PATIENT INFORMATION SHEET Control Group	***(Insert Local Trust Letterhead and Contact Details)***

PRE-EMPTIVE PHARMACOGENTIC TESTING FOR PREVENTING ADVERSE DRUG REACTIONS (PREPARE STUDY)

PRINCIPAL INVESTIGATOR: PROFESSOR SIR MUNIR PIRMOHAMED

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends or relatives if you wish. If there is anything that is not clear, or if you would like more information, please ask. This is a voluntary project, and if, when you have heard about the study, you would prefer not to take part, your decision will be accepted without question and will not affect the standard of care you receive.

WHAT IS THE PURPOSE OF THE STUDY?

Most diseases or illnesses require treatment with medication, which can either cure the disease or control the symptoms. Unfortunately these medications can sometimes have side effects, some of which can be serious. We all vary in how our body responds to medication, which can result in differences in how well it works. There is recent evidence to suggest that a person's genetics (the basic building blocks of life) play an important role in this variability. Humans have around 20,000 genes which all have specific functions relating to different processes in the body. For example, some genes produce an enzyme or protein which breaks down medications. Variability in these genes may make some people break down a medication very quickly whereas others may break it down very slowly.

Currently, your genetics are not being taken into account when a doctor prescribes you a medication. Everyone receives a standard dose and choice of medication, regardless of how we break down or respond to the medication. Recent advances in technology mean we can now test a person's normal variation in genes and use the information to work out if a medication or particular dose is likely to help them or result in side effects. This process is call personalised medicine.

The purpose of this study is to find out if personalising medication lowers the chance of experiencing serious side effects. We will do this by comparing the standard way medications are prescribed with a method that takes into account an individual's genetic information. Additionally, information will be collected to find out if the new method improves quality of life and is cost effective.

WHY HAVE I BEEN CHOSEN AND DO I HAVE TO TAKE PART?

You have been chosen for the study to participate in the control arm because you have been given a new medication, or are soon to start a new medication, which has been prescribed for you by your doctor in a standard way. This medication is already registered and is therefore safe to use at the dose you are currently taking.

We are recruiting a total of 8100 patients from 8 different countries across Europe and need 1500 patients from the United Kingdom. Participation is voluntary and if you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. You will be free to withdraw from the study at any time without giving a reason.

WHAT WILL HAPPEN TO ME IF I TAKE PART?

If you decide to take part in this study it will not affect your usual clinical care in any way. That is, you will continue to take all current medications or continue with any planned treatments, as prescribed by your doctor/GP. If you decide to take part we will:

- Take either a 9mL blood sample (2 teaspoons) or saliva sample (approximately half a teaspoon) to look at your genes. This information will not be used to tailor your new medication because you are in the control (comparison) group, but it is important information for the statistical analysis.
- Obtain information from your health care records regarding your medical history and the medications you are taking.
- Inform your GP of your participation in the study.
- Follow you up with a telephone call, between 2 and 3 times over the 18 month follow up period. These calls will take around 15-20 minutes and we will ask you questions relating to changes to your medical history, the medications you are taking and any admissions to hospital.
- Ask you to contact the research nurse if you experience any side effects to your medication or have an emergency admission to hospital
- Ask you to fill in an online questionnaire 2 times over the 18 month follow up period. This will also help us to collect information regarding any side effects you may have experienced.

If you do experience any side effects or have an adverse reaction to the medication, we will check your health records to find out whether your doctor has ordered any further blood tests or investigations and record the results. Depending on the severity of the side effects or reaction, we may ask you if we can take additional blood samples:

- 9mL blood sample (2 teaspoons) to assess the drug levels in your body **(a maximum of 36mls (8-9 teaspoons) will be collected within a rolling 4 week period)**
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- If we are unable to collect a blood sample from you, we will do a thumb/finger prick test to collect a small blood sample

During the course of the study, we will ask that you:

- Inform us if you experience any side effects which you think may be due to the new medication or have an emergency admission to hospital
- Inform the research nurse if you start taking another medication that we are interested in (we will provide you with a list of the medications that are of interest to us in this study).

  - For each new medication of interest that you start within the 18 month follow up period, we would like to conduct up to a further 3 telephone calls and ask that you complete the online questionnaire up to a further 2 times. However, this is not compulsory.
- Inform us if your contact details change.
- Inform us if you become pregnant.

WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?

The disadvantages of taking part in this study may be:

- Some minor short lasting discomfort from having a blood test.
- Collecting half a teaspoon of saliva may take some time, although the amount does not cause any problems in adults.
- Additional time to complete the telephone surveys.

Taking part in the study will not affect your current treatment, nor will it affect your ability to obtain insurance for health purposes.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

It is unlikely that the study will be of direct benefit to you immediately; however, it may benefit you in the future, if it is found that genetic testing when starting a medication may lower the chance of experiencing side effects. You will also have an opportunity at the end of the study period to request a card on which your genetic information is printed. This may be of some benefit to you in the future.

WHAT WILL HAPPEN TO MY BLOOD TEST?

Your blood sample will be assigned a random code and all identifiable information (such as name and contact details) will be removed before the sample leaves the hospital. Your blood samples will stored as detailed below:

- The sample to look at your genes will be sent to the University of Liverpool where it will be stored. A small amount of this sample will be sent to Liverpool Clinical Laboratories at the Royal Liverpool Hospital and used to obtain your genetic results. The remaining sample will be stored at the University of Liverpool until it is used up.
- The sample to monitor drug levels will be sent to the University of Liverpool where it will be stored until used up. A small amount (approximately 400 microliters) will be sent to Dr. Margarete Fischer-Bosch-Institute of Clinical Pharmacology in Germany for analysis

Your blood sample will be considered a gift to the University of Liverpool, which will act as custodian of all the samples obtained as part of this project. In some cases, a small amount of your sample will be provided to other researchers and may be sent to other countries inside and outside Europe. Your sample may be used in the future for unspecified research however, it is important to remember that the sample will only be identified by a code and therefore it will not be possible to trace it back to you. This testing will be restricted to investigating genes and other factors that affect

how patients respond to medications.

In the short-term, it is unlikely that the sample will be of any commercial value to the University or the hospital. However, it is possible that there may be some commercial value in the future, although it is important to note that any commercial value is likely to be due to findings in a group of patients rather than from samples from a single patient. You will not be paid for taking part in the study, nor will you derive financial benefit from future discoveries.

WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

As stated above the research team at the research site will be the only people who have access to your identifiable information and contact details. All information collected about you during the course of the research will also be kept strictly confidential. Any information about you, which leaves the hospital, will have your name and address removed so that you cannot be recognised from it.

WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?

Results from the project will be published in leading international medical journals.

WHO IS ORGANISING AND FUNDING THE RESEARCH?

This study has been designed by the Ubiquitous Pharmacogenomics Consortium and is being carried out by doctors and pharmacists at various hospitals and pharmacies across Europe (Austria, Spain, Greece, United Kingdom, The Netherlands, Slovenia and Italy). The study is sponsored by a grant from the European Union.

WHO HAS REVIEWED THE STUDY?

All research studies are reviewed by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed by [North West Liverpool Central Research Ethics Committee]

CONTACT FOR FURTHER INFORMATION

If you need further information or are worried about any aspect of the study, please do not hesitate to contact the research nurse working on the study, **[NAME]**, on **(INSERT CONTACT DETAILS]**

THANK YOU FOR READING THIS INFORMATION LEAFLET