Hyper-early Diagnosis in Oncology Clinical Management

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HM CIOCC

Oncology Days ECI 48 WORKING TOGETHER TO IMPROVE QUALITY AND REDUCE INEQUALITIES WARSAW 2026

Disclosures

Research Funding: Guardant Health, Amadix

Speaking: Servier, Merck, Palex

Travel expenses: Merck, Roche

Agenda

- Importance of hyper-early cancer detection & population awareness
- Risk-population selection: classical and “hidden” risk factors
- Single-tumor hyper-early detection tests
- Multicancer hyper-early Detection tests (MCED)
- HM CIOCC Hyper-Early Detection & Prevention Unit
- Conclusions

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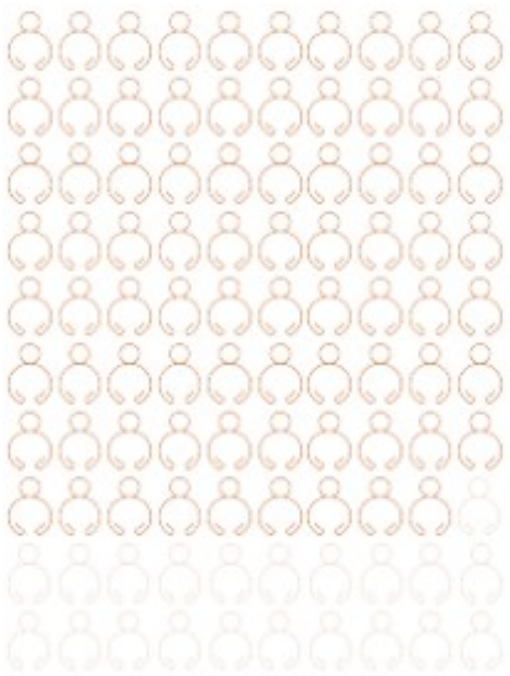
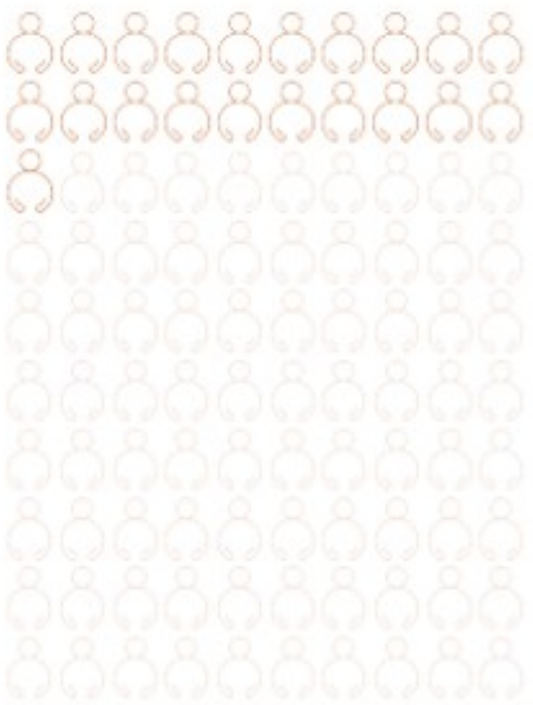
Cancer remains one of the leading causes of death worldwide.

Early detection dramatically improves survival:



89%

survival when diagnosed at **early stages**



21%

survival when diagnosed at **advanced stages**

Why Population Awareness Matters

- Many cancers remain asymptomatic for years
- Screening participation is suboptimal
- Public understanding of risk is limited
- Early detection reduces mortality and treatment burden

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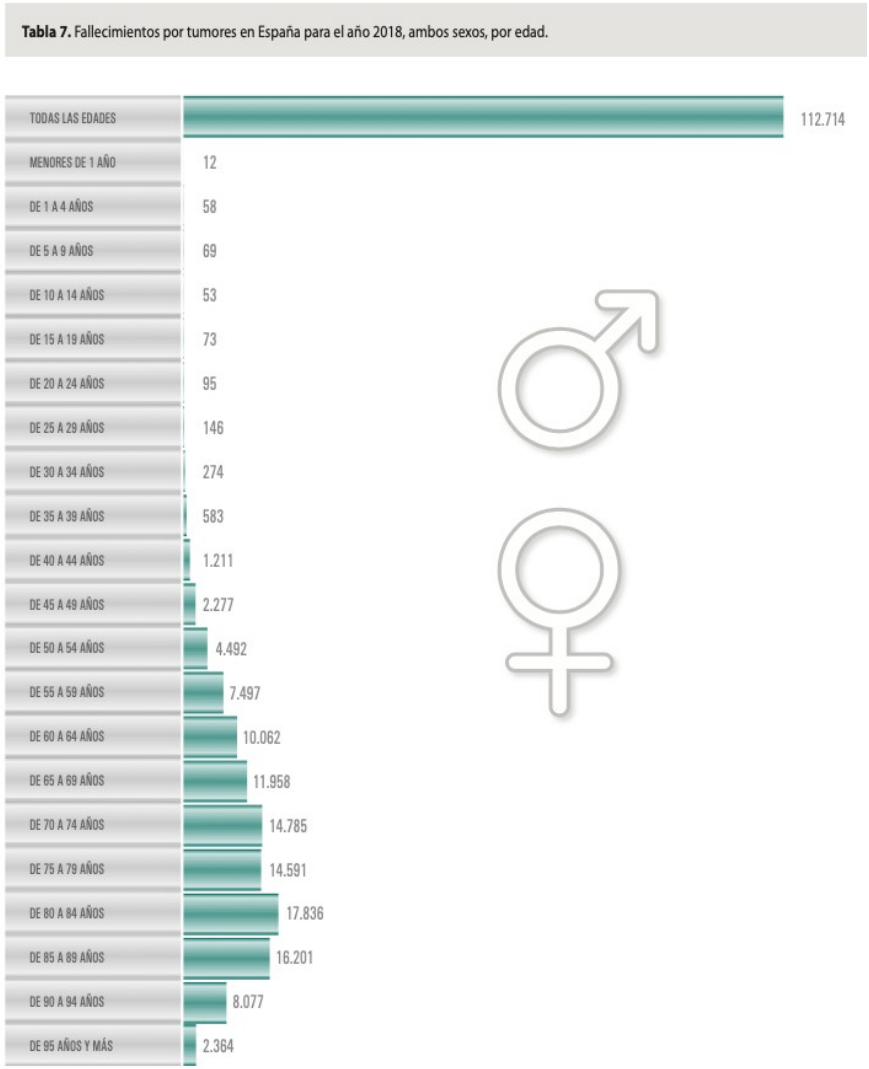
Classical Risk Factors

- **Age**
- Family history & hereditary syndromes
- Tobacco & alcohol
- Obesity, diet, sedentary lifestyle
- Chronic inflammation (IBD, hepatitis, etc.)
- Environmental exposures



“Hidden” Risk Factors Identified by AI

AI-based models can detect risk patterns invisible to classical epidemiology:

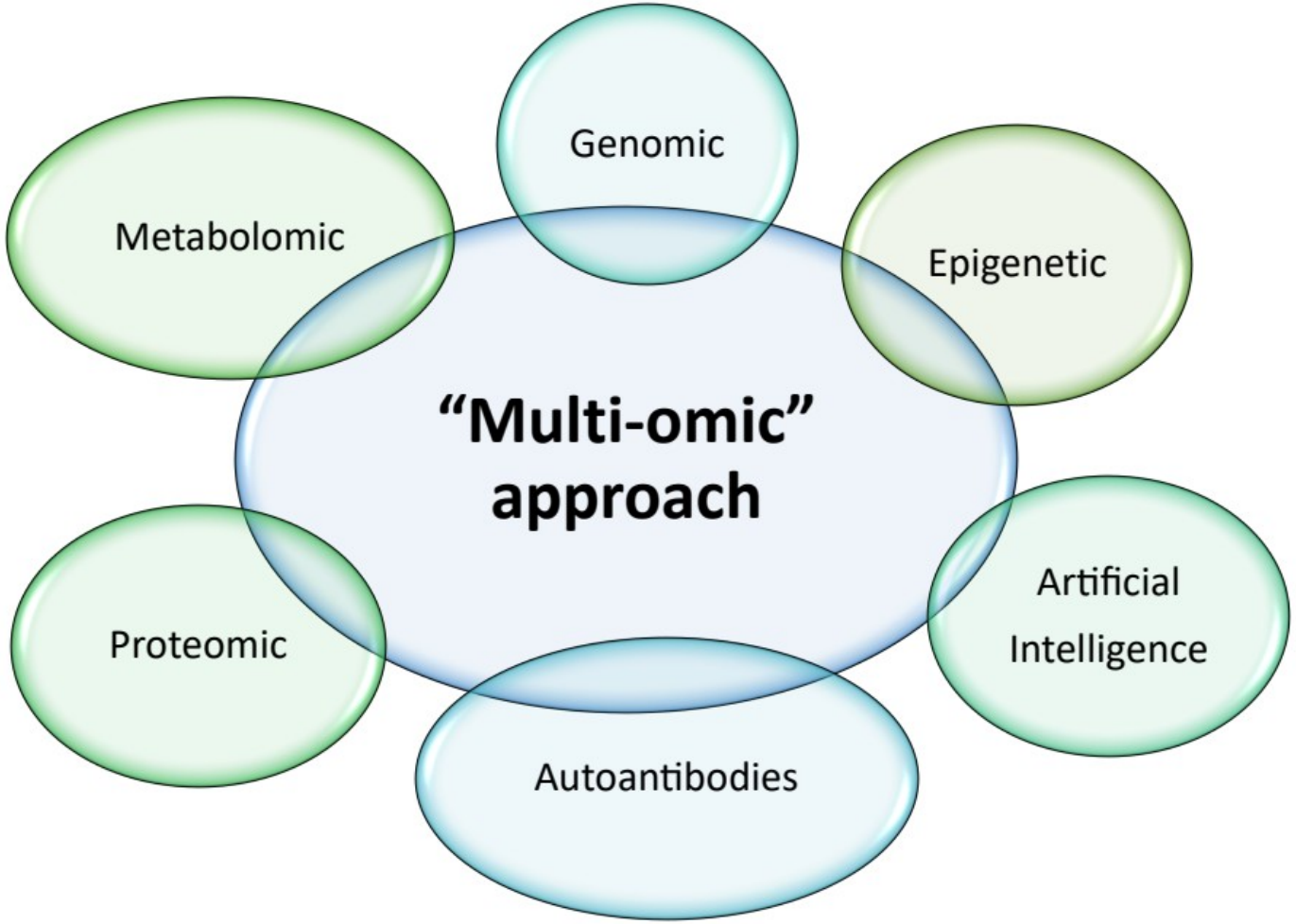
- Polygenic risk scores
- Radiomic signatures
- Longitudinal EHR-based risk trajectories
- Multi-omic risk fingerprints
- Behavioral and metabolic micro-patterns

Why AI-Enhanced Risk Stratification Matters

“Pre-test” concept

- Identifies high-risk individuals missed by traditional criteria
- Enables personalized screening intervals
- Reduces over-screening in low-risk populations
- Supports cost-effective implementation

Hyper-early detection of cancer



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Single-tumor hyper-early detection tests

- To improve screening programs: colorectal cancer
- To extend the hyper-early detection to additional tumour types

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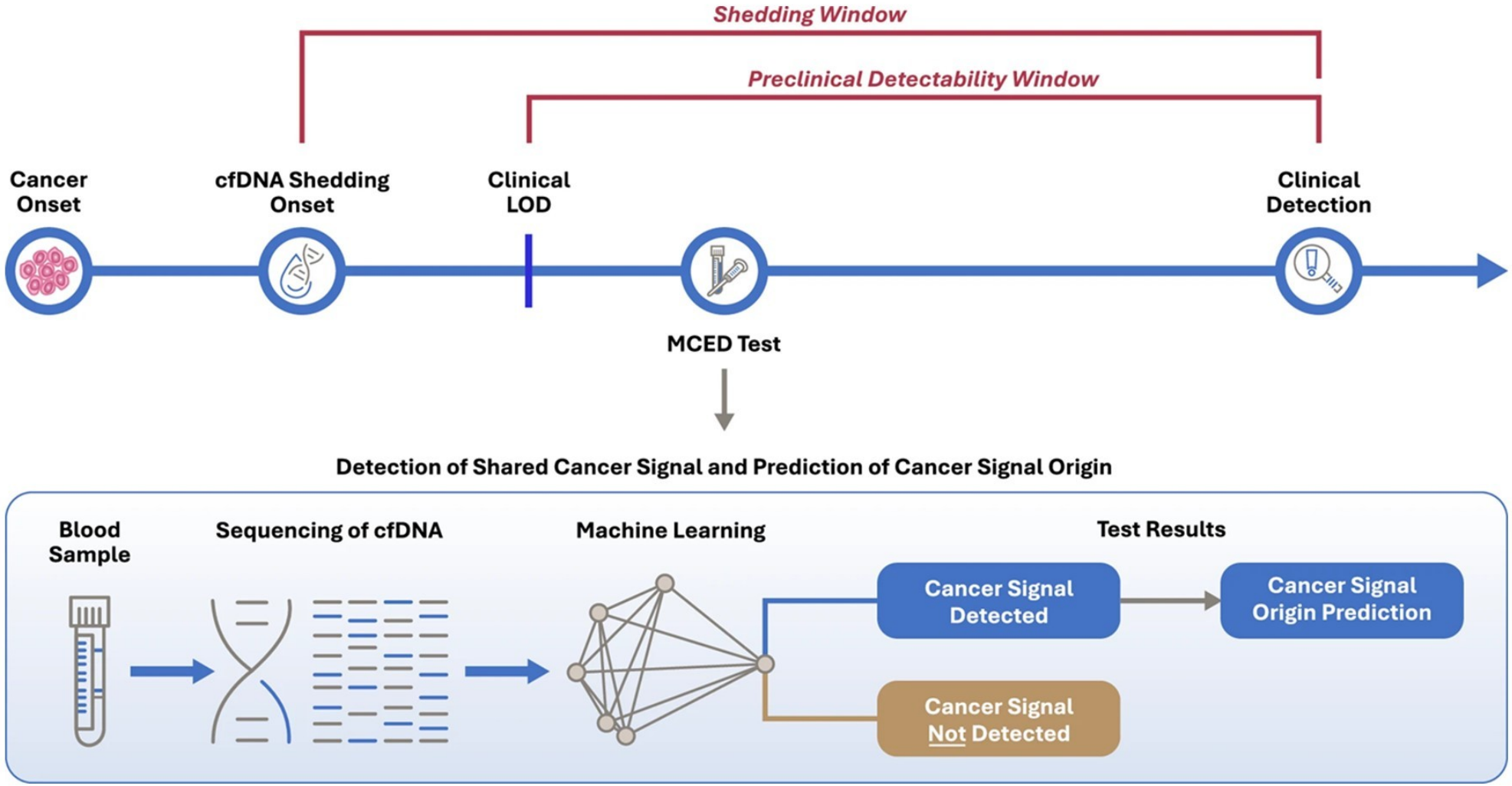
How do these assays work?



Vittone J et al. npj Precision Oncology 2024

How are these assays developed?

ALGORITHM DEVELOPMENT

PERFORMANCE

(sensitivity, specificity)

Validate PERFORMANCE in a real-world screening population

(sensitivity, specificity, PPV, NPV)

CLINICAL UTILITY

↓ mortality

↓ late-stage diagnoses

A large number of assays are currently under development

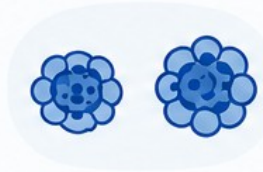
Test Name	Target/Technology	Tumor Type	Participants	Availability Status
Galleri	cfDNA methylation	50+ Cancers	Adults 50+ years old with elevated risk	Marketed- CLIA waiver, not FDA/CMS approved
OverC	cfDNA methylation	Lung, esophagus, liver, pancreas, ovary	Adults 50+ years old with elevated risk	In development
PanSeer	cfDNA methylation	Stomach, esophagus, colorectal, lung, and liver	Adults 50+ years old with elevated risk	In development
Harbinger Health (Test name TBD)	cfDNA methylation	High risk (lung, GI, hereditary)	High risk adults/smokers	In development
CancerGuard (precursor-CancerSEEK)	cfDNA methylation combined with protein configuration	26 different cancers	Adults 50+	In development
SeekInCare	cfDNA multidimensional cancer risk score	>20 types	Cohort known cancer patients and healthy controls	In development

Mao M. et al, JCO Global Oncology August 2023; : Massaad et al. AACR 2025 LB252; Wade R et al. Health Technol Assess. Jan 2025; Liang N et al. Nat Biomed Eng 2021;5(6):586-599; Imai M et al. Int J Clin Oncol 2025 Jan 12;30(2):180-193, Klein EA et al. Ann Oncol 32(9):1167-1177, Vittone J et al. npj Precis Oncol 8(1):91; Chen X et al. nature commun July 2020 11, 3475; Buchanan AH et al J Clin Oncol vol 41, 16 suppl June 2023.

But…

What is the path to routine clinical implementation of hyper-early detection assays?

Traditional Screening vs. Hiper-early Detection

A) Traditional Screening		VS.	B) Hiper-early Detection
Population-based		Target approach	Individualized
Invitation to target population		How people are reached	People come because of interest in their health
Few tumors		Tumors detected	Many tumors
Segregated care		Care model	Total prevention with the same medical team
Isolated interpretation		Data interpretation	Integrated interpretation

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OUR EXPERIENCE…

Every year we are visiting by more than 400 healthy people

Hyper-early detection and prevention Unit

1) Research

Hyper-early detection and prevention Unit

1) Research

↓ Education

2) Clinical assistance

Hyper-early detection and prevention Unit

Comprehensive Personalized Assessment

1) Traditional screening exams

+

2) Molecular hyper-early detection assays

Mission of the Unit

1. Clinical Pillar (Assistance)

- Personalized risk assessment
- Tailored screening programs
- Access to advanced molecular tests
- Multidisciplinary evaluation

2. Education Pillar (Teaching)

- Training healthcare professionals
- International courses
- Public awareness campaigns
- Patient empowerment initiatives

3. Research Pillar

- Participation in MCED trials
- Development of AI-based risk models
- Translational research in liquid biopsy
- Collaboration with international consortia

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Take home messages

- Early detection is a major unmet need
- Molecular early detection tests show enormous potential
- Clinical implementation is a big challenge

Take home messages

- Early detection is a major unmet need
- Molecular early detection tests show enormous potential
- **Clinical implementation is a big challenge**
  - Personalized approach
  - Trained phisicians
  - Comprehensive interpretation of assays and exams results
  - Molecular assays should complement, not replace, established screening

Hyper-early cancer diagnosis supports the goals of excellence and innovation advocated by OECI.

We have a unique opportunity—and responsibility—to collaborate and drive further progress

Thank you

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