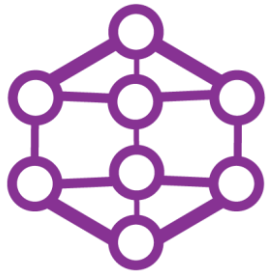
SHIELD

Early Detection of Heritary Pancreatic Cancer

Key Facts

11.6M EU Funding

Horizon Europe



26 Partners

13 Countries

48 Months

May 2025 – April 2029

5,000 Individuals

1,000 in Surveillance

7 Clinical Sites

Across Europe

- **Duration: May 2025 - April 2029 (48 months)**
- **Budget: €14.1 million (€11.6M EU funding)**
- **Coordinator: University Medical Centre Maribor, Slovenia**

The Challenge & Innovation

- 3rd leading cause of cancer deaths in Europe (projected 2nd in US by 2030)
- 5-year survival rate: <10% (one of the deadliest cancers)
- 85% diagnosed too late for curative treatment
- Early detection increases survival to 42% with surgery
- 140,116 new cases in Europe (2020) with 132,134 deaths
- Economic burden: €721 million direct costs in Germany alone (2015)

- **29% of Cancer Deaths in Europe**
- Third Leading Cause of death in Europe, Second in U.S. by 2030
- **Less than 10% 5-Year Survival Rate**

Economic impact
- €721 Million in Direct Costs (Germany, 2015)

Population statistics
- Doubling Cases from 1990 (196,000) to 2017 (441,000)
- Rising Mortality Rates: 2 deaths/100K (Age 35–39) (Age 35–10K) → 90 deaths/100+ (Age 80+)

- **50% Increase in Deaths in EU by 2025**
- 495,773 New Cases, 466,003 Deaths Globally in 2020
- 50% of cases diagnosed at an advanced stage

Why Current Approaches Fail

The Economic Challenge:

- MRI-based surveillance costs ~€1,100 per scan
- Imaging capacity is limited → waiting lists, system strain
- Current surveillance programs: fragmented, hospital-based, limited reach
- Direct Out-of-Pocket Costs (out of work, travel, etc.)
- No approved biomarker tests for early PDAC detection

Existing Diagnostic Methods:

- CA19-9 biomarker: lacks sensitivity/specificity, misses Lewis-negative cases
- Imaging (MRI, CT, EUS): expensive, limited access, radiation exposure
- No population screening programs (low incidence makes false positives unacceptable)

CA19-9 Biomarker

- Low Sensitivity
- Misses Lewis-negative cases
- False positives

Imaging Methods

- High cost: €1,100 per MRI
- Limited access/capacity
- Radiation exposure

Healthcare System

- Fragmented programs
- Limited reach
- No standardized screening

THE GAP

No FDA-approved or CE-IVD biomarker tests for early PDAC detection
High-risk individuals not systematically identified

SHIELD VISION 2035

Transforming Pancreatic Cancer Early Detection

Systematic Identification
High-risk individuals systematically identified across EU

National Integration
Integrated into national screening programs

30%

5-Year Survival Rate Target

Up from 10% today

Accessible Testing
Accessible, affordable annual blood test €500

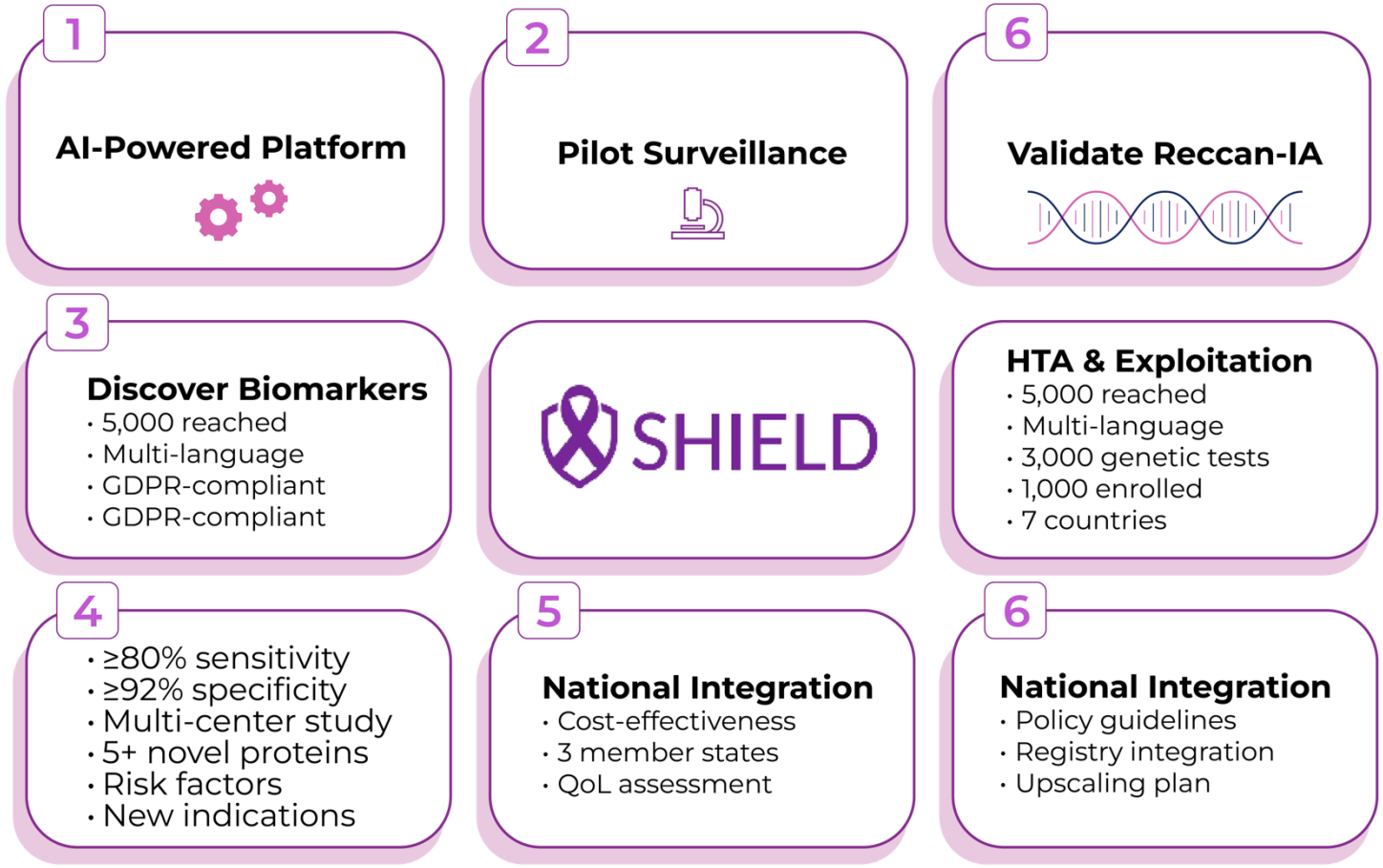
Operational Program
Full program operational in target regions within 2 years post-project

Benefit 1
Cost-Effective: €8,202/QALY
50% less than MRI surveillance

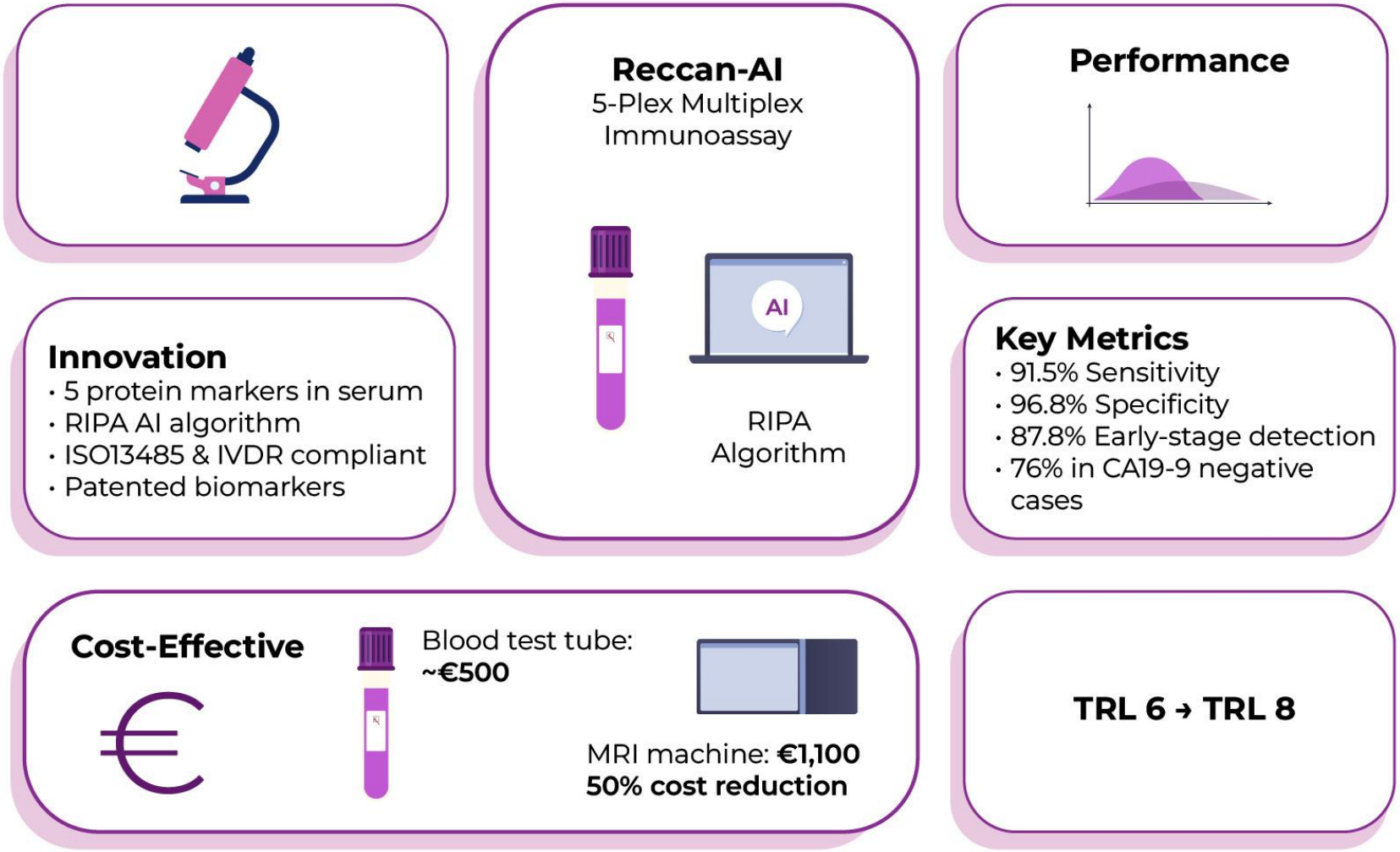
Benefit 2
Zero Out-of-Pocket Insurance & national program coverage

Benefit 3
Sustainable for Health Systems
Frees MRI capacity, enables scale

SHIELD Objectives



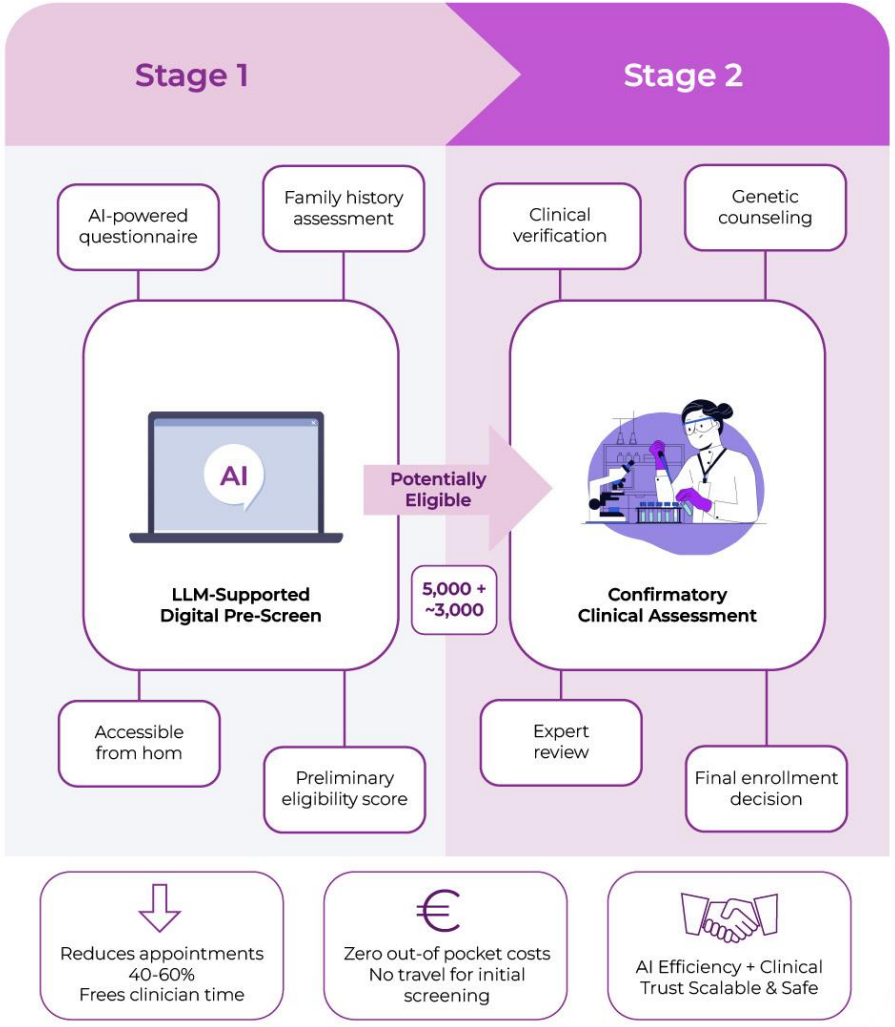
The Innovation - Reccan-IA Test



What is Reccan-IA?

- 5-plex multiplex immunoassay (blood-based)
- Measures 5 protein markers in serum
- RIPA software: Risk Indicating PDAC Algorithm
- Developed under ISO13485 & IVDR standards
- Patented biomarkers (WO2024170800A2, US20110257029A1)

The Innovation - Two-Stage Screening



Stage 1: LLM-Supported Digital Pre-Screening

- AI-powered conversational interface evaluates eligibility online
- Automated assessment of family history and risk factors
- Accessible 24/7 from anywhere (remote areas, limited mobility)
- Natural language processing addresses health literacy gaps
- Generates preliminary eligibility score

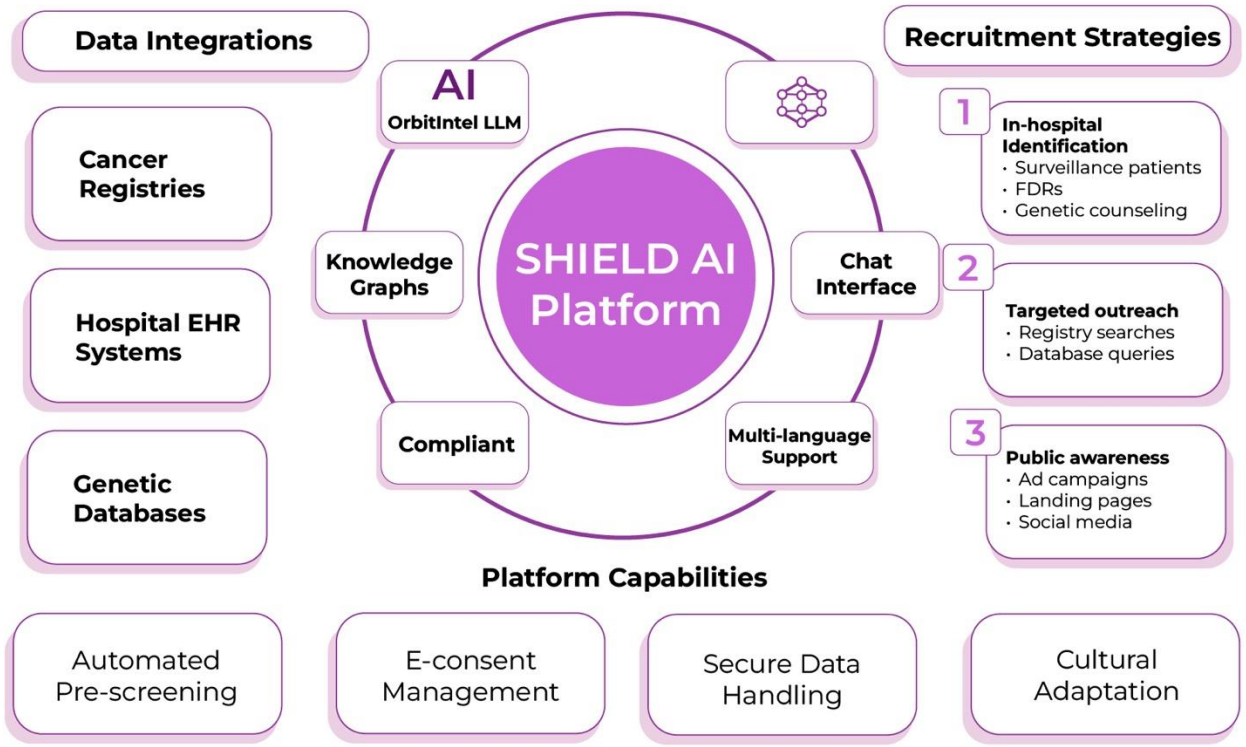
Stage 2: Confirmatory Clinical Assessment

- Clinical partners verify AI-generated eligibility
- Genetic counselors review and provide guidance
- Final enrollment decision by medical professionals
- Ensures accuracy, safety, ethical oversight

Reduces unnecessary clinical appointments by 40-60%, frees clinician time

No travel costs for initial screening, flexible timing, reduced anxiety through clear information

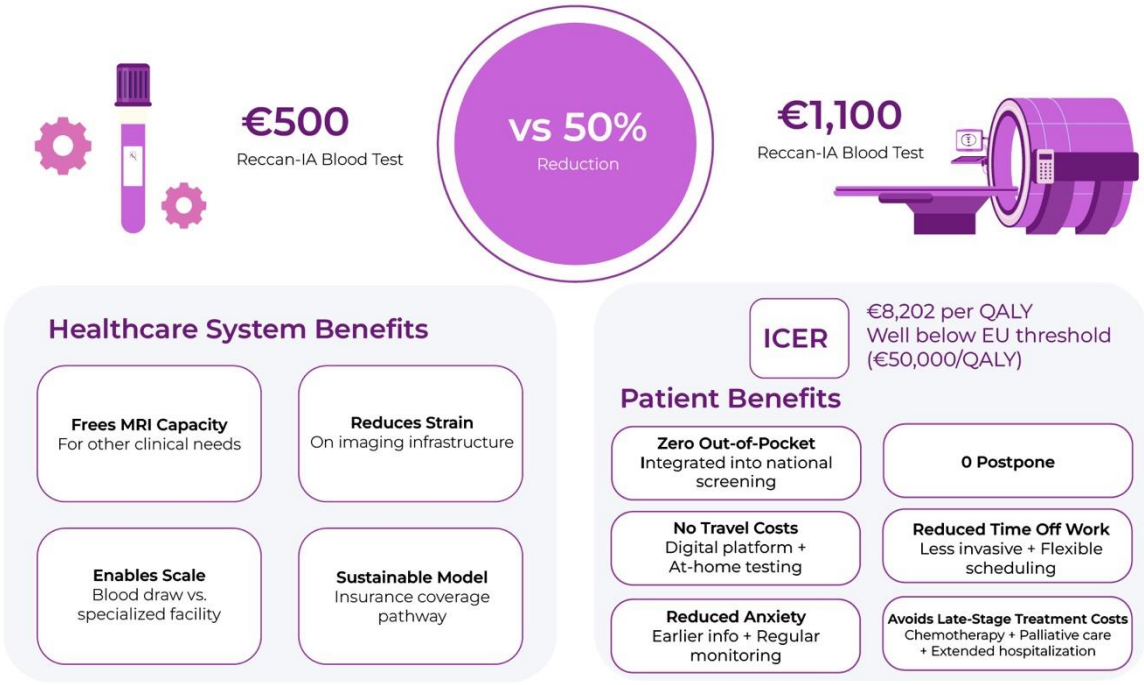
AI-Powered Platform Architecture



Key Platform Features:

- Interactive chat-based interface for eligibility screening
- OrbitIntel LLM (on-premises, domain-specific, GDPR-compliant)
- Knowledge graphs from patient data, family history, genetic databases
- Culturally adapted responses, metaphor-appropriate communication
- (7 EU languages)
- Integration with national cancer registries and hospital EHR systems
- E-consent management
- Secure data handling (anonymization, pseudonymization, differential privacy)

Economic Value



Value for Healthcare System:

- Frees MRI capacity for other clinical needs
- Reduces strain on imaging infrastructure
- Enables scalable surveillance (blood draw vs. specialized facility)
- Insurance coverage model → sustainable reimbursement pathway

Value for Individuals:

- Zero out-of-pocket costs (integrated into national screening)
- Reduced indirect costs: no travel for initial screening (digital platform), at-home genetic testing kits available
- Reduced anxiety: clear information, AI chat support, regular monitoring
- Less invasive: blood test vs. repeated MRI/EUS procedures

Expected Impact

KPI 1	KPI 2	KPI 3	KPI 4
5,000 Individuals Reached	**3,000** Genetic Tests Offered	**1,000** Enrolled in Surveillance	**≥80% / ≥92%** Sensitivity / Specificity

KPI 5	KPI 6	KPI 7	KPI 8
€ 50% Cost Reduction vs. MRI	**2+** National Authorities Integration	**0.5 s.d.** Quality of Life Improvement	**5+** Novel Biomarkers Discovered

Reduce Late-Stage Diagnosis
Systematic early detection in high-risk populations

Increase 5-Year Survival to 30% by 2035
From <10% today

Equitable Access
Remote areas
- Low health literacy
- Underserved populations

Reduce Economic Burden
Cost-effective surveillance
Integration into national programs

Early detection saves lives - genetic risk is addressable

Pre-screening + Innovative blood test + AI platform = scalable, cost-effective solution

About SHIELD

Project SHIELD uses innovative multiplex immunoassays and AI for comprehensive early detection and monitoring of high-risk individuals with pancreatic cancer, ensuring strong ethics, privacy, and regulatory compliance through expert oversight.

SHIELD is developing a simple, affordable blood test to detect pancreatic cancer at its earliest, most treatable stage. By identifying and testing people with elevated genetic risk, SHIELD aims to reduce late-stage diagnoses and increase Europe's five-year survival rate from under 10% today to 30% by 2035.

DETECTION

Early detection for high-risk individuals enables timely diagnosis

SHIELD aims to pioneer a proactive approach to identifying pancreatic ductal adenocarcinoma (PDAC) at its earliest stages, when treatment is most effective. To achieve this, SHIELD will develop and optimise a multi-purpose recruitment platform to support the implementation of a structured surveillance program. This platform is expected to include a user-friendly web interface and conversational AI, ensuring accessibility, privacy compliance (GDPR), and support for localisation. By leveraging large language models, the platform will facilitate automation, optimisation, and secure management of sensitive data.

The platform will be co-created with patient organisations and medical experts to ensure usability and alignment with clinical guidelines. It will prioritise access for remote populations and individuals with limited health literacy, promoting equity in early detection.

SHIELD plans to pilot a surveillance program targeting the early detection of PDAC in high-risk individuals. These individuals will be identified through a multi-faceted recruitment strategy, including in-hospital identification, targeted outreach, and public awareness campaigns. Eligibility will be assessed based on genetic testing and family history, and those eligible will be invited to enrol in a structured surveillance program involving annual MRI scans and blood collection to monitor for early signs of disease.

The program is set to be implemented across seven European regions, including three regions of specific interest, and in collaboration with existing screening programs such as IDIKA. SHIELD aims to reach over 5,000 individuals, offer 3,000 genetic tests, and enrol at least 1,000 participants in the annual surveillance program.

DIAGNOSTICS

A cost-effective blood test for fast, affordable, and accurate diagnosis

SHIELD will support the clinical validation of Reccan-IA, a 5-plex protein-based blood test, along with the Risk-Indicating PDAC Algorithm (RIPA). An observational clinical study is planned to evaluate the test's sensitivity (>80%), specificity (>92%), positive predictive value (PPV), negative predictive value (NPV), and its potential impact on quality of life.

This objective aligns with SHIELD's mission to develop an affordable and accessible biomarker-based test using blood samples for early pancreatic cancer detection. The clinical validation study will stratify the participant population by age, sex, and risk factors, aiming to demonstrate robust performance across diverse groups.

SHIELD will also aim to identify novel protein biomarkers through next-generation proteomics (Olink Explore) to expand the test's diagnostic capabilities for additional high-risk indications, such as new-onset diabetes (NOD). Planned analyses include bioinformatics and pathway exploration to investigate the biological mechanisms behind protein signatures, alongside the collection of lifestyle data to examine the interplay between environmental and genetic risk factors.

Key targets include the discovery of over 5 novel biomarkers and the establishment of meaningful risk factor associations to support future diagnostic innovation.

IMPACT

Fewer late diagnoses lead to earlier treatments and reduce overall mortality

SHIELD is committed to reducing the number of late-stage pancreatic cancer diagnoses by enabling earlier detection and intervention. A key objective is to assess the feasibility and cost-effectiveness of deploying the Reccan-IA test and surveillance program in high-risk populations. This assessment will aim to demonstrate potential healthcare cost reductions and improved patient outcomes through earlier diagnosis and treatment.

The project will focus on developing a scalable and affordable solution and will engage with key stakeholders to explore the innovation and implementation potential of Reccan-IA across the targeted regions. Planned evaluations include cost- effectiveness studies in three EU Member States and monitoring quality of life outcomes among surveillance participants.

To ensure long-term impact, SHIELD will work to scale up the surveillance program for integration into regional and national early detection initiatives. The project will collaborate with key opinion leaders (KOLs), government agencies, and healthcare systems to explore integration pathways.

This upscaling objective aligns directly with SHIELD's vision of embedding accessible and affordable diagnostic tools into routine healthcare, with the goal of reducing cancer mortality across Europe.

Table

Project Acronym:	SHIELD
Project Name:	Comprehensive Surveillance of High-risk Individuals and Health Integration for Early detection of Pancreatic cancer utilising innovative multiplex immunoassays
Grant Agreement number:	101214779
Call Identifier:	HORIZON-MISS-2024-CANCER-01
Topic:	HORIZON-MISS-2024-CANCER-01-03
Type of action:	HORIZON-IA
Starting Date:	1 May 2025
Duration:	48 months

What We Do

Project SHIELD aims to transform the early detection and monitoring of pancreatic cancer.

The projects combines cutting-edge multiplex immunoassays with artificial intelligence to identify high-risk individuals with greater accuracy and speed.

SHIELD’s Innovative Approach

The SHIELD project aims to address the current challenges in early pancreatic cancer detection by validating an innovative blood-based diagnostic test, specifically developed for early identification of pancreatic ductal adenocarcinoma (PDAC) in high-risk individuals. As part of its efforts, SHIELD will also pilot an early detection program in Greece, Slovenia, and Lithuania.

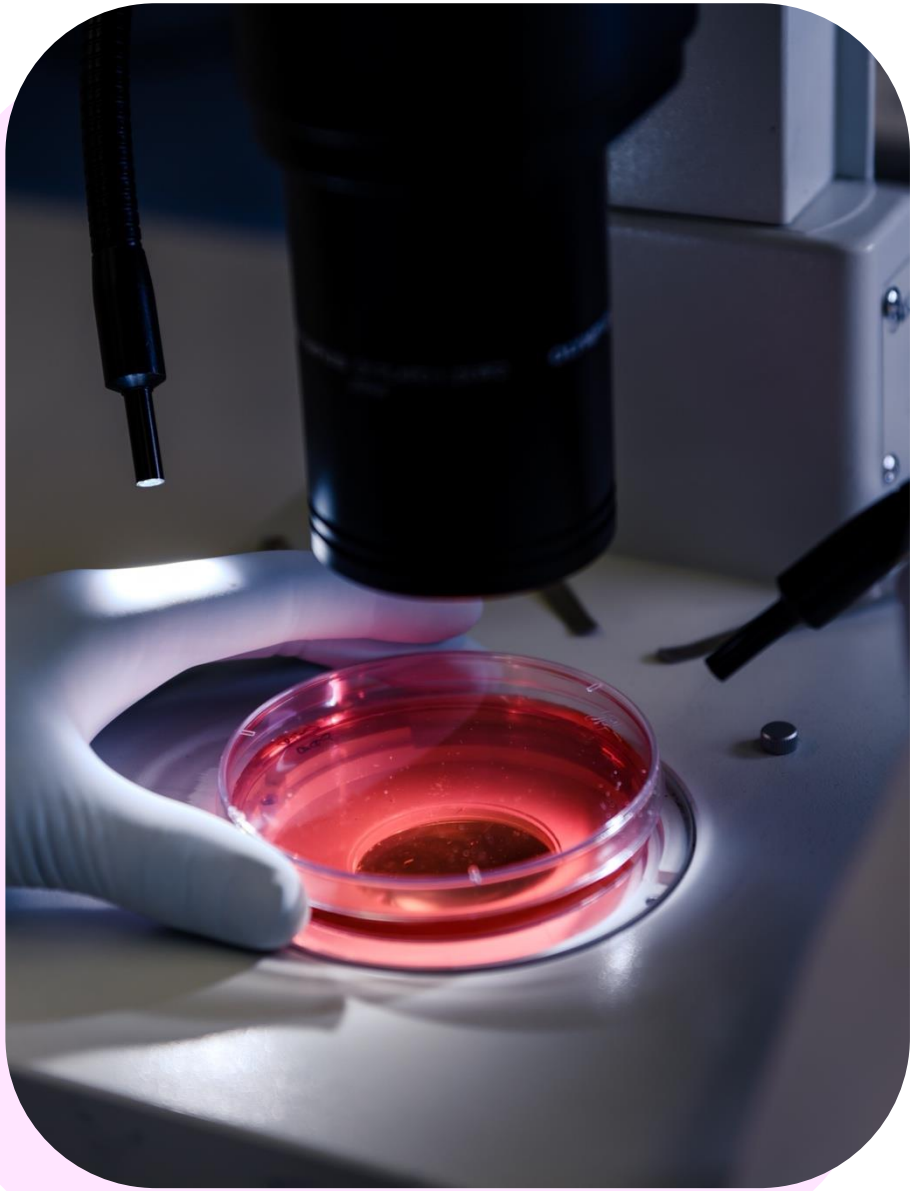
Developed by project partner Reccan, this novel test uses a 5-plex multiple immunoassay to analyze protein readouts and generate a probability score for pancreatic cancer.

Early studies involving over 450 samples have shown outstanding performance, with sensitivity exceeding 91% and specificity greater than 96%.

SHIELD’s plan includes the clinical validation of the test in a prospective, multi-center study across seven EU countries, focusing on individuals with familial or genetic risk factors.

Additionally, the project seeks to identify new protein biomarkers for other risk indicators such as new-onset diabetes (NOD). Collaboration with national screening authorities will support the integration of the test into existing healthcare programs, while partnerships with patient organizations aim to boost recruitment and ensure access for those who need it most.

Looking ahead to 2035, SHIELD envisions a fundamental transformation in pancreatic cancer diagnostics, with the ambitious goal of raising the 5-year survival rate in Europe to 30%. This crucial initiative forms part of the European Cancer Mission's efforts in the area of prevention and early detection of heritable cancers.



SHIELD Methodology

The SHIELD project is built upon a carefully structured methodological approach, organized into distinct phases designed to revolutionize early detection of pancreatic cancer.

Phase 1: Building the AI-powered foundation

The initial phase is all about developing the robust, AI-empowered platform. This cutting-edge platform will be central to every identification strategy within our surveillance program and will manage the clinical study data.

Phase 2: Identifying high-risk individuals

We'll focus on developing and implementing precise identification strategies. This includes a thorough assessment of an individual's heritable genetic risk for pancreatic ductal adenocarcinoma (PDAC), determining their eligibility for inclusion in the SHIELD surveillance program for early detection.

Phase 3: Launching the surveillance program and clinical validation

Once high-risk individuals are successfully identified and recruited, the project moves into Phase 3: implementing the surveillance program and launching the crucial clinical validation study.

Phase 4: Validating and expanding biomarkers

Clinical samples will undergo rigorous analysis using the GMP-manufactured Reccan-IA. This process adheres to strict regulatory guidelines to ensure the validation of our study endpoints. Additionally, we'll implement a biomarker discovery pipeline to expand the test's applications to other high-risk groups.

Final phase: Integration and impact

In the project's final phase, we'll adopt a multifaceted approach. This includes robust communication efforts, health technology assessment, proactive policymaking, and strategic exploitation of our innovation. The ultimate goal is to seamlessly integrate SHIELD into existing screening programs, maximizing its impact on pancreatic cancer early detection.

SHIELD Outcomes

The SHIELD project has a bold ambition: to pilot a comprehensive surveillance program tailored specifically for individuals with a high inherited genetic risk for pancreatic cancer.

Our goal is to co-create this program hand-in-hand with key partners, including patient organizations, leading experts, and national screening authorities in our target regions. This collaborative approach will help us develop a scalable model that can seamlessly integrate into existing national screening initiatives, much like the successful programs already in place for colorectal, breast, and cervical cancers.

Reaching more people, expanding access

We're committed to expanding our reach and raising awareness through an innovative online recruitment platform. This platform isn't just a website; it's a dynamic tool designed to engage a broader audience, including those in remote areas, through interactive features like AI-driven chats and comprehensive educational resources. By offering free risk assessments for individuals with a family history of pancreatic cancer, the SHIELD platform will provide accessible and proactive opportunities for those at higher risk.

Making Genetic Testing Routine

There is an urgent unmet clinical need to enhance early detection of pancreatic cancer to improve patient outcomes, significantly meliorate their quality of life, and reduce mortality rates. The current practice in many countries in Europe and the US has significant gaps in effectively identifying high-risk individuals and employing targeted surveillance strategies. To address these gaps, a multi-faceted approach is required. First, the identification of individuals with a heritable genetic risk is crucial. Expanding access to genetic testing for those with a family history of pancreatic cancer, especially among first-degree relatives, is essential to recognise individuals at significantly higher risk due to genetic predispositions such as BRCA2, CDKN2A, PRSS1, and STK11/LKB1 mutations.

These individuals should be the primary focus of enhanced surveillance programs. Second, there is a need for designing effective surveillance programs that utilise improved biomarker tests. These programs should be tailored to monitor high-risk populations closely, initiating screening at younger ages based on specific genetic profiles. Finally, the development of novel, easy-to-use, accessible, and cost-effective early detection methods, such as routine blood-based tests, is imperative. Currently, no FDA-approved or CE-IVD biomarker tests exist for the early detection of PDAC. These new methods must exhibit high sensitivity for early stage PDAC and specificity, within high-risk groups. Addressing these clinical needs will be critical to reducing the burden of pancreatic cancer and improving survival outcomes across EU and the world.

Thank you.

GET IN TOUCH

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SHIELD Project

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