

Multi-cancer tests in screening

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Part 1: Multicancer tests in context

Part 2: How the UK NSC is developing a point of view

The UK National Screening Committee (UK NSC) has **not made any recommendations on the use of multicancer tests for screening in the UK** as there is no evidence yet that their use in a screening programme does indeed lead to more good than harm at reasonable cost.

Part 1: Multicancer tests in context



The cancer screening landscape is complex

Historically, screening programmes (tests, pathways) have been designed to target specific conditions.

With multicancer tests in screening, different conditions are grouped together to be targeted by a single test.

This presents unique questions for their evaluation

Cancers have different natural histories. And each multicancer test performs differently for the cancers it can detect.

Aggregate outcomes could obscure significant variation in cancer-specific benefits and harms.

Indeed, a multicancer test could potentially lead to net harms for some cancer sites.

Multicancer test A



And questions for their deployment



Comparing multicancer tests that include different cancers against each other and single cancer programmes

First mover advantage, innovation and ethics.

Cancer-specific outcomes may be needed for policymaking.

Part 2: How the UK NSC is developing a point of view

Horizon scanning

Carr, D. J., & Welch, H. G. (2023). *JAMA Internal Medicine*, *183*(10), 1144–1151. https://doi.org/10.1001/jamainternmed.2023.3603

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Test	Trial name	Study type	Sample size	Study population	Primary outcome ^b	End date
Multiple assays	Collecting Blood Samples From Patients With and Without Cancer to Evaluate Tests for Early Cancer Detection	Observational	2000	Aged 40-75 y, with cancer or high suspicion of cancer or healthy participants	Test performance	February 2025
OverC (ctDNA; Guangzhou Burning Rock Dx Co, Ltd)	A Prospective Multi-Cancer Early-Detection Test In Asymptomatic Individuals (PREVENT)	Observational	12 500	Aged ≥40 y	Test performance	December 2028
OverC (ctDNA; Guangzhou Burning Rock Dx Co, Ltd)	Pan-Cancer Early Detection Project (PREDICT)	Observational	14 026	Aged 40-75 y, with cancer or with benign diseases in tumor sites or healthy participants	Test performance	March 2023
ctDNA (Wuhan Ammunition Life-tech Co, Ltd)	Clinical Study of Pan-cancer DNA Methylation Test in Plasma	Observational	3000	Aged ≥18 y, with high suspicion of cancer or noncancerous diseases or healthy participants	Test performance	August 2023
Elypta (metabolomic)	Multi-Cancer Early Detection (MCED) of Firefighters	Observational	2000	Actively working firefighters	Test performance	December 2030
Elypta (metabolomic)	GAGomes for Multi-Cancer Early Detection in High-Risk Adults	Observational	1256	Aged 55-80 y with significant smoking history	Test performance	March 2025
Elypta (metabolomic)	GAGomes for Multi-Cancer Early Detection in Asymptomatic Adults	Observational	9170	Aged 18-80 y, with cancer or healthy participants	Test performance	March 2025
Harbinger Health (ctDNA)	Development and Validation of Harbinger Health Test for Early Cancer Detection	Observational	10 000	Aged 20-79 y, with cancer or healthy participants	Test performance	July 2025
Adela Inc (ctDNA)	cfDNA Assay Prospective Observational Validation for Early Cancer Detection and Minimal Residual Disease	Observational	7000	Aged ≥40 y, with cancer or healthy participants	Test performance	December 2026
Freenome (multiomics)	The Sanderson Study: A Case Control Study for the Development of Multiomics Blood Tests for Cancer Screening	Observational	8000	Aged ≥30 y, with cancer or healthy participants	Test performance	September 2025
Freenome (multiomics)	The Vallania Study: A Case Control Study for the Development of Multiomics Blood Tests for Cancer Screening	Observational	5400	Aged ≥30 y, with cancer or healthy participants	Test performance	December 2024
Galleri (ctDNA; GRAIL)	PATHFINDER 2: A Multi-Cancer Early Detection Study	Observational	20 000	Aged ≥50 y, healthy participants	Test performance ^c	July 2026
Galleri (ctDNA; GRAIL)	REFLECTION: Real World Evidence for Learnings in Early Cancer Detection, a Cinical Practice Learning Program for Galleri	Observational	35 000	Aged ≥22 y, healthy participants	Test performance	August 2026
Galleri (ctDNA; GRAIL)	The SUMMIT Study: Cancer Screening Study With or Without Low Dose Lung CT to Validate a Multi-Cancer Early Detection Test	Observational	13 035	Aged 55-77 y, high-risk smokers	Test performance	August 2030
Galleri (ctDNA; GRAIL)	Does Screening With the Galleri Test in the NHS Reduce the Likelihood of a Late-Stage Cancer Diagnosis?	Randomized clinical trial	140 000	Aged 50-77 y, healthy participants, intervention blood test with results vs control standard care	Numbers of stage III and IV cancers diagnosed	February 2026

Table 1. Active Multicancer Detection Studies Accepting Healthy Volunteers in Clinical Trials.gov^a

MCD Task Group

A sub-group of individuals with specialist expertise to support the UK NSC.

Methods statement:

- What are the most appropriate methods for evaluating multicancer tests?
- What outcomes measures are necessary?
- Single cancer or multi-cancer (aggregate) outcomes?
- What do we need to know about the algorithms that multicancer tests use to predict a cancer site? How would we evaluate changes to these algorithms over time?

Multicancer tests raise complex ethical questions in screening, for example:

Mitigating harms: If detecting a cancer type with a multicancer test has net harms, what results should be reported to the individual and their clinician?

Comparing tests: Imagine multicancer test A screens for 20 cancers and multicancer test B for 10 cancers. Multicancer test B leads to significantly fewer deaths from the 10 cancers than Multicancer test A. It is not clinically or cost-effective to use both tests in parallel and total quality-adjusted life-years gained may be equivalent. What do you prioritise: breadth of cancers detected or depth of clinical effectiveness?

Preparing for a complex future

- The future of screening may involve risk, AI, and potentially multicancer tests.
- Traditionally, screening trials required 1-2 decades for definitive results. Given the speed and range of advances occurring, more agile approaches will be needed in future.
- But agility should **not** lead to a watering down of standards.
- The UK NSC is actively working with partners to consider and develop innovative means of generating high-quality, long-term, randomised evidence to support screening policy at scale.

Questions?

Department of Health & Social Care