

NHS Cancer Vaccine Launch Pad (CVLP) – Participant Information Sheet

IRAS Project ID: 325291

What is the NHS Cancer Vaccine Launch Pad?

The NHS Cancer Vaccine Launch Pad (CVLP) is looking to find people who may be able to take part in research trials for personalised vaccines to treat cancer. By supporting these trials, NHS England (NHSE) aims to speed up the development of personalised treatments for cancer patients.

What are you being asked to do?

We are offering patients having their cancer removed or biopsied the opportunity to have their cancer DNA analysed for changes that could be targeted for personalised treatment.

If you wish to take part, you will be asked to sign a consent form. We will ask for your permission to access information about you and your cancer to assess whether you would be suitable for any research trials of personalised cancer vaccines. To do this, we will also need some of your unused cancer tissue after all routine tests have been done and a blood sample (if applicable). The research trial may be at a different NHS hospital so you may need to travel if you are suitable and choose to be part of the trial. It is important to understand that being part of the CVLP does not guarantee that you will be able to take part in a research trial as not all patients are suitable for cancer vaccines.

The image below shows what is involved if you consent to take part in the CVLP.



Your decision to be part of the CVLP will not affect the standard or type of care you will receive from your hospital or doctor, now or in the future. If you do not wish to take part in the CVLP, we will not use your tissue, collect a blood sample or collect any information about you; nor will the standard of care you receive or your legal rights be affected.

What type of treatment is being offered in the research trials?

The CVLP is looking for people who may be suitable for cancer vaccine research trials. Vaccines are usually used to stop people from getting a disease, such as polio or measles. Researchers are now looking at using vaccines to stop cancer coming back after it has already been treated. Cancer vaccines stimulate the body's immune system to recognise and attack cancer cells.

Cancer vaccines are designed using genetic (DNA) changes found in a person's cancer. They are individually made for each person. Cancer vaccines are being tested in research trials to understand how well they work.

What will happen if you decide to take part in the CVLP?

We will ask you to sign the CVLP consent form, giving your permission to share your information and a blood (if applicable) and tissue sample. Please keep this information sheet to remind you of what you were asked to do. A letter will also be sent to your GP informing them that you have consented into the CVLP.

Once you have signed the consent form, the following will happen:

1. **A sample of your cancer will be collected.** As part of your normal care, you will be having some or all of your cancer removed. If this has already happened, samples from your previous surgery or biopsy will be used. You will not need to undergo extra procedures to get a tissue sample for the CVLP.
2. **A sample of your blood may be collected.** Not all patients will be approached for a blood sample. This is dependent on the requirements of the research trial. If you are required to provide a blood sample this may be collected at the same time as your surgery or biopsy or at a different time. You will be asked to give up to 30ml (6 teaspoons) of blood.
3. **Information about you and your cancer will be collected.** Staff at your hospital may ask you questions and look at your medical records to collect information about you and your cancer, and your treatment now and in the future. We would also like to check your progress yearly until the end of the CVLP. This information will be collected and stored securely within the CVLP database.
4. **Information about you and your cancer will be shared.** Staff at your hospital will share your contact details and information about you and your cancer diagnosis securely with delegated trial staff at the NHS hospital where the research trial is being run.

What are the possible benefits to you?

By taking part in the CVLP, you might be able to take part in a research trial and receive personalised cancer vaccine treatment before it is widely available. For people who receive this personalised treatment, it may reduce the chance of their cancer growing or coming back.

Not everyone will be suitable to take part in a research trial and the research may not benefit you directly. This is because we are still finding out how effective the treatment might be.

You can also benefit from the knowledge that you are helping medical research to improve cancer treatment. The tests and treatments being used for you were developed with the help of patients who took part in research years ago. The more patients that take part in research, the faster progress can be made as more human samples can be studied.

What are the possible risks to you?

There are no significant health risks to donating samples for research purposes to the CVLP. You will only be agreeing to the use of your remaining tissue sample after it has been used as part of your standard of care and giving an additional blood sample, if applicable.

What will happen with your samples if you decide to take part in the CVLP?

After your operation or biopsy, your tissue will be sent to an NHS laboratory to diagnose your cancer. This is the standard process in the NHS that happens for all cancer patients.

If you consent to take part in the CLVP, some of your left-over tissue that would normally be held by the NHS laboratory or discarded, will be sent to a company running research trials, along with your blood sample will also be sent to the company. The company will carry out genetic tests (DNA) relating to your cancer to see if you are eligible for their research trial.

Any research using your samples or information will have to be ethically approved before it takes place. When samples are provided to a partner company, they are required to only use the samples for the research they said they would do. Researchers are bound by a strict agreement to make sure of this.

You will not receive any financial reward for donating any of your samples. Samples you have donated will only be used for medical research and not for any other purpose.

Where will your samples be stored?

Your blood (if provided) and tissue sample will be stored by the partner company so they can carry out testing for their research trial. Any remaining tissue will be returned to your NHS hospital trust after testing or disposed of following a documented disposal process if the sample cannot be used anymore. The partner company may be in the UK or overseas.

How will we use information about you?

We will need to use information from your medical records for this research project. This information will include the following:

- Your name,
- Your NHS number,
- Your contact details, and
- Your data held by your local hospital and NHS England, such as your date of birth, ethnicity, cancer diagnosis, the treatment you are receiving for your cancer now and in the future, and the genetic (DNA) information about your cancer.

This information will be used 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.

Some of your information will be sent to outside of the UK. They must follow our rules about keeping your information safe.

Further details on NHS England privacy notice can be found here:

<https://www.england.nhs.uk/contact-us/privacy-notice/how-we-use-your-information/public-and-partners/cancer-vaccine-launchpad/>

How will your information be stored? Who will be able to access it?

NHS England is the sponsor for this research project based in the United Kingdom. The sponsor and the Southampton Clinical Trials Unit (SCTU), who act on behalf of NHS England, will be using information from you and your medical records for the CVLP.

Your data, such as your date of birth, ethnicity, cancer diagnosis, the treatment you are receiving for your cancer now and in the future, and the genetic (DNA) information about your cancer will be stored electronically in a secure NHS database. Only NHS staff involved in the CVLP will be able to see data that identifies you personally. If you may be suitable to take part in a research trial, your contact details will be shared with the nearest NHS hospital where the research trial is being run. This is so they can contact you to invite you to take part in the research trial.

Any information shared with external companies that partner with the CVLP will be pseudonymised. This means any information that could identify you such as your name, date of birth, contact details or NHS number will be removed and replaced with a code. The code allows you to be re-identified by your NHS trust or NHS England if you decide to take part in a research trial.

Your hospital team and NHS England will hold your identifiable information for at least 10 years. This is to allow later analysis of patients who take part, and possibly enable enrolment in future research trials.

Once we have finished the CVLP, 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. The design of the CVLP fully complies with the Data Protection Act (2018) and UK General Data Protection Regulation.

What are your choices about how your information is used?

You can stop being part of the CVLP at any time without giving a reason. Simply contact your hospital and let them know. You do not need to explain why. Withdrawing from the study will not affect the standard of care or treatment you will be receiving. Your legal rights will also not be affected. If you change your mind, any samples in storage as part of the CVLP will be destroyed in the way human tissue from hospitals are normally destroyed. Any information stored about you as part of the CVLP will be deleted so that it cannot be used further.

If you change your mind after a long time, your sample may already have been used and destroyed. The CVLP cannot recall samples or information from researchers once they have been used. However, we will request the deletion of any remaining data about you within the CVLP so it will not be used for any further research. We need to manage your records in specific 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.

If you agree to take part in this study, you may have the option to take part in future research using your data collected as part of this study.

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/
- our leaflet available from NHS England website - <https://www.england.nhs.uk/cancer/>
- by asking one of your hospital team, or
- by sending an email to cvlp@soton.ac.uk.

Who is organising and funding the CVLP?

The CVLP is a collaboration between NHS England, which leads the health service in England; the Genomic Medicine Service, which is a part of the NHS that specialises in genetic testing in healthcare; and leading cancer vaccine manufacturers who are setting up cancer vaccine research trials. This research project has been ethically reviewed by the East of England – Essex Research Ethics Committee. The Southampton Clinical Trials Unit (SCTU) are coordinating the day-to-day running of this research project.

How to contact us?

If you would like to find out more about the CVLP, please speak to your local clinical care team (doctor/nurse):

Doctor/nurse's name: *(Insert)*

Telephone number: *(Insert)*

Name of hospital: *(Insert)*

For confidential advice, support and information on health-related matters, please contact the Patient Advice and Liaison Service (PALS). They provide a point of contact for patients, their families and their carers.

Follow this link on the NHS website - <https://www.nhs.uk/nhs-services/hospitals/what-is-pals-patient-advice-and-liaison-service/> to learn more about PALS. For the contact details and further information please check your local hospitals website *[Insert local NHS site PALS website]*.