

BSR Biologics Register for Rheumatoid Arthritis (BSRBR-RA)

Study Newsletter – Spring 2018

Now recruiting new therapies

You can now recruit a number of new therapies to the BSRBR-RA study – the full list is shown here.

Please remember, to register a patient starting any one of these therapies, they must:

- Have a diagnosis of Rheumatoid Arthritis
- Be aged over 16 years old
- Be willing to sign and initial the consent form

If they are stating Humira, Remicade or Enbrel, then they can not have had a previous exposure to a biologic/biosimilar therapy.

If they are starting a new treatment with any other therapy, they may have had previous exposure to one or more treatments.

If already registered with the BSRBR-RA, you will be able to reregister them when starting the new therapy. They will be assigned a new ID number and the follow up period will be started again. The re-registration will also count as a new accrual for your site.

We would appreciate it if you could please use **trade names** (such as Remicade, Remsima, Benepali) rather than generic name (such as infliximab, etanercept) on registration and follow up paperwork to avoid confusion. Thank you!

BSRBR-RA recruits:

Humira
Enbrel
Remicade
Inflectra
Remsima
Flixabi
Benepali
Erelzi
Rixathon
Cimzia
Actemra/RoActemra
Kevzara
Olumiant
Xeljanz



Online submission of data

The online data entry portal is now well under development, and is planned to be launched in 2019 following a period of data migration and system testing. The system will allow you to register patients and also submit follow up data, as well eventually providing features such as HAQ mapping and recruitment figures. If there is a feature that you think would be useful on the system, please get in touch with the team (details overleaf) who will see if this is possible.



Time to think about... delegation logs

Electronic delegation logs will be a key part of the online portal, as they will determine who is granted access to register patients and submit follow up data – these roles will be delegated and approved by the Principal Investigator.

In the coming months we will request a copy of your site delegation log, please can you begin to get this up to date ready for the request. A blank copy can be downloaded from the website:

http://bsrbr.org/hospitals/researchdevelopment/documents/ (section 5)

Rheumatology 2018 – May 1-3, Liverpool

The team will have a stand **(D39)** in the exhibition hall – please come and say hello! In addition, there are a number of talks and poster presentations using BSRBR-RA data

Tuesday 1st May

13.15-14.15 (Room 3A) – Latest Project News from the Biologics Registers

14.15-15.45 (Room 3A) – BSR Biologics Registers – Scientific Update

Poster 087: "Refractory Disease in Rheumatoid Arthritis: Results from the British Society of Rheumatology Biologics Register for Rheumatoid Arthritis"

Thursday 3rd May

Poster 243: "Long-term risk of serious infections in patients with rheumatoid arthritis treated with rituximab: five year data from the British Society for Rheumatology Biologics Register for Rheumatoid Arthritis (BSRBR-RA)"

Poster 241: "Profiling rheumatoid arthritis biosimilar switchers: data from the British Society for Rheumatology Biologics Register for Rheumatoid Arthritis"

Reporting Serious Adverse Events (SAEs)

Thank you for reporting serious adverse events (SAEs) on the BSRBR-RA follow up forms. We would be grateful if you could always please include these items when you report Serious Adverse Events:

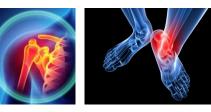
On the follow-up form:

- Diagnosis and event details
- Date of event (and discharge date if applicable)
- Reason the event is classed as serious (tick box)
- **Biologic/biosimilar** therapy start/stop dates (page 1 please use trade name)

Attached to the follow-up form:

Event of Special Interest (ESI) form (if applicable)

Any relevant additional information about the event (such as a discharge summary) would also be welcomed. Thank you!





All ESI forms can be downloaded from our website:

http://bsrbr.org/hospitals/datacollection/adverse-events/esi-forms/

If you are reporting an SAE to us but do not have the required information available, please note this on the follow up form so that a request for an ESI form/further details is not sent.

Contact us!

If you have any questions about the study, please don't hesitate to get in touch! Our fantastic project administration team can be contacted via the below details:

Email: Biologics.register@manchester.ac.uk

Telephone: 0161 275 1652 / 7390

Website: www.bsrbr.org

Follow us on twitter for news and updates!

@BSRBR RA