

GRAIL

# Capital Markets Day

May 13, 2024

This informational meeting regarding GRAIL, LLC ("GRAIL," "we," "us," "our" or the "Company") is for you to familiarize yourself with the company.

This presentation contains forward-looking statements. These statements may relate to, but are not limited to, expectations of future operating results or financial performance; our belief in our ability to develop our multi-cancer test and other products to our expectations and on the expected timeline; the expected timelines of our clinical studies and associated regulatory and commercial milestones, including regulatory approval and reimbursement attainment in one or more markets, and our ability to translate those results into commercial application; our ability to translate our early cancer detection capabilities into other areas of the cancer care continuum; the anticipated performance and impact of our multi-cancer test and other products; our understanding of development of our industry more generally; and the expected intended use population for our multi-cancer test and other products, as well as assumptions relating to the foregoing. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "ongoing," "plan," "potential," "predict," "should," "will," "would," or the negative of these terms or other comparable terminology. You should not put undue reliance on any forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results, and will not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved, if at all.

Forward-looking statements are based on information available at the time those statements are made and/or management's good faith beliefs and assumptions as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. In light of these risks and uncertainties, the forward-looking events and circumstances discussed in this presentation may not occur and actual results could differ materially from those anticipated or implied in the forward-looking statements. These risks and uncertainties include the Company's multi-cancer test and other products not performing as expected or in a more limited intended use population; clinical results not being replicated in future studies or not translated into real world or commercial application; substantial delays or failures in clinical studies, failure to obtain regulatory approvals on the basis of our planned and ongoing studies or at all; reliance on a sole supplier for certain materials; failure to obtain or maintain appropriate intellectual property protection; our ability to establish and maintain partnerships; our expectations about our market opportunities; and our ability to obtain partial or full reimbursement coverage for Galleri or our other products. Except as required by law, GRAIL, LLC. does not undertake any obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.

This presentation contains statistical data, estimates and forecasts that are based on independent industry publications or other publicly available information, as well as other information based on our internal sources. Certain information about other companies in our industry have also been pulled from publicly available sources. This information involves many assumptions and limitations, and you are cautioned not to give undue weight to these estimates. We have not independently verified the accuracy or completeness of the data contained in these industry publications and other publicly available information. Accordingly, we make no representations as to the accuracy or completeness of that data nor do we undertake to update such data after the date of this presentation.

This presentation shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of any securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

# GRAIL leadership presenting today



**Bob Ragusa**  
Chief Executive Officer



**Aaron Freidin**  
Chief Financial Officer



**Joshua Ofman MD, MSHS**  
President



**Sir Harpal Kumar**  
President, Biopharma  
& Europe





# Agenda

- 1 Introduction
- 2 Investment highlights
- 3 The promise of multi-cancer early detection (MCED)
- 4 Commercial strategy
- 5 Scientific background & clinical evidence
- 6 Opportunity beyond asymptomatic screening
- 7 Financial profile & inflection points





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# Investment highlights



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Detect cancer early,  
when it can be cured.

# GRAIL highlights

## Focused on detecting cancer early, when it can be cured<sup>1</sup>

- Current recommended screening is limited, and most deadly types of cancers are found too late
- Multi-cancer early detection (MCED) is the solution for effective population screening

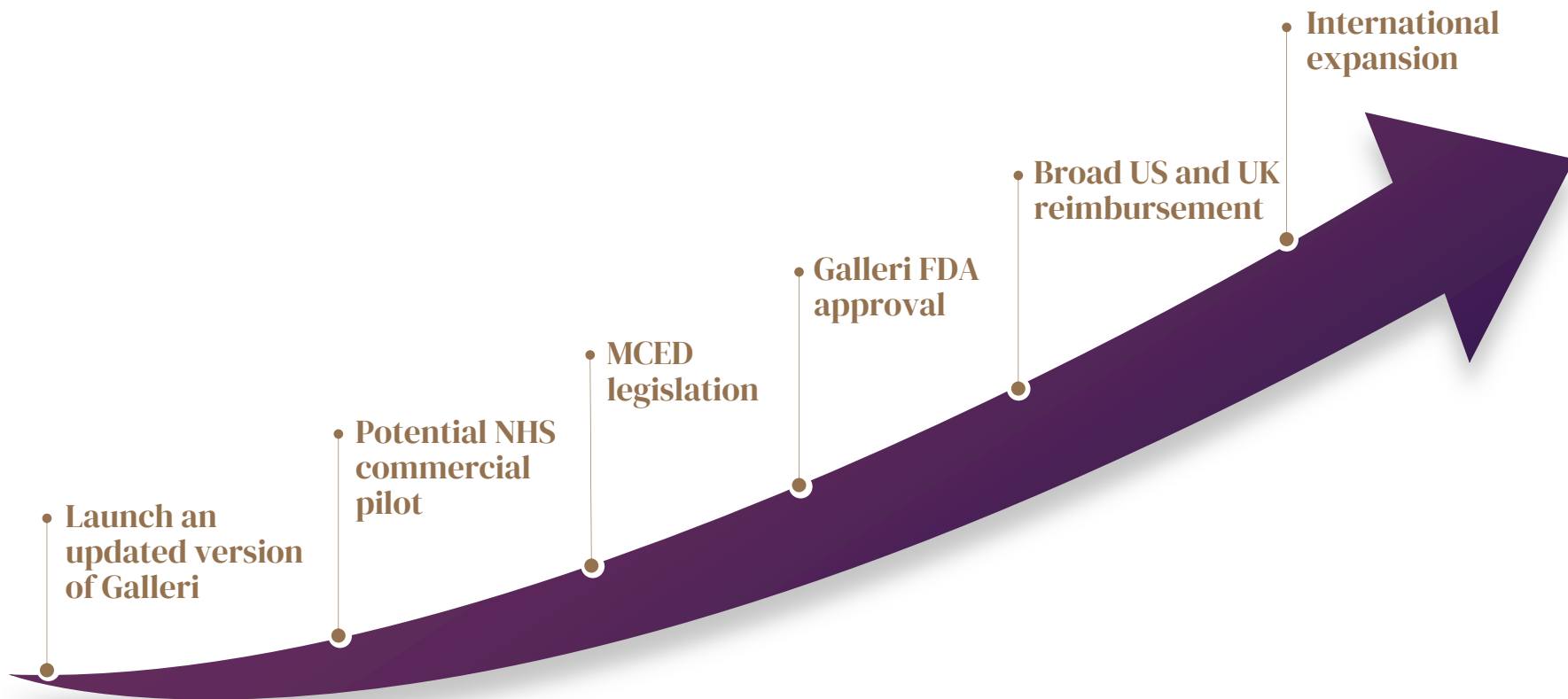
## Uniquely suited to address one of the most meaningful opportunities in healthcare

- Galleri<sup>®</sup> was designed for population-scale screening
- Expansive evidence program setting the standard for MCED development

## A leader in expansive global market

- Sold >180k commercial Galleri tests through March 2024
- Expanding commercial Galleri adoption in US, with large global opportunity
  - Rolling FDA submission in progress
  - Commercial agreement in place with NHS England
- Investing to enable commercial scale and sustained global leadership
- Proprietary methylation platform yields product portfolio across cancer care continuum

# Multiple catalysts to drive value



# The global opportunity for MCED is significant



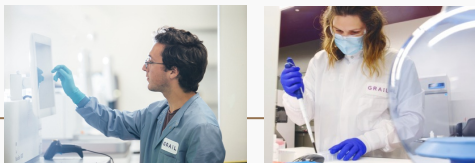


# Our vision: Population-scale multi-cancer early detection (MCED)

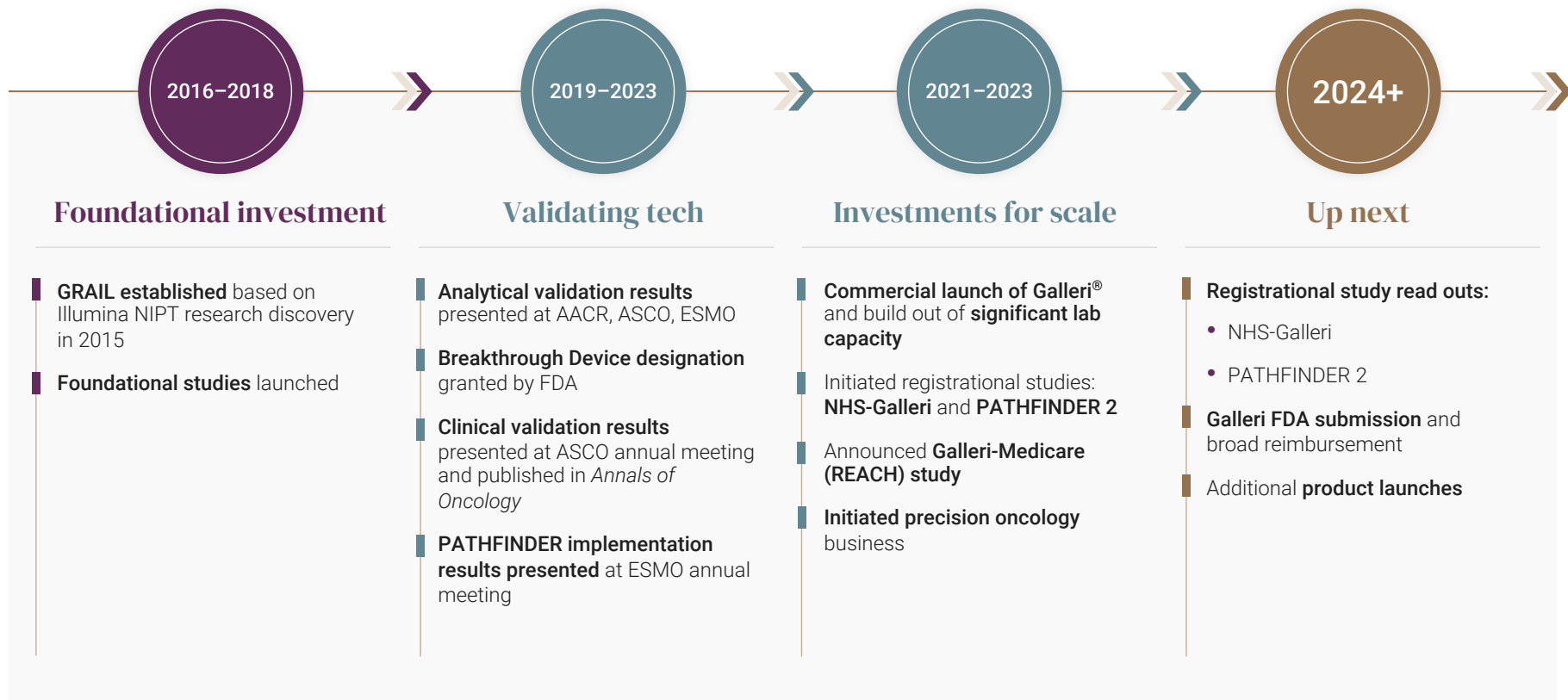


Laying the groundwork today

**to intercept the opportunity**



# GRAIL has made rapid progress since inception



# GRAIL's scientific leadership is shaping the MCED field

# >385,000

Clinical study participants

>260  
Publications in leading forums<sup>1</sup>

ASCO

Cancer Cell

THE LANCET Oncology

ANNALS OF ONCOLOGY

AACR

ESMO

nature

ESMO

ANNALS OF ONCOLOGY

ORIGINAL ARTICLE

Clinical validation of a targeted methylation-based multi-cancer early detection test using an independent validation set

E. A. Klein<sup>1</sup>, D. Richards<sup>1</sup>, A. Cohn<sup>1</sup>, M. Tummala<sup>1</sup>, R. Lapham<sup>1</sup>, D. Cosgrove<sup>1</sup>, G. Chung<sup>1</sup>, J. Clement<sup>1</sup>, L. Gao<sup>1</sup>, N. Hunkapiller<sup>1</sup>, A. Jamshidi<sup>1</sup>, K. N. Kurtzman<sup>1</sup>, M. V. Seiden<sup>1,2,3</sup>, C. Swanton<sup>1,4,5</sup> & M. C. Liu<sup>1,3</sup>

**THE LANCET**

200 YEARS OF THE BEST SCIENCE FOR BETTER LIVES

Editorial: The Lancet's 200 years: much more to come (page 1018)

Articles: Integrated management of HER2-positive and HER2-negative breast cancer (page 1021)

Review: Blood biomarkers for medication early detection (page 1024)

Medical History: Life at the Lancet: a collection of memories (page 1026)

£3.00 Registered as a newspaper ISSN 0140-6736 Founded 1823 - Published weekly

# Robust Galleri adoption prior to broad reimbursement



**\$93M** FY23 revenue

**>180k** Commercial Galleri tests sold

**>10k** Ordering providers

**>100** Commercial partnerships

**TIME**

Best Inventions of 2022

*The Atlantic*

2022 Breakthroughs of the Year

**FAST COMPANY**

World Changing Ideas of 2022

**FORTUNE**

2023 Change the World List

# GRAIL has established a robust, sustainable lead

Early investment and market experience drive continued advantage





# Strong company leadership

## Executive team



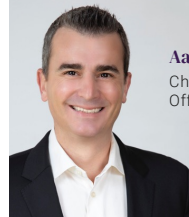
**Bob Ragusa**  
Chief Executive Officer



**Joshua Ofman, MD, MSHS**  
President



**Sir Harpal Kumar**  
President, Biopharma Business & Europe



**Aaron Freidin**  
Chief Financial Officer



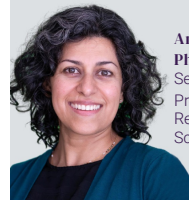
**Andy Partridge**  
Chief Commercial Officer



**Julie Currie**  
Chief People Officer



**Jeffrey Venstrom, MD**  
Senior Vice President of Medical Affairs & Chief Medical Officer



**Amoolya Singh, PhD**  
Senior Vice President of Research and Chief Scientific Officer



**Paul Ciccolella**  
Senior Vice President, Global Development & Operations



**Satnam Alag, PhD**  
Senior Vice President, Software Engineering & Chief Security Officer



**Abram Barth, JD, MPH**  
General Counsel



**Greg Summe**  
Founder & Managing Partner at Glen Capital, and previously Chairman & CEO at PerkinElmer



**Steve Mizell**  
Served as Executive Vice President & Chief Human Resources Officer at Merck



**Bill Chase**  
Served as Executive Vice President, Finance & Administration & Chief Financial Officer at AbbVie

## Board Members



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# The promise of Multi-Cancer Early Detection

# Cancer has a significant impact

**19M**

New cases annually<sup>2</sup>

**\$25T**

Estimated global economic cost of cancer care 2020-2050<sup>1</sup>

**10M**

Deaths annually<sup>2</sup>

**#2**

Cause of death globally<sup>3</sup>

# Cancers are often found too late

>80%

Cancer deaths result from cancers without recommended screening<sup>1</sup>

86%

Of cancers are not found through recommended screening<sup>2</sup>

~4x

Survival rate when diagnosed **EARLY**<sup>3</sup>

<sup>1</sup> US National Center for Health Statistics, with eligibility for and adherence to guideline based low-dose computed tomography screening for lung cancer.

<sup>2</sup> NORC at the University of Chicago. Based on five year survival rate. <sup>3</sup> Data on file from Surveillance, Epidemiology, and End Results (SEER) 18 Regs Research Data, Nov 2023 Submission. Includes persons aged 50 – 79. Estimated deaths per year in 2020 from American Cancer Society Cancer Facts and Figures 2020. Available at: [www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2020/cancer-facts-and-figures-2020.pdf](http://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2020/cancer-facts-and-figures-2020.pdf).

# MCED is the solution for effective population screening

## Today's standard of care screenings

### LIMITED YIELD

- Maximum **4 screenings available** for any one person<sup>1</sup>
- Find **only 14%** of cancers<sup>2</sup>
- Many times more likely to have a cancer not screened for<sup>3</sup>

## Adding additional single-cancer screenings

### IMPRACTICAL AT POPULATION SCALE

- Single cancer tests are impractical for less prevalent cancers
- Optimizes sensitivity over specificity
- Results in low PPV for each test and a high cumulative false positive rate

## Deploying an MCED test

### VIABLE POPULATION SOLUTION

- Allows screening for cancer with a single low false-positive rate
- Identifies cancer signal of origin
- Prioritizes PPV and cancer yield

PPV: positive predictive value.

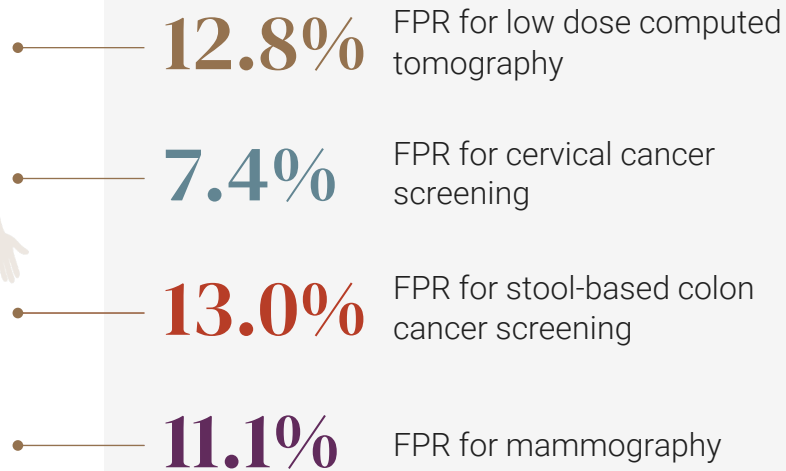
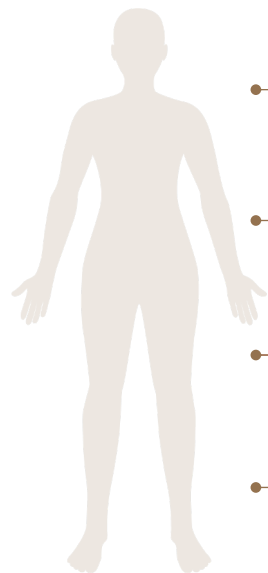
<sup>1</sup> United States Preventative Services Task Force (USPSTF) recommended cancer screening guidelines A or B (breast, cervical, colorectal, and lung), plus prostate which is C and widely implemented in the US. Grades A and B recommendations mean USPSTF suggests providers offer or provide that particular service, and grade C recommendations mean USPSTF suggests offering or providing such service for selected patients depending on individual circumstances. Grade A recommendations indicate that USPSTF recommends the service with a high certainty that the net benefit is substantial, while grade B recommendations indicate that USPSTF recommends the service and there is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. <sup>2</sup> NORC at the University of Chicago. <sup>3</sup> Clarke, Hubbell, Ofman. Cancer Cell. 2021;39(4):447-448. SEER Program, 2020 and USPSTF guideline recommendations



# Stacking single cancer tests results in an unacceptable cumulative false positive rate

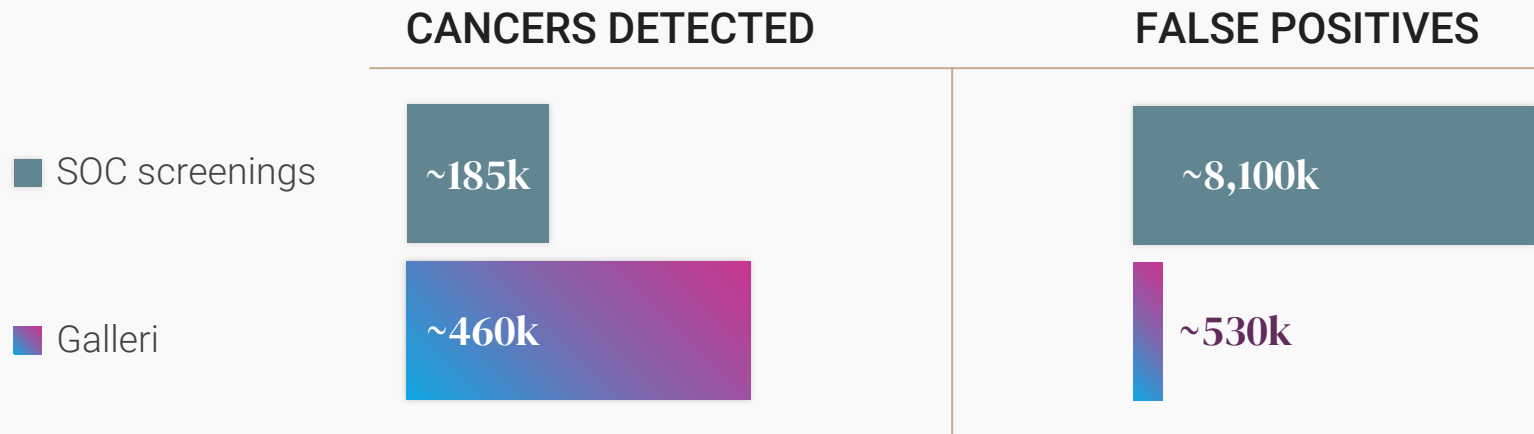
**A 60-year-old female with a history of smoking screened for 4 cancers would have a high false positive rate**

(Illustrative)



Real world validation in Prostate, Lung, Colorectal, and Ovarian (“PLCO”) study showed high cumulative false positive rates<sup>1</sup>

# Galleri + standard of care screening enables detection of more cancers more efficiently



**~65% reduction in cost to diagnose one cancer<sup>1</sup>**


# Galleri<sup>®</sup>: Clinically-validated, commercially-available MCED test<sup>1</sup>

-  Simple blood test
-  Very low false positive rate
-  Predicts cancer signal origin
-  Identifies aggressive cancers



# Galleri compares favorably to current standard of care

## Galleri and SOC performance

CANCER	TESTING METHOD	POSITIVE PREDICTIVE VALUE (%)	FALSE POSITIVE RATE (%)
Multi-	 <b>Galleri*</b> (blood test)	<b>43.1</b>	<b>0.5</b>
Prostate <sup>1</sup>	Blood test	30	10.4
Cervical <sup>2</sup>	Cytology / HPV test	19.0	7.4
Lung <sup>3</sup>	Low-dose CT scan	3.8	12.8
Breast <sup>4</sup>	Mammography	4.4	11.1
Colorectal <sup>5</sup>	Colonoscopy**	**	**
	Stool-based screening (FIT)	1.2	13.0

\* Results based on MCEd test that became Galleri.

\*\* Colonoscopy is considered both a screening and diagnostic test, in part because it detects both precancerous and cancerous lesions. As a result, it is not comparable across PPV and false positive rates.

<sup>1</sup> (i) PPV: CA: A Cancer Journal for Clinicians, March 2010, and (ii) False Positive Rate: Annals of Family Medicine, May 2009. Prostate screening is an USPSTF grade C.

<sup>2</sup> (i) PPV: International Journal of Cancer, May 2019, and (ii) False Positive Rate: JAMA, August 2018

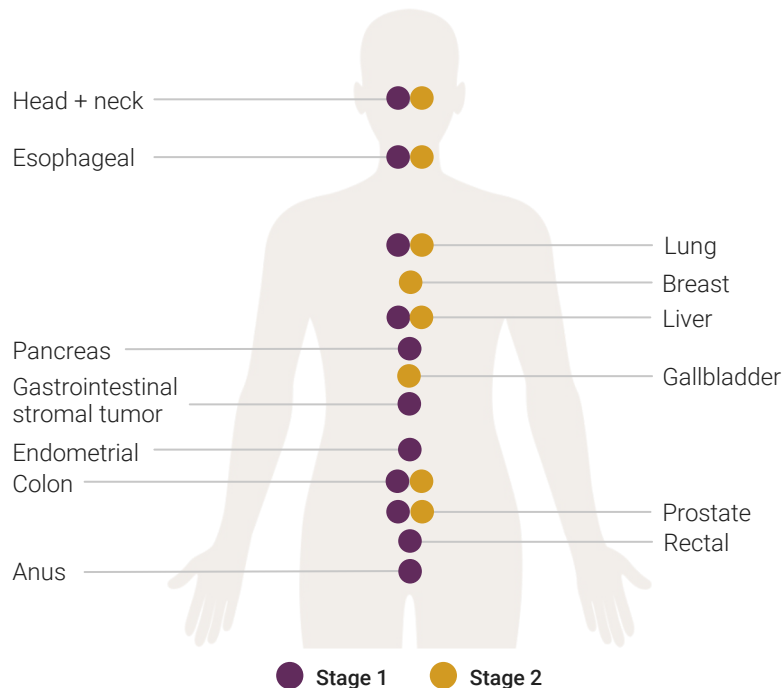
<sup>3</sup> (i) PPV: New England Journal of Medicine, May 2013, and (ii) False Positive Rate: Annals of Internal Medicine, April 2015

<sup>4</sup> Source for PPV and False Positive Rate: Radiology. 2017; 283(1): 49-58.

<sup>5</sup> PPV and False Positive Rate: Abdominal Radiology, August 2016

# Commercial use of Galleri is finding early cancers

## EXAMPLES OF CONFIRMED EARLY-STAGE CANCERS



“

Without multi-cancer early detection, I would be dead now. I was diagnosed with pancreatic cancer 18 months ago. I've had six months of chemotherapy and surgery, [and] currently no evidence of disease....

**That would not be the case if I had not got this early.... So clearly, early detection saved my life.**

**Roger Royse, Galleri patient**

*November 2023, multi-cancer detection FDA advisory committee meeting*

”



# Galleri test report is designed to provide a clear, easy to understand result

## Detection

**"Cancer Signal Detected"**: Test detected DNA methylation patterns associated with cancer

**"No Cancer Signal Detected"**: Test did not detect DNA methylation patterns associated with cancer

## Prediction

To guide diagnostic evaluation, Galleri provides a Cancer Signal Origin (CSO) prediction

**Galleri** Firstname Last  
GRAIL ID: ID1234567890

### Multi-cancer early detection test report

Patient	Sample	Ordering Provider
Name: Firstname Lastname	GRAIL ID: ID123456789	Name: Firstname Lastname, MD
Patient ID: PathPat1234567890	Sample Type: Whole Blood	Location: Academic Hospital - Clinic 1
DOB: 01-JAN-1965	Report Date: 15-OCT-2023 / 18:13 PT	Address: 123 Maple St. Unit 321 Rainbow Town, CA 94000
Bio Sex: Female	Collection Date: 05-OCT-2023	Phone: (123) 456-7890 Fax: (987) 654-3210

#### Your Result

**DETECTION**

**Cancer Signal Detected**

The Galleri<sup>®</sup> test detected DNA methylation patterns that are often associated with cancer in your blood sample. In a clinical study<sup>a</sup>, on average, 4 out of 10 people with a "Cancer Signal Detected" result received a cancer diagnosis (Positive Predictive Value or PPV was 43%).

**What this result means** **What this result does not mean**

The Galleri test looked for a signal often associated with cancer in your blood sample and found one. A healthcare provider should conduct an evaluation for cancer.

A "Cancer Signal Detected" result is NOT a diagnosis of cancer. Diagnostic testing by a healthcare provider is needed to confirm if you have cancer.

#### Your Predicted Cancer Signal Origin

**PREDICTION**

**Cancer Signal Origin<sup>b</sup>**

**FIRST CSO PREDICTION**  
Pancreas, Gallbladder  
Pancreas, Extrahepatic Bile Duct, Gallbladder.

**SECOND CSO PREDICTION**  
Liver, Bile Duct  
Liver, Intrahepatic Bile Duct.

To guide diagnostic evaluation, Galleri provides your Cancer Signal Origin (CSO) prediction. The CSO prediction offers information about the tissue type or organ associated with the Cancer Signal.

The size of the bar under the CSO represents the match of the DNA methylation pattern to cancers of that tissue or organ. A longer bar reflects a better match. Diagnostic evaluation should be prioritized in the context of the clinical presentation.

The size of the bar does NOT represent the probability of having cancer. Two CSO predictions rarely indicate the presence of multiple primary cancers.

a. PATHFINDER (NCT0424796)<sup>1</sup> was a prospective, interventional return of results study (n = 6,682) to assess the implementation of an early version of the Galleri test in a clinical setting. Participants were >50 years with and without additional cancer risk. A pre-specified reanalysis of blood samples (n = 8,376) was completed with the Galleri test.

b. The signal origin predictions are organized into 21 Cancer Signal Origins, which are listed in the methods section. For more information, please visit [galleri.com/test-report](https://galleri.com/test-report).

**GRAIL** Laboratory Director: John Abram, MD | CLIA #0502154430 | CAP #8169563  
1525 O'Brien Dr., Menlo Park, CA 94025 | 833-MY-GALLERI (833-694-2553) | FAX 650-999-9000 | [customerservice@galleri.com](mailto:customerservice@galleri.com)  
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# GRAIL provides clinical support services for positive tests



Access to peer-to-peer consultations



Patient care navigation



Galleri re-test program



Positive result resource center



Tumor board



GRAIL



# Commercial strategy

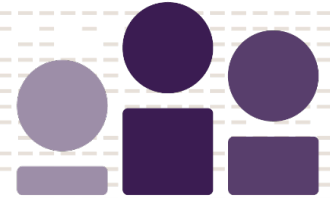
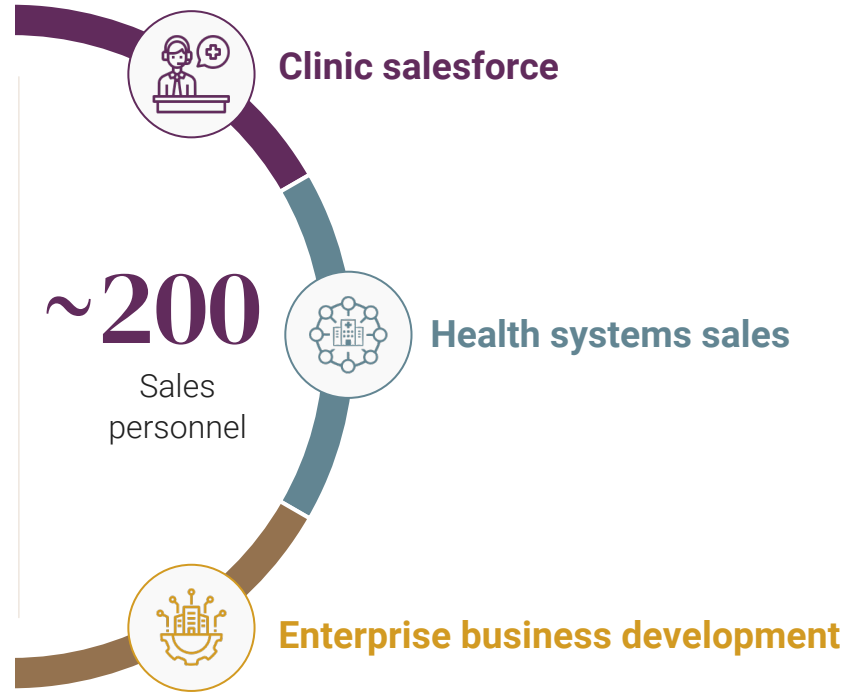
# Today's commercial strategy focused on multiple stakeholders

- **Providers & clinics:** Offer innovative, cutting-edge health offerings
- **Health systems:** Opportunity to increase revenues and attract new customers
- **Employers:** Proven early adopters of new technologies with clear value drivers
- **Life insurance:** Promoting preventive health and wellness



# Focused commercial team drives adoption

**MCED  
market  
leader**




# NHS England roll out could be first national health system MCED implementation



**NHS**

- Commercial agreement with NHS – known for high evidence standards for new technologies – could enable national roll-out after NHS-Galleri trial completion expected in 2026
- An early pilot could be initiated in 2024 subject to early study results
- Galleri has regulatory approval (UKCA mark)



NHS  
data anticipated to  
enable additional  
payor systems

*“Lives are saved when cancers are caught early, and this test has the potential to transform cancer care forever – especially for the types that often don’t show symptoms until a later stage, when they can be much harder to treat.”*

- Amanda Pritchard, CEO, NHS England, 2023

# GRAIL has made investments for scale



## Invested in operational scale

~65,000 sf CAP-accredited, CLIA-certified lab facilities  
Sufficient capacity to support multiple years of growth

## Established US and UK footprint

>1,300 employees

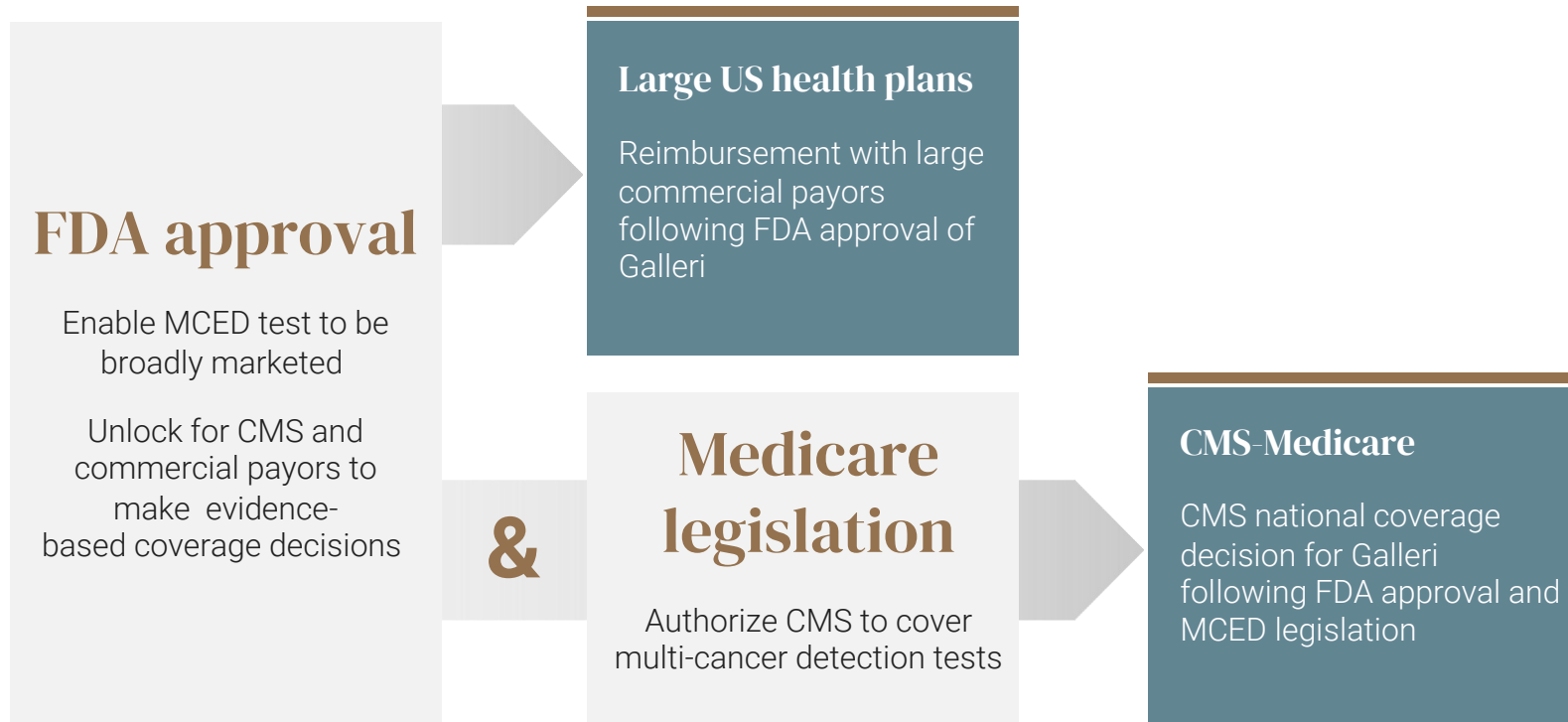
Operations in Menlo Park, CA; Research Triangle Park, NC;  
Washington, D.C.; and London, UK

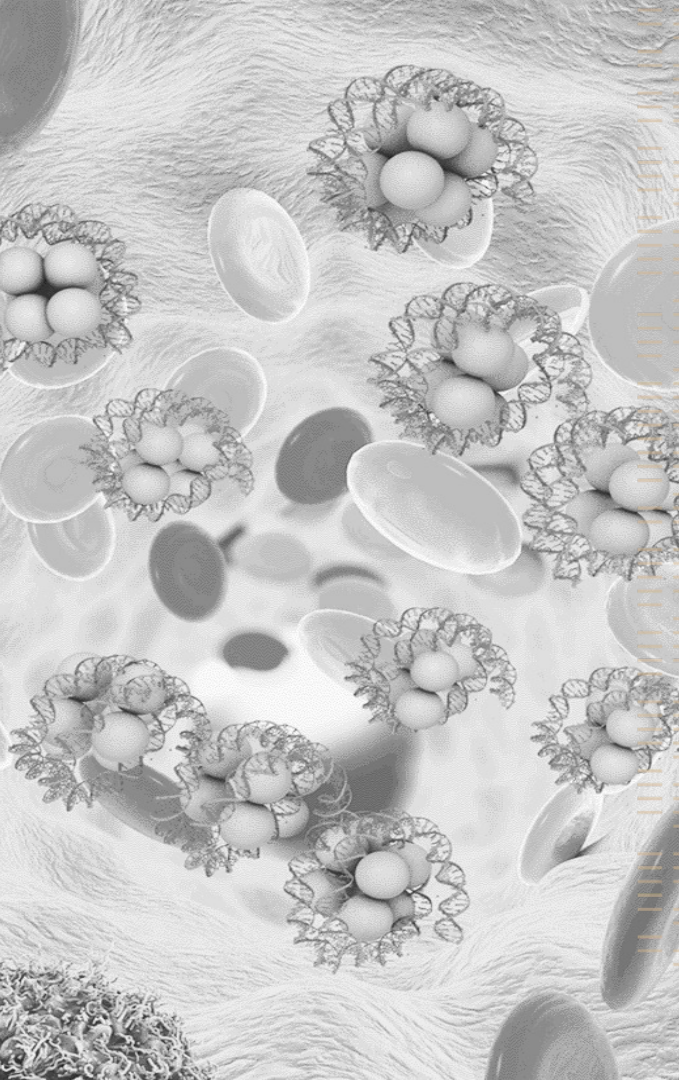
## Demonstrated execution

>450,000 clinical and commercial tests through our labs



# Future potential inflection points to unlock broad access to Galleri

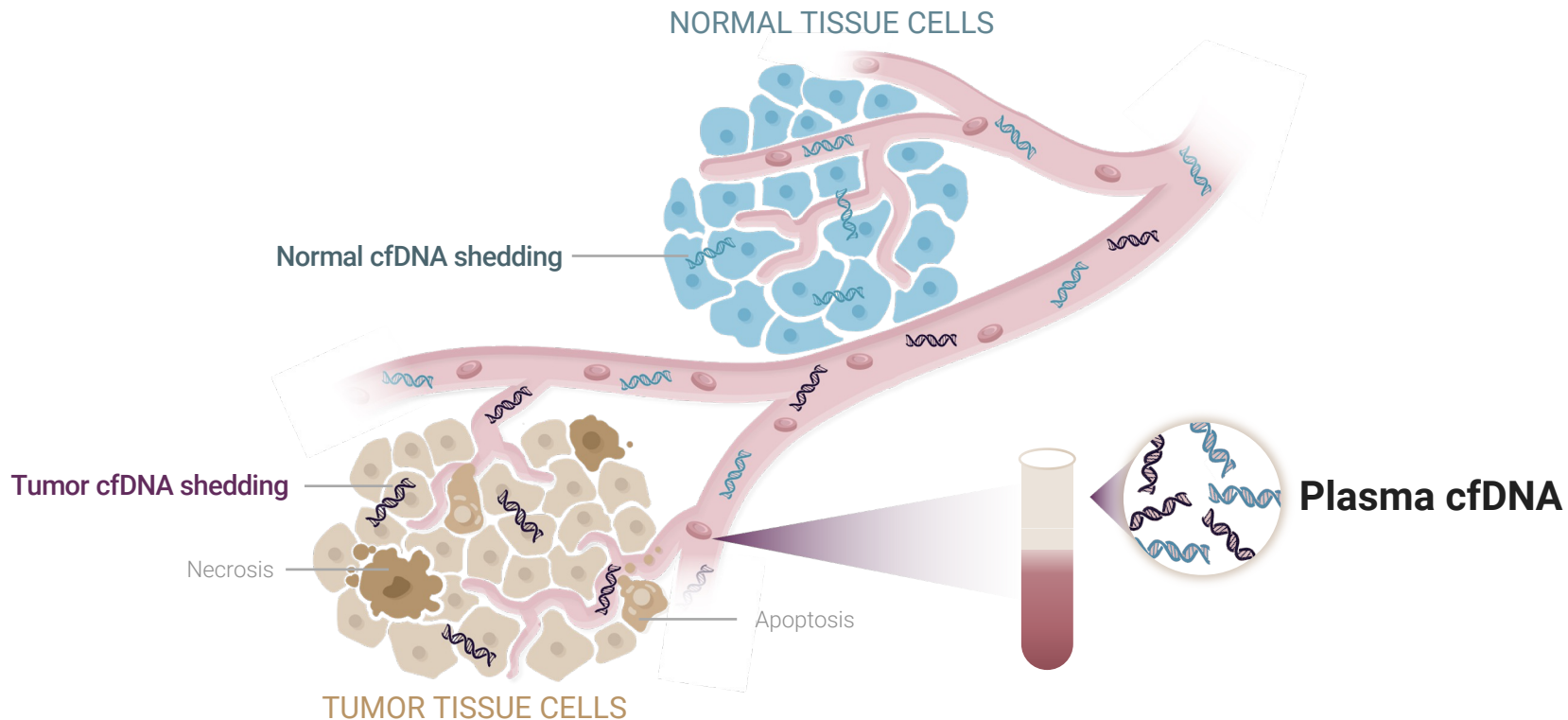




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# Scientific background and clinical evidence

# Tumors shed nucleic acids (cfDNA) carrying cancer-specific information into blood



# Our targeted methylation panel is uniquely suited for detecting cancer

Many cancer hallmarks are identifiable via methylation signals; methylation also leaves fingerprints in cell differentiation, enabling identification of CSO



Hanahan D. Hallmarks of Cancer: New Dimensions. Cancer Discov. 2022.

Patterns of 5-methyl Cytosine are maintained during cell division - epigenetic memory

Methylation is a silencing signal - blocking transcription and organizing chromatin into an inactive state

Methylation patterns are established during development in a cell type specific manner through the balance of Tet and DNMT activities

Methylation patterns are modified during aging, by environment, and disease

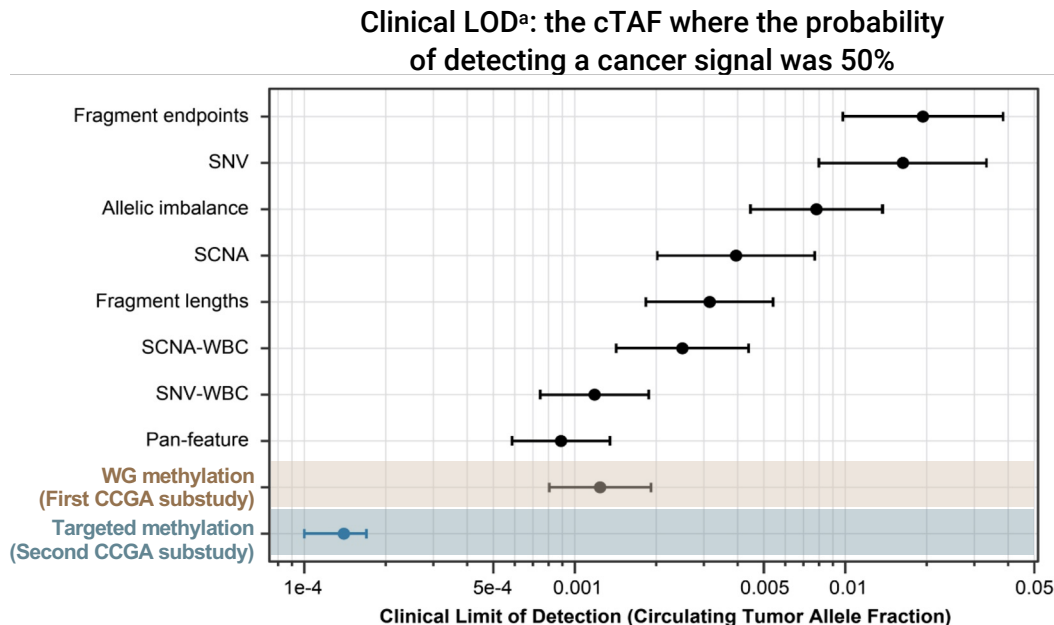
Hyper and hypomethylation have pleiotropic effects in cancer

# Unbiased evaluation identified our targeted methylation approach

Targeted methylation achieved  $\geq 10x$  better LOD vs whole genome methylation

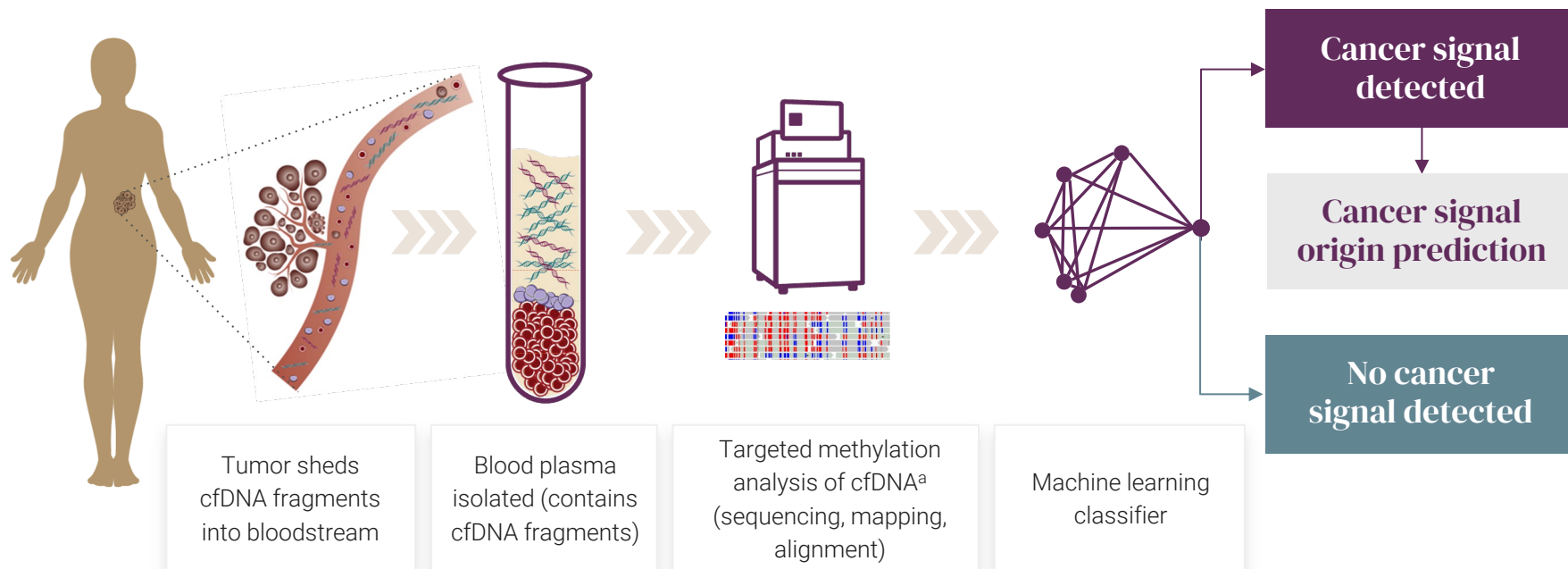
Unbiased comparison of detection using many approaches

Combining other approaches did not improve performance over methylation



# Multi-cancer early detection with Galleri

Targeted methylation NGS-based assay and machine learning used to analyze cfDNA in a blood sample to detect cancer and predict cancer signal origin (CSO)



# CSO identification is critical feature in an MCED test

**“The Panel believes that MCD tests should have a tissue-of-origin**

**component** to the device as it would guide targeted diagnostic work-up and minimize the risks associated with whole body imaging and multiple follow-up diagnostic procedures.”

- FDA MCD AdCom Summary Report, November 2023

“

“An ideal tool for universal screening would...accurately predict tumor site to efficiently direct the diagnostic evaluation of those with a positive test result.”

– Ahlquist 2018<sup>1</sup>

“...Since the diagnostic and therapeutic odyssey following a positive result depends on anatomically localizing the cancer, identification of the tissue of origin is required for any [MCED] test.” – Putcha 2021<sup>2</sup>

“The ability to identify the tumor of origin for the true positive patients would be highly valuable to guide subsequent clinical decision making, as there is no prior knowledge of the disease location at an early stage of cancer disease.”

– Constantin 2022<sup>3</sup>

”



# Clinical evidence program designed to support regulatory approvals and reimbursement

## DISCOVERY & CLINICAL VALIDATION



## REGISTRATION ENABLING



## POST-PMA / REIMBURSEMENT SUPPORT

### CCGA 1 & 2

- Unbiased discovery identified technology
- Development of targeted methylation assay to improve sensitivity and specificity

### CCGA 3

- Clinical validation of assay in case-controlled population
- Establishment of initial performance parameters

### PATHFINDER

- Clinical validation in asymptomatic intended use population

### NHS-Galleri

- RCT to demonstrate clinical utility (stage shift) at population scale
- Larger study to confirm performance
- Large-scale safety data, including post-positive diagnostic investigations
- Modeling of mortality benefits
- Value of annual screening
- Broad ethnic group/population diversity data

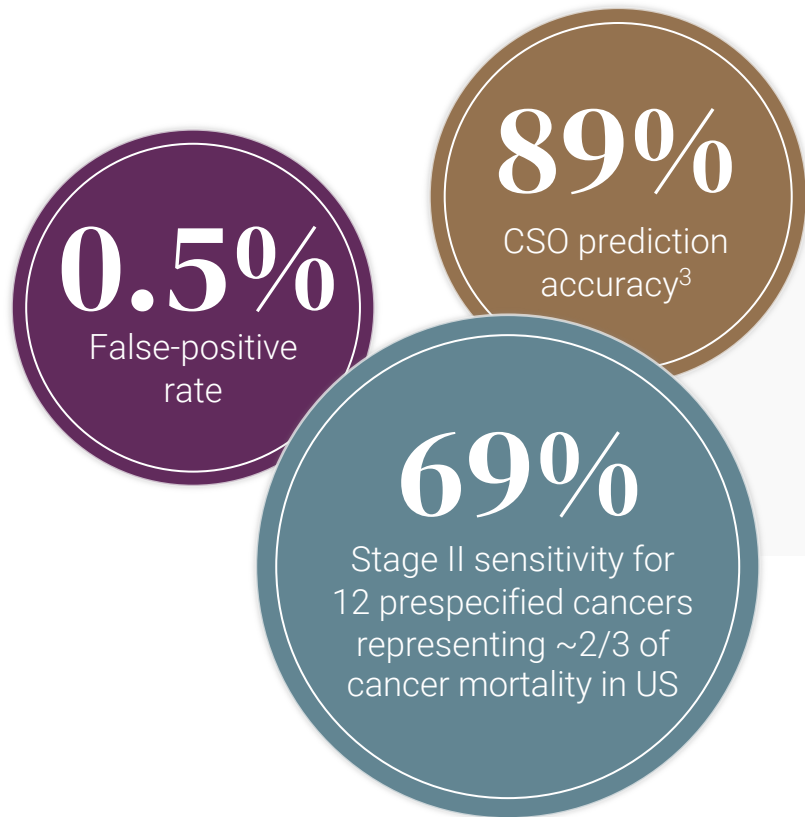
### PATHFINDER 2

- US safety data in larger study
- Broad ethnic group/population diversity data

### Galleri-Medicare

- Validation and clinical impact in the Medicare population
- Value of annual screening

# CCGA3 demonstrated ~68% sensitivity for detecting deadly early-stage cancers with a low false positive rate



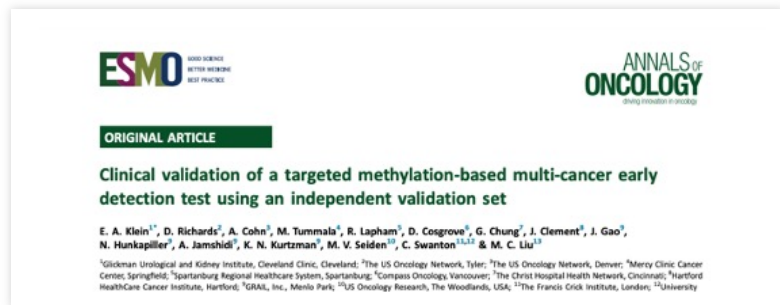
- Detected cancer signal across >50 AJCC<sup>1</sup> cancer types
- 44% PPV (modeled)<sup>2</sup>

# Implementation data generally consistent with case-controlled studies

## CCGA3

Modeled PPV at 99.5% specificity:

~44%

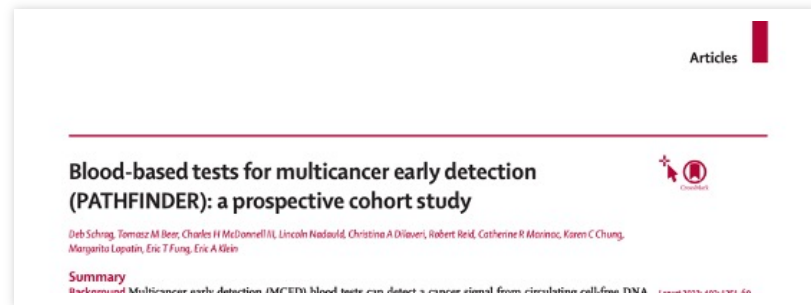


CCGA3 results, *Annals of Oncology*, June 2021

## PATHFINDER

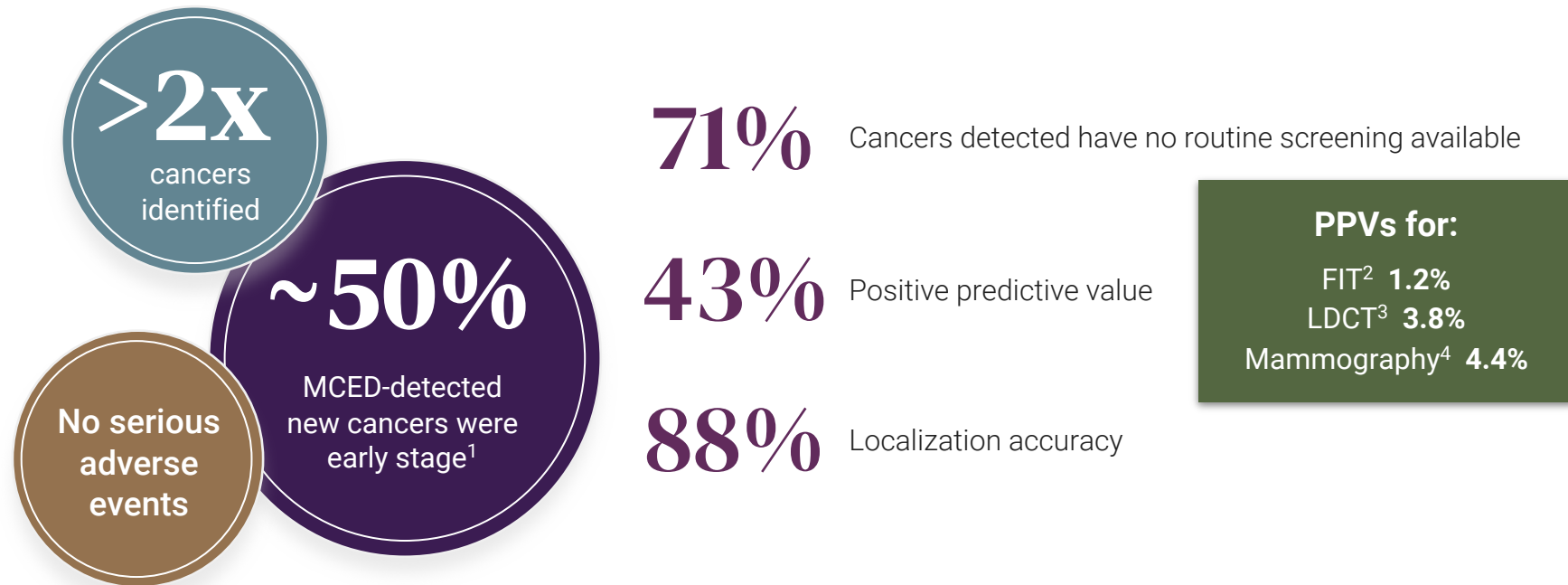
Observed PPV at 99.5% specificity:

~43%



PATHFINDER results, *The Lancet*, October 2023

# PATHFINDER: Galleri more than doubled the number of cancers identified when added to standard of care screening



Galleri performance data: Schrag, et al. PATHFINDER: A prospective study of a multi-cancer early detection blood test. ESMO 2022.

Localization: CSO (cancer signal of origin) prediction accuracy of first or second predicted classifications in true positive population.

<sup>1</sup> Proportion of MCED-detected new cancers without SOC screening identified in stage 1 or 2. <sup>2</sup> Pickhardt, P.J. Emerging stool-based and blood-based non-invasive DNA tests for colorectal cancer screening: the importance of cancer prevention in addition to cancer detection. *Abdom Radiol* 41, 1441–1444 (2016). <sup>3</sup> *N Engl J Med*. 2013 May 23;

368(21): 1980–1991. <sup>4</sup> USPSTF. 2016. Lehman, et al. *Radiology*. 2017;283(1):49-58.

SOC: USPSTF recommended cancer screening. FIT: fecal immunochemical test. LDCT: low dose computed tomography.

# cfDNA is advantageous for population-scale early detection



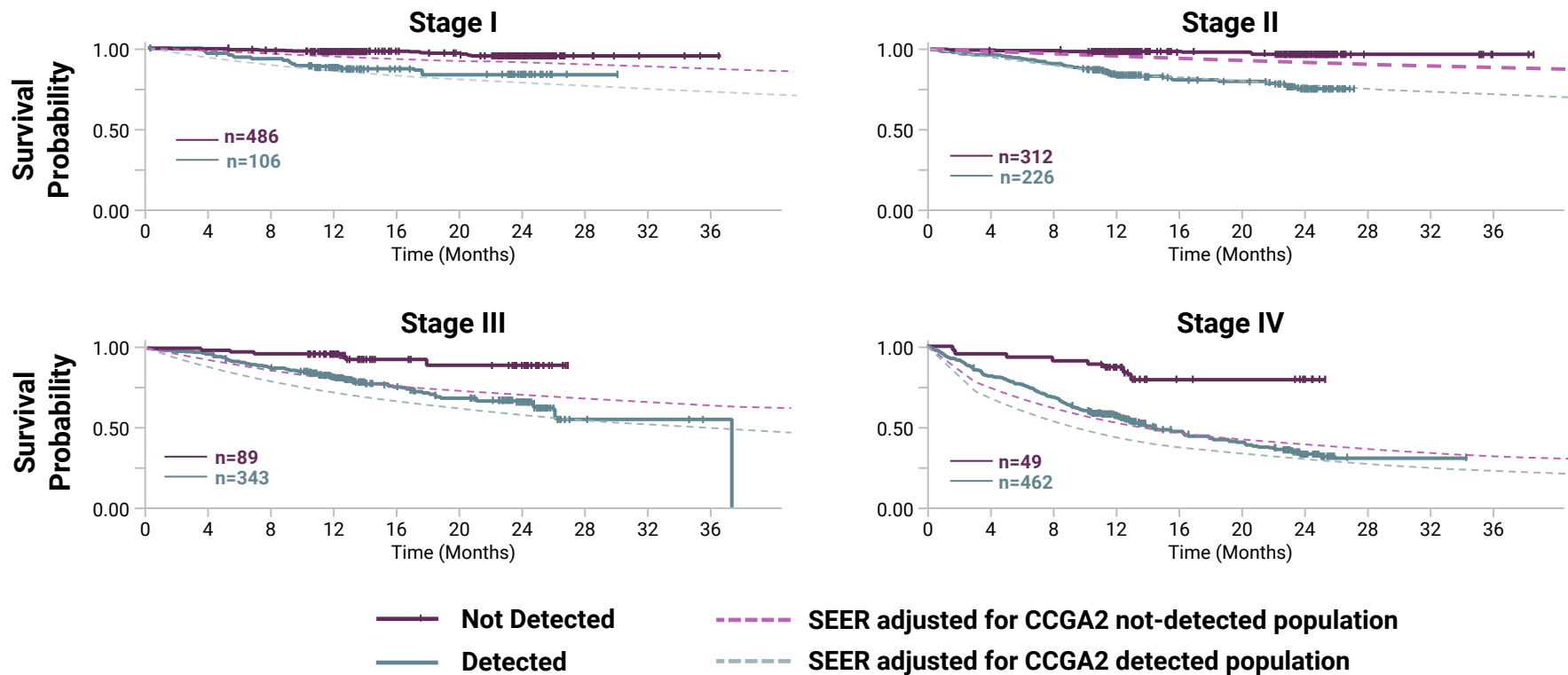
Higher tumor cfDNA levels  
tend to be associated  
with more aggressive cancers



MCED test using targeted  
methylation cfDNA-based cancer  
detection preferentially detects  
more lethal cancers, which may  
help avoid overdiagnosis

# Galleri is unlikely to contribute to over-diagnosis

Undetected cancers had a better prognosis





GRAIL

# Ongoing registrational studies and real world evidence program



# Registrational studies progressing

## NHS-Galleri

Randomized clinical trial in UK designed to demonstrate clinical utility at population scale

- Large study to confirm test performance
- Enables collection of large-scale safety data, including post-positive diagnostic investigations and modeling of mortality benefits
- Repeat testing to demonstrate value of annual screening
- Fully enrolled with ~140k study participants; final data anticipated in 2026

## PATHFINDER 2

Interventional multi-center study in U.S. health systems

- Large study to collect safety data in U.S. population
- Enrollment targeted to enable broad ethnic group/population diversity data
- >30k of ~35k study participants enrolled as of March 31, 2024

# NHS-Galleri: Assessing clinical utility of MCED test for population screening in the UK

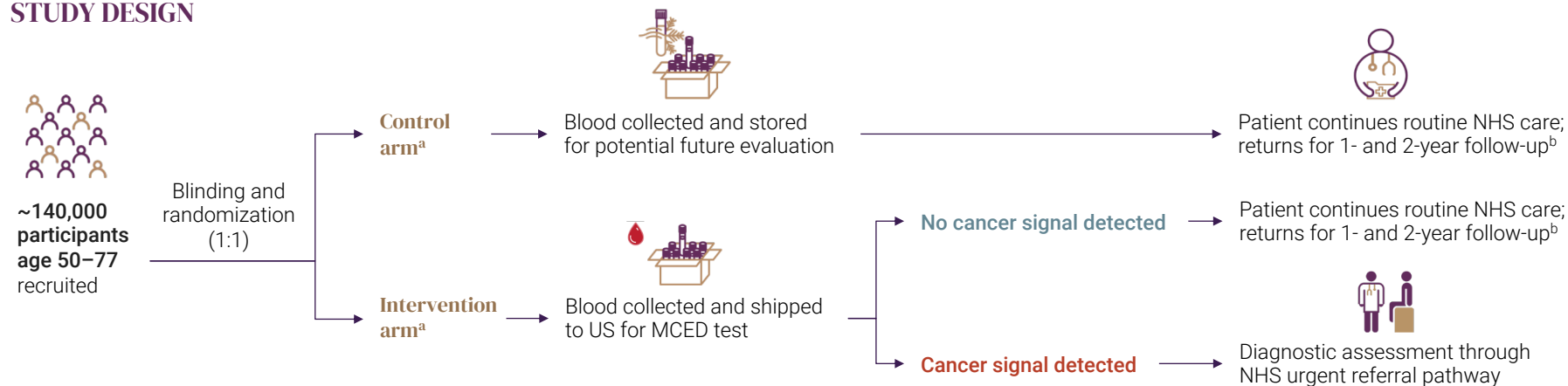
## STUDY OBJECTIVES

**Support NHS long term ambition to catch 75% of cancers at early stage**

- Randomized, controlled study evaluating implementation of Galleri alongside existing screening
- Participants to provide three blood draws over two years

**Fully enrolled in ~10 months**

## STUDY DESIGN

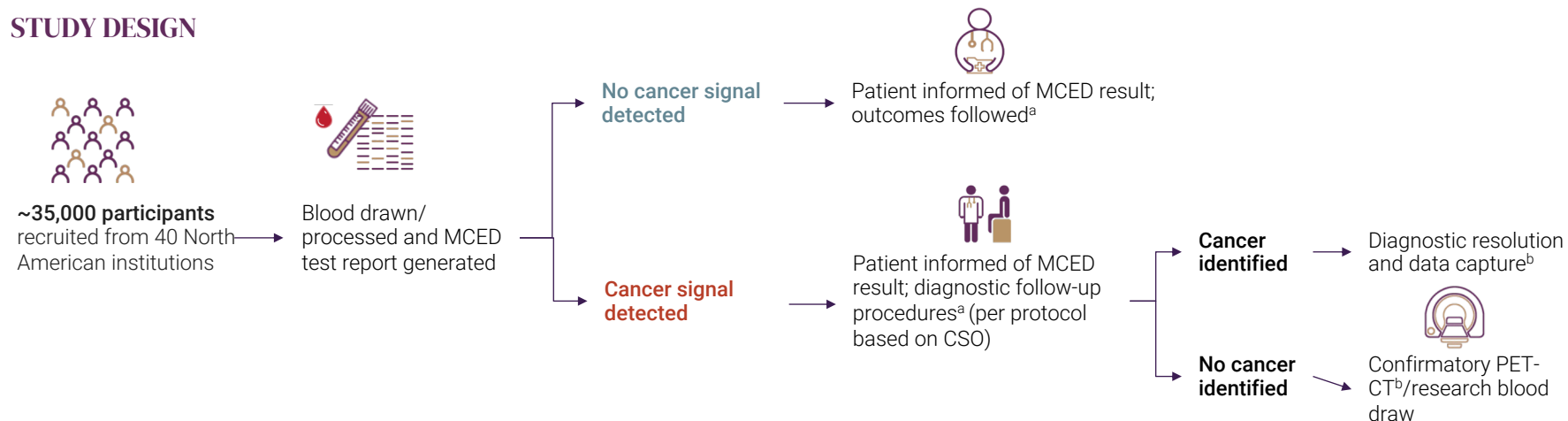


# PATHFINDER 2: A multicenter study with returned results in North American healthcare systems

## STUDY OBJECTIVES

- Enrolling ~35k participants ≥50 years of age
- Evaluating safety and performance of Galleri MCED test in eligible individuals for cancer screening
- Assessing number/types of diagnostic procedures needed for resolution

## STUDY DESIGN



# Announced REACH study in November 2023

## CMS is investing in Galleri testing for Medicare beneficiaries

- Galleri-Medicare study to measure performance & outcomes in large-scale real-world cohort
- First-of-its-kind study will be conducted under FDA approved IDE and measure clinical impact vs a synthetic control
- 50K Medicare beneficiaries will receive usual care + an annual Galleri test

Medicare beneficiaries in the US face the **highest unmet need** for early cancer detection

# Real-world evidence is an important component of GRAIL's evidence collection

## REACH (Galleri-Medicare study)

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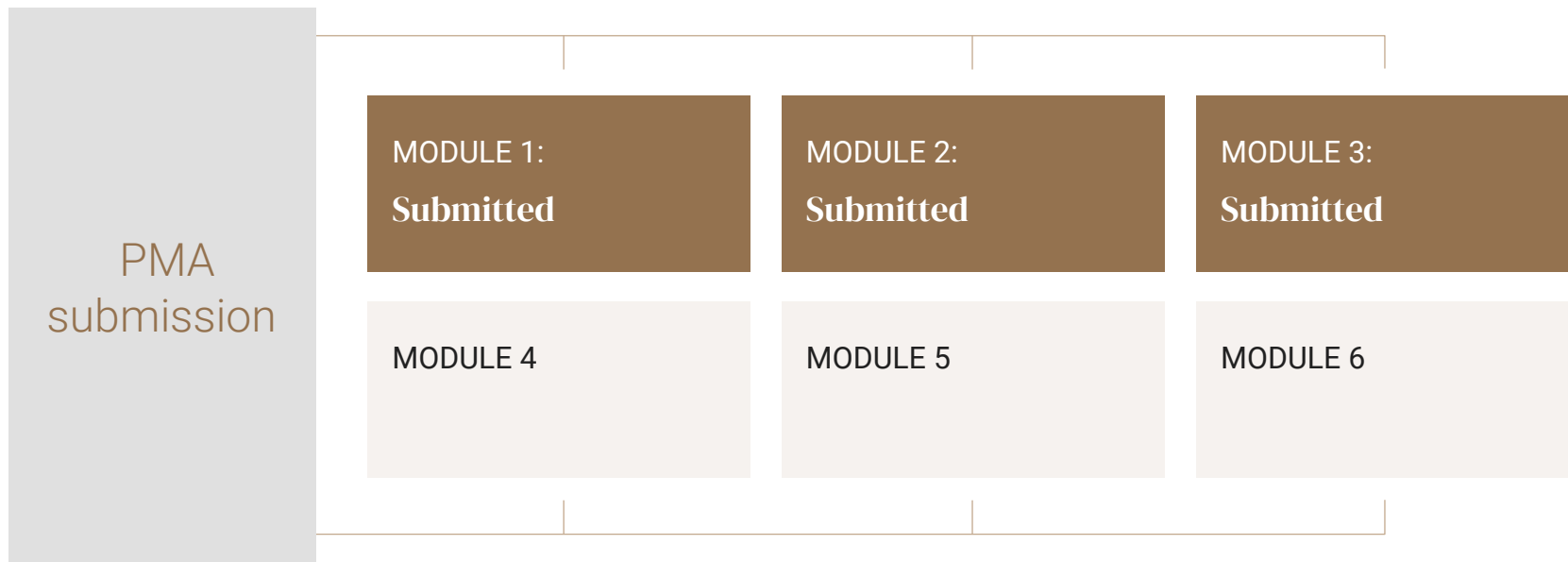
- Understand real-world clinical impact of Galleri in Medicare population
- Demonstrate commitment to underrepresented minority populations
- Engage CMS in support of coverage for Galleri

## Clinical surveillance

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- Develop and execute on clinical surveillance strategies
- Generate data from the fast-growing body of evidence to evaluate commercial Galleri use

# We are progressing our rolling modular PMA



**Final PMA submission anticipated in 1H 2026; ~12 month review period expected**



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# Opportunity beyond asymptomatic screening



# Symptomatic detection is a significant unmet need

~16M US PATIENTS/YEAR PRESENT WITH NON-SPECIFIC SYMPTOMS

## Many symptomatic patients are burdened with a prolonged diagnostic odyssey

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- >70% of patients with non-specific but concerning symptoms undergo imaging, scoping, biopsies, and other procedures
- >25% of patients take 4+ months to reach a diagnosis
- MCED testing provides opportunity to accelerate diagnosis and avoid harmful procedures
- Reimbursement using an existing coverage pathway may be possible

# SYMPLIFY: Strong results in a symptomatic patient population

## OVERALL AND TRENDS BY DIAGNOSTIC PATHWAY

**323** Cases for which MCED test detected a cancer signal

**244** In whom cancer was diagnosed

**98.4%** Overall specificity

**66.3%** Overall sensitivity

**75.5%** PPV

**97.6%** NPV

**90.3%** Overall accuracy of CSO prediction<sup>a</sup>

- Sensitivity increased with increasing age and cancer stage
- Highest sensitivity for patients in the upper GI referral pathway

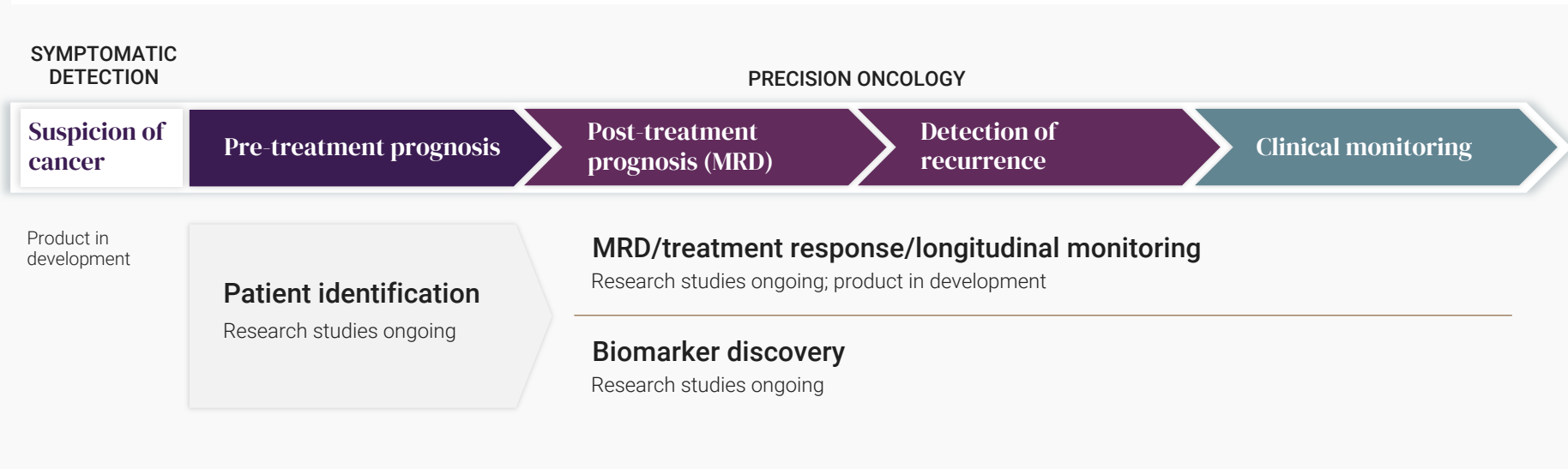


UNIVERSITY OF  
OXFORD

THE LANCET  
Oncology

ASCO<sup>®</sup>

# Product portfolio expanding across continuum of care



**Methylation-based platform enables disease prognostication, risk stratification, MRD detection, biomarker subtyping, and treatment/recurrence monitoring**

# Precision oncology demand is growing

## Research Use Only (RUO)



**Partnered with several leading oncology companies**

First pilot project in 2020

Enabled broader collaborations with RUO launch in 2023

## Clinical development



**AstraZeneca strategic collaboration** for CDx development

Expanding existing research relationships to clinical studies

## Clinical testing



Potential application of precision oncology includes clinical MRD/monitoring product

# GRAIL's methylation-based research platform is highly differentiated

## Technology advantages

- **Non-invasive test** enables cancer detection, classification, and monitoring with **limited plasma input and no tumor tissue; multi-cancer**
- 7–10-day clinical turnaround
- Quantitative measure of tumor burden

## Validated performance

- Sensitivity<sup>1</sup> on par with tumor-informed methods
- Quantitative output correlates with mutation panels
- Robust and reproducible test performance
- Low assay failure rate

# Demonstrated utility in precision oncology

## Heme prognosis, MRD



## Solid tumor prognosis, molecular response



## Multi-cancer subtyping



Munugalavadla, et al. Utility of ctDNA-based targeted methylation MRD assay for hematological malignancies. *Cancer Res* 1 April 2023.

Bar, et al. Response to first-line (1L) pembrolizumab (pembro) + chemotherapy (chemo) in non-small cell lung cancer (NSCLC) by blood tumor mutational burden (bTMB): the phase 2 KEYNOTE-782 trial. *Cancer Res* 15 April 2023.

Hong, et al. Tumor-naïve pre-surgical ctDNA detection is prognostic in clinical stage I lung adenocarcinoma. *NACLC* 2023.

Roychowdhury-Saha, et al. Analytical Performance of a Cell-free DNA Targeted Methylation Test for Early Lung Adenocarcinoma (LUAD) Recurrence Prediction. *NACLC* 2023.

Huang, et al. cfDNA Methylation-Based Pan-Hematologic Prognostic Classification. *Blood* 2023.

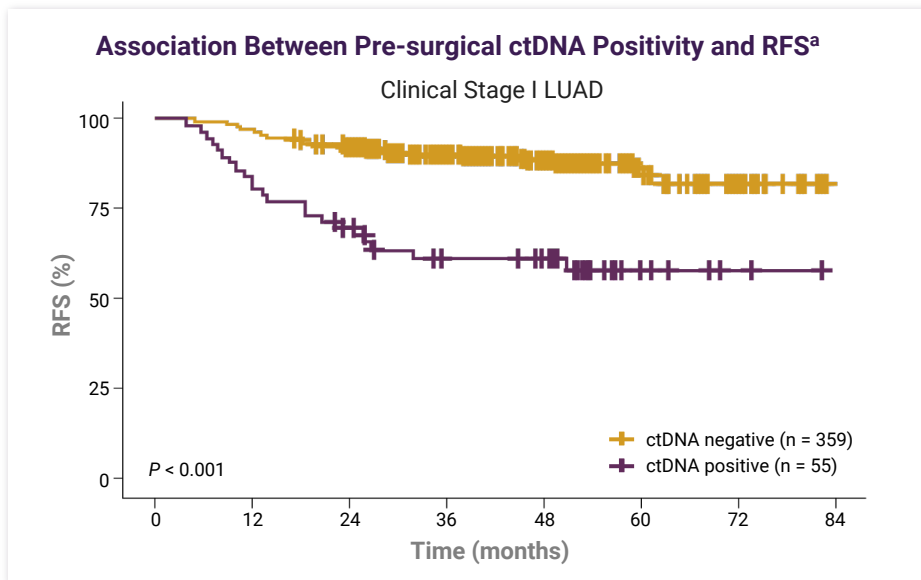
Melton, et al. A Novel Tissue-Free Method to Estimate Tumor-Derived Cell-Free DNA Quantity Using Tumor Methylation Patterns. *Cancers* 2024.

Nance, et al. Identification of cancer subtypes with a ctDNA-based targeted methylation assay. *Cancer Res* 15 March 2024.

Bar, et al. Association of circulating free DNA (cfDNA) maximum variant allele frequency (mVAF) levels with clinical outcomes in patients (pts) with metastatic nonsquamous non-small cell lung cancer (NSCLC) treated with pembrolizumab (pembro) + chemotherapy (chemo) in the phase 2 KEYNOTE-782 trial. *Cancer Research*.

# GRAIL's customizable platform demonstrates clinically meaningful lung cancer risk stratification

The Lung Prognosis Test performed prior to surgery exhibits clinically meaningful risk classification in clinical stage I lung adenocarcinoma



**Hazard ratio of relapse-free survival by Lung Prognosis Test result**

**3.8**

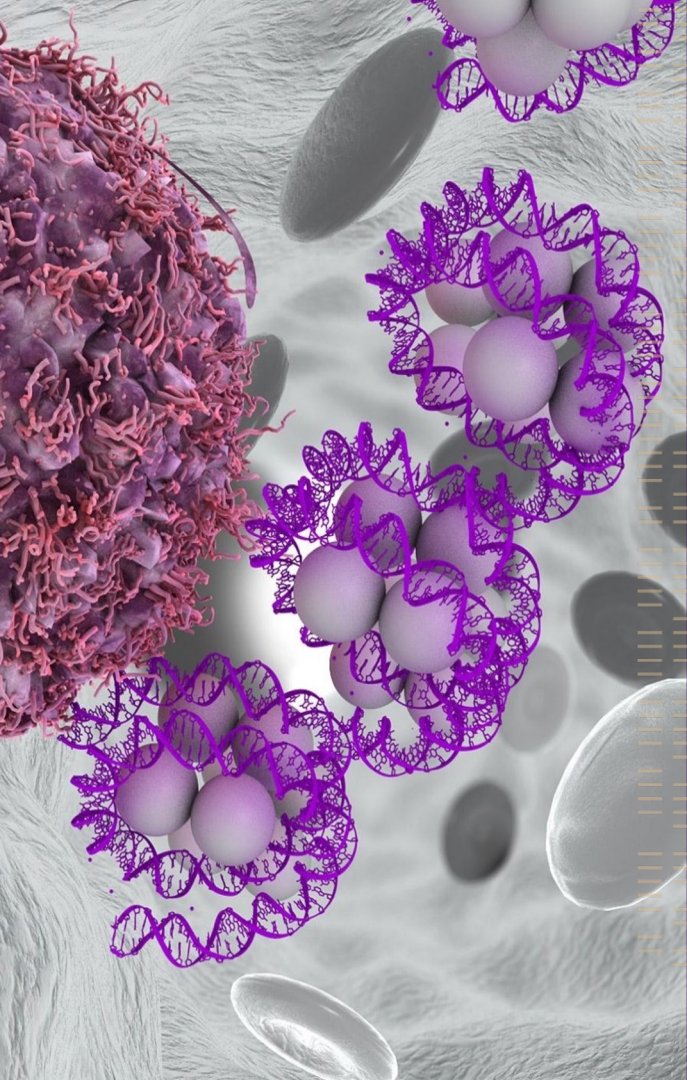
95% CI: 2.3-6.4  
p<0.001

Test positive Stage I patients experienced recurrence rates similar to unselected stage II patients<sup>b</sup>, suggesting potential to benefit from intensified therapy

RFS: relapse free survival. LUAD: lung adenocarcinoma.

Tumor-naïve pre-surgical ctDNA detection is prognostic in stage I lung adenocarcinoma, associating with PD-L1 positivity and high-grade histological subtype. Poster presented at the IASLC North American Conference on Lung Cancer (NACLC); Chicago, Illinois, USA; December 1-3, 2023.

<sup>a</sup> P-values represent log-rank P-values. Of 414 patients with clinical stage I LUAD analysed, 55 were ctDNA positive. <sup>b</sup> Yun et al., J. Thorac. Dis, 2019.



GRAIL

# Financial profile and inflection points



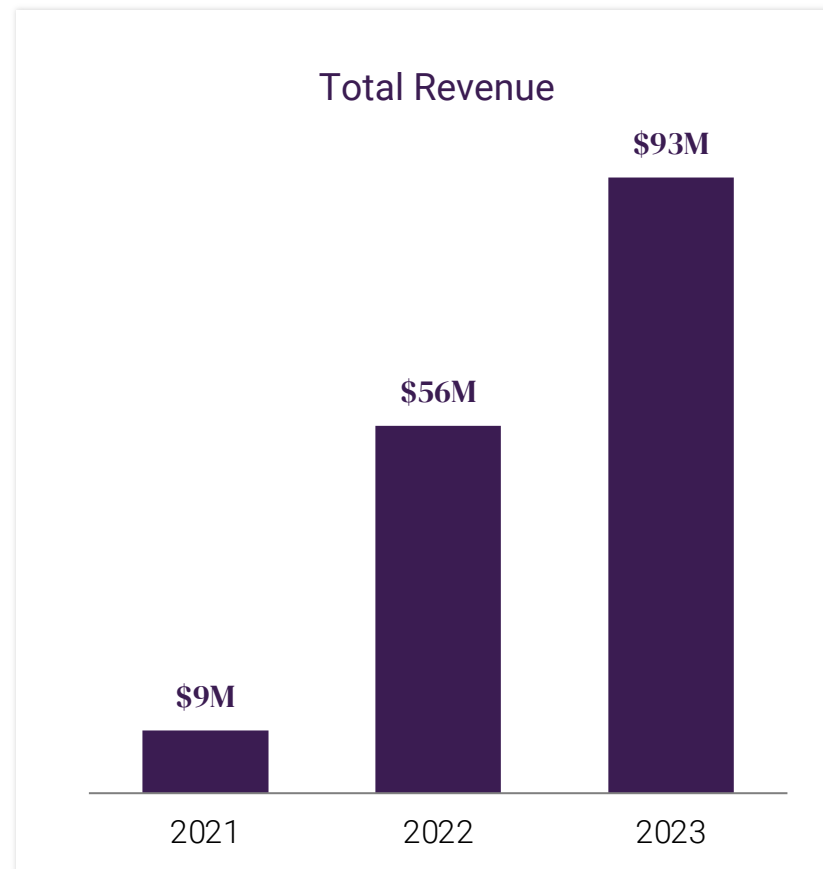
# Financial profile

## Revenue

- FY 2023: \$93M, 68% growth year-over-year
- Q1 2024: \$27M, 36% growth year-over-year

## Anticipated trend

- Strong revenue growth to continue
- Reductions in COGS/test in medium-term
- Operating loss declining over time
- Continued investments towards reimbursement
- Line of sight to profitability with reimbursement



# Well capitalized to drive strategy

2.5 years of cash funds through 2026+

**Fully funded  
through major  
milestones:**



*PMA filing*



*Full NHS Study Data*

Pro Forma Cash

~\$1 billion

2024 U.S. Galleri Sales

30-50% Growth

2023 Cash Burn  
*Adjusted for cash-based LTI*  
**\$532M**

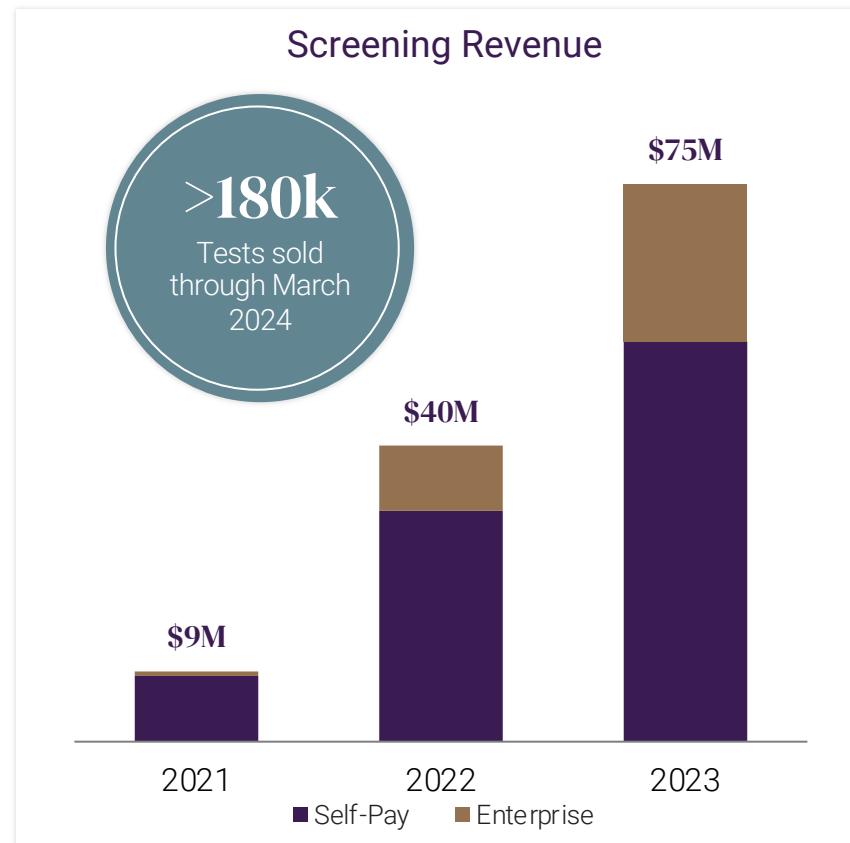
Projected  
Cash Burn 2H24\*  
**~\$250 M**

*\* Estimated cash burn post separation, based on illustrative spin date of June 12.  
Inclusive of expected cash burn June 13-Dec 31.*

# MCED screening revenue to grow over time

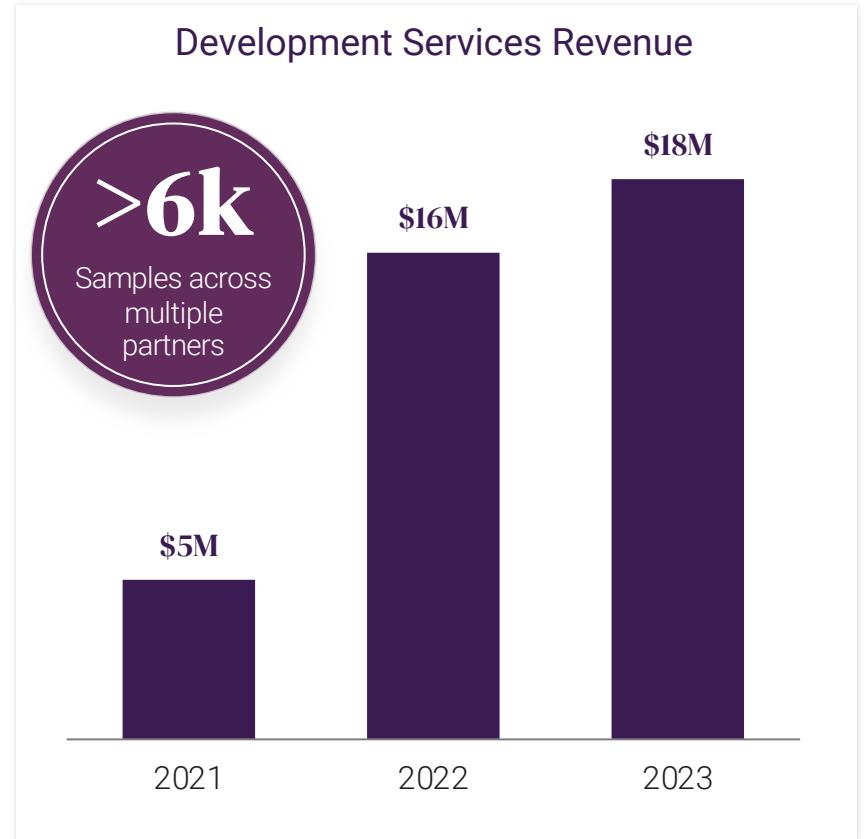
- Established commercial market leadership
- >100M intended use population in U.S. and potential implementation in UK
- Newer version of Galleri will enable price reductions
- Compliance with annual testing anticipated to grow

**U.S. screening market transforms with FDA approval**



# Precision oncology business diversifies our revenue

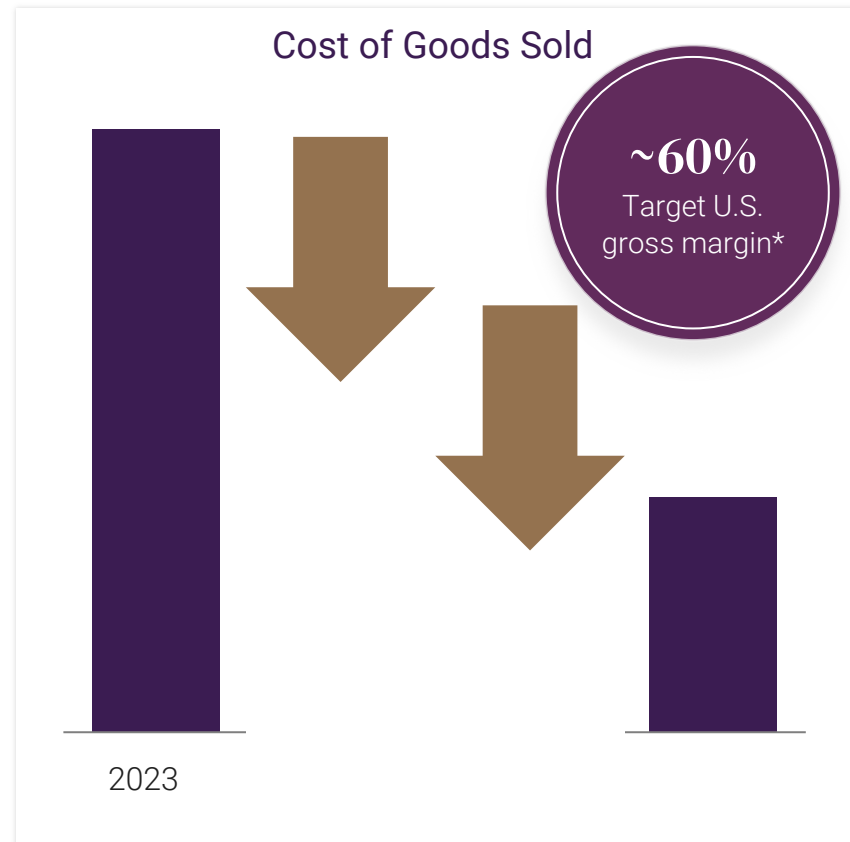
- Large number of oncology studies
- Significant need to identify residual disease or recurrence early to inform treatment decisions
- Pharma services partnerships generating pipeline of companion diagnostic products
- Potential to leverage existing technology to enter market with a clinical LDT



# Gross margin expected to improve over time

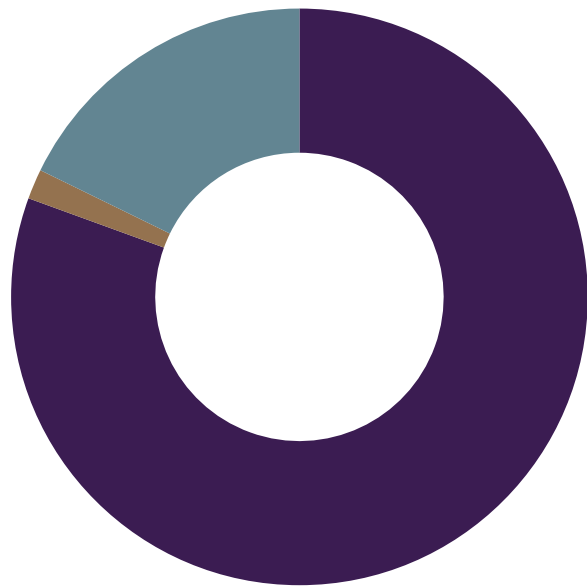
- Transition to automated platform expected in 2024
- Volume-based efficiencies achieved over time
- Ongoing development & technological advances to contribute to reductions over time

*\*Standalone cost of goods will include a royalty to ILMN, described in Form 10*



# Product revenue mix expected to diversify over next few years

## GRAIL 2023A



## GRAIL 2028E

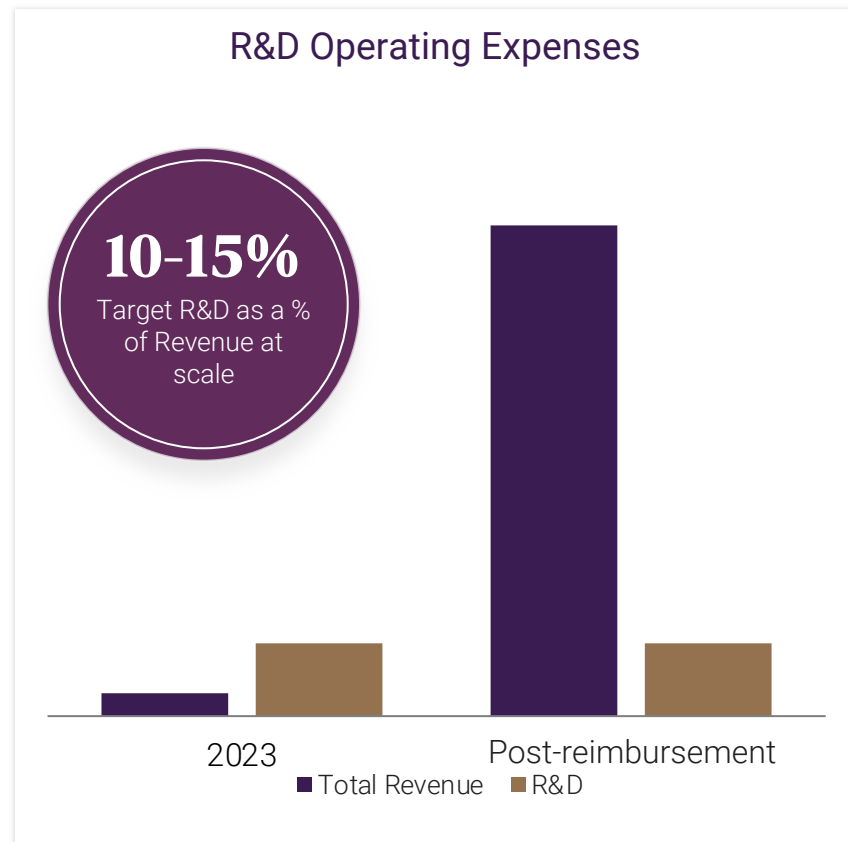


■ Galleri - US   ■ Galleri - International   ■ Precision Oncology & Symptomatic Detection

# R&D costs decreasing as a % of revenues

## Key drivers

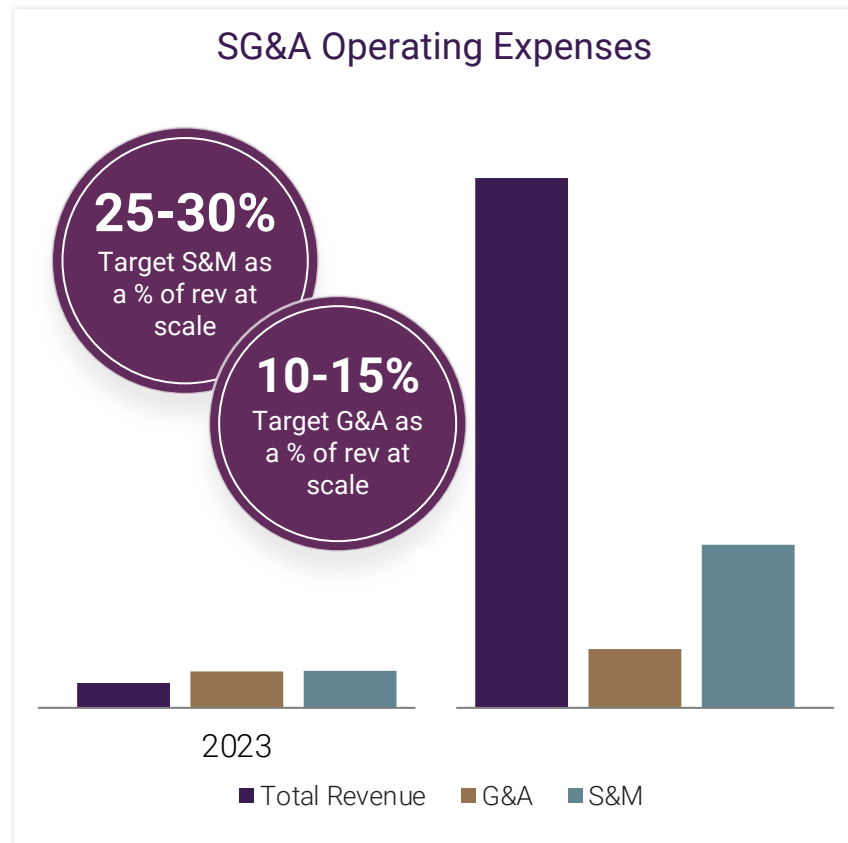
- Completion of clinical studies
- Launch of automated platform
- Continued investment in innovation & new product development



# SG&A costs become more efficient over time

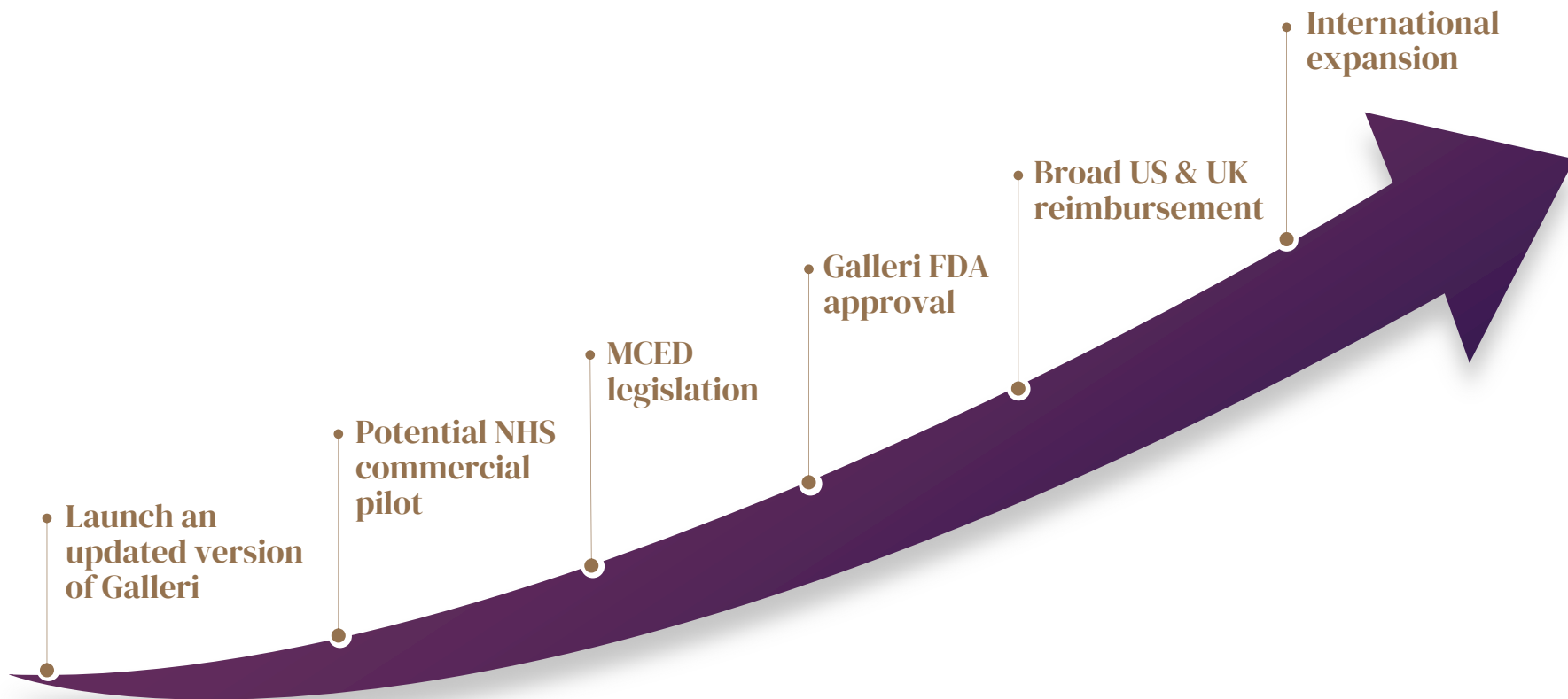
## Key drivers

- Build Galleri channels
- Progress pre-reimbursement sales through focused initiatives
- Salesforce expansions with regulatory approvals
- Pipeline product launches
- International expansions





# Multiple catalysts to drive value





GRAIL

Detect cancer early,  
when it can be cured.

# Non-GAAP Measures

## Overview

**Adjusted Gross Profit/(Loss)** is a key performance measure that our management uses to assess our operational performance, as it represents the results of revenues and direct costs, which are key components of our operations. We believe that this non-GAAP financial measure is useful to investors and other interested parties in analyzing our financial performance because it reflects the gross profitability of our operations, and excludes the indirect costs associated with our sales and marketing, product development, general and administrative activities, and depreciation and amortization, and the impact of our financing methods and income taxes.

Calculated as gross profit/(loss) adjusted to exclude amortization of intangible assets and stock-based compensation allocated to cost of revenue.

**Adjusted EBITDA** is a key performance measure that our management uses to assess our financial performance and is also used for internal planning and forecasting purposes. We believe that this non-GAAP financial measure is useful to investors and other interested parties in analyzing our financial performance because it provides a comparable overview of our operations across historical periods. In addition, we believe that providing Adjusted EBITDA, together with a reconciliation of net income (loss) to Adjusted EBITDA, helps investors make comparisons between our company and other companies that may have different capital structures, different tax rates, different operational and ownership histories, and/or different forms of employee compensation.

Calculated as as net income (loss) adjusted to exclude interest (income) expense, income tax expense (benefit), depreciation, impairment of goodwill, stock-based compensation, amortization of intangible assets, and Illumina/GRAIL merger & divestiture legal and professional services costs.

# Non-GAAP Measures FY 2023

Non-GAAP Adjusted Gross Profit (\$ in millions)	FY 2023	FY 2022
<b>Gross Loss</b>	<b>\$(95.6)</b>	<b>\$(116.4)</b>
Amortization of intangible assets	133.9	133.9
Stock-based compensation	1.9	0.9
<b>Adjusted Gross Profit</b>	<b>\$40.2</b>	<b>\$18.4</b>

Non-GAAP EBITDA (\$ in millions)	FY 2023	FY 2022
<b>Net Loss – GAAP</b>	<b>\$(1,465.7)</b>	<b>\$(5,399.1)</b>
Interest income	(8.0)	(1.7)
Income tax benefit	(41.9)	(42.2)
Amortization of intangible assets	138.3	138.3
Depreciation	20.4	16.4
Impairment of goodwill and intangibles	718.5	4,700.4
Illumina/GRAIL merger/divestiture legal and professional services costs	17.3	12.1
Stock-based compensation	97.2	75.7
<b>Adjusted EBITDA</b>	<b>\$(523.9)</b>	<b>\$(500.1)</b>

# Non-GAAP Measures Q1 2024

Non-GAAP Adjusted Gross Profit (\$ in millions)	Q1 2024	Q1 2023
<b>Gross Loss</b>	<b>\$(21.9)</b>	<b>\$(25.6)</b>
Amortization of intangible assets	33.5	33.5
Stock-based compensation	0.4	0.3
<b>Adjusted Gross Profit</b>	<b>\$12.0</b>	<b>\$8.2</b>

Non-GAAP EBITDA (\$ in millions)	Q1 2024	Q1 2023
<b>Net Loss – GAAP</b>	<b>\$(218.9)</b>	<b>\$(193.7)</b>
Interest income	(2.9)	(2.2)
Income tax benefit	(5.6)	(8.0)
Amortization of intangible assets	34.6	34.6
Depreciation	5.4	5.2
Illumina/GRAIL merger/divestiture legal and professional services costs	6.3	4.8
Stock-based compensation	29.1	21.5
<b>Adjusted EBITDA</b>	<b>\$(152.0)</b>	<b>\$(137.8)</b>