Switch
Treatment Options for Refractory Rheumatoid Arthritis

Delete this, then print first page of Information Sheet and Consent Form on Trust/Hospital headed paper

SWITCH: Clinical Trial for Patients with Rheumatoid Arthritis who haven't benefited from an initial TNF-blocking drug.

IMPORTANT INFORMATION ABOUT THE FUTURE OF THE SWITCH CLINICAL TRIAL

Dear SWITCH Study Participant,

Many thanks for your participation to date in the SWITCH study, a clinical trial comparing three types of drugs in the treatment of rheumatoid arthritis. We are writing to you today to update you on some recent developments in the study, explain why they have happened and explain how you will be affected.

At the end of 2014 the SWITCH study's funders (the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme) came to a decision to withdraw their future funding for the study. The reason they made this difficult decision was simply because they could not justify the additional timeframe, and therefore resource, that would be needed to recruit all the participants to complete the study. It is important to highlight, that the decision was in no way made due to any concerns about the safety of the study; the study is still safe for all current participants to continue with. The decision was purely due to the difficulties in justifying additional finances needed to support finding enough participants including within an acceptable timeframe.

Unfortunately this means there will be some changes for those people taking part in the study.

The way you will be affected depends on whether you are still receiving treatment as part of the study:

Participants who are still receiving their study treatment

- **Treatment:**
  If you are still in the first 48 weeks of your treatment (the interventional phase), and you are still receiving the drug you were allocated at the time you joined the study then you will continue with your treatment as normal until week 48. As mentioned above, there are no safety concerns about the treatments and it is completely safe to carry on taking part in the study.

After week 48, you will continue to be treated according to your hospital's local policy. This is the same as was described in the original Participant Information Sheet you were given when you joined the study.

- **Visits:**
  You will still be asked to come to visits at your hospital every 12 weeks until you reach week 48 of your study treatment so we can continue to collect information about the study from you. It is still important that we collect as much information as possible about the people taking part and therefore it is important that you carry on taking your treatment and coming to the visits.

  However, previously we would have asked you to carry on coming to clinical study visits after your study treatment had finished to continue collecting information about you for the SWITCH study. Instead, your doctor will decide how often you need to come to hospital visits. There will be no more information collected about you at these visits specifically for the SWITCH study.

  Also, if for any reason you stop taking your study treatment before week 48, then you will no longer be required to provide information for the SWITCH study after 24 weeks (this is the time to undertake the primary study analysis); once again, your doctor will decide how often you need to come to hospital visits and what information needs collecting.

Participants who have finished their study treatment

- If you have already finished 48 weeks of study treatment then your next visit will be your last visit and we will not be asking you to come back for any more visits to collect information about you for the study. Instead, your doctor will decide how often you need to come to hospital visits and there will be no study information collected about you at these visits.

Please note: Regardless of whether or not you are still receiving your study treatment, you will still receive NHS care for the treatment of your Rheumatoid Arthritis; there will be no reduction in the standard of NHS care you will receive.

X-rays and bone densitometry scans

In addition, study participants at some hospitals were having x-rays of their hands and feet and bone densitometry scans of their back and legs (your research team will be able to discuss with you whether this applies to you as these parts of the study were optional and hospital sites had the choice to undertake them or not). Although the study will still use the information from the scans performed so far, no further scans will be performed for the study from this date forward.

- **What will happen to the results of the research study?**

Unfortunately, as there have been fewer participants recruited onto the study than we had planned we will not be able to draw significant conclusions as we intended. However the data is still important and useful: we will be able to look for potential patterns of how well the treatments work which will inform further research in this area. The Health Technologies Assessment programme will publish any outcomes from the study on their website. If you would like to obtain a copy of the published results, please ask your doctor. We may also be able to combine the results with those from other studies, in order to strengthen our findings. If your information is used in combination with other studies, your personal details will not be used to identify you.

We are very keen that you continue your participation in the study and allow us to collect information about you at your next visit and until the end of your study treatment (where relevant). However, if for any reason you should wish to withdraw from the study then please contact your doctor to discuss this.

If you have any questions about anything in this letter, please talk to your doctor at:

<<Enter PI, nurse name>>

<<contact details for site>>

SWITCH: Clinical Trial for Patients with Rheumatoid Arthritis who haven't benefited from an initial TNF-blocking drug.

Participant ID:	Initials:
Date of Birth:	NHS/Hospital Number:
EudraCT Number: 2010-023880-17	Principal Investigator:

IMPORTANT INFORMATION ABOUT THE FUTURE OF THE SWITCH CLINICAL TRIAL

We would like to thank you for your participation in the SWITCH trial and taking the time to read this letter.

We would be grateful if you could acknowledge receipt of the letter below.

I confirm that I have read and understand the information sheet above and have had the opportunity to ask questions. ☐

I agree to a copy of this acknowledgement form being sent to the CTRU. ☐

Participant:

Signature……

Name (block capitals)……

Date……