

Privacy Notice for the Virtual Cardio-oncology research initiative (VICORI)

Background – why we need research into cardio-oncology

Heart disease and cancer are the commonest causes of death in the UK. Treatments are leading to better outcomes which means people are living longer with these conditions. This means more people are living with both conditions. These conditions interact on many levels and yet there is little current research focused on these interactions. The Virtual Cardio-Oncology Research Initiative (VICORI) is a collaborative programme funded by the British Heart Foundation (BHF) and Cancer research UK (CRUK) to investigate, using data collected as part of national audits, the interaction between heart disease and cancer. VICORI is supported by patient and professional organisations including: The National Institute for Cardiovascular Outcomes Research (NICOR), The British Cardiovascular Society, The British Cardiovascular Intervention Society, Macmillan Cancer Support, Public Health England, Independent Cancer Patients Voice, The NIHR Medical Informatics & Data Linkage (MIDL) Strategy Group, The British Cardio-Oncology Society.

The VICORI team are overseen by a Programme Governance Board which includes two lay members and is responsible for ensuring the project is carefully managed and patient-focused. VICORI is responsible for reporting findings from the cardio-oncology research programme. This study will progress under the umbrella of our partner and stakeholder organisations (Public Health England - PHE, National Institute for Cardiovascular Outcomes Research - NICOR and University of Leicester). The results from the cardio-oncology research program will inform clinicians' decisions when managing and treating patients with cardiovascular disease and cancer.

National Cardiovascular and Cancer Audits

The National Cardiac Audit Programme (NCAP) and National Cancer Registration and Analysis Service (NCRAS) collect audit data on patients in the UK with cardiovascular disease or cancer. NCRAS is managed by Public Health England (PHE) and NCAP is managed by the National Institute for Cardiovascular Outcomes Research (NICOR).

NICOR audits include the following:

MINAP: The myocardial infarction national audit project. This contains data on patients suffering myocardial infarction in England, Wales and Northern Ireland whether or not managed procedurally

BCIS: The adult cardiovascular interventions audit provides comparative data on percutaneous coronary interventions and transcatheter aortic valve implantations (TAVI) for the UK

SCTS: The national adult cardiac surgical audit collects data on all major heart operations in the UK including coronary artery bypass surgery (CABG) and cardiac valve surgery

Congenital heart disease: The national congenital heart disease audit includes all procedures and operations in both children and adults relating to structural defects, congenital arrhythmias and cardiomyopathies

Heart failure: The national heart failure audit includes patients discharged from an acute hospital admission with a primary diagnosis of heart failure

Cardiac rhythm management: This captures audit data on UK patients requiring a device or procedure for cardiac rhythm disorders

NCRAS audits include the following:

Data is taken from a wide variety of sources and collated and linked to produce a single, comprehensive record for each patient. In recent years other sources of data have been added, including the National

Cancer Audits in Lung, Colo-rectal, Head and Neck, Breast, Prostate and Upper GI cancers, plus that from new datasets, including the Cancer Outcomes and Services Dataset (COSD), the Radiotherapy Dataset RTDS), the Systemic Anti-Cancer Therapy dataset (SACT) and the Diagnostic Imaging Dataset (DIDs).

Linking cardiovascular and cancer audits - VICORI

The VICORI database will consist of all NICOR and NCRAS audit data. Both these audits already contain data from Hospital Episode Statistics (HES) – coded data about hospital admissions, and Office for National Statistics (ONS) – on dates and causes of death. These data will also be included in VICORI. Both NICOR and NCRAS contain patient identifiable data but this is not required at present for VICORI. Therefore NICOR will pseudonymise the data by encrypting items of data which could be used for identification of individual patients. The data will then be transferred to PHE. The same pseudonymisation process will be used for the NCRAS data to enable linkage. The Office for Data Release (ODR) of PHE will be the data controller for this linkage. VICORI will only access and analyse de-identified linked audit data.

Data Controller:

Tariq Malik, Head, Office for Data Release, Public Health England, UK.

The VICORI project consists of 4 work packages, each with a work package lead. VICORI will act as data controller to prepare the de-identified linked VICORI data required for each work package with the work package analyst. The academic partners working in collaboration with VICORI are listed below.

VICORI – legal basis and purpose for holding and analysing data

Both NICOR and NCRAS conform to Data Protection Act legislation and the General Data Protection Regulation (GDPR) when collecting and managing patient identifiable data, working with the Confidentiality Advisory Group (CAG) of the NHS Health Research Authority (HRA), the Care Quality Commission (CQC) and the Healthcare Quality Improvement Partnership (HQIP) to ensure data is handled under section 251 of the NHS Act 2006.

The processes of linkage uses pseudonymised data and as such does not require separate CAG approval (as confirmed by the Health Research Authority HRA). At present all linked data analysed by the VICORI team will be de-identified. Obtaining patient consent is not practical given the scale of these data. VICORI will therefore process and analyse these data on the basis of a Legitimate Interest as defined in article 6 of GDPR. Research ethical approval for VICORI has been obtained (Ethics Ref: 18/NE/0123, **Sponsor Reference No:** UOL 0656 / IRAS: 237503/ EDGE: 105514).

These data are processed for the purposes of conducting cardio-oncology research.

Specific aims are:

- To investigate if cardiac conditions are managed differently in cancer patients and cardiovascular outcomes are influenced by a prior cancer diagnosis (workpackage 1)
- To investigate if cardiovascular treatments, interventions and surgery alter cancer risk or outcomes (workpackage 2)
- To investigate if cancer treatments cause long term adverse cardiovascular diseases states or cardiovascular events (workpackage 3)
- To investigate if pre-existent cardiac disease alters cancer management or outcomes (workpackage 4)

Data will be retained in the first instance until Dec 30th 2022 (the current duration of VICORI funding). Subject to further funding, permissions will be sought to extend this to continue to extend this research beyond this date.

VICORI will take care of your data

The VICORI group have relevant training in data security and confidentiality and all data will be stored securely. As only de-identified data will be analysed, it will not be possible to share identifiable data with third parties or in publications.

VICORI – patient and public oversight

Our study concept and design has been developed in consultation with our patient and public involvement committee (PPI). Our lead lay/patient/relative representatives, as study collaborators, will ensure an appropriate patient-centred focus is maintained during project delivery and the dissemination of study findings. The lay representatives will attend the Programme Management Group meetings and support the drafting of ‘Plain English’ summaries of all study publications which will be provided as links on the websites of VICORI and the partner organisations to facilitate wider patient and public understanding of the findings and their implications.

Who will VICORI data be shared with?

VICORI is a collaborative partnership between patients, academics and our institutional supporters. To maximise the research outputs and therefore the benefits to patients, de-identified data will be shared with the following partners, all of whom have appropriately rigorous data security arrangements in place.

University of Leicester, Centre for Medicine, University Road, Leicester, LE1 7RH, UK. Lead investigator Dr David Adlam

University of Birmingham. Centre for Childhood Cancer Survivor Studies, Institute of Applied Health Research, Robert Aitken Building, Birmingham, B15 2TY, UK. Lead investigator Professor Mike Hawkins

University of Oxford. Nuffield Department of Population Health, Richard Doll Building, Old Road Campus, Oxford, OX3 7LF. Lead investigator Professor Sarah Darby

Royal Marsden Hospital. The Royal Marsden NHS Foundation Trust. Downs Road, Sutton, Surrey, SM2 5PT, UK. Lead investigator. Dr Alistair Ring

Imperial College London, Royal Brompton Hospital, London, SW3 6NP, UK. Lead investigator Dr Alex Lyon

University of Leeds. Clinical and Population Sciences Department, School of Medicine, University of Leeds, Leeds LS2 9JT, UK. Lead investigator Dr Chris Gale

University College London, Farr Institute of Health Informatics Research, University College London, UK. Lead investigator. Dr Amitava Banerjee

London School of Hygiene and Tropical Medicine, UK. Lead investigator Dr Krishnan Bhaskaran

Patient opt-out and complaints

However, we can remove patients from the data if requested. Patients wishing to opt-out and withdraw data from the NICOR or NCRAS audits and therefore VICORI can do so by contacting in writing:

NICOR: James Chal, NICOR Chief Operating Officer, 2nd Floor, 1 St Martin's le Grand, London, EC1A 4NP or email nicor-generalenquiries@bartshealth.nhs.uk

NCRAS: Director, National Cancer Registration and Analysis Service, Public Health England, Wellington House, London, SE1 8UG or email optout@phe.gov.uk

Patients also have the right to complain about any aspect of this programme to the supervisory authority, the Information Commissioners Office (<https://ico.org.uk/global/contact-us/>)