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Liverpool Experimental Cancer Medicine Centre biomarker discovery programme

Submission date 25/11/2019	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol
Registration date 10/12/2019	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 27/01/2025	**Condition category** Cancer	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
The Liverpool Experimental Cancer Medicine Centre (LECMC) seeks to support early-phase clinical trials and laboratory-based cancer research in Liverpool, and through the ECMC network, more widely throughout the UK. One of the key strategic areas and objectives of the LECMC is to identify novel biomarkers of efficacy, resistance and drug safety in cancers including those of the pancreas, head and neck, breast liver and lung. In order to achieve this, the scientists and clinicians within the LECMC need good-quality prospective samples with linked data on treatments, side effects and outcomes. The biomarker discovery programme involves research groups within the University of Liverpool with interests in key strategic areas of the LECMC. The programme will involve the collection of samples from patients with cancer or pre-cancerous disease relevant to each of these groups for usage in research projects, specifically for the purpose of investigating biomarkers for cancers. The aim of the programme is to enable research which would identify biological markers for surgical outcomes, responses to therapy and early diagnosis from a variety of sources; with a goal of leading to the development of personalised treatment regimes, stratification of patients and development of preventative approaches to cancers.

Who can participate?
Individuals aged over 16 years, with any of the following:
1. Suspected or actual diagnosis of cancer of the head and neck or pre-cancerous oral conditions and individuals who have been treated for these conditions in the past
2. Suspected or actual diagnosis of pancreatic cancer and individuals who have been treated for pancreatic cancer in the past
3. Confirmed early, locally advanced or metastatic breast cancer
4. Suspected or actual diagnosis of primary or secondary hepatobiliary malignancy
5. Suspected or actual diagnosis of lung cancer, thymic malignancy or mesothelioma and individuals who have been treated for these conditions in the past

What does the study involve?
The study involves providing biological samples and clinical information at different stages of cancer treatment.

What are the possible benefits and risks of participating?
The programme is not expected to affect the current treatment of any individual participant or directly benefit them. However, it is intended that this work will lead to new ways of diagnosing, monitoring and treating cancer. Most samples are intended to be collected at the same time as a planned medical procedure so no risks above those expected in standard medical care are expected. Biopsy samples may cause a level of discomfort. These samples are optional.

Where is the study run from?
The study is coordinated by the Liverpool Experimental Cancer Medicine Centre (UK) and the Liverpool Clinical Trials Centre (UK).

When is the study starting and how long is it expected to run for?
February 2018 to March 2028

Who is funding the study?
Liverpool Experimental Cancer Medicine Centre (UK)

Who is the main contact?
Mrs Sara Martin

Contact information

Type(s)
Public

Contact name
Mrs Sara Martin

Contact details
Office 294
William Henry Duncan Building
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United Kingdom
L7 8TX
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
239896

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number

CPMS 41118, IRAS 239896

Study information

Scientific Title
Liverpool Experimental Cancer Medicine Centre (LECMC) biomarker discovery programme and prospective sample collection

Study objectives
Current study hypothesis as of 09/11/2023:
The Liverpool Experimental Cancer Medicine Centre (LECMC) seeks to support early-phase trials and translational science in Liverpool, and through the ECMC network, more widely throughout the UK. One of the key strategic areas and objectives of the LECMC is to identify novel biomarkers of efficacy, resistance and drug safety in the areas of pancreatic, head and neck, breast, hepatobiliary, thoracic and haematological malignancies. In order to achieve this, the scientists and clinicians within the LECMC need good-quality prospective samples with linked data on treatments, side effects and outcomes.

The researchers intend to initiate a broad programme for biomarker discovery involving, initially, five research groups within the University of Liverpool with interests in key strategic areas of the LECMC. These are the Mersey Head and Neck Oncology Research Group, the Pancreatic Cancer Research Group, the Breast Cancer Research Group, the Hepatobiliary Cancer Research Group and the Thoracic Cancer Research Group. The researchers would like to collect appropriate samples from patients with cancer or pre-cancerous disease relevant to each of these groups for usage in research projects, specifically for the purpose of investigating biomarkers for cancers. In doing so they hope to enable research which would identify markers for surgical outcomes, responses to therapy and early diagnosis from a variety of sources; with a goal of leading to the development of personalised treatment regimes, stratification of patients and development of preventative approaches to cancers.

Previous study hypothesis:
The Liverpool Experimental Cancer Medicine Centre (LECMC) seeks to support early-phase trials and translational science in Liverpool, and through the ECMC network, more widely throughout the UK. One of the key strategic areas and objectives of the LECMC is to identify novel biomarkers of efficacy, resistance and drug safety in cancers including those of the pancreas, head and neck and breast. In order to achieve this, the scientists and clinicians within the LECMC need good-quality prospective samples with linked data on treatments, side effects and outcomes.

The researchers intend to initiate a broad programme for biomarker discovery involving, initially, three research groups within the University of Liverpool with interests in key strategic areas of the LECMC. These are the Mersey Head and Neck Oncology Research Group, the Pancreatic Cancer Research Group and the Breast Cancer Research Group. The researchers would like to collect appropriate samples from patients with cancer or pre-cancerous disease relevant to each of these groups for usage in research projects, specifically for the purpose of investigating biomarkers for cancers. In doing so they hope to enable research which would identify markers for surgical outcomes, responses to therapy and early diagnosis from a variety of sources; with a goal of leading to the development of personalised treatment regimes, stratification of patients and development of preventative approaches to cancers.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 03/09/2019, Liverpool East Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8345; nrescommittee.northwest-liverpooleast@nhs.net), ref: 19/NW/0298

Amendment 02, to extend recruitment for a further 5 years until 31/03/2028, was approved on 11/04/2023, by North West – Liverpool Central Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; Tel: +44 (0)207 104 8345; liverpoolcentral.rec@hra.nhs.uk), ref: 19/NW/0298

Study design
Non-randomized; Observational; Design type: Cohort study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Pancreas, head and neck, breast, hepatobiliary and lung cancers

Interventions
Current interventions as of 09/11/2023:
Methodology depends upon the research strand in question and the specific condition that the patient has. However, for every visit for each part of the programme the relevant clinical and sample details will be recorded in a strand-specific and condition-specific manner on REDCap (the Liverpool Clinical Trials Centre REDCap system is a web-based application that can be used for collecting and collating clinical data securely in a manner that is straightforward and easy to understand for site staff, storing the data in a secure database at LCTC).

Most samples will be taken alongside either routine clinical care or medically-advised procedures. Samples taken outside of specific medical procedures already taking place are typically either non-invasive (such as saliva) or minimally invasive (such as blood). The only exception to this is the Head & Neck - Post Treatment Toxicity which includes the possibility of taking biopsied tissue samples outside of normal clinical procedures and medically-advised procedures. Some samples are from archived or diagnostically-taken Formalin-Fixed Paraffin-Embedded (FFPE) tissue. Tissue is typically tumour, however, there are some cases where adjacent areas (for comparative purposes) or areas affected by treatment are taken. All samples are voluntary and patients are able to refuse or agree to provide any or all samples at any or all specific points in the programme pathway.

Summary of research strands and branches as follows:

Head & Neck - Cancer Presumed Diagnosis:
1. Patient undergoes the informed consent procedure, signing a consent form; and is recruited to the programme.
2. Pre-surgical samples taken - blood and saliva.
3. Samples recovered from archive (where available) - tissue.

4. Intra-surgery, biopsy, or scrape samples - tissue and blood.
5. Follow-up visits including sample collection (blood, saliva plus samples from any further biopsies taken), or clinical follow-up visits with data only (in which case no samples are taken and only the relevant clinical data is recorded on REDCap).
6. End of involvement in the study (which can be the end of the programme period, patient death or patient withdrawal) - data entry only. End of involvement recorded on REDCap and final data entered. LECMC is informed via e-mail where applicable (e.g. for notification of withdrawal).

Head & Neck - Cancer Known Diagnosis:
1. Patient undergoes the informed consent procedure, signing a consent form; and is recruited to the programme.
2. Pre-surgical samples taken - blood and saliva.
3. Samples recovered from archive (where available) - tissue.
4. Intra-surgery, biopsy, or scrape samples - tissue and blood.
5. Follow-up visits including sample collection (blood, saliva plus samples from any further biopsies taken), or clinical follow-up visits with data only (in which case no samples are taken and only the relevant clinical data is recorded on REDCap).
6. End of involvement in the study (which can be the end of the programme period, patient death or patient withdrawal) - data entry only. End of involvement recorded on REDCap and final data entered. LECMC is informed via e-mail where applicable (e.g. for notification of withdrawal).

Head & Neck - Post-Treatment Toxicity:
1. Patient undergoes the informed consent procedure, signing a consent form; and is recruited to the programme.
2. Pre-surgical samples - blood and saliva.
3. From archive - tissue (where available).
4. Biopsy of affected sites - tissue, blood and saliva.
5. At treatment - blood and saliva.
6. Follow-up visits including sample collection (blood, saliva plus samples from any further biopsies taken) or clinical follow-up visits with data only (in which case no samples are taken and only the relevant clinical data is recorded on REDCap).
7. End of involvement in the study (which can be the end of the programme period, patient death or patient withdrawal) - data entry only. End of involvement recorded on REDCap and final data entered. LECMC is informed via e-mail where applicable (e.g. for notification of withdrawal).

Pancreas - Surgical:
1. Patient undergoes the informed consent procedure, signing a consent form; and is recruited to the programme.
2. Pre-surgical samples taken - blood, urine and previously taken tissue (where available).
3. Samples taken during surgery - tissue (from a Tru-Cut biopsy), bile, pancreatic juice and cyst fluid (where available).
4. Follow-up/adjuvant treatment visits including sample collection (blood, saliva, urine and faeces), or clinical follow-up visits with data only (in which case no samples are taken and only the relevant clinical data is recorded on REDCap).
5. Recurrence (where applicable) - blood, tissue, saliva, urine and faeces.
6. End of involvement in the study (which can be the end of the programme period, patient death or patient withdrawal) - data entry only. End of involvement recorded on REDCap and final data entered. LECMC is informed via e-mail where applicable (e.g. for notification of withdrawal).

Pancreas - Non-Surgical:
1. Patient undergoes the informed consent procedure, signing a consent form; and is recruited to the programme.

2. Diagnosis samples - blood, tissue, saliva, urine, faeces and cyst fluid (where available).
3. Archived diagnostic samples - taken from pre-existing archived tissue.
4. Pre-treatment samples - blood, saliva, urine, faeces and cyst fluid (where available).
5. During treatment/follow-up visits including sample collection (blood, saliva, urine, faeces and cyst fluid) or clinical follow-up visits with data only (in which case no samples are taken and only the relevant clinical data is recorded on REDCap).
6. Recurrence (where applicable) - blood, tissue, saliva, urine, faeces and cyst fluid
7. End of involvement in the study (which can be the end of the programme period, patient death or patient withdrawal) - data entry only. End of involvement recorded on REDCap and final data entered. LECMC is informed via e-mail where applicable (e.g. for notification of withdrawal).

Breast - Early Stage Breast Cancer:
1. Patient undergoes the informed consent procedure, signing a consent form; and is recruited to the programme.
2. Baseline - blood.
3. Tumour biopsy (FFPE tissue block), or tumour tissue from surgery (FFPE block).
4. Follow-up visits including sample collection (blood) or clinical follow-up visits with data only (in which case no samples are taken and only the relevant clinical data is recorded on REDCap).
5. On disease progression (blood), or upon non-CNS recurrence (blood and FFPE tissue).
6. End of involvement in the study (which can be the end of the programme period, patient death or patient withdrawal) - data entry only. End of involvement recorded on REDCap and final data entered. LECMC is informed via e-mail where applicable (e.g. for notification of withdrawal).

Breast - Breast Cancer with CNS Involvement:
1. Patient undergoes the informed consent procedure, signing a consent form; and is recruited to the programme.
2. Baseline - blood.
3. Primary tumour biopsy - FFPE tissue block.
4. Lumbar puncture (if taken) - cerebrospinal fluid.
5. Brain metastasis biopsy - blood, tissue and cerebrospinal fluid.
6. Follow-up visits including sample collection (blood), or clinical follow-up visits with data only (in which case no samples are taken and only the relevant clinical data is recorded on REDCap).
7. On disease progression (blood), or upon non-CNS recurrence (blood and FFPE tissue).
8. End of involvement in the study (which can be the end of the programme period, patient death or patient withdrawal) - data entry only. End of involvement recorded on REDCap and final data entered. LECMC is informed via e-mail where applicable (e.g. for notification of withdrawal).

Thoracic:
1. Patient undergoes the informed consent procedure, signing a consent form; and is recruited to the programme.
2. Pre-treatment samples taken - blood, saliva, sputum, urine and faeces (where available).
3. Samples recovered from archive (where available) - tissue and pleural fluid.
4. Samples taken during surgery or biopsy - tissue and pleural fluid.
5. Post-treatment/follow-up visits including sample collection (blood, saliva, sputum, urine and faeces), or clinical follow-up visits with data only (in which case no samples are taken and only the relevant clinical data is recorded on REDCap).
6. End of involvement in the study (which can be the end of the programme period, patient death or patient withdrawal) - data entry only. End of involvement recorded on REDCap and final data entered. LECMC is informed via e-mail where applicable (e.g. for notification of withdrawal).

Hepatobiliary:
1. Patient undergoes the informed consent procedure, signing a consent form; and is recruited

to the programme.
2. Diagnosis samples taken - blood, saliva, urine and faeces (where available).
3. Samples recovered from archive (where available) - tissue.
4. Pre-surgical/pre-treatment samples taken - blood, saliva, urine and faeces (where available).
5. Samples taken during surgery, biopsy or endoscopy - tissue and bile.
6. Follow-up/adjuvant treatment visits including sample collection (blood, saliva, urine and faeces), or clinical follow-up visits with data only (in which case no samples are taken and only the relevant clinical data is recorded on REDCap).
7. Recurrence (where applicable) - blood, tissue, saliva, urine and faeces.
8. End of involvement in the study (which can be the end of the programme period, patient death or patient withdrawal) - data entry only. End of involvement recorded on REDCap and final data entered. LECMC is informed via e-mail where applicable (e.g. for notification of withdrawal).

Previous interventions:
Methodology depends upon the research strand in question and the specific condition that the patient has. However, for every visit for each part of the programme the relevant clinical and sample details will be recorded in a strand-specific and condition-specific manner on REDCap (the LCTU REDCap system is a web-based application that can be used for collecting and collating clinical data securely in a manner that is straightforward and easy to understand for site staff, storing the data in a secure database at LCTU).

Most samples will be taken alongside either routine clinical care or medically-advised procedures. Samples taken outside of specific medical procedures already taking place are typically either non-invasive (such as saliva) or minimally invasive (such as blood). The only exception to this is the Head & Neck - Post Treatment Toxicity which includes the possibility of taking biopsied tissue samples outside of normal clinical procedures and medically-advised procedures. Some samples are from archived or diagnostically-taken Formalin-Fixed Paraffin-Embedded (FFPE) tissue. Tissue is typically tumour, however, there are some cases where adjacent areas (for comparative purposes) or areas affected by treatment are taken.

All samples are voluntary and patients are able to refuse or agree to provide any or all samples at any or all specific points in the programme pathway.

Summary of research strands and branches as follows:

Head & Neck - Cancer Presumed Diagnosis:
1. Patient undergoes the informed consent procedure, signing a consent form; and is recruited to the programme.
2. Pre-surgical samples taken - blood and saliva.
3. Samples recovered from archive (where available) - tissue.
4. Intra-surgery, biopsy, or scrape samples - tissue and blood.
5. Follow-up visits including sample collection (blood, saliva plus samples from any further biopsies taken), or clinical follow-up visits with data only (in which case no samples are taken and only the relevant clinical data is recorded on REDCap).
6. End of involvement in the study (which can be the end of the programme period, patient death or patient withdrawal) - data entry only. End of involvement recorded on REDCap and final data entered. LECMC is informed via e-mail where applicable (e.g. for notification of withdrawal).

Head & Neck - Cancer Known Diagnosis:
1. Patient undergoes the informed consent procedure, signing a consent form; and is recruited to the programme.
2. Pre-surgical samples taken - blood and saliva.

3. Samples recovered from archive (where available) - tissue.
4. Intra-surgery, biopsy, or scrape samples - tissue and blood.
5. Follow-up visits including sample collection (blood, saliva plus samples from any further biopsies taken), or clinical follow-up visits with data only (in which case no samples are taken and only the relevant clinical data is recorded on REDCap).
6. End of involvement in the study (which can be the end of the programme period, patient death or patient withdrawal) - data entry only. End of involvement recorded on REDCap and final data entered. LECMC is informed via e-mail where applicable (e.g. for notification of withdrawal).

Head & Neck - Post-Treatment Toxicity:
1. Patient undergoes the informed consent procedure, signing a consent form; and is recruited to the programme.
2. Pre-surgical samples - blood and saliva.
3. From archive - tissue (where available).
4. Biopsy of affected sites - tissue, blood and saliva.
5. At treatment - blood and saliva.
6. Follow-up visits including sample collection (blood, saliva plus samples from any further biopsies taken) or clinical follow-up visits with data only (in which case no samples are taken and only the relevant clinical data is recorded on REDCap).
7. End of involvement in the study (which can be the end of the programme period, patient death or patient withdrawal) - data entry only. End of involvement recorded on REDCap and final data entered. LECMC is informed via e-mail where applicable (e.g. for notification of withdrawal).

Pancreas - Surgical:
1. Patient undergoes the informed consent procedure, signing a consent form; and is recruited to the programme.
2. Pre-surgical samples taken - blood, urine and previously taken tissue (where available).
3. Samples taken during surgery - tissue (from a Tru-Cut biopsy), bile and pancreatic juice.
4. Follow-up/adjuvant treatment visits including sample collection (blood and urine), or clinical follow-up visits with data only (in which case no samples are taken and only the relevant clinical data is recorded on REDCap).
5. Recurrence (where applicable) - blood, tissue and urine.
6. End of involvement in the study (which can be the end of the programme period, patient death or patient withdrawal) - data entry only. End of involvement recorded on REDCap and final data entered. LECMC is informed via e-mail where applicable (e.g. for notification of withdrawal).

Pancreas - Non-Surgical:
1. Patient undergoes the informed consent procedure, signing a consent form; and is recruited to the programme.
2. Diagnosis samples - blood, urine and tissue (where available)
3. Archived diagnostic samples - taken from pre-existing archived tissue.
4. Pre-treatment samples - blood and urine.
5. During treatment/follow-up visits including sample collection (blood and urine) or clinical follow-up visits with data only (in which case no samples are taken and only the relevant clinical data is recorded on REDCap).
6. Recurrence (where applicable) - blood, urine and tissue.
7. End of involvement in the study (which can be the end of the programme period, patient death or patient withdrawal) - data entry only. End of involvement recorded on REDCap and final data entered. LECMC is informed via e-mail where applicable (e.g. for notification of withdrawal).

Breast - Early Stage Breast Cancer:
1. Patient undergoes the informed consent procedure, signing a consent form; and is recruited

to the programme.
2. Baseline - blood.
3. Tumour biopsy (FFPE tissue block), or tumour tissue from surgery (FFPE block).
4. Follow-up visits including sample collection (blood) or clinical follow-up visits with data only (in which case no samples are taken and only the relevant clinical data is recorded on REDCap).
5. On disease progression (blood), or upon non-CNS recurrence (blood and FFPE tissue).
6. End of involvement in the study (which can be the end of the programme period, patient death or patient withdrawal) - data entry only. End of involvement recorded on REDCap and final data entered. LECMC is informed via e-mail where applicable (e.g. for notification of withdrawal).

Breast - Breast Cancer with CNS Involvement:
1. Patient undergoes the informed consent procedure, signing a consent form; and is recruited to the programme.
2. Baseline - blood.
3. Primary tumour biopsy - FFPE tissue block.
4. Lumbar puncture (if taken) - cerebrospinal fluid.
5. Brain metastasis biopsy - blood, tissue and cerebrospinal fluid.
6. Follow-up visits including sample collection (blood), or clinical follow-up visits with data only (in which case no samples are taken and only the relevant clinical data is recorded on REDCap).
7. On disease progression (blood), or upon non-CNS recurrence (blood and FFPE tissue).
8. End of involvement in the study (which can be the end of the programme period, patient death or patient withdrawal) - data entry only. End of involvement recorded on REDCap and final data entered. LECMC is informed via e-mail where applicable (e.g. for notification of withdrawal).

Intervention Type
Other

Primary outcome(s)
The primary outcome measure for this programme will be the number of publications produced by research projects supported by the programme. Each project supported by the programme will have its own outcome measures which will be considered by the programme management team during the project adoption process.

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
31/03/2028

Eligibility

Key inclusion criteria
This will vary according to tumour type. In general, the populations will consist of patients undergoing standard diagnosis and treatment for malignancies and premalignant disease in disease areas which are of interest to the LECMC. All patients must, in addition to fulfilling the medical requirements, complete an informed consent procedure including the physical signing of a consent form.

Head and Neck:
Presumptive or acute diagnosis of head and neck squamous cell cancer (HNSCC) or recognised oral premalignant conditions (OPML) including but not exhaustively oral epithelial dysplasia

(OED), proliferative verrucous leucoplakia (PVL), and those individuals who have been treated for these conditions in the past.

Pancreas:
All patients with suspected or actual diagnosed Pancreatic Ductal Adenocarcinoma (PDAC), and those individuals who are undergoing or have been treated for PDAC in the past.

Breast:
Samples from all patients with histologically and/or cytologically confirmed early, locally advanced or metastatic breast cancer including patients with central nervous system (CNS) involvement defined as metastases to the brain parenchyma, metastases to the leptomeninges and/or paraneoplastic disorders.

Added 09/11/2023:
Hepatobiliary:
All patients with suspected or actual diagnosis of primary or secondary hepatobiliary malignancy.

Thoracic:
Presumptive, past or actual diagnosis of lung cancer, thymic malignancy or mesothelioma, and those individuals who have been treated for these conditions in the past.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Sex
All

Key exclusion criteria
1. Individuals who are unable to consent
2. Under 18 years of age
3. Unable to read or translate patient information sheet and/or consent form

Date of first enrolment
01/01/2020

Date of final enrolment
31/03/2028

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Royal Liverpool and Broadgreen University Hospitals NHS Trust
Royal Liverpool University Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP

Study participating centre
The Clatterbridge Cancer Centre NHS Foundation Trust
Clatterbridge Hospital
Clatterbridge Road
Bebington
Wirral
United Kingdom
CH63 4JY

Study participating centre
Aintree University Hospital NHS Foundation Trust
University Hospital Aintree
Fazakerley Hospital
Lower Lane
Liverpool
United Kingdom
L9 7AL

Study participating centre
The Walton Centre NHS Foundation Trust
Lower Lane
Liverpool
United Kingdom
L9 7LJ

Sponsor information

Organisation

University of Liverpool

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK; Grant Codes: C52547/A28210

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes