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Participant Information Sheet

Study Title:

PROTEAN Proteomic Profiling of Oesophageal and Gastroesophageal Junction Adenocarcinoma Neoantigens

Chief Investigator: Professor Russell Petty

Local Principal Investigator: TBC

We're inviting you to take part in a research study

Before you choose whether or not to take part, we want you to understand why we are doing the study. We also want to tell you what it will involve if you agree to take part. Please take time to read this information sheet carefully. You can ask us any questions and talk to other people about it if you want. We'll answer your questions and give you any additional information you ask for. You don't have to decide straight away.

Why are we doing this study?

People with oesophageal (gullet) and gastroesophageal (stomach/gullet) cancers get treatments such as, chemotherapy, radiotherapy and surgery. While the treatments are effective, scientists and doctors are working together to develop more effective treatments called cancer immunotherapy. Immunotherapy triggers your immune system to treat the cancer and to recognise and attack cancer cells and control their growth. These new immunotherapy treatments include vaccines against cancers. When cancer immunotherapies work, they can provide durable long lasting cancer control often with few side effects, and as such they are recognised as an important breakthrough in cancer treatment. There are some immunotherapy treatments for oesophageal and gastroesophageal cancers, but they only work in a small number of people and a key need is to increase the proportion of patients for whom cancer immunotherapies will prove effective.

There are markers in the cancer cells called neoantigens. Neoantigens may play an important role in helping the body make an immune response

against cancer cells. Neoantigens can sometimes help doctors work out which immunotherapy will be best for a person. To be able to develop more immunotherapy treatments we first have to find out which neoantigens are in oesophageal and gastroesophageal cancers.

This study will collect cancer tissue samples from people with oesophageal and gastroesophageal cancer. Scientists from the company Platinum Informatics Ltd working in the School of Life Sciences at the University of Dundee will analyse the cancer tissue to see if they can find any neoantigens and determine the profile of neoantigens in each person's tumour.

We will also check information from your local NHS tests to see how your cancer progresses. We will look to see if there is any connection with the results from blood samples, the neoantigens we find and how your cancer progresses.

In the future we hope that we'll be able use the neoantigens to find new, more effective immunotherapies. Doctors would then be able to test a person's cancer tissue to find out what neoantigens they contain and what immunotherapy will work best for them. In this way we aim to have the means to make each person's cancer therapy more precisely designed for them to increase the chances of successful treatment.

Why have I been asked?

We're contacting you because you have oesophageal or gastroesophageal cancer.

Do I have to take part?

No. Taking part in this study is entirely your choice. If you choose to take part, you can withdraw from the study at any time. You don't have to give a reason for not taking part or for stopping. If you don't want to take part or want to stop the study, the medical care you get and your relationship with the medical or nursing staff looking after you won't be affected. If you decide to withdraw from the study, data or tissue already collected will be kept and used in the study. If you choose to stop taking part in the study, we won't take any more tissue samples but we'd like to keep collecting information about your health from your hospital records for up to 18 weeks

after your first biopsy. If you don't want this to happen, tell us and we'll stop. If you lose the capacity to tell us that you are happy to continue in the study, your previous wishes to take part in the study will remain valid, unless the study changes significantly.

What will happen to me if I take part?

A member of your oncology clinical team will check your medical notes to see if you're able to take part. They will check the study is appropriate for you and if it will be safe for you to take part. This will include looking at what type of cancer you have and what treatments you have had or are being planned. They will discuss the study with you when you attend for your oncology appointment. If you decide you want to take part in the study, your oncology clinical team will pass your details to the research team. The research team member will contact you and explain why we are doing the study and the benefits and risks of taking part. They'll make sure that you've been able to ask any questions you have. You'll be given time to consider taking part in the study (at least 24 hours). You can talk to other people about the study if you want to. You'll have the chance to ask further questions after reading this information sheet, before making up your mind.

Being in the study won't change your treatment and clinical care.

At the start of the study

- We will ask you to complete a consent form which we will discuss with you before you sign it. You'll be given a copy of the consent form.
- Blood sample – we'll take approximately 20 ml of blood (4 teaspoons). We'll try to take this at the same time as you're having blood taken for your clinical care.
- Tumour biopsies – we'll take up to 10 samples at the one time, approximately 2mm each. We aim to take the biopsies for the study at the same time as you're having a procedure needed for your clinical care. For example, during an endoscopy, during surgery or when you're having a stent put in. If these tumour biopsies are being taken at the time of endoscopy we will also take 2 biopsies approximately 2mm each of the normal tissue in the oesophagus or stomach right beside the tumour at the same time. The biopsy may be from your main tumour or,

if you have developed metastases, (cancer which has spread to a different part of your body) the biopsy may be taken from there.

If it is not possible to get the samples when you're having a clinical care procedure, we'll ask you to consider having a separate procedure to have a biopsy for the study only. Your oncologist will discuss these biopsies with you. They'll help you to decide whether or not you want to go ahead with this.

- Medical details – we'll look at your medical records and laboratory results to get information about your cancer, treatments and medical history.

During the study

- Blood sample – we'll take 1 or 2 20 ml samples of blood. We'll only do this if you are having blood taken for your clinical care.
- Tumour biopsies – we'll take tumour biopsies on up to 3 more occasions. We'll only take the biopsies for the study at the same time as you're having a procedure needed for your clinical care. For example, during an endoscopy, during surgery or when you're having a stent put in. These tumour biopsies are optional and you can still take part in the study without providing them. Let us know if you do not want to have extra biopsies taken.
- Medical details - we'll look at your medical records and laboratory results to get information about your cancer, treatments and medical history.

At the end of the study (18 weeks after first biopsy)

- Blood sample – we'll take approximately 20 ml of blood. We'll try to take this at the same time as you are having blood taken for your clinical care.
- Medical details - we'll look at your medical records and laboratory results to get information about your cancer, treatments and medical history.

You'll be in the study for 18 weeks.

What will happen to the samples I donate?

Your blood and biopsy samples will be pseudo-anonymised, meaning your name/contact details will not be on them but they will have a study code

instead. Your research team will send your samples to the University of Dundee. Your blood samples will be analysed by University of Dundee staff in laboratories in the School of Medicine. Your biopsy samples will be analysed by Platinum Informatics Ltd staff based in laboratories in the School of Life Sciences, University of Dundee.

Some of the blood samples will be used to allow researchers to learn about differences and changes in an individual's genetic makeup (human DNA). This may help to discover the role that genetics play in disease and treatment. The genetic tests are done only for research and will not be useful for your clinical care, you will not get the results of these tests.

When the blood and biopsy analysis has been completed, if you agree, any unused samples will be stored at the University of Dundee in the Tayside Biorepository. These samples will be stored for future research and may include research with commercial organisations. If you do not agree for these samples to be stored, any unused samples remaining at the end of the study will be disposed of.

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VISIT SCHEDULE

Procedures	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
	Screening	Baseline Up to 28 days after visit 1	Week 6	Week 12	Week 18
Sign consent form	X				
Check medical history	X				
Height & weight	X				
Check current medications	X	X	X	X	X
Biopsy		X			
Biopsy **(optional)**			X A maximum of 3 further research biopsy samples will be collected between day 1 and week 18		
Blood sample		X			X
Blood sample **(optional)**			X A maximum of 2 further research blood samples will be collected between day 1 and week 18		
Medical details		X	X	X	X
Check if any illness since last visit		X	X	X	X

Where it is possible all visits will be at the same time as your standard hospital visits.

If possible, the visit 1 and visit 2 procedures will be carried out on the same day.

If you are not due to come into the hospital around the time of the visits, we will contact you by telephone you instead.

Will taking part in the study affect my usual care?

No, you'll continue to receive your usual medical care.

What are the possible benefits of taking part?

The study won't immediately benefit you. We hope what we learn from this study will benefit patients with your type of cancer in the future.

What are the possible disadvantages and risks of taking part?

The tissue biopsy samples will be collected wherever possible when you undergo biopsy procedures as part of your routine care. If that is not possible, then the biopsies will be carried out for the study purpose only. Collecting these tissue samples is considered safe, but the possible risks include:

- Bleeding at the time the samples are removed.
- Infection at the site where the samples are removed.
- Pain at the time the samples are removed.

These complications happen 1 in 1000 endoscopic biopsies and are usually minor and short-lived (discomfort or minor bleeding at biopsy sites). Risks change due to the technical aspects of the biopsy (e.g., size of the needle, location or size of the sample) and patient characteristics. The risks for major complications increase with the more biopsies taken.

There may be other risks we cannot predict. For more information about the risks, please speak with your doctor.

How will I know the results of the study?

We will send out a newsletter to all participants with the results of the study. We expect the study to be completed by the end of July 2023. It is common for it to take some time, as long as one year, after the study is completed, for the results to be ready to be published. So, it is likely that it will be some time before we send out the results newsletter to participants.

Who is organising and funding this research?

This study is being sponsored by the University of Dundee. It is being funded by Platinum Informatics Ltd. The study is being organised by Professor Russell Petty.

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

The Chief Investigator, Prof Russell Petty, has links with several patient support groups and charities. These groups and charities have provided the views of oesophageal cancer patients and their carers regarding clinical research into the disease. We have taken their views into account when we have developed the study. The CI will continue to engage with these groups as the results become available. This will allow us to have a patient view of how we understand the results, tell patients about the results and plan future research.

What COVID-19 precautions will be in place when I come for my visits?

It is likely that your visits will happen when you are attending the hospital for clinical care appointments. The current Government COVID-19 guidelines for the country you are in will be in place when you come for your visits. This may include wearing facemasks, handwashing, social distancing when appropriate, checking your temperature and asking about any recent COVID-19 symptoms.

Staff will wear face masks and other personal protective equipment (PPE) when appropriate.

What will happen with the information collected about me?

Identifiable information and the information collected about you during the study will be stored by your local NHS research team. Only certain members of the research team will be able to see this information.

People who don't need to know who you are won't be able to see your name or contact details. Your data will have a code number instead. Only certain members of your local research team will have the link between your code number and your personal information.

Information collected about you during the study is called "study information". Your study information will be securely stored on password-protected databases in the University of Dundee. Your study information will be shared with staff at Platinum Informatics Ltd. They will not have access to any details which would identify you.

Your study information will be kept securely for 5 years after the end of the study. After 5 years, your identifiable information held locally will be removed,

and the rest of the information will be kept for research purposes. If you'd like to be informed about future studies that you might be interested in taking part in, we'll ask your permission for us to hold your contact details.

We'll ask your permission to tell your GP that you are taking part in this study.

Information which identifies you won't be published or shared.

Your anonymised study information may be shared with other researchers.

What if something goes wrong?

If you are concerned about taking part in the study, you have the right to discuss your concern with a researcher involved in carrying out the study or a doctor involved in your care.

If you have a complaint about your participation in the study, first of all you should talk to a researcher involved in the study. You can also make a formal complaint. You can make a complaint to a senior member of the research team or to the Complaints Officer:

INSERT details of local complaints department

If you think you have come to harm due to taking part in the study, there aren't any automatic arrangements to get financial compensation. You might have the right to make a claim for compensation. If you wish to make a claim, you should think about getting independent legal advice, but you might have to pay for your legal costs.

Insurance

The University of Dundee is sponsoring the study.

The University of Dundee has a policy of public liability insurance which provides legal liability to cover damages, costs and expenses of claims.

Tayside Health Board is a member of the NHS Scotland Clinical Negligence and Other Risks Insurance Scheme (CNORIS) which gives legal liability cover of NHS Tayside for this study.

As the trial involves University of Dundee staff carrying out clinical research on NHS Tayside patients, these staff will hold honorary contracts with

Tayside Health Board. This means they will be covered under Tayside's membership of the CNORIS scheme.

Other Scottish Health Boards are participating as study sites and they are also members of CNORIS. This will cover their liability for carrying out the study.

NHS Health Trusts in England are taking part as study sites and they have membership of a scheme like CNORIS from the NHS Litigation Authority (NLA).

NHS Health Trusts in Wales are taking part as study sites and they have membership of a scheme like CNORIS from the Welsh Risk Pool.

NHS Health Trusts in Northern Ireland are taking part as study sites and they have membership of a scheme similar to CNORIS from the Clinical Negligence Fund.

If you apply for health, life, travel or income protection insurance you may be asked questions about your health. These questions might include questions about any medical conditions you have or have had in the past. You might also be asked if you have had any genetic tests or about taking part in this study. We do not expect that taking part in the study will adversely affect your ability to buy insurance. Some insurers may use this information to limit the amount of cover, apply exclusions or increase the cost of insurance. Your insurer may take in to account any medical conditions you have, including any which are diagnosed as part of a research study, when deciding whether to offer insurance to you.

Your information will remain confidential unless we are legally required to make it known by Court order or by law.

Who has reviewed this study?

This study has been reviewed and approved by REC details TBC Ethics Committee who are responsible for reviewing research which is carried out in humans. The Research Ethics Committee doesn't have any objections to this study going ahead.

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Data Protection Privacy Notice

How will we use information about you?

We'll need to use information from you and your medical records for this research project.

This information will include NHS number, name and contact details. 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.

When we have finished the study, we will keep 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.

What are your choices about how your information is used?

- You can stop participating in the study at any time, without giving a reason, but we'll keep information about you that we have already collected.
- If you choose to stop taking part in the study, we'd like to continue collecting information about your health from your hospital records for up to 18 weeks after your first biopsy. If you don't want this to happen, tell us and we'll stop.
- We need to manage your records in controlled and tightly regulated 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.

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/
- http://www.ahspartnership.org.uk/tasc/for-the-public/how-we-use-your-information
- https://www.dundee.ac.uk/information-governance/dataprotection/
- http://www.nhstayside.scot.nhs.uk/YourRights/PROD_298457/index.htm

Contact details for further information

Thank you for taking the time to read this Participant Information Sheet and for considering taking part in this study.

If you'd like more information or want to ask questions about the study, please contact the research team using the contact details below.

Principal Investigator: TBC

Phone:

Email: TBC

Research Nurse: TBC

Phone: TBC

Email: TBC

You can contact us Monday – Friday between 09:00-17:00.

Outside of those hours, if you need advice, you can contact your out-of-hours GP service/NHS24 via 111.