

# NHS Cancer Vaccine Launch Pad (NHS CVLP)

<b>Submission date</b> 09/07/2024	<b>Recruitment status</b> Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 09/10/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 23/05/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Personalised cancer vaccines are a type of cancer treatment designed to target an individual's unique cancer cells. They are created by analysing a patient's tumour and identifying specific DNA changes that are unique to that cancer, then using that information to create a vaccine tailored to that patient. The intention is that the cancer vaccine will stimulate the immune system to specifically recognise and destroy the cancer cells.

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, the CVLP aims to speed up the development of personalised treatments for cancer patients.

### Who can participate?

NHS cancer patients in England aged over 16 years with capacity to consent.

### What does the study involve?

Upon consent, the following will occur:

1. Small sections of the tumor will be cut from the diagnostic block by a histopathologist (a doctor who specializes in studying tissues). These sections will be sent to CVLP partners for nucleic acid extraction and sequencing. Nucleic acids are molecules like DNA and RNA that carry genetic information.
2. A blood sample, up to 30 milliliters, will be drawn and sent to CVLP partners. This sample may be tested for germline nucleic acid (genetic information you were born with) and tumor circulating free DNA (genetic material released by the tumor into the bloodstream).
3. Baseline demographic (like age and gender) and clinical data will be recorded by the clinical or research team and sent with the biological material in a pseudonymised form (using codes instead of names to protect your identity). This data will also be centrally held by Southampton Clinical Trials Unit (SCTU) to coordinate with cancer vaccine trial partners and sites. A clinical liaison team will oversee this process.
4. During Phase 1, sequencing data will be held by industry partners. If you are eligible for a cancer vaccine trial, the clinical liaison team will inform your clinical team and local trial sites. Pseudonymised codes will be used to identify patients when communicating with clinical teams or linking patients with NHS cancer vaccine trial sites. Any other information shared outside the NHS CVLP framework will also be pseudonymised.

5. If you are eligible for a cancer vaccine trial, your home clinical or research team, or the team at the nearest cancer vaccine trial site, will approach you for further discussion and a separate consent.

What are the possible benefits and risks of participating?

By taking part in the CVLP, participants might be able to take part in a research trial and receive personalised cancer vaccine treatment before it is widely available. For participants 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 trial may not benefit all participants directly. This is because we are still finding out how effective the treatment might be.

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

Where is the study run from?

The study is coordinated by the Southampton Clinical Trials Unit and is being run in NHS hospitals in England. The study is sponsored by NHS England.

When is the study starting and how long is it expected to run for?

May 2023 to December 2030

Who is funding the study?

NHS England (UK)

Who is the main contact?

Southampton Clinical Trials Unit at [cvlp@soton.ac.uk](mailto:cvlp@soton.ac.uk)

### **Study website**

<https://www.southampton.ac.uk/ctu/cancer-vaccine-launch-pad.page#home>

## **Contact information**

### **Type(s)**

Scientific

### **Contact name**

Miss Nicole Keyworth

### **Contact details**

Southampton Clinical Trials Unit, Southampton General Hospital

Southampton

United Kingdom

SO16 6YD

+44 2381205154

[cvlp@soton.ac.uk](mailto:cvlp@soton.ac.uk)

## **Additional identifiers**

EudraCT/CTIS number

Nil known

**IRAS number**

325291

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

CPMS 57835, IRAS 325291

## **Study information**

**Scientific Title**

Establishing a UK platform to collect tumour samples and perform DNA/RNA sequencing for the development of personalised cancer vaccines

**Acronym**

CVLP

**Study objectives**

The objectives of the NHS Cancer Vaccine Launch Pad (CVLP) are to:

1. Identify cancer patients undergoing resection or biopsy of their tumours who could be eligible for personalised mRNA therapies such as cancer vaccines.
2. Create a pathway for collection and transfer of tumour samples, blood samples and pseudonymised clinical data during routine NHS care.
3. Send samples for DNA extraction, molecular analysis and sequencing initially in partnership with industry (Phase 1) and later to be performed by the NHS Genomic Medicine Service (Phase 2).
4. Use the results to accelerate access of eligible cancer patients to cancer vaccine trials.

The programme aims to profile up to 10,000 tumour samples in a phased approach over 7 years. To achieve this we will enrol patients diagnosed with different cancers and seek their consent for:

1. Collection of surplus tumour biopsies or surgical resection samples to be sent to genetic testing laboratories for DNA or RNA extraction and sequencing.
2. Collection of a blood sample to perform relevant tests for cancer vaccines, eg: circulating free tumour DNA or sequencing of healthy cells to compare to the tumour.
3. Collection of routine clinical data on demographics, staging, diagnostic tests, treatment and outcomes.
4. The linkage of this data in a database held by a central team to co-ordinate between clinical sites, industry partners and cancer vaccine trial sites.
5. Onwards referral of potentially eligible patients to CV trials or linked research studies provided relevant research ethics approval has been granted - for which separate consent will be sought.

No specific therapeutic intervention will be carried out under this protocol and any activities for the CVLP will happen in addition to routine genetic testing that is carried out as standard of care. If CV gain regulatory approval we hope the CVLP pathway will become part of routine care.

**Ethics approval required**

Ethics approval required

### **Ethics approval(s)**

Approved 20/08/2023, East of England – Essex Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8177; essex.rec@hra.nhs.uk), ref: 23/EE/0178

### **Study design**

Observational cohort study

### **Primary study design**

Observational

### **Secondary study design**

Cohort study

### **Study setting(s)**

Hospital, Medical and other records

### **Study type(s)**

Other

### **Participant information sheet**

See study outputs table

### **Health condition(s) or problem(s) studied**

Cancer vaccine studies in various cancer types

### **Interventions**

Eligible patients with a number of different cancers will be approached around the time of diagnostic biopsy or surgical resection. This could be either during their initial diagnosis of cancer or at the time of recurrence. In all cases the patient will be aware that a diagnosis of cancer has already been made, or is a strong possibility. The patient will be approached by the clinical team managing their care to discuss the study and a standard patient information sheet will be provided.

Patients who agree to take part will have their informed consent confirmed and recorded by one of the clinical team or a research associate.

Following consent, the following will occur:

1. Cuttings of sections of tumour from the diagnostic block under the supervision of a histopathologist, for forwarding to CVLP partners (Phase 1) for extraction and sequencing of nucleic acid.
2. Drawing of a blood sample (up to 30mls) also for forwarding to CVLP partners. Potential tests performed on blood samples include germline extraction of nucleic acid for the comparison with the tumour sample or tumour circulating free tumour DNA.
3. Recording of baseline demographic and clinical data will be done by the clinical or research team. This will be sent along with biological material in a pseudonymised form. Data will be held centrally by the Southampton Clinical Trials Unit (SCTU).
4. During Phase 1 sequencing data will be held by industry partners. If a patient is deemed to be eligible for a cancer vaccine trial this will be fed back to the clinical liaison team who will inform

the clinical teams and any local trial sites. The pseudonymised codes will only be used for re-identifying patients when communicating with the clinical team or to link patients with NHS cancer vaccine trial sites. Any other information shared outside the NHS CVLP framework will be pseudonymised.

5. If a patient is deemed eligible for a cancer vaccine trial they will be approached by either their home clinical or research team, or by the team at the nearest cancer vaccine trial site for further discussion and a separate consent.

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome measure**

1. Number of participants recruited to the CVLP by September 2024
2. Number of participants recruited to the CVLP measured every 12 months until study closure
3. Proportion of eligible patients approached that consent to participate in the CVLP measured every 12 months until study closure
4. Proportion of tumour samples available for analysis measured at 2 weeks post consent to a cancer vaccine trial
5. Number of participants proceeding to participate in a cancer vaccine trial measured monthly until study closure

### **Secondary outcome measures**

Number of sequencing outputs from NHS laboratories used for manufacturing of therapeutic personalised cancer vaccines measured every 12 months until study closure

### **Overall study start date**

01/05/2023

### **Completion date**

31/12/2030

## **Eligibility**

### **Key inclusion criteria**

1. Be over the age of 16 years
2. Have a tumour which has been, or will be resected or biopsied
3. Have the capacity to consent to involvement in the CVLP
4. Have sufficient tumour available for genomic analyses

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

16 Years

**Sex**

Both

**Target number of participants**

10,000

**Key exclusion criteria**

1. Under the age of 16 years
2. Incapable of giving informed consent

**Date of first enrolment**

31/08/2024

**Date of final enrolment**

31/03/2026

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre****Maidstone**

Maidstone Hospital

Hermitage Lane

Maidstone

United Kingdom

ME16 9QQ

**Study participating centre****Tunbridge Wells Hospital**

The Tunbridge Wells Hospital

Tonbridge Road

Pembury

Tunbridge Wells

United Kingdom

TN2 4QJ

**Study participating centre****Southampton**

Southampton General Hospital

Tremona Road

Southampton

United Kingdom  
SO16 6YD

**Study participating centre**  
**University Hospital Lewisham**  
Lewisham High Street  
London  
United Kingdom  
SE13 6LH

**Study participating centre**  
**Queen Elizabeth Hospital**  
Woolwich Stadium Road  
Woolwich  
London  
United Kingdom  
SE18 4QH

**Study participating centre**  
**Royal Surrey County Hospital**  
Egerton Road  
Guildford  
United Kingdom  
GU2 7XX

**Study participating centre**  
**Royal Sussex County Hospital**  
Eastern Road  
Brighton  
United Kingdom  
BN2 5BE

**Study participating centre**  
**Conquest Hospital**  
The Ridge  
St. Leonards-on-sea  
United Kingdom  
TN37 7RD

**Study participating centre**  
**Eastbourne District General Hospital**  
Kings Drive  
Eastbourne  
United Kingdom  
BN21 2UD

**Study participating centre**  
**Addenbrookes**  
Addenbrookes Hospital  
Hills Road  
Cambridge  
United Kingdom  
CB2 0QQ

**Study participating centre**  
**Queens Hospital**  
Rom Valley Way  
Romford  
United Kingdom  
RM7 0AG

**Study participating centre**  
**Colchester General Hospital**  
Colchester District General Hosp.  
Charter Way  
Turner Road  
Colchester  
United Kingdom  
CO4 5JL

**Study participating centre**  
**Ipswich Hospital**  
Heath Road  
Ipswich  
United Kingdom  
IP4 5PD

**Study participating centre**  
**Stoke Mandeville Hospital**  
Mandeville Road



Aylesbury  
United Kingdom  
HP21 8AL

**Study participating centre**

**Wycombe Hospital**  
Queen Alexandra Road  
High Wycombe  
United Kingdom  
HP11 2TT

**Study participating centre**

**Hillingdon Hospital**  
Hillingdon Hospital  
Pield Heath Road  
Uxbridge  
United Kingdom  
UB8 3NN

**Study participating centre**

**Churchill Hospital**  
Churchill Hospital  
Old Road  
Headington  
Oxford  
United Kingdom  
OX3 7LE

**Study participating centre**

**Queens Medical Centre, Nottingham University Hospital**  
Derby Road  
Nottingham  
United Kingdom  
NG7 2UH

**Study participating centre**

**Nottingham City Hospital**  
Hucknall Road  
Nottingham  
United Kingdom  
NG5 1PB

**Study participating centre**

**Warwick Hospital**

Lakin Road  
Warwick  
United Kingdom  
CV34 5BW

**Study participating centre**

**New Cross Hospital Royal Wolverhampton**

Wolverhampton Road  
Heath Town  
Wolverhampton  
United Kingdom  
WV10 0QP

**Study participating centre**

**Walsall Manor Hospital**

Moat Road  
Walsall  
United Kingdom  
WS2 9PS

**Study participating centre**

**Royal Stoke University Hospital**

Newcastle Road  
Stoke-on-trent  
United Kingdom  
ST4 6QG

**Study participating centre**

**Salford Royal Hospital**

Stott Lane  
Eccles  
Salford  
United Kingdom  
M6 8HD

**Study participating centre**

**The Royal Oldham Hospital**  
Rochdale Road  
Oldham  
United Kingdom  
OL1 2JH

**Study participating centre**  
**Fairfield General Hospital**  
Fairfield General Hospital  
Rochdale Old Road  
Bury  
United Kingdom  
BL9 7TD

**Study participating centre**  
**Rochdale Infirmary**  
Whitehall Street  
Rochdale  
United Kingdom  
OL12 0NB

**Study participating centre**  
**St. James's University Hospital**  
Beckett Street  
Leeds  
United Kingdom  
LS9 7TF

**Study participating centre**  
**Leeds General Infirmary**  
Great George Street  
Leeds  
United Kingdom  
LS1 3EX

**Study participating centre**  
**Weston Park Hospital**  
Whitham Road  
Sheffield  
United Kingdom  
S10 2SJ

**Study participating centre**

**Derriford Hospital**

Derriford Road  
Derriford  
Plymouth  
United Kingdom  
PL6 8DH

**Study participating centre**

**Musgrove Park Hospital**

Parkfield Drive  
Taunton  
United Kingdom  
TA1 5DA

**Study participating centre**

**Yeovil District Hospital**

Higher Kingston  
Yeovil  
United Kingdom  
BA21 4AT

**Study participating centre**

**Royal Devon and Exeter Hospital**

Royal Devon & Exeter Hospital  
Barrack Road  
Exeter  
United Kingdom  
EX2 5DW

**Study participating centre**

**North Devon District Hospital**

Raleigh Park  
Barnstaple  
United Kingdom  
EX31 4JB

**Study participating centre**

**Bristol Haematology & Oncology Centre**  
Horfield Road  
Bristol  
United Kingdom  
BS2 8ED

**Study participating centre**  
**Southmead Hospital**  
Southmead Road  
Westbury-on-trym  
Bristol  
United Kingdom  
BS10 5NB

**Study participating centre**  
**Royal United Hospital Bath**  
Combe Park  
Bath  
United Kingdom  
BA1 3NG

**Study participating centre**  
**Cheltenham General Hospital**  
Sandford Road  
Cheltenham  
United Kingdom  
GL53 7AN

**Study participating centre**  
**Gloucestershire Royal Hospital**  
Great Western Road  
Gloucester  
United Kingdom  
GL1 3NN

**Study participating centre**  
**Royal Lancaster Infirmary**  
Ashton Road  
Lancaster  
United Kingdom  
LA1 4RP

**Study participating centre**  
**Royal Blackburn Hospital**  
Haslingden Road  
Blackburn  
United Kingdom  
BB2 3HH

**Study participating centre**  
**Cumberland Infirmary**  
Newtown Road  
Carlisle  
United Kingdom  
CA2 7HY

**Study participating centre**  
**West Cumberland Hospital**  
Homewood  
Hensingham  
Whitehaven  
United Kingdom  
CA28 8JG

**Study participating centre**  
**Sunderland Royal Hospital**  
Kayll Road  
Sunderland  
United Kingdom  
SR4 7TP

**Study participating centre**  
**South Tyneside District General Hospital**  
Harton Lane  
South Shields  
United Kingdom  
NE34 0PL

**Study participating centre**

**The James Cook University Hospital**  
Marton Road  
Middlesbrough  
United Kingdom  
TS4 3BW

**Study participating centre**  
**North Tyneside General Hospital**  
Rake Lane  
North Shields  
United Kingdom  
NE29 8NH

**Study participating centre**  
**Broomfield University Hospital**  
Broomfield Hospital  
Court Road  
Chelmsford  
United Kingdom  
CM1 7ET

**Study participating centre**  
**Basildon University Hospital**  
Nethermayne  
Basildon  
United Kingdom  
SS16 5NL

**Study participating centre**  
**Southend University Hospital**  
Prittlewell Chase  
Westcliff-on-sea  
United Kingdom  
SS0 0RY

**Study participating centre**  
**Royal Bournemouth General Hospital**  
Castle Lane East  
Bournemouth  
United Kingdom  
BH7 7DW

**Study participating centre**

**Poole Hospital**

Longfleet Road  
Poole  
United Kingdom  
BH15 2JB

**Study participating centre**

**St Marks Hospital**

Watford Road  
Harrow  
United Kingdom  
HA1 3UJ

**Study participating centre**

**East Surrey Hospital**

Canada Avenue  
Redhill  
United Kingdom  
RH1 5RH

**Study participating centre**

**Basingstoke and North Hampshire Hospital**

Aldermaston Road  
Basingstoke  
United Kingdom  
RG24 9NA

**Study participating centre**

**University Hospital of North Tees**

Hardwick Road  
Stockton-on-tees  
United Kingdom  
TS19 8PE

**Study participating centre**

**Great Western Hospital**

Marlborough Road



Swindon  
United Kingdom  
SN3 6BB

**Study participating centre**  
**Milton Keynes University Hospital**  
Standing Way  
Eaglestone  
Milton Keynes  
United Kingdom  
MK6 5LD

**Study participating centre**  
**Royal Hampshire County Hospital**  
Romsey Road  
Winchester  
United Kingdom  
SO22 5DG

**Study participating centre**  
**Castle Hill Hospital**  
Castle Road  
Cottingham  
United Kingdom  
HU16 5JX

**Study participating centre**  
**Bedford Hospital South**  
Kempston Road  
Bedford  
United Kingdom  
MK42 9DJ

**Study participating centre**  
**Luton and Dunstable University Hospital**  
Lewsey Road  
Luton  
United Kingdom  
LU4 0DZ

**Study participating centre**  
**West Middlesex University Hospital**  
Twickenham Road  
Isleworth  
United Kingdom  
TW7 6AF

**Study participating centre**  
**University Hospital Coventry & Warwickshire**  
Clifford Bridge Road  
Walsgrave  
Coventry  
United Kingdom  
CV2 2DX

**Study participating centre**  
**Russells Hall Hospital**  
Pensnett Road  
Dudley  
United Kingdom  
DY1 2HQ

**Study participating centre**  
**Manchester Royal Royal Infirmary**  
Cobbett House  
Oxford Road  
Manchester  
United Kingdom  
M13 9WL

**Study participating centre**  
**Wythenshawe Hospital**  
Southmoor Road  
Wythenshawe  
Manchester  
United Kingdom  
M23 9LT

**Study participating centre**

**Chesterfield Royal Hospital**  
Chesterfield Road  
Calow  
Chesterfield  
United Kingdom  
S44 5BL

**Study participating centre**  
**Harrogate District Hospital**  
Lancaster Park Road  
Harrogate  
United Kingdom  
HG2 7SX

**Study participating centre**  
**Rotherham General Hospital**  
Moorgate Road  
Rotherham  
United Kingdom  
S60 2UD

## **Sponsor information**

**Organisation**  
NHS England

**Sponsor details**  
Wellington House, 133-155 Waterloo Road  
London  
England  
United Kingdom  
SE1 8UG  
-  
[england.cancervaccinelaunchpad@nhs.net](mailto:england.cancervaccinelaunchpad@nhs.net)

**Sponsor type**  
Government

## **Funder(s)**

**Funder type**

Industry

Funder Name

NHS England as sponsor will be receiving funding from multiple industry companies

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

31/12/2031

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	version 8	22/03/2024	23/07/2024	No	Yes