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SHIELD is co-funded by the European Union, under Grant Agreement no. 101214779. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the Health and Digital Executive Agency. Neither the European Union nor the granting authority can be held responsible for them. This work has received funding from the Swiss State Secretariat for Education, Research and Innovation (SERI).

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EARLYSCAN

Early Screening & Hereditary Cancer Awareness Network Cluster

Strengthening prevention and
early detection strategies
for heritable cancers



PREDI-LYNCH

PREDI-LYNCH is co-funded by the European Union (grant no. 101213916) and supported by the 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 or SERI. Neither the European Union nor the granting authority can be held responsible for them.

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A unified effort to boost early detection of heritable cancers.

EARLYSCAN operates under the Mission on Cancer priority area “Prevention & early detection – early detection of heritable cancers” and aims to maximise the impact of EU investment by aligning efforts, reducing duplication, and accelerating translation into practice.

Heritable cancers represent a major opportunity for earlier diagnosis and improved outcomes, as individuals with inherited genetic risk can benefit from targeted identification, surveillance, and follow-up. By working collaboratively across projects and countries, EARLYSCAN addresses early detection as an end-to-end pathway challenge rather than a single test-performance issue.

The cluster brings together three projects with distinct but complementary clinical focuses and technological approaches:

DISARM focuses on improving risk assessment and early detection of ovarian cancer across multiple European countries through an implementation-ready, CE-marked, risk assessment tool (CanRisk) and through innovative, minimally-invasive and affordable liquid biopsy approaches.

PREDI-LYNCH targets early detection of cancers in individuals with Lynch syndrome, the most common hereditary cancer predisposition, using non-invasive liquid biopsy technologies combined with artificial intelligence.

SHIELD addresses early detection and surveillance of pancreatic ductal adenocarcinoma in individuals with familial or genetic risk, validating an innovative blood-based multiplex immunoassay within a multi-centre European study.

By focusing on inherited genetic risk and an end-to-end pathway approach, EARLYSCAN aims to:

- + Identify people at high cancer risk
- + Recruit and support them in surveillance programmes
- + Test and monitor them over time
- + Return results and ensure appropriate follow-up

EARLYSCAN addresses this full pathway by coordinating research across countries, cancer types, and health systems, helping ensure that evidence is comparable, scalable, and ready for real-world use.



DISARM Project

Motivation

Ovarian cancer is the deadliest of female cancers, with survival rates remaining low worldwide and incidence on the rise.

The World Ovarian Cancer Coalition has identified ovarian cancer as a global health priority, calling attention to regional inequalities in access to prevention and care.

Technology

Clearer risk assessment and earlier detection has the potential to transform ovarian cancer management — helping to avoid or delay invasive preventive surgeries and to improve survival outcomes. Current approaches, such as the CA-125 biomarker, lack the sensitivity and specificity needed for reliable early detection.

DISARM is evaluating the clinical routine implementation of a CE-marked risk assessment tool, CanRisk, for clearer risk assessment and is pioneering a multi-analyte approach to early detection, testing innovative, minimally invasive liquid biopsy assays across more than 2,000 women in five countries (Czech Republic, Greece, United Kingdom, Lithuania and Portugal).

Its early detection assays include:

- + **OVA-GLY** – a glycoprotein-based blood serum test using an innovative nanoparticle platform
- + **OVA-VOC** – detection of patterns of volatile organic compounds from blood plasma
- + **OVA-miRNA** – blood plasma based circulating miRNA signatures
- + **OVA-MULTIMODAL** – combining diverse biomarker data to improve accuracy and reliability



Tackling ovarian cancer's reputation for being a "silent killer" through advanced risk assessment and early detection across Europe



Project Website

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Disarm-EU



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Expected Outcomes

By combining cutting-edge science, digital innovation, and stakeholder engagement, DISARM aims to improve outcomes for those at risk of ovarian cancer while strengthening prevention and early detection strategies across Europe.

Improved outcomes for people with inherited genetic risk

DISARM will support personalised risk assessment and earlier detection for ovarian cancer, helping to reduce mortality and improve the quality of life of those at risk across Europe. DISARM will also deploy the OVA-ONLINE digital tool, a platform for genetic counselling and patient support.

Greater accessibility and adoption of innovative solutions

By focusing on affordability and real-world healthcare needs, the DISARM project will develop solutions that can be widely implemented across diverse healthcare systems and populations.

Stronger foundations for innovation and policy uptake

DISARM will generate evidence to support future policies, while creating opportunities for the implementation of the CE-marked CanRisk risk assessment tool and for stakeholders to further develop, adopt, and commercialise early detection technologies.

Together, these outcomes will help pave the way for clearer risk assessment, earlier detection, more personalised care, and stronger health systems in the fight against ovarian cancer.

To support translation into healthcare systems, the interactive policy support dashboard, OVA-VIEW, will enable decision-makers to explore findings and regional trends.

The DISARM project will also address social, ethical and funding considerations, which are key to real-world adoption.

Overall, this marks DISARM as the first-large scale multi-country study of it's kind, designed to advance ovarian cancer risk assessment and earlier detection.



SHIELD Project

Motivation

Pancreatic cancer remains one of the deadliest cancers in Europe, with fewer than 10% of patients surviving five years after diagnosis.

Because symptoms often appear only at late stages, early detection in individuals with genetic or familial risk represents a major opportunity to improve outcomes. SHIELD addresses this challenge by developing innovative blood based screening tools and coordinated surveillance strategies across multiple European countries.

Technology

The SHIELD project develops and validates innovative technologies for the early detection of pancreatic cancer, including:

- + **Multiplex immunoassay**–based blood tests that detect specific protein biomarkers associated with early-stage pancreatic cancer.
- + **Artificial intelligence and data-driven tools** to analyse biomarker and clinical data and identify individuals at high genetic risk.
- + **A surveillance platform** for recruiting and monitoring high-risk individuals across multiple European countries.
- + **Multicentre clinical validation** studies to evaluate the diagnostic performance of the test and integrate it into screening programmes.



Comprehensive Surveillance of High-risk Individuals and Health Integration for Early Detection of Pancreatic Cancer utilising Innovative Multiplex Immunoassays.



Project Website

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Expected Outcomes

The SHIELD project aims to:

- 1 Develop a simple, affordable, and non-invasive blood test for early pancreatic cancer detection.
- 2 Improve screening strategies for individuals with genetic or familial risk.
- 3 Reduce late-stage diagnoses and enable earlier treatment interventions.
- 4 Contribute to increasing the five-year survival rate in Europe from under 10% to around 30% by 2035.



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.

PREDI-LYNCH Project

Motivation

People with **Lynch syndrome** live with high, lifelong cancer risk and burdensome invasive surveillance (e.g., frequent colonoscopies and gynaecological/urological procedures).

PREDI-LYNCH is designed to validate non-invasive liquid biopsy tests that can **safely reduce invasive procedures** and **detect cancer earlier**, improving comfort, equity, and outcomes with strategies that are acceptable and scalable across Europe.

Technology

PREDI-LYNCH is pioneering a multianalyte approach to early detection, testing innovative, minimally invasive liquid biopsy assays within a large, multicentre European randomized study. Its diagnostic portfolio includes:

- + **ctDNA shallow whole genome sequencing (shallow WGS)**
Blood based ultra low coverage WGS to detect circulating tumour DNA via genome wide fragmentation/copy number signals characteristic of early cancer.
- + **UroScout**
urine based mutation profiling assay for somatic mutations associated with urothelial cancer.
- + **MSI Plus**
PCR based microsatellite instability detection in Urine and vaginal swabs, targeting mismatch repair deficiency - the hallmark of Lynch associated cancers.
- + **qFIT stool testing**
A quantitative, stool-based assay for the detection of occult hemoglobin, providing an adjustable threshold to enhance sensitivity for the early detection of colorectal lesions and advanced neoplasia.



PREDI-LYNCH

Validated non-invasive liquid biopsy tests for cancer PREDiction in LYNCH syndrome



[Project Website](#)

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AI driven signal integration. PREDI-LYNCH develops multimodal AI models that fuse ctDNA fragmentation, MSI, and mutation signatures with clinical metadata to deliver robust, individualized risk predictions.

Models are trained on diverse, high-risk cohorts to minimize algorithmic bias and ensure high performance and generalizability beyond traditionally White-centric datasets.

Beyond the assays (people centred, implementation ready)

WP2 – Co creation with patients & clinicians: participatory design to ensure tests, pathways and communications are intuitive, acceptable, and actionable.

WP8 – Acceptability, behaviour & adherence: standardized instruments to evaluate anxiety/cancer worry, preferences, and uptake; human centred nudges to support sustained participation.

WP10 – Ethics, equity & implementation science: frameworks for data protection, consent, and equity by design; health system readiness, policy engagement, and scalability across EU settings.

Expected Outcomes

The PREDI-LYNCH Project aims to provide:

- 1** Clinical grade performance of non invasive tests: Sensitivity/specificity and operational thresholds for ctDNA shallow WGS, UroScout (urine), MSI Plus (urine/vaginal), and qFIT (stool) across European cohorts—establishing readiness for real world use.
- 2** Validated, multimodal AI for integrated genomic and metabolomic signal detection and risk stratification, trained on diverse, underrepresented, high-risk cohorts to mitigate bias and enhance external validity..
- 3** Reduction of invasive surveillance (target ~30–50%): A risk stratified pathway that safely decreases unnecessary colonoscopies and gynecological/urological procedures while detecting cancers 12–24 months earlier—lowering physical burden, complications, and costs. (Targets subject to trial validation)
- 4** Implementation blueprint & EARLYSCAN integration: Socio economic and ethical assessments to ensure affordability, scalability, and acceptability; harmonized pathways, endpoints, and recruitment standards aligned with the EARLYSCAN cluster for coordinated EU wide roll out.
- 5** Earlier cancer detection & better outcomes: Identification of tumor DNA, MSI, and somatic mutations enables earlier diagnosis, improving treatment success and reducing morbidity—moving from reactive to predictive surveillance.
- 6** Improved quality of life & adherence: A less invasive strategy that boosts acceptability, adherence, and psychological well being (reduced anxiety/cancer worry), measured with validated questionnaires and patient reported outcomes.
- 7** Health economic & policy evidence: Comparative cost effectiveness of invasive vs. non invasive strategies to support reimbursement, value based screening decisions, and development of EU guidelines.
- 8** Equity advancement: Prioritization of under represented groups in validation cohorts to close generalizability gaps and broaden access to precision prevention across diverse health systems and populations.

