

Blood-based and Imaging-based Options for CRC Screening

Aasma Shaukat MD MPH Director GI Outcomes Research

Robert M. and Mary H. Glickman Professor of Medicine

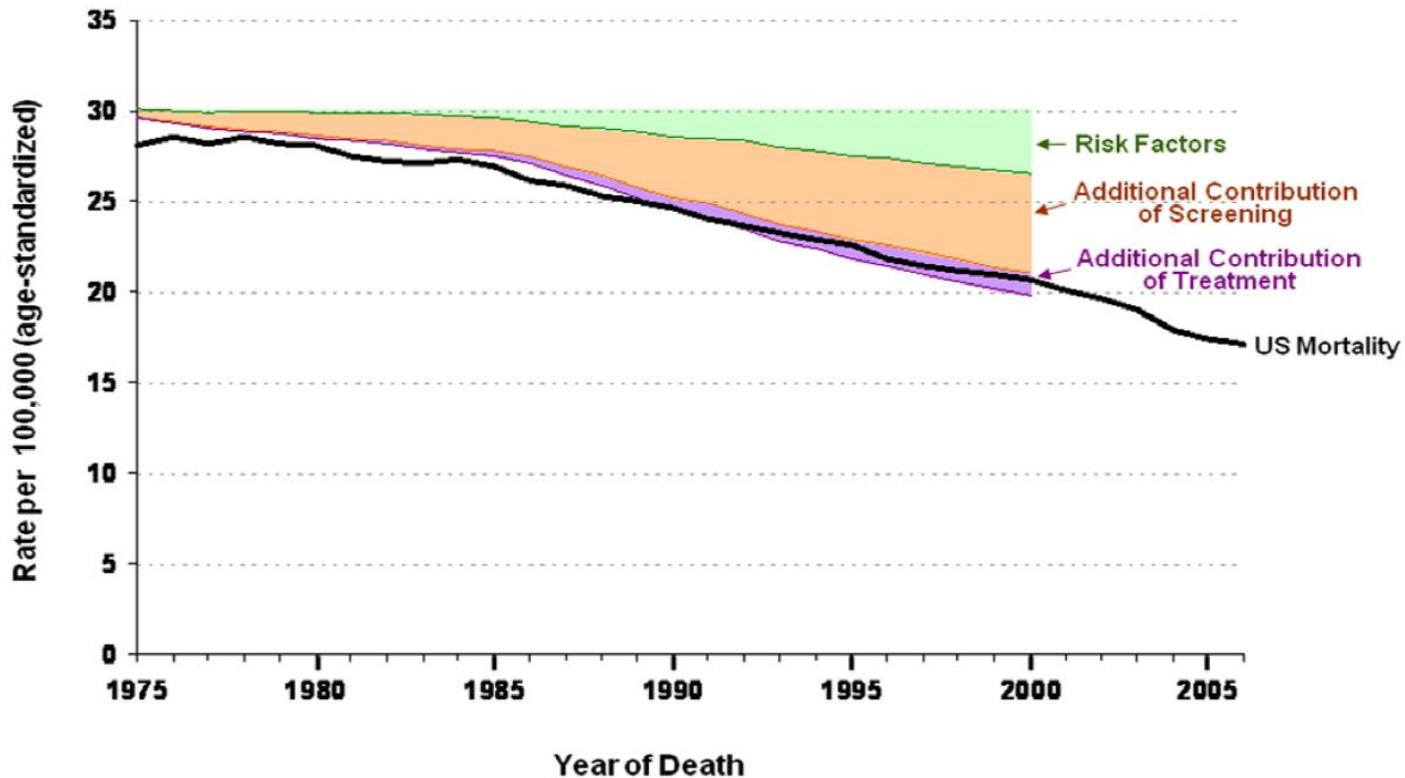
Professor of Population Health

NYU Grossman School of Medicine

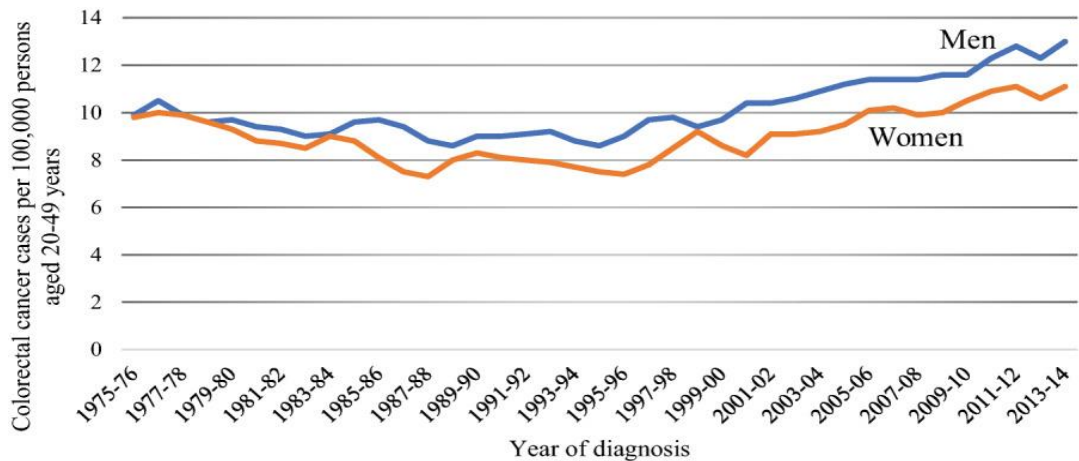
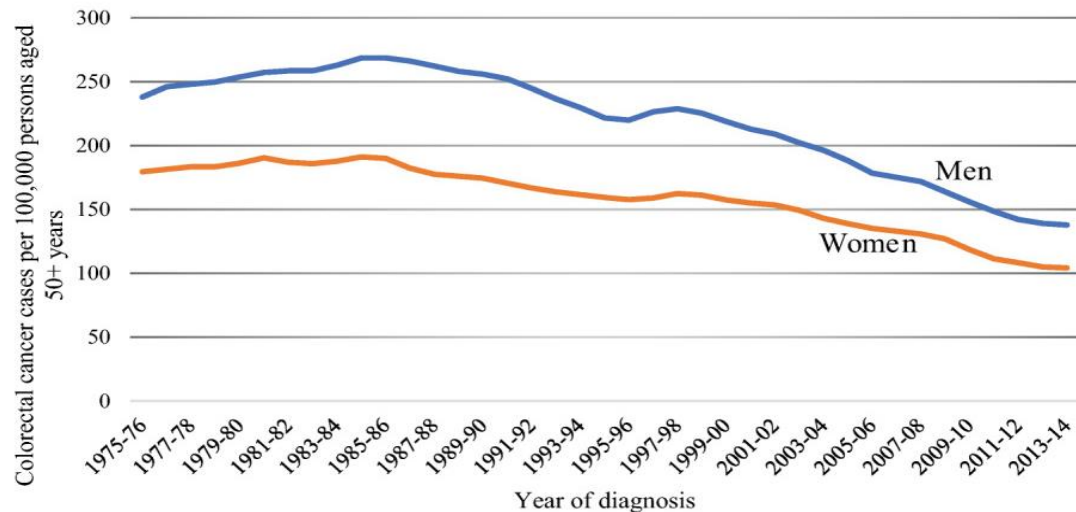
Objectives

- Review recent trends in Colorectal cancer (CRC) Incidence in the US
- Updates on recent evidence on CRC Screening
- Improving adherence to CRC screening
- Current and future options for CRC screening
- Take home points

CRC Mortality Over Time



CRC Incidence



When Should Screening Start For CRC?

American College of Gastroenterology

- Recommended in all adults 50 to 75 years of age
- Suggest in all average risk adults 45 to 49 years of age
- Recommend decision to screen after 75 be individualized

US Preventive Services Task Force

- Recommended in all adults 50 to 75 years of age
- Recommended in adults 45 to 49 years of age
- Recommended that clinicians selectively offer screening in adults 76-85 years of age

US Multi Society Task Force

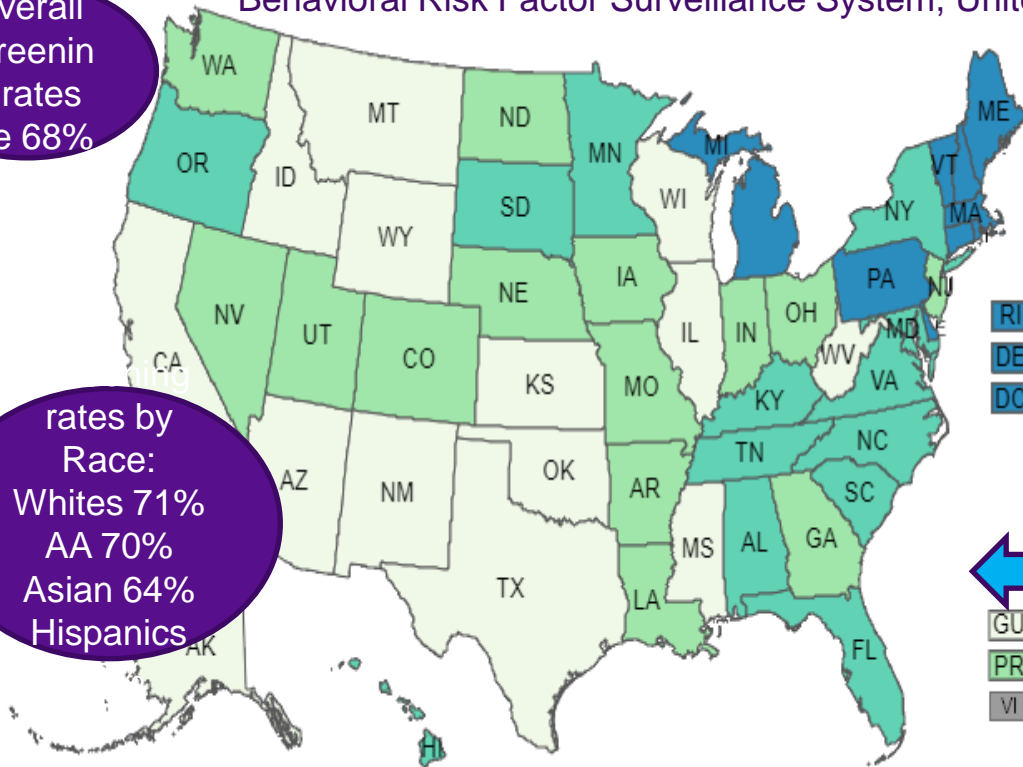
- Suggested to all average-risk adults ages 45 to 49
- For adults ages 76 to 85, the decision to start or continue screening should be individualized and based on prior screening history, life expectancy, CRC risk, and personal preference
- Screening is not recommended after age 85

2020: Percentage of Adults 50–75 Years fully meeting USPSTF recommendation for CRC Screening, by State

Behavioral Risk Factor Surveillance System, United States, 2020

Overall screening rates are 68%

rates by Race:
Whites 71%
AA 70%
Asian 64%
Hispanics



Health Insurance:

Yes 71%

No 40%

Regular HCP:

Yes 73%

No 36%

Crude Prevalence

(%)

53.9 - 70.9

71.0 - 74.3

74.4 - 77.1

77.2 - 81.2

Data unavailable

Quantile

Legend Settings

21 million

adults 45-49

yrs

**What do we need to
Build?
And who will come?**

**Newly Eligible + Overdue+ never
screened**

Endoscopic capacity+ Access

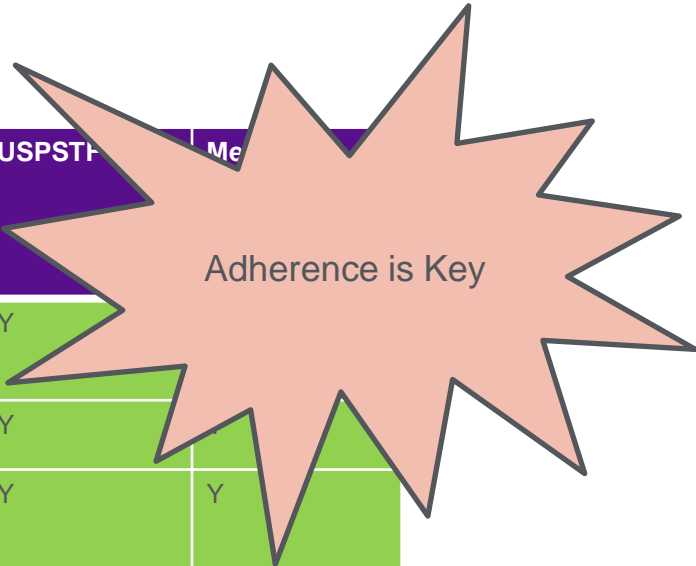
Ensuring Health Equity

What got us here may
not be enough to get
us there

80% in
every
Communit
y

CRC Screening Options

Modality	Sensitivity CRC	Sensitivity AA	Specificity	Invasive	USPSTF	Me
Colonoscopy	96%	95%	90%	Y	Y	
FIT	74%	24%	96%	N	Y	
mtsDNA stool	92%	42%	87%	N	Y	Y
Septin-9	48%	-	91%	N	N	Y
Liquid Biopsy	-	-	-	N	TBD	TBD



Approach to Colon Cancer Screening



1 Step Tests

2 Step tests

Colonoscopy

Stool Based
Imaging based:
CTC
Colon Capsule
Blood based

Preferred CRC Screening Tests Among 1,000 Unscreened Americans

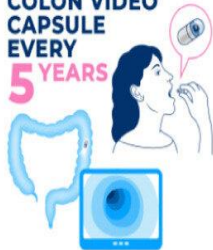
US MSTF Five Recommended Tests

US MSTF Tier 1 Tests

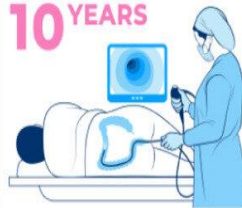
MULTITARGET
STOOL DNA TEST
EVERY
3 YEARS



COLON VIDEO
CAPSULE
EVERY
5 YEARS



COLONOSCOPY
EVERY
10 YEARS



FIT
EVERY
YEAR



COLON CT SCAN
EVERY
5 YEARS



FIT
EVERY
YEAR



COLONOSCOPY
EVERY
10 YEARS



40-49
yo

34.6%

28.2%

13.7%

12.2%

11.3%

68.9%

31.1%

≥50
yo

37.3%

22.9%

13.6%

18.7%

7.6%

77.4%

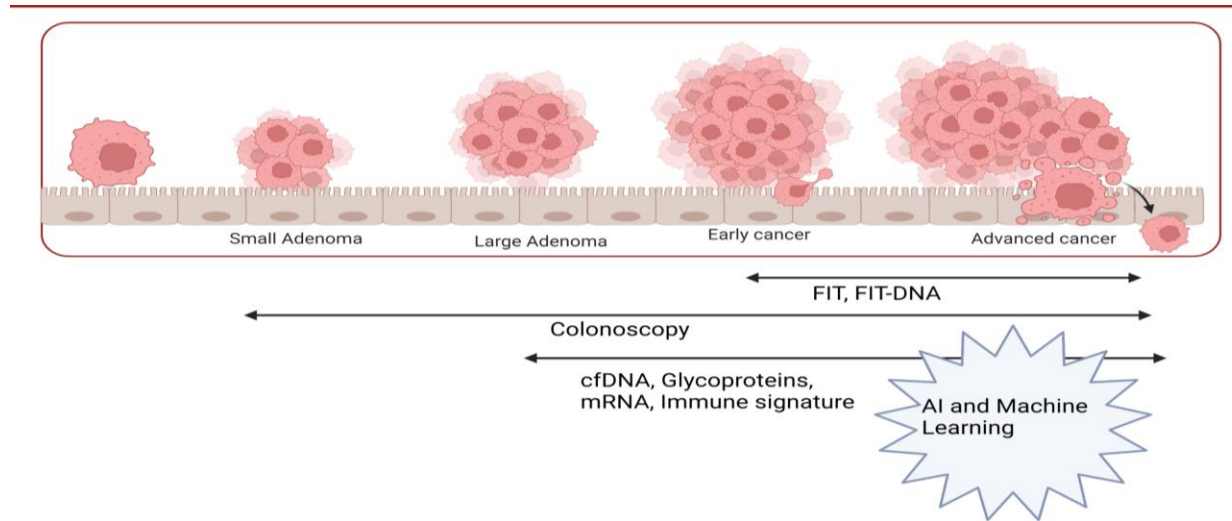
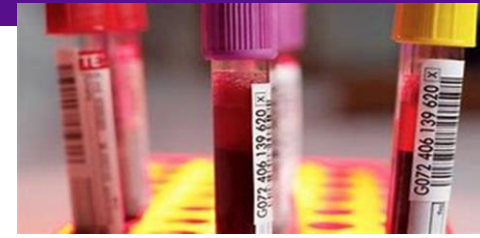
22.6%

Makaroff KE et al. Patient Preferences for Colorectal Cancer Screening Tests in Light of Lowering the Screening Age to 45 Years, *Clinical Gastroenterology and Hepatology* (2022). DOI: [10.1016/j.cgh.2022.07.012](https://doi.org/10.1016/j.cgh.2022.07.012)

Future Trends



Blood Based CRC screening tests



Test	Details of Technology	Special Considerations	Completion	Notes
Stool and blood based				
Clinical genomics	Stool and blood-based biomarker (NCT00843375) for CRC and AN	Study plans to recruit 1800 average risk individuals 18 years+	◆ 2022	
Blood-Based				
Freenome	Cell free DNA plus artificial intelligence for CRC and AN (NCT04369053)	Aims to recruit 25,000 average risk individuals between 45-85	◆ 2022	
Guardant	ctDNA LUNAR test to detect cell free tumor DNA in blood (NCT04136002)	Aims to recruit 10,000 average risk individuals between 45-84 years	◆ 2022	87% sensitive, 90% specific for CRC; 12% sensitive for Adv adenoma
CancerSEEK	Multi-cancer detection test for 8 common cancers, including CRC Detects circulating proteins and mutations in circulating tDNA	(NCT04213326) has enrolled 6399 cancer free as well as individuals with cancer, ages 50 and older since 2019	◆ 2022	
GRAIL	◆ Multi-cancer early detection test (breast, colorectal, pancreatic, lung and hematologic malignancies)	◆ In validation study, specificity 99.5%, sensitivity for cancer 51.5% ◆ Ongoing prospective validation study with 6,600	◆ 2022	Available for \$949. Not covered by insurance

Setting the Bar: CMS National Coverage Decision

← CMS.gov

Centers for Medicare & Medicaid Services

About Us Newsroom Data & Research

MCD

Medicare Coverage Database

Search

Reports

Downloads



← Back to Screening for Colorectal Cancer - Blood-Based Biomarker Tests

Contents

Decision Summary

Decision Memo

Bibliography

National Coverage Analysis (NCA)

Decision Memo

Screening for Colorectal Cancer - Blood-Based Biomarker Tests

CAG-00454N

Expand All | Collapse All



Decision Summary

The Centers for Medicare & Medicaid Services (CMS) has determined that the evidence is sufficient to cover a blood-based biomarker test as an appropriate colorectal cancer screening test once every 3 years for Medicare beneficiaries when performed in a Clinical Laboratory Improvement Act (CLIA)-certified laboratory, when ordered by a treating physician and when all of the following requirements are met:

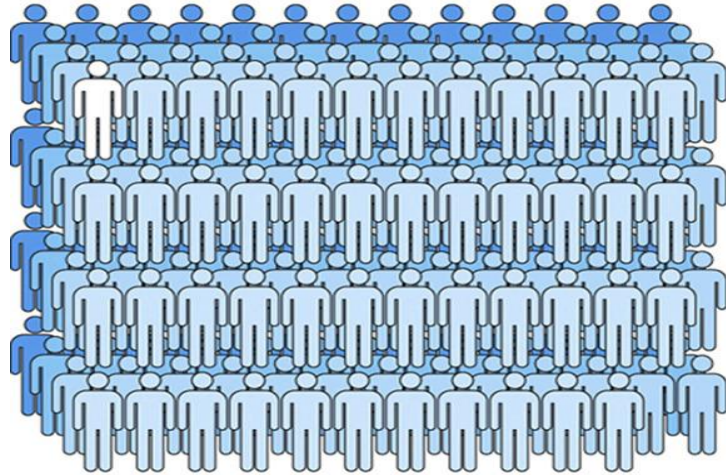
Sensitivity for CRC	74%
Specificity for CRC	90%
FDA approval	

Practical questions

- How ordered? → Information required
- How completed? → Navigation or not
- How collected? → Clinic, commercial lab, mobile phlebotomy, home
- How processed? → Commercial lab, central lab, regional labs
- Turn around time? → 2 days to 14 days
- Require interpretation? → Clinician or staff?
- How is follow up colonoscopy ensured?

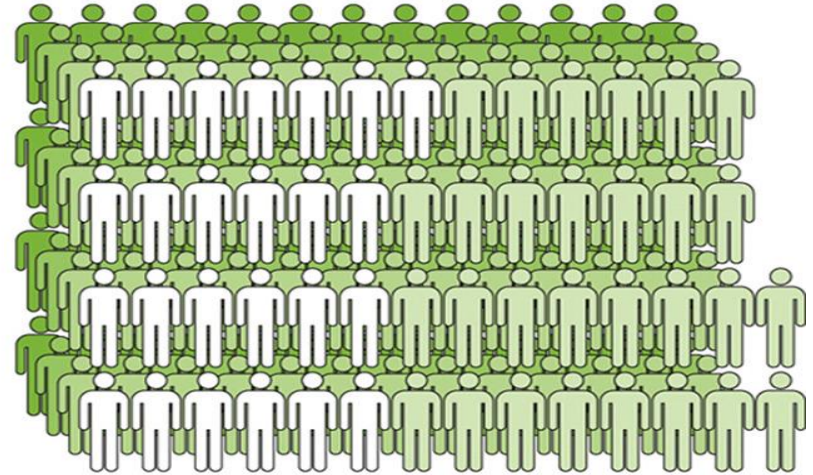
Adherence to Blood based tests 413 randomized adults

Blood Test Arm



99.5% (CI95: 97.3%-100%)
completed test

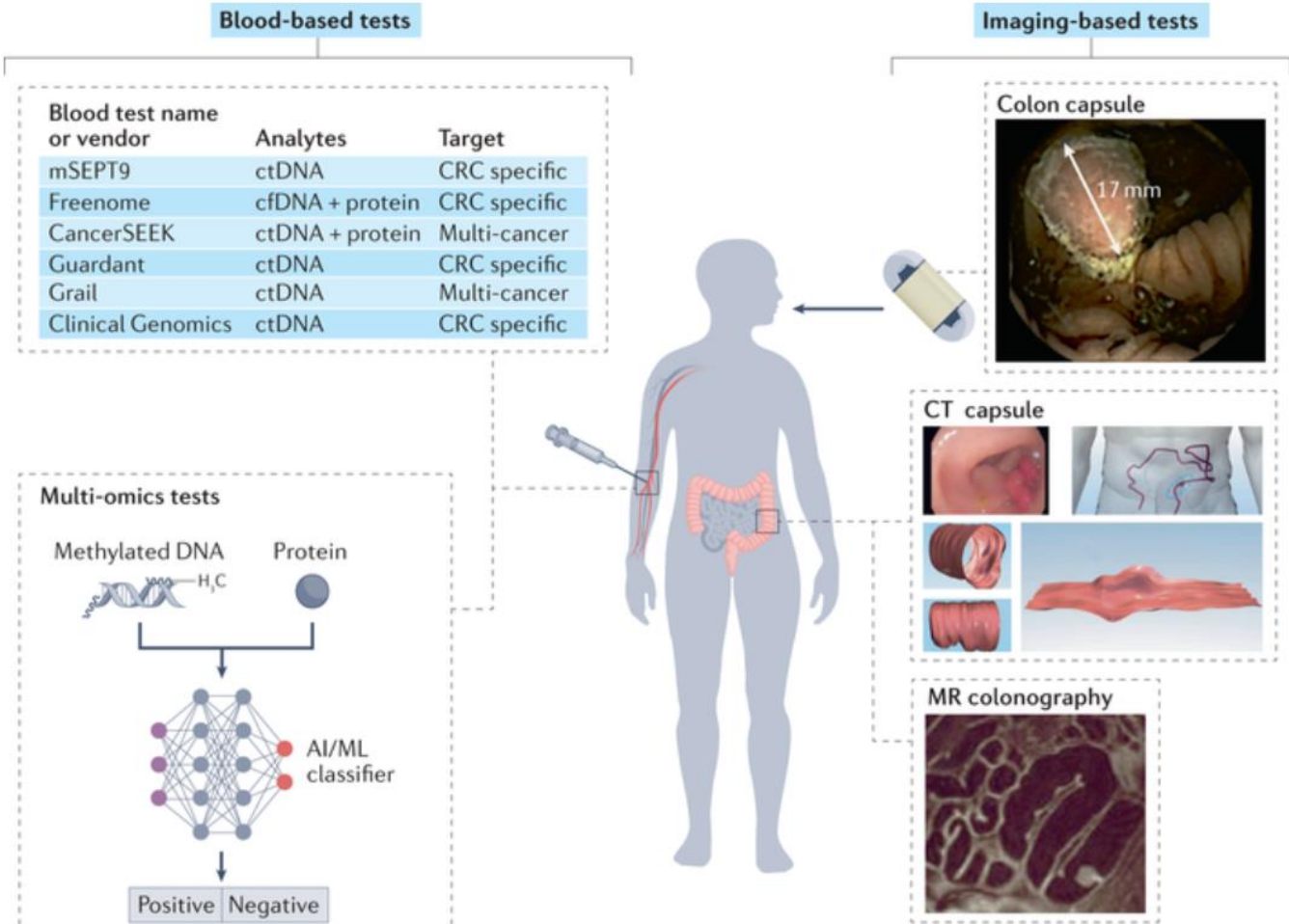
FIT Arm



88.1% (CI95: 83.0%-91.8%)
completed test

= a difference of **11.4%** (CI95: 6.9%-15.9%, $p < .001$)

Summary



Shaukat, A., Levin, T.R. Current and future colorectal cancer screening strategies. *Nat Rev Gastroenterol Hepatol* (2022). <https://doi.org/10.1038/s41575-022-00612-y>

Summary

- Screening for CRC is effective, current rates at 70%
- Programmatic approaches are needed to identify unscreened
- Adherence is key
- New blood and imaging based options under development



Thank you!

