Primary Aim

To monitor the long-term safety of biologic, biosimilar, and other new targeted therapies in the UK
Where is the data used?

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

**Independent Study**
Over 50 scientific academic study papers have been published using BSRBR-RA data

**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](https://www.rheumatology.org.uk/practice-quality/registers)
Clinical Research Network and Accruals

BSRBR-RA is part of the NIHR Clinical Research Network Portfolio. This means that the study is eligible for consideration for support from the Clinical Research 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/clinical-research-network/
Recruitment Eligibility

- Aged 16 Years or over
- Diagnosis of Rheumatoid Arthritis
- Starting eligible biologic treatment
- 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
- **HUMIRA** *(adalimumab originator)*
- **ENBREL** *(etanercept originator)*
- **REMICADE** *(infliximab originator)*

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

#### BIOSIMILARS
- **HULIO** *(adalimumab)*
- **AMGEVITA** *(adalimumab)*
- **HYRIMIZ** *(adalimumab)*
- **IMRALDI** *(adalimumab)*
- **RIXATHON** *(rituximab)*
- **IDACIO** *(adalimumab)*
- **RUXIENCE** *(rituximab)*
- **ERELZI** *(etanercept)*
- **BENEPALI** *(etanercept)*
- **INFLECTRA** *(infliximab)*
- **REMSIMA IV** *(infliximab)*
- **REMSIMA SC** *(infliximab)*
- **FLIXABI** *(infliximab)*

#### OTHER TARGETED THERAPIES
- **OLUMIANT** *(baracitinib)*
- **ROLACTEMRA** *(tocilizumab)*
- **CIMZIA** *(certolizumab)*
- **KEVZARA** *(sarilumab)*
- **XELJANZ** *(tofacitinib)*
- **RINVOQ** *(upadacitinib)*
- **JYSELECA** *(filgotinib)*
- **IDACIO** *(adalimumab)*
- **RUXIENCE** *(rituximab)*

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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
Start date of biologic (within 6 months of registration)

Completed and initialed current version Consent Form*

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

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

Patient
- HAQ Questionnaire
- EQ5D Questionnaire
- Patient Baseline Questionnaire (sent directly to patient from the BSRBR-RA team)
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 for 3 years, questionnaires and diaries are sent directly to patients.
Follow-up Data Capture

1) Biologic therapy
Includes any changes to the patient's biologic/biosimilar therapy (start & stop dates, dose, route, and reasons for discontinuation)

2) Other RA therapy
Includes any changes to the patient's DMARD therapy (start & stop dates and reasons for discontinuation) 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)
The BSRBR-RA is Online!

What does this mean for you?

No more paper forms!

Retrieve patient study data

Enter data on the BSRBR-RA Database

Preview queries

Address queries

We still collect the same data we have collected for several years
Welcome to the BSRBR-RA Database!

What's New?

Patient List
Patient Summary
Missing ESI Forms
View Follow-ups
Querying system
Site File
Welcome to the BSRBR-RA Database!

Patient List

- Keep track of your centre's registered participants
- Search for individual participants
- View follow up timeline & see when their next follow is due
- Access the Patient Summary Page
Welcome to the BSRBR-RA Database!

Patient Summary

- Complete the Patient Baseline & upload consent forms
- See follow up timeline & complete any follow ups due
- View & Edit patient Demographics
- See any queries for the patient
Welcome to the BSRBR-RA Database!

View Follow-ups

- View follow-ups currently due
- View follow-ups for the next month
- View follow-ups for the next 3 months
- Access follow-ups to be entered
Welcome to the BSRBR-RA Database!

Querying system

- Communicate with the study team to ensure correct and complete data
- Respond to queries
- Pharmacovigilance Queries
- Provide feedback to the BSRBR-RA study team
Welcome to the BSRBR-RA Database!

Missing ESI Forms

- List of all missing ESI for your centre
- Upload and complete any outstanding ESI forms
- View details and category of adverse events
Welcome to the BSRBR-RA Database!

Site File

- View and Amend Delegation Log
- View site file documents such as CVs
- View approved Database User Accounts
Data Entry Types

- **Radio Buttons**
- **Date Field**
  - Date completed: dd/mm/yyyy
  - *For ‘vague’ dates, if day is missing enter 15 with the month and the year, if only the year is known enter 15/06 for day and month*

- **Drop Down list**
- **Text box**
  - Detail of other
Advantages of online data collection

**TIME EFFICIENT**
Data will be available to us in real time, queries can be dealt with more efficiently

**MORE ACCURACY**
Less data duplication and better data validation

**BETTER COMMUNICATION**
All queries and feedback will be communicated to the study team and logged onto the system

**IMPROVED SECURITY**
Data entered on the system will be encrypted
Registering an Account

Once your signed CV and GCP certificate has been received by us and you have completed this training guide you can register for an account

1. **Register for an account**
   - 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 the register can be found here:
https://www.bsrbr.org/database/training-help/training/

Getting in touch with us is easy

Please contact the team if you have any questions

BSRBR-RA Team: 0161 275 1652 / 7390
biologics.register@manchester.ac.uk