Barts Health NHS Trust
Contact: ashwin.kalra@nhs.net

Participant Information Sheet: DETECT-2 Study

Study Title: Direct to Patient testing at Cancer diagnosis for Precision Prevention-2 (DETECT-2)

IRAS number: 319066 REC Reference: 23/LO/0677

We would like to invite you to take part in our research study.

Before you decide, it is important that you understand what this study is about and what taking part would mean for you. Please take your time to read this information sheet. If there is anything that is not clear, or if you would like more information, please ask us.

Please find a list of definitions for technical words at the end of this document.

1. What is the DETECT-2 Study?

DETECT-2 is a research study to evaluate offering genetic testing at home.

Genetic testing is often advised for patients who develop certain cancers. This is currently done for bowel, womb, and ovarian cancer in the NHS. Patients being offered genetic testing should receive clear and accurate information about what the impacts that genetic testing may have.

Currently, genetic testing information is provided at a hospital appointment and genetic testing is usually done by a straightforward blood test.

The DETECT-2 study will see if genetic testing can be offered **at home** instead of in hospital. Genetic testing information will be given by a web-based decision aid – the 'web-app'. This decision aid is designed to help patients make decisions about genetic testing by providing information on the options and outcomes relevant to their health. This web-app can be used on a smartphone, tablet, or a computer. Participants will also have access to a '**telephone helpline**' for counselling support, any queries and help as needed. This helpline will be staffed by members of the DETECT-2 study team including a number of study counsellors during helpline working hours during the week. Voicemail messages can be left outside of working hours. Support will also be accessible by email. Genetic testing will be done at home via a saliva (spit) genetic test instead of a blood test. **This is called "direct-to-patient" testing.** The saliva genetic test is as good as the blood genetic test. The 'web-app'

does not generate any decisions about your care, treatment or diagnosis, but it provides you with information to help you make a decision.

This study will investigate how many people accept genetic testing by direct-to-patient testing compared to traditional genetic testing undertaken in hospital. This study will also assess the impact of both types of methods of delivering testing in terms of satisfaction, quality-of-life, and mental well-being, measured by standard questionnaires.

We hope to recruit approximately 832 people to the study and patients will be followed-up for one year.

2. Why have I been invited?

You have been invited to take part in this study as you are eligible for genetic testing. This is because you have developed either bowel, womb, or ovarian cancer. If you are invited, you will have met NHS criteria for genetic testing.

3. Why am I being offered a genetic test?

Genetic testing is offered to many people who develop cancer. Testing is performed on DNA. DNA is material in the cells of the body that carries genetic information. People who develop cancer may have faults in their DNA code. These are called genetic alterations. These are also called genetic mutations, or gene faults. These can be inherited from a person's parents.

These alterations may cause people to develop cancer. Medical teams often test people's genes if they develop cancer. This can detect if a patient carries a genetic alteration linked with their cancer. Finding out if someone has a genetic alteration may help treat their cancer better. It can allow measures to prevent them from getting other cancers. Also, it may identify if their family members may have the same alteration.

4. What is the purpose of this study?

The DETECT-2 study will compare two different ways to perform genetic testing.

Most patients currently have genetic testing in hospital after discussing testing with a member of their cancer team. This study aims to find out if genetic testing can be offered at home using a web-based decision aid tool on your mobile phone or tablet device, or via a website.

The DETECT-2 study aims to assess if genetic testing provided at home is as acceptable to patients as genetic testing in a hospital clinic. It will measure how many patients accept genetic testing at home, and see what their experiences of using this new strategy are. The study will test the impact of genetic testing at home on a person's mental wellbeing, satisfaction, and quality-of-life. It will also test if genetic testing at home is cost-effective.

5. What will happen to me if I decide to take part?

If you decide to take part, you will be asked to read and sign the consent form to confirm that you understand the study and that you agree to participate. We will ask you to complete a questionnaire about yourself which will include details about your lifestyle, medical history, family, and how you feel physically and mentally. This questionnaire will take approximately 20 minutes to complete.

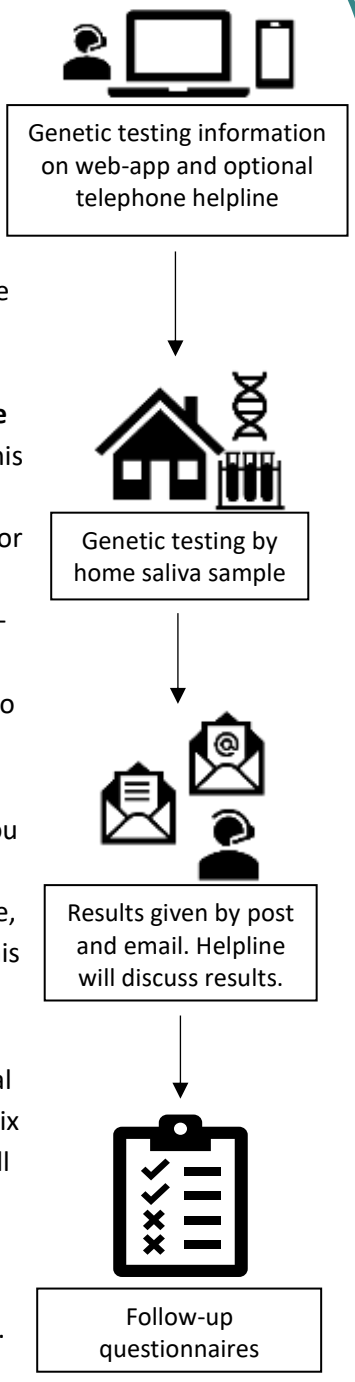
Then, you will be assigned into one of the two groups in the study. This happens purely by chance. This will be done randomly by a computer. Participants are unable to choose which group they are assigned to. Each individual has the same chance of being assigned to either group in the study. This process is called randomisation. The two groups are:

1. Participants who receive genetic testing information on a specially developed web-app decision aid – the 'web-app'. This group will be offered genetic testing **at home**. This method of genetic testing is called **direct-to-patient testing**.
2. Participants who receive genetic testing information from a member of their cancer team. This group will be offered genetic testing in hospital. This method of genetic testing is called **mainstreaming**.

Contact: ashwin.kalra@nhs.net

If you are part of the direct-to-patient testing group:

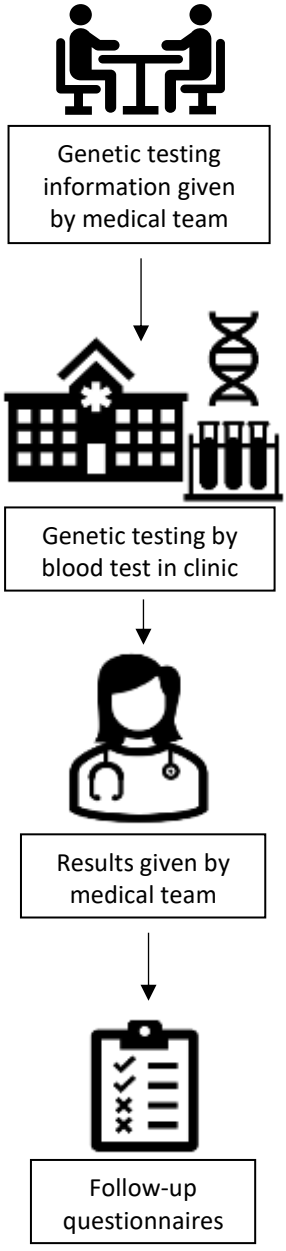
- You will be given login details to the DETECT-2 web-app. The web-app is accessible on smartphones, tablets, and computers. The web-app has information and animations about genetic testing. This will help you decide if you would like to undergo genetic testing. You will have time to look at this information at your convenience with whomever you like. If you have any questions, or would like further information or counselling support, you can use the optional **'telephone helpline'** to speak to a study counsellor. You will be able to use the web-app to accept or decline genetic testing. If you accept testing, you will be required to provide consent for genetic testing as per standard NHS practice. This will be done through the web-app. A saliva collection kit will be posted to your home. The kit will have instructions on how to perform the test and post it to the lab in a pre-paid box. The saliva test involves spitting into a tube. **The saliva test is as accurate as the blood test**. Very occasionally you may be asked to repeat the saliva test. This may happen if there are any technical problems with sample processing. If this happens again (persists for two tests), you will be offered blood genetic testing. For this, you will be sent a blood collection kit that you can take to your GP or cancer clinic to have your blood taken. Then you can post your sample to the lab in a pre-paid box.
- After making your decision to accept or decline genetic testing you will be asked to complete questionnaires. These will take approximately 10 minutes to complete.
- Your genetic test result will be given to you by post and by email. If your result shows that you have a cancer-causing genetic alteration or an uncertain result, you will be asked to contact the **telephone helpline**. This is to discuss your result and what it means for you with the study counsellor. If you do not contact the helpline, the research team counsellor will contact you to make an appointment to have this discussion.
- Your genetic test result will be shared with your cancer team and your GP.
- You will then be asked to complete questionnaires about your physical and mental health, quality-of-life, and satisfaction. These will be sent to you at three weeks, six months, and twelve months after you receive your genetic testing results. This will inform the research team about the impact of having genetic testing at home. These will take 10-15 minutes to complete.
- If you decline genetic testing, we will ask you to complete a questionnaire about the reasons for your decision. This will take approximately 5 minutes to complete.
- We will also ask you questions about your experience of using the web-app decision aid.
- You may be contacted by the research team to take part in a telephone/video interview. This will explore your attitudes, experiences, and perspectives on undergoing genetic testing. Taking part in an interview is optional.
- Please contact the DETECT-2 study team if you have any queries or need any counselling support regarding genetic testing or any help with the App. Your cancer team have been requested to direct any queries to the DETECT-2 study team.



Contact: ashwin.kalra@nhs.net

If you are part of the mainstreaming group:

- You will receive information about genetic testing from a member of the medical team treating your cancer. You will be able to accept or decline genetic testing following this discussion with your cancer team. If you accept testing, you will be required to provide consent for genetic testing as per standard NHS practice. The test will be performed by the usual way that your hospital performs genetic testing. Most hospitals in the UK perform this by a blood test.
- After making your decision to accept or decline genetic testing you will be asked to complete a questionnaire. This will take approximately 2 minutes to complete.
- Your cancer team will contact you with the results of your genetic test. They will discuss what the result means for you. They will also inform your GP about this result.
- You will then be asked to complete questionnaires about your physical and mental health, quality-of-life, and satisfaction. These will be sent to you at three weeks, six months, and twelve months after you receive your genetic testing results. These will take 10-15 minutes to complete.
- If you decline genetic testing, we will ask you to complete a questionnaire about why you have declined testing. These will take 5 minutes to complete.
- You may be contacted by the research team to take part in a telephone/video interview. This will explore your attitudes, experiences, and perspective on undergoing genetic testing. Taking part in an interview is optional.



6. Can I choose which group I wish to belong to?

No, this is not possible. It is important for the study that people are randomly assigned to the two groups. This will be decided by a computerised programme.

7. Do I have to take part?

No, taking part is completely voluntary. If you choose to not take part, this will not affect the care you receive in any way. You will still be offered genetic testing as part of your routine NHS care.

8. What are the possible advantages of taking part?

If you take part in the study, you will be offered genetic testing. Everyone who is offered genetic testing is given information about the potential risks or benefits of genetic testing. This may have implications for your cancer treatment, as well as preventing other cancers in yourself and your family.

You may be assigned to receive genetic testing information and genetic testing at home. You will not have to attend a hospital for this to take place.

Taking part in this study will help us compare if patients are as willing to perform genetic testing using a direct-to-patient approach compared to patients having genetic testing in clinics.

9. What are the possible disadvantages of taking part?

Genetic testing is offered as part of standard NHS cancer care. Some people who receive positive genetic test results may feel frightened, sad or upset about their test result. A positive result may mean that you find out that you have an increased risk of developing other cancers. This may be a result that you were not expecting.

10. Will my GP be informed of my participation?

Your GP will be told about you taking part in the DETECT-2 study.

The DETECT-2 study team will share a copy of your results from genetic testing with your GP.

11. What if I decide to withdraw from the study?

You are free to withdraw from the study at any time, through personal choice or without giving any reason for doing so and this will not affect the care you receive in any way. If you choose to withdraw from the study after you undergo genetic testing, you will still be given your genetic testing result.

12. Who are researchers involved in the project?

The project will be run under the leadership of Prof Ranjit Manchanda, DETECT-2 Chief Investigator, and coordinated by the Barts Clinical Trials Unit at Queen Mary University of London. A PhD student (Dr Kalra) working with Prof Manchanda is involved in the DETECT-2 study and their involvement is part of an educational project.

In order to conduct this study we are collaborating with external organisations:

UBQO Ltd, working with the DETECT-2 team has helped develop the web-app for use in DETECT-2 (for patients allocated to the 'direct-to-patient' arm).

Genetic testing for the study is undertaken by an accredited lab in the UK.

13. Will my taking part in this study be kept confidential?

Any information that you provide will be stored on a secure username/password protected database. Your participation in the study and the information that you provide will be treated as confidential.

People who do not need to know who you are will not be able to see information that may identify you. You will be assigned a unique random number called a patient Study ID number which will be used instead.

You will not be directly identifiable from any analysis of the study data or the outcomes of the study.

14. How will my data be collected and how will it be used?

Queen Mary University of London is the Sponsor and Data Controller for this study based in the United Kingdom. We will be using information from you and/or your medical records to undertake this study, which means in legal terms, patient data is being used as part of a task in the public interest. This means that we are responsible for looking after your information and using it properly. We will keep identifiable information about you for 25 years after the study has finished.

You can find further details of QMUL's data protection privacy notice for research participants in http://www.arcs.qmul.ac.uk/media/arcs/policyzone/Privacy-Notice-for-Research-Participants.pdf, which includes access to QMUL's record retention schedule.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum amount of personally identifiable information possible.

The NHS will collect information from you and/or your medical records for this research study in accordance with our instructions.

Members of the research team, the study Sponsor (QMUL), or regulatory authorities (authorised personnel) may look at your medical notes, and information collected during the study (data or samples), to check that that the study is being conducted to the required standards. Any accessed information will be kept confidential.

Information that may identify you is required for this study will be held securely with strict arrangements about who can access the information. The information is stored in order to conduct this study as follows:

Research team at QMUL

Your name, postal address, email address and telephone/mobile number will be used to allow us to contact you about the research study, to make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. If you are in the mainstreaming arm, the DETECT-2 study team will receive a copy of your results from genetic testing from your cancer team, via secure encrypted email. The information will only be used for the purpose of this study, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance.

We will also ask permission for identifiable details being collected by the study to be shared with NHS England and databases such as ONS/NDRS/NCRAS/Cancer registries and other national databases to link with the data they hold about you. The research team may use your identifiable details in order to retrieve information about you from national databases (e.g. Health and Social Care Information Centre, NHS Digital, ONS) and national cancer registries (e.g. National Disease Registration Service), for future ethically approved research. However, as this is for future research this is optional and you do not need consent to this in order to take part in the study.

For the 'web-app' (direct-to patient arm only):

Your name, mobile number, email address, and the type of cancer you have will be used in order that you can register to the web-app and use the web-app within this study. The web-app has been developed by the research team specifically for this study with the help of UBQO Ltd using a platform called Clinibee. When registering your details to use the web-app you will be asked to review and agree to the Clinibee's Privacy Policy/Terms of Service which can also be found at the following web-pages:

https://www.clinibee.com/privacy-policy

https://www.clinibee.com/terms

Usage data will be collected on how you use the web-app. This is an important outcome for our study.

Genetic Testing Laboratory for the saliva genetics test (direct-to patient arm only):

Your name, mobile number, email address and postal address, date of birth, gender and special category personal data (including medical and health information, genetic data and the race/ethnic origin) will be used in order to post the saliva sample kit to your home and to make contact if there are any issues with the saliva genetics test. Your personal data may be transferred to a third party, such as the lab Testing Facility, which may (depending on the test to be performed) be located outside of the UK.

The DETECT-2 study team will receive a copy of your genetic test results from the genetics laboratory, which will then be provided to you. The DETECT-2 study team will also share this report with your cancer team and your GP.

As per standard genetics laboratory practices, identifiable information about you will need to be stored indefinitely by the genetics laboratory.

Individuals from QMUL and regulatory organisations may look at your research records to check the accuracy of the research study. Your NHS site will pass these details to us (Queen Mary University of London) along with the information collected from you and/or your medical records.

We will ask for your permission on the consent form for your coded clinical information to be stored for this research and to be used, or shared with other researchers, for future ethically approved research.

You can find out more about how we use your information at:

- at www.hra.nhs.uk/information-about-patients/
- our website available from www.detect-2.co.uk
- by asking one of the research team
- by sending an email to data-protection@qmul.ac.uk

15. What will happen to any samples that I give?

If you are allocated to the mainstreaming arm, genetic testing will be performed by the usual way that your hospital performs genetic testing. Most hospitals in the UK perform this by a straightforward blood test. No additional samples will be collected specifically for this study.

If you are allocated to the direct-to-patient arm, genetic testing will be performed with a saliva (spit) test. This saliva collection kits specific to this study and will be regarded as a gift from you to Queen Mary University of London (QMUL).

Your saliva sample will be sent to an NHS accredited lab for genetic testing. To perform the test DNA will be extracted from your saliva test but there is likely to be surplus DNA remaining.

The surplus DNA sample will be returned to QMUL and stored securely and indefinitely, and may be used for future ethically approved research. Certain samples may be sent outside of the UK (other countries worldwide) for analysis.

All such samples will have your personal details removed and will be identified only by your unique Study ID number to protect your identity. Your samples will only be used for research related purposes.

We will ask for your permission for your samples to be stored and/or tested for this research. We will also ask permission for this to be used, or shared with other researchers, for future ethically approved research. However, as this is for future research this is optional and you do not need consent to this in order to take part in the study.

16. What happens at the end of the study?

The results of this study will be presented at conferences and published in scientific journals. Results will also be disseminated through support groups, web sites, and cancer charities. Your personal details will not be included in any such publication.

You will be able to see the results of the DETECT-2 study on our study website. Our study newsletters will also be on the website which you can freely access. Should you require any additional information, you can contact the DETECT-2 study team on bartsctu-detect-2@qmul.ac.uk.

17. What if something goes wrong?

If you have any questions, you should contact the research team. They will do their best to answer any questions. The contact details are provided at the end of this information sheet. If there is something that you are unhappy with and wish to complain formally, you can do this by contacting your 'local' Patient Advice and Liaisons Service (PALS) for independent advice on taking part in a clinical trial. Please ask your research nurse for further information if you would like the contact details of your local service.

PALS – The Royal London Hospital
Phone: 0203 594 2040
Email**:** bartshealth.familycontact@nhs.net

All communication will be treated in strict confidence.

Every care will be taken to ensure your safety during the study. However, QMUL has special (no-fault) insurance in the unlikely event that you are harmed as a result of taking part in the study. If you wish to complain, or have any concerns about any aspect of the way you

have been approached or treated during this study, the normal NHS complaints mechanism will be available to you.

18. Who has reviewed the study?

This study has been reviewed and approved by a Research Ethics Committee to protect the interests of any patients that may take part. This study has been given a favourable opinion by the London – Brighton and Sussex Research Ethics Committee to conduct this study in the UK.

19. Who is funding the research?

This study is funded by GlaxoSmithKline (GSK), Barts Charity, North East London Cancer Alliance and the North Central London Cancer Alliance. It is also supported by the National Cancer Research Institute (NCRI) and number of patient support groups and charities. None of the staff at NHS sites involved in the study will receive payment specific to their involvement in this research.

20. Where can I get further information about the project?

- Local Principal Investigator: Professor Ranjit Manchanda
- Site Contact: Dr Ashwin Kalra, Clinical Research Fellow in Gynaecological Oncology. Email: ashwin.kalra@nhs.net

Contact: ashwin.kalra@nhs.net

21. List of definitions

Decision aid: a tool designed to help patients make decisions by providing information on the options and outcomes relevant to their health.

Direct-to-patient genetic testing: Genetic testing performed by a patient at home. In this study this is supported by a web-app decision and telephone helpline.

DNA: Material in the cells of the body that carries genetic information. DNA is responsible for determining how cells grow and work. DNA is organised into genes.

Genetic alteration: Also called a genetic mutation or fault. A change in a gene that may change the way a gene works, causing cells to work differently. Different alterations have different effects on how genes work.

Genetic testing: Testing genetic material in a laboratory to identify a genetic alteration. Genetic material can be collected from a patient using a saliva or blood test.

Identifiable information: Information that can be used to identify who someone is. For example, this can include their name, date of birth, address, or NHS number.

Mainstreaming: Genetic testing offered to patients diagnosed with cancer by their cancer care team.

Randomisation: The process in a research study of assigning patients by chance to different study groups that receive different interventions. In the DETECT-2 study, randomisation occurs by a computer programme. This means that each individual has the same chance of being assigned to either group in the study. The two intervention groups in this study are (a) mainstreaming genetic testing by the cancer care team, and (b) Direct to patient testing.

Thank you

Thank you for considering taking part in this study and for taking the time to read this Patient Information Sheet which is yours to keep. If you decide to take part in the study, we will also give you a copy of your signed consent form.

You can find further details about the DETECT-2 Study at our website:

www.detect-2.co.uk

DETECT-2

Queen Mary University of London

NHS Barts Health NHS Trust

Contact: ashwin.kalra@nhs.net

NHS Barts Health NHS Trust

women's precision prevention

Barts CTU Barts Clinical Trials Unit

GSK

NHS North East London Cancer Alliance

NHS North Central London Cancer Alliance

barts CHARITY

NCRI National Cancer Research Institute

CANCER RESEARCH UK | CITY OF LONDON CENTRE

UCL • King's • Barts • Crick

St MARK'S THE NATIONAL BOWEL HOSPITAL

Imperial College London

MANCHESTER 1824 The University of Manchester

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

NHS London North West University Healthcare NHS Trust

Great Ormond Street Hospital for Children NHS Foundation Trust

NHS University College London Hospitals NHS Foundation Trust