652

biologics.register@manchester.ac.uk