

Analytical comparison of a point-of-care PSA assay system with laboratory-based reference methods in a community setting

**Study Reference: EDX-PCA-004 - EDX Prostate Point Of Care Holism
– EPPOCH**

Why have I been asked to take part?

You have been invited to take part in our research study called EPPOCH. Before you decide whether you wish to take part, it is important for you that you understand why the research is being done and what it will involve.

Please take time to read the following leaflet carefully and discuss with friends, relatives, or your GP. Ask if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

This study is looking at a new blood test that aims to help diagnose prostate cancer quickly and easily in community settings, such as local clubs or workplaces.

The purpose of the study is to compare this new test that is for research use only, with the standard accredited laboratory tests (Prostate specific antigen/PSA) currently used to check for prostate cancer. The new test is designed to provide faster results using a smaller blood sample.

Using the blood sample collected during this study, we want to find out:

- Whether the new test gives accurate results for detecting prostate cancer



- Whether blood samples taken without using a needle give similar results to blood samples taken with a needle
- How easy the test is for healthcare professionals to use outside of a hospital or laboratory setting
- If patients are comfortable having their blood tested in this way

The results from this study will help us understand whether the test could be used safely and effectively in community-based settings in the future.

Who is organising and funding the research

This study is organised and funded by EDX Medical Limited (EDX), the company developing the new test. EDX is an established medical diagnostics company that develops and evaluates tests used in healthcare.

The study is being carried out in partnership with the Graham Fulford Trust (GFT) and the Scottish Prostate Cancer Initiative (SPCI). GFT is a registered charity that runs prostate cancer awareness and screening programmes in local communities. SPCI is a not-for-profit organisation that carries out similar work to GFCT across Scotland.

As part of their work, GFCT and SPCI organise prostate cancer screening events in community settings such as sports clubs, social clubs, and workplaces, often at the invitation of employers. Their experience in delivering community-based screening will support the safe and effective running of this study.

What would taking part in the study involve?

Most participants will provide one additional blood sample. Some participants may also be asked to provide a small sample using the Tasso Plus device. If this applies to you, a member of the research team will explain the procedure and answer any questions you may have before the sample is collected.

If you decide to take part in this study, a member of the research team will be available to talk through this information sheet and the consent form with you, either remotely or in person. They will make sure you understand what taking part involves and answer any questions you may have. If you are happy to take part, you will be asked to sign the consent form electronically.

Taking part is entirely voluntary. If you decide not to take part, this will not affect you in any way.

If you agree to take part, the following will happen during your visit:

- You will attend the testing site once. As part of the GFCT/SPCI programme, the first blood sample (about one teaspoon) will be taken for your routine prostate biomarker testing.
- At the same time, an additional second blood sample (about one teaspoon) will be taken for this study.
- The second blood sample will be sent to the EDX laboratory and tested using the new prostate cancer test. The results will be compared with the standard laboratory prostate biomarker test carried out on your first sample.

- In some participants, we may also collect a small blood sample using a Tasso Plus Device, which collects blood from the upper arm without the need for a needle in the vein.
- You will complete a short acceptability questionnaire after your blood sample has been taken.
- The research team will follow up your test results of your first blood sample for up to one month to collect information for the study.

Any extra blood that is not needed for the study may be stored, with your permission, to help future research into prostate health.

Do I have to take part?

No - taking part is voluntary.

If you do decide to take part, you can withdraw from the study at any time, without providing a reason. Your decision will not affect your participation in the charity's PSA testing programme or any results you receive from it.

How will my study sample be used?

Your study sample will be used to assess the performance of a new point of care prostate cancer test. Your sample will be tested using the new test and the result will be compared to the result from the standard lab test carried out by GFCT/SPCI.

What are the possible benefits of taking part?

Taking part will help us find out whether this new test is safe and effective. If successful the new test could make prostate cancer screening quicker and more convenient, encouraging more people to participate in screening and thus improving the detection rates of prostate cancer.

What are the possible disadvantages and risks of taking part?

The possible risks and disadvantages of taking part in this study are low. During your visit, a blood sample will be taken as part of the GFCT/SPCI testing. An additional small volume of blood (approximately one teaspoon) will be collected at the same time as this sample.

Having blood taken may cause temporary discomfort, such as mild pain, bruising, or light-headedness. This may be more uncomfortable for individuals who have a fear of needles. No additional visits or procedures are required beyond those already planned.

The Tasso Plus device is applied to the upper arm and may cause mild skin irritation, temporary marks, or minor bruising.

What will happen if something goes wrong?

It is very unlikely that anything could go wrong. If it does, then we will provide compensation for any injury caused by taking part in this study.

If you are concerned about any aspect of this study, please speak to a member of the study team and they will do their best to answer your questions. Alternatively you can contact GFCT/SPCI (info@tgfct.org.uk / info@scottishprostate.com)

EDX Medical Ltd, the Sponsor of the study can be contacted at Contact@edxmedical.com

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



You can withdraw from the study at any time, without any given reason. If you wish to withdraw from the study, you should contact GFT/SPCI, they will pass a notice of study withdrawal to the study sponsor.

If you withdraw, The Sponsor shall delete all records, data and samples associated with your participant ID. The Sponsor shall confirm this action has been completed and communicate this to SPCI/GFCT. SPCI/GFCT shall confirm to you that your records, data and samples have been destroyed and confirm that you are no longer participating in the trial.

If you have any concerns, you should speak with the study team. If you remain unhappy and wish to complain formally, you can contact Graham Fulford Trust on this number: 01926419959. And SPCI on this number 0800 6523 233

Will taking part in this study be kept confidential?

Yes, your participation in the study will be completely confidential, your data will only be shared with the study sponsor and any appointed sub processors in pseudonymised format, meaning that there is no way to identify you or your participation in the study

How will we use information about you?

We will need to use information from you gathered during your visit for this research project.

This information will include the following;

Information requested	Information held by
Name	Site
Contact Details	Site
Date of Birth	Site and Sponsor

Ethnicity	Site and Sponsor
Gender at Birth	Site and Sponsor
Family history of prostate, breast or ovarian cancer -if prostate history which relation -if breast history which relation -if ovarian history which relation	Site and Sponsor
Total PSA value (ng/ml)	Site and Sponsor
Free PSA value (ng/ml)	Site and Sponsor

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.

EDX is responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- Clinical testing laboratories
- Genetic counselling organisations
- Laboratory information systems service providers
- Cloud storage providers

We will keep all information about you safe and secure by:

- securing paper records in locked cabinets
- giving people who see your contact details the same expectations of confidentiality as your doctor
- using passwords and MFA to make sure only authorised people can see your information
- ensuring your information is stored and transmitted in encrypted form

- regularly testing the security of our digital systems

How will we use information about you after the study ends?

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.

We will keep your study data for the duration of the study plus 10 years. The study data will then be fully anonymised and securely archived or destroyed.

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.

You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

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

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

- At <http://www.hra.nhs.uk/patientdataandresearch>
- by asking one of the research team
- by sending an email to the sponsors Data Protection Officer at Contact@edxmedical.com or
- by ringing us on +44 7460816732

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

You will not be given individual feedback on your results from this study, as the additional (second) blood sample and the Tasso Plus Sample (if applicable to you) is being used for research purposes only. However, if you want to know, the clinical team can tell you about the overall findings of the study when it is finished. The results of the study may also be published in papers and presentations, but your identity will never be revealed.

The pseudonymised data will be stored for duration of the study plus 10 years. The study data will then be fully anonymised and securely archived or destroyed.

Who has reviewed the study?

All research outside the NHS is reviewed by an independent group of people called an Ethics Committee to protect your interests. This study has been reviewed and given favourable opinion by the Research Ethics committee.

Thank you for taking the time to read this information sheet and considering taking part in this research study.

Principal Investigator: Dr Anand Sharma

Study Sponsor: EDX Medical Limited

You may contact the research team by telephone:

Graham Fulford Trust on this number: 01926419959

SPCI on this number 0800 6523 233