

COLLEGE OF POPULATION HEALTH

Multi-Cancer Early Detection: Understanding the Pathfinder Study and Clinical Implementation

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December 8, 2022



Today's Presenters



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Eric Klein, MD
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Professor of Surgery
Cleveland Clinic Lerner College of Medicine



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Associate Dean for Strategic Development
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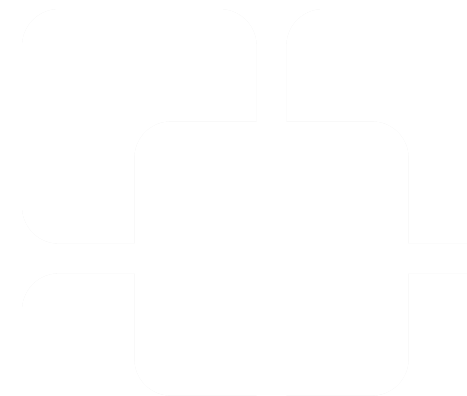
The Promise of Multicancer Early Detection

Eric A. Klein, MD
Emeritus Professor and Chair
Glickman Urological and Kidney Institute
Cleveland Clinic Lerner College of Medicine

Fellow, Stanford Distinguished Careers Institute

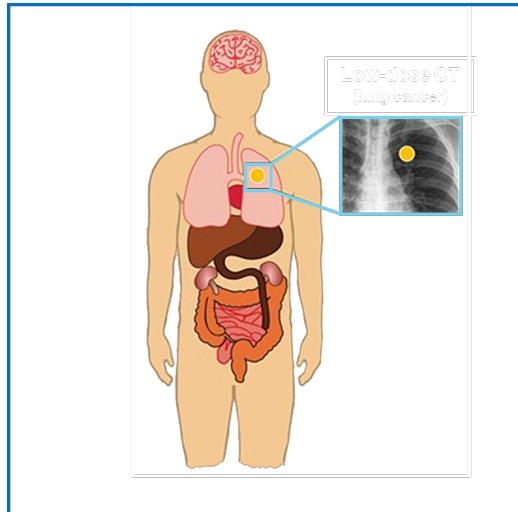
Disclosure:

I am a consultant for GRAIL, Inc

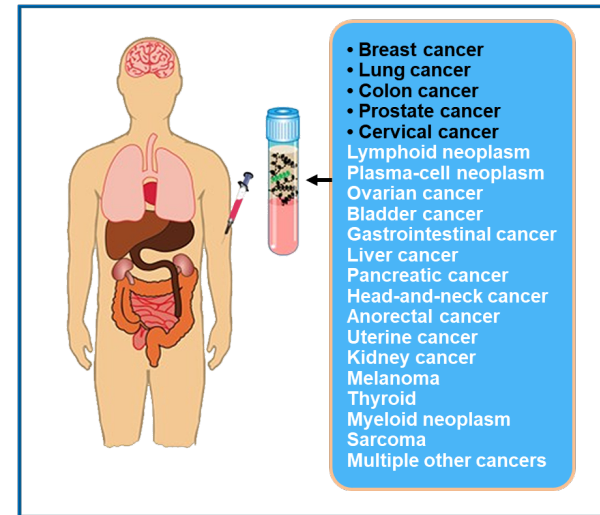


Paradigm Shift

Screening for individual cancers

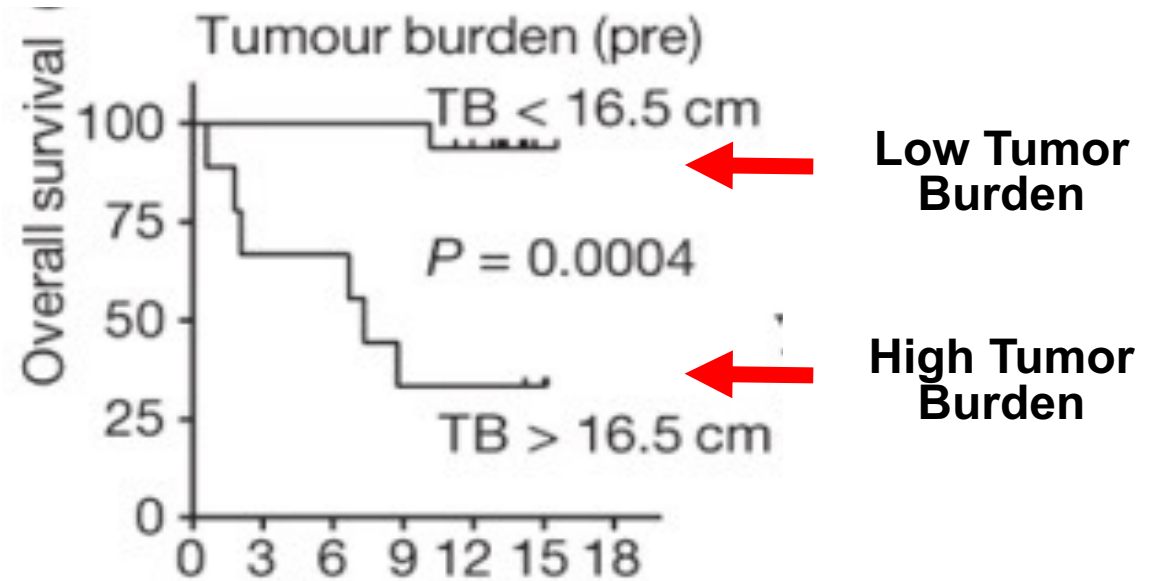
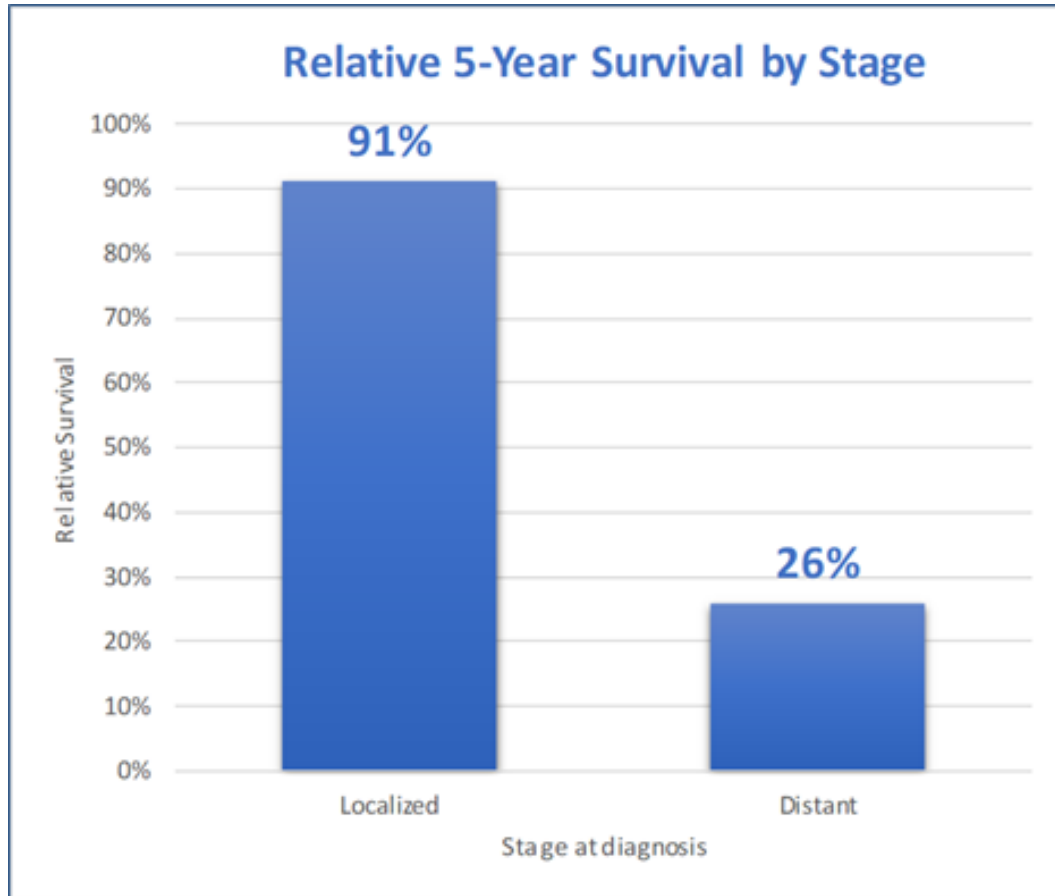


Screening individuals for cancer



- Why is this necessary?
- How is it possible?

Why Early Detection is Important



Why is this Necessary?

Despite this:

USPSTF Recommendations for Cancer Screening

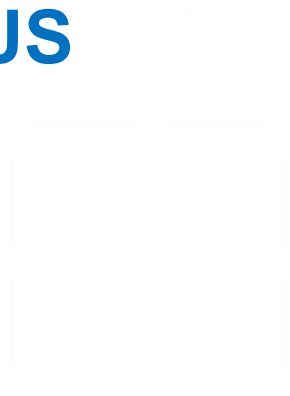
Cancer	Grade	Population	Modality/ Recommendation
Cervical	A	Women aged 21 to 65	Regular screening (3–5 years) using cervical cytology and/or HPV tests
Colorectal	A B	Adults aged 50 to 75 Adults aged 45-49	Regular annual screening, multiple effective methods available
Breast	B C	Women aged 50 to 74 Women aged 40 to 49	Biennial screening mammography
Lung	B	Adults aged 55–80, with history of smoking	Annual low-dose computed tomography (LDCT) screening
Prostate	C	Men aged 55 to 69	Periodic PSA screening on case-by-case basis



Mortality



> 600,000 people die of cancer every year in the US



Limitations of Current Screening Paradigm

Compelling Rationale for a Paradigm Shift to Include MCED

~ 600,000 cancer deaths per year in the US despite current screening

**70% of all cancers are not found
Unscreened cancers account for ~70% of deaths**

**Adherence rates are sub-optimal
5% (lung) - 80% (cervical)**

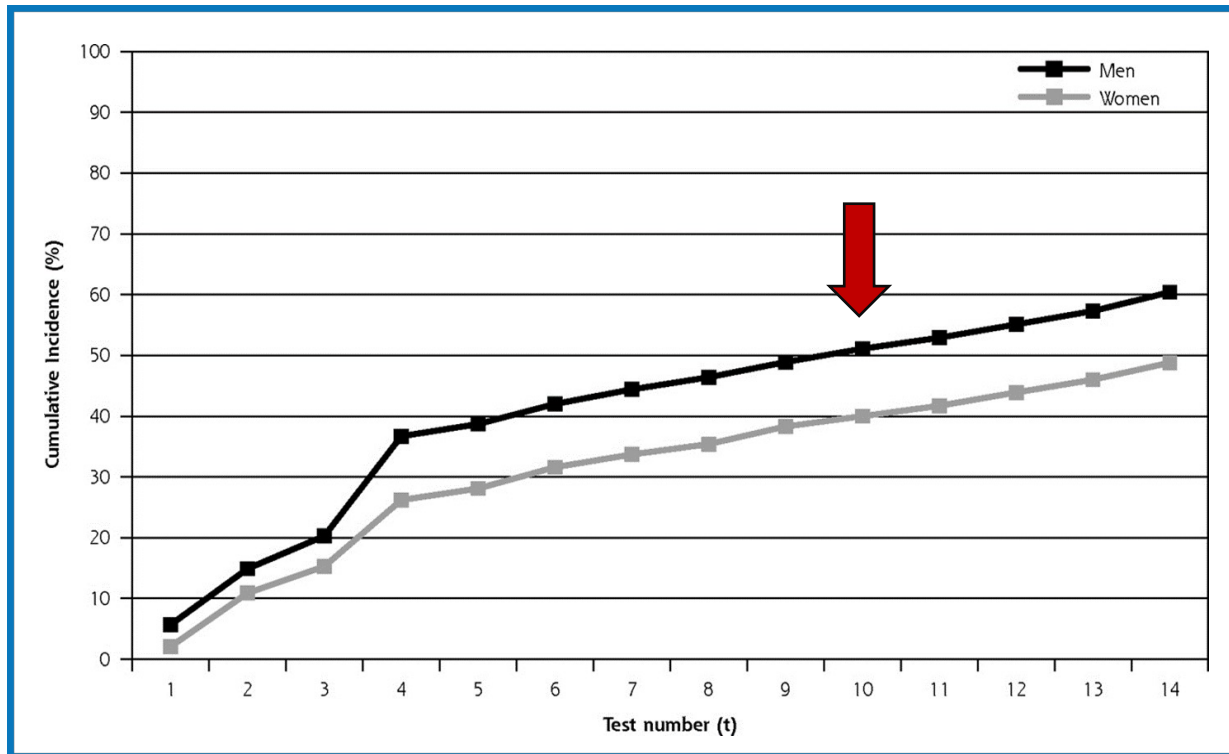
More likely to be diagnosed with a different cancer than those targeted by screening

PPV for single cancers is <10%

Cumulative false positive rates are high (40-50%)

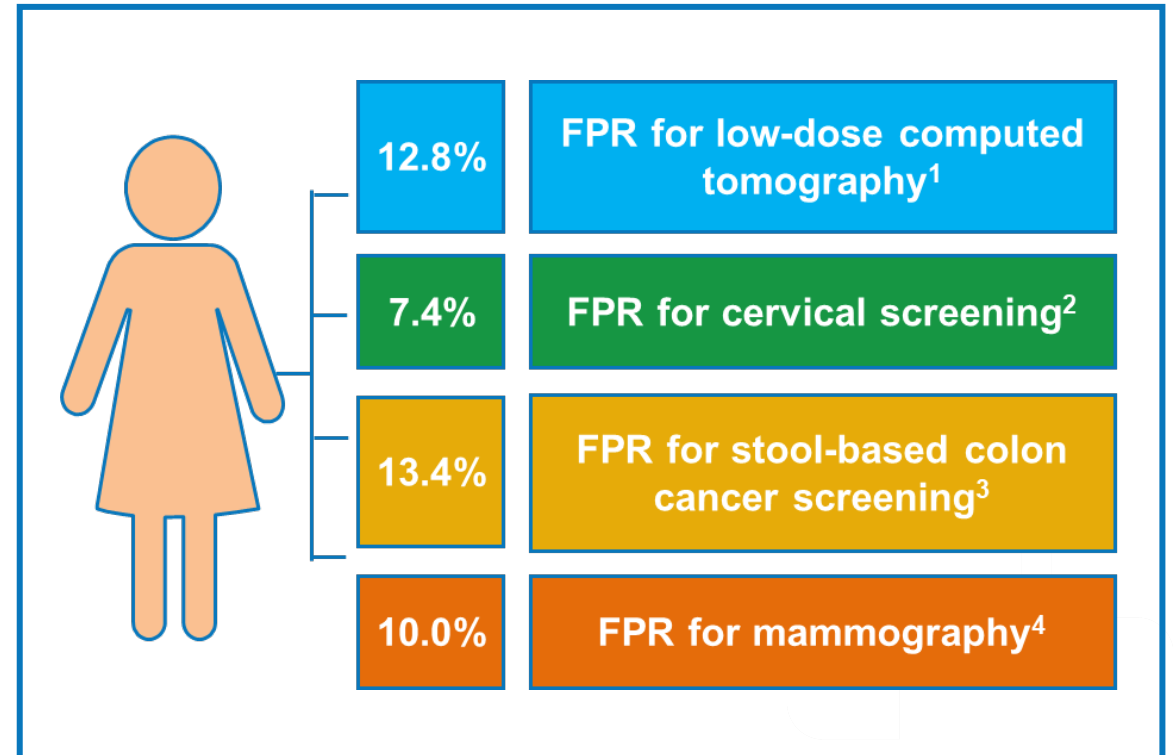
Cumulative False-Positive Rate From Single-Cancer Screening

Cumulative probability of a false-positive result in the PLCO trial



Croswell et al. *Ann Fam Med* 2009;7:212-222

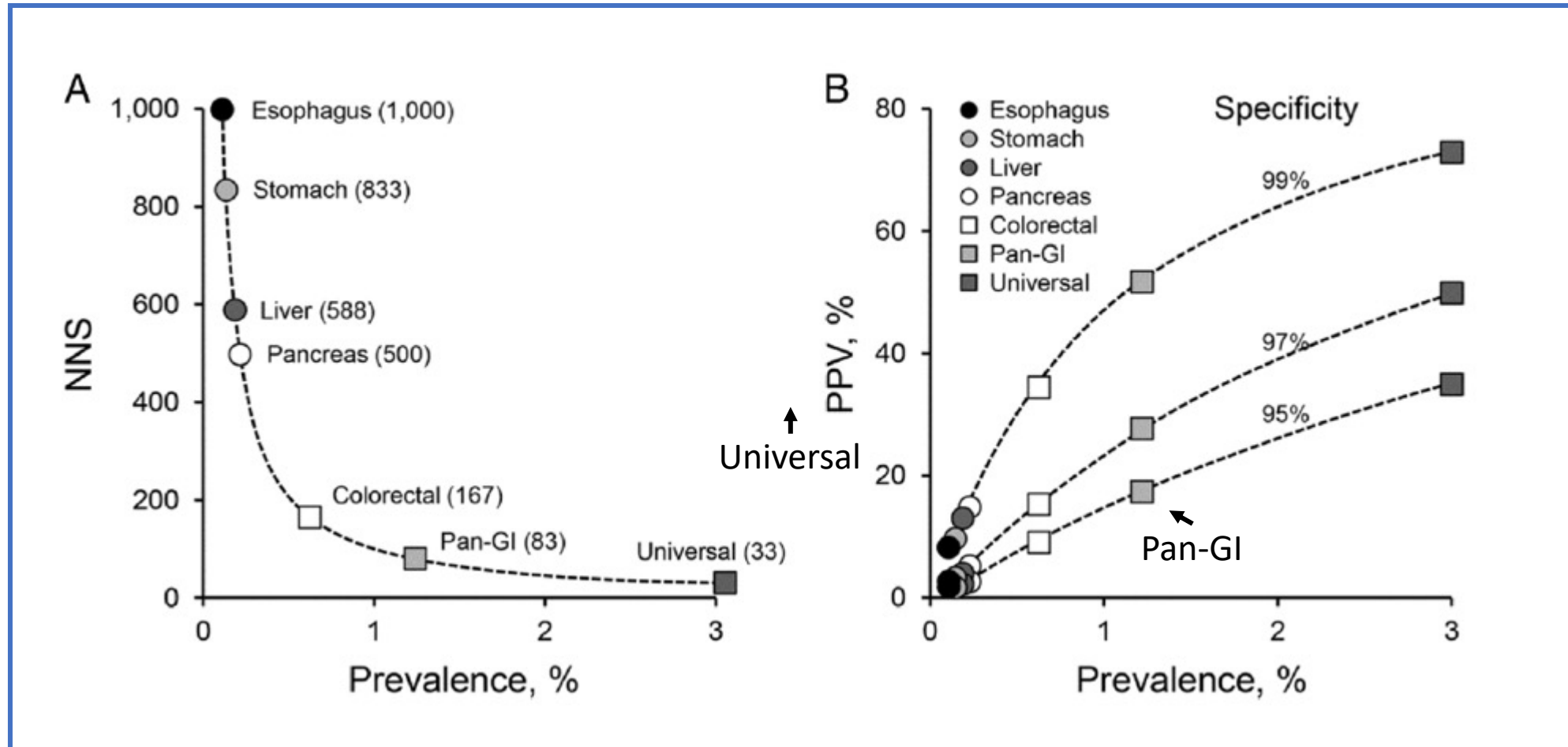
A 60-year-old women with a history of smoking screened for 4 cancers would have a 43.6% false positive rate (FPR)¹⁻⁴



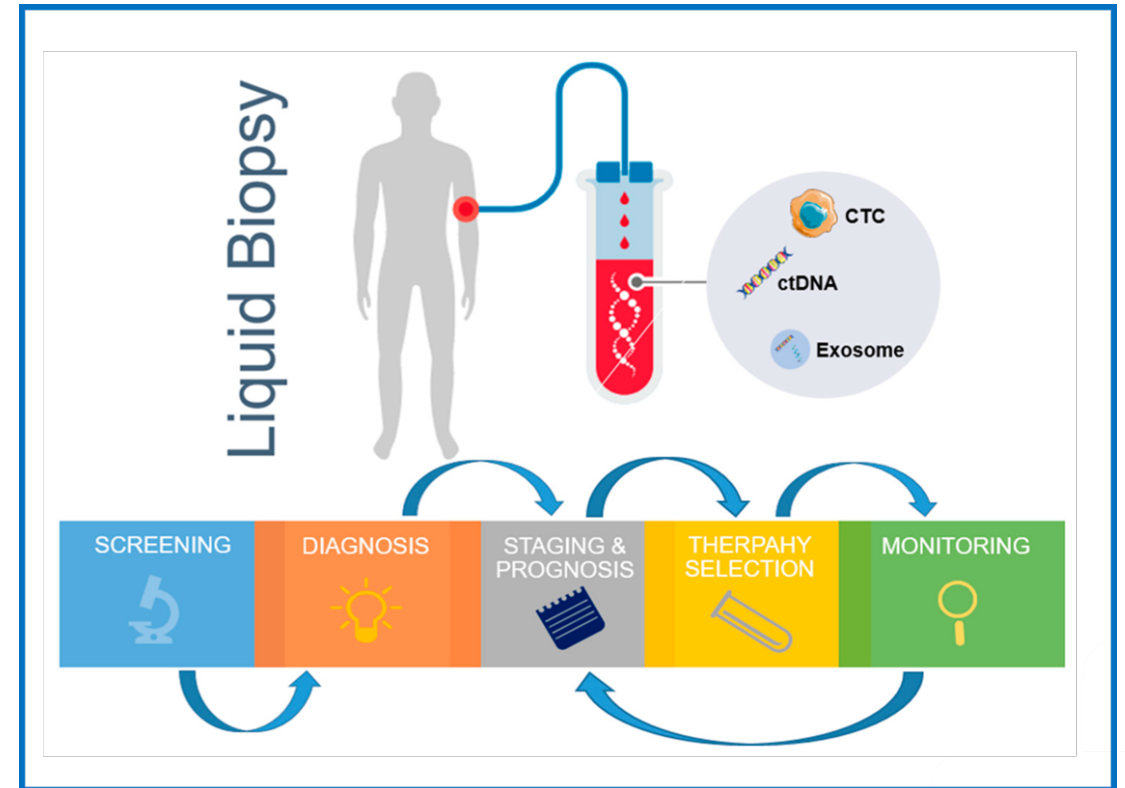
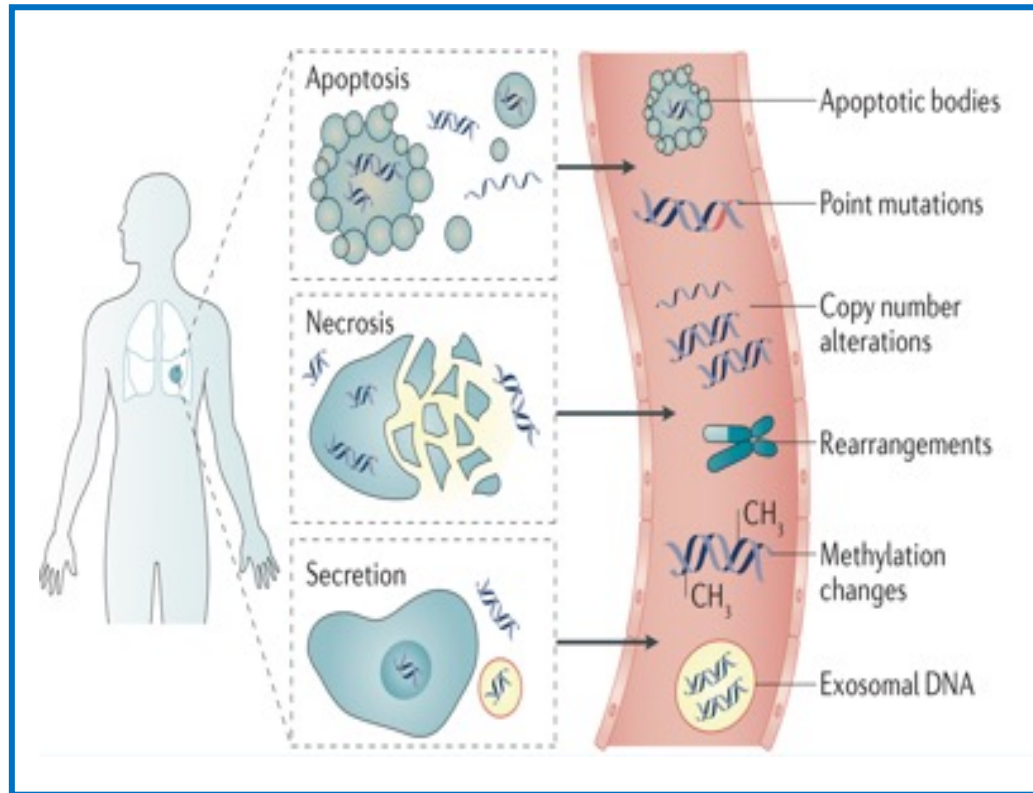
Pinsky PF, et al. *Ann Intern Med*. 2015;162:485-491. 2. Melnikow J, et al. *JAMA*. 2018;320:687-705. 3. US Food and Drug Administration (FDA) premarket approval (PMA) P130017 4. Lehman CD, et al. *Radiology*. 2017;283:49-58

Universal Cancer Screening Improves Efficiency

Effect on NNS & PPV



Liquid Biopsy

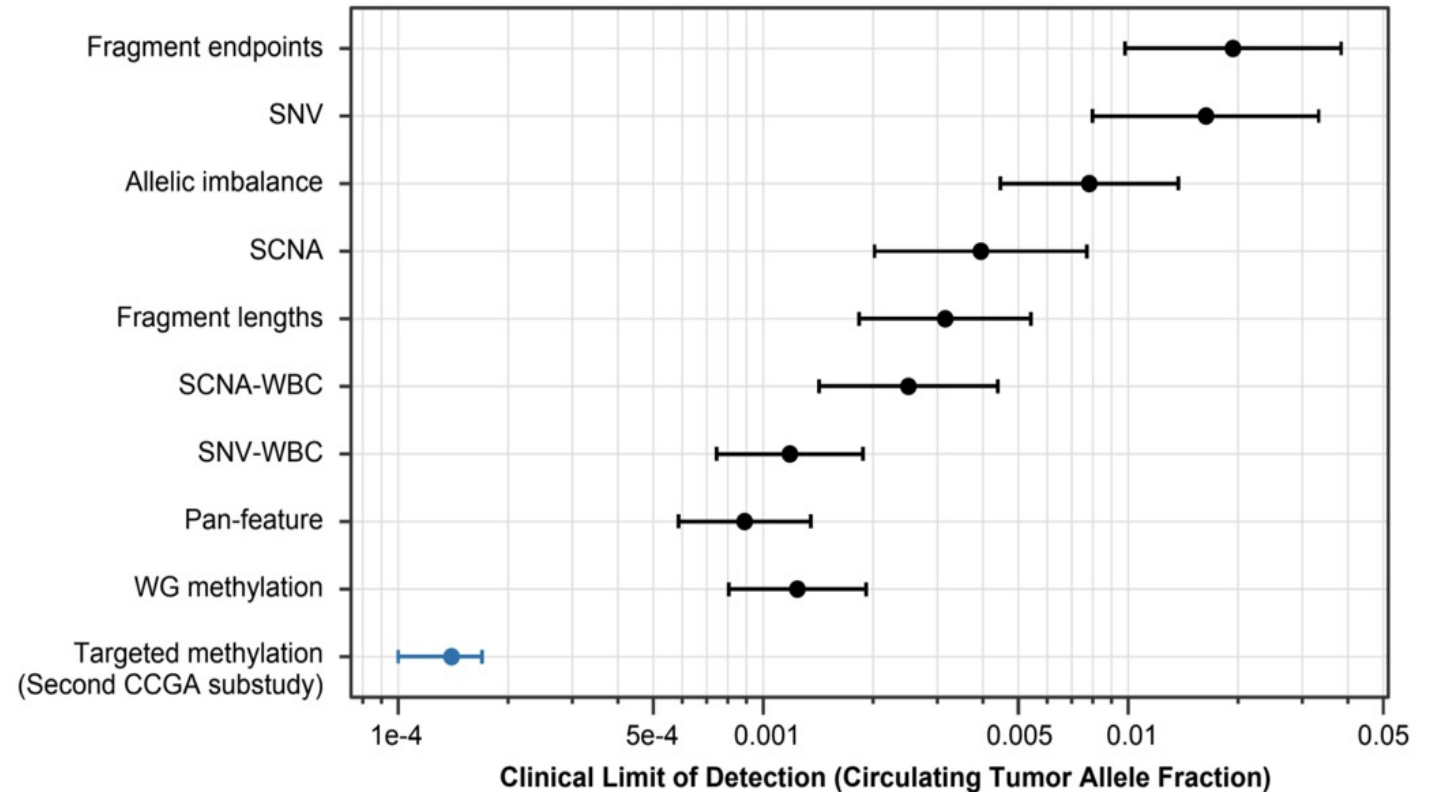
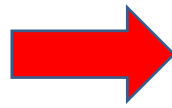


Key Concepts for Understanding MCED

- **MCED is not about finding a particular cancer type**
- **MCED should not be compared to tests that screen for individual cancers**
- **MCED is intended as an adjunct to standard screening tests**
- **MCED is a screening test and requires a diagnostic evaluation**

Cancer Signals in Blood

- Methylation
- Mutations
- Chromosomal copy number alterations
- Fragmentomics
- Proteins
- miRNA
- Microvesicles
- Multi-Analyte

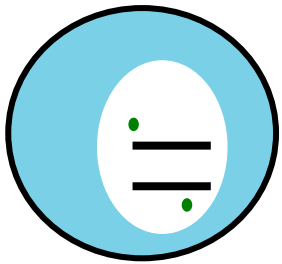


The targeted methylation assay underlying Galleri is based on a shared cancer signal across many cancer types

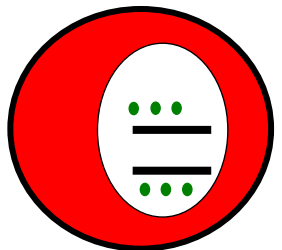
Biology of Methylation

Integration of Genomic and Epigenomic Data

Normal cell



Cancer cell



Tissue-specific methylation 'fingerprints'

Lung



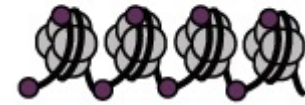
Liver



Colon



Non-cancer colon cfDNA fragment



Non-cancer liver cfDNA fragment



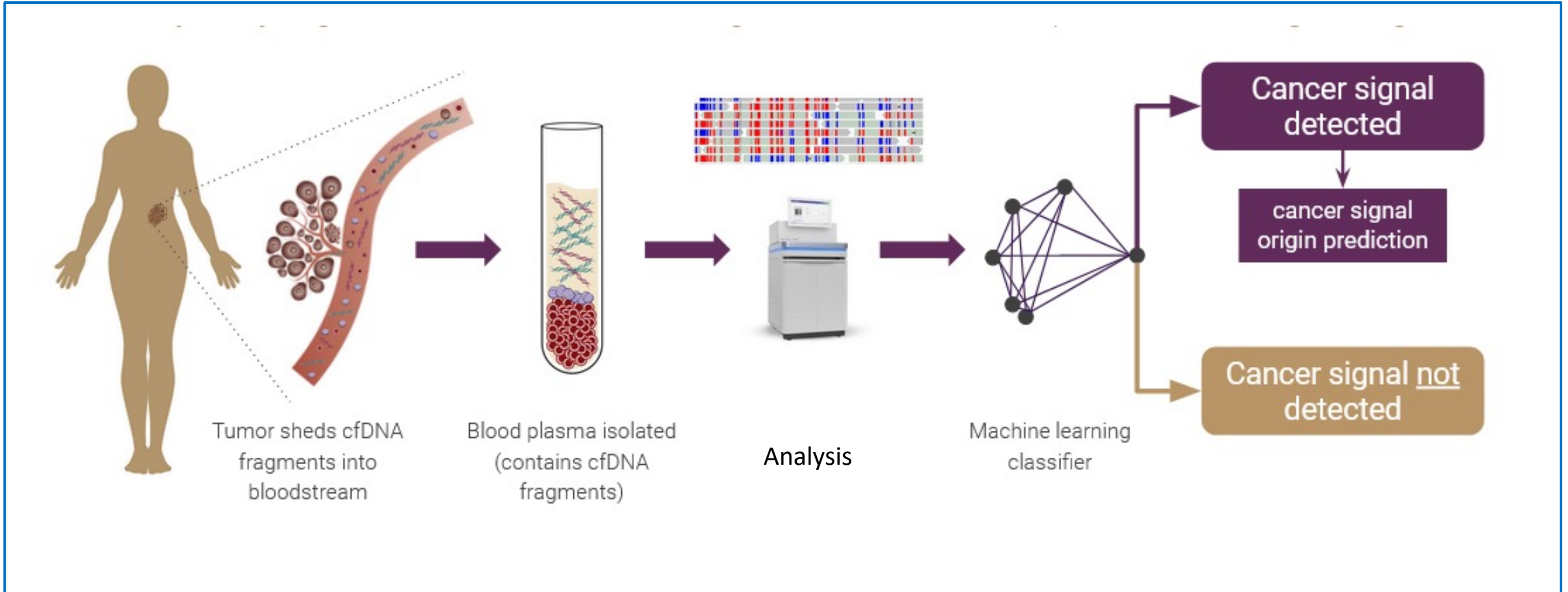
Non-cancer lung cfDNA fragment



Colon cancer cfDNA fragment



MCED Clinical Workflow



Results Report

Multi-cancer early detection test report

Patient	Sample	Ordering Provider
Name: Firstname Lastname	GRAIL ID: ID123456789	Name: Firstname Lastname, MD
Patient ID: PathPar1234567890	Report Date: 15-OCT-2019 / 18:13 PT	Location: Academic Hospital - Clinic 1
DOB: 01-JAN-1965	Collection Date: 20-SEP-2019 / 21:39 PT	Address: 123 Maple St. Unit 321 Rainbow Town, CA 94000
Bio Sex: Female		Phone: (123) 456-7890
Email: firstnamelastname@email.com		Fax: (987) 654-3210

Results

Cancer Signal Detected

The Galleri® test detected DNA methylation signals associated with cancer in the analyzed cell-free DNA obtained from the patient's sample. **Detection of a cancer signal is not a diagnosis of cancer. Diagnostic evaluation for cancer should be conducted.**

Top Predicted Signal Origins to Guide Diagnostic Evaluation

Head & Neck

Signal Origin(s) Score



Included sub-categories of the predicted origins:

- **Head & Neck:** Oropharynx, Hypopharynx, Nasopharynx, Larynx, Lip and Oral Cavity (including Oral Tongue), Nasal Cavity, Paranasal Sinuses, Major Salivary Glands
- **Lung:** Lung, Bronchus

This chart displays the top score(s) of Cancer Signal Origins predicted by the Galleri test. The size of each bar represents confidence in predicting cell or tissue origin of detected cancer signal: long bar reflects higher confidence and short bar reflects lower confidence in cancer signal origin. This chart does not provide an indication of the overall likelihood of cancer.

Cancer signals are organized into 21 Cancer Signal Origins, which are listed in the Method section. For more information, please visit www.galleri.com/test-report.

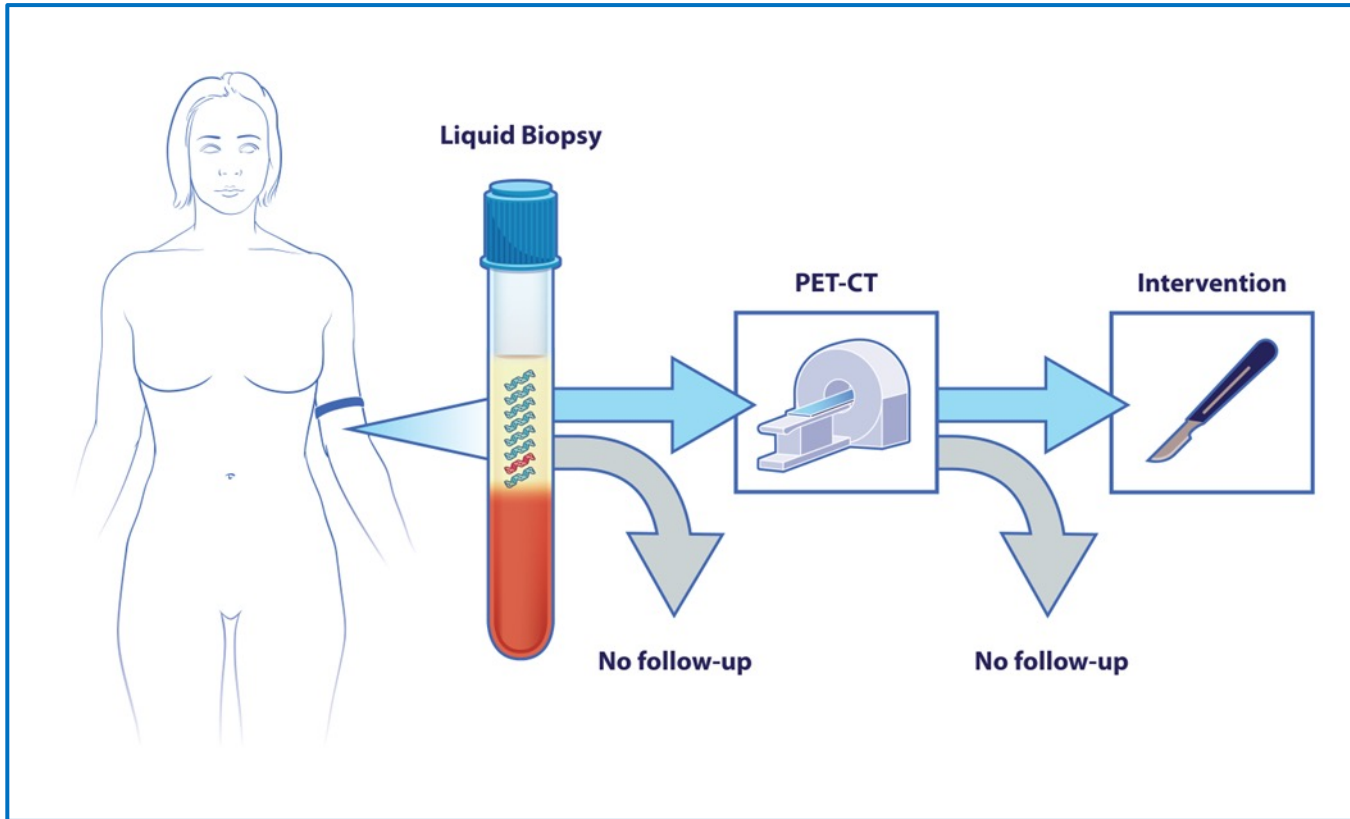
Published MCED Studies

CancerSeek/DETECT-A

Circulating Cancer Genome Atlas (CCGA)

Pathfinder

DETECT- A Study

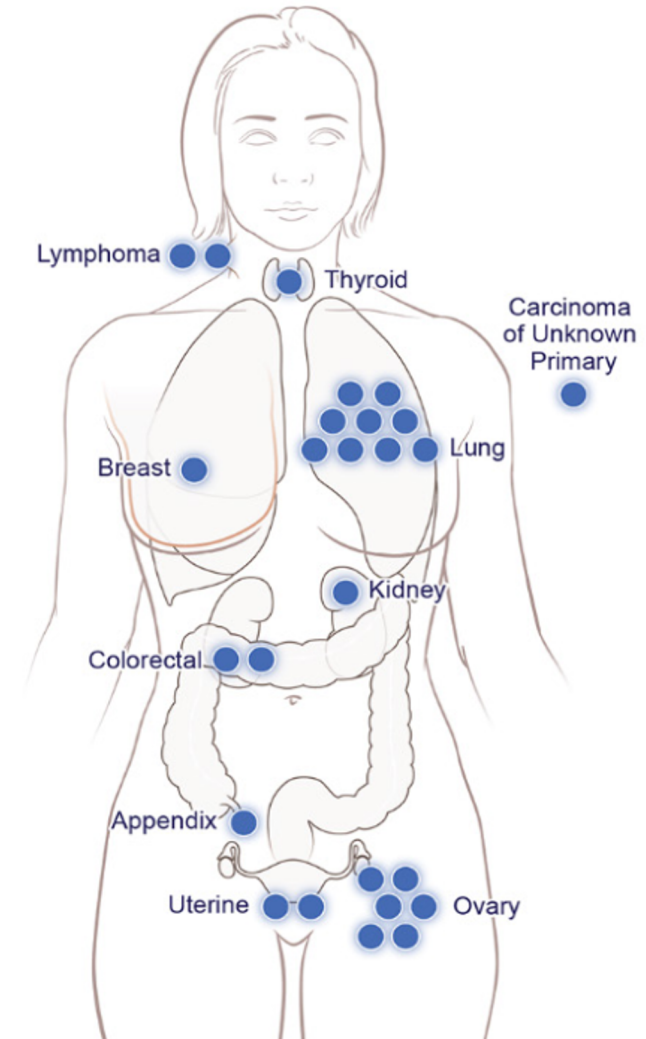
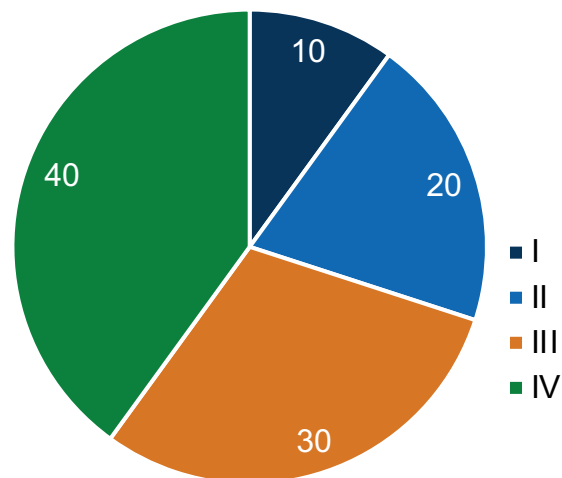


- **10,000 women, ages 65 – 75**
- **No current or previous known cancer**

DETECT-A: Results and Test Performance

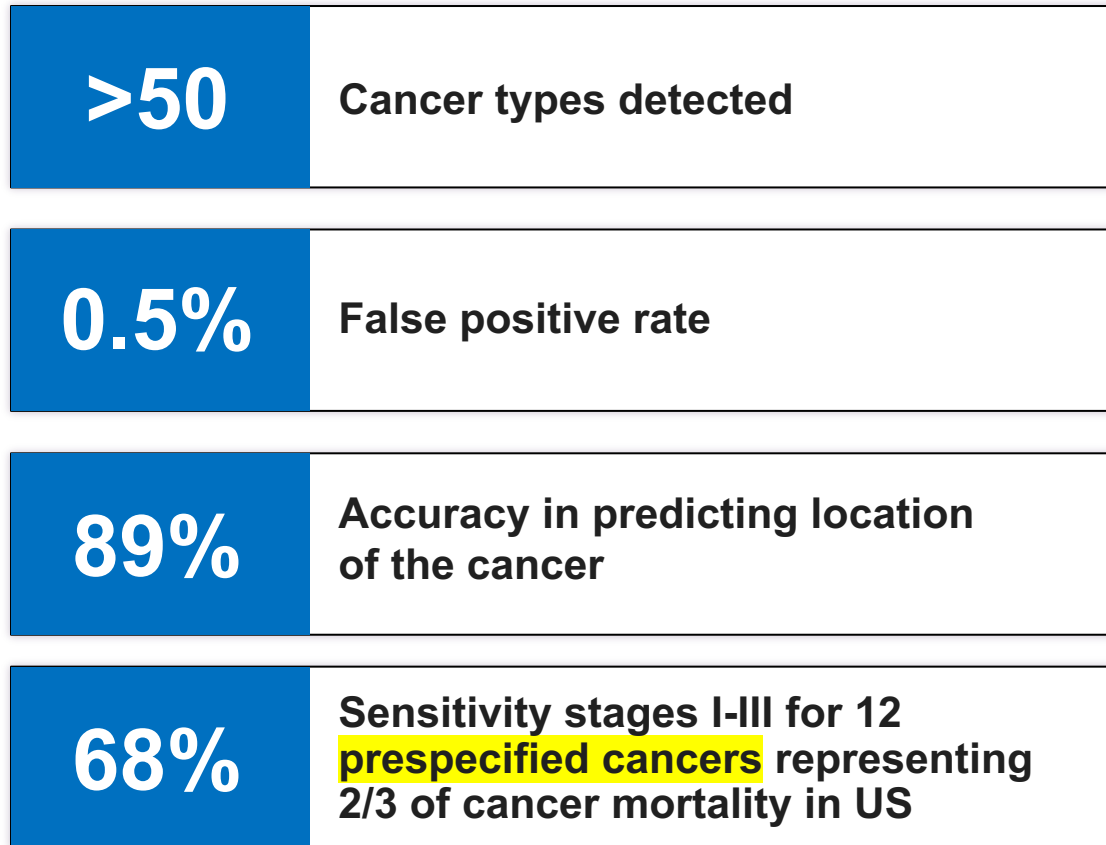
- 9,911 women were screened
 - 26 cancers were detected
 - Double the number of cancers detected by standard-of-care screening alone.

Stage at Diagnosis, %



Results of CCGA3

Prospective, Case-Control, Discovery & Validation Study



> 50 cancers, including unscreened cancers such as:

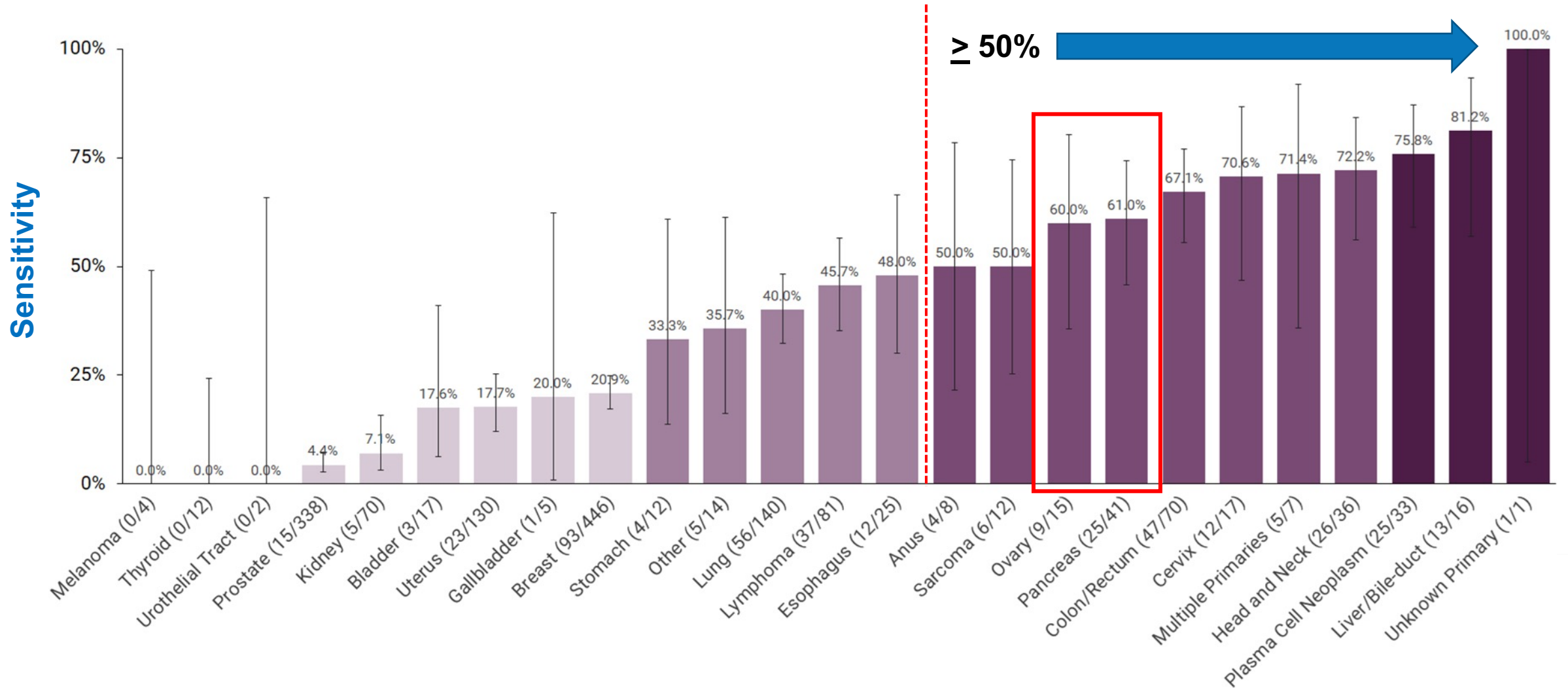
- Anus
- Corpus uteri (2 types)
- Esophagus
- Exocrine pancreas
- Gallbladder
- Hodgkin and non-Hodgkin lymphoma
- Bile duct (3 types)
- Kidney
- Larynx
- Leukemia
- Liver
- Melanoma of the skin
- Malignant pleural mesothelioma
- Merkel cell carcinoma
- Nasopharynx
- Neuroendocrine (3 types)
- Oral cavity
- Oropharyngeal
- Oro- and hypo-pharynx
- Ovary
- Plasma cell myeloma
- Renal pelvis and ureter
- Soft tissue sarcoma (5 types)
- Small intestine
- Stomach
- Testis
- Urinary bladder
- Vagina
- Vulva

USPSTF Recommended screening programs

Breast | Cervix uteri | Colon and rectum | Lung | Prostate

N = 4,077

Sensitivity of Cancer Signal Detection by Cancer Type: Stage I-II



PATHFINDER

Prospective Study in Intended Use Population

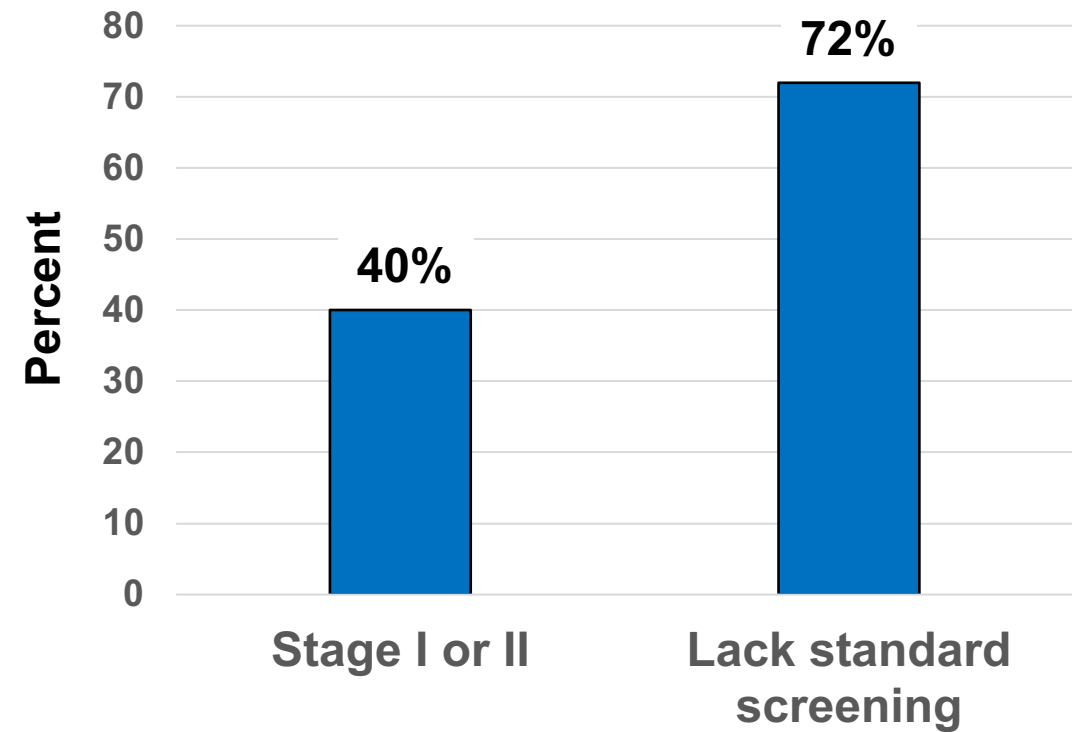


Results returned to provider and participant

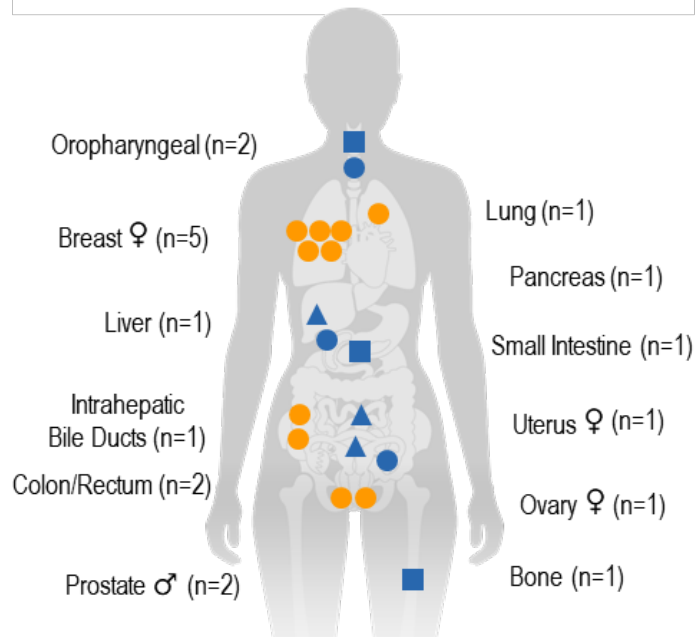
PATHFINDER

Cancer signal was detected in 1.4% (92/6621 participants)

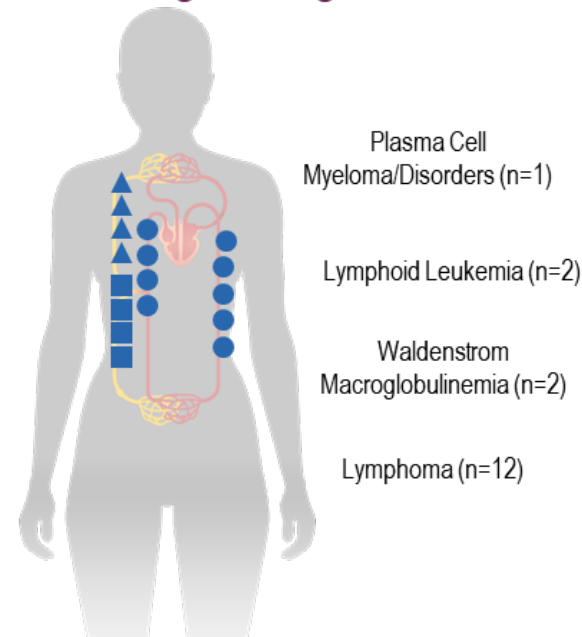
MCED Detected Cancers



18 Participants
had 19 Solid Tumors



17 Participants had
17 Hematologic Malignancies



▲ Stage I ■ Stage II ● Stage III/IV/No Stage ● USPSTF cancer screening^a ● No standard screening^b

Consistent Results Across Studies

Clinical Validation Study (CCGA3)		
0.5% False positive rate	44% Positive predictive value	89% Localization accuracy

Confirmatory Intended Use Population Study (PATHFINDER)*		
0.5% False positive rate	43% Positive predictive value	88% Localization accuracy**

Galleri Commercial Experience

Confirmed Diagnoses

108 Confirmed cancers to date based on short-term follow up

94% of these cases had a correctly predicted first or second Cancer Signal Origin

Stage I:

- Esophagus
- Pancreas
- Gastrointestinal Stromal Tumor
- Uterus
- Head and Neck

Stage II:

- Breast
- Liver
- Colon
- Rectum
- Head and neck

Reported Cancer Types

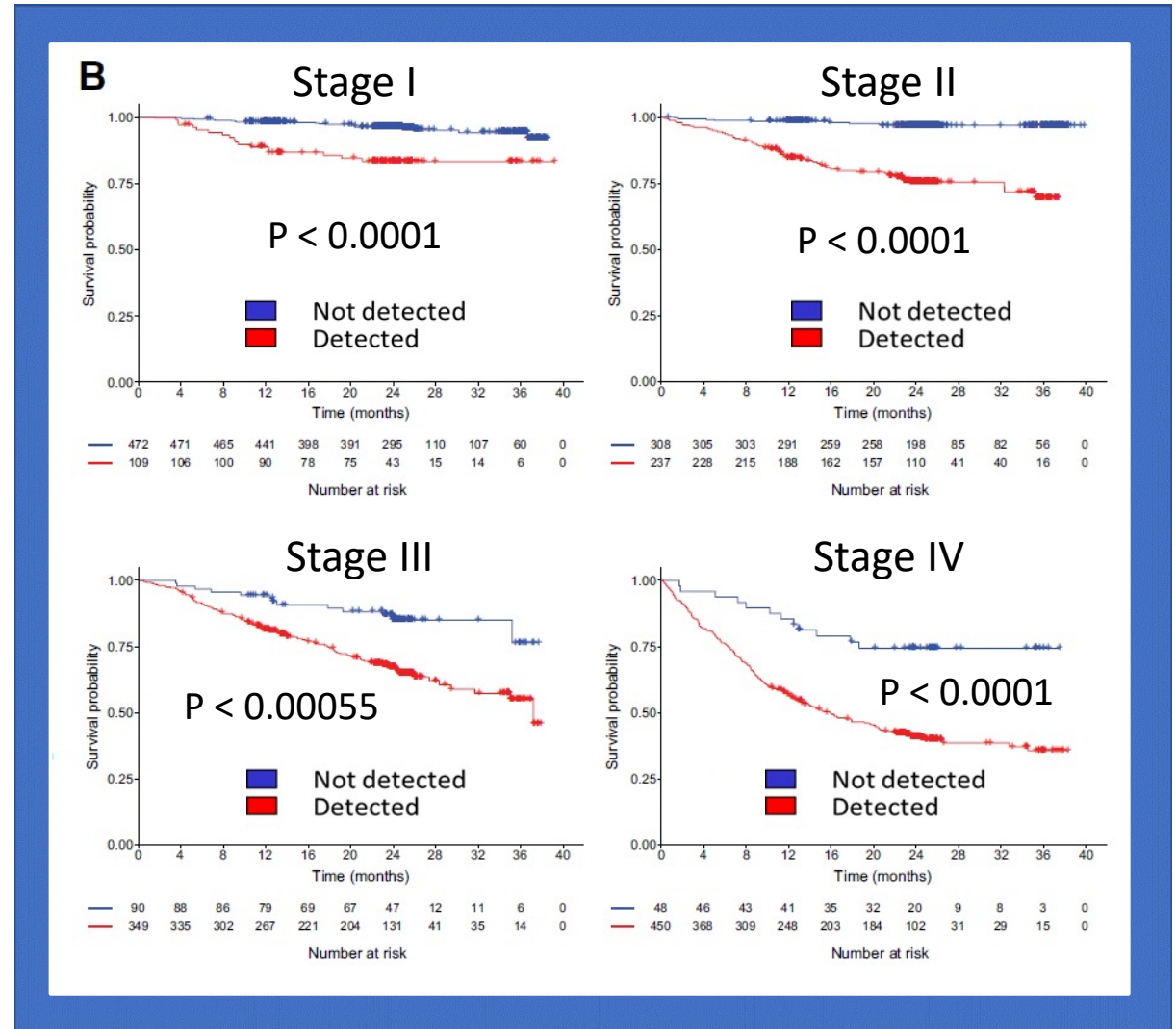
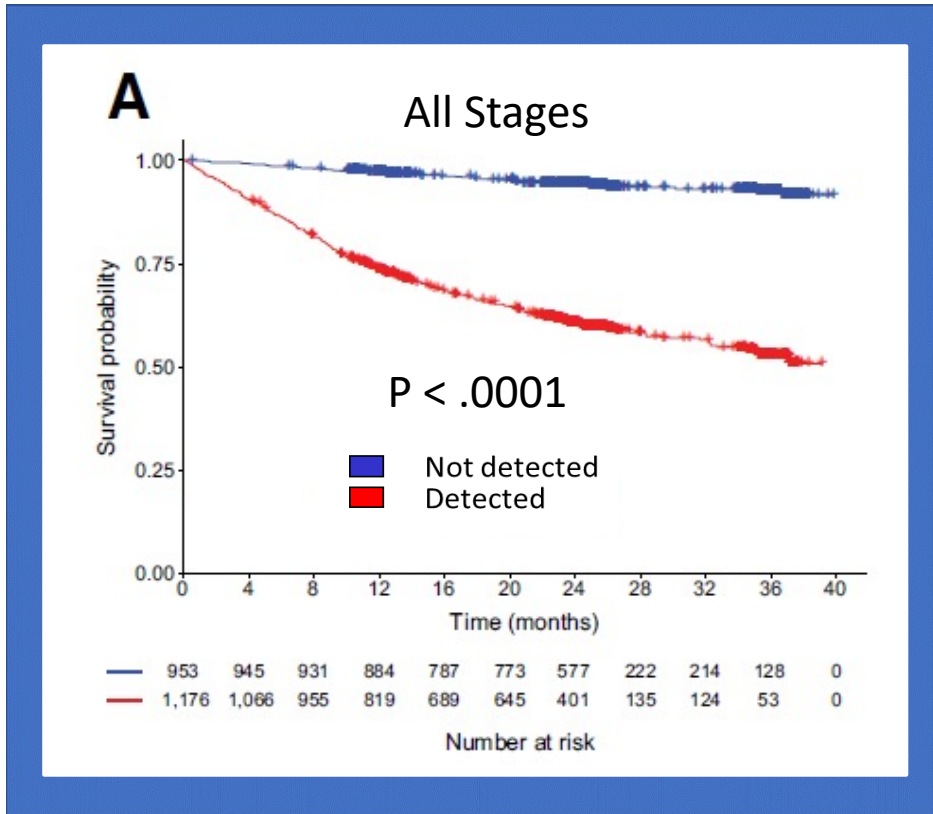
- Anus
- Bile Duct
- Bladder
- Breast
- Chronic Lymphocytic Leukemia
- Colon
- Esophagus
- Gastrointestinal Stromal Tumor
- Head and Neck
- Hodgkin Lymphoma
- Kidney
- Leiomyosarcoma
- Liver
- Lung
- Lymphoma
- Melanoma
- Multiple myeloma
- Neuroendocrine
- Non-Hodgkin
- Lymphoma
- Ovary
- Pancreas
- Prostate
- Rectum
- Testicle
- Tongue
- Tonsil
- Uterus
- Waldenstrom's Macroglobulinemia

Out of 130 voluntarily reported "Cancer Signal Detected" cases with diagnostic resolution

Voluntary reporting of diagnostic follow up and resolution by ordering physicians to GRAIL

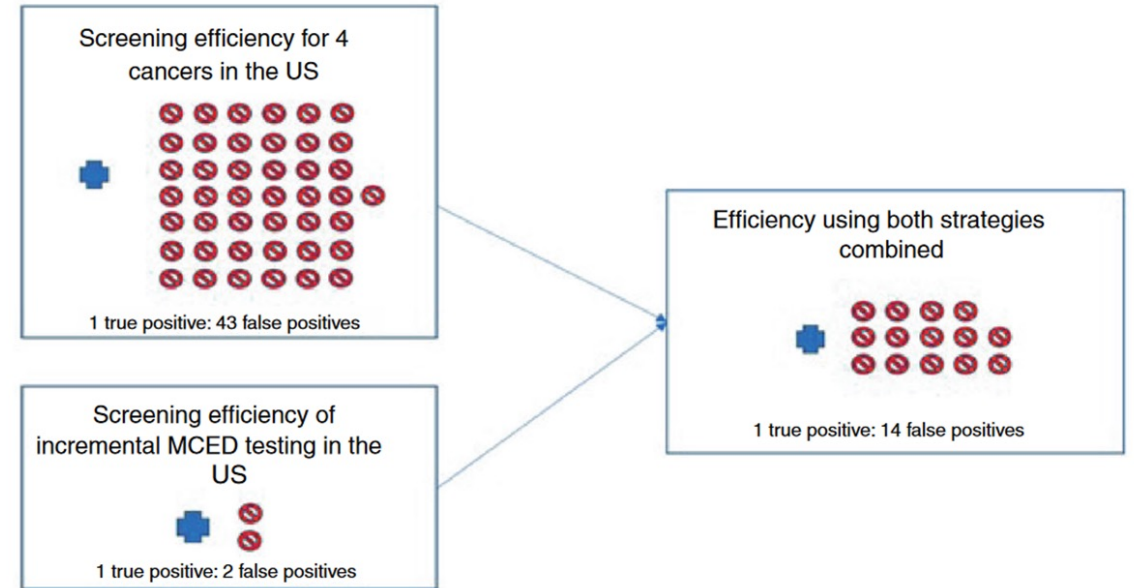
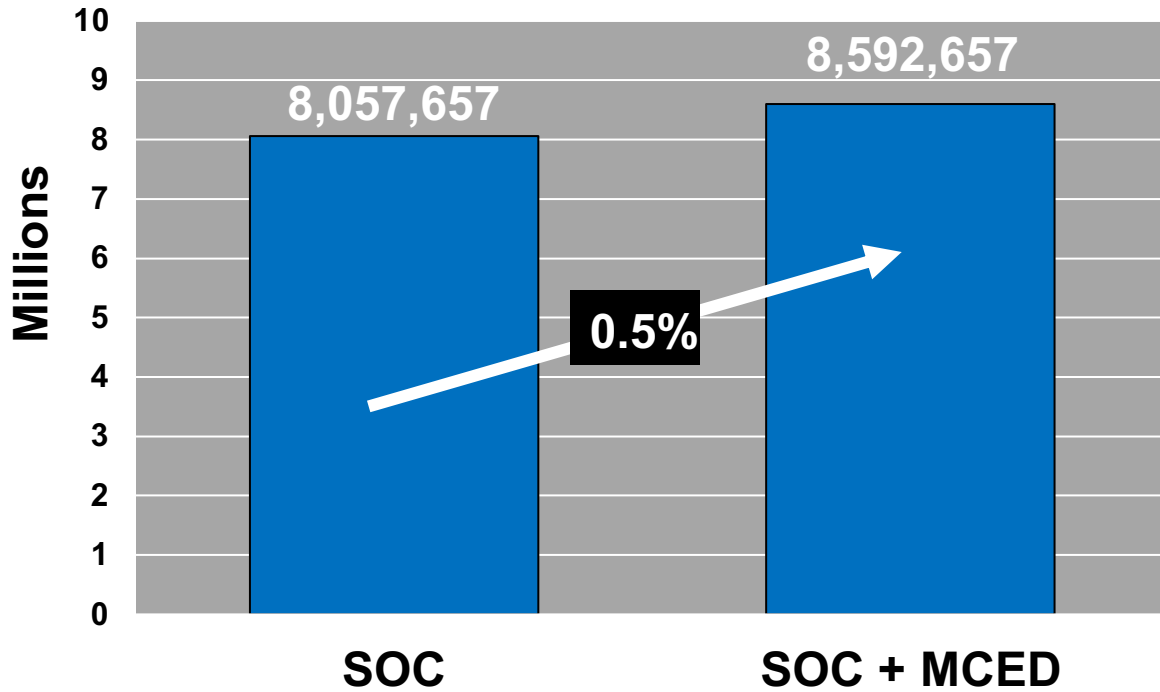
Do MCEDs Overdetect Nonlethal Cancers?

■ Not detected
■ Detected



False Positives

Eligible for screening (ages 50-79): 107M

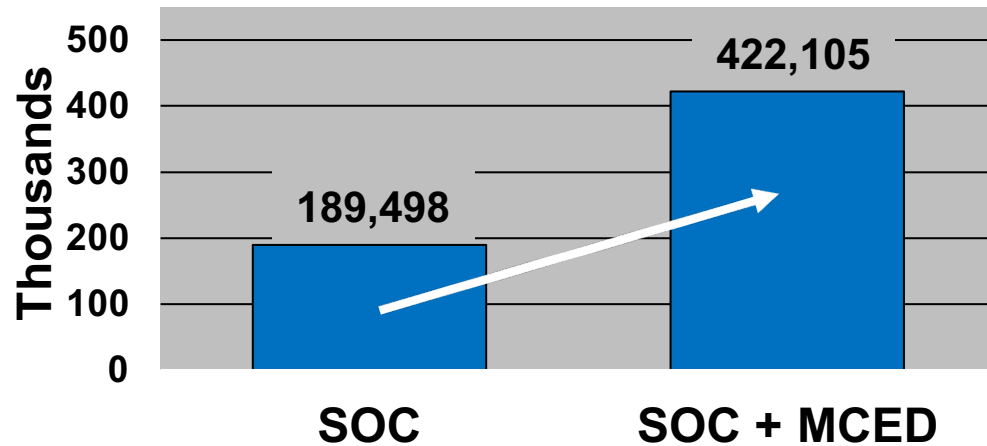


Cost

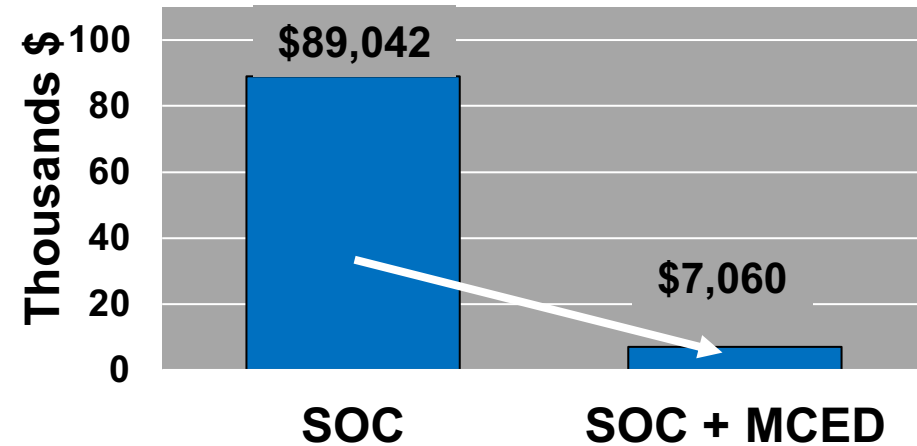
Current SOC cost: \$16.9B

MCED cost: \$3B

Number of Cancers Detected



Cost per Cancer Detected



2.2X increase in CDR results in a 12.6X reduction in cost

Eligible to be screened ~107M (aged 50 – 79)

Intended Use

- **Adjunct to current screening tests**
- **In the short term**
 - **Higher risk of cancer**
 - **Smokers**
 - **Strong family history**
 - **Known genetic carrier or syndrome (BRCA, others)**
 - **Prior history of cancer**
 - **Pediatric cancer survivors**
 - **Immunosuppressed**
 - **Worried well**
- **In the long term**
 - **General population – adults over 50**

Despite this

USPSTF Recommendations for Cancer Screening

Cancer	Grade	Population	Modality/ Recommendation
Cervical	A	Women aged 21 to 65	Regular screening (3–5 years) using cervical cytology and/or HPV tests
Colorectal	A B	Adults aged 50 to 75 Adults aged 45-49	Regular annual screening, multiple effective methods available
Breast	B C	Women aged 50 to 74 Women aged 40 to 49	Biennial screening mammography
Lung	B	Adults aged 55–80, with history of smoking	Annual low-dose computed tomography (LDCT) screening
Prostate	C	Men aged 55 to 69	Periodic PSA screening on case-by-case basis



Mortality

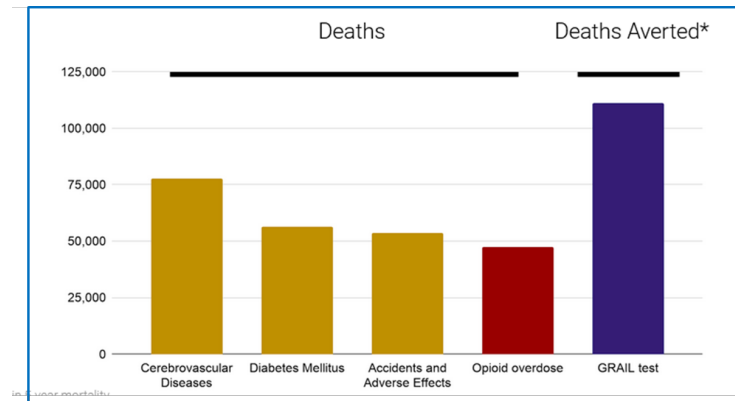


> 600,000 people die of cancer every year In the US

Adding MCED has the potential...



To achieve this



26% Reduction in Cancer Mortality

The Value of MCED at the Population Level

Advantages	Practical Effects
Detects cancers not currently screened for	Increases overall cancer detection rate
Improves efficiency of screening	
Shifts diagnosis to earlier stages	
Reduced cost per cancer detected	

MCED Implementation in the Clinic

Mylynda B. Massart, MD, PhD
UPMC Primary Care Precision Medicine
Department of Family Medicine
Clinical and Translational Science Institute
Institute for Precision Medicine
University of Pittsburgh

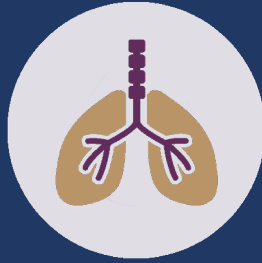


Disclosures:

Grail Speaker Bureau

Colon
Cancer

Lung Cancer
(high-risk groups)



Challenges of Current Cancer Screening Paradigm:

Breast
Cancer

Cervical
Cancer



- Current challenges in cancer screening:
 - Second leading cause of death
 - Cancer has a huge cost burden
 - Screening is limited 5 cancers only 4 with USPSTF guidelines A/B
 - Current screening paradigms are invasive, time consuming and present significant barriers to access
 - Adherence to current screening is not at goal
 - Covid-19 has caused a dramatic drop in screening
 - Cancellations
 - De-prioritization by health systems early in pandemic
 - Fear of exposure by patients
 - Increased barriers and disparity gaps

Missing
Many
Cancers:

USPSTF Screening covers
29% of annual cancer
incidence age 50-79

71% incident cancers
without current
screening modality

Cancer	Prevalence (%)	USPSTF Recommended Screening	Sensitivity (%)	Specificity (%)	Positive Predictive Value (%)	Compliance with Recommended Screening (%)
Breast	0.6	Biennial mammography, women ages 50-74	87	89	4.4	78.3
Cervical	<0.1	Triennial cytology or quinquennial cytology/HPV test women ages 21-65	95	85.5	<1	80
Colorectal	0.65	Decennial colonoscopy	75-93% adenomas	86%	3.9-100 depending on study and reference (avg. 22.9%)	69.7
		Triennial stool-based screening (Cologuard)	6mm or greater	86.6	3.7	
		Annual Stool based screening (FIT) Ages 45-75	92.3	94.9	8.7	
			73.8			
Lung	1.1 (high risk)	Annual low-dose CT ages 50-80	85	87	6.9	5
Prostrate	15.5	Biennial PSA testing, men 55-69	21	91	30	33

Accuracy of Mammograms

The best we have needs
To be better.

- Overall the sensitivity of mammography is about 87%
 - Mammography identifies 87% of women who have breast cancer
 - The chance of having a false positive result after one mammogram ranges from 7-12% depending on age.
 - It is estimated that over 10 years of annual mammography screening, 50% of women will experience at least one false positive recall, 17% false positive short-interval follow-up and 11% a false positive biopsy recommendation.

<https://health.ucdavis.edu/news/headlines/half-of-all-women-experience-false-positive-mammograms-after-10-years-of-annual-screening-/2022/03>

New Cancer Screening Paradigm

Goal:

- Shift cancer detection to earlier stage to hopefully increase treatability
- Provide screening for cancers without previous rigorous screening options

To be successful:

- Low false positives
- Ability to localize the cancer with high accuracy
- Limit over diagnosis (not over detect indolent cancers)
- Need data from prospective studies that show that liquid biopsies deliver benefits to patients beyond being non-invasive such as increasing quality-adjusted life-years.

The Galleri Test in My Practice

When do I discuss Galleri

- Annual Physical/Wellness
- Cancer Screening Appointment
- Other

Who do I discuss Galleri with

- All patients 50 years or over
- 50 years or over and additional risk factor
- 40y-50y with additional risk factors
- Other

How do I discuss Galleri

- Pre-visit materials: videos, brochures, website
- During visit: brochures, flip chart, verbal
- Sample language

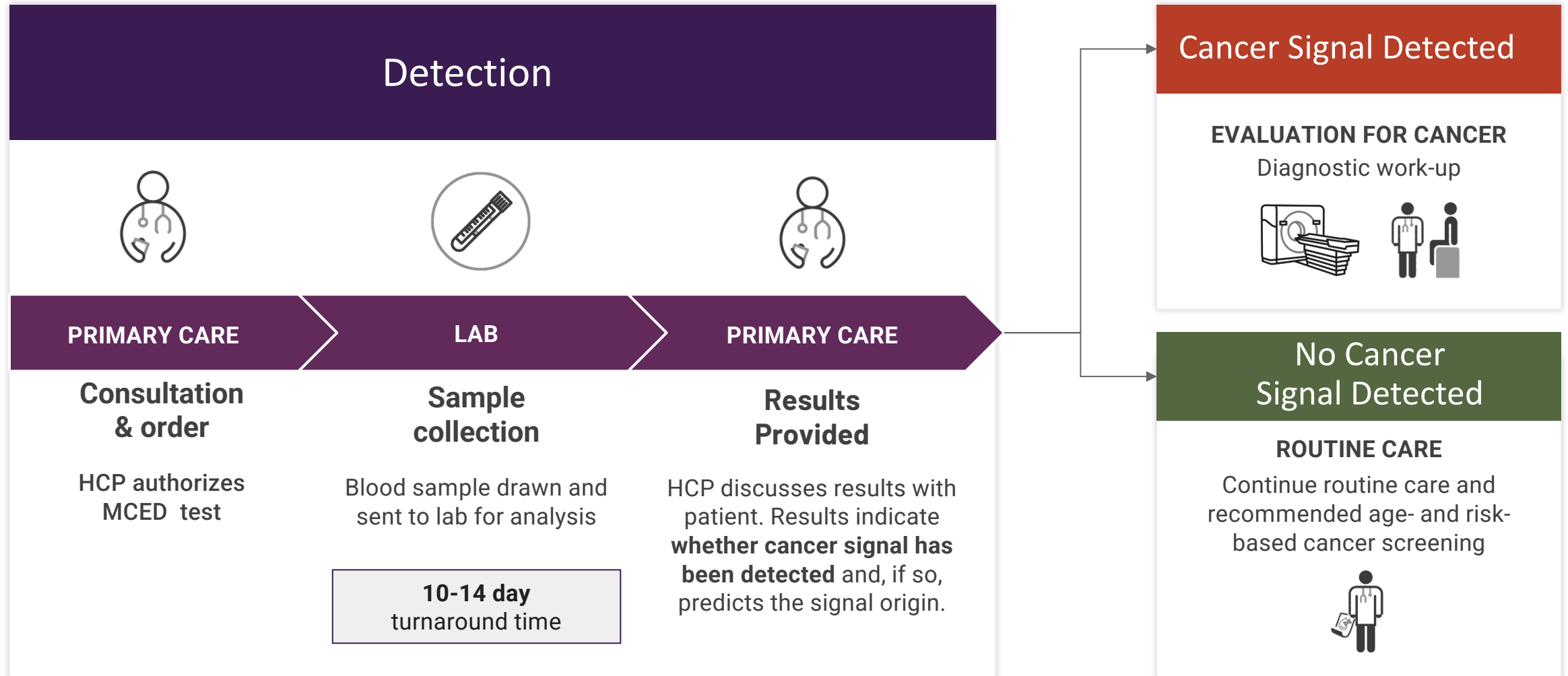
How to obtain a sample

- In office blood draw
- Kit given to patient or sent to patient's home
 - Quest, Mobile phlebotomy

Discussing results

- Copy of results for patient
- No cancer signal detected
- Cancer Signal detected

The Galleri test can easily be integrated into existing clinical workflows



GRAIL post-positive test support for ordering providers

Test ordered



MSLs can reach out for peer to peer discussion and knowledge share



MSLs can reach out to referred specialist to educate on MCED and address questions about the test

Test report received – 10 days

CSO based Clinical Considerations

Clinical Care Considerations
Galleri™ Test Results

CANCER SIGNAL DETECTED
Top Predicted Signal Origin: LUNG
Included cancers: Lung, Bronchus, Neuroendocrine cells

What Does a "Cancer Signal Detected" Mean?
The Galleri test detected DNA methylation signals associated with cancer in the patient sample. Evaluation for cancer should be conducted.

Clinical Considerations*
Lung and bronchus cancers represent 13.7% of all new cancer cases and are the leading cause of cancer death in the United States. There are two main categories of lung cancer: non-small cell lung cancer (squamous cell carcinoma, large cell carcinoma, and adenocarcinoma) and small cell lung cancer (small cell carcinoma and combined small cell carcinoma). Smoking is the leading cause of lung cancer and lung cancer death.

Workup Considerations**

- Health and Family History
 - Smoking status/history
 - Occupational/environmental exposures
- Physical examination
- Imaging
 - LDCT Chest CT +/- contrast
 - FN/US if clinically indicated
- Blood work
 - CEA, BMP
- Consider retesting, if cancer not found
- If cancer is not found, consider clinical monitoring with shared decision making
- Consider referral to a thoracic oncologist for clinically suspicious findings

- MSLs can share:
- Pathfinder Study case report examples when available
 - CSO Axis of confusion education

Sample Test Reports


Negative Test - Cancer Signal Not Detected

Galleri Firstname Last
GRAIL ID: ID1234567890

Multi-cancer early detection test report

Patient	Sample	Ordering Physician
Name: Firstname Lastname Patient ID: PathPar1234567890 DOB: 01-JAN-1965 Bio Sex: Female Email: firstname.lastname@email.com	GRAIL ID: ID123456789 Report Date: 15-OCT-2022 / 18:13 PT Collection Date: 20-DEC-2022 / 21:39 PT	Name: Firstname Lastname, MD Location: Academic Hospital - Clinic 1 Address: 123 Maple St. Unit 321 Rainbow Town, CA 94000 Phone: (123) 456-7890 Fax: (987) 654-3210

Your Result

 **No Cancer Signal Detected**

The Galleri[®] test did not detect DNA methylation patterns that are associated with cancer in your blood sample. In a clinical trial^a, fewer than 1% of individuals with this result were projected to have cancer.

✓ What this result means

The Galleri test looked for a cancer signal in your blood sample and did not find one. Continue with routine cancer screening tests your healthcare provider recommends.


⊗ What this result does not mean

Although the Galleri test did not find a cancer signal in your blood, this result does not completely rule out the possibility of cancer. The Galleri test does not detect all cancers and not all cancers can be detected in the blood.


This result does not predict whether you will develop cancer in the future.

FPO

🗨️ Talk to your healthcare provider about the following topics

 **Continue routine cancer screenings**

Discuss which screening tests are right for you. Screening is recommended for colon/rectum, breast, cervix, lung (for those at risk), and prostate cancers.

 **Repeat testing with Galleri**

Adding Galleri to annual wellness visits can improve the chances of finding cancer early when it is more treatable. Talk to your healthcare provider about whether annual testing with Galleri is appropriate for you.

^a The Circulating Cell-free Genome Atlas (CCGA) Study (NCT02889978) substudy 3 (CCGA3)[†] included cancer (n=2623) and non-cancer (n=1254) participants. It was estimated that 99.4% of participants with a "no cancer signal detected" result would not have cancer based on Galleri test performance adjusted for SEER cancer incidence in the 50-79 years age group[†].

GRAIL Laboratory Director: Rita Shakhovich MD, PhD | CLIA #0502154430 | CAP #149563
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Positive Test - Cancer Signal Detected

Galleri Firstname Last | GRAIL ID: ID1234567890

Multi-cancer early detection test report

Patient	Sample	Ordering Provider
Name: Firstname Lastname Patient ID: PathPar1234567890 DOB: 01-JAN-1965 Bio Sex: Female Email: firstname.lastname@email.com	GRAIL ID: ID123456789 Report Date: 15-OCT-2019 / 18:13 PT Collection Date: 20-SEP-2019 / 21:39 PT	Name: Firstname Lastname, MD Location: Academic Hospital - Clinic 1 Address: 123 Maple St. Unit 321 Rainbow Town, CA 94000 Phone: (123) 456-7890 Fax: (987) 654-3210

Results


Cancer Signal Detected

The Galleri[®] test detected DNA methylation signals associated with cancer in the analyzed cell-free DNA obtained from the patient's sample. **Detection of a cancer signal is not a diagnosis of cancer. Diagnostic evaluation for cancer should be conducted.**

Top Predicted Signal Origins to Guide Diagnostic Evaluation

Head & Neck

Signal Origin(s) Score



This chart displays the top score(s) of Cancer Signal Origins predicted by the Galleri test. The size of each bar represents confidence in predicting cell or tissue origin of detected cancer signal; long bar reflects higher confidence and short bar reflects lower confidence in cancer signal origin. This chart does not provide an indication of the overall likelihood of cancer.

Cancer signals are organized into 21 Cancer Signal Origins, which are listed in the Method section. For more information, please visit www.galleri.com/test-report.

Included sub-categories of the predicted origins:

- **Head & Neck:** Oropharynx, Hypopharynx, Nasopharynx, Larynx, Lip and Oral Cavity (including Oral Tongue), Nasal Cavity, Paranasal Sinuses, Major Salivary Glands
- **Lung:** Lung, Bronchus

Considerations from Clinical Studies

- In the interim analysis of the PATHFINDER study, it was estimated that 40.4% (95% CI 27.6%-54.7%) of participants had cancer diagnosed among participants with "signal detected" results (see Positive Predictive Value in the "Clinical Studies" section for details).
- The Galleri test may produce a "Cancer Signal Detected" result, but subsequent diagnostic evaluation may not reveal a cancer diagnosis. Even if the diagnostic evaluation of the Cancer Signal Origin(s) is negative, the likelihood that the individual has cancer remains elevated and may warrant further evaluation.
- In the Circulating Cancer Genome Atlas (CCGA) validation study, Galleri detected cancer signals across more than 50 cancer types.
- Please visit www.galleri.com/test-report for more information or contact GRAIL at 833-694-2553.

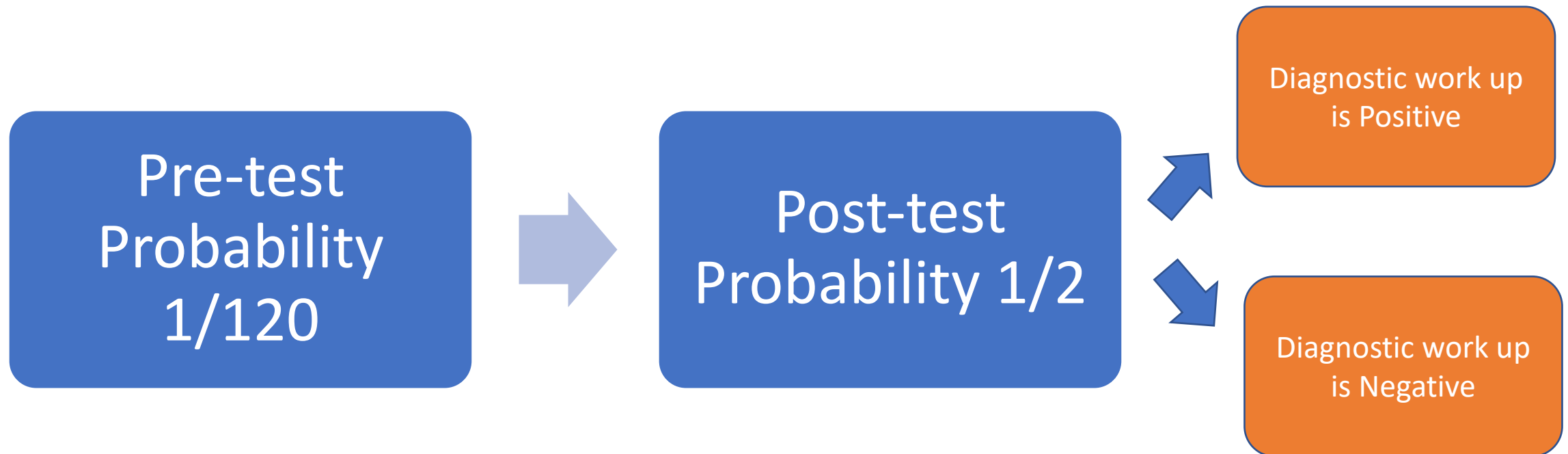
Comments:

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Page 1 only of sample test report shown.

*For intended use population: Adults with an elevated risk of cancer such as those aged 50+ years. Use of Galleri is not recommended in individuals who are pregnant, 21 years old or younger, or undergoing active cancer treatment.

Personalized medicine and weighing risk (SCREEN vs TEST):



Negative testing: how frequent to repeat?

Residual risk and False negatives (0.6%): specific cancer has poor sensitivity, type of tumor

Does not secrete cfDNA into blood stream at high enough levels to detect

Cancer is pre-detection level



Plan for positive results and collaboration of care

1-2% of those tested will have a positive results

Each positive results is a post test probability of 1 out of 2 for cancer

How can we best collaborate and prepare to care for patients with a positive screen.

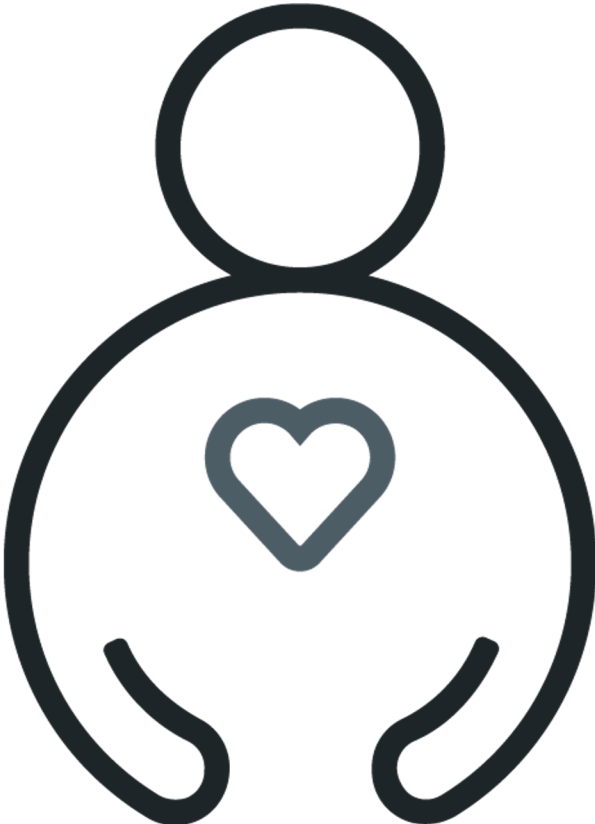
- Support patients and their providers
- Minimize invasive procedures
- Minimize cost
- Maximize identification of cancer in timely manner

MCED Test in My Practice

Cancer Signal Detected

None to Date

PATIENT CLINICAL PROFILE



Age:
Overall Health:
Cancer Screening History:
Reason for MCED Test:
Cancer Signal Origin Prediction:

Evaluation:

Diagnostic Resolution:

Additional Information:

DISCLAIMER: Information is provided by the treating provider for educational and illustrative purposes only and does not represent GRAIL clinical data or claims.

PATIENT CLINICAL PROFILE



Age: 56 year old female

Overall Health: obese, multiple fibrous cysts (pancreas, liver, abdomen, uterus)

Cancer Screening History: routine screening up to date

Reason for Test: confused about biopsy results, cancer, not cancer?

Patient Response: Patient very relieved, had been anxious for years that a cancer was being missed.

Additional Information:

PATIENT CLINICAL PROFILE



Age: 57 year old male

Overall Health: very healthy

Cancer Screening History: current

Reason for Test: family history significant for one or more cancers in every generation on both sides of the family including younger brother who died of cancer.

Patient Response: extremely relieved and excited to have a larger screening test that he can undergo each year given his family history and the constant stress of "waiting for cancer".

Additional Information:

PATIENT CLINICAL PROFILE



Age: 79

Overall Health: very healthy, hx of skin cancer x1

Cancer Screening History: current

Reason for Test: patients husband had cancer and her mom and she feels empowered to have a test that can supplement routine screening and catch cancer early if possible.

Patient Response: relieved and planning to do annual screening

Additional Information:

Early detection can help reduce disparities in late stage diagnosis and mortality

African-Americans

African Americans have the **highest mortality rate** of any racial or ethnic group for all cancers combined and most major cancers

Hispanics/Latinos

Hispanics/Latinos are more likely to be **diagnosed with advanced stages of disease**

Native Hawaiians and Pacific Islanders

Native Hawaiians and Pacific Islanders are **30 percent more likely to be diagnosed with cancer** compared to non-Hispanic whites



Thank you

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