Galleri® Blood-Based Screening Test for Early Detection of Multiple Types of Cancer

September 23, 2026

Molecular and Clinical Genetics Panel

GRAIL, Inc.

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Galleri® Introduction

Josh Ofman, MD, MSHS

Chief Executive Officer

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Cancer is a Leading Cause of Death in Adults ≥ 50 Years in the United States

Recommended Screening*
(USPSTF A or B)

No Recommended Screening



BREAST COLORECTAL LUNG CERVICAL

ALL OTHER INVASIVE CANCERS
(E.G., PANCREATIC, OVARIAN, LIVER)

~30%

Cancer deaths
each year in US with
Recommended Screening

~70%

Cancer deaths
each year in US with
No Recommended Screening

Ofman et al., 2025
*Prostate cancer screening is recommended on an individual basis (USPSTF Grade C) and is not included here.

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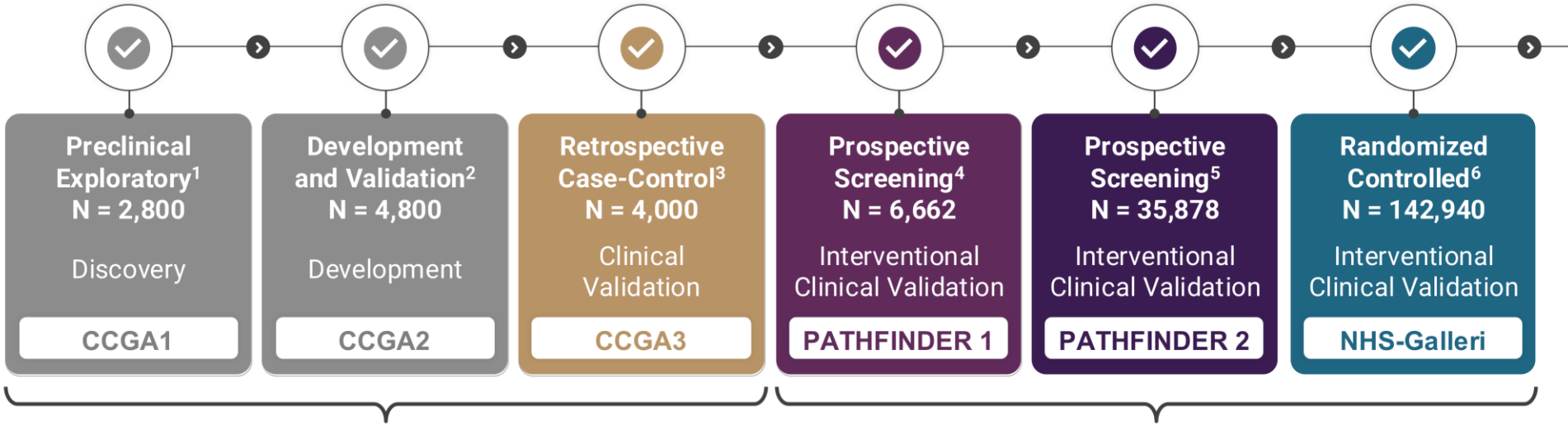
Proposed Intended Use of Galleri

- Galleri is intended for **screening for the early detection of multiple types of cancer**, in adults aged 50 years or older.
- Galleri is intended for the **prediction of Cancer Signal Origin in individuals with a Cancer Signal Detected** test result.
- **Patients should continue to adhere to guideline-recommended screening.**

Population-Scale Studies Used for Test Development, Validation, and Implementation



>180,000 Participants enrolled in ongoing studies evaluating real-world clinical use, etc

1. Jamshidi et al., 2022; 2. Liu et al., 2020; 3. Klein et al., 2021; 4. Schrag et al., 2023; 5. Giridhar et al., 2026; 6. Swanton et al., 2026

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Galleri Detects a Shared Cancer Signal, Not Individual Cancers One at a Time

How Galleri works[1]

- Looks for cancer-associated methylation patterns in cell-free DNA
- Detects a shared cancer signal that may arise from many cancer types
- **Detection cannot be selectively turned off by cancer type**

Shared cancer signal detected

What happens when a signal is detected

- Reports Cancer Signal Detected
- Provides accurate CSO to guide targeted diagnostic evaluation
- **Detected signals must be reported to the doctor and patient and diagnostically evaluated**

Cancer type-by-type results are best considered in context of Galleri's shared cancer signal approach

1. Klein et al., 2021

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PATHFINDER 2 and NHS-Galleri Support that Galleri is a Safe and Effective Screening Option

	PATHFINDER 2 N = 21,418*	NHS-Galleri N = 50,739*
Positive Predictive Value (PPV)	**77.0%** (65.8 – 85.4%)	**66.2%** (56.7 – 74.6%)
False-Positive Rate	**0.15%** (0.09 – 0.25%)	**0.26%‡** (0.18 – 0.39%)
Episode Sensitivity (12 Months) 12 cancers responsible for $^{2}/_{3}$ of US cancer deaths	**61.3%** (52.4 – 69.6%)	**52.1%††** (46.9 – 57.2%)
Episode Sensitivity (12 Months)† All cancers	**35.0%** (29.8 – 40.5%)	**31.6%††** (28.5 – 34.8%)
Cancer Signal Origin Prediction Accuracy	**94.3%** (88.2 – 97.4%)	**91.9%** (87.9 – 94.6%)

* Weighted
† MCED-detected cancers/all cancers diagnosed over a 12-month period
†† NHS-Galleri episode sensitivity metrics are for the prevalent round of screening
‡ NHS-Galleri does not capture recurrences which contributes to apparent increase in False-Positive Rate compared with PATHFINDER 2
Galleri – Data through 12 months of follow-up

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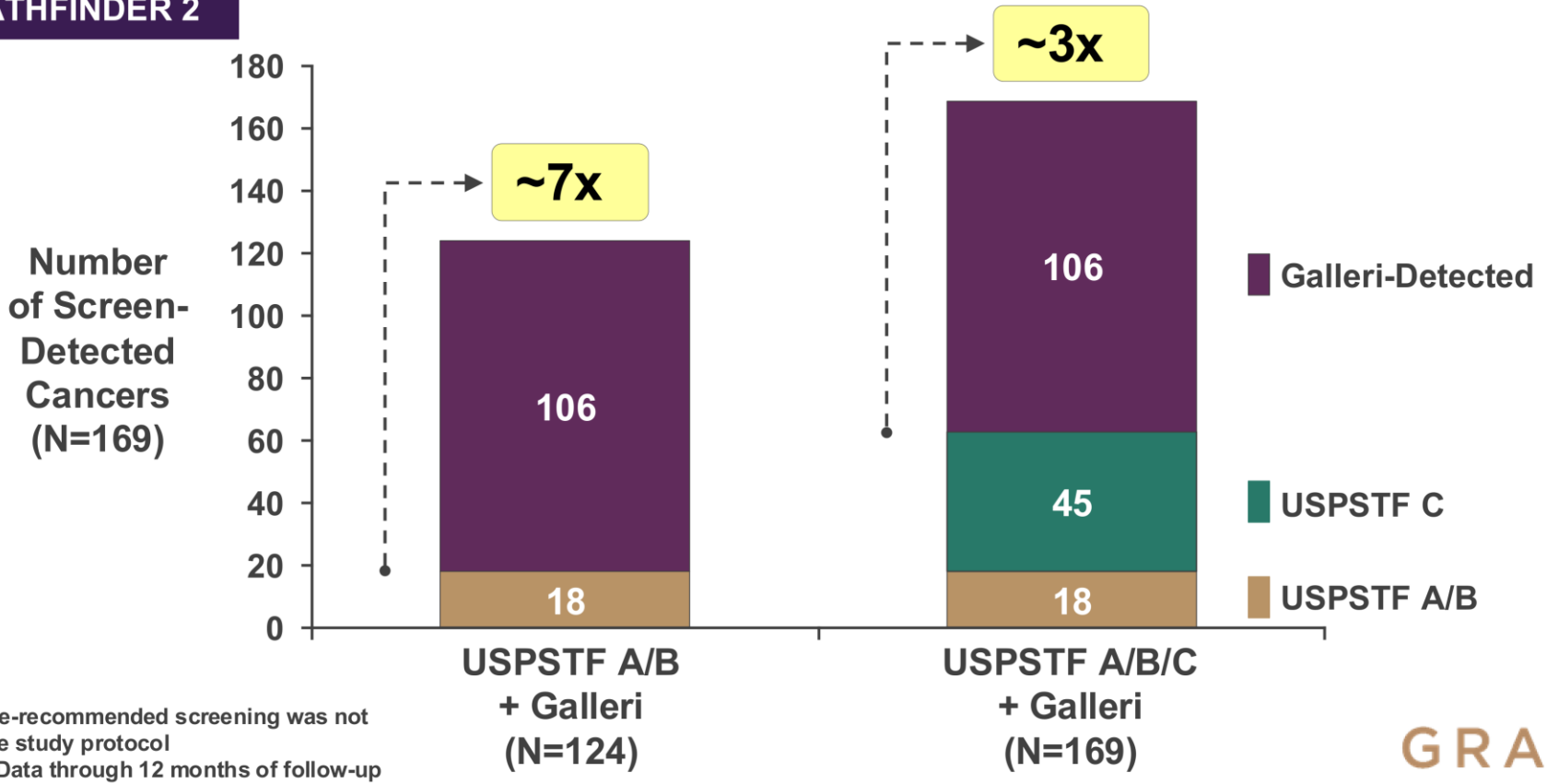
Galleri Increases Total Number of Cancers Detected When Used in Addition to Guideline-Recommended Screening*

PATHFINDER 2



*Guideline-recommended screening was not part of the study protocol
Galleri – Data through 12 months of follow-up

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Galleri Detected New Cancers Predominantly at Stages With Opportunity for Curative Treatment

PATHFINDER 2

Cancer Stage, % (N)	Percent of Galleri-Detected New Cancers N = 90
Stage I	**30.0%** (27)
Stage II	**18.9%** (17)
Stage III	**20.0%** (18)
Stage IV	**26.7%** (24)
No Stage Expected	**4.4%** (4)

Stages I-II: 48.9%

Stages I-III: 68.9%

76% (47/62) Do Not Have Recommended Screening

- Head & Neck (n=13)
- Liver (n=13)
- Lung (n=6)*
- Colon/Rectum (n=5)*
- Lymphoid lineage (n=5)
- Breast (n=4)*
- Pancreas (n=3)
- Prostate (n=3)
- Anus (n=2)
- Kidney (n=2)
- Plasma cell lineage (n=2)
- Stomach, Esophagus (n=2)
- Bladder, Urothelial tract (n=1)
- Testis (n=1)

Galleri – Data through 12 months of follow-up

*USPSTF grade A/B-recommended screening is available for lung, colorectal, and breast cancers

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Galleri Detects Clinically Meaningful Cancers and Complements Existing Screening to Expand Detection

PATHFINDER 2

- **All Galleri-detected cancers were identified before clinical suspicion**
  - **82%** of participants with stages I-III cancers received treatment with curative intent
  - **75%** of participants with Galleri-detected cancers had cancer types without USPSTF A/B-recommended screening programs*
  - Galleri also detected interval cancers, including breast and colorectal cancers, and recurrent cancers

- **84%** of cancers not detected by Galleri either were cancer types with USPSTF A/B/C-recommended screening† or were diagnosed at stage I

*** Includes breast, cervix, colorectal, and lung**
† Includes cancers with common screening options (breast, cervix, colorectal, prostate) or with screening in a high-risk population (lung)
Guideline-recommended screening was not part of the study protocol

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Key Criteria from 2023 FDA Molecular and Clinical Genetics Panel Meeting



Detect multiple, clinically meaningful cancers, including unscreened cancers, using a simple blood draw



Predict cancer signal origin to assist with diagnostic workup



High positive predictive value and a **low false-positive rate** to limit unnecessary workups



Galleri meets all of these criteria, supporting its safety, effectiveness, and positive benefit-risk in the intended use population

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FDA 24 Hour Summary: Molecular and Clinical Genetics Panel Advisory Committee Meeting; 2023 Nov 29

Agenda

Unmet Need	**Mylynda B. Massart, MD, PhD** Associate Professor, Medical Director UPMC Primary Care Precision Medicine Center Department of Family Medicine University of Pittsburgh
Development and Validation	**Sir Harpal Kumar, FRCR, FMedSci** Chief Scientific Officer & President, Global Clinical and Medical Affairs GRAIL
PATHFINDER 2 Results	**Nima Nabavizadeh, MD** Professor of Radiation Medicine Oregon Health & Science University
NHS-Galleri Results	**Professor Peter Sasieni, CBE, PhD** Professor of Cancer Epidemiology, Centre Co-Lead for the Centre for Cancer Screening, Prevention and Early Diagnosis Queen Mary University of London
Clinical Perspective	**Mylynda B. Massart, MD, PhD**
Conclusion / Q&A Moderator	**Sir Harpal Kumar, FRCR, FMedSci**

Additional Experts

Christina Clarke Dur, PhD, MPH
Vice President, Epidemiology and Distinguished Scientist
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Eric A. Klein, MD
Distinguished Scientist
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Eric Fung, MD, PhD
Chief Medical Officer
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Margarita Lopatin, MS
Vice President, Biometrics
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Megan Hall, PhD
Senior Vice President, Global Medical Affairs
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Oliver Venn, PhD
Senior Vice President, Research
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Benefits of Guideline-Recommended Cancer Screening and Need for Additional Options

Mylynda B. Massart, MD, PhD

Associate Professor, Medical Director
UPMC Primary Care Precision Medicine Center
Department of Family Medicine
University of Pittsburgh

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Cancer Remains a Leading Cause of Morbidity and Mortality in the United States

- **~2 million** new cases and **>600,000** deaths annually[1]
- **~40% lifetime risk** of cancer diagnosis[1]
- **1 in 6** people will die from cancer[2]
- **~90%** of all cancers in adults ≥50 years
  - **6% increase** in risk with each additional year of life thereafter

1. Siegel et al., 2026; 2. SEER 21 cancer incidence 2021-2023, analyzed with DevCan software

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USPSTF Recommends Screening Tests for Five Cancer Types

Cancer Type	Grade	Eligible Population	USPSTF Recommended Screening
BREAST	B	Women | 40 - 74 years	Mammography
CERVICAL	A	Women | 21 - 65 years	Cytology ± HPV Test
COLORECTAL	A	Adults | 50 - 75 years	Colonoscopy Stool-based screening (sDNA) Stool-based screening (FIT)
	B	Adults | 45 - 49 years	
	C	Adults | 76 - 85 years	
LUNG	B	Adults | 50 - 80 years*	Low-dose CT
PROSTATE	C	Men | 55 - 69 years‡	PSA blood test

- Many unscreened cancer types including some of the most fatal (e.g., pancreatic and ovarian)

*Adults 50 – 80 years old with ≥ 20 pack-year smoking history who currently smoke or have quit within the past 15 years
‡Individual decision for periodic PSA-based screening after discussion of benefits and harms with clinician

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Guideline-Recommended Single-Cancer Screening Prioritizes Sensitivity

Cancer Type	USPSTF-Recommended Test	Sensitivity (%)	Specificity (%)	PPV (%)
BREAST	Mammography	87.4 – 87.6% for DCIS or invasive cancer	90.2 – 92.2% for DCIS or invasive cancer	5.2 – 6.9%[1] for DCIS or invasive cancer
CERVICAL	Cytology / HPV test	95.2% for grade 2+ neoplasia	85.5% for grade 2+ neoplasia	0.1 – 0.8%[2] for invasive cancer
COLORECTAL	Colonoscopy	*Reference Standard*		
	Stool-based screening (sDNA)	93.9% for invasive cancer	90.6% for advanced neoplasia	3.4%[3] for invasive cancer
	Stool-based screening (FIT)	74% for invasive cancer	94% for invasive cancer	3.2%[4] for invasive cancer
LUNG	Low-dose CT	80.3 – 93.3%	76.4 – 78.6%	6.9%[5]
PROSTATE	PSA blood test	73.2%	85.4%	22 – 27%[6]

DCIS: ductal carcinoma in situ; 1. Lee et al., 2023; 2. Kim et al., 2018 and Melnikow et al., 2018; 3. Imperiale et al., 2024; 4. Robertson et al., 2017 and Lin et al., 2021 5. Jonas et al., 2021; 6. Harris and Lohr, 2002

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False-Positive Risk Accumulates Across Screening Tests and Over Time

- **False positives are inherent to all screening tests**
  - e.g., 1 in 11 women receive false-positive mammogram result with each test[1]
- **False-positive risk accumulates across multiple screening rounds**
  - **PLCO Cancer Screening Trial (3-year study)[2]**
    - Cumulative risk of ≥1 false-positive result approached 50% for women[2]
    - Exceeded 60% for men over repeated screening rounds[2]
- **False-positive risk also accumulates within single screening period across screening tests**
  - Many individuals undergo multiple single-cancer screening tests in the same screening period
  - Each test carries an independent false-positive risk

1. Lee et al., 2023; 2. Croswell et al., 2009

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Benefits of Early Detection

- The aim of cancer screening is to identify earlier-stage disease, for which treatment is more likely to be curative, in non-symptomatic individuals[1]
- Many fatal cancers are clinically silent until advanced stages[2]
- Modern therapies have improved outcomes for many regionally advanced cancers
- Detection before distant metastasis can enable meaningful treatment options

1. Duffy S et al., Nature Reviews Clinical Oncology 2026
2. American Cancer Society – The Cancer Atlas – Early Detection

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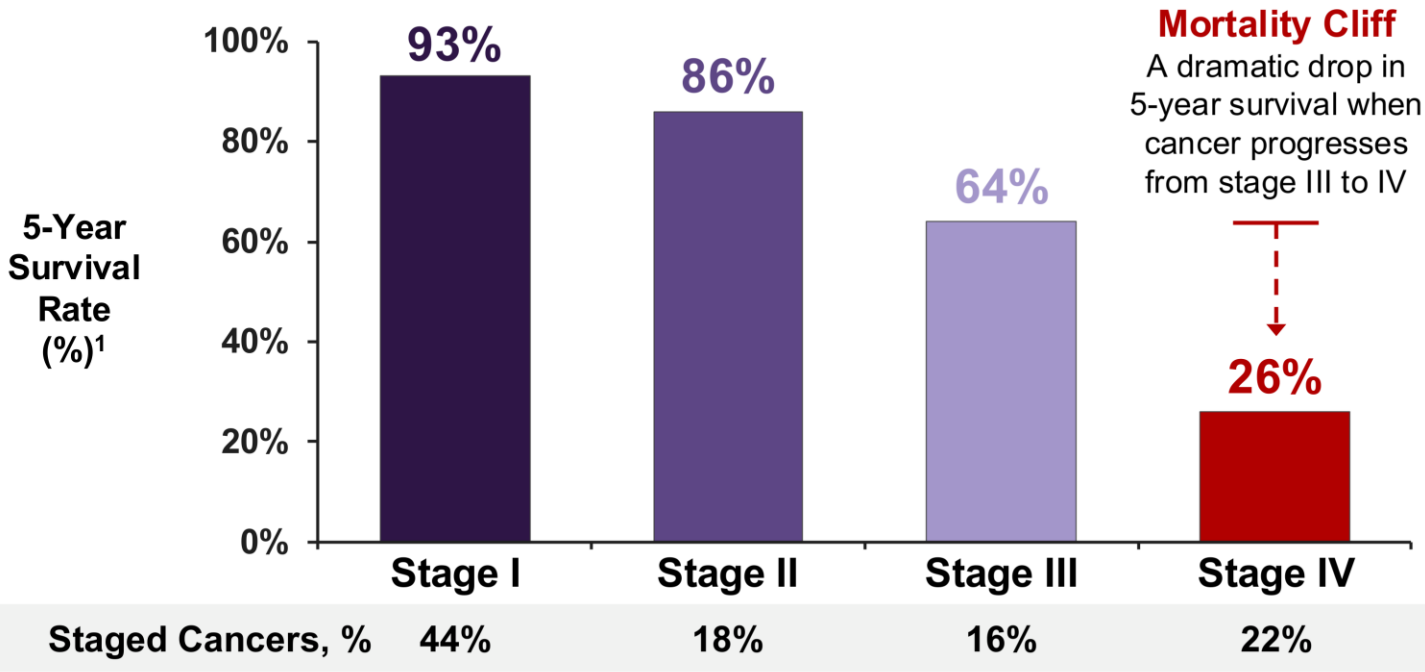
A Sharp Decline in 5-Year Survival Between Stage III and Stage IV



Mortality Cliff

A dramatic drop in 5-year survival when cancer progresses from stage III to IV

<5%

5-year survival for certain stage IV cancers

e.g., pancreas, stomach, esophagus, and liver

- Stage IV cancers are usually managed with palliative intent with goal of improving quality of life
- Most cancer deaths are from cancers diagnosed at stage IV

1. SEER 17 registries, cancer incidence diagnosed 2016-2017 followed through 2022, AJCC 7th edition stage

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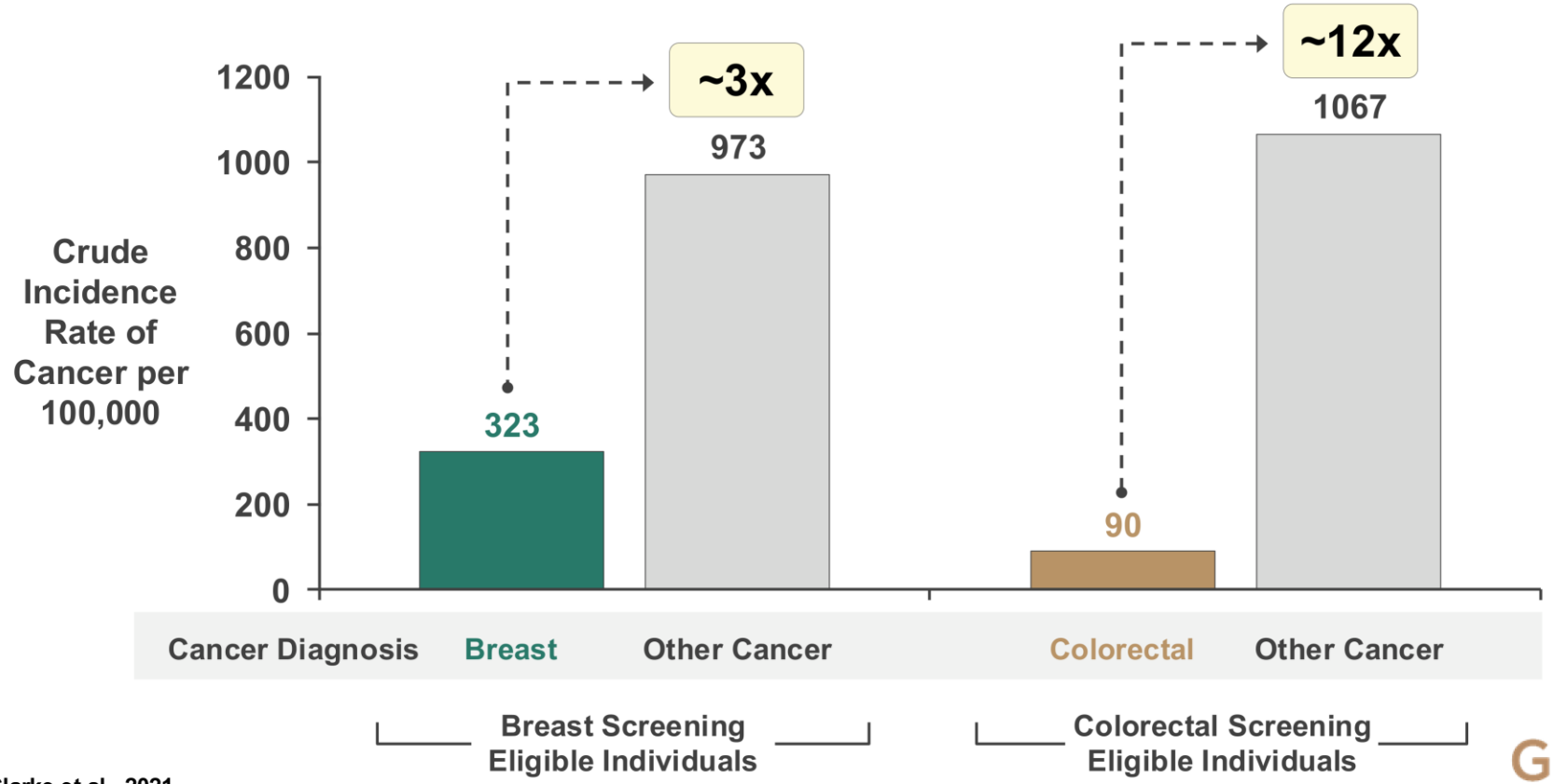
Individuals are More Likely to Have a Different Cancer Than the One Being Screened



Clarke et al., 2021

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Need for Additional Cancer Screening Options

- Guideline-recommended screening provides a clear public health benefit
- Many cancers lack population-based screening options
  - Later stage at diagnosis
  - Fewer treatment options
  - Poorer morbidity and mortality outcomes
- Broad detection needed, especially for unscreened cancers



An MCED approach capable of detecting multiple cancers in a single test has potential to improve patient outcomes



Galleri Device Development and Validation

Sir Harpal Kumar, FRCR, FMedSci

Chief Scientific Officer

President, Global Clinical and Medical Affairs

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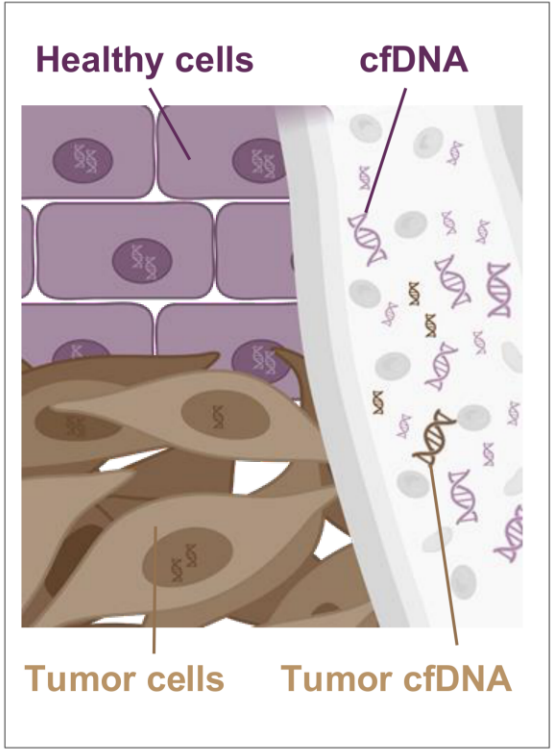
Galleri Detects Shared Cancer-Specific DNA Methylation Patterns in Cell-Free DNA (cfDNA) from Blood



- All cell types release cfDNA into bloodstream
- Cancer cells exhibit abnormal DNA methylation patterns
  - Creates shared cancer signal across multiple tumor types[1]
- Galleri analyzes methylation patterns using machine learning to determine[2]
  - Presence of a cancer signal [Yes/No]
  - Cancer Signal Origin (CSO) and Supplemental CSO (CSO-S) to guide diagnostic evaluation
- Methylation signals may be detected while patients are still asymptomatic

1. Hanahan & Weinberg, 2000; 2. Klein et al., 2021

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CCGA Showed Combining Other cfDNA Approaches Did Not Increase Methylation-Only Test Performance

Sample (DNA type)	Assay	Classifier
Plasma (cfDNA)	WGBS	▪ WG methylation
Plasma (cfDNA) WBC (gDNA)	Targeted sequencing	▪ SNV ▪ SNV-WBC
Plasma (cfDNA) WBC (gDNA) Tumor (gDNA)	WGS	▪ Fragment endpoints ▪ Allelic imbalance ▪ SCNA ▪ Fragment lengths ▪ SCNA-WBC

- Methylation-only provided:
  - Highest specificity
  - Highest CSO accuracy
  - Greatest opportunity for scalability, efficiency, and localization capability
- Supporting its selection as the foundation for the Galleri classifier

CCGA, Circulating Cell-free Genome Atlas; cfDNA, cell-free DNA; CSO, cancer signal origin; gDNA, genomic DNA; SCNA, somatic copy number alterations; SNV, single nucleotide variants; WB, whole blood; WBC, white blood cell; WGBS, whole-genome bisulfite sequencing; WGS, whole-genome sequencing. Jamshidi et al., 2022.

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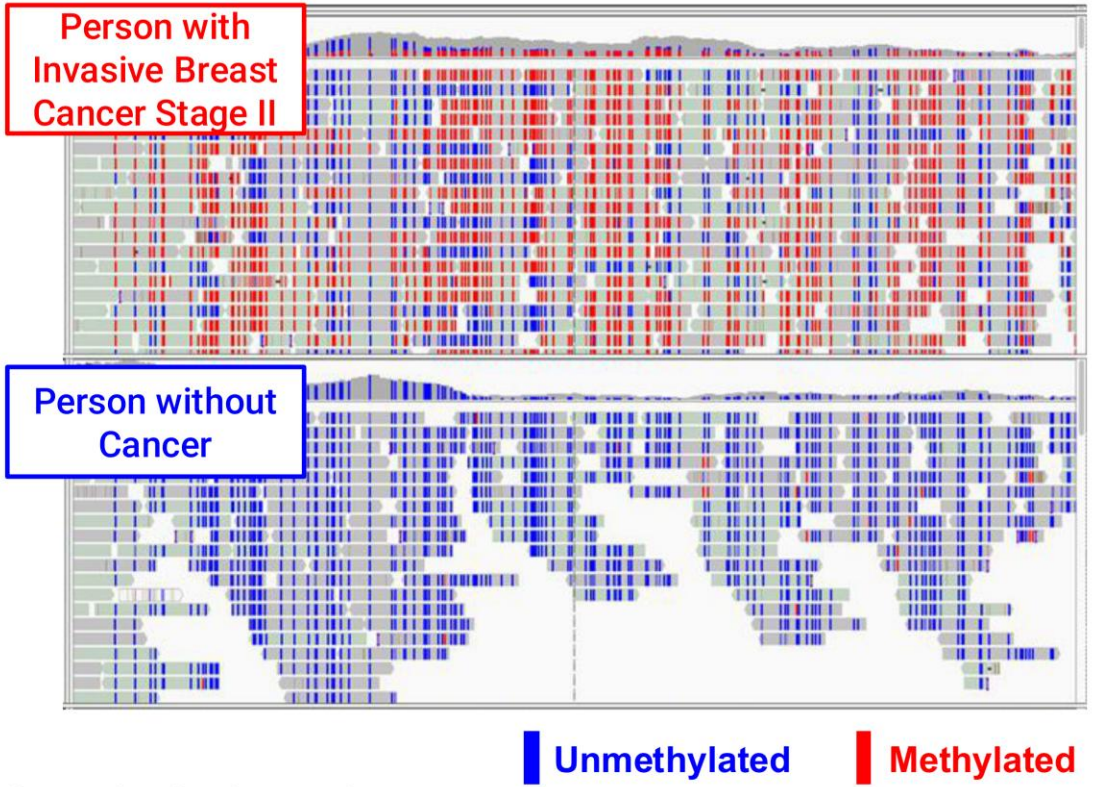
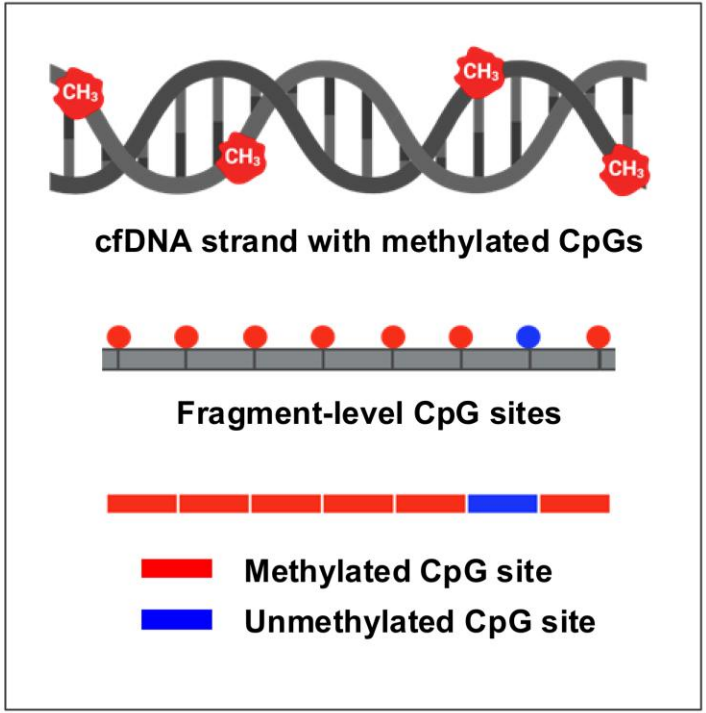
DNA Methylation Patterns in cfDNA Distinguish Cancer from Non-Cancer





CpG = cytosine-phosphate-guanine
Aravanis et al., 2018

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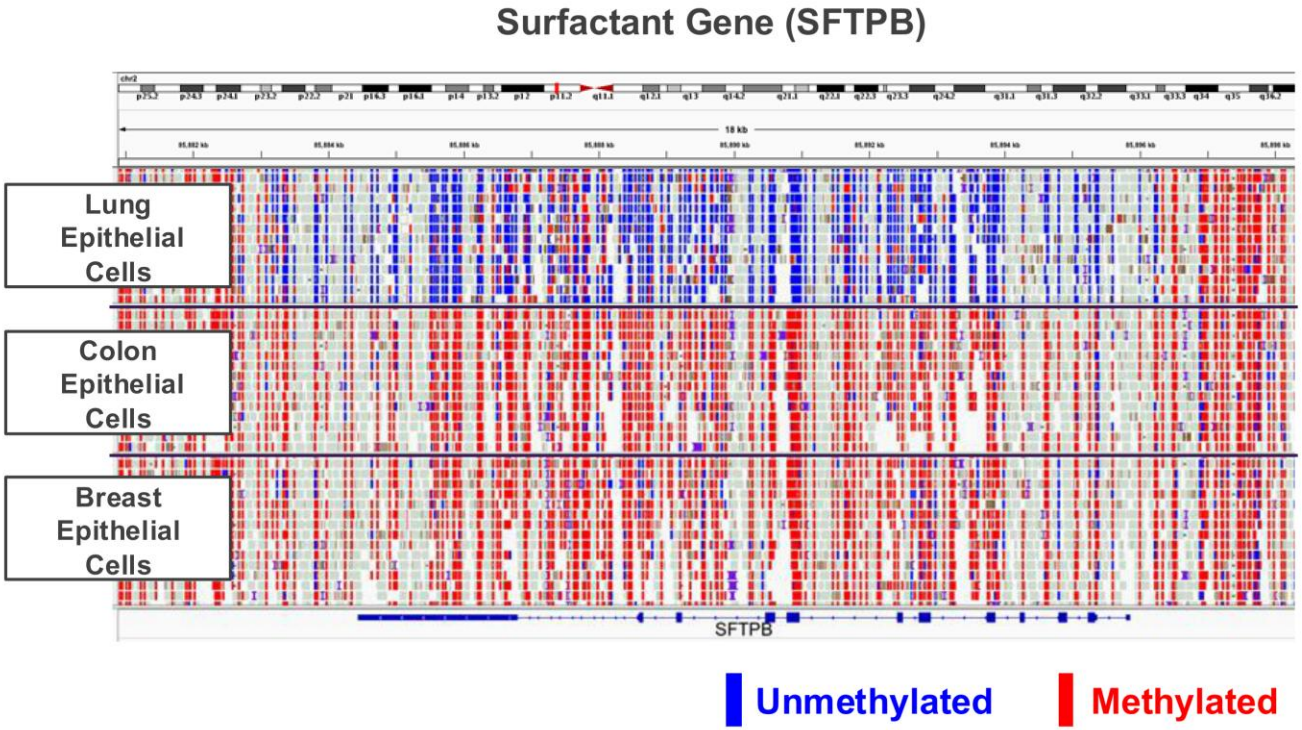
Methylation Patterns Also Identify Cancer Signal Origin



- Methylation patterns are established during development in a cell-type-specific manner
- Each cell type in the body has a unique pattern of methylation and tissue-specific gene expression

SFTPB, surfactant protein B
GRAIL Data on File GR-2023-0112

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CCGA Clinical Validation Substudy Demonstrated Strong Test Performance

% (95% CI)	CCGA3† N = 4,077	
False-Positive Rate	**0.5%**	(0.2 – 1.0%)
Test Sensitivity 12 cancers responsible for $^{2}/_{3}$ of US cancer deaths*	**76.3%**	(74.0 – 78.5%)
Test Sensitivity All cancers	**51.5%**	(49.6 – 53.3%)
Cancer Signal Origin Accuracy	**88.7%**	(87.0 – 90.2%)

Cancer status **known** at time of blood draw

***Anus, bladder, colon/rectum, esophagus, head and neck, liver/bile duct, lung, lymphoma, ovary, pancreas, plasma cell neoplasm, and stomach.**
†These data were part of device development and are not part of the safety and effectiveness data for the Galleri PMA

Klein et al., 2021

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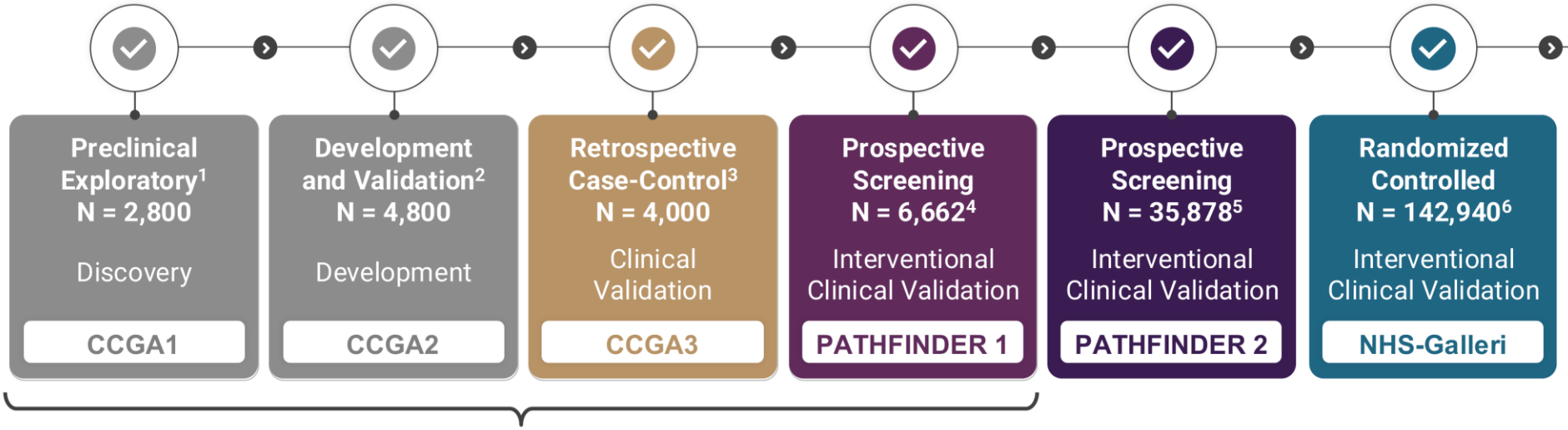
Case-Control Studies Set the Stage for Prospective Clinical Studies



- Established technical performance
- Provided foundation for evaluating clinical performance in large prospective studies in the intended-use population

1. Jamshidi et al., 2022; 2. Liu et al., 2020; 3. Klein et al., 2021; 4. Schrag et al., 2023; 5. Giridhar et al., 2026; 6. Swanton et al., 2026

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PATHFINDER 2 Results

Nima Nabavizadeh, MD

Professor of Radiation Medicine

Oregon Health & Science University

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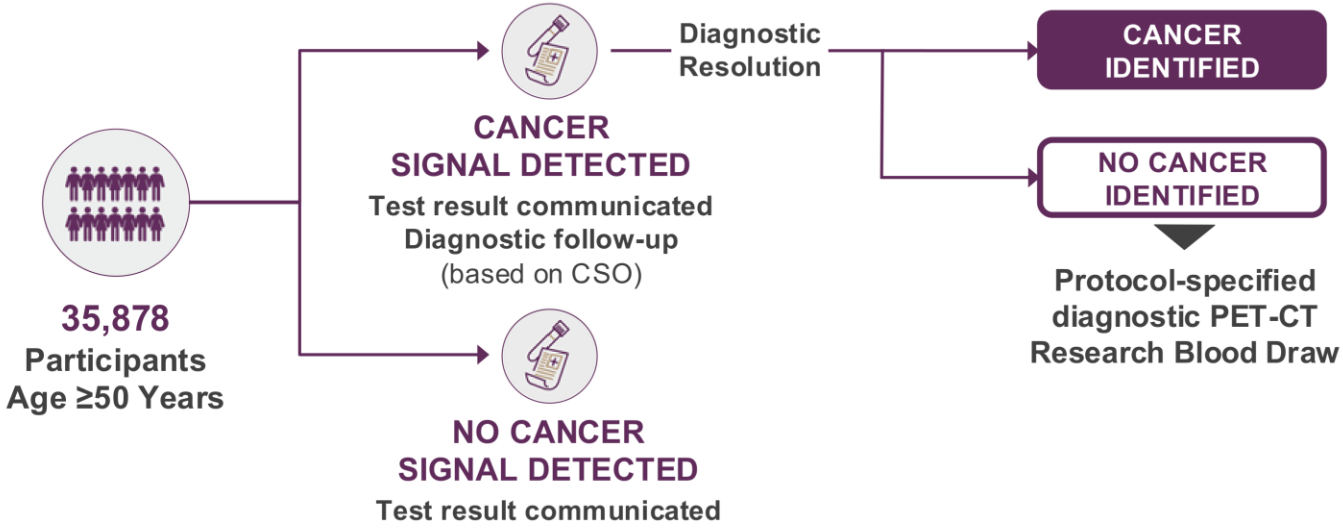
Prospective Multicenter Study >35,000 Participants from 32 North American Healthcare Systems

PATHFINDER 2

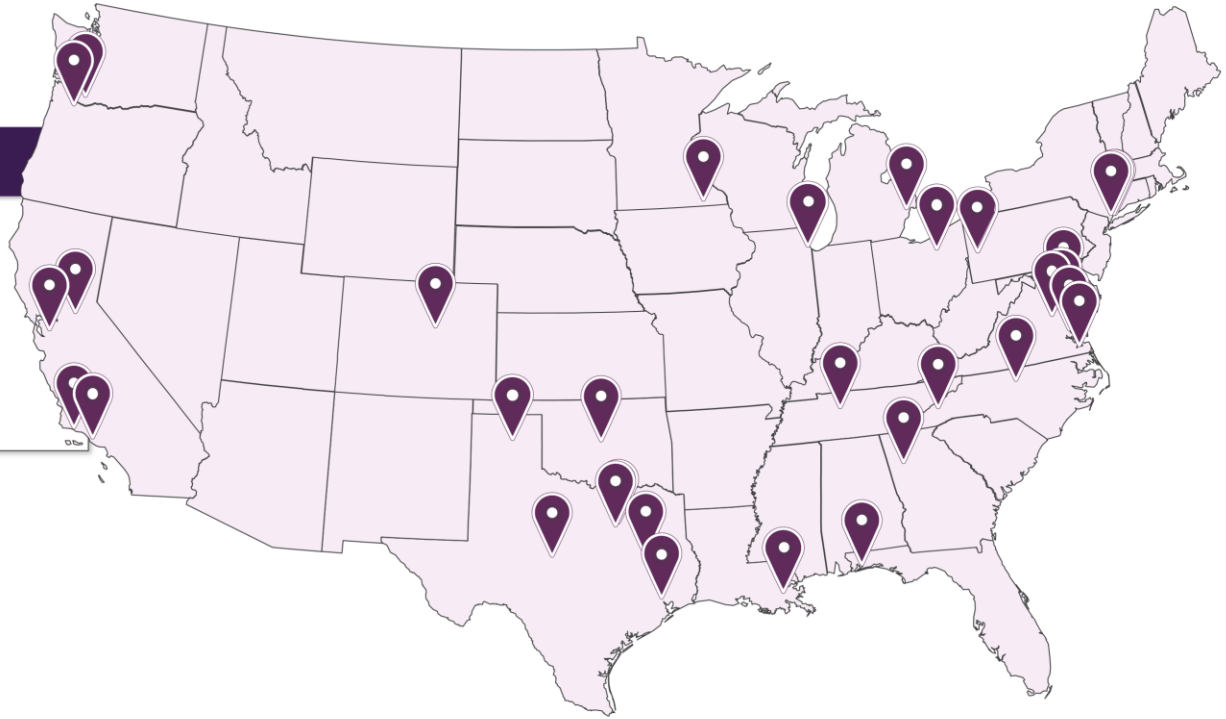




96% of Participants Enrolled Across United States*, Providing Broad Geographic and Demographic Representation

PATHFINDER 2

Sites represented broad geographic location, demographics, and academic vs non-academic settings



*4% enrolled from one site in Canada (Toronto).

Giridhar et al. Poster Presented at American Association for Cancer Research (AACR) Annual Meeting April 5-10, 2024.

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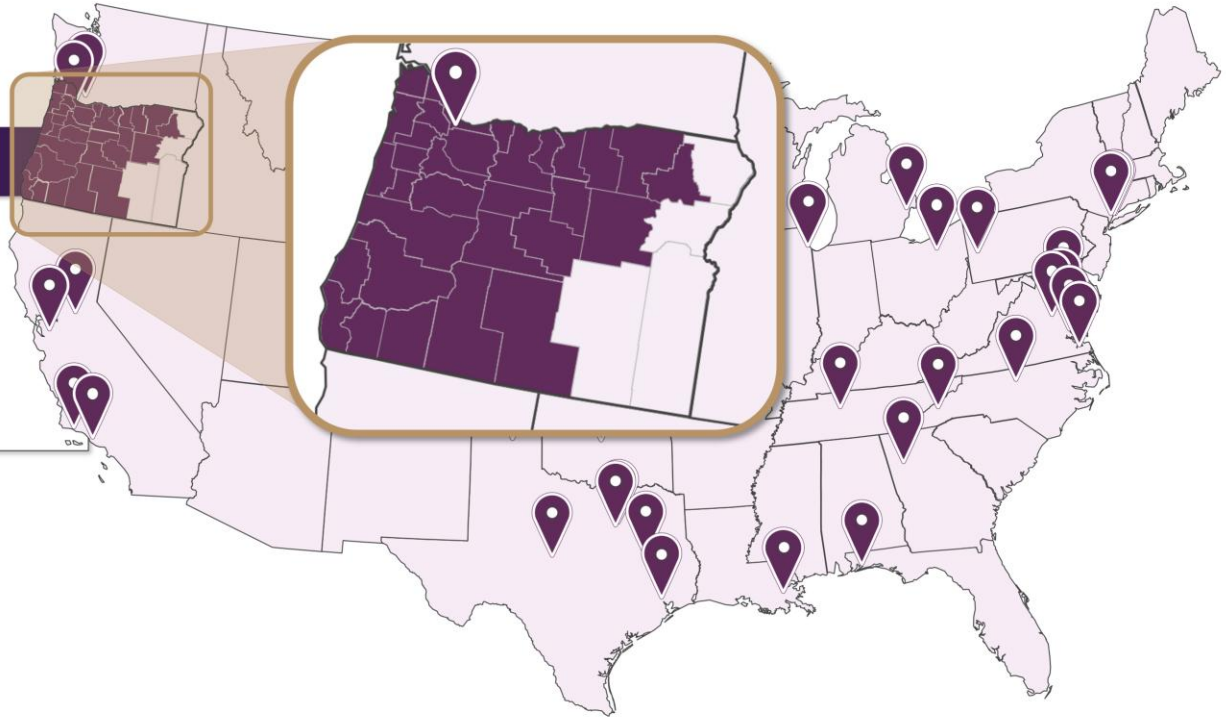

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PATHFINDER 2 Enrolled a Large, Diverse Intended-Use Population

PATHFINDER 2

		PATHFINDER 2 N = 25,125	
Age, Mean Years (SD)		**64.7** (8.2)	
50-59 Years		**27%**	6,796
60-69 Years		**44%**	11,143
≥70 Years		**29%**	7,186
Male		**43%**	10,856
Race	**White**	**81%**	20,402
	Black or African American	**8%**	2,066
	Asian	**6%**	1,420
Hispanic or Latino, Yes		**7%**	1,735

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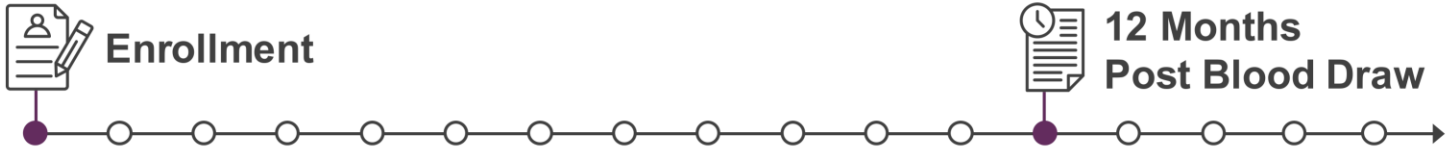
Baseline Clinical Characteristics

PATHFINDER 2

		PATHFINDER 2 N = 25,125	
BMI (kg/m^2)	<25	33%	8,208
	25 to <30	36%	9,053
	≥30	31%	7,798
Smoking Status	Current	4%	918
	Former	28%	6,927
	Never	69%	17,280
Prior Cancer History		10%	2,507
Genetic Cancer Predisposition		6%	1,502

~25,000 Participants with Completed 12-Month Follow-up

PATHFINDER 2



35,878
Participants Consented

25,578 participants ≥12 months of follow-up

10,300 participants <12 months of follow-up

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Galleri Exhibited High PPV and NPV Through 12 Months of Follow-up

PATHFINDER 2

		Cancer Diagnosed by 12 Months	
		Yes N = 303	**No** N* = 21,115
Galleri Test Result	**Positive** N = 138	**106**	**32**
	Negative N = 21,281	**197**	**21,084**

Performance Metric (95% CI)	
PPV	**77.0%** (65.8 – 85.4%)
NPV	**99.07%** (98.93 – 99.2%)

- **PPV** = Probability a person with **positive** result **has** cancer
- **NPV** = Probability a person with **negative** result **does not** have cancer

*Weighted
Galleri – Data through 12 months of follow-up

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99.85% Specificity Corresponds to a 0.15% False-Positive Rate Minimizing Unnecessary Diagnostic Workup

PATHFINDER 2

		Cancer Diagnosed by 12 Months	
		Yes N = 303	No N* = 21,115
Galleri Test Result	Positive N = 138	106	**32**
	Negative N = 21,281	197	**21,084**

Specificity	=	False-Positive Rate
99.85% (99.75 – 99.91%)		**0.15%** (0.09 – 0.25%)

*Weighted
Galleri – Data through 12 months of follow-up

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Galleri Demonstrated an Episode Sensitivity of 35% Across All Cancers Through 12 Months of Follow-up

PATHFINDER 2

		Cancer Diagnosed by 12 Months	
		Yes N = 303	**No** N* = 21,115
Galleri Test Result	**Positive** N = 138	**106**	32
	Negative N = 21,281	**197**	21,084

Episode Sensitivity

35.0%

(29.8 – 40.5%)

*Weighted

Galleri – Data through 12 months of follow-up

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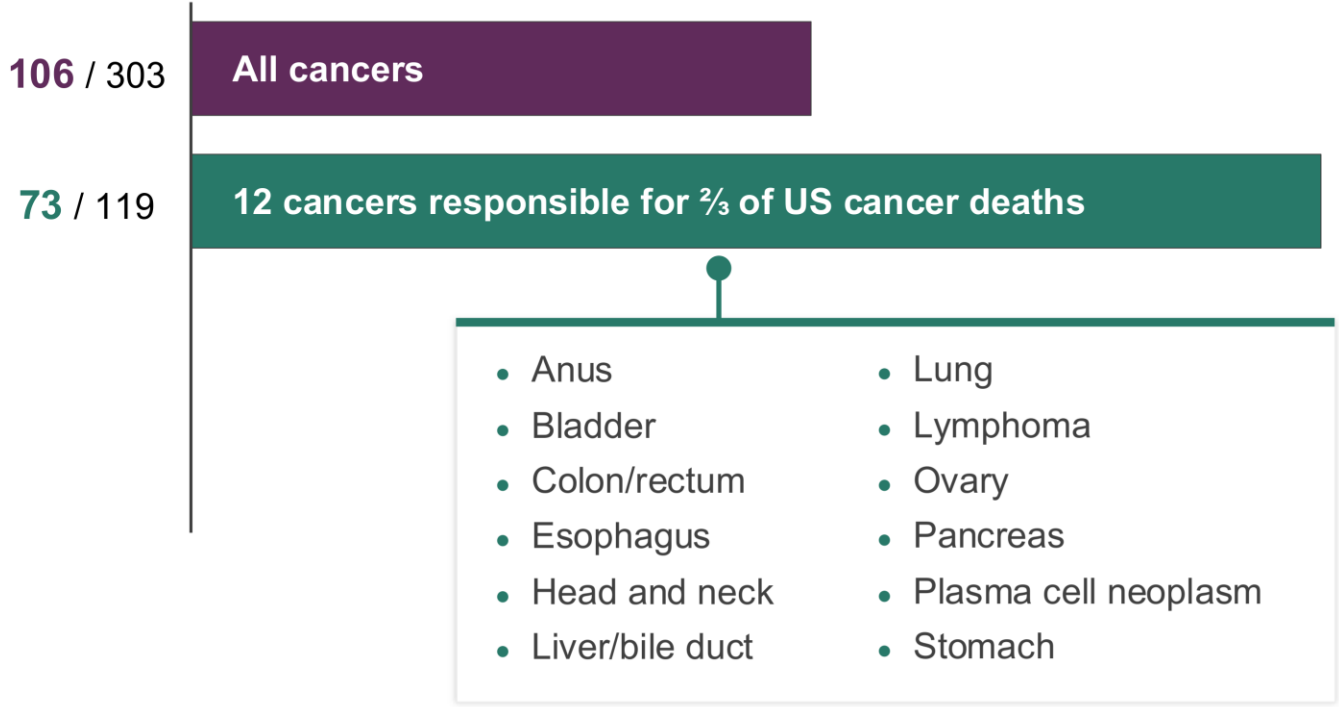
61.3% Episode Sensitivity for 12 Prespecified Cancers Responsible for Two Thirds of US Cancer Deaths

PATHFINDER 2



Galleri – Data through 12 months of follow-up

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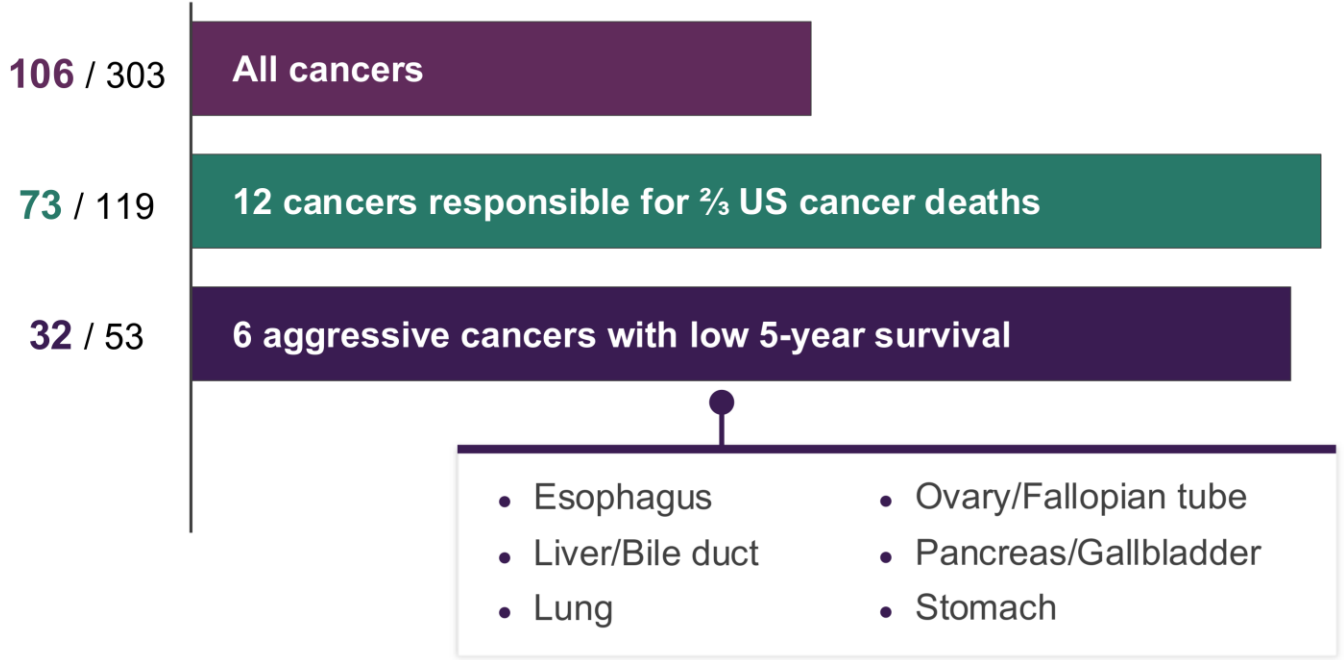
60.4% Episode Sensitivity for 6 Aggressive Cancers with Low 5-Year Survival

PATHFINDER 2



Galleri – Data through 12 months of follow-up

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84% of Participants with False-Negative Results had Cancers with Recommended Screening Options or That Were Stage I

PATHFINDER 2

Cancer Type	No Cancer Signal Detected with Cancer Diagnosis within 12 Months N = 197	
With SOC Screening Options*	59.9%	118
Without SOC Screening Option and Stage I	24.4%	48

84.3%

Galleri – Data through 12 months of follow-up
*USPSTF A/B/C-grade recommended screening: breast, cervical, colon/rectum, lung, prostate

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Galleri-Detected Cancers Predominantly at Stages With Opportunity for Curative Treatment

PATHFINDER 2

Cancer Stage, % (N)	Percent of Galleri-Detected New Cancers N = 90
Stage I	**30.0%** (27)
Stage II	**18.9%** (17)
Stage III	**20.0%** (18)
Stage IV	**26.7%** (24)
No Stage Expected	**4.4%** (4)

Stages I-II: 48.9%

Stages I-III: 68.9%

76% (47/62) Do Not Have Recommended Screening

- Head & Neck (n=13)
- Liver (n=13)
- Lung (n=6)*
- Colon/Rectum (n=5)*
- Lymphoid lineage (n=5)
- Breast (n=4)*
- Pancreas (n=3)
- Prostate (n=3)
- Anus (n=2)
- Kidney (n=2)
- Plasma cell lineage (n=2)
- Stomach, Esophagus (n=2)
- Bladder, Urothelial tract (n=1)
- Testis (n=1)

Galleri – Data through 12 months of follow-up

*USPSTF grade A/B-recommended screening is available for lung, colorectal, and breast cancers

GRAIL

82% of Participants with Positive Galleri Result and Stages I–III Cancer Treated with Curative Intent

PATHFINDER 2

Treatment Intent	Stage	True Positives	
	All Cancers (incl. unstaged or recurrent)	62%	66 / 106
Curative	Stages I-III	82%	51 / 62
	Stage IV	38%	9 / 24

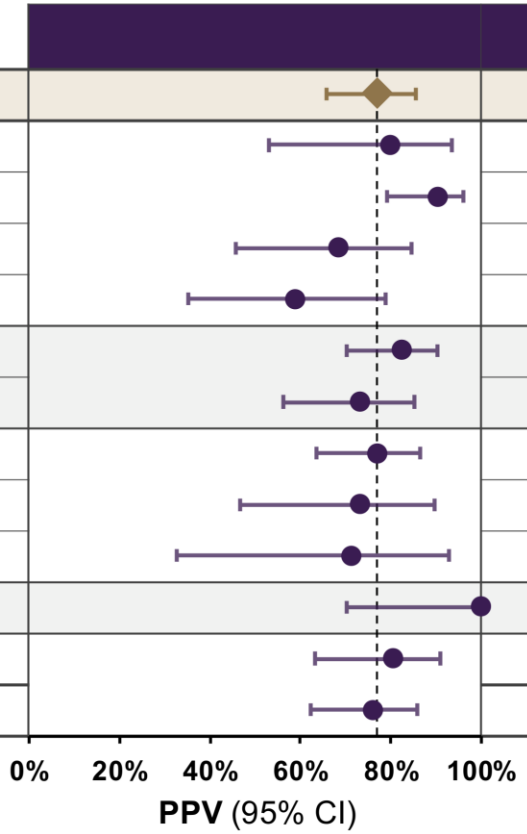
Galleri – Data through 12 months of follow-up

GRAIL

Consistent PPV Across Subgroups

PATHFINDER 2

	Subgroup, % (n/N)	PPV	
	Overall	77%	106 / 138
Age Group (Years)	50 – 59	80%	12 / 15
	60 – 69	91%	48 / 53
	70 – 79	68%	36 / 53
	80+	59%	10 / 17
Sex	Female	83%	47 / 57
	Male	73%	59 / 81
Race	White	77%	86 / 112
	Black or African American	73%	11 / 15
	Asian	71%	5 / 7
Ethnicity	Hispanic or Latino	100%	9 / 9
Cancer History	Yes	81%	25 / 31
	No	76%	81/107



Galleri – Data through 12 months of follow-up

GRAIL

Distribution of Cancers Diagnosed During Follow-Up

303 Participants with Cancer Diagnosis

PATHFINDER 2

	Galleri Test Result		
	Positive	Negative	Total
Participants with Cancer Diagnosed	**106**	**197**	**303**
New Primary Cancer	**85%** (90)	**90%** (178)	**88%** (268)
Recurrent Cancer	**15%** (16)	**10%** (19)	**12%** (35)

Galleri – Data through 12 months of follow-up

GRAIL

High CSO Prediction Accuracy Guides Diagnostic Evaluation

PATHFINDER 2

	CSO Accuracy (95% CI)	n / N
CSO Prediction Accuracy	**94.3%** (88.2 – 97.4%)	**100** / 106

Galleri – Data through 12 months of follow-up

GRAIL

Accurate CSO Prediction Guides Efficient and Timely Diagnostic Resolution

PATHFINDER 2

	Time to Diagnostic Resolution (Days)	
	Median	IQR
All Galleri-Positive Participants	46	29 - 93
True Positives	36	24 – 61
False Positives	75	42 – 136

- Claims-based study of 458,818 insured US patients with cancer[1]
  - Median time to diagnostic resolution = **118 days**

1. Gitlin et al., 2023

MCED-V2 – Data through 12 months of follow-up

GRAIL

PATHFINDER 2 Safety

Most Participants With a Positive Galleri Test Result Underwent Diagnostic Evaluation

PATHFINDER 2

	Galleri Cancer Signal Detected			
	Cancer Diagnosis N = 133		No Cancer Diagnosis N = 96	
Primary Safety Analysis ≥ 1 diagnostic evaluation performed after positive Galleri test result communicated	**96.2%**	**128** / 133	**93.8%**	**90** / 96
Diagnostic evaluation before test result	**3.8%**	**5** / 133	**4.2%**	**4** / 96
No diagnostic evaluation performed	–	**0** / 133	**2.1%**	**2** / 96

MCED-V2 – Data through 12 months of follow-up

GRAIL

Invasive Procedures Occurred Primarily in Participants With Cancer

PATHFINDER 2

Participants with Events, % n	Galleri Cancer Signal Detected: Cancer Diagnosis N = 128		No Cancer Diagnosis N = 90	
Invasive procedure	**90.6%**	116	**47.8%**	43
Surgical	**15.6%**	20	**4.4%**	4
Non-surgical	**80.5%**	103	**46.7%**	42
Endoscopy	**36.7%**	47	**36.7%**	33
Biopsy	**53.1%**	68	**11.1%**	10
Non-invasive procedure	**9.4%**	12	**52.2%**	47

- **Benign conditions that warranted surgical intervention were found in all 4 participants who underwent surgery and were not diagnosed with cancer**

MCED-V2 – Data through 12 months of follow-up

GRAIL

Low Overall Rate of Invasive Procedures Following Screening

PATHFINDER 2

	12-Month Analyzable Set N = 25,114
Primary Endpoint: Proportion of participants with invasive procedure(s) to evaluate positive Galleri test result	0.6%
Secondary Endpoint: Number of invasive procedures per analyzable participant	0.01

Invasive procedure = Biopsy, endoscopy, surgery, or other (Pap smear)

MCED-V2 – Data through 12 months of follow-up

GRAIL

Few Adverse Events Occurred During Diagnostic Evaluation

PATHFINDER 2

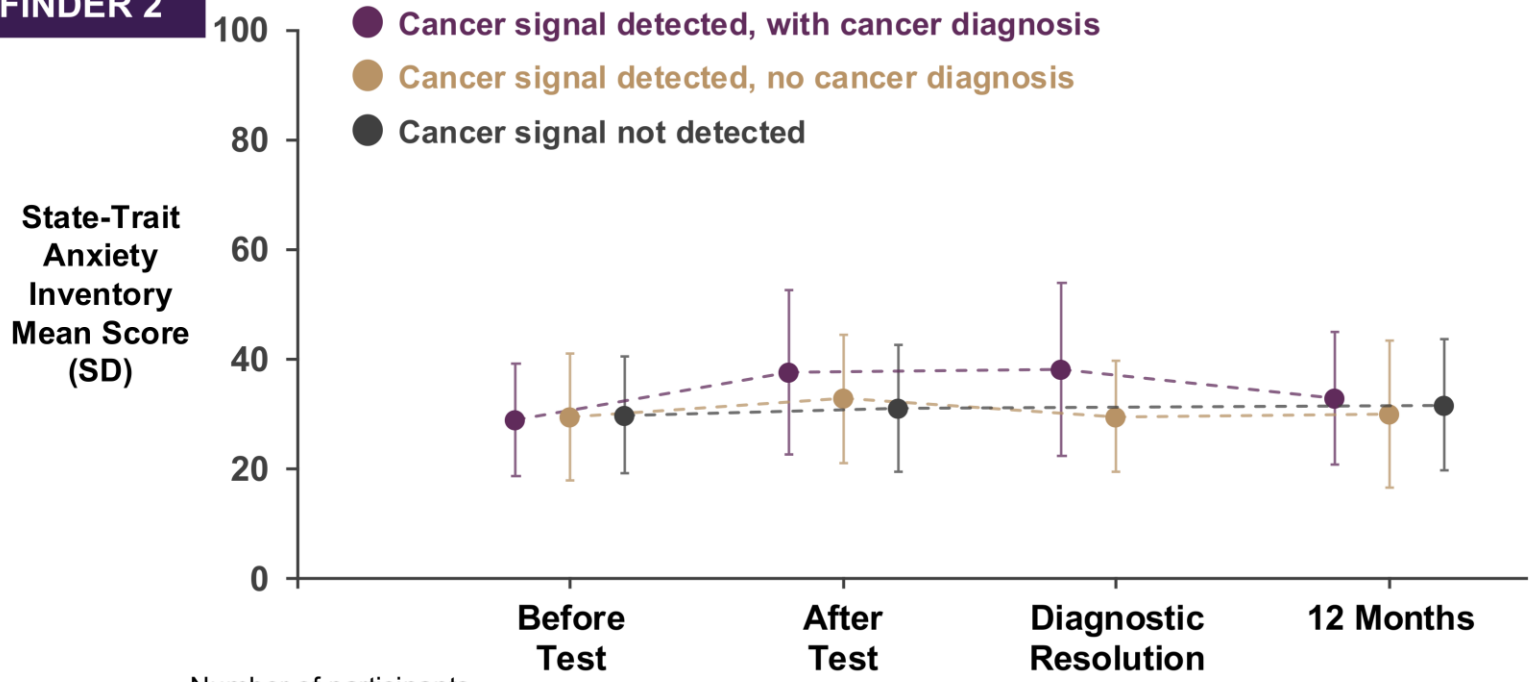
# Participants With	Cancer Diagnosis N = 127		No Cancer Diagnosis N = 78		Resolution Not Reached N = 13	
Any Adverse Event	**6.3%**	8	**1.3%**	1	–	0
Mild	**4.7%**	6	**1.3%**	1	–	0
Moderate	**0.8%**	1	–	0	–	0
Severe	**0.8%**	1	–	0	–	0
Serious Adverse Event	**0.8%**	1	–	0	–	0

MCED-V2 – Data through 12 months of follow-up

GRAIL

Modest and Transient Effects on Participant-Reported State Anxiety

PATHFINDER 2



Number of participants	Before Test	After Test	Diagnostic Resolution	12 Months
Cancer signal detected, with cancer diagnosis	127	82	57	77
Cancer signal detected, no cancer diagnosis	96	57	40	52
Cancer signal not detected	23,874	17,751	N/A	14,967

GRAIL

Galleri Did Not Reduce Utilization of USPSTF A/B-Recommended Cancer Screening

PATHFINDER 2

Cancer Type	Participants Up-to-Date with Screening, Adherence (%)			
	Baseline		12 Months	
BREAST	80%	10,147 / 12,659	81%	10,211 / 12,659
CERVICAL	49%	3,995 / 8,129	49%	3,990 / 8,129
COLORECTAL	81%	18,271 / 22,668	81%	18,446 / 22,668
LUNG	15%	165 / 1,094	20%	216 / 1,094

Galleri does not rule out presence of cancer; adherence to guideline-recommended screening remains essential

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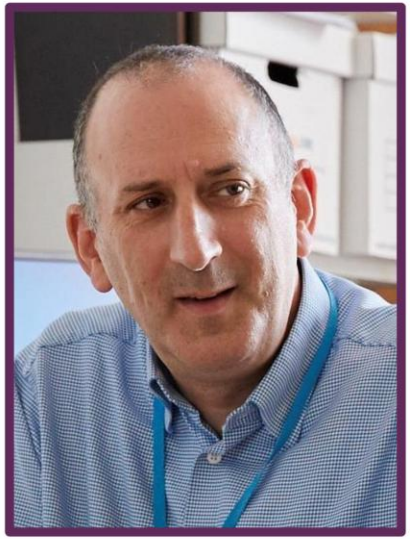

NHS-Galleri Results

Professor Peter Sasieni, CBE, PhD

Professor of Cancer Epidemiology,

Director of the Cancer Research UK Cancer Prevention Trials Unit

Queen Mary University of London

GRAIL

NHS-Galleri Population and Screening Practices Comparable to the United States

NHS-Galleri

NHS-Galleri results are generalizable to US population

- ✓ Population cancer mortality rates are almost identical
- ✓ Similar cancer risk demographics
- ✓ Comparable stage distributions for common cancers
- ✓ Diagnostic pathways broadly aligned with US practice
- ✓ Screening programs available in UK for cancers with USPSTF A/B recommendations*

* No organized screening program for prostate cancer in UK

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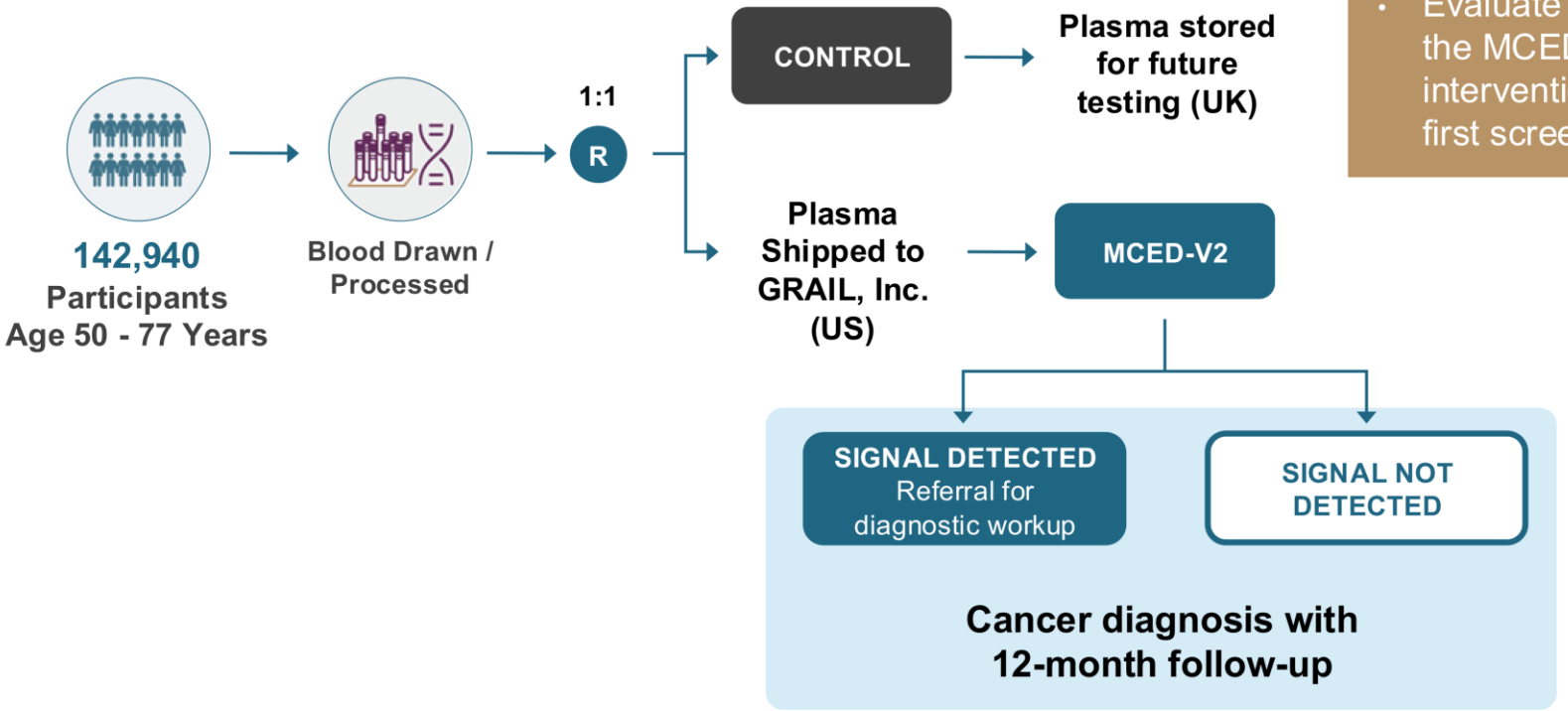
NHS-Galleri: Prospective Randomized Trial Including More Than 140,000 Participants



PMA Primary Objective:

- Evaluate performance of the MCED test in the intervention arm in the first screening round.

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NHS-Galleri PMA Objectives: Prespecified Subset of Protocol Objectives Using First Round of Data

Protocol

Protocol Primary Objective:

- Stages III/IV cancer incidence reduction after 3 screening rounds

Protocol Selected Secondary Objectives:

- Evaluate performance of the MCED test in the intervention arm in each screening round and aggregated
- Stage IV cancer incidence reduction after 3 screening rounds

PMA

PMA Primary Objective:

- Evaluate performance of the MCED test in the intervention arm in the first screening round

PMA Selected Secondary Objective:

- Stage IV reduction in the first screening round

Demographics Well-Balanced Between Study Arms

NHS-Galleri

		Intervention Arm N = 71,122		Control Arm N = 71,128	
Age, Mean Years (SD)		**65.0** (7.6)		**65.0** (7.5)	
50-64 Years		**45%**	32,214	**45%**	32,186
≥ 65 Years		**55%**	38,907	**55%**	38,942
Male		**50%**	35,399	**50%**	35,389
Race	**White**	**94%**	66,552	**94%**	66,566
	Black, African, Caribbean or Black British	**1.4%**	1,016	**1.5%**	1,038
	Asian or Asian British (Mostly South Asian)	**3.3%**	2,360	**3.3%**	2,365
Deprivation Index	**Quintile 1 (Most Deprived)**	**23%**	16,071	**23%**	16,062
	Quintile 2	**20%**	13,942	**20%**	13,980
	Quintile 3	**21%**	15,034	**21%**	14,956
	Quintile 4	**20%**	14,372	**20%**	14,476
	Quintile 5 (Least Deprived)	**16%**	11,469	**16%**	11,414

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NHS-Galleri: Performance Results Consistent with PATHFINDER 2

NHS-Galleri

		Cancer Diagnosed by 12 Months	
		Yes N = 820	**No** N* = 49,919
NHS-Galleri Test Result	**Positive** N = 391	**259**	**132**
	Negative N = 50,347	**561**	**49,786**

PPV **66.2%** (56.7 – 74.6%)

NPV **98.89%** (98.78 – 98.98%)

*Weighted
Galleri – Data through 12 months of follow-up

GRAIL

NHS-Galleri: Episode Sensitivity and Specificity Consistent with PATHFINDER 2

NHS-Galleri

		Cancer Diagnosed by 12 Months	
		Yes N = 820	**No** N* = 49,919
NHS-Galleri Test Result	**Positive** N = 391	**259**	**132**
	Negative N = 50,347	**561**	**49,786**

Episode Sensitivity	Specificity	=	False-Positive Rate
31.6% (28.5 – 34.8%)	**99.74%** (99.61 – 99.82%)		**0.26%‡** (0.18 – 0.39%)

* Weighted

‡NHS-Galleri does not capture recurrences as true positives, contributing to an apparent increase in the false-positive rate compared with PATHFINDER 2

Galleri – Data through 12 months of follow-up

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Galleri Performance Strongest in Cancers with Greatest Screening Need

NHS-Galleri

	Episode Sensitivity		
	%	95% CI	n / N
12 cancers responsible for $^{2}/_{3}$ of US cancer deaths*	**52.1%**	46.9 – 57.2%	**188** / 361
6 aggressive cancers with low 5-year survival**	**60.9%**	53.0 – 68.3%	**92** / 151

Galleri – Data through 12 months of follow-up

* Anus; Bladder or Urothelial Tract; Colon or Rectum; Esophagus; Head and Neck; Liver or intrahepatic Bile-Duct; Lung; Lymphoid Lineage; Ovary or Fallopian Tubes; Pancreas, Extrahepatic Bile-Duct or Gallbladder; Plasma Cell Lineage; Stomach

** Esophagus; Liver or Intrahepatic Bile-Duct; Lung; Ovary or Fallopian Tubes; Pancreas, Extrahepatic Bile-Duct or Gallbladder, Stomach

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Galleri Detected Cancers Predominantly at Stages With Opportunity for Curative Treatment

NHS-Galleri

Cancer Stage, % (N)	Percent of Galleri-Detected New Cancers N = 259
Stage I	16.6% (43)
Stage II	20.8% (54)
Stage III	31.3% (81)
Stage IV	25.5% (66)
No Stage Expected*	1.5% (4)
Missing	4.2% (11)

Stages I-II: 37.5%

Stages I-III: 68.7%

Galleri – Data through 12 months of follow-up

* No stage expected for brain and spinal cord, leukemia, myeloma and plasma cell disorders, polycythemia vera, cancer of unknown primary

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High Accuracy of Cancer Signal Origin (CSO) Prediction

NHS-Galleri

	CSO Accuracy (95% CI)	n / N
CSO Prediction Accuracy	**91.9%** (87.9 – 94.6%)	**238** / 259
CSO or CSO-S Prediction Accuracy	**93.1%** (89.3 – 95.6%)	**241** / 259

CSO-S: CSO-Supplemental
Galleri – Data through 12 months of follow-up

GRAIL

78% of Participants with False-Negative Results had Cancers with Recommended Screening Options or That Were Stage I

NHS-Galleri

Cancer Type	No Cancer Signal Detected with Cancer Diagnosis within 12 Months N = 561	
With SOC Screening Options*	61.7%	346
Without SOC Screening Option and Stage I	16.8%	94

78.4%

Galleri – Data through 12 months of follow-up
*USPSTF A/B/C-grade recommended screening: breast, cervical, colon/rectum, lung, prostate

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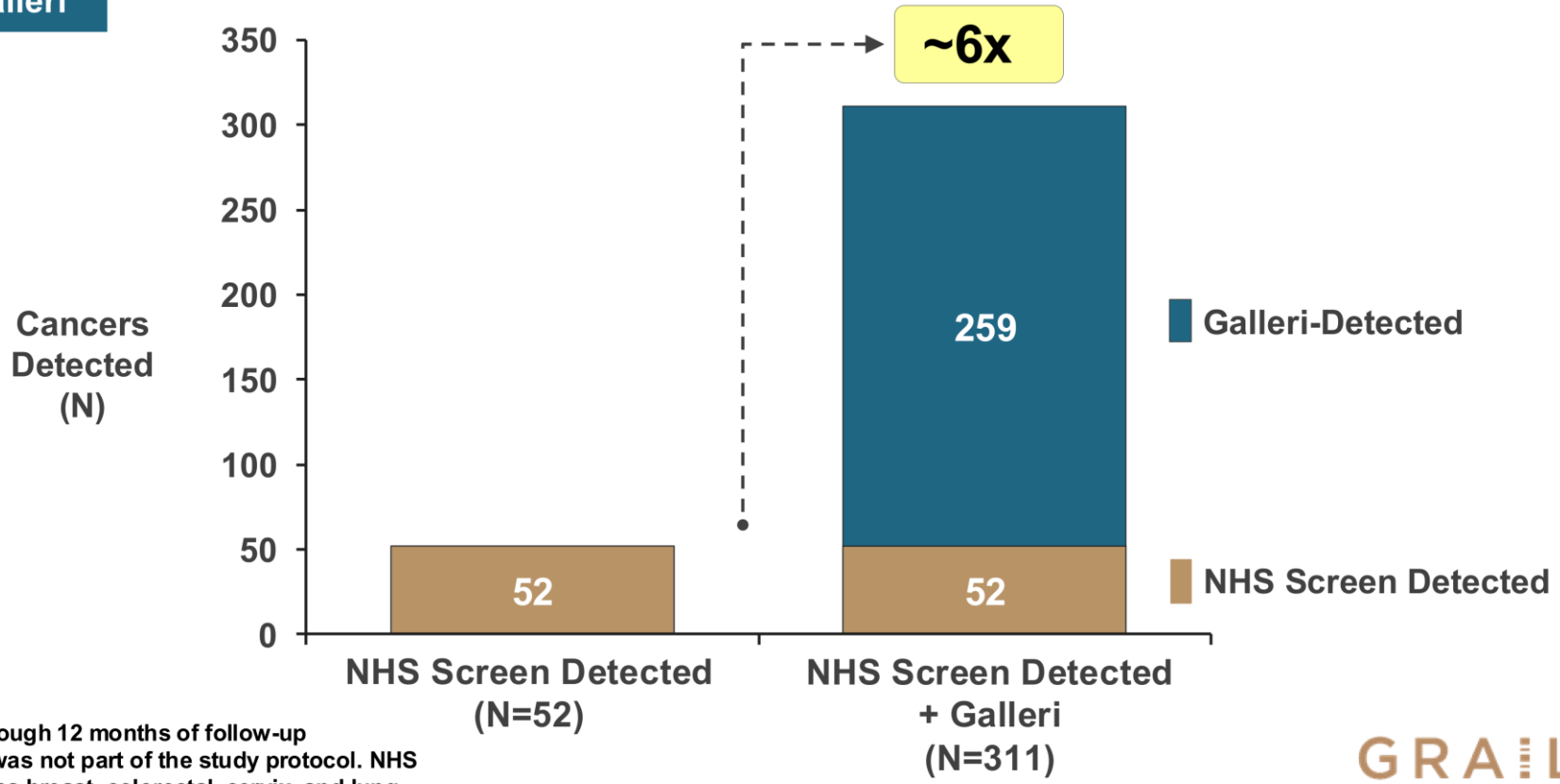
Galleri Increases Total Number of Cancers Detected When Used in Addition to NHS Screening*

NHS-Galleri



Galleri – Data through 12 months of follow-up
*NHS screening was not part of the study protocol. NHS screening includes breast, colorectal, cervix, and lung

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Adverse Events in NHS-Galleri Were Primarily Related to Phlebotomy

NHS-Galleri

	Intervention Arm N = 71,122	Control Arm N = 71,128
Adverse Event Relatedness		
Procedure-related	251	263
Phlebotomy	211	251
Other	40	12
Device-related*	20	0
Procedure- & Device-related	2	0
Related Adverse Event Severity		
Mild	224	228
Moderate	46	33
Severe	3	2

* Device-related AEs represent AEs recorded after referral to the NHS following a positive result, and most were anxiety

MCED-V2 – Data through 12 months of follow-up

GRAIL



A Primary Care Perspective on the Need for Multi-Cancer Early Detection

Mylynda B. Massart, MD, PhD

Associate Professor, Medical Director
UPMC Primary Care Precision Medicine Center
Department of Family Medicine
University of Pittsburgh

Patients Have Been Waiting for Broader Cancer Screening Options

"Why don't we have a blood test that can screen for all cancers?"

Throughout my career, I have heard this question from:



Patients with Strong Family Histories of Cancer

Concerned about inherited cancer risk and the possibility of developing cancer in the future



Highly Engaged Patients

Proactively seeking information and asking about the latest advances in cancer prevention



Patients in Rural and Underserved Communities

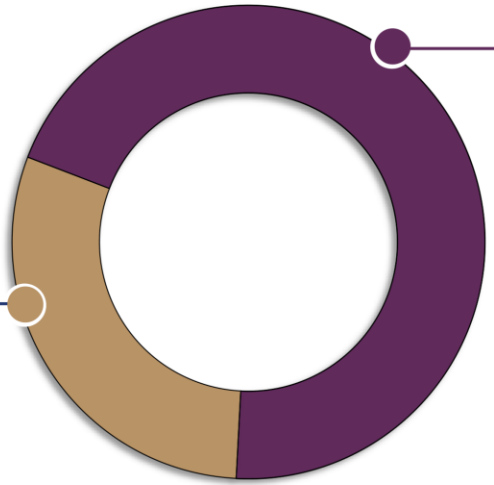
Facing barriers to specialty care and comprehensive screening options

Patients understand that current screening addresses only a limited number of cancers and continue to seek broader screening options

Current Screening Saves Lives, but Most Cancer Deaths Occur Outside of Existing Screening Programs

USPSTF Grade A or B Recommended Screening





~70% of cancer deaths from types without recommended screening[1]

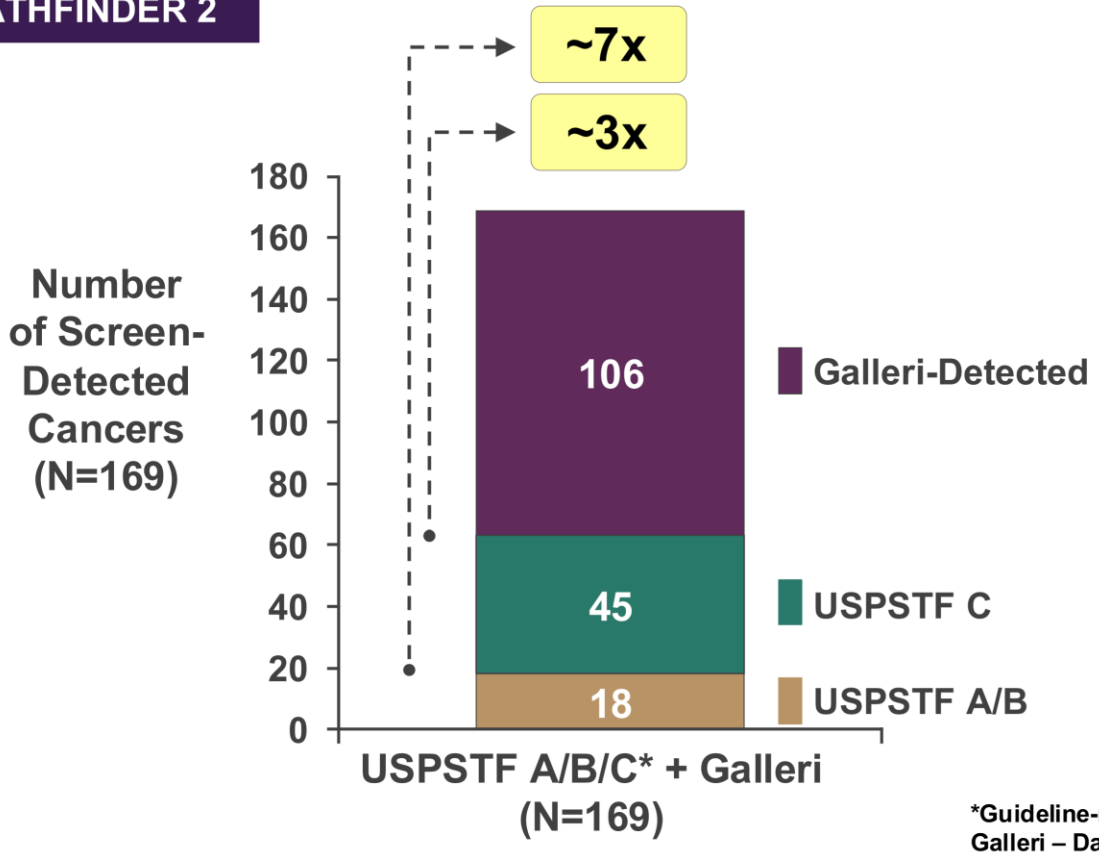
These programs have had a meaningful impact and should remain the foundation of cancer prevention

Patients frequently ask about cancers such as pancreatic, ovarian, liver, and other cancers without recommended screening

1. Ofman et al., 2025; includes cancer types other than breast, colorectal, cervix, and smoking-eligible lung

Galleri Detected Additional Clinically Meaningful Cancers

PATHFINDER 2



Of the 106 additional cancers detected with Galleri

75%

were cancers without recommended screening options

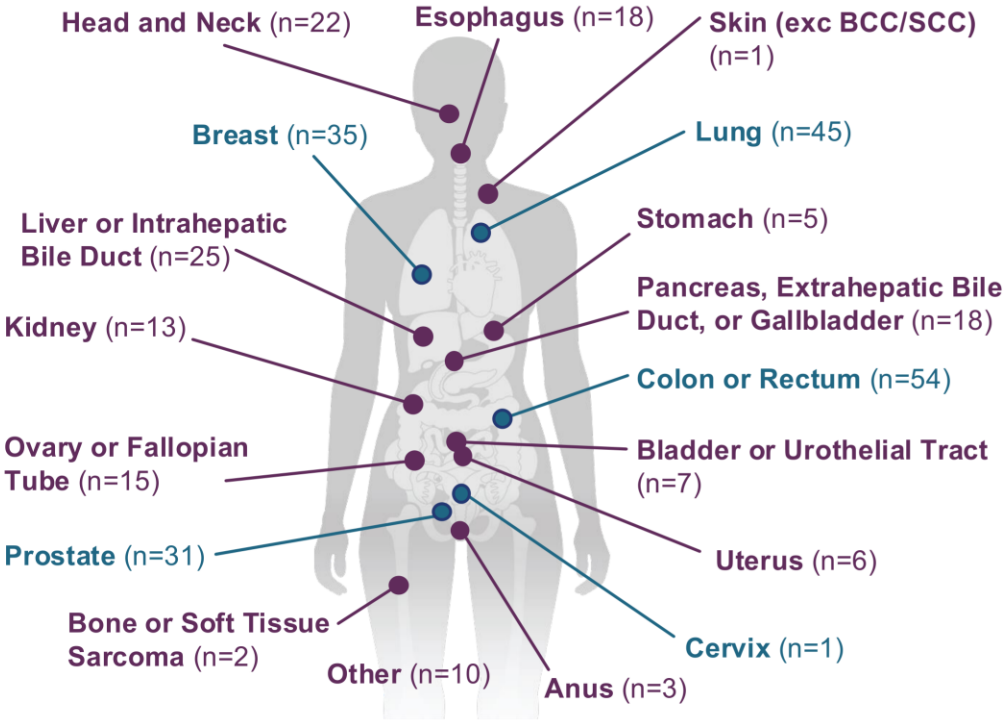
*Guideline-recommended screening was not part of the study protocol
Galleri – Data through 12 months of follow-up

Broader Detection with Galleri Delivers A More Efficient Screening System

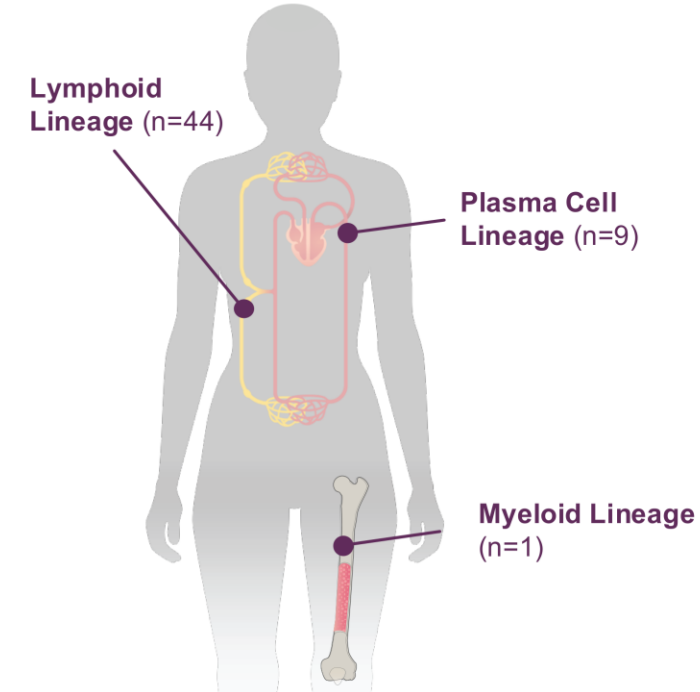
PATHFINDER 2 & NHS-Galleri

● Cancers with recommended screening ● Cancers without recommended screening

Solid Tumors



Hematologic Malignancies



Most Galleri-Detected Cancers Were Treated With Curative Intent

PATHFINDER 2

Participants with a true-positive Galleri result

- **82%** (51/62) with **stages I-III** cancer treated with curative intent

Why this matters

- Goal is to identify cancers when treatment has potential to meaningfully change outcomes
- Detection before widespread metastatic disease creates opportunities for curative treatment

These data demonstrate that many of the additional cancers detected by Galleri were identified early with opportunity for curative treatment

>91% Accurate Cancer Signal Origin Prediction Guides Targeted Diagnostic Evaluation

Cancer Signal Detected

A Cancer Signal Detected result is NOT a cancer diagnosis.

It is necessary to conduct a diagnostic workup to determine if cancer is present. A healthcare provider will determine the next steps to take.

- The Galleri test found a cell-free DNA methylation pattern associated with cancer.
- 77 out of 100 people with a Cancer Signal Detected result received a cancer diagnosis in PATHFINDER 2 (Positive Predictive Value was 77.0%).[3]

Cancer Signal Origin (CSO) prediction

Ovary

What is included: Ovary, Fallopian Tube, Primary Peritoneum.

Next steps for healthcare providers:

- Perform a diagnostic workup guided by the predicted Cancer Signal Origin (CSO). The Galleri test predicts the CSO with 94.3% accuracy.[3]
- If the diagnostic workup is negative or inconclusive, cancer may be absent or located elsewhere. Complimentary retesting may be useful in diagnostic resolution. See Galleri.com/retest for more information.
- Visit Galleri.com/positive-support for further assistance.

Cancer Signal Origin - Supplemental

Female Reproductive Tract Signal

If the diagnostic evaluation based on the predicted Cancer Signal Origin does not lead to a cancer diagnosis, consider expanding the diagnostic evaluation to other organs possibly affected (Ovary, Uterus, Cervix).

Diagnostic Pathway Following Positive Galleri Result is Targeted and Clinically Manageable

PATHFINDER 2

	PATHFINDER 2	
False-Positive Rate [95% CI]	**0.15%**	0.09 – 0.25
Cancer Signal Origin Prediction Accuracy [95% CI]	**94.3%**	88.2 – 97.4
Time to Diagnostic Resolution – Any Positive Result | Days [IQR]	**46 Days**	29 – 93
Time to Diagnostic Resolution – False Positive | Days [IQR]	**75 Days**	42 – 136
Invasive Procedure to Evaluate – Any Positive Result | Participants [n/N]	**0.6%**	159 / 25,114
Positive Result, Invasive Procedure, Cancer Diagnosis | Participants [n/N]	**90.6%**	116 / 128

A Negative Result Reinforces Routine Screening and Symptomatic Follow-up

No Cancer Signal Detected

The Galleri test did not find a cell-free DNA methylation pattern associated with cancer.

The Galleri test does not detect a signal for all cancers.

Fewer than 1 out of 100 people with a No Cancer Signal Detected result received a cancer diagnosis in PATHFINDER 2 (Negative Predictive Value was 99.1%).[3]

Next steps:

Continue cancer screenings

Continue with cancer screening tests as recommended by a healthcare provider. Other cancer screening may be recommended based on age and risk factors, such as screening tests for Breast, Cervical, Colorectal, Lung or Prostate cancer.

Any new or concerning symptoms should be evaluated by a healthcare provider.

This result should not alter any ongoing surveillance plans for a previously diagnosed cancer.

Incorporate the Galleri test into a proactive health routine

When completed annually, the Galleri test can improve the chances of finding cancer earlier, when it is more treatable. This result does not predict whether cancer will develop in the future.

Every Additional Opportunity Matters

Galleri

- Detects additional clinically meaningful cancers
- Very low false-positive rate
- Highly accurate cancer signal origin prediction
- Targeted, clinically manageable follow-up
- Most cancers treated with curative intent

Patients want opportunity.

They want options.

They want the chance to fight their disease while the chance to survive is possible.

Findings support a favorable benefit-risk profile and the potential for meaningful patient benefit when added to guideline-recommended screening programs



Conclusion

Sir Harpal Kumar, FRCR, FMedSci

Chief Scientific Officer

President, Global Clinical and Medical Affairs

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PATHFINDER 2 and NHS-Galleri Support that Galleri is a Safe and Effective Screening Option

	PATHFINDER 2 N = 21,418*	NHS-Galleri N = 50,739*
Positive Predictive Value (PPV)	**77.0%** (65.8 – 85.4%)	**66.2%** (56.7 – 74.6%)
False-Positive Rate	**0.15%** (0.09 – 0.25%)	**0.26%‡** (0.18 – 0.39%)
Episode Sensitivity (12 Months) 12 cancers responsible for $^{2}/_{3}$ of US cancer deaths	**61.3%** (52.4 – 69.6%)	**52.1%††** (46.9 – 57.2%)
Episode Sensitivity (12 Months)†	**35.0%** (29.8 – 40.5%)	**31.6%††** (28.5 – 34.8%)
Cancer Signal Origin Prediction Accuracy	**94.3%** (88.2 – 97.4%)	**91.9%** (87.9 – 94.6%)
Screen-Detected Cancers in addition to guideline-recommended programs**	**3x – 7x**	**6x**

*Weighted
**Guideline recommended screening was not part of the study protocol
† MCED-detected cancers/all cancers diagnosed over a 12-month period
†† NHS-Galleri episode sensitivity metrics are for the prevalent round of screening
‡ NHS-Galleri does not capture recurrences which contributes to apparent increase in false-positive rate compared with PATHFINDER 2
Galleri – Data through 12 months of follow-up

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The Evidence Base is Substantial and Post-Approval Learning Continues

Study	Number of Subjects	Upcoming Evidence	Additional Evidence Generation with Galleri
PATHFINDER 2 Prospective interventional Single test	~35,000	2-year 3-year	✓ Less Common Cancers ✓ Adherence to Recommended Screening ✓ Continued Safety Follow-up
NHS-Galleri Randomized controlled 3 annual tests	~140,000	4-year	
REACH Prospective interventional 3 annual tests	Up to ~50,000	1-year 2-year 3-year	
Real-World Evidence Observational, commercial data	~200,000 Galleri tests	TBD	

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Robust Education and Clinical Support Plan Designed to Mitigate Key Risks of MCED Testing

No Cancer Signal Detected

Goal: Avoid false reassurance

- Galleri does not replace guideline-recommended screening
- Patients should remain attentive to symptoms
- Patients should continue ongoing surveillance for previously diagnosed cancers

Patient + Provider Materials | **IFU Language**

Cancer Signal Detected

Goal: Guide appropriate, efficient evaluation

- CSO-specific guidance based on NCCN + ACS recommendations
- Peer-to-peer consults, DocMatter platform
- Early Cancer Detection Board
- Field medical support

One-page CSO guides | **Workflow white paper**

Galleri is Safe and Effective and has a Positive Benefit-Risk Profile

- **Galleri increases detection of clinically meaningful cancers**
  - **3x – 7x** increase in screen-detected cancers
  - **69%** of detected cancers stages I-III
  - **82%** of stages I-III cancers detected treated with curative intent
  - **75%** of detected cancers without recommended screening options
- **Strong test performance**
  - **0.15%** false-positive rate and **61%** episode sensitivity for aggressive cancers
- **Accurately predicts Cancer Signal Origin (CSO)**
  - **>91%** accurate CSO prediction
  - Guides targeted diagnostic evaluations and minimizes unnecessary diagnostic procedures
- **Favorable safety profile**
  - Study-related adverse events were uncommon and non-serious
  - Psychological and mental health impacts were modest and transient
  - No impact on actual adherence to guideline-recommended screening* at 12-month follow-up

*** Guideline recommended screening was not part of the study protocol**

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Galleri® Blood-Based Screening Test for Early Detection of Multiple Types of Cancer

September 23, 2026

Molecular and Clinical Genetics Panel

GRAIL, Inc.

GRAIL

SLIDES SHOWN DURING Q&A SESSIONS

GRAIL has Developed a Suite of Post-Positive Resources to Support Clinicians After a Cancer Signal is Detected

Expert Consensus on Multi-Cancer Early Detection Implementation in Medical Practice:

Guidance for Integration and Post-Positive Workflows

Authors: Charles Atwood, MD[1]; Judy Koutlas, RN, MS, OCN[2]; Marc Matrana, MD[3]; Peter Mazzone, MD, MPH[4]; Nima Nabavizadeh, MD[5]; Elizabeth O'Donnell, MD[6]; Edwin Ostrin, MD, PhD[7]; Anil Saldanha, MS[8]; Margaret Tempero, MD[9]; Candace Westgate, DO[10]

1. VA Pittsburgh Healthcare System; 2. Sarah Cannon Cancer Network; 3. Ochsner Health; 4. Cleveland Clinic; 5. Oregon Health & Science University; 6. Dana-Farber Cancer Institute; 7. MD Anderson Cancer Center; 8. Rush University Medical Center; 9. UCSF Health; 10. Community Health Network

Mayo Clinic Recommended Diagnostic Pathways by CSO

Table 1. Diagnostic Algorithm for Positive MCD Signal based on Multidisciplinary Expert Opinion.

Cancer Signal Origin	Diagnostic testing
Anus	Anoscopy, Sigmoidoscopy
Bladder Urothelial Tract: Renal, Pelvis, Ureter, Urethra	CT urogram or retrograde pyelogram with contrast, cystoscopy
Bone and Soft Tissue: Skeletal Muscle and other connective tissue, vascular tissue, Bone and Cartilage	MRI with contrast; CT Chest, Abdomen and Pelvis; PET-CT
Breast	Mammography; Ultrasound/MRI/biopsy as indicated
Cervix	Cytology; Colposcopy
Colon, Rectum	Colonoscopy
Head and Neck: Oropharynx, hypopharynx, nasopharynx, larynx, lip, and oral cavity including tongue, nasal cavity, paranasal sinus, major salivary glands	Flexible nasal endoscopy; CT or MRI of head and neck
Kidney	Triple-phase renal CT
Liver, Bile duct	Triple phase abdominal CT; Alpha-fetoprotein (AFP)
Lung	Chest CT; bronchoscopy as indicated

Cancer Signal Origin	Diagnostic testing
Lymphoid lineage	PET-CT
Melanocytic lineage	Full body skin exam
Myeloid lineage	Blood work followed by Bone Marrow Biopsy
Neuroendocrine cells of lung or other organs	Chest CT with or without contrast, CT Abdomen Pelvis; CT Head and neck as indicated
Ovary: Fallopian tube, primary peritoneum	Transvaginal ultrasound, CA-125; CT Pelvis as indicated
Pancreas, Gallbladder	Pancreas CT Protocol or MR cholangiopancreatography
Plasma Cell Lineage	Blood work followed by Bone Marrow Biopsy
Prostate	PSA and multi-parametric MRI of the prostate
Stomach, Esophagus (Upper GI)	Upper GI endoscopy
Thyroid	Thyroid ultrasound
Uterus	Transvaginal ultrasound

No-charge retest is recommended within 6 months if a patient with a CSD result has a negative diagnostic workup

This process must be complete prior to submitting a second sample

Comprehensive diagnostic workup has occurred for a patient with a **Cancer Signal Detected** result and **does not yield** a **cancer diagnosis.**

GRAIL MSL or Medical Information sends **Retest Request Form** and **Test Requisition Form (TRF)** to HCP

HCP completes both forms and returns via email at medicalinformation@grailbio.com or via fax to 1-650-433-6057



GRAIL Medical Information **reviews** form and **sends approval** via email to HCP if case meets criteria within 2 business days.

*Denial will also be communicated via email

If the retest is approved, a new **test kit will automatically ship** to the patient and be marked as a retest.

Positive Result Resource Center • Retest Resources (Galleri Retest Request Form, Galleri Test Requisition Form)

Medical Support for Cancer Signal Detected Results

Field-based and in-house Medical Science Liaisons (MSLs) for white glove support

Positive Result Resource Center for Diagnostic Referral Toolkit, Post-Positive Payer Coverage assistance for continuity of care and more

DocMatter Clinician Community online forum for on-the-go, **peer to peer insights** related to MCED

Medical Support Services team available for result review, inquiries, patient assistance, diagnostic center resources

To include your center in the diagnostic resource document, scan the QR code and complete the form

Galleri **Retest Program** if workup does not yield a cancer diagnosis

Peer to peer consultations and Early Cancer Detection Board with independent, **nationally recognized, physician** specialists

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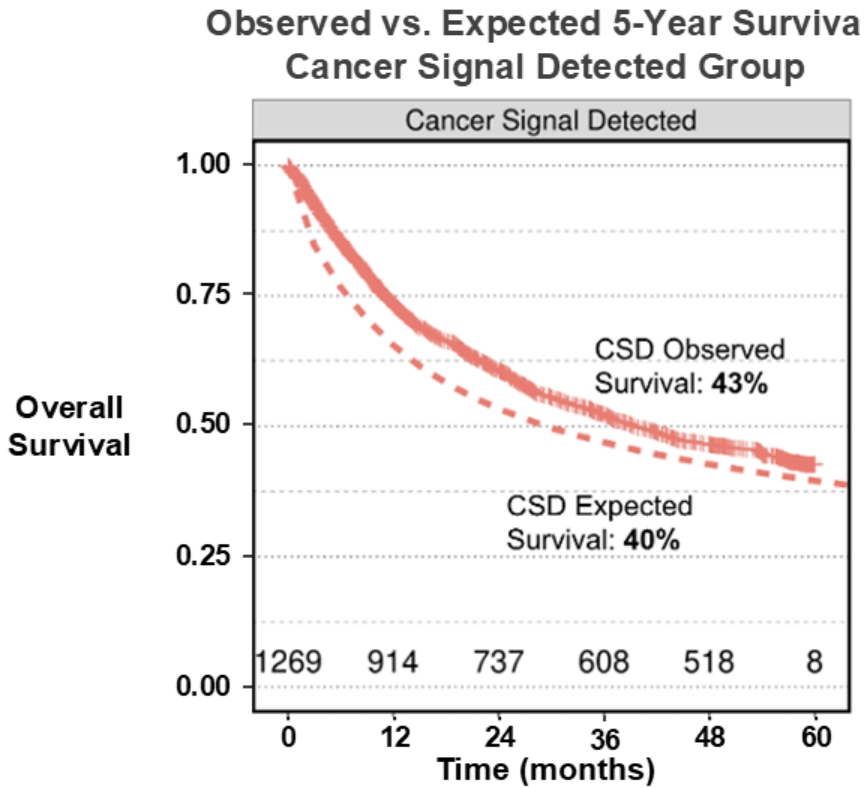
Cancer Patients With a Cancer Signal Detected Have Long-Term Survival Similar to US General Population (CCGA3)



- Cancer Signal Detected group had similar stage-specific survival to cancers detected by conventional means, as reported in SEER – they are not overdiagnosed but also not micrometastatic
- Hazard ratio for Cancer Signal Detected vs. SEER = 0.72 (95% CI: 0.67, 0.78) (healthy volunteers)

CSD, cancer signal detected; HR, hazard ratio; NCSD, no cancer signal detected; SEER, Surveillance, Epidemiology, and End Results.
a. Defined as the time from the date of blood sample collection to the date of death or last date the participant was confirmed alive. Dotted lines: blue vs red, respectively; Swanton C, et al. 2025.

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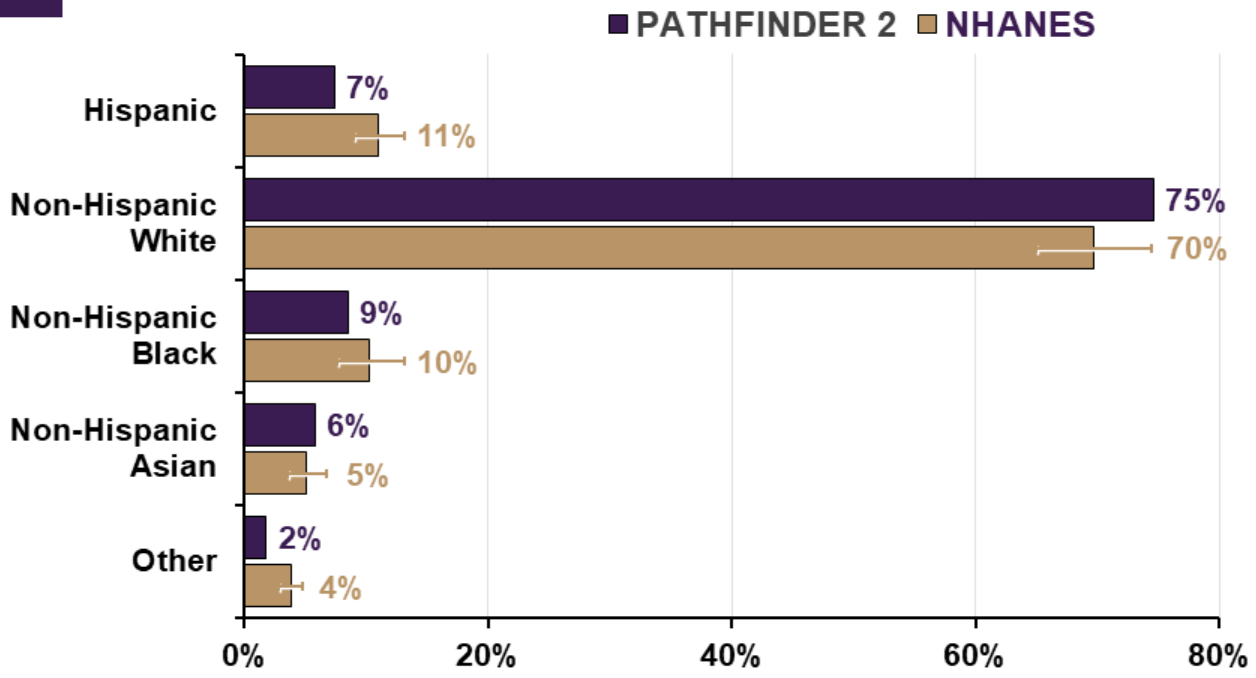
PATHFINDER 2 Study Population Largely Reflects the US Racial/Ethnic Distribution per NHANES

PATHFINDER 2



NHANES: National Health and Nutrition Examination Survey
[1]Missing race/ethnicity data: 1.8%
[2]Other includes non-Hispanic Native American, non-Hispanic multiracial, and non-Hispanic Native Hawaiian or other Pacific Islander
Gadgeel S., et al., 2025

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Consistent MCED-V2 Test Performance in PATHFINDER 2 Between PMA and Full Study Cohorts (MCED-V2)

Metric	PMA cohort N = 22,698	Full study cohort[1] N = 32,007
Episode Sensitivity	**40.4%** (35.3%,45.8%)	**39.3%** (34.9%,44.0%)
Specificity	**99.64%** (99.55%,99.71%)	**99.64%** (99.57%,99.70%)
PPV	**62.1%** (55.5%,68.4%)	**60.3%** (54.5%,65.8%)
MCED Cancer Detection Rate	**0.59%** (0.49%,0.69%)	**0.54%** (0.47%,0.63%)
MCED Cancer Signal Detection Rate	**0.94%** (0.83%,1.08%)	**0.90%** (0.80%,1.01%)
Positive Likelihood Ratio	**111.6** (86.6,143.9)	**108.9** (87.6,135.2)
Number Needed to Screen	**171** (144,202)	**185** (159,215)
CSO1 Prediction Accuracy	**91.7%** (85.8%, 95.3%)	**87.3%** (81.5%,91.5%)

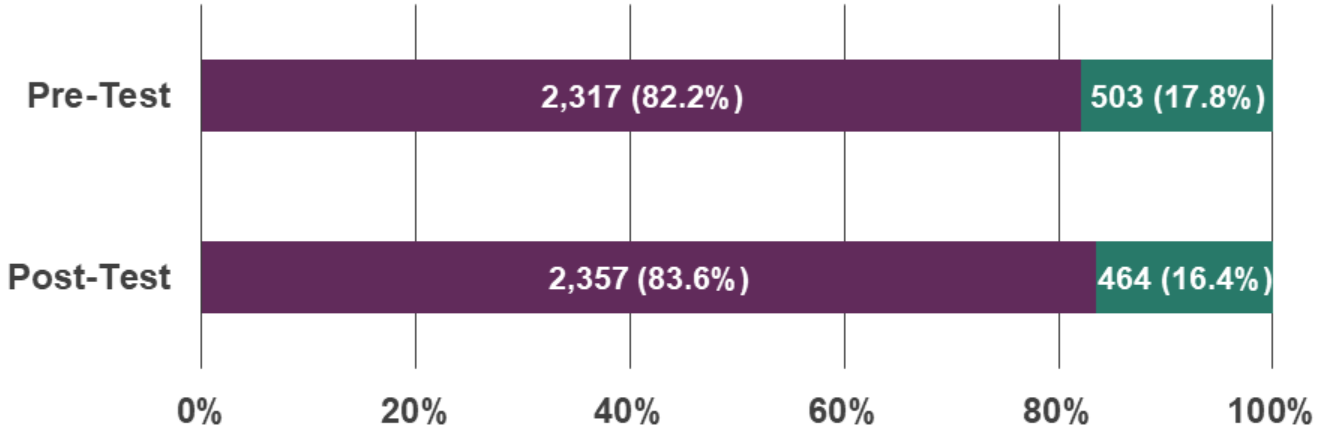
[1]MCED-V2 data presented at ASCO Annual Meeting 2026

GRAIL

Real-World Evidence Shows >80% Adherence to Mammography Screening Guidelines Before and After MCED Testing

Women with a negative initial MCED-V2 test between 7/1/22 and 6/30/23
N = 19,727

2 years of continuous claims enrollment pre- and post-initial MCED-V2 test
N = 2,820



McDonnell C et al., American Association for Cancer Research (AACR) Annual Meeting, 2026

GRAIL

Weighted Baseline Characteristics for Galleri Consistent with MCED-V2 Analyzable Population

PATHFINDER 2

		Cancer Signal Detected				No Cancer Signal Detected			
		Weighted N = 138		Unweighted N = 131		Weighted N = 21,281		Unweighted N = 7,635	
BMI (kg/m^2)	< 25	**34%**	47	**31%**	41	**32%**	6,891	**32%**	2,417
	25 to < 30	**33%**	45	**34%**	44	**36%**	7,707	**35%**	2,674
	≥ 30	**33%**	46	**35%**	46	**31%**	6,617	**33%**	2,522
Smoking Status	Current	**8%**	11	**8%**	11	**3%**	715	**6%**	426
	Former	**42%**	58	**44%**	57	**28%**	5,912	**25%**	1,929
	Never	**50%**	69	**48%**	63	**69%**	14,654	**69%**	5,280
Prior Cancer History*		**23%**	31	**24%**	31	**10%**	2,106	**9%**	686
Genetic Cancer Predisposition		**7%**	10	**8%**	10	**6%**	1,281	**6%**	428

*Excludes personal history of invasive solid tumor or hematologic malignancy and/or prior cancer treatment within 3 years prior to enrollment

GRAIL

Galleri Performs Similarly in Participants With and Without a Personal History of Cancer, With a Higher Cancer Detection Rate in Survivors

PATHFINDER 2

	Prior Cancer History N = 2,137*		No Prior Cancer History N = 19,281*	
Positive Predictive Value (PPV)	25 / 31	**80.6%** (63.1 – 91.0%)	81 / 107	**76.0%** (62.2 – 85.9%)
False-Positive Rate	6 / 2,074	**0.29%** (0.13 – 0.64%)	26 / 19,041	**0.13%** (0.07 – 0.25%)
Episode Sensitivity (12 Months)	25 / 63	**39.7%** (28.5 – 52.0%)	81 / 240	**33.8%** (28.1 – 39.9%)
Cancer Signal Origin (CSO) Prediction Accuracy	23 / 25	**92.0%** (75.0 – 97.8%)	77 / 81	**95.1%** (88.0 – 98.1%)
Cancer Detection Rate	25 / 2,137	**1.17%** (0.79 – 1.74%)	81 / 19,281	**0.42%** (0.34 – 0.52%)

* Weighted
Galleri – Data through 12 months of follow-up

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Cancers Detected By Galleri in PATHFINDER 2 Full Dataset (35K) and NHS-Galleri 3-Year Dataset (1/2)

Cancer Type	Site	Histology	Breast Subtype(s)
Breast	Breast	Carcinoma, undifferentiated, NOS	Unknown subtype
	Breast	Adenocarcinoma, NOS	ER/PR positive, HER2 negative;Unknown subtype
	Breast	Apocrine adenocarcinoma	Unknown subtype
	Breast	Invasive carcinoma of no special type	ER/PR positive, HER2 negative;HER2 positive (regardless of ER/PR status);Unknown subtype
	Breast	Invasive micropapillary carcinoma	Unknown subtype
	Breast	Lobular carcinoma, NOS	ER/PR positive, HER2 negative;Unknown subtype
	Breast	Infiltrating duct and lobular carcinoma	ER/PR positive, HER2 negative;Unknown subtype
	Breast	Infiltrating duct mixed with other types of carcinoma	Unknown subtype
	Breast	Paget disease and infiltrating duct carcinoma of breast	Unknown subtype
	Breast	Adenocarcinoma with neuroendocrine differentiation	Unknown subtype
	Breast	Metaplastic carcinoma, NOS	Unknown subtype
	Nipple	Invasive carcinoma of no special type	Unknown subtype

Cancer Type	Site	Histology
Lung	Bronchus	Adenocarcinoma, NOS
	Lung	Large cell carcinoma, NOS
	Lung	Large cell neuroendocrine carcinoma
	Lung	Carcinoma, undifferentiated, NOS
	Lung	Pleomorphic carcinoma
	Lung	Small cell carcinoma, NOS
	Lung	Non-small cell carcinoma
	Lung	Squamous cell carcinoma, NOS
	Lung	Squamous cell carcinoma, keratinizing, NOS
	Lung	Squamous cell carcinoma, large cell, nonkeratinizing, NOS
	Lung	Basaloid squamous cell carcinoma
	Lung	Adenocarcinoma, NOS
	Lung	Solid carcinoma, NOS
	Lung	Carcinoid tumor, NOS
	Lung	Neuroendocrine tumor, grade 2
	Lung	Lepidic adenocarcinoma
	Lung	Invasive mucinous adenocarcinoma
	Lung	Adenocarcinoma with mixed subtypes
	Lung	Acinar adenocarcinoma of the lung
	Lung	Adenocarcinoma with neuroendocrine differentiation

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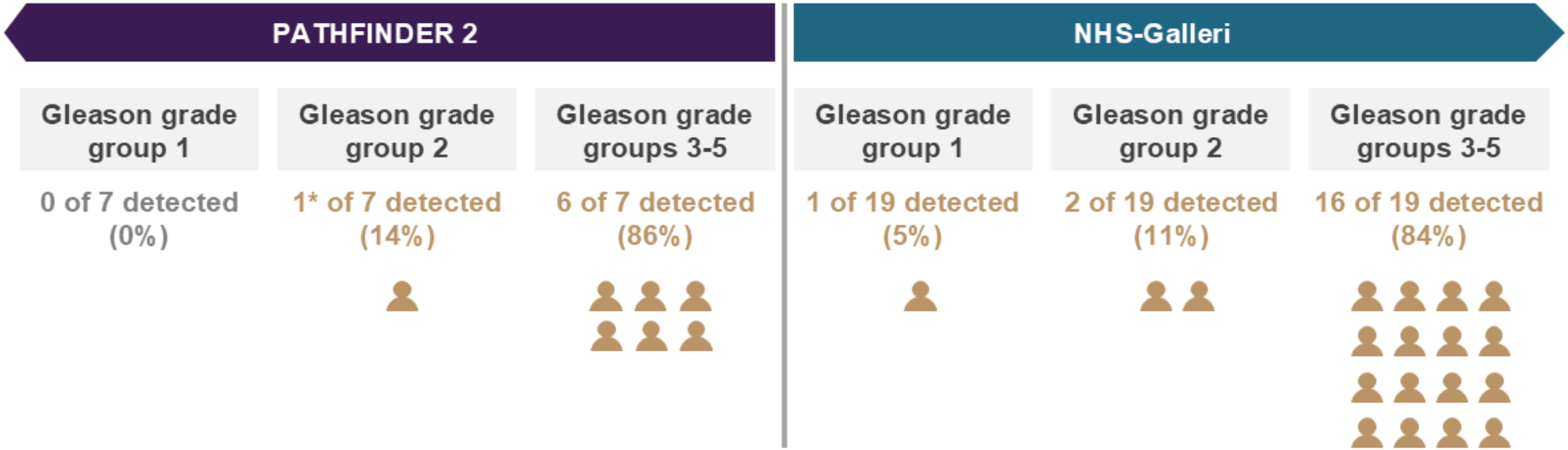
Cancers Detected By Galleri in PATHFINDER 2 Full Dataset (35K) and NHS-Galleri 3-Year Dataset (2/2)

Cancer Type	Site	Histology
Colon/ Rectum	Appendix	Adenocarcinoma, NOS
	Appendix	Serrated adenocarcinoma
	Appendix	Goblet cell adenocarcinoma
	Ascending	Adenocarcinoma, NOS
	Ascending	Adenocarcinoma in tubulovillous adenoma
	Ascending	Mucinous adenocarcinoma
	Cecum	Adenocarcinoma, NOS
	Cecum	Adenocarcinoma in tubulovillous adenoma
	Cecum	Mucinous adenocarcinoma
	Descending	Adenocarcinoma, NOS
	Descending	Mucinous adenocarcinoma
	Hepatic flexure	Adenocarcinoma, NOS
	Hepatic flexure	Adenocarcinoma in tubulovillous adenoma
	Rectosigmoid junction	Adenocarcinoma, NOS
	Rectum	Squamous cell carcinoma, NOS
	Rectum	Adenocarcinoma, NOS
	Rectum	Adenocarcinoma in adenomatous polyp
	Rectum	Adenocarcinoma in tubulovillous adenoma
	Rectum	Mucinous adenocarcinoma
	Sigmoid	Adenocarcinoma, NOS
	Sigmoid	Adenocarcinoma in adenomatous polyp
	Sigmoid	Adenocarcinoma in tubulovillous adenoma
	Sigmoid	Mucinous adenocarcinoma
	Splenic flexure	Adenocarcinoma, NOS
	Transverse	Adenocarcinoma, NOS
	Transverse	Mucinous adenocarcinoma

Cancer Type	Site	Histology
Cervix	Cervix	Squamous cell carcinoma, HPV-positive
Prostate	Prostate	Small cell carcinoma, NOS
	Prostate	Adenocarcinoma, NOS
	Prostate	Ductal adenocarcinoma
	Prostate	Infiltrating duct mixed with other types of carcinoma

Galleri Preferentially Detects Higher Gleason Grade Prostate Cancer



Only a single prostate cancer (1 of 26 = 4%) detected by Galleri in PATHFINDER 2 and NHS-Galleri was Gleason grade group 1

*The Galleri-detected Gleason grade group 2 prostate cancer was metastatic at diagnosis
Excluded from analysis: 5 prostate cancer recurrences (PATHFINDER 2) and 17 cases with missing stage or grade (7 PATHFINDER 2, 10 NHS-Galleri)

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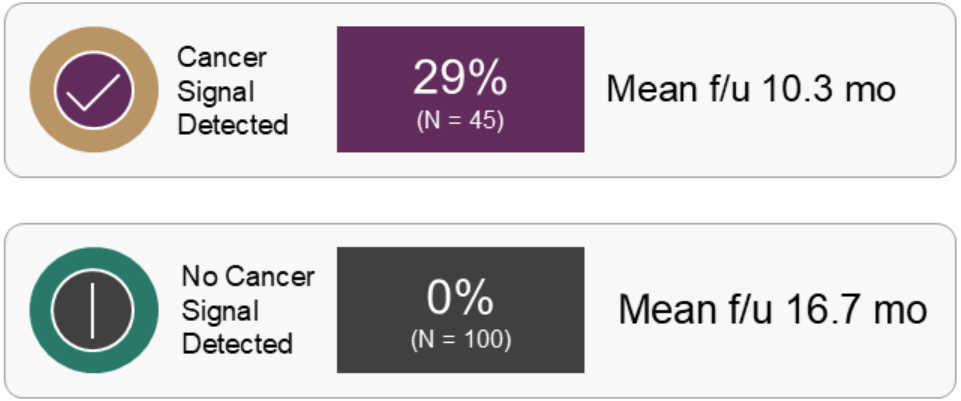
In Real-World Data, a Negative Retest Result Indicates a Low Likelihood of Current Cancer, Whereas a Positive Retest Indicates a Higher Likelihood



Risk of Subsequent Cancer Diagnosis



- 145 real-world users had an initial cancer signal detected but a negative diagnostic workup, prompting a Galleri retest within 3-6 months
- 45 had a persistent cancer signal detected on retest; 100 had no cancer signal detected on retest
- Of the 118 with a determined clinical status, **13 of 45 (29%) with a persistent cancer signal detected had a confirmed cancer diagnosis**
- **None (0 of 100, 0%) of those with no cancer signal detected on retest** → no need for further diagnostic workup

Westgate et al. ESMO 2024

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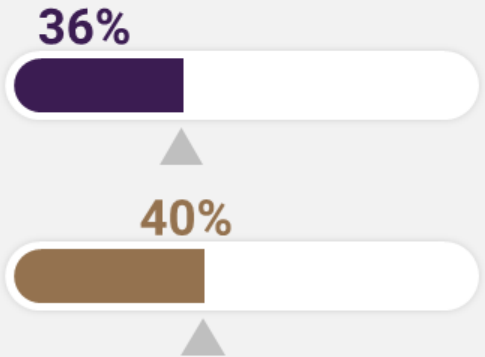
Galleri Detected Interval and Screening-Ineligible Cancers in PATHFINDER 2

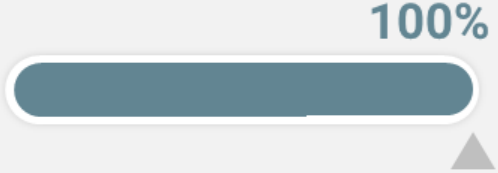
In participants who were eligible for and up-to-date with guideline-recommended cancer screening at the time of diagnosis, Galleri detected **interval cancers** that were not found by routine screening:

- 5 of 14 (**36%**) breast cancers detected by Galleri
- 2 of 5 (**40%**) colorectal cancers detected by Galleri

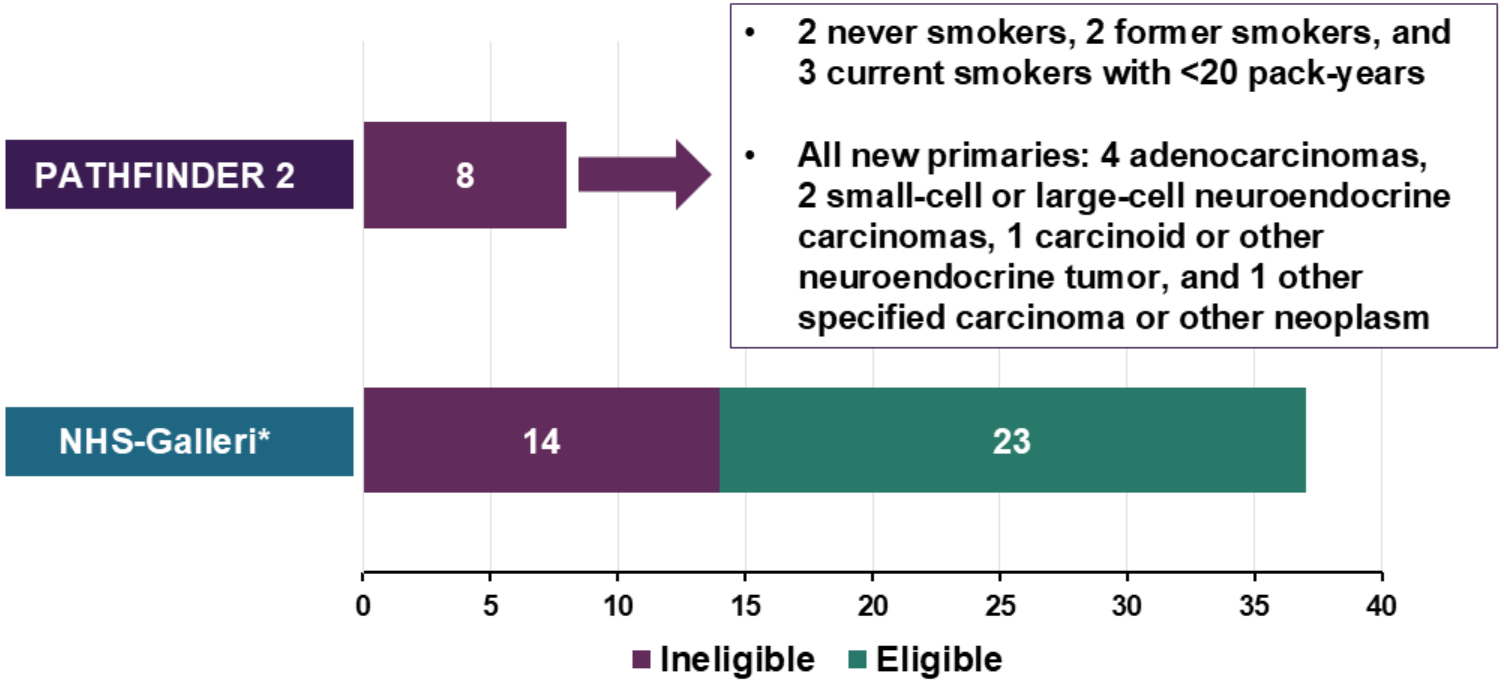


In participants who were not eligible for guideline-recommended lung cancer screening based on their smoking history, Galleri detected **screening-ineligible cancers:**

- 8 of 8 (**100%**) lung cancers detected by Galleri



Galleri Detects Lung Cancer in People Ineligible for LDCT Screening Based on Smoking History



- 2 never smokers, 2 former smokers, and 3 current smokers with <20 pack-years
- All new primaries: 4 adenocarcinomas, 2 small-cell or large-cell neuroendocrine carcinomas, 1 carcinoid or other neuroendocrine tumor, and 1 other specified carcinoma or other neoplasm

*For 6 participants in NHS-Galleri, grams of tobacco were converted to cigarette packs based on the NHS Stoke-on-Trent Primary Care Toolkit.

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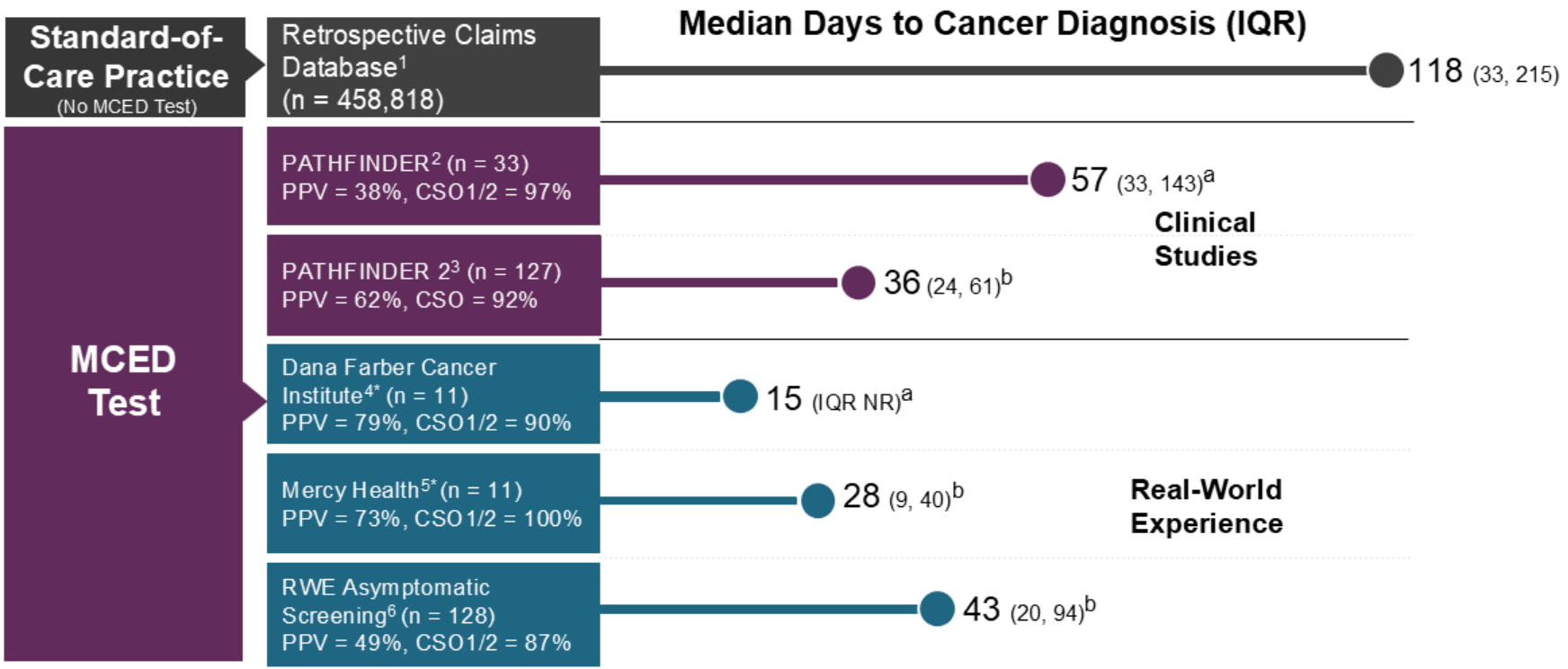
Galleri Cancer Signal Detection Prompts Efficient Diagnostic Resolution



1. Gitlin M et al., 2023 (The index date in this study was set to the date of an office visit occurring fewer than 4 weeks prior to the first diagnostic test date *or* on the first diagnostic test date if no office visit was recorded.); 2. Schrag D, et al., 2023; 3. Nabavizadeh N, et al., 2025; 4. O'Donnell E, et al., 2025; 5. Semenkovich N, et al., 2024 (One patient at Mercy Health underwent two tests (both positive) after initial follow-up imaging was unable to localize a cancer; PPV and CSO prediction accuracy at Mercy Health are based on personal communication.); 6. Matrana M, et al., 2025 (Empirical PPV = cancer diagnosis rate among persons with a positive MCED test, completed diagnostic work-up, and clinical follow-up reported by their healthcare provider.); *These analyses were conducted independently of GRAIL and may not reflect real-world performance in other health systems or clinics. [a]Median time to diagnosis in true positive cases. [b]Median time to diagnostic resolution for those reported.

Exposure to Ionizing Radiation was Limited During Targeted Diagnostic Evaluation in PATHFINDER 2

PATHFINDER 2

- < 1% (186/25,114) of PATHFINDER 2 participants had an imaging test as a result of a positive test
- 77.3% of participants with a positive test result had at least one imaging test with ionizing radiation during the CSO-guided targeted workup

PATHFINDER 2	MCED-V2+, Cancer diagnosis at resolution (n = 125)	MCED-V2+, No cancer diagnosis (n = 78)	MCED-V2+, Diagnostic resolution not achieved (n = 13)	All MCED-V2+ (n = 216)
1+ imaging test with radiation during targeted diagnostic work-up	97 (77.6%)	61 (78.2%)	9 (69.2%)	167 (77.3%)
CT scan	63 (64.9%)	40 (65.6%)	9 (100.0%)	112 (67.1%)
Ga68 Dotatate PET	2 (2.1%)	0	0	2 (1.2%)
Mammogram	7 (7.2%)	7 (11.5%)	0	14 (8.4%)
PET-CT	47 (48.5%)	28 (45.9%)	0	75 (44.9%)
Bone scan, X-ray, or other	2 (2.0%)	3 (4.9%)	1 (11.1%)	6 (3.6%)

- During the targeted diagnostic evaluation, the median per-participant dose was 14.1 mSv in participants both with and without a cancer diagnosis at diagnostic resolution
  - This is similar to the expected amount of exposure from one CT scan of the abdomen and pelvis (15.4 mSv) and much lower than the US occupational exposure limit of 50 mSv per year[1,2]

1. RadiologyInfo™ (Radiological Society of North America, Inc.) Radiation dose. 2025. https://www.radiologyinfo.org/en/info/safety-xray
2. University of California, San Francisco. Know your dose. How much radiation? 2025. https://knowyourdose.ucsf.edu/how-much-radiation

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