PATIENT INFORMATION SHEET AND CONSENT FORM

STUDY TITLE : South African Rheumatism and Arthritis Association (SARAA) Registry of patients on Biologic Disease modifying anti-rheumatic therapies (DMARDS) for rheumatic diseases - Surveillance of adverse events

PROTOCOL NUMBER: SABIO 001

SPONSOR: SARAA

The South African Rheumatology and Arthritis Association (SARAA), an association of doctors specialising in the field of rheumatology, would like to enrol you onto the Biologics Register and invite you to participate in a research study on biologic therapies in rheumatic disease. This patient information leaflet contains the details of the Registry and the research study and what is being requested of you. Please read the information provided. If there is any information that is unclear, please ask your doctor for this to be explained. Participation in this study is your choice. If you do not wish to take part, you do not have to. You will receive the best standard of care whether you take part or not. You will be given a copy of the signed Patient Information and Consent Form to keep.

What is the reason for the study?
This study is to establish how safe the biologic therapies are in the treatment of rheumatic diseases. The aim is to assess whether these treatments have more side effects such as infections or cancers, than usual treatments. It will also establish how safe these treatments are when taken for a long period of time. This will mean that you will be followed up to assess the frequency of side effects.

The Registry will contain details on how patients are treated, and will allow us to better understand the condition and how it is being treated. SARAA will use this information to make presentations, compile reports and to analyse the information to make recommendations on the future treatment of rheumatic diseases. This is, in the end, in the interest of the country's healthcare and all patients.

Why have I been chosen?
You have been chosen to participate either because you are going to start a biologic treatment, currently taking one of the biologic treatments or on an established treatment and can provide a useful comparison. Your participation is entirely voluntary. It will not influence any treatment that you will receive. Your treatment will be determined by your clinical condition and will be started and stopped as appropriate. If you do agree to participate, then you will be requested to sign the consent form. You are free to withdraw from the study at any time without any penalty or loss of benefit to which you are entitled. If you decide to withdraw from the study your information

collected before you withdraw will still be part of the study data. However no new information about you will be collected.

What does it involve?

1. You will have to agree to complete a HAQ questionnaire which will take about 5 minutes. The HAQ questionnaire will assess how your arthritis affects you. In addition you will be contacted by the SARAA research nurse every 12 months to complete the 'Patient follow up' questionnaire. You will be asked to update all your medications, inform us of any hospitalisation or infections in the past 12 months. The questionnaire will take 5 minutes to complete.
2. You will have to agree that your doctor will provide relevant information from your medical records to the researchers.
3. You will have to agree that your name and the information will be registered in a database held by SARAA. SARAA will however never release information that could be used to identify an individual and will not give any third party access to the database.
4. SARAA will keep the information on the registry indefintely, so as to ensure that South Africa builds up a good understanding of the disease and its treatment.

Is my personal information kept confidentially?

Any information obtained in connection with the study that can identify you will remain confidential. Your study doctor will include information about you medical history, procedures, test results and response to therapy. Your identifiable information can only be accessed by the SARAA research team which includes the investigators, research nurse and database managers – E2 solutions (or any other contractor who may take over from them). Your name and other personal information will be coded. You can only be identified by a unique number which will be allocated to you. Your identifiable information will be kept secret from every-one else and will not be disclosed without your permission. All the staff and contractors that will work on this project will be bound by the strictest rules of confidentiality and non-disclosure.

Will my participation affect my healthcare?

The Registry and study is only about your healthcare information, and will not influence the care you have received, or will receive. This is what one calls a "non-intervention" study, which means that SARAA in no way determines or prescribes what treatment you get. It merely documents what happens in your care.

ETHICS APPROVAL OF TRIAL

The Protocol of this clinical trial was submitted for approval to the Pharmaethics, a research ethics committee registered with the National Health Research Ethics Council. Written approval has been granted by Pharmaethics for the conduct of the trial. The study has been structured in accordance with the Guidelines on Clinical Trials and Ethics in Health Research, published by the Department of Health and the Declaration of Helsinki (last updated October 2008), adopted by the World medical Association (WMA), which deals with the recommendations guiding doctors in biomedical research involving human participants. Copies of these documents may be obtained from the study doctor should you wish to review it.

Contact person for the study
You can contact your treating doctor should you require more information about the study or the Registry. His/her contact details are:

DR _____

_____	_____	_____
Email	Fax no	Telephone no

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I,_____(insert full name), a patient of Dr _____(insert initials and surname), with my ID number_____, of address _____ _____and Tel no:_____and email address_____,

Hereby confirm and acknowledge that -

Please initial or mark each box to indicate your agreement with each statement.
Please ask if you are unsure about anything:

- I have read and understood the patient information sheet provided for the above study and my inclusion in the SARAA registry. I understand the importance of this, and the implications of my information being included. ☐
- My participation is voluntary and I am free to withdraw at any time, without my medical care or legal rights being affected. ☐
- I agree that my information may be included into the SARAA biologics registry, irrespective of whether I am being treated with a biologic or not. ☐
- I agree to participate in the above mentioned study and Registry and to complete the questionnaires and survey or assist the doctor in completing it. ☐
- My treating doctor may provide the SARAA researchers with information that is relevant for the study and Registry, from my health records. ☐
- I understand and agree that my data, as entered into the Registry, may be used for future studies and analysis, in the manner described on this form, in the interest of health information, health planning and in the ultimate interest of all patients with rheumatic diseases. ☐
- I agree to my personal information to be held in a registry by SARAA ☐

and the data base administrator E2 solutions (or its successor), together with data that is collected during the study.

- I agree to and understand that no identifiable information will be released to any third party. My information may be included with those of other patients in a de-identifiable format as part of research reports, articles, presentations and the like. I understand that this is for scientific purposes and advancing the understanding of the disease and its treatment.

Name of participant	Date	Signature
Name of Person taking consent	Date	Signature

1 for patient; 1 for case notes; 1 for the researcher at SARAA.