OPTIC

Views on **Opt**imising **I**mmune **C**heckpoint Inhibition in Cancer

Information for participants taking part in focus group discussions

We are inviting you to take part in a research study looking at patient views on changing the way we give immunotherapy treatments for cancer.

Please take time to read the following information carefully. Discuss it with friends and family if you wish. Take time to decide whether or not you want to take part.

You are free to decide whether or not to take part in this research study. If you choose not to take part, this will not affect the care you get from your own doctors in any way. You can also stop taking part in the study at any time, without giving a reason.

If anything is not clear or if you would like more information, please speak to the research team who will answer your questions.

Thank you for reading this information. If you decide to take part, you will be given a copy of this information sheet and asked to sign a consent form. You will be given a copy of the consent form to keep for your records.

What is the project about?

This study will look at patient views about changing the way that we give immunotherapy treatment for cancer. These medicines work by encouraging the body's own immune system to fight against cancer cells.

What are we trying to find out?

Immunotherapy treatments can be effective for many different types of cancer including kidney cancer, melanoma (a type of skin cancer) and some types of lung cancer.

Immunotherapy treatment can be given to patients:

- Whose cancer has been treated (with surgery and/or radiotherapy) and has not spread to other parts of the body. In this case it aims to prevent or delay cancer from coming back.

OR

- Whose cancer has spread to other parts of the body to help control the cancer.

Immunotherapy treatments are usually given via a thin tube inserted into a patients arm every 2-6 weeks (depending on the specific treatment). Most patients will need to have treatment for at least a year. Some patients will be recommended ongoing treatment even if the treatment works well.

The decision about which dose to use, how often to give this treatment and for how long to give it is based on the results of research trials. Although we know that treatment given this way is effective, it may be that by giving a lower dose, giving the treatment less often or giving the treatment for a shorter amount of time works just as well, it just has not been tested yet. Giving less immunotherapy could improve quality of life for patients and lead to fewer side effects.

This study aims to understand patient views around changing the way we give immunotherapy. The results of this study will help us design and carry out future trials with different ways of giving immunotherapy. It will also help us understand how to talk to patients about these trials.

Why would we like to talk to you?

You are being invited to take part in this study because you currently have or have previously had kidney cancer, melanoma or lung cancer, or you have been a carer for someone who has had one of these cancers. Immunotherapy can be used to treat all these cancer types. We are interested in

hearing about your experiences and your views. There are no right or wrong answers.

Who are we?

Our team is based at the Medical Research Council Clinical Trials Unit at University College London (UCL). The project lead is Dr Sophie Merrick who is a doctor specialising in cancer treatment (oncologist) and is completing her PhD at UCL.

What will be involved?

If you take part, you will be part of a focus group discussion with 4 to 8 patients who have, or have previously had kidney cancer, lung cancer or melanoma. This study will also have separate group interviews with carers of patients who have, or have previously had one of these cancers.

After signing the consent form you will be asked to fill out a background questionnaire which will take less than ten minutes to complete. This will include details about your demographics and health information.

After completing the questionnaire, we will contact you via email to let you know when the focus group will be.

What will the focus group discussion be like?

The focus group discussion will take around an hour and a half. We would like to hear your views about other ways we could give immunotherapy treatment. You do not have to talk about anything you do not want to talk about, and you do not have to talk about your own experience.

We hope that this study will help us design and run trials that will test giving immunotherapy in different ways and help us understand how best to communicate this to patients.

We will make an audio and visual recording of the focus group so that we can remember what is said.

Where will the focus group discussions take place?

The focus group discussions may take place online or in person. If it is difficult for you to attend in person, you will be offered the option of attending online. If you are attending in person you will be told ahead of time where this will be.

Is the research confidential?

Yes and No

What is **NOT** confidential?

We will ask people attending the focus group discussion not to share what other people have said. However, because there are a number of people in the focus group, it is impossible to say that the information discussed will stay confidential. Therefore, it is very important that you do not talk about anything that you do not want to share with others.

If you decide to stop taking part in the focus group discussion, what you have said up until that point will still be included on the recording.

What **IS** confidential?

We will not feedback any of the information discussed in the focus group to your cancer team.

We will take care to always protect your personal identity and nothing you talk about will be linked to you. We will keep any direct identifiers (such as your name and contact details, which we need to arrange the focus group) separate from the data we collect from you. We will not keep your name and contact details after the study has ended.

We might use some quotes of what you have said, but we will never use your real name or any personal details. Anonymised data (without names, so no one can tell who said what) will be stored and may be used for other studies but will only be seen by researchers authorised by me. Information collected on the background questionnaire will also be kept confidential.

What will you gain?

You will probably not gain anything directly from participating. However, your involvement could help design future clinical trials and help us to communicate more effectively with future patients.

What are the possible risks?

There is very little risk to taking part in this research study. There is a small risk that something upsetting may come up while we are talking. If this happens, we will ask you if we can contact anyone to help support you, and we will give you information about appropriate support groups.

Will you be compensated?

Yes, we will reimburse you with a £25 voucher for participating in the focus group. If your focus group takes place in person we will also reimburse your travel expenses.

More information about taking part

Do I have to take part in this study?

No, it is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and you will be asked to sign a consent form. If you decide not to take part in this study, this will not affect the care you receive at your cancer clinic.

Can I stop taking part after I've joined the study?

If you decide to take part in this study, you can stop taking part at any time and without giving a reason. However, the focus group discussion will be influenced by your input and if you decide to stop taking part after the focus group has started what you have said up until that point will still be included in the recording. It will not be possible to remove this from the recording or analysis.

How will my data be stored and collected?

The information you provide in the discussion will be separated from your personal details and stored securely at the Medical Research Council Clinical Trials Unit at UCL. Only researchers directly involved in this study will have access to the data. As participation is anonymous it will not be possible for us to withdraw your data once the focus group is over.

University College London (UCL) is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. We will keep the recording and transcript from the focus group discussion for 10 years.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order 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 personally identifiable information possible.

You can find out more about how we use your information at www.ctu.mrc.ac.uk/general/privacy-policy

In exceptional cases when, during a focus group, someone tells the researcher about something that the researcher deems a danger to the individual or someone else, then the researchers' duty to keep the information confidential can be outweighed by the need to disclose information in the public interest. In these circumstances the researcher may have to contact a relevant medical professional.

How will my data be used in future and other research?

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with relevant legislation, ethics and NHS research policy requirements.

The information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research. It will not be used to make decisions about future services available to you, such as insurance.

What will happen to the results of this study?

We will publish findings from this study in publications and reports so that anyone who is interested can see them. You can ask us for a copy of any publication. Your identity and any personal details will be kept confidential. No named information about you will be published in any report of this study.

Who is funding and organising this study?

This study will form part of Dr Sophie Merrick's PhD which is funded by the Medical Research Council and supported by Cancer Research UK. University College London is the sponsor of the study and has overall responsibility for how it is carried out. University College London is responsible for ensuring the study is carried out ethically and in the best interests of the study participants.

Who has reviewed this project?

This project has received ethical approval from University College London Research Ethics Committee (Ethics ID 23347/001).

What if there is a problem during the study?

If you wish to complain or have any concerns about any aspects of the way you have been approached or treated by members of the research team while taking part in the study, UCL complaints mechanisms are available to you. Please email Dr Duncan Gilbert on duncan.gilbert@ucl.ac.uk if you would like more information about this. If you feel your complaint has not been resolved, you can contact the Chair of the UCL Research Ethics Committee on ethics@ucl.ac.uk.

Thank you for taking the time to read this information and considering taking part.

Local Data Protection Privacy Notice

The controller for this project will be University College London (UCL). The UCL Data Protection Officer provides oversight of UCL activities involving the processing of personal data, and can be contacted at data-protection@ucl.ac.uk

This 'local' privacy notice sets out the information that applies to this particular study. Further information on how UCL uses participant information can be found in our 'general' privacy notice. For participants in health and care research studies, click here.

The information that is required to be provided to participants under data protection legislation (GDPR and DPA 2018) is provided across both the 'local' and 'general' privacy notices.

The categories of personal data used will be as follows:

- Demographics
- Cancer history and treatment
- Previous enrolment in a clinical trial

The lawful basis that would be used to process your *personal data* will be performance of a task in the public interest.

The lawful basis used to process *special category personal data* will be for scientific and historical research or statistical purposes.

If we are able to anonymise or pseudonymise the personal data you provide we will undertake this and will endeavour to minimise the processing of personal data wherever possible.

If you are concerned about how your personal data is being processed, or if you would like to contact us about your rights, please contact UCL in the first instance at data-protection@ucl.ac.uk.

How to contact us

If you have any questions or need any more information, please contact:

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