



epigenomics
DETECTING CANCER IN BLOOD

Liquid Biopsy
Cancer Screening
and Detection

Company Presentation



SAFE HARBOR STATEMENT

Forward Looking Statements

This communication contains certain forward-looking statements, including, without limitation, statements containing the words “expects”, “future”, “potential” and words of similar import.

Such forward-looking statements involve known and unknown risks, uncertainties and other factors, which may cause our actual results of operations, financial condition, performance, or achievements, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements.

Such factors include, among others, the following: uncertainties related to results of our clinical trials, the uncertainty of regulatory approval and commercial uncertainty, reimbursement and drug price uncertainty, the absence of sales and marketing experience and limited manufacturing capabilities, attraction and retention of technologically skilled employees, dependence on licenses, patents and proprietary technology, dependence upon collaborators, future capital needs and the uncertainty of additional funding, risks of product liability and limitations of insurance, limitations of supplies, competition from other biopharmaceutical, chemical and pharmaceutical companies, environmental, health and safety matters, availability of licensing arrangements, currency fluctuations, adverse changes in governmental rules and fiscal policies, civil unrest, acts of God, acts of war, and other factors referenced in this communication.

Given these uncertainties, prospective investors and partners are cautioned not to place undue reliance on such forward-looking statements.

We disclaim any obligation to update any such forward-looking statements to reflect future events or developments.

MANAGEMENT TEAM PRESENTERS



Chief Executive Officer

Greg Hamilton has over 20 years of management experience in molecular diagnostics, manufacturing and professional service industries.

Prior to joining Epigenomics, Mr. Hamilton was an executive at multiple diagnostic companies including AltheaDx Inc., Enigma Diagnostics Inc., Third Wave Technologies Inc., and Hologic Inc. Mr. Hamilton received his MBA from the University of Chicago and his Bachelor of Science in Finance from Purdue University.



President and Chief Scientific Officer

Jorge Garces has over 20 years of management experience in the life sciences industry.

Jorge has served as a senior executive at AltheaDx Inc., Enigma Diagnostics, Inc., GenMark Diagnostics, Inc., TWT/Hologic, Inc., and Genzyme Genetics.

Dr. Garces earned a doctorate in Cell and Molecular Biology from the City University of New York and completed a postdoctoral fellowship at the University of Massachusetts Medical School. He received an MBA from the Kellogg Graduate School of Management at Northwestern University.

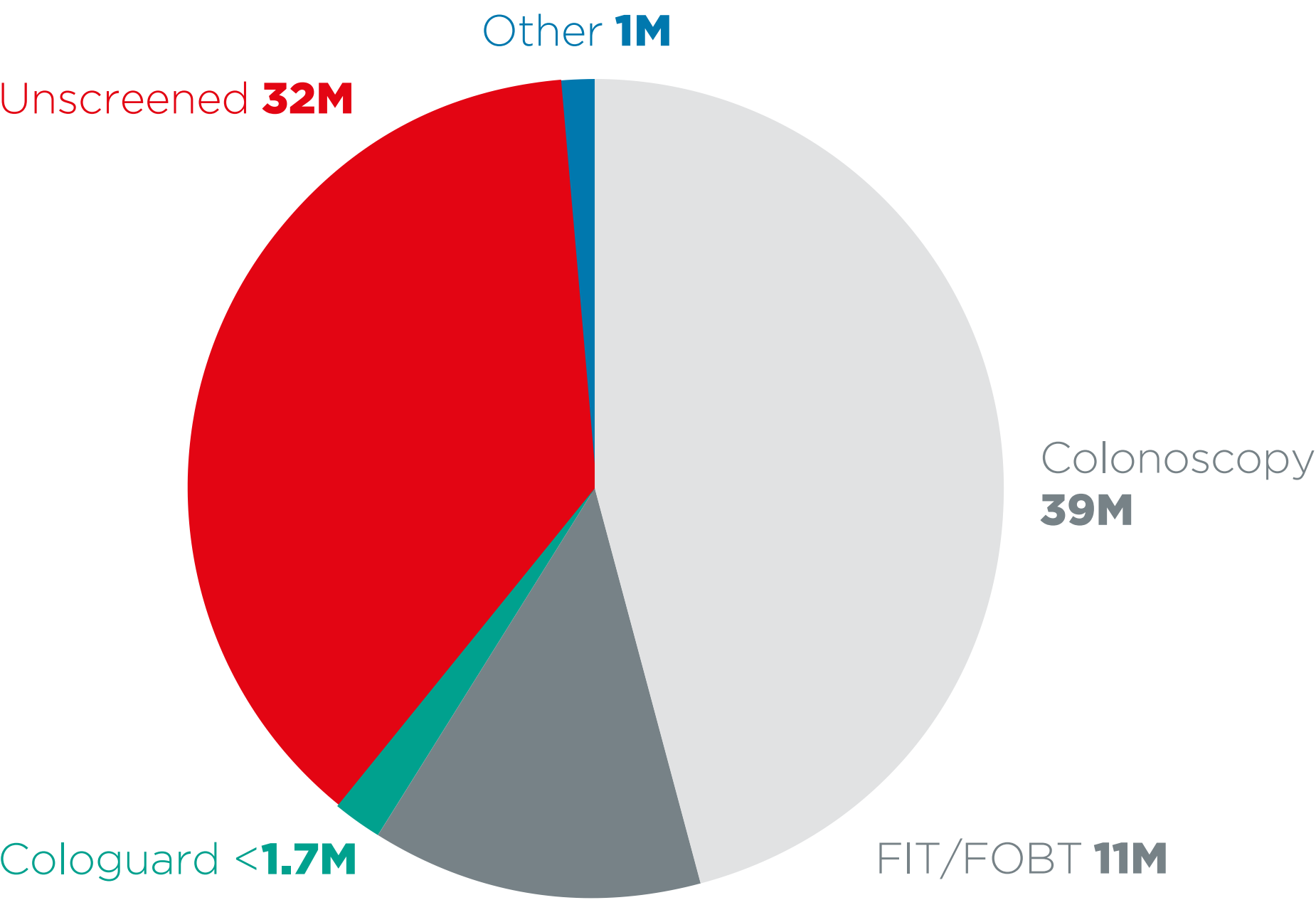
FIRST FDA APPROVED BLOOD-BASED COLORECTAL CANCER SCREENING TEST

Epi proColon[®] is indicated for colorectal cancer screening:

- in average-risk patients 50 – 75 years old
- patients who were offered and declined colonoscopy and stool-based fecal immunochemical tests (FIT)



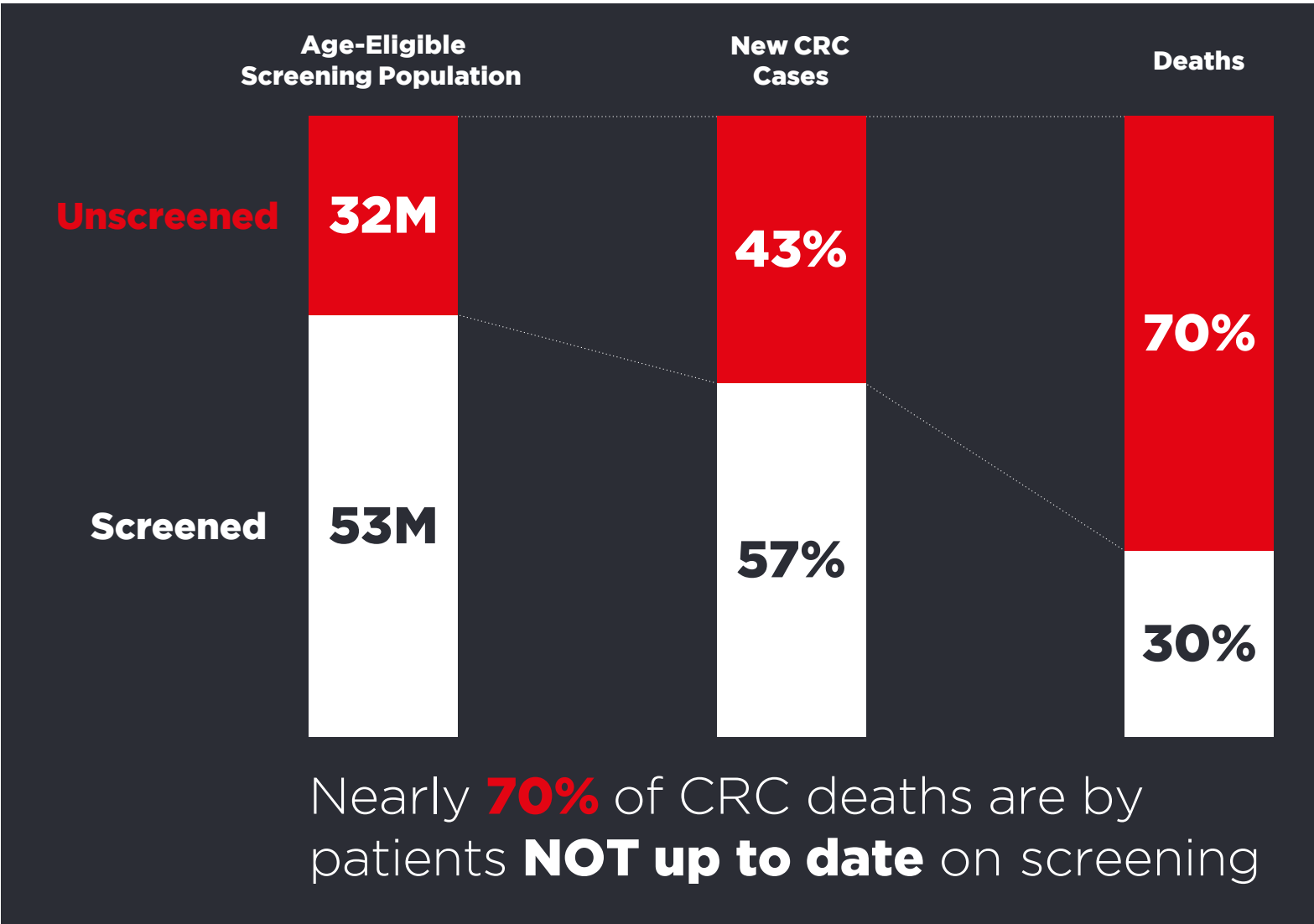
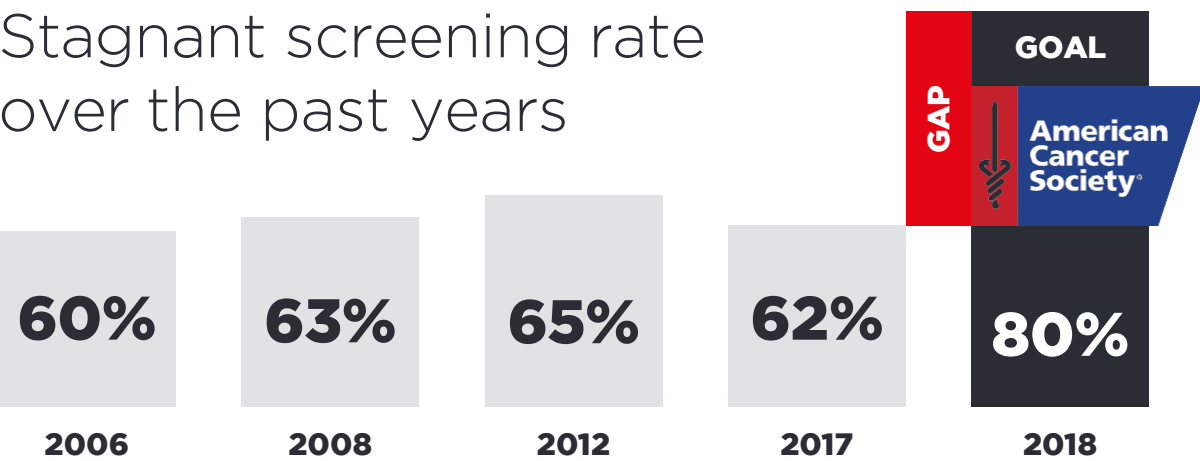
CRC MARKET OVERVIEW



ACS guideline lowering screening age from 50 to 45 will add another 20M patients

Sources: Centers for Disease Control and Prevention, "Vital Signs", November 2013; American Cancer Society Cancer Facts and Figures, 2015. Data from the BRFSS survey reported in MMWR 60(26):884-889, MMWR 62(44):881-888 www.census.gov/popclock/data_tables.php?component=pyramid. Kaur et al., Intern Med 2016, 6:3. Doubeni et al., Gastroenterology 2018, Volume 154, Issue 6. ACS Guidelines, 2018

Stagnant screening rate over the past years

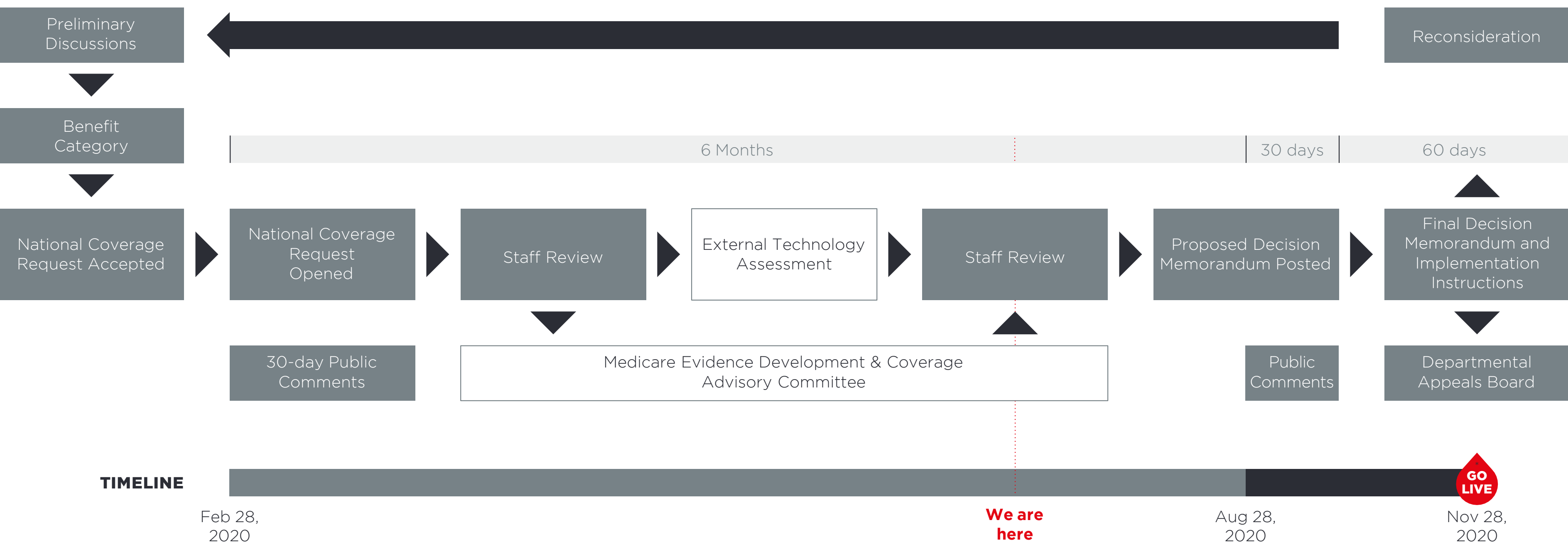


KEY REIMBURSEMENT COVERAGE MILESTONES

Medicare Coverage

- | | | |
|--------------|---|-------------------------------|
| 2016 | ✓ | FDA-Approval |
| 2019 | ✓ | CMS sets final Price => \$192 |
| Feb 28, 2020 | ✓ | NCD “opened” |
| Aug 28, 2020 | ● | Proposed Decision Memo |
| Nov 28, 2020 | ● | Final Decision Memo |

MEDICARE NATIONAL COVERAGE DETERMINATION PROCESS



*Assumes positive coverage decision

CMS DECISION CRITERIA

Reasonable

- **Food and Drug Administration (FDA Approved)**
 - Safe and Effective
- **Clinical Utility**
 - Provides clear benefits by reducing Colorectal Cancer (CRC) incidence and mortality
 - Benefits are equivalent or better in comparison to other methods currently covered by CMS
- **Low Risk**
 - Blood collection is a standard procedure in clinical care and considered to be minimal risk
 - Positives are referred to colonoscopy, which is an approved method routinely used in CRC screening
 - Overall colonoscopy burden is lower as compared to the “gold standard”
- **Cost Effective**
 - Increased CRC screening participation in the pre-Medicare population reduces CRC incidence and mortality, while the additional screening costs can be largely offset by long term Medicare treatment savings

Necessary

- **An estimated nine million Medicare beneficiaries are not up to date with CRC screening**
 - Approximately one out of every three eligible adults 65 years of age (YOA) and older remain unscreened for CRC
- **Blood-based tests have demonstrated significantly higher adherence rates than existing methods**
- **Epi proColon® has the potential to:**
 - Save over 225,000 lives and
 - Detect nearly 400,000 cancers among all the Medicare beneficiaries currently unscreened for CRC



KEY RATIONALE FOR MEDICARE COVERAGE

FDA Approved (PMA) Test

Published peer-reviewed microsimulation data on long-term benefits, harms, and testing interval

Overwhelmingly positive public support

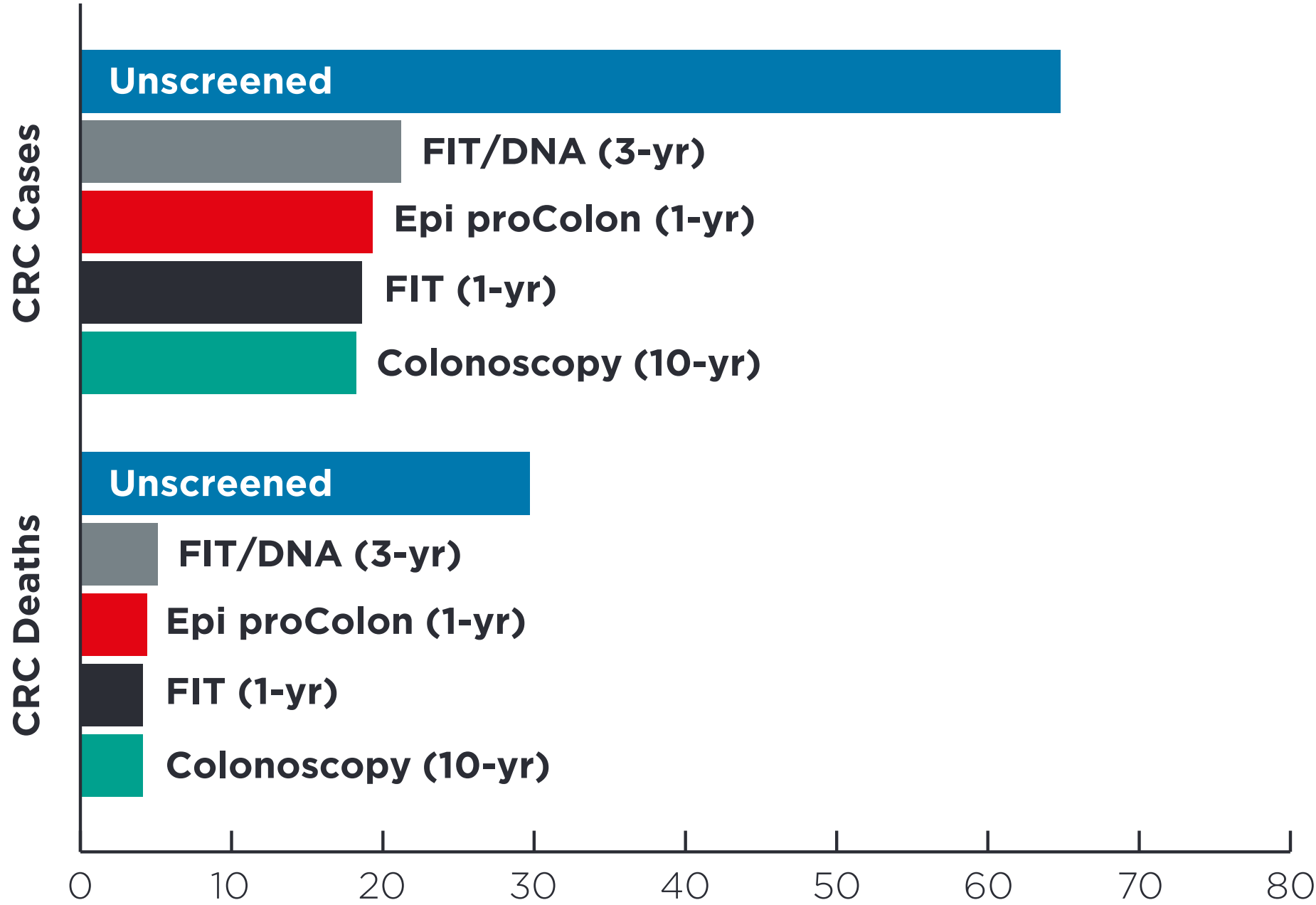
Inclusion in 2020 National Comprehensive Cancer Network (NCCN) CRC Screening Guidelines

Cost Effective



NON-INVASIVE CRC SCREENING

Non-Invasive Screening Methods in Comparison to “No Screening” and Colonoscopy

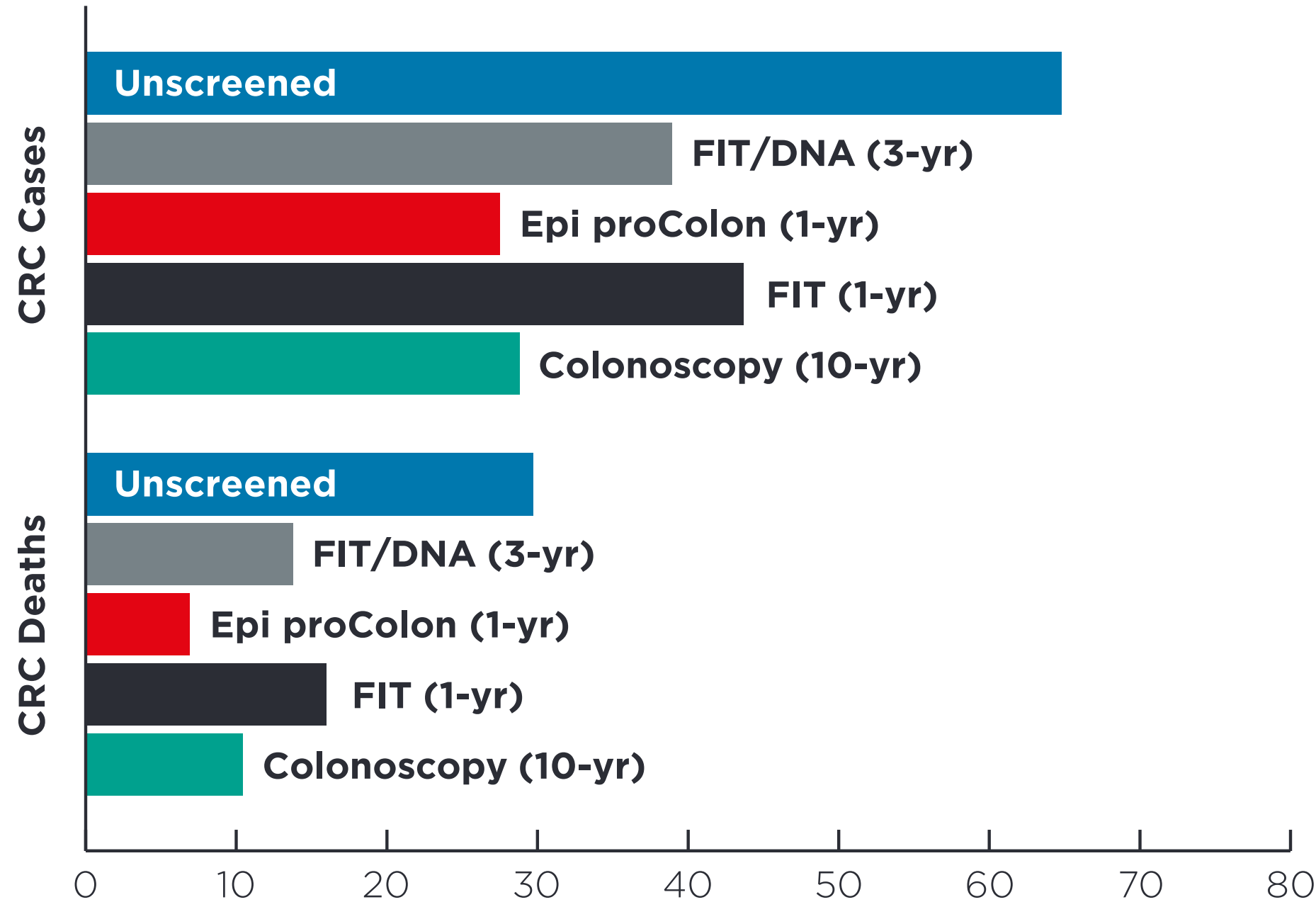


D'Andrea E, Ahnen DJ, Sussman DA, et al.
Quantifying the impact of adherence to
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NON-INVASIVE CRC SCREENING REPORTED ADHERENCE

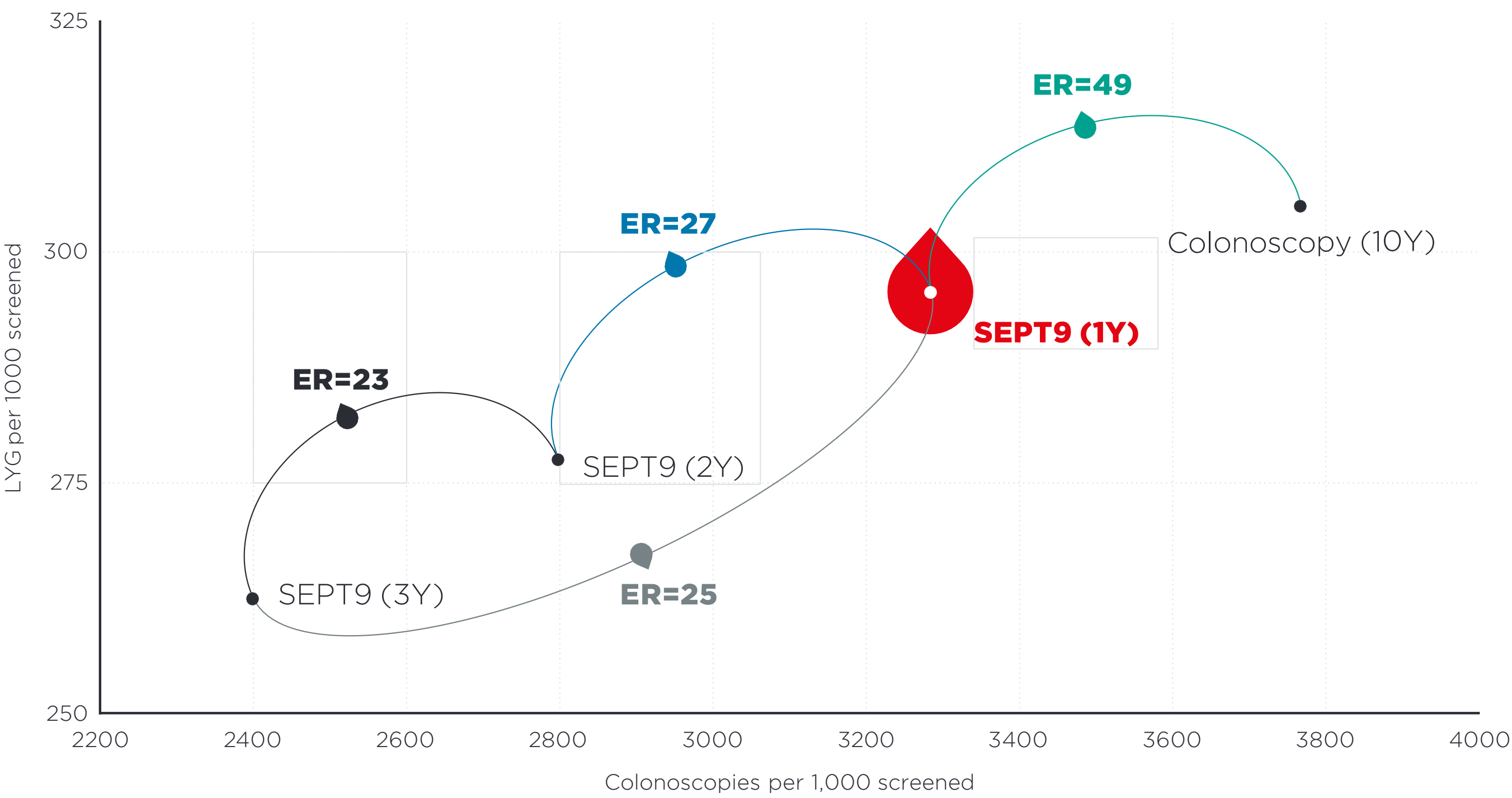
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YEARLY INTERVAL IS BEST CHOICE FOR SEPT9 SCREENING

Lifetime number of colonoscopies and life-years gained (LYG) by SEPT9 screening interval



The efficiency ratio (ER) provides a measure of the benefits from screening (LYG) along with the burden of testing (COL) required to achieve those gains and is calculated as the incremental number of colonoscopies divided by the incremental life-years gained (incremental burden to benefit).

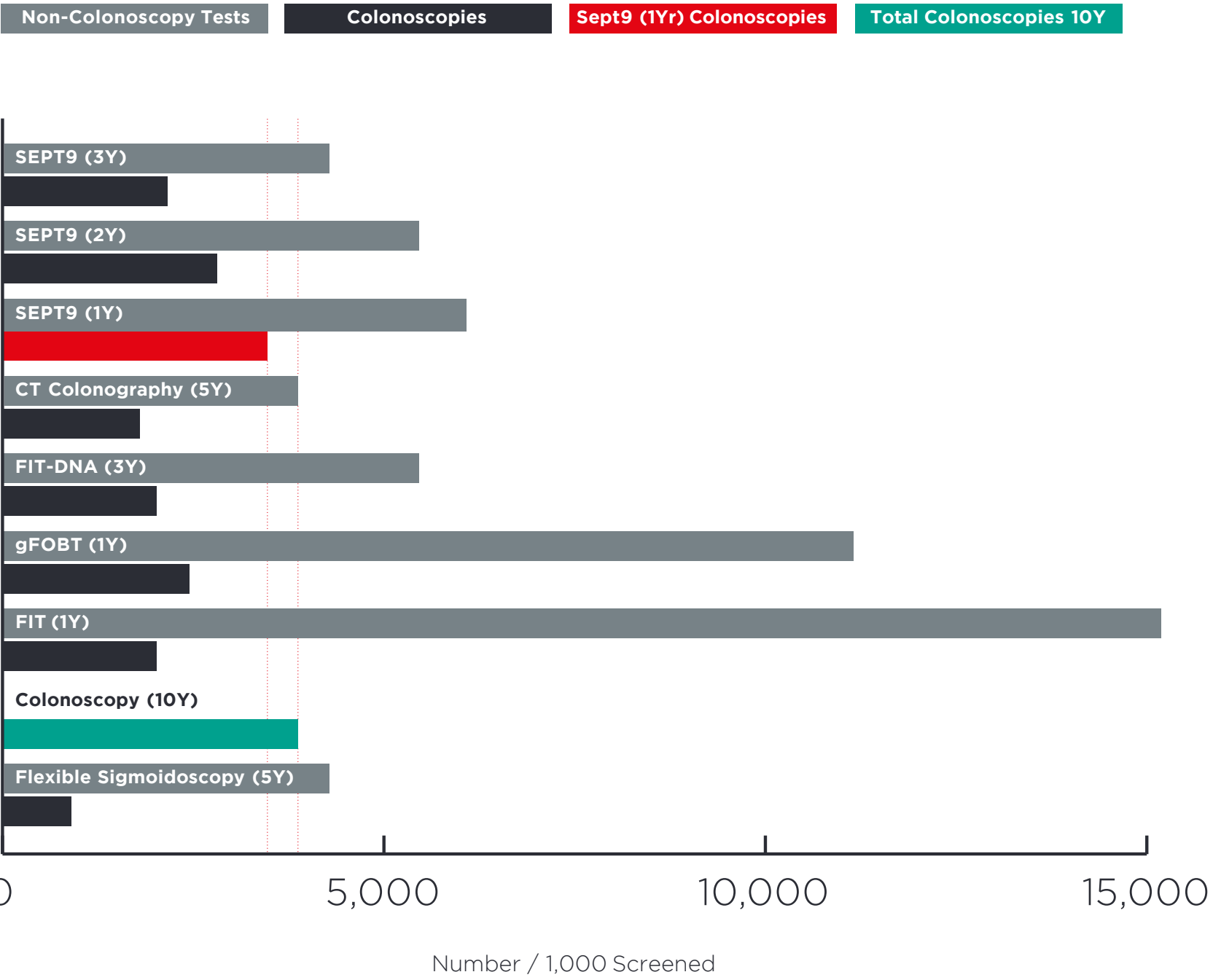
We used it to compare screening intervals for SEPT9.

USPSTF and ACS consider an ER of 39 or less as an acceptable number of incremental colonoscopies per life-year gained.

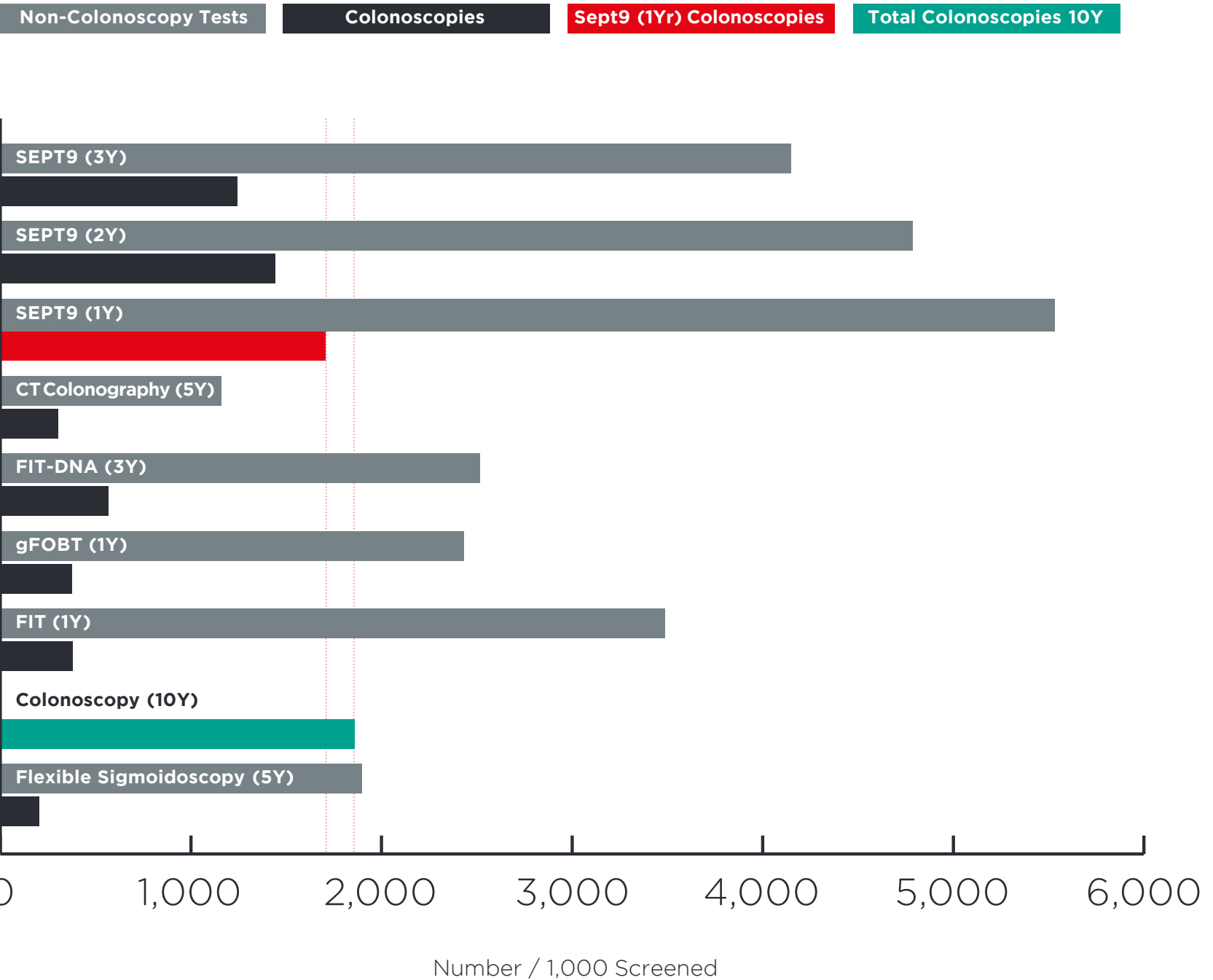
Therefore, an annual interval resulted as the best choice for SEPT9 screening.

ASSOCIATED HARMS

Number of Tests per 1000 Screened:
Full (100%) Adherence



Number of Tests per 1000 Screened:
Reported Adherence



NCCN – GUIDELINE INCLUSION

The new 2020 NCCN guidelines state that although the mSEPT9 blood test is “not recommended for routine screening”, it however “**can be considered for patients who refuse other screening modalities**”

- Consistent with Epi proColon’s (Septin9) FDA-approved indications:
 - The Epi proColon test is indicated to screen adults.... who have been offered and have a history of not completing CRC screening.... USPSTF 2008 CRC screening guideline (tests) should be offered and declined prior to offering the Epi proColon test...”.
- Impact of microsimulation model data not yet included in guidelines

HOW SCREENING SAVES MEDICARE MONEY

- **1 of 3 eligible Individuals are not screened**
- Over 30 million Americans are not up to date with CRC screening
- These folks account for 76% of all CRC deaths
- **Increased screening would save Medicare Billions of Dollars in treatment costs**
- Increased CRC screening participation in the pre-Medicare population would reduce CRC incidence and mortality, resulting in net long-term Medicare savings
- The shift in cost burden away from Medicare is estimated at a savings of \$25.5B over 50 years with merely 10% increase in CRC screening adherence

	NCI-Sponsored Cost Model 1						NCI-Sponsored Cost Model 2					
	MISCAN (\$)						SimCRC (\$)					
	2010	2020	2030	2040	2050	2060	2010	2020	2030	2040	2050	2060
DIFFERENCE BETWEEN ENHANCED SCREENING AND CURRENT TRENDS SCENARIO												
PRE-MEDICARE POPULATION (50-64 YEARS)												
Screening (A)	1.7	14.5	23.3	29.5	34.5	38.5	1.8	14.3	23.1	29.2	34.2	38.2
Treatment	0.5	1.0	-0.3	-1.3	-2.1	-2.7	0.2	-0.4	-3.9	-6.4	-8.4	-10.1
Total	2.1	15.5	23	28.2	32.5	35.7	2.0	13.9	19.2	22.9	25.8	28.1
MEDICARE POPULATION (65+ YEARS)												
Screening (B)	0.1	1.7	4.9	8.4	10.7	12.6	0.0	0.9	4.0	7.2	9.6	11.6
Treatment (C)	0.0	-1.1	-7.1	-15.9	-24.2	-30.9	0.0	-1.5	-9.4	-21.9	-34.2	-44.3
Total	0.1	0.5	-2.1	-7.5	-13.5	-18.3	0.0	-0.6	-5.4	-14.7	-24.6	-32.7

“Increased CRC screening participation in the pre-Medicare population could reduce CRC incidence and mortality, while the additional screening costs can be largely offset by long term Medicare treatment savings” Goede, et.al.

www.longdom.org/open-access/recognizing-diagnostic-gap-in-colorectal-cancer-2165-8048-1000219.pdf
www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/colorectal-cancer-facts-and-figures/colorectal-cancer-facts-and-figures-2017-2019.pdf
www.ncbi.nlm.nih.gov/pmc/articles/PMC4467468/



MEDICARE REIMBURSEMENT KEY MILESTONE

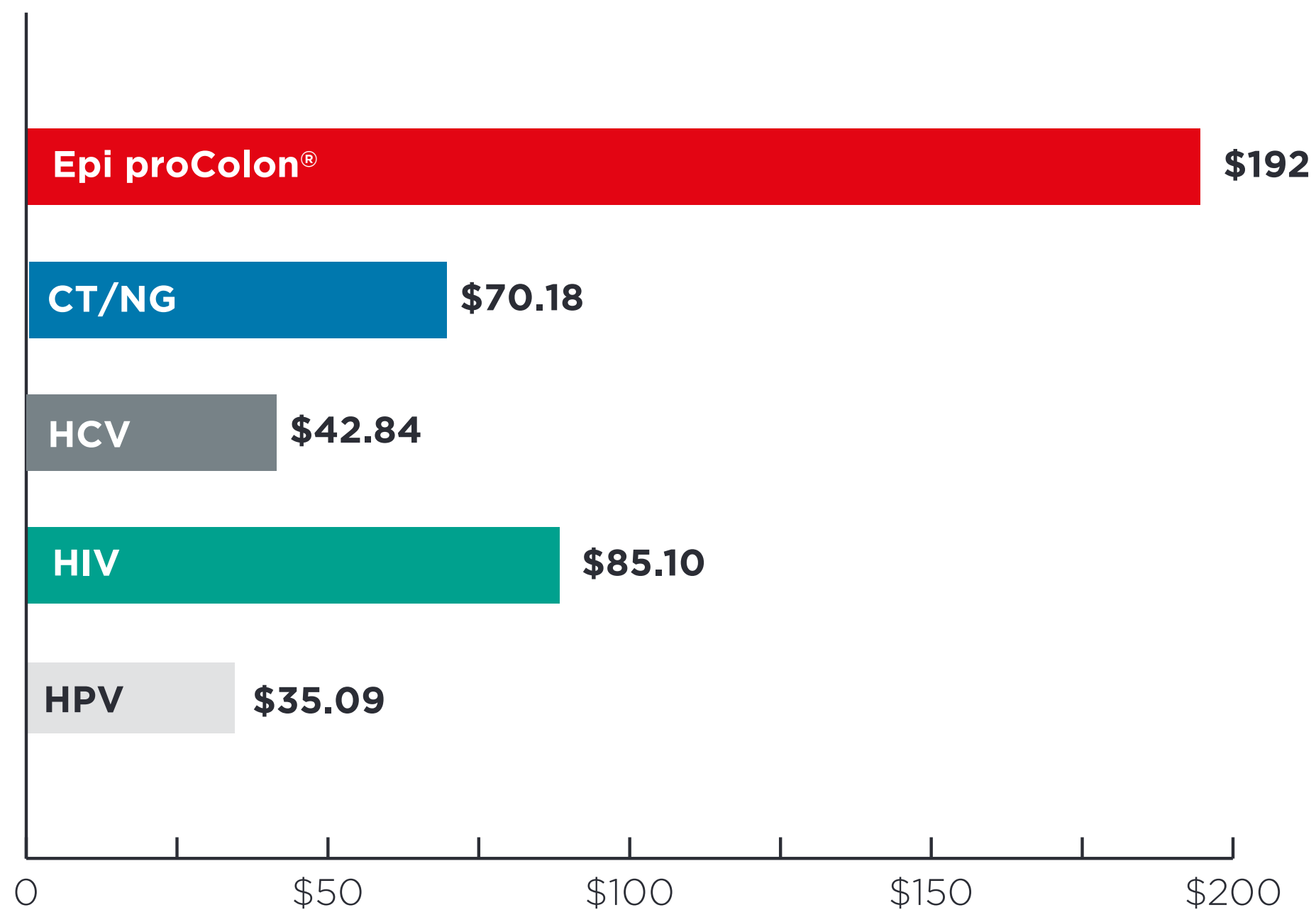
Rate

- \$192
- CPT Code 81327

Coverage

- National Coverage Decision (NCD)
- Legislation

HIGH VALUE SCREENING TEST



Clinical Lab Fee Schedule 2018 CMS.gov. 2018 Preliminary Gapfill rates 2018 CMS.gov

EPI PROCOLON REVENUE STREAM IMPACT

Epi proColon

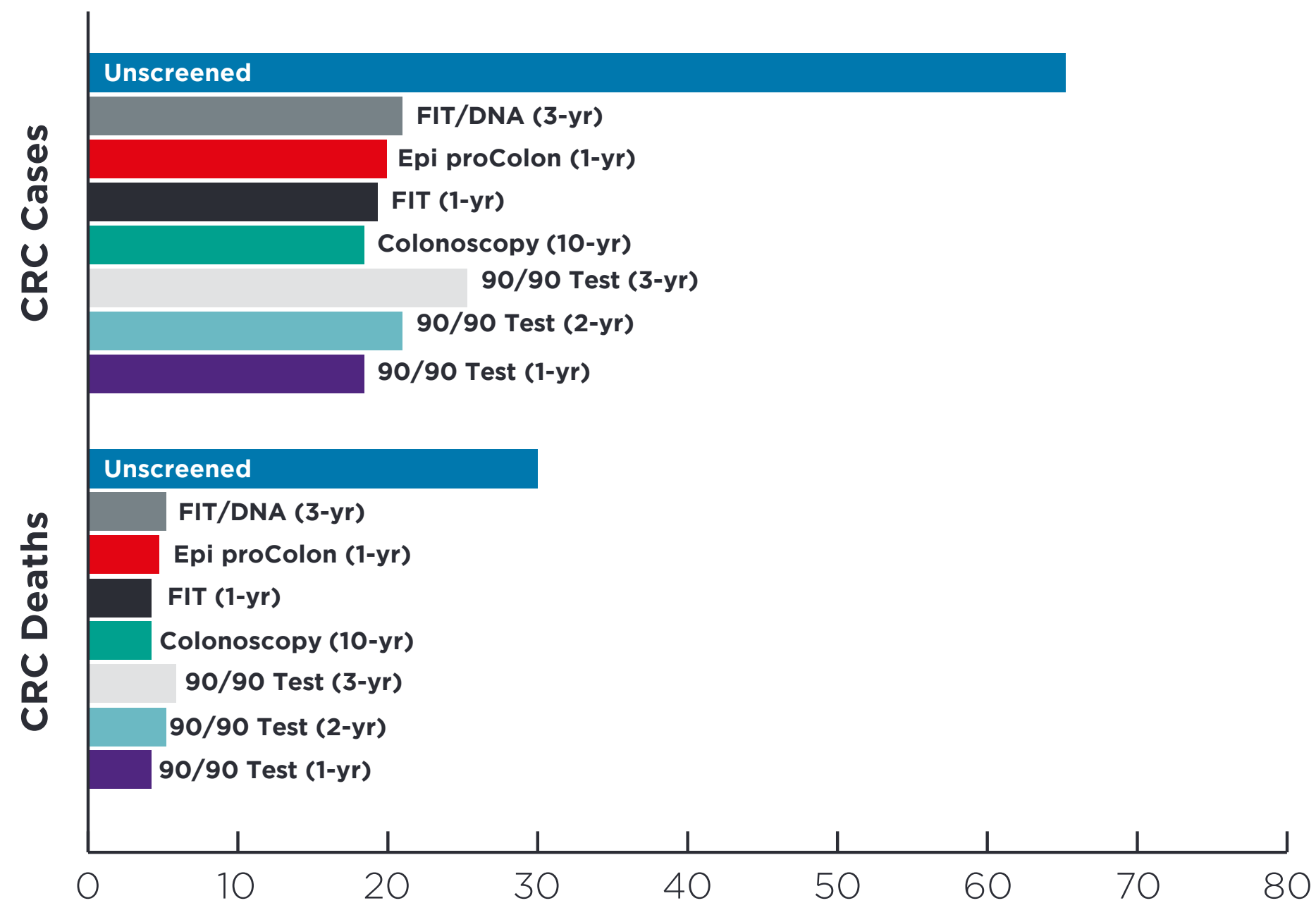


Direct CLIA Model



COMPETITION/FUTURE POTENTIAL TESTS IN 5-6 YEARS

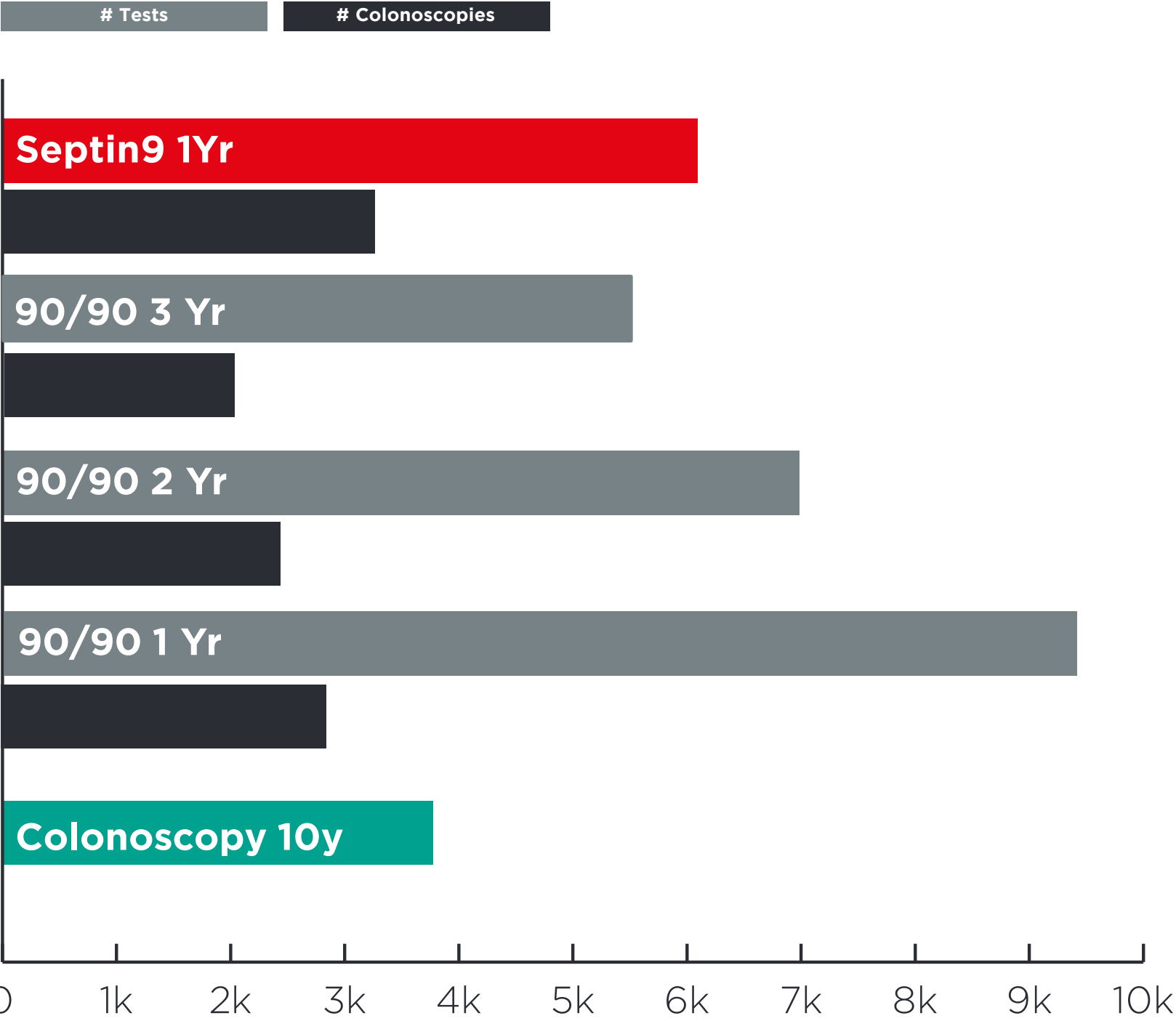
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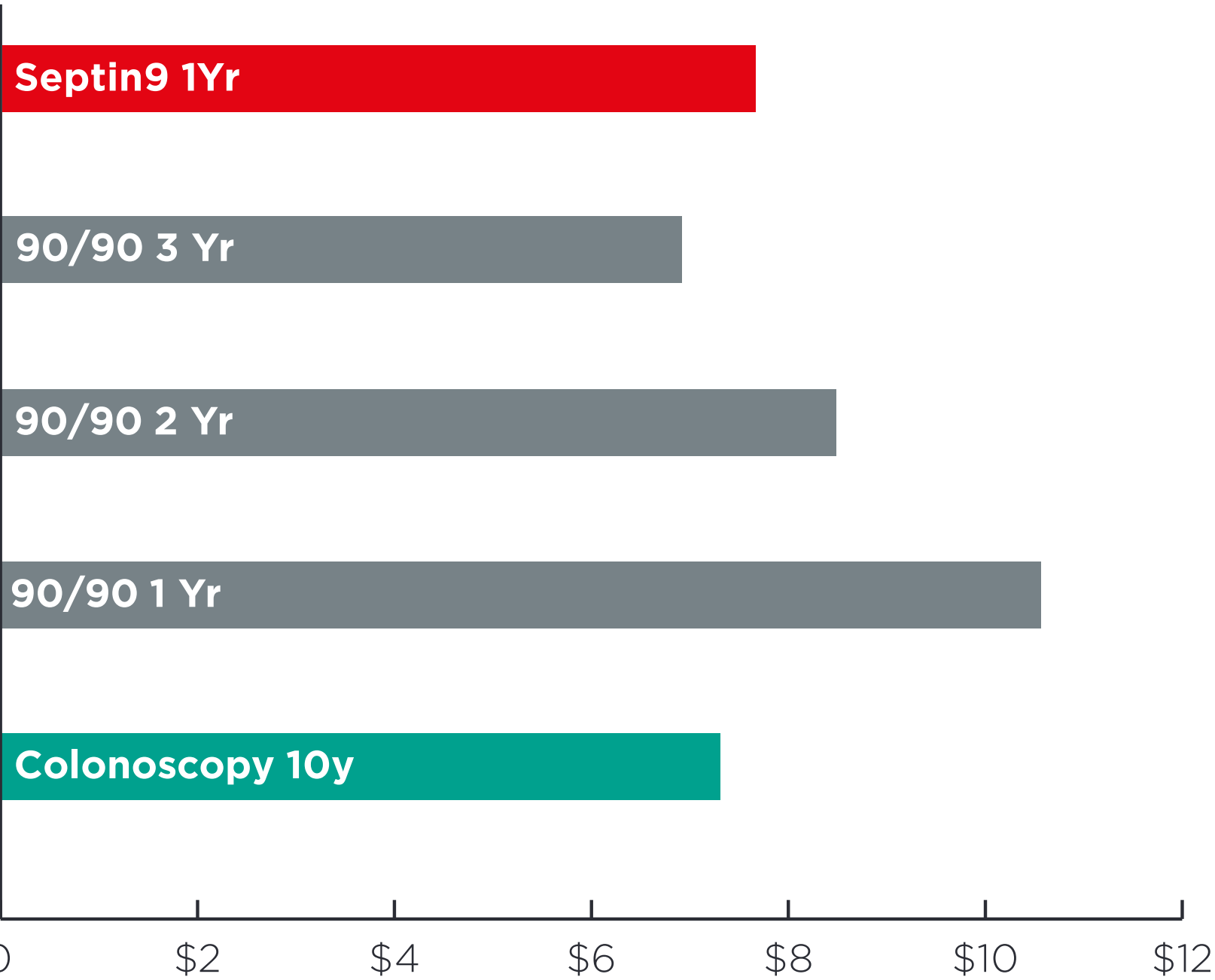
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COMPETITION/FUTURE POTENTIAL TEST HARMS

Harms



Total Cost (Millions)





PRODUCT PIPELINE

CRC EPC: 45 – 49 year-old FDA approval

- FDA “roadmap” via Cologuard
~1,000 patients
Specificity in an average risk
45 – 49 age group
- Opportunity
20M patients
>\$3.5B per year market

Liver Cancer: HCCBloodTest™

- >\$3B market opportunity
- ~ 3 years to FDA approval

NEXT STEPS

1. Upon reimbursement milestones capitalize company for R&D activities
2. Initiate FDA trial for 45-49 label extension
 - a) 12 months
 - b) ~\$3M
3. Conduct additional HCC clinical studies

FINANCIAL OVERVIEW

Q1-2020 Financial Highlights

EURm	Q1-2020	Q1-2019	Variance
REVENUE	0.2	0.3	(0.1)
ADJ. EBITDA*	(2.7)	(3.0)	0.3
Net result	(3.0)	(3.0)	0.0
Cash consumption	(3.3)	4.3	1.0
Liquid Assets **	11.0		

2020 Financial Outlook

Revenue

EUR 1 to 2M

EBITDA*

EUR -10.5m
to -12.5m

Cash Burn

EUR -10.5m
to -12.5m

*EBITDA before share-based payment expenses
**Cash and cash equivalents incl. marketable securities

SHARE INFORMATION

ISIN	DE000A11QW50
Segment	Prime Standard, FSE
IPO	2004
Total Shares	47.1 Million
Freefloat	64%
Coverage	Warburg Research Pareto Securities AS First Berlin Equity Research Encode Ideas

Shareholders

Deutsche Balaton AG	16.22%
Bridger Healthcare Ltd.	9.66%
Altium	5.19%
683 Capital	5.16%

Ticker

Bloomberg: ECX:GR
Reuters: EXXG.DE

Thomson ONE: ECX-XE
ADR OTC: EPGNY EPGNF

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