Public title

Hereditary Pancreatic Cancer Early Surveillance program

Scientific Title

Surveillance of High-risk Individuals and Early detection of Pancreatic cancer to detect pancreatic cancer early in people at higher inherited or family risk.

Acronym

PACES

Study objectives

The main objectives of the study are to :

(1) identify people at elevated inherited/familial risk of pancreatic cancer,

(2) follow them longitudinally with structured surveillance to detect disease earlier, and

(3) use the resulting data/samples to validate and develop biomarkers and prediction tools.

Tier 1: Patient Identification, Pre-screening, Genetic evaluation

Primary objective: To perform an initial risk/eligibility assessment through a public-facing digital pre-screening tool (e.g., chatbot/web platform) based on personal and family history (and other relevant risk factors), in order to identify individuals potentially at increased risk of pancreatic cancer and triage/direct those individuals to a participating clinical site for confirmatory eligibility assessment and subsequent germline genetic evaluation and risk stratification.

Secondary objectives: Classify participants by pathogenic/likely pathogenic variants in the targeted gene panel; assess the distribution of genetic syndromes in the referred population; correlate genetic profiles with clinical/demographic risk factors; generate a baseline cohort for longitudinal surveillance.

Tier 2: Surveillance program

Primary objective: Identify pancreatic ductal adenocarcinoma (PDAC) at an early stage in people with hereditary/familial risk using serial imaging and/or biomarker tracking.

Secondary objectives: Support development/training/validation of AI-based risk prediction models; build a harmonized dataset integrating genetics, family history, clinical factors, imaging, and biomarkers; provide a research-ready platform for biomarker discovery/validation; establish and refine evidence-based surveillance protocols.

Tier 3: Validation & Biomarker Discovery – translational output

is to evaluate the clinical performance of the Reccan-IA blood test for detecting pancreatic ductal adenocarcinoma (PDAC) in familial and genetically high-risk individuals, by determining its sensitivity and specificity relative to clinical diagnosis based on MRI (with histopathology confirmation when applicable). Create a high-quality, ethically governed biorepository that supports future translational research beyond the initial scope of SHIELD

Secondary objectives:

The clinical validation component of SHIELD aims to **prospectively evaluate the clinical performance** of a novel blood-based diagnostic approach for the early detection of pancreatic ductal adenocarcinoma (PDAC) in individuals at increased hereditary or familial risk. To estimate sensitivity, specificity, PPV and NPV for identifying individuals who meet Tier 1/Tier 2 eligibility criteria (mirroring the kind of performance metrics already used in Tier 3 for Reccan-IA).

The biomarker discovery component of SHIELD aims to expand scientific knowledge of early PDAC biology and to support the **development of next-generation diagnostic tools**. Its objectives are to identify and characterize **novel proteomic and molecular biomarkers** associated with early PDAC and pre-clinical disease stages.

Study design

prospective, multicentre, longitudinal surveillance and sample-collection program

Primary design

prospective, non-interventional

Secondary study design

longitudinal, multicentre observational

Study Setting

home, hospital

Study Types

genetic evaluation / risk stratification

exploratory discovery research

Health condition(s) or problem(s) studied

pancreatic ductal adenocarcinoma (PDAC)

Interventions

LLM powered screening/eligibility conversation and assessment

Genetic risk evaluation with risk stratification

Diagnostic test evaluation

Intervention Type

Other

Primary outcomes

Tier 1:

Proportion of approached individuals against those who used the public facing interfaces and those who meet SHIELD high-risk eligibility criteria based on genetic results.

Tier 2:

Longitudinal adherence rate to annual follow-up schedule (e.g., MRI completion and blood sampling)

Completeness and quality of the surveillance dataset (clinical, imaging, genetic, biospecimen data)

Tier 3:

Sensitivity (proportion of true PDAC cases correctly identified by a novel biomarker test) and specificity (proportion of non-PDAC individuals correctly identified as negative), relative to clinical diagnosis based on MRI (confirmed by histopathology when applicable).

Secondary

Tier 1:

Frequency of pathogenic or likely pathogenic variants

Proportion of genetically high-risk individuals enrolled into the clinical validation of Reccan-IA

Tier 2:

Incidence of PDAC or high-grade precursor lesions detected during surveillance

Number and quality of biological samples collected and banked for future biomarker research

Tier 3:

PPV and NPV of Reccan-IA.

Performance in different high-risk subgroups (familial high-risk, genetic high-risk, and NOD).

Sensitivity for early-stage **Key inclusion criteria**

Tier 1 - eligibility assessment

- Ability to sign the eConsent
- Age >= 18

Tier 1 - genetic evaluation

- Individuals with a personal or family history suggestive of heritable pancreatic cancer syndromes, age 40+ (or 10 years younger than the youngest affected family member's age at onset, per the protocol text).
- Family-history patterns that can qualify include (examples listed in the protocol): 1 first-degree relative (FDR) with PDAC (with additional qualifiers/limits), 1 FDR plus other cancers/risk factors (e.g., NOD, pancreatitis, IPMN), 2 second-degree relatives (SDR), or meeting CAPS criteria (Annex referenced).
- Individuals with newly diagnosed pancreatic cancer (age ≥18) are eligible to enter Tier 2 directly per the Tier 1 synopsis.

Tier 2 - Surveillance program & sample collection

- Written informed consent and adult age ≥18 years.
- Either: treatment-naïve, confirmed PDAC (with preferred stage distribution targets/limits noted in the protocol), included to build a reference cohort.
- Or: "overall healthy" individuals with familial/hereditary risk, including any of the following high-risk categories: familial clustering patterns (e.g., ≥2 relatives with PDAC with at least one FDR; or two affected FDRs), or carriers of specific pathogenic/likely pathogenic variants with required family history and age thresholds (e.g., BRCA1/2, PALB2, ATM with an affected FDR/SDR; CDKN2A/FAMMM; STK11/Peutz-Jeghers; Lynch genes with affected FDR/SDR; PRSS1 hereditary pancreatitis with pancreatitis history).

Tier 3 - Validation & Biomarker Discovery

- Participants enrolled in the SHIELD surveillance program constitute the cohort for the clinical performance validation of Reccan-IA and the biomarker discovery

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Participant types

Patients

Age group

Adult

Sex

Both

Target number of participants

Tier 1 Genetic evaluation / risk stratification: 3000

Tier 2 Surveillance program & sample collection: 1000

Tier 3 Validation & Biomarker Discovery: 1000

Key exclusion criteria

Tier 1 - eligibility assessment:

- Refusal of consent.

Tier 1 - genetic evaluation:

- Refusal of consent.
- Mental or other disabilities that prevent understanding and providing informed consent.

Tier 2 surveillance program & sample collection:

- Individuals receiving treatment that could affect biomarker levels.
- Acute inflammation that could interfere with biomarker analysis (the protocol notes leaving a minimum 3-month window after end of treatment).
- Chronic inflammation/infection, except chronic pancreatitis.
- Prior treatment for PDAC (prior resection, radiotherapy, or chemotherapy).
- Current immunosuppressive treatment (e.g., systemic steroid therapy or chemotherapy).
- Systemic treatment for cancer within the last 3 months (because it could affect biomarker levels being measured).

Tier 3 Validation & Biomarker DiscoveryNo additional exclusion criteria, beyond Tier 1 and Tier 2

Date of first enrolment

April 2026

Date of final enrolment

November 2028

Countries of recruitment

Greece, Slovenia, Lithuania, Spain, Belgium, Denmark, and Sweden.

Study participating centers

Study Centre Name	Address	City	Country	Zip

Lund University (LUND)	Paradisgatan 5c	Lund	Sweden	22100
Ethniko kai Kapodistriako Panepistimio Athinon (UOA)	6 Christou Lada Str	Athens	Greece	10561
Vilnius University (VU)	Universiteto g. 3	Vilnius	Lithuania	01513
Univerzitetni klinicni center Maribor (UKCM)	Ljubljanska ulica 5	Maribor	Slovenia	2000
Centre Hospitalier Universitaire de Liège (CHUL)	Avenue de l'Hopital 1	Liege	Belgium	4000
Region Syddanmark (RSYD)	Damhaven 12	Vejle	Denmark	7100
Hospital Universitario HM Sanchinarro / Fundación de Investigación HM Hospitales (FiHM)	Plaza del Conde de Valle Suchil, N 2, Planta 1	Madrid	Spain	28015

Plain English summary of protocol

Background and Study Aims

Pancreatic ductal adenocarcinoma (PDAC) is one of the hardest cancers to treat because it is often found late, when curative treatment is no longer possible. In SHIELD, the focus is on people with a higher inherited (genetic) and/or familial risk of PDAC, because targeted surveillance in this group may allow earlier detection than in the general population.

SHIELD project under which this study is carried out, is a multi-centre European clinical research project that focuses on people with higher inherited or familial risk. This group is more suitable for structured surveillance than the general population and may benefit most from earlier detection approaches. The project also recognizes that existing tools have important limitations, for example, the commonly used biomarker CA19-9 is not suitable as a stand-alone early detection test, and imaging-based approaches are resource-intensive.

To this end, SHIELD brings together: (1) eligibility assessment, risk stratification & genetic risk evaluation, (2) a structured surveillance program, and (3) harmonized collection of clinical data and blood samples to support research. The main aims are to create a well-characterized high-risk cohort and to validate an innovative blood-based test (Reccan-IA,) for earlier PDAC detection in a prospective multi-center study across seven EU countries. SHIELD also aims to build a high-quality dataset and biobank resource to support biomarker discovery/validation and the development of predictive models to improve risk stratification and early detection in the future.

Who Can Participate?

Adults may be eligible if they have a personal and/or family history suggesting inherited or familial pancreatic cancer risk (including people meeting specific family-history patterns and/or carrying certain inherited gene variants). Adults (18+) who are newly diagnosed with pancreatic cancer may also be included to provide a reference cohort for research and test validation.

What Does the Study Involve?

The SHIELD study uses an online platform to provide information about the programme and to support initial eligibility pre-screening using structured questions on personal and family history.

The platform includes a chat-based (conversational) interface and LLM-based tools designed to support knowledge extraction and to help optimise recruitment/screening and parts of surveillance workflows (for example, structuring questionnaire information and guiding users through steps).

Individuals flagged as potentially eligible via pre-screening are directed to a participating clinical site, where the clinical team confirms eligibility and obtains informed consent before any study procedures take place.

Depending on the pathway, the study includes genetic evaluation (using a cheek swab or blood sample) and/or participation in an observational surveillance programme with annual follow-up that can include imaging (MRI, or EUS if medically indicated) and annual blood sampling (up to about 20 mL).

Samples are processed locally, serum samples are shipped to the SHIELD biobank at Lund University for approved research use, and shared study data are pseudonymised (coded) with the re-identification key kept at the local clinical site.

What Are the Possible Benefits and Risks of Participating?

Potential benefits include participating in structured monitoring if you are at higher risk, and contributing to research aiming to improve earlier detection and outcomes for PDAC. Potential risks include brief discomfort/bruising from blood draws, possible anxiety related to learning about genetic risk or participating in surveillance, and MRI-related risks depending on local standard procedures. Handling of personal data is GDPR-aligned and limits external sharing pseudonymized datasets.

Where the study is run from?

The study is implemented across seven initial clinical sites in: Lund (Sweden), Athens (Greece), Vilnius (Lithuania), Maribor (Slovenia), Liège (Belgium), Vejle (Denmark), and Madrid (Spain).

When does the study take place?

The SHIELD project runs from 1 May 2025 to 30 April 2029. The timeframe of the clinical investigation is set between April 2026 and November 2029, with final results published in April 2029.

Who is funding the study?

The SHIELD project received funding from the European Union's Horizon Europe Research and Innovation Programme under Grant Agreement No 101214779 and Swiss State Secretariat for Education, Research and Innovation (SERI). Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union. Neither the European Union nor the granting authority can be held responsible for them.

Who is the main contact?

For any questions regarding the study, confidentiality or data protection, please contact the coordinator of the project, dr. Izidor Mlakar, izidor.mlakar@um.si or the clinical coordinator of the project, Anna Brodén anna.broden@reccandiagnostics.com.

Results and Publications

Publication and dissemination plan?

Results will be disseminated to scientific, clinical, patient, and policy audiences. Patient organizations and policy stakeholders are part of the wider project approach and will be involved in dissemination and engagement activities.

The study protocol will be submitted for publication to a peer-reviewed journal and/or made publicly with the registry record updated once published.

Main study findings (and key secondary analyses) will be submitted to peer-reviewed journals using gold open access where feasible, alongside conference abstracts and presentations at relevant international meetings.

Publications will follow recognized authorship and reporting standards appropriate to the study design (e.g., CONSORT extension(s) where applicable; observational reporting guidelines where relevant), and will include clear descriptions of eligibility assessment, surveillance procedures, and analysis methods.

Plain-language summaries of the protocol and results will be produced for non-specialist audiences (website/news posts, printable summaries, and materials suitable for patient communities). Patient representatives will be involved in shaping lay communications (wording, formats, and channels) to improve clarity and accessibility, reflecting the project's engagement approach.

We will also publish policy-oriented outputs (briefings, stakeholder workshops, targeted communications to health authorities) that will be used to support translation of findings into practice where appropriate.

Target publication date is between May 2026 and December 2029

IPD sharing plan

Individual participant data will not be shared in identifiable form. The study will collect directly identifiable information (such as names, postal addresses, or other direct personal identifiers), however, any data outputs prepared for sharing will be de-identified and reviewed to minimise re-identification risk.

Only anonymised and/or aggregated data will be made publicly available. Open datasets will be limited to non-identifying derived outputs and will not include any information that could reasonably identify an individual participant.

Any public sharing beyond these anonymised/aggregated datasets (e.g., richer data extracts) will not be provided openly and would require an explicit governance process (ethics/legal review as applicable, and an assessment of re-identification risk), and may be declined if adequate safeguards cannot be assured.

Intention to publish date

December 2029

Contact(s)

Public, Scientific, Principal Investigator: dr. Izidor Mlakar, izidor.mlakar@um.si

Public, Scientific, Anna Brodén anna.broden@reccandiagnostics.com.

Study Centre Name	Address	PI	Phone	Email
Lund University (LUND)	Paradisgatan 5c, Lund , Sweden , 22100	Prof. Roland Andersson		roland.andersson@med.lu.se
Ethniko kai Kapodistriako Panepistimio Athinon (UOA)	6 Christou Lada Str , Athens, Greece ,10561	Prof. Ioannis Papanikolaou		ispapn@hotmail.com
Vilnius University (VU)	Universiteto g. 3, Vilnius, Lithuania , 01513	Prof. Aiste Gulla		aiste.kielaite-gulla@mf.vu.lt

Univerzitetni klinicni center Maribor (UKCM)	Ljubljanska ulica 5 , Maribor, Slovenia , 2000	Maja Ravnik	+386 (0)2 321 1000	maja.ravnik@ukc-mb.si
Centre Hospitalier Universitaire de Liège (CHUL)	Avenue de l'Hopital 1 , Liege, Belgium, 4000	Dr Jean-Philippe Loly		jploly@chuliege.be
Region Syddanmark (RSYD)	Damhaven 12, Vejle , Denmark , 7100	Sisse Helle Njor		sisse.helle.njor@rsyd.dk
Hospital Universitario HM Sanchinarro / Fundación de Investigación HM Hospitales (FiHM)	Plaza del Conde de Valle Suchil, N 2, Planta 1 , Madrid , Spain, 28015	Dr Luka Mihic Gongora		lmihic@hmhospitales.com