



The British Society for Rheumatology
Biologics Register Ankylosing Spondylitis
(BSRBR-AS)

Participant Transparency Information Sheet

You are receiving this notification because you agreed to take part in the BSRBR-AS study. The BSRBR-AS has been set up to monitor the safety of treatments for Ankylosing Spondylitis (AS) patients and to find out more about how treatments affect the lives of AS patients in areas like work, driving and general quality of life. The study collects data from you directly through patient questionnaires and from your local rheumatology team when you attend your routine rheumatology appointments at the hospital for your AS.

We are required by law to let you know what we do with your data and how we keep them safe.

What we do with your data?

The University of Aberdeen and the British Society for Rheumatology, as data controllers for BSRBR-AS study, are responsible for processing your data fairly and lawfully according to the Data Protection Act. Processing data here means collecting, using and sharing data you provide through study questionnaires and data your rheumatology team collects as part of your routine clinical care. Data processing will only ever be for the purposes of this study. When you signed the consent form to participate in the BSRBR-AS study you gave us permission to process these data.

How do we keep your data safe?

The data we receive from you and your rheumatology department are treated with utmost confidence.

Paper: All study documents (consent form, questionnaires and diary cards) will identify you using a unique ID number. Documents with your name and contact details are stored separately from all other study materials. When we receive a diary card with your name on it we will obscure your name before filing it away. All study materials are kept in locked cabinets and are accessible to BSRBR-AS staff only.

Electronic data: Our study database is held at the Robertson Centre for Biostatistics at the University of Glasgow. Access to the database is password protected and every user has his/her individual user name and password. Access to the database is also role and location based. This means that staff will only see what they need to see in order to perform their duties. For instance rheumatology nurses in Newcastle will only have access to data of their patients, and at the University of Aberdeen your name and address is only available to the persons who send you questionnaires but not to the person who enters questionnaire data into the database. Who gets access to the database is determined by the University of Aberdeen and the Robertson Centre for Biostatistics. Before we grant access to anybody we check that they are entitled to have access and have undergone the necessary training. Any access to study information held on University of Aberdeen computers is restricted to the BSRBR-AS team via a University of Aberdeen username and password. Any files that

contain participants' names and contact details have an additional password that is only known to the BSRBR-AS team.

Who might we share your data with: Approved data processors (who have appropriate security measures in place) might have access to your data for data processing purposes only.

- Researchers outside the BSRBR-AS can apply to the British Society for Rheumatology to get access to an anonymised study data set to answer important research questions. If your information is provided as part of a larger dataset to researchers outside of the BSRBR-AS team, we will not include any information that could identify you. We will also replace your unique study ID with another random ID number.
- A pharmaceutical company (UCB) who manufactures one of the therapies we study might have access to your study data for further safety monitoring but this will not contain your name, NHS or CHI number, address or full date of birth. As this company is international, there is a small possibility that medical information from the study may be sent outside Europe/ the European Union.
- Any study results or published reports using your data will not include your name, full date of birth, NHS/CHI number or address. We publish results from the study as we go. These are shared and presented globally. The researchers who work with the data use anonymised datasets, which means they do not contain any information that could identify you. There is a section on our website where you can see the scientific publications of our study.

What do we mean with "data linking": When you consented to the study you were asked permission to link your study data to certain information about your health that is held in national databases. If you agreed to this, we share some identifiable information (including your name, NHS or CHI number, address and date of birth) with NHS national databases/registers such as NHS Digital and NHS Central Register. This allows us to get additional information about your health, for instance about your hospital stays and appointments outside rheumatology or if you develop a serious condition such as cancer. This information will allow us to verify information we already hold and to fill in the gaps where information is incomplete. With this additional information we will be able to reconstruct a more complete picture of your AS and the safety of biologic treatment. From your number of out-and inpatient hospital appointments will also be able to work out the healthcare costs associated with AS. We will not get any data from your GP through data linkage.

What if you do not wish to continue with the study?

You can choose to withdraw from all or part of the study at any time by contacting the researchers at the University of Aberdeen on 01224 437141 or via bsrbr-as@abdn.ac.uk. These details are printed on all questionnaires that you receive from us.

If you notify us that you wish to withdraw from the study, we will not contact you again. However, we will use the data collected prior to your withdrawal.

If you would like to provide feedback to us, or have any questions, please drop an e-mail to bsrbr-as@abdn.ac.uk or call 01224 437141 and ask for Claudia Zabke, the Study Manager.

How long will we keep your data?

Your data will be kept for 10 years after the closing of the study.

Jargon buster

(taken from <http://readgroup.co.uk/wp-content/uploads/2017/02/GDPR-Jargon-Buster-PART-1.pdf>)

Personal Data: A person's data (name, ID number, location data, online identifiers or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of the natural person).

Personally Identifiable Information (PII): Any bit of information (data) that allows you to identify an individual person.

Consent: Unambiguous indication, or clear positive action an individual gives (via verbal agreement, or expressed in writing) signifying they agree with the processing of their Personal Data. Consent can also be called 'permissions'.

Data Controller: The organisation that collects and uses Personal Data. The Data Controller is a person who (either alone or jointly or in common with other persons) determines the purposes for which, and the manner in which, any personal data are, or are to be, processed.

Data Processor: The organisation that processes personal data on behalf of the Data Controller. The Data Processor is any person (other than an employee of the Data Controller) who processes data on behalf of the Data Controller.

For more information please visit our website www.abdn.ac.uk/bsrbr-as

Meanwhile I would like to thank you for your willingness to take part in the study.

Professor Gary J Macfarlane
Chief Investigator