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BIOMARKERS IN ONCOLOGY

the importance of **screening and early detection**

Marc Van Den Bulcke
Sciensano

Brussels, 30 September 2026

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Conflict of interest

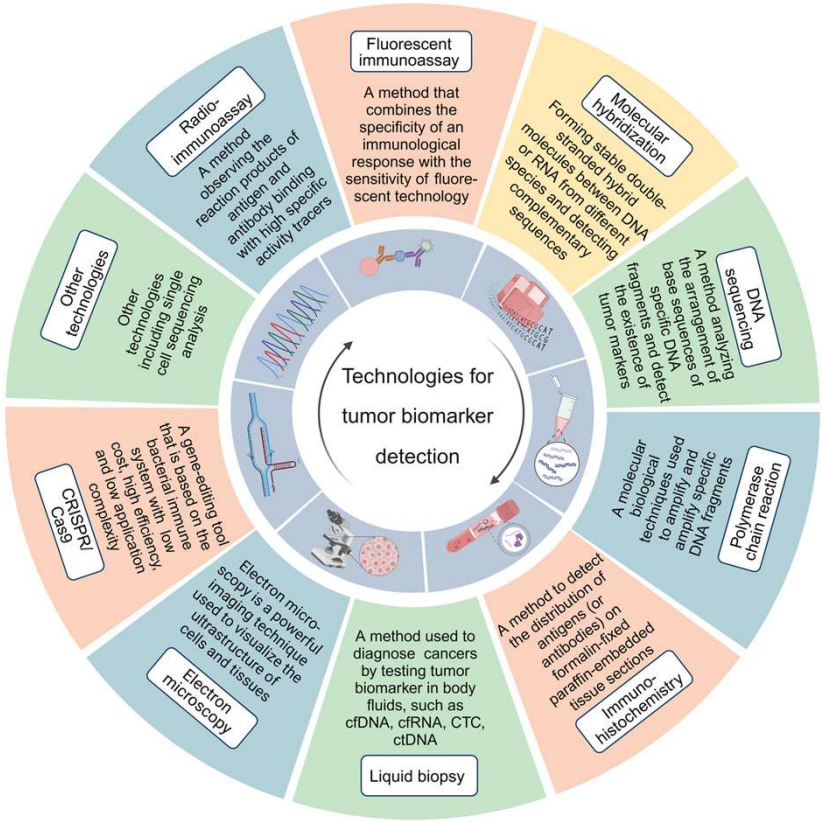
All presented statements are on my own responsability

No Conflict of Interest

Key topics

- Precision early detection and prevention of cancer
- Multi-cancer early detection: GRAIL trial
- From EC to national level: the 2021-2030 European Odyssee
  - PCP and PPI initiatives
  - JA Personalized Cancer Medicine (call for PPP) - EPPERMED
  - JA EUnetCCC

CANCER BIOMARKERS ECOSYSTEM



Cancer Biomarkers Market is projected to reach more than 65 billion euro by 2032

Increasing incidence of cancer, growing awareness of early diagnosis and growing investments in the research and development of cancer biomarkers, along with the extensive use of these biomarkers for diagnosis, drug discovery, and development are key factors driving growth.

SEGMENT LEADERSHIP:

- Regional Leader: North America
- Technology Leader: Omics technologies
- Cancer Type Leader: Breast cancer
- Application Leader: Diagnostics
- End User Leader: Diagnostic labs

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Zhou, Y., Tao, L., Qiu, J. *et al.* Tumor biomarkers for diagnosis, prognosis and targeted therapy. *Sig Transduct Target Ther* **9**, 132 (2024). https://doi.org/10.1038/s41392-024-01823-2

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Building precision early detection and prevention of cancer

A transversal crosstalk from basic research to social sciences

Suzette Delaloge
Department of Cancer Medicine & Cancer Interception Programme
Gustave Roussy, France

INTERCEPTION
GUSTAVE ROUSSY
Le programme de prévention personnalisée des cancers

Challenges

- Tackle the moving target of **cancer epidemiology**
- Transform our **knowledge** on carcinogenesis into efficient **prevention strategies**
- Build **cost-effective, acceptable and desirable** prevention strategies
- Ally **risk assessment, early detection and risk reduction** in a global strategy!
- Build **sustainable** economical models
- Tackle cancer-related health **inequalities**
- **Replace therapeutic strategies** is the ultimate goal!

Assessing individual risk at a given time allows for the implementation of appropriate interventions

Social and cultural determinants

Age, gender, genetic determinants

Exposure
Tobacco, alcohol, infectious agents, sun, pollutants, diet, excess weight, radiation, sedentary lifestyle, hormones, etc.

Identification of a situation with increased risk several years before the event

Targeted intervention

Cancer



PERSONALISED INTERCEPTION: A MIX OF RISK ASSESSMENT, EARLY DETECTION AND RISK REDUCTION



Precision cancer prevention must be built at the public health level

AACR American Association for Cancer Research Annual Meeting April 17-22, 2026 SAN DIEGO
AACR.ORG/AACR2026 | #AACR26

Exposome analysis
Social, cultural, lifestyle, infectious, environmental, medical, hormonal, occupational, etc.

Understanding cancer biology

Biomarkers
Circulating /tissue/ imaging

Intrinsic factors
Age and gender
Genetic
Epigenetics





PUBLIC HEALTH

"PRIMORDIAL" PREVENTION

Primary **Secondary**

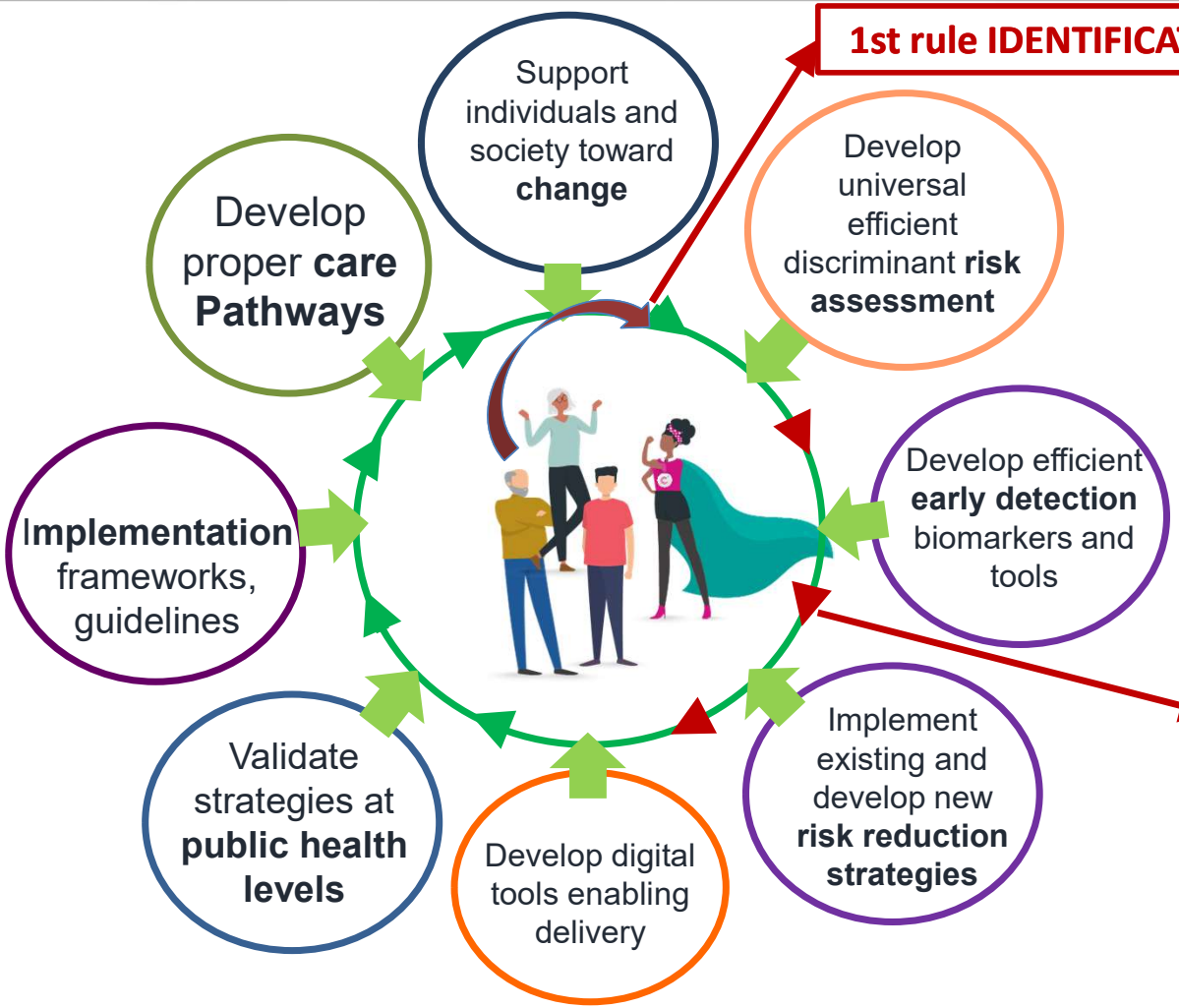
PERSONALISED PREVENTION
1. Identify cancer risk situations
2. Early detection and risk reduction based on risk and biology

(PRECISION PREVENTION)

Health

Building personalized cancer prevention

AACR American Association for Cancer Research
Annual Meeting
April 17-22, 2026 SAN DIEGO
AACR.ORG/AACR2026 | #AACR26



1st rule IDENTIFICATION OF CITIZENS' NEEDS AND WISHES

PrevAction: From science to public health policies

RÉPUBLIQUE FRANÇAISE
Liberté
Égalité
Fraternité

Inserm
La science pour la santé
From science to health

2026

EARLY PREPARATION & ACCOMPANYING OF NEW PREV. STRATEGIES

- Early health economic modelling of interventions
- Acceptability, socio-psychological framework, preparedness

Precision prevention: germline genetics have opened the path

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Precision interventions have impact on incidence & some of them on mortality

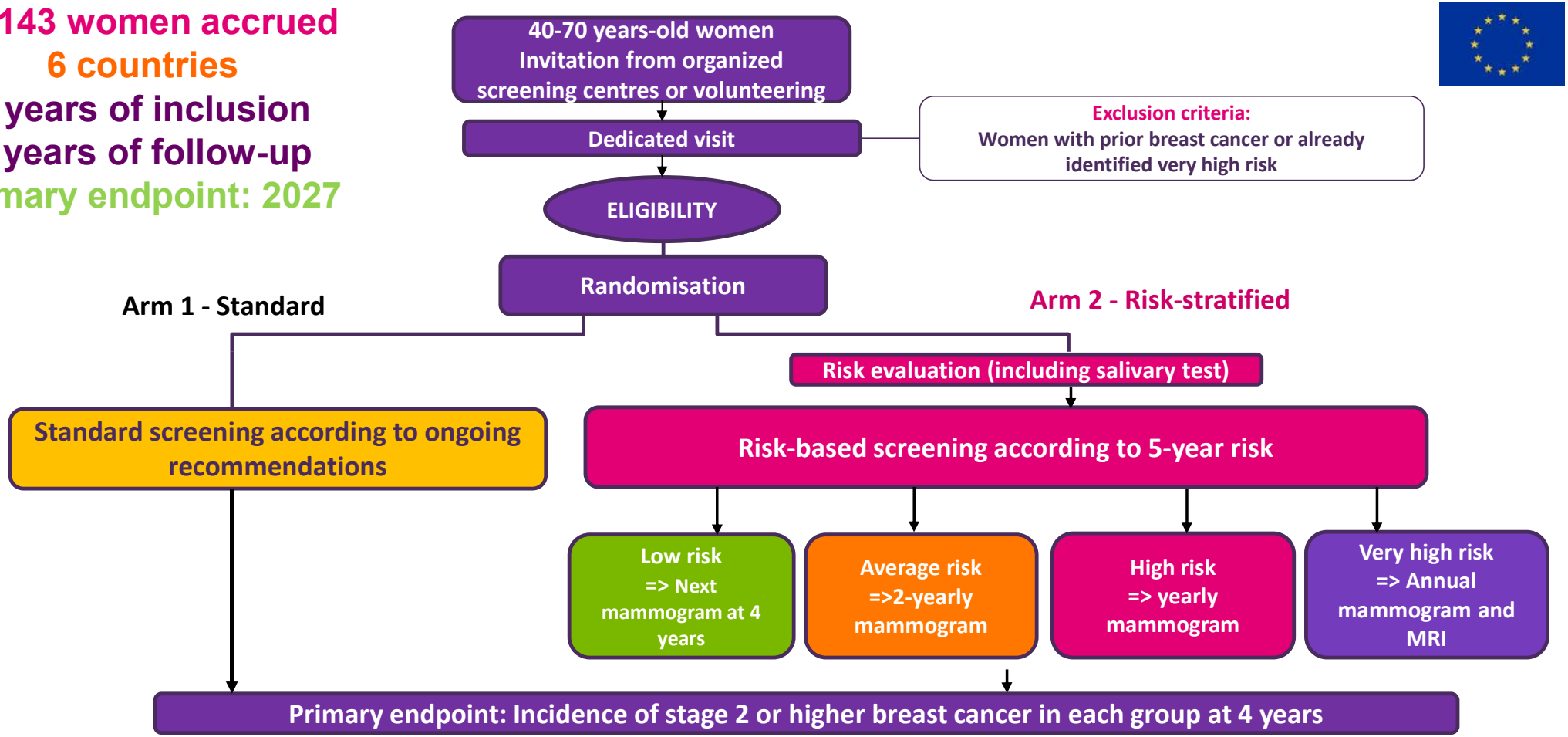
Germline alterations - cancer	Early detection means (LoE)	Risk reduction measures (LoE)
BRCA1/2 – breast and ovarian	Breast MRI (+ mammography) (IIA)	Prophylactic mastectomy (IIA) and adnexectomy (IIA), endocrine therapies (IIIB), lifestyle interventions (IV)
Other BC genes – breast and ovarian	Low level evidence, attitude derived from BRCA1/2 data	
Lynch syndrome – broad spectrum	Colonoscopy/gastroscopy, pelvic ultrasound, etc. (II-III)	Prophylactic hysterectomy and adnexectomy (III), lifestyle (IV), aspirin (IIB)
Multiple genes - Pancreatic cancer	Pancreatic MRI / endoscopic ultrasound (III)	Lifestyle (IV)
TP53 – broad spectrum	Breast MRI (III), whole body MRI (IIB), other	Prophylactic mastectomy (IV) lifestyle (IV)

Kotsopoulos JAMA Oncol 2024; Lubinski, JAMA Oncol 2024; Metcalfe Br J Cancer 2023; Burn et al Lancet 2020; Blackford JAMA Oncol 2024; Hered Cancer Clin Pract 2019; Consul Am J Roent 2021

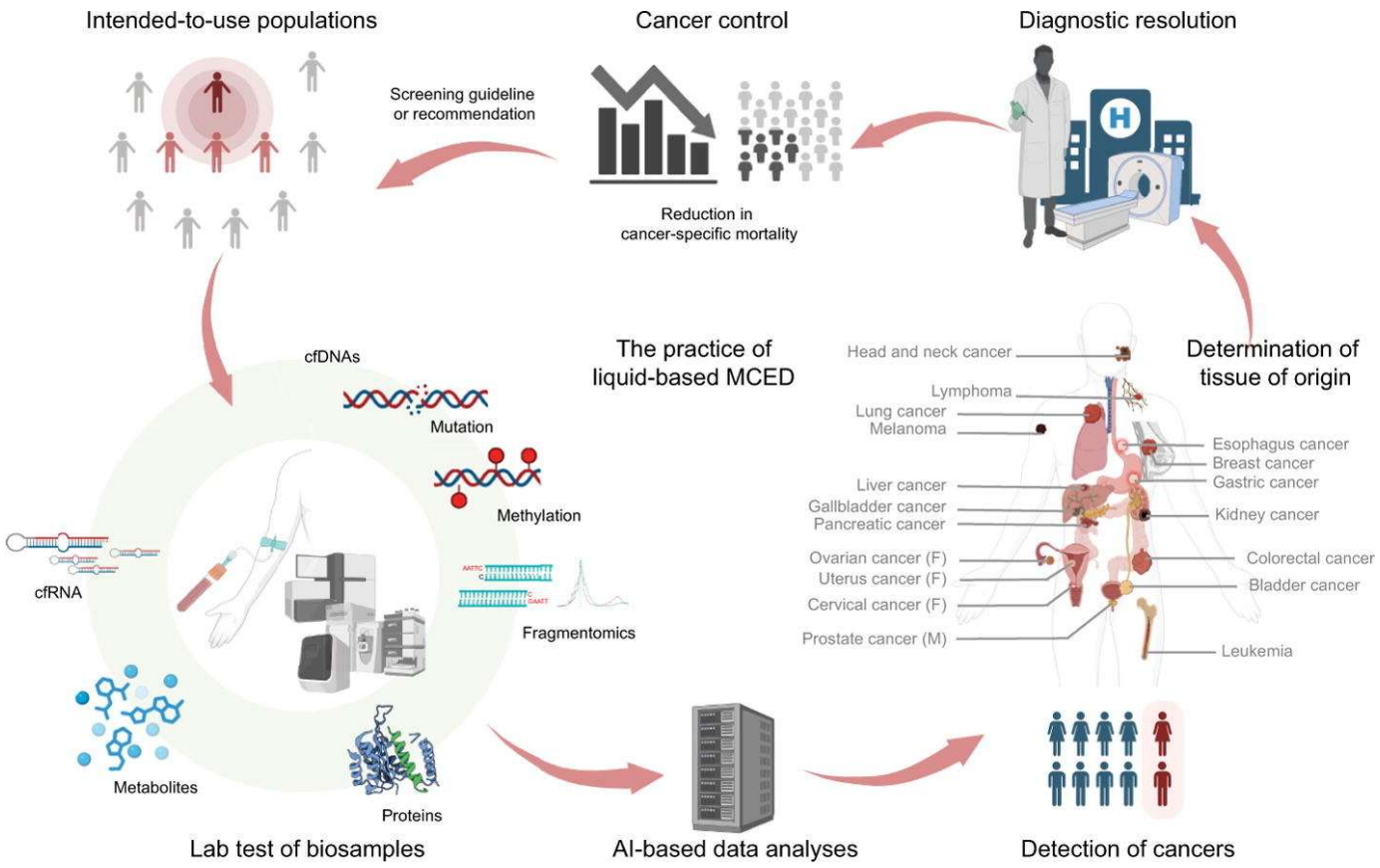
MyPeBS aims to demonstrate the value of risk-based screening at a public health level

MyPeBS
Personalising Breast Screening

53,143 women accrued
6 countries
4 years of inclusion
4 years of follow-up
Primary endpoint: 2027



Multi-cancer early detection (MCED) testing



NHS-Galleri: Primary results from a randomised controlled trial

Although the primary endpoint was not met, adding annual MCED testing to standard-of-care cancer screening substantially increased screen-detected cancers and reduced Stage IV cancers and emergency presentations.

This evidence combined with the favourable safety profile and robust performance suggests that integrating MCED into population screening programs may help reduce late stage cancer burden.

Robert Charles Swanton et al.
J Clin Oncol **44**
DOI:10.1200/JCO.2026.44.17_suppl.LBA100

Yongjie Xu, et al Liquid biopsy-based multi-cancer early detection: an exploration road from evidence to implementation, Science Bulletin, Volume 70, Issue 17, 2025, Pages 2852-2867

Thoughts on outcomes of GRAIL MCED trial (E. Topol)

Current mass screening ignores the Bayesian principle of priors—that using a test for **low-risk individuals** will lead to false positives and low predictive value. large number of people who may have microscopic cancer but are not being detected. Any medical test will only be as good for accuracy as the population it is tested in. There is a need to improve the signal and decrease the noise.

There are 2 major ways to improve the accuracy.

- One would be to enrich the population to be tested, using the "AI biopsy" described above with all of the **longitudinal clinical information**. That would be comprehensive: inclusive of analyzing trends in lab data even within the normal range, all scans, nutrition, socioeconomic features, and environmental exposures such as air pollution.
- **individualized genomic/biologic risk determination**. Now that we have large language models with multimodal input capabilities, the analytic challenge is clearly surmountable.

Then we have defined **a high-risk population** that may derive marked benefit from an MCED test.

Early detection at the Stage 1 level may require multi-omic MCEDs, not just one focused on methylation or DNA sequence. But, as discussed above, this may make the **cost prohibitive**

enriching the population tested is the driver towards higher sensitivity, without the need for multi-omic assessment, the **trade-offs of the individual's genomic assessment vs more omics of the blood sample** deserves consideration.

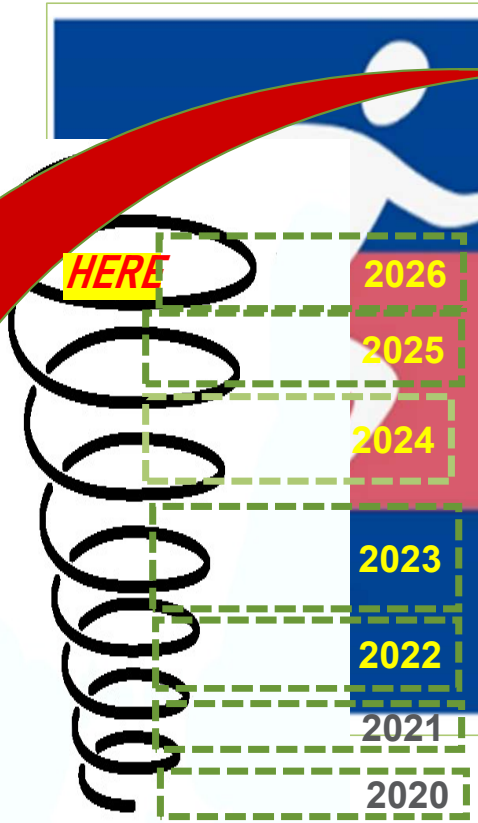
Conclusions and perspectives

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- A lot is ongoing worldwide to build personalized (incl. precision) cancer prevention collectively
- Moving from limited indications to a broad strategy requires **large scale prospective demonstration**
- Must be developed at the **public health level**
- **Risk assessment - early detection - risk reduction** strategies must synergize to be more impactful
- Many implementation challenges remain
- **A close collaboration between research areas** has the potential to accelerate developments in the field
- This research must be **participative** and consider patients' wills and vision

From EC to national level: the 2021-2030 European Odyssee







Different levels, different tools, different partners
One goal: Beating Cancer

This project has re.
from the European Uni.
Horizon 2020 research and
innovation programme under
grant agreement No 874467

Precommercial procurement (PCP)

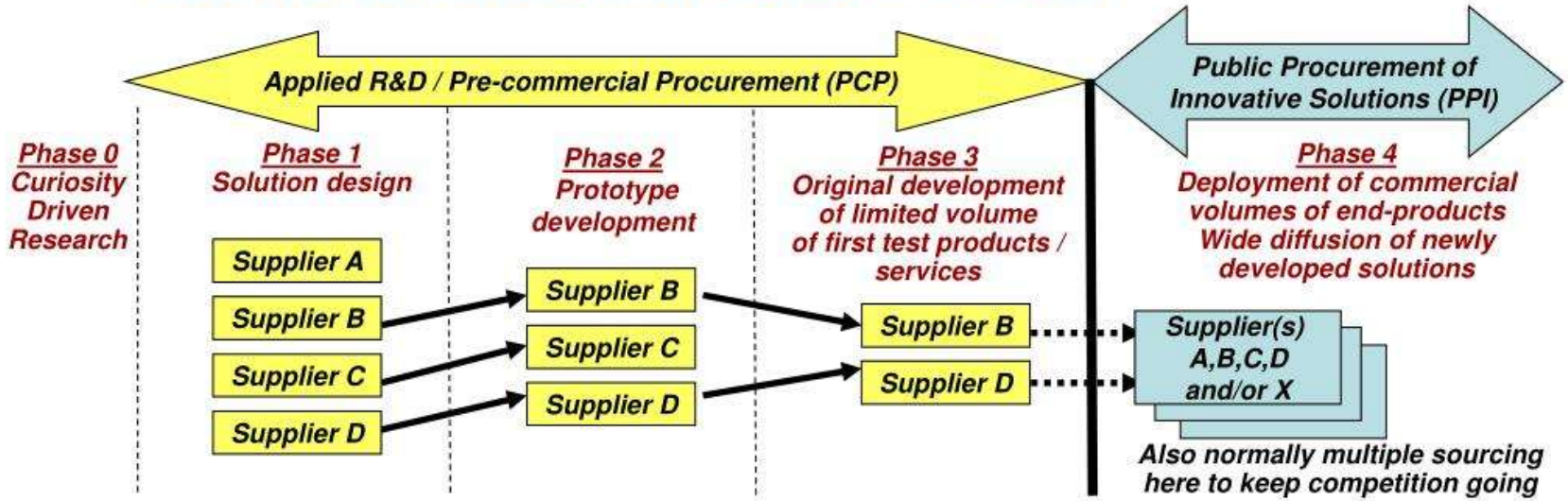
&

Public Procurement of Innovation (PPI)

PCP-PPI

European Commission

- **PCP to steer the development of solutions towards concrete public sector needs, whilst comparing/validating alternative solution approaches from various vendors**
- **PPI to act as launching customer / early adopter / first buyer of innovative commercial end-solutions newly arriving on the market**



Objectives:

- **Price/quality products that better fit public sector needs**
- **Earlier customer feedback for companies developing solutions**
- **Better take-up/Wider commercialisation of R&D results**

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 874467

oncNGS PCP challenge (2019)

Challenge: developing an integrated pan-cancer liquid biopsy solution for solid tumors & Lymphoma

Pre-analytical analysis



Pan-cancer tumour marker kit



Liquid biopsy analysis



DNA profiling by NGS



ICT decision support



Interpretation & Reporting

ONCNGS PCP

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 874467

oncNGS consortium: 8 buyers



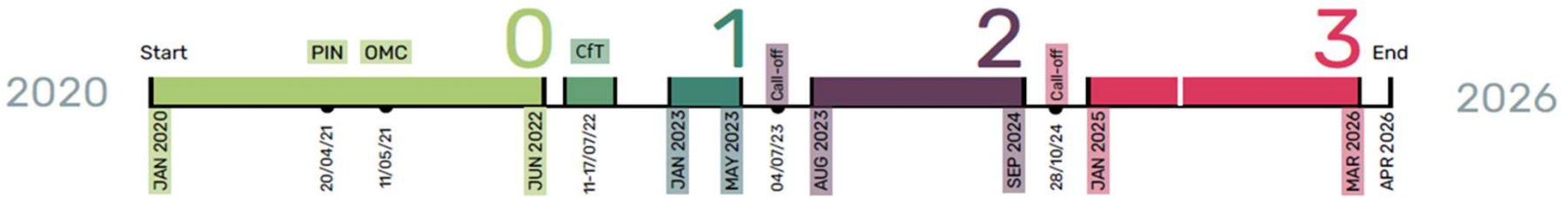
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 874467

oncNGS consortium: 6 supporting entities



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 874467

oncNGS PCP: from unmet need to proof of concept



Phase 0
CURIOSITY DRIVEN RESEARCH

TECH spec
IP-FTO
Business Case
Prior Notification
Strategy
CE-IVD strategy
GDPR implications
Tender
Eval.COM (criteria, members)
Dissemination

pre-commercial tender

Phase 1
SOLUTION DESIGN

AGILENT
oncoDNA
HUFIAT Con.
KU Leuven

Phase 2
PROTOTYPE DEVELOPMENT

Prototyping and analytical testing

AGILENT
HUFIAT Con.
KU Leuven

Phase 3
CLINICAL ASSESSMENT

Clinical validation of a limited set of pre-commercial solutions

AGILENT
KU Leuven/oncoDNA

ONCNGS PCP

Framework agrement

Phase 1 contracts	Phase 2 contracts	Phase 3 contracts
Bidder → Contractor	Bidder → Contractor	Bidder → Contractor

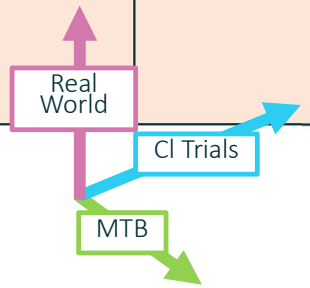
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 874467

OncNGS: foresighted (hopefully) ctDNA diagnostics

	innovative	comprehensive	versatile	modular	upgradable	quick intuitive	shareable	customizable	low cost
Academia/Healthcare specifications	Beyond state-of-art	Full ESCAT coverage, but must-have and nice to have alterations	Solid tumors + hemato	To be applied in different oncology settings and diseases	new alterations must be easy to be added/included	From wetlab to diagnostic report in 7 days	Ready for federated and real-world learning	Tested at the pilot buyers' sites	Around € 1.000
Company-driven innovation	Proprietary wet-lab and bioinformatics solutions incorporated	As above panels of different sizes + epigenomics and/or shallow sequencing integrated with genomic readouts	Compliant but with different combinatorial formats	'modules' interpreted in a creative way	optimized sequencing space	graphical eye-catching solutions	Several additional formats being proposed	adaptation, troubleshooting, refinement beyond pure beta-testing	Now commercially available as RUO, some around € 400

















This project has received funding from the European Union's Horizon 2020 research and innovation grant a

ctDNA diagnostics: regulatory requirements in advanced non-resectable cancer, USA vs EU

	Approval	Approval pathway	Competent authority	Geographic compliance	Reimburs-ement	Implemen-tation	Data use and re-use
USA	by indication, if ctDNA fails tDNA recommended	- breakthrough device designation - *ex ante* definition of clinical data requirements - special exemptions for **up-grading (e.g. MSK IMPACT genes 341 ➞ 410 ➞ 468 ➞ 505)**	FDA		private insurance (not the subject of regulatory approval)	outsourcing from private service providers preferred, with major exceptions	Service providers may use molecular info to refine proprietary ctDNA algorithms
EU	by indication, when tissue not available	EU In Vitro Diagnostic Regulation (IVDR 2017/746) – class C • **Scientific validity** • **Analytical performance** • **Clinical performance**	• Notified Bodies (NB) • EMA and MS Competent Authorities + stakeholders (Biomed Alliance etc) • IVD Expert Panels: Medical Device Coordination Group (MDCG), etc • guidelines (e.g. by ESMO)	in single Member States (MS), districts, or regions	public and private healthcare, fragmented regulatory landscape	Insourcing (lab kit) preferred but outsourcing and other models applied	to be defined

Designed for EU: innovative-comprehensive-versatile-modular-upgradable-quick/intuitive-shareable-customizable-low cost

European Call for the future Next Generation Sequencing (NGS) solutions for cancer

ONCNGS PCP

oncNGS PPI

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 874467

www.oncngs.eu



JA PCM
Joint Action Personalised Cancer Medicine

JA PCM

Marc Van den Bulcke
Cancer Centre
Sciensano - Belgium



Co-funded by
the European Union

JA Personalised cancer Medicine (JA PCM)

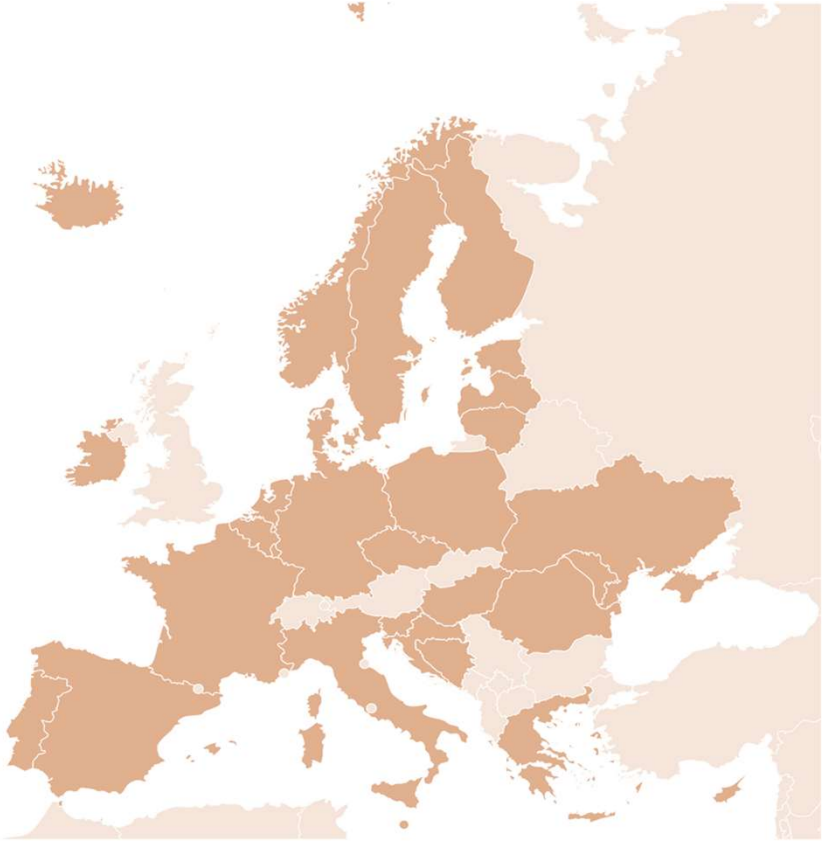
- Timeline: Nov 2025 – Nov 2029
- Funding: 31.6 Million € (80% EU contribution / 20% in kind)
- Consortium:
  - 29 Countries
  - 145 Partners (45 Competent authorities (CA) & 100 Affiliated entities (AE))
  - 6 Associated Partners (AP)

Medical Care Organisation	71
Research Organisation	41
Public & Governmental Organisation	32
Professional Network	5
Patient Organisation	2

- Building on:

can.heal

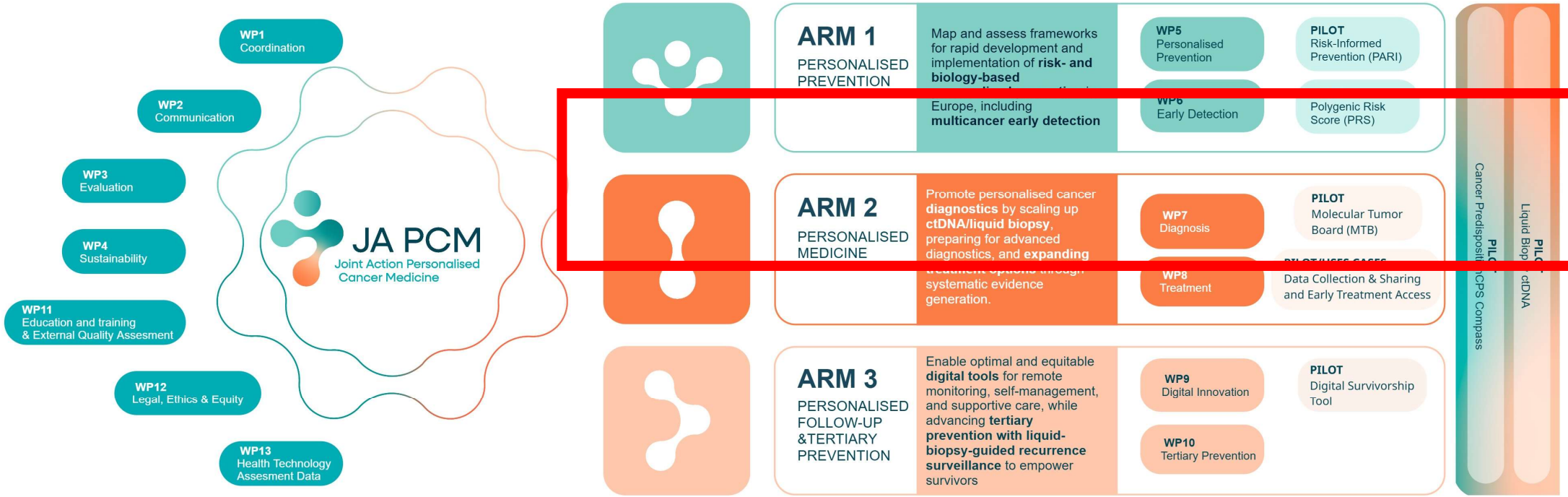
PCM4EU
Personalised Cancer Medicine for all EU Citizens



Website: https://japcm.eu/

JA PCM WORKPLAN

oncNGS opportunities



Seven pilots

Pathway, access, and implementation of **risk-informed cancer prevention** across Europe

Developing and testing care pathways that adapt cancer prevention strategies to individual risk profiles

Implementation readiness for **polygenic risk scores** in screening (breast & prostate cancer)

Exploring how genetic information can help better estimate cancer risk and inform prevention.

Supranational **molecular tumor board** for complex cases/countries without MTB

Strengthening the use of molecular data to support clinical decision-making in multidisciplinary tumour board meetings

Continuous **data collection** via a federated sharing platform

Developing ways to securely collect and analyse real-world cancer data from multiple countries, in order to build larger patient cohorts and generate evidence that can inform decisions on cancer treatments and improve patient outcomes.

- The pilot contains two use cases: 1) Expanding Treatment Space; and 2) Managed Entry Agreements

Digital tools for remote monitoring, needs assessment, self-management, and supportive care

Developing and testing digital tools to support the remote monitoring of patients' health status.

Personalised management of cancer predisposition across the patient journey (CPS Compass)

Integrating information on genetic predisposition into different stages of the patient journey, from screening to follow-up.

LB-ctDNA: Implementation of ctDNA guided decision-making across the patient journey

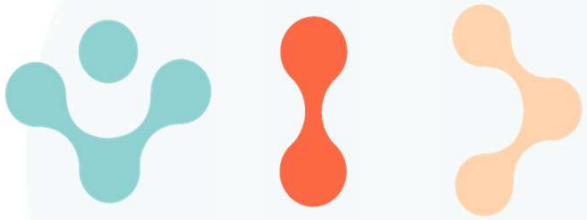
Assessing the use of blood-based tests to detect, monitor, or follow cancer in a less invasive way.

JA PCM
Joint Action Personalised Cancer Medicine

Co-funded by the European Union

Main activities

Technical activities



- Readiness and implementation of **risk-informed personalised prevention** across Europe, including multi-cancer early detection (screening) and personalised risk assessment
- **Liquid biopsy implementation** for early detection, tumour profiling, resistance monitoring, minimal residual disease, and recurrence surveillance (including EQA program)
- Set-up a **supranational molecular tumor board** for complex cases and countries without MTB
- **Expanding treatment options** through systematic evidence generation
- Enable optimal and equitable **digital tools for remote monitoring, self-management and supportive care**
- Personalised management of **cancer predisposition** across the patient journey

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State-of-play

- Pilots:
  - Process of development
    - ✓ Call for expression of interest and participant selection + role definition (surveys, interviews)
    - ✓ Definition and planning
    - ✓ Budget allocation strategy
    - ✓ MS4 Coordination fund: will be sent by mail
    - ✓ MS36 Internal report WP10 I - Mapping the Adoption of Liquid Biopsy and Minimal Residual Disease Monitoring Across Europe: https://zenodo.org/records/20733150
  - Amendment to the Grant Agreement: budget allocation from SC to the selected pilot participants
  - Private sector collaboration

JA PCM Joint Action Personalised Cancer Medicine
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Collaboration with the private sector (PS)

- Objectives:
  - Support JA PCM activities
  - Explore/ Develop a framework for long-term collaboration
- Activities
  - Private sector platform via the website
  - Expression of Interest (EOI) for PS
  - Memorandum on Private Sector Engagement in the JA PCM
  - Webinars targeting the PS
    - Analysis of the opinions collected during the webinar is ongoing
  - One-to-one meetings are ongoing
- Next
  - Webinars to collect public and patient opinions, held separately for each audience. 26-27 October
  - Launch the value proposition on the Private sector platform

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Belgian participation in JA PCM

WPs	Sciensano (CA)	CHU Liège (AE)	CUSL (AE)	Jessa (AE)	KU Leuven (AE)	SCK CEN (AE)	UGent (AE)	UZA (AE)	VUB (AE)	IJB (AE)
WP1 Coordination	Coordinator									
WP2 Communication	Lead									
WP3 Evaluation	Collab WP1									
WP4 Sustainability	Collab WP1									
WP5 Prevention	Lead (sub)task	X			X (Subtask L)		X	X		
WP6 Early detection	Co-Lead task - ELSI				X		X			
WP7 Diagnosis	Obs		X	X	X		X	X (Task CoL)		X
WP8 Treatment	Obs		X	X		X		X		X (Subtask L)
WP9 Digital tools survivorship	Co-Lead				X (Task Lead)					
WP10 Tertiary prevention	Collab WP9			X (Subtask L)	X			X		
WP11 Education & EQA	Obs				X (EDU)					
WP12 ELSI	Co-Lead									
WP13 Data, HTA and access	Obs		X							
PILOTS										
WP5 PARI	Co-Lead									
WP6 PRS										
WP7/WP8 MTB	Obs		Obs				Obs			
WP8 continuous data collection	Active									
WP8 Use Case 8.1: Treatment space	Active							Obs	Active	
WP8 Use Case 8.2: MEA	Active									
WP9 Digital tools survivorship	Co-Lead									
CPS Compass	Co-Lead	Obs								
Liquid biopsy				Active	Active		Active			Active

Associated partners:

- Stichting Kankerregister
- BSPHO (Pediatrie): MTB Pilot & CPS Compass (change to AE)

JA PCM Joint Action Personalised Cancer Medicine

Co-funded by the European Union

Contact information

Coordinator: Sciensano

Email: japcm.coordination@sciensano.be

JA PCM
Joint Action Personalised Cancer Medicine

Funded by the European Union

SRIA ROADMAP ON PERSONALIZED PREVENTION



The SRIA identified ten challenges for the implementation of personalised prevention, including:
Challenge 1: The broad scope of promotion and prevention;
Challenge 2: Continuous evidence synthesis system supporting personalised prevention;
Challenge 3: The PROPHET Framework implementation;
Challenge 4: Data collection and integration, and Data Infrastructure;
Challenge 5: Community Engagement and trust;
Challenge 6: Health Professionals and Policy Makers involvement;
Challenge 7: Regulatory aspects and synergy with private sector;
Challenge 8: Access, Equity and Coverage; Challenge 9: Ethical, Legal, Social Issues (ELSI); Challenge 10: Changing behaviour.

For each challenge, state of the art, gaps, priorities and implementation, and final considerations are detailed.

EUROPEAN PARTNERSHIP ON PERSONALIZD MEDICINE

https://prophetproject.eu/wp-content/uploads/2025/06/PROPHET-SRIA.pdf



EUnetCCC
ONEFORALL
Co-funded by the European Union

Annual meeting

Shaping the future of cancer care, research and education in Europe

Strengthening collaboration across initiatives: the role of thematic clust and the EU Health Policy Platfo

Co-funded by the European Union

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Context

Cancer remains one of the leading causes of death worldwide.

European nations are united in a massive commitment to fight this threat, through Europe's Beating Cancer Plan & subsequent joint actions

234 partners across 31 countries are committed in laying the foundations for a **sustainable European Cancer ecosystem** built around 3 complementary components:

- A European Comprehensive Cancer Infrastructure of CCCs and CCCNs
- A collaborative oncology network
- A dedicated governance & sustainability mechanisms



Ambition

Build a Sustainable European Infrastructure of CCCs and CCCNs

To ensure 90% of patients have access to a CCC by 2030…

…and receive high-quality cancer care as close to home as possible.





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