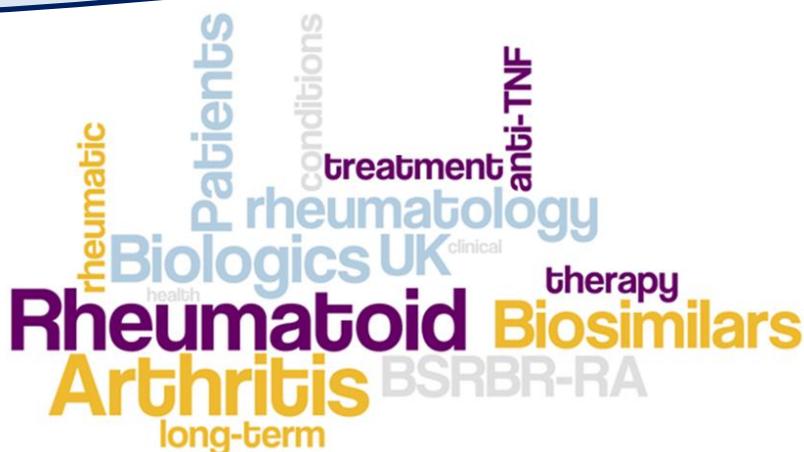


Welcome to the BSRBR-RA study newsletter, which is circulated to participants who are involved in this important research study. It may have been a while since you have heard from us, so we just wanted to send an update to you on how things are going, what we have found out so far and what we hope to find out in the future.



What is the BSRBR-RA study?

We are **proud** to be one of the largest registers **in the world** for rheumatoid arthritis (RA) patients receiving new treatments. Since 2001, we have registered **over 23,000** people who have started treatment with a biologic therapy, biosimilar or DMARD therapy.

The BSRBR-RA (based in the Biologic Studies Group at the University of Manchester) is what is known as a long-term prospective **observational** cohort study. This means that we recruit people who are starting treatment with a biologic therapy, and then collect information via questionnaires at regular intervals to see how things are going. Alongside this group, we collect data from a comparison group of people with RA who are receiving treatment with non-biologic DMARD therapy (such as methotrexate or sulphasalazine) who have never received biologic treatment.

Currently, we collect information from participants directly every six months for three years, but we continue to collect information from your consultant beyond this time. The data collected from both the participant and the consultant in the biologic group are used alongside the data collected from the people in the comparison group, to **compare** the **safety and effectiveness** of the treatments and see if there is any increased risk of developing certain types of illnesses in the biologic therapy group or not. We are different from a clinical trial, as **we do not influence the treatment**

you receive, but rather watch what happens when you take the treatment that your consultant rheumatologist prescribes you. Although these treatments are fully licensed and prescribed by the NHS there is still a need to monitor their **impact in the long term**, which is the main role of the BSRBR-RA.

By participating in the study you will help us build up the amount of data we have for analysis. With more data, we will be able to reach **better-informed conclusions** on the long-term safety of the treatments. Of course, all of the data submitted to us is treated **confidentially**, and your identifiable information will strictly not be shared with anyone outside the study team, aside from the national **Health & Social Care Information Centre (HSCIC)** for data-flagging purposes. The HSCIC (or National Records of Scotland) collect statistics on health outcomes across the UK in collaboration with the NHS. Examples of this data include information on any resident of the UK who dies or develops a cancer. When a study participant is flagged, in the rare event that one of these health outcomes occurs, the researchers are informed. This means we have **lifelong follow-up** for all participants providing maximal amounts of information about long-term use of biologic therapy in adults with rheumatoid arthritis. **Thank you for your ongoing valuable contribution to this research.**



The journey from PhD student to Professor with the BSRBR-RA



Professor Kimme Hyrich, Principal Investigator on the BSRBR-RA. Kimme is also a consultant rheumatologist at the Manchester Royal Infirmary.

Kimme Hyrich came over from Canada (Winnipeg or the “Peg”) to the Arthritis Research UK Epidemiology Unit (now called the ARUK Centre for Musculoskeletal Research), at the University of Manchester in 2001 as a PhD student. She started working on the BSRBR-RA data as part of her studies and her early work showed the benefit of receiving methotrexate in combination with anti-TNF therapies. Kimme was awarded her PhD in 2005. Not long after, she took up a Consultant Rheumatologist post at the Central Manchester University Hospital NHS Foundation Trust and was promoted to Senior Lecturer in the Unit and Principal Investigator for the BSRBR-RA. As a clinical epidemiologist, Kimme has supervised many PhD students who have worked on the BSRBR-RA data over the years. Her main research interests are understanding how drugs work in both adult and childhood inflammatory arthritis, in particular looking at the safety of biologic therapies. In August 2015, Kimme was promoted to Professor of Epidemiology. In her spare time, Kimme enjoys spending time with her four year old daughter, Elsa and her husband John. She loves to travel, especially to Canada to visit her family and show Elsa where she grew up.

Biosimilars and the BSRBR-RA

“Biologic” medicines (which are made from living organisms using biotechnology techniques) have been used to treat rheumatoid arthritis in the UK since the end of the 1990’s. Many of these drugs are now reaching the end of their patents which means that other manufacturers can make similar versions of these medicines, known as “biosimilars”. This will result in a greater choice of treatments for patients available in the NHS but at the same time, because these drugs are not exactly identical to the original biologics, the BSRBR-RA study has been extended to follow patients receiving these new drugs. If you do start a biosimilar, please make sure your rheumatology team has either registered you with the BSRBR-RA (if you have not been registered before) or updated our records (if you are already participating in the study). If you want to read more about biosimilars, there is information available on the NRAS website: www.nras.org.uk/news/first-biosimilars-for-rheumatoid-arthritis-launch-in-uk



Dr Kath Watson coordinates the BSRBR-RA study and works with Prof. Hyrich and the team to process/analyse the data that you send us.



What is the Biologic Studies Group?

The Biologic Studies Group is a group of researchers based at the University of Manchester who are interested in the long-term health outcomes of new ‘biologic’ and ‘biosimilar’ therapies prescribed in the UK for rheumatic conditions such as rheumatoid arthritis and lupus in adults and arthritis in children.



Finding out what patients with RA want to see in our research

Representatives of the BSRBR-RA team were lucky to be able to meet some members of the National Rheumatoid Arthritis Society (NRAS), which is a charity organisation dedicated to providing information and support for people diagnosed with Rheumatoid Arthritis and other conditions.

The purpose of the visit was for the BSRBR-RA to hold a focus group to investigate what data could be collected directly from patients, as well as to find out how would be best to collect these data. We also discussed how best to engage with patients who are registered on the study, to encourage the completion of the questionnaires, as well as to update participants on study progress.

We have included a summary of discussions below, but if you have anything that you would like to add then please get in touch! (Contact details at end of page 4)



Above - Prof. Kimme Hyrich meeting members of NRAS; some of whom were already involved in the BSRBR-RA .



How to collect the data

The focus group noted that that patients need a choice of data capture methods. For some patients, filling out a paper based form isn't possible due to their illness, and a web-based option to submit data would be welcomed. This may require a change to how we contact patients, so we will now look in to potentially collecting the patient's email address at the time of registration, in order to send reminders about completing questionnaires and so forth.

Which data

Currently, data are collected from you every six months for three years, and information on drug changes, hospital admissions and referrals is collected on a study 'diary'. Information about how you are feeling is also collected.

The focus group weren't aware that we would like to know temporary stops in their study diaries, and indicated that it was important to record medication start/stop dates in the diaries in 'real-time' otherwise this may be forgotten.

Remember:

You are always welcome to return to the study even if you miss returning some questionnaires!

Keeping participants updated

The focus group stated that often patients don't know how the data they submit are being used, so it is important to keep patients updated with any results or publications that are generated. Newsletters should be more regular, and links with NRAS stronger to get the research findings across to the wider community.

The BSRBR-RA is developing an online Patient Portal!

If you would be interested in finding out more, answering a few questions online, providing feedback or maybe being part of a focus group please contact:

Neil Wall, Portal Development Administrator
neil.wall@manchester.ac.uk





Dietary Advice for Patients on Biologic Therapy

Our findings show that, although we found the risk of bacterial infections (such as listeria and salmonella) to be low in patients on biologic therapy, our data suggests it could be lowered further by following the advice issued by the Food Standards Agency (FSA) for all patients on treatments which affect the immune system.

To further reduce the risk of these types of infections, the FSA advise that certain types of food should be avoided such as:

Blue veined cheese



Unpasteurised milk and ice-cream



Pâté



Undercooked eggs



Feta and goats cheese

Where can more information about Rheumatoid Arthritis and available support be found?

★ The **National Rheumatoid Arthritis Society (NRAS)** is an organisation whose aim is to provide information and support for people suffering from Rheumatoid Arthritis, along with their family, friends, carers, and anyone with an interest in RA. **They have a freephone helpline – 0800 2987650 or you can look at their website for more information: www.nras.org.uk**



★ The **British Society for Rheumatology (BSR)** is an organisation supporting health professionals working in the field of arthritis; their web page has a section with information for patients: **[www.rheumatology.org.uk/Patient Information](http://www.rheumatology.org.uk/Patient%20Information)**



★ **Arthritis Research UK** is a charity which campaigns on behalf of people with arthritis and funds research into making a difference to the lives of people with arthritis: **www.arthritisresearchuk.org**



★ The **BSRBR-RA** has a web page with information for participants in the study which can be found here: **<http://bit.do/BSRBR-RA>**



The **BSRBR-RA** is coordinated at the University of Manchester; the study manager Dr Kath Watson has been involved since the very beginning and leads a team of around 15 people. The project assistants are available to answer any questions you have about the study. We are unfortunately unable to provide any medical advice regarding your rheumatoid arthritis; for this, you should contact your rheumatology department.



Dr Kath Watson and the team at the University of Manchester

BSRBR-RA

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Follow: [@BSRBR_RA](https://twitter.com/BSRBR_RA) for study news and updates.

CONTACT US



You can use our handy QR code to take you direct to our patient information page!

