### Adult Participant Information Sheet

### Biomarkers of Relapse In ulcerative colitis patients after Tofacitinib dose rEduction

### BRITE

*Thank you for taking the time to read this leaflet.*

You are being invited to take part in a research study. Before you decide, it is important that you understand why the research is being carried out and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your GP if you wish. Do not hesitate to ask us if there is anything that is not clear, or if you would like more information. Please take time to decide whether you wish to take part.

**What is the purpose of the study?**

Tofacitinib is a new and effective treatment for patients suffering from ulcerative colitis (UC).

Current practice is to commence treatment at a higher induction dose, and if a good response occurs then to reduce the dose to the lower maintenance dose. However, some patients, following reducing to the maintenance dose, will experience a relapse requiring returning to the higher dose. Unfortunately, currently we do not have any way of predicting who is more likely to relapse.

The purpose of this study is to identify factors that may help us predict who is more likely to relapse following reduction of the tofacitinib dose. We hope that determining such factors would help us tailor our therapy to individual patients, enabling us to identify patients who may benefit from remaining on the higher dose.

**Why have I been asked to participate?**

You have been asked to participate because you are on tofacitinib and are being considered to have your dose reduced to the maintenance dose.

**Do I have to take part?**

No. It is up to you to decide whether or not to take part. If you decide not to take part it will not affect the standard of care you receive. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you do decide to take part, you are still free to withdraw at any time and without giving a reason. This would not affect the standard of care you receive. If you do withdraw from the study, with your consent, we would still like to keep any data collected up until the point of withdrawal and may also collect follow-up data that is collected as part of standard care.

**What will happen to me if I agree to take part in this study?**

If you agree to take part, you will go ahead with your flexible sigmoidoscopy (camera test) as planned. If during the procedure it is determined that you have had a good response to tofacitinib, the endoscopist will take a series of 12 extra biopsies for this study in addition to 2-4 standard biopsies. The biopsy samples will be used for two purposes; 1, to make another assessment of how active your colitis is and 2, to carry out scientific analysis to identify genes that may act as predictors of relapse. This analysis aims to study RNA (a photocopy of the DNA), which acts as a messenger and can give important clues about the processes that occur within the bowel during disease relapse.

Immediately following the procedure, in addition to standard baseline blood tests we will also take an additional vial of blood for this study (approximately 5 teaspoons). This will be to allow us to perform analyses looking for inflammatory messengers and markers that may predict relapse.

Should you undergo another flexible sigmoidoscopy if you were to relapse, and after 44 weeks of dose reduction as is standard, the study biopsies and blood tests will be repeated in addition to standard tests. Otherwise, you will be managed by your treating team in the standard way. Your participation in the study will end if the relapse means that you need to stop tofacitinib and commence a different drug, or if the relapse means that you require a surgery to remove the large bowel. Participating in this study will not affect how you are treated. We will monitor your progress and collect your data that will come from your standard investigations and management.

At the time of disease relapse (if this occurs) and at week 44, we would also ask for a stool test (faecal calprotectin) as a routine test. No additional tests will be performed on the stool and we would request this as routine, even if you were not participating in this study. We ask that you bring the stool specimen pot and give this to the study investigator at the time of the endoscopy procedure.

**Are there any risks to me?**

There are no additional risks to you if you take part in the study. Taking part in the study will not affect your current treatment, nor will it affect your ability to obtain insurance for health purposes. There are no additional risks taking biopsies at the time of endoscopy and will only had 2-3 additional minutes to the procedure. There will be no additional risks to you from taking blood tests for the study and these will be taken at the same time as your routine blood tests.

**What are the possible benefits of taking part?**

Although there are no direct benefits to you by taking part, the results and analyses from this study may help other patients who have ulcerative colitis and are being treated with tofacitinib.

**What will happen if I don't want to carry on with the study?**

If you change your mind about taking part in the study, then that is no problem. You can stop being part of the study at any time, without giving a reason. You will be withdrawn from the study and you will be monitored and treated in the same way as any other IBD patient.

**What will happen to my blood samples?**

Your blood samples will be sent to the laboratory at St Thomas’ for standard analyses, with the additional vial sent to King’s College London for analysis of relevant inflammatory proteins and markers. Your samples may also be stored anonymously for an extended period for use in future studies. The results of the routine clinical bloods and biopsies will be accessed by the research team.

**What will happen to my stool samples?**

Stool samples will be sent to our pathology department where they will then be sent to King’s College Hospital to be analysed for levels of faecal calprotectin, a protein which is increased when the bowel is inflamed. No additional testing will be performed on stool for the study. We would have requested this to monitor levels of inflammation whether you enrolled in this study or not.

**What will happen to my biopsy samples?**

Some of your biopsy samples will be sent to the histopathology laboratory at St Thomas’ for analysis in the standard manner. These will also be processed and stored in the standard manner. Some of your biopsy samples will also be sent to a laboratory at King’s College London (Guy’s campus) for analysis to investigate whether any specific gene or immune markers may predict relapse occurring. Your samples may also be stored anonymously for an extended period for use in future studies.

**If I participate will my personal medical information be kept confidential?**

All information that is collected about you during the course of the project will be kept strictly confidential. Any information about you, which leaves the research centre, will have your personal details removed so that you remain anonymous. Anonymised results generated from this study will be made available to researchers in the scientific community, including scientists from the pharmaceutical company (Pfizer) who have supported this study.

All study data will be kept in a secure office for clinical research staff at Guy's & St Thomas' Hospital for up to a maximum of seven years. Only members of the medical and research team with the adequate security clearance will have access to the office. They will also be kept as safe as possible from other damage such as fire or water damage.

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

The results and analyses will form the basis of a post-doctoral research degree (MD (Res)) at King’s College London. We hope to be able to publish the results of this research and will be happy to provide you with a summary of the conclusions in lay terms and a copy of the publication, if you request it. This will be posted to you. You will not be identifiable in this publication.

**Who is conducting the research?**

This study will be carried out by a Clinical Research Fellow (Dr Sailish Honap) under the supervision of Dr Peter Irving (Consultant Gastroenterologist) at Guy’s and St. Thomas’ NHS Trust and King’s College London.

**Who has reviewed the study?**

All research in the NHS is reviewed by an independent group of people know as the Research Ethics Committee (Yorkshire & The Humber - Leeds East Research Ethics Committee) to protect your safety, rights, wellbeing and dignity.

**How have patients and the public been involved in this study?**

There has been involvement from IBD patient representatives that sit on our project board committee, which takes place at Guy’s and St Thomas’ Hospitals. They act as a patient voice and review how we plan to conduct the study to ensure everything is above board. There were no concerns raised by patient representatives on the panel and the project was approved.

**Who is organising and funding the research?**

This study is funded by an unrestricted grant from Pfizer (a pharmaceutical company).

The sponsor of the research is Guy’s and St. Thomas’ NHS Trust and is co-sponsored by King’s College London. The sponsor may decide to stop the study at any time and if this happens the reasons will be explained to you. This will not affect your on-going clinical care. Any anonymised data that has been collected up until this time point will be used for analyses.

**What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the Guy’s and St Thomas’ Patients Advice and Liaison Service (PALS) on 020 7188 8801, pals@gstt.nhs.uk. The PALS team are based in the main entrance on the ground floor at St Thomas’ Hospital and on the ground floor at Guy’s Hospital in the Tower Wing.

In the event that something does go wrong and you are harmed during the research and this is due to someone’s negligence then you may have grounds for legal action for compensation against Guy’s and St Thomas’ NHS Trust and/or King’s College London but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

**How will we use information about you?**

As co-sponsors of this research Guy’s and St Thomas’ NHS Foundation Trust and King’s College London University need to use information from you and from your medical records for this research project. This information will include your initials/name/ contact details/ date of birth/NHS number.  People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

**Will my information be shared?**

Anonymised results generated from this study will be made available to scientists from the pharmaceutical company (Pfizer) who have supported this study.

Pfizer will be sent the results in the form of an anonymised written aggregated / summarized study report.

**What are your choices about how your information is used?**

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from [central NHS records/ your hospital/ your GP]. If you do not want this to happen, tell us and we will stop.

We need to manage your records in specific ways for the research to be reliable. This means that we won’t be able to let you see or change the data we hold about you.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

**Where can you find out more about how your information is used?**

You can find out more about how we use your information

* at [www.hra.nhs.uk/information-about-patients/](https://www.hra.nhs.uk/information-about-patients/)
* our leaflet available from [www.guysandstthomas.nhs.uk/research/patients/use-of-data.aspx](https://mail.gstt.nhs.uk/owa/redir.aspx?C=DHTFy2BXy6XgCwTzWQQyVehkHzf7okb1ADRMS6LSbDPLPF6M25XYCA..&URL=http%3a%2f%2fwww.guysandstthomas.nhs.uk%2fresearch%2fpatients%2fuse-of-data.aspx) and [www.kcl.ac.uk/research/support/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research](http://www.kcl.ac.uk/research/support/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research)
* by asking one of the research team (contact details below)
* by contacting our data protection officer: Nick Murphy-O'Kane, Contact: [DPO@gstt.nhs.uk](https://mail.gstt.nhs.uk/owa/redir.aspx?C=QGqIYjXYn0PhosYe3tfRMO4lKEy1VrFyGNyZxJ_5O4HLPF6M25XYCA..&URL=mailto%3aDPO%40gstt.nhs.uk) or Albert Chan info-compliance@kcl.ac.uk

**I have some further questions or if there is problem, who can I ask?**

If you would like any further details, please contact Dr Sailish Honap (Clinical Research Fellow) or Dr Peter Irving (Consultant Gastroenterologist/Principal Investigator) through the gastroenterology department on 02071882499. They can also be contacted via the gastro admin team by emailing gst-tr.gastroenterologyofficestaff@nhs.net