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Testing a standardised reporting tool (PACT-UK) for pancreatic cancer

Submission date 25/09/2026	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 06/10/2026	**Overall study status** Ongoing	
Last Edited 06/10/2026	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Pancreatic cancer is difficult to diagnose and treat. CT scans are used to assess pancreatic tumours and help doctors plan treatment. Inconsistent reporting can make results harder to compare and plan treatment and carry out research. PACT-UK is a national structured reporting tool designed to help radiologists describe pancreatic cancer CT scans in a consistent way. IMAGINE PACT will assess how consistently radiologists use PACT-UK when reporting pancreatic cancer CT scans across NHS hospitals. The study will assess agreement between different radiologists and consistency when the same radiologist reviews the same scan on two occasions. It will also identify areas where the reporting tool may need refinement or additional training.

Who can participate?
The study includes adults aged 18 years or over who have had a pancreatic CT scan and a PACT-UK report as part of routine NHS care for suspected or confirmed pancreatic cancer, subject to the study eligibility criteria.
No additional scans, tests or hospital visits are required.
There are two routes into the study:
1. Prospective cohort: NHS patients who meet the eligibility criteria may be approached by the research team and asked to provide written consent.
2. Retrospective cohort: historical cases from the preceding two years may be included where it is not practicable to contact a patient to ask for consent, for example if they have died or cannot be contacted. Patient's information will only be used in this way where the appropriate NHS approvals are in place, including Section 251 support following advice from the NHS Confidentiality Advisory Group (CAG).

What does the study involve?
IMAGINE PACT uses CT scans and associated PACT-UK structured reports that have already produced as part of routine NHS care. No additional scans, tests, treatments or hospital visits are required.
For the prospective cohort, eligible patients are approached for consent before their study information is accessed.
For the retrospective cohort, historical cases may be identified from routinely held clinical records under the approved Section 251 pathway, where prospective consent is not practicable,

for example if they have died or can no longer be contacted. Information from these patients will only be used where the required approvals are in place, including Section 251 support from the Health Research Authority, following advice from the Confidentiality Advisory Group, and where the patient has not opted out.
For the retrospective cohort, the National Data Opt-Out will be checked and respected in accordance with the approved study arrangements. A study-specific opt-out mechanism is also available. Patients who do not want their information to be included in IMAGINE PACT can contact their local research team/treating team at the participating hospital. The request will be recorded locally and communicated to the study team before information relating to the patient is included.
Patients can opt out without giving a reason, and the National Data Opt-Out is respected. Details of how to opt out are set out in the study's Fair Processing Notice, available as an attached document.
Before information leaves the participating hospital, identifying details such as name, NHS number and date of birth are replaced with a unique study code. The link between the patient's identity and their code remains securely at the originating hospital and is not shared with the central research team.
Participating radiologists independently review selected pseudonymised CT scans and complete the PACT-UK structured report without seeing other radiologists' reports. The same radiologists repeat the assessment for a subset of scans after a minimum interval of four weeks.
For full details on how information is used and protected, including the current list of participating hospitals and local opt-out contacts, please see the attached IMAGINE PACT Fair Processing Notice.

What are the possible benefits and risks of participating?
There is no expected direct benefit to an individual from taking part or from their information being included. The results may help improve consistency in pancreatic cancer CT reporting across the NHS, which could support refinement of PACT-UK and associated training, clearer communication between doctors and better-informed treatment decisions for future patients.
No additional procedures are involved, so there are no additional medical risks.
The main potential risk relates to the use of confidential health information. This is addressed through pseudonymisation, secure research systems, restricted access, retention of the local linkage record at the originating hospital and the approved governance arrangements.

Where is the study run from?
The study is sponsored by The Christie NHS Foundation Trust (UK) and is being carried out in partnership with the Institute of Cancer Research and participating NHS specialist hospitals in England and Scotland.

When is the study starting and how long is it expected to run for?
October 2026 to October 2028

Who is funding the study?
Pancreatic Cancer UK

Who is the main contact?
1. Mona Khoo, mona.khoo@nhs.net
2. Dr Ganesh Radhakrishna, g.radhakrishna@nhs.net

Contact information

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Public

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Additional identifiers

Integrated Research Application System (IRAS)
368584

Central Portfolio Management System (CPMS)
72734

Study information

Scientific Title
IMAGINE PACT: Imaging dataset curation for the multicentre validation of PACT-UK (Pancreatic Cancer Reporting Template UK)

Acronym
IMAGINE PACT

Study objectives
Primary objectives:
To assess the inter-rater and intra-rater reliability of PACT-UK structured reporting for pancreatic cancer CT imaging across multiple NHS sites, establishing whether standardised annotation achieves acceptable consistency for multi-centre research and clinical use

Secondary objectives:
1. To identify PACT-UK template elements demonstrating suboptimal inter- or intra-rater reliability and implement iterative evidence-based refinements, including clarification of definitions, terminology, and reporting criteria, with reassessment of reliability following refinement
2. To curate a quality-assured, pseudonymised multicentre imaging dataset of pancreatic cancer studies with standardised PACT-UK annotations from participating NHS HPB centres, sufficient to support the primary reliability analysis and secondary descriptive objectives of this study
3. To describe variation in structured reporting practice across participating NHS HPB centres and assess the feasibility of implementing PACT-UK structured reporting across multiple NHS sites

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/07/2026, East Midlands Derby Research Ethics Committee (2 Redman Place, Stratford, London, EC20 1JQ, United Kingdom; +44 (0)207 1048 154; derby.rec@hra.nhs.uk), ref: 26/EM/0174

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cancer and neoplasms

Interventions
IMAGINE PACT is a prospective and retrospective observational cohort study designed to evaluate the PACT-UK structured reporting template for pancreatic cancer imaging across UK NHS HPB centres. The study will use a statistically robust multi-reader multi-case (MRMC) methodology to evaluate inter- and intra-rater reliability of structured radiology reporting using a multicentre imaging dataset derived from routine clinical care.

A group of radiologists from participating hospitals will independently review a selected set of pseudonymised scans and complete a PACT-UK structured report for each one, without seeing what other radiologists have written. The same radiologists will repeat the assessment for a subset of scans after a minimum interval of 4 weeks and without access to their previous reports.

The primary reliability analyses are restricted to CT imaging. MRI scans acquired as part of routine NHS care may be collected where available for dataset curation and secondary methodological objectives.

The prospective cohort uses written informed consent. The retrospective cohort may use historical information under Section 251 support where prospective consent is not practicable and the approved safeguards and regulatory requirements are met.

Identifying information is replaced by a unique Study ID at the originating NHS site before imaging and associated reports are transferred to the central research systems. The local linkage record remains at the originating site.

Intervention Type
Other

Primary outcome(s)
1. Inter-rater and intra-rater reliability of the PACT-UK structured reporting tool across participating NHS HPB centres, measured using intraclass correlation coefficient (ICC) for continuous variables and Cohen's or Fleiss' kappa for categorical and ordinal variables during the primary reliability assessment. The primary focus is vascular involvement extent scores for the portal vein, superior mesenteric vein, superior mesenteric artery and common hepatic artery. Intra-rater repeat assessment occurs after a minimum interval of 4 weeks. Measured at during the study, following data collection.

Key secondary outcome(s)
1. Template optimisation: post-refinement inter-rater and intra-rater reliability scores for PACT-UK elements identified as having suboptimal agreement in the primary analysis, measured using ICC for continuous variables and kappa for categorical/ordinal variables following iterative template refinement and additional radiologist training. Measured following the primary analysis.
2. Imaging dataset completeness: proportion of registered cases with a fully completed PACT-UK structured report; distribution of image quality scores meeting pre-specified quality thresholds; and completeness of imaging metadata fields, including modality and acquisition parameters. Measured during and at the end of the study
3. Implementation/feasibility: recruitment rate expressed as cases successfully registered and uploaded per site per month; proportion of eligible patients successfully enrolled across sites; and variation in PACT-UK reporting practice between participating sites using descriptive statistics. Measured throughout recruitment and at study completion.

Completion date
01/10/2028

Eligibility

Key inclusion criteria
1. Adults aged 18 years or over at the time of imaging
2. Suspected or confirmed pancreatic neoplasm discussed at a hepatopancreatobiliary (HPB) multidisciplinary team meeting
3. Non-metastatic disease at the time of imaging

4. Contrast-enhanced CT of the pancreas performed as part of routine NHS clinical care*
5. Availability of a completed PACT-UK structured radiology report associated with the imaging study

* MRI scans acquired as part of routine clinical care may additionally be included for dataset curation and secondary objectives but are not eligible for the primary reliability analysis.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Evidence of distant metastatic disease at the time of imaging
2. Imaging studies that are technically inadequate for structured reporting

Date of first enrolment
06/10/2026

Date of final enrolment
01/04/2027

Locations

Countries of recruitment
United Kingdom

England

Scotland

Study participating centre
The Royal Marsden NHS Foundation Trust
Fulham Road

London
England
SW3 6JJ

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
England
M13 9WL

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
Beckett Street
Leeds
England
LS9 7TF

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
England
NE7 7DN

Study participating centre
Glasgow Royal Infirmary
84 Castle Street
Glasgow
Scotland
G4 0SF

Sponsor information

Organisation

The Christie NHS Foundation Trust

ROR
https://ror.org/03v9efr22

Funder(s)

Funder type
Government

Funder Name
Pancreatic Cancer UK

Alternative Name(s)
PCUK

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository
1. Repository: Pseudonymised imaging and PACT-UK are held in XNAT, a secure research system hosted by the Institute of Cancer Research (UK). Pseudonymised study data is held in REDCap at The Christie NHS Foundation Trust.
2. Data: Pseudonymised CT imaging, PACT-UK structured reports, year of birth, sex, ethnicity and pathology status.
Directly identifiable patient information is not transferred to the central research team. Identifying information is replaced by a unique Study ID at the originating NHS site, and the local linkage record remains at that site.
3. Availability and access: Not publicly available. Access is restricted to approved members of the study team and analysts, and all access is logged and monitored. Aggregate results will be published; no individual will be identifiable.
4. Use beyond this study: Any request to use the data for other research would need separate ethical approval and governance review before access could be considered.
5. Consent: Written informed consent is obtained for the prospective cohort. The retrospective cohort is included without individual consent only where the required approvals are in place,

including Section 251 support, with the National Data Opt-Out and a study-specific opt-out applied.
6. Anonymisation: The data are pseudonymised, not anonymised. The central team does not hold the key linking study codes to individuals; it stays securely at each participating hospital.
7. Ethical or legal restrictions: Data are confidential patient information; access is governed by the conditions of the REC opinion and, for the retrospective cohort, CAG support.

The pseudonymised dataset will be retained after study completion in accordance with Sponsor policy and NHS records-management requirements. Pseudonymised participant-level datasets will not be made publicly available. Where data underlying publications are made available, only fully anonymised or aggregated data will be considered, following independent governance review and appropriate data-access agreements. Any future secondary use will be subject to independent governance review and separate ethical approval where required.

IPD sharing plan summary
Stored in non-publicly available repository