



## **PARTICIPANT INFORMATION LEAFLET**

### **Assessing the Effectiveness of the NicoTest™ in helping people to stop smoking**

*Please also read the form “Health Research and You”*



*The purpose of this leaflet is to provide you with information on this study. You are welcome to take it home to read and consider whether you wish to participate. You are being invited to take part in a research study. Before taking part, we will ask you to sign a consent form which you may keep a copy of.*

*Thank you for reading this information leaflet.*

*Please note that all usual treatments are available from this pharmacy and you are not obliged to use the NicoTest™ – it is your choice.*

## **Invitation to participate**

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 others if you wish. Ask us if there is anything that is not clear or if you would like more information. Please take the time you need to decide whether or not you wish to take part.

## **Overview of the NicoTest Trial: What is being done and why?**

Smokers smoke for many reasons. However, it is a fact that there are two important aspects to consider when quitting; the physical addiction and the psychological need. Medication can help with the physical addiction and counselling can help with the psychological need.

Smokers also quit for many reasons but deciding what is the best way to quit can be difficult, even for nurses and doctors. Most professionals will make an educated guess based on a smokers smoking history. However, helping smokers to quit has still been a matter of trial and error....until now:

The NicoTest is a new way to help smokers to quit by making a treatment recommendation based upon an assessment of their individual levels of addiction and dependency. It uses new technology and offers a promising personalised programme. Your pharmacy is involved in a study that is testing if, or by how much, a smoker's chances of quitting are improved by the personalised NicoTest approach rather than the "one size fits all" approach. This means that some smokers wishing to quit will be invited to use the NicoTest (if they wish; they have a choice of all other current approaches instead).

The NicoTest uses a fingerprick blood sample from a smoker to analyse their genetics for only a few key variations which have been shown in scientific studies to have strong links to smoking and addiction. This enables the NicoTest to recommend the right medication at the right dose. This is only part of the NicoTest programme. The NicoTest also uses an online programme that helps smokers overcome the psychological need for nicotine. The NicoTest online programme is called the "Flight to Freedom" and includes 6 milestones that will help smokers prepare and continue their quit successfully. There are also other parts to the online programme which many quitters have found helpful, useful and fun.

The NicoTest provides detailed information about what treatment will help the smoker to quit successfully. For the NicoTest to provide a complete Personalised Treatment Programme some personal information is collected. For example, you will be asked about your age, height, weight and how many cigarettes you smoke.

By submitting a blood sample, you are consenting to the use of your data for this study. All data collected is used to provide smokers with a Personalised Treatment Programme, to improve the programme and to enable the NicoTest to be tailored to the smokers needs. Your information is stored on a secure server and cannot be accessed by unauthorised persons. When you register with the online programme you will be emailed a password, which you can change to something more memorable. We will not share any of your personal information with any other 3<sup>rd</sup> party. For example, if your insurance company asks us if you smoke we cannot and will not give them any information. It would be illegal and unethical to do so. If your pharmacist has provided the NicoTest to you then they will be able to access information to help them understand your health needs.

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

People find it very difficult to stop smoking. Because the way in which each person responds to their medication is different, a medication and a dose of medicine that is tailored to the individual could help people to quit more easily. This is because the side-effects and cravings should be minimised.

This study is testing a new way to help smokers to quit which involves measuring whether quit rates for participants are improved when compared to the service that is currently offered by the NHS.

The product on offer - which is free to the participants of this study - looks at a person's genetic makeup and lifestyle to predict how well the person will respond to their medicine. The study will be carried out in pharmacies and will involve:

1. your providing a small blood sample (four drops from a fingerprick)
2. the use of the internet to answer questions about your lifestyle and smoking behaviour
3. measurement of nicotine breakdown products in your saliva and breath.

Although the blood sample will only be taken once, the study will be run over 1 year. This is because we need you to re-visit your pharmacy at certain times in order to collect your medication and in order to do more saliva or breath tests, which should only take a few minutes. These tests help us to measure your smoking status.

### **Why have I been chosen?**

This study will involve around 500-1000 smokers. You have been chosen because you are a smoker who wants to give up and is happy to set a realistic quit date (quit date being that day on which you start your medication and therefore do not smoke any more). You have also been included in the study because you have an email address.

### **Do I have to take part?**

It is up to you to decide whether or not to take part. 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 decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

### **What will happen to me if I take part?**

First of all you will read the information leaflets and sign a consent form.

### **On your first visit: (the process will take around 30 minutes)**

The pharmacist will measure your level of nicotine breakdown product in your saliva (this will involve a "dipstick"-type test). The pharmacist will also measure the level carbon monoxide in your breath.

The next step involves the NicoTest™ process. A summary diagram of this part of the process is shown overleaf (page 3). The pharmacist will ask you to prick your finger using a simple and safe device. You will then place a drop of blood onto each of two pieces of absorbent paper. Once the sample is dry, it will be sent off to laboratories for genetics analysis (the pharmacist will post it for you free of charge). We will then investigate your genetic variation in your DNA (specifically within the dopamine receptor D2 gene, the dopamine beta hydroxylase gene and Cytochrome P450 2A6 gene).

Finally, you will be asked to complete a six-step questionnaire on the internet in the pharmacy. This works out your smoking (behavioural) habits and lifestyle. Pharmacy staff will be glad to help you if you are unsure of anything. You will need to enter your barcode (that is provided on the outer packaging of your NicoTest™) at the start of the test. The internet-based activity also involved typing in your chosen quit date: this is the first day that you become a non-smoker and is the first day that you start your medication. Prior to your quit date, you can change this date at any time.

The information from this testing will let NicoTest™ compile a personalised treatment report for you. The report will be emailed to you. This will suggest your ideal medication which could be nicotine replacement therapy or a medicine called bupropion (Zyban™). If nicotine replacement is recommended then a dose will also be recommended (determining whether you take gum or patches).



**Other visits to the pharmacy: (each visit should take a few minutes)**

We would then ask you to take your personalised treatment report back to your pharmacy or pick it up online at the pharmacy. The pharmacist can then issue you with the correct medication unless they think that you are unsuitable. You will need to start your course of medication on the day of your chosen “quit date” (this is the date that you recorded on the internet and it is stored for your reference). To get the most out of the process, you will need to stick to the recommended course of treatment as described in your personalised treatment report.

Please note: if your personalised treatment recommendation involves using bupropion (zyban) then you will first of all need to visit your GP because this needs to be prescribed.

Just before you buy your medicine, the pharmacist will ask you to provide a breath test and a saliva test.

Additional visits to the pharmacy will be once per week for the first 4 weeks after starting your medication. Other visits will be at 3 months, 6 months and 9 months after finishing your medication. This is to monitor your progress. You may find that you can combine some of your visits with the collecting of your medication.

If you have a mobile phone, you will receive a text message to remind you to come back to the pharmacy. Following up your progress is very important as this is the only way to see if the test helps you, and others, quit over the longer term.

**Your choice of what happens to your blood sample:**

As the NicoTest is about empowerment – empowering smokers to make informed choices about their health – the NicoTest invites smokers to decide how their blood sample will be used. This means that when you complete the computerized registration process you will be given a choice as to whether you want the company that makes the NicoTest to keep your sample in an anonymous database (for future research) or to destroy your sample.

**About keeping your sample on an anonymous basis:**

Given our charitable research origins, it is our company policy NOT to sell any data to any commercial organisation. Were beneficial research purposes to be identified we would ideally make the anonymous DNA data available to Non-Governmental Organisations (NGOs) engaged in healthcare research to facilitate and accelerate their research programmes. Our interest would be in licensing back any potential outcomes from that research using our experience and capabilities in this sector to provide patients with personalised treatment solutions. It is our policy neither to sell the DNA sample nor provide it to a commercial organisation. We would always contact you in the event that a research opportunity of the type described in this paragraph arose in order to get your informed consent to our use of your DNA sample in this way. We can assure you that we would comply with the then current best practice to ensure that any DNA sample we provided to an NGO had been anonymised. For the reasons outlined above we request that users choose this option but if you have any concerns please choose the *destroy the sample* option. Whichever option you choose we confirm that the primary use to which your DNA sample will be put is to advise you of your Personalised Treatment Programme and to carry out an internal validation of your PTP and the NicoTest™ Quit Programme.

**About destroying your sample:**

We will analyse your DNA sample and advise you of your Personalised Treatment Programme. Beyond being used by us to internally validate your PTP and the NicoTest™ Quit Programme, your DNA sample will not be used for research purposes and once the analysis required for the development and validation of your PTP is complete your sample will be destroyed. Once we have destroyed your sample you will still be able to participate in the interactive online programme in the same way that anyone else does. As long as you remain a user of the interactive programme you will receive emails relating to that process. You may opt-out of that email contact once you have quit.

If you would like to know more about the NicoTest then please visit our website. If you have a question that is not answered on our website then please contact us at [info@g-nostics.com](mailto:info@g-nostics.com).

We will use your genetic information combined with your lifestyle questionnaire data to predict which medicine is best for you and at which dose. We will also compare the success rates of the NicoTest™ in terms of how much it helps people to quit smoking with the success rate reported without using the NicoTest™. This way, statisticians will be work out whether using the NicoTest™ affects chances of quitting.

**What are the alternatives?**

At the moment, no other personalised treatment programme of this sort is available.

**What are the side effects of any treatment received when taking part?**

There may be side-effects for some people although the test is designed to minimise these compared to the current level experienced within the NHS. It is your Pharmacists responsibility to explain the side-effects and contra-indications for you chosen treatment. The providers of NicoTest™ do not provide the medication, they only provide the recommendation.

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

Although giving up smoking is not easy, we hope that the personalised treatment programme will help you to give up more easily. However, this cannot be guaranteed. The information we get from this study may also help us to treat future smokers. Your full participation is greatly appreciated.

**What if new information becomes available?**

Sometimes during the course of a research project, new information becomes available about the treatment/drug that is being studied. If this happens, your pharmacist will tell you about it and discuss with you whether you want to continue in the study. Through the website-based activity, you will be given the choice of whether you wish for your sample to be destroyed after taking part in this study or if you would like it to be kept for later research.

**What happens when the research study stops?**

Once this research study stops, the test will no longer be available free of charge. However, we are hoping that people will be able to have access to this test in pharmacies in the future.

**What if something goes wrong?**

'If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for this advice. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms should be available to you.'

**Will my taking part in this study be kept confidential?**

All personal information which is collected about you during the course of the research will be kept strictly confidential. The web-based activities comply with the data protection act and European Directives.

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

This study is being sponsored by the Guildford Clinical Pharmacology Unit (University of Surrey campus). The company that has developed the NicoTest™ is g-Nostics Ltd. The cost of the saliva testing and the NicoTest™ will be paid for by g-Nostics Ltd.

**Who has reviewed the study?**

Research Ethics approval for this study has been granted by an NHS-approved Research Ethics Committee in the area responsible for your pharmacy. This committee does not endorse the product: they are independent.

**Further Information**

You will find more information about the NicoTest™ on the website [www.NicoTest.com](http://www.NicoTest.com).

***Thank you for reading this.***