



MST Access Diagnostics Forum Presentation

6 December 2022 [ASX:RHY](#)

*A transformative and predictive
cancer diagnostics technology company*

rhythmbio.com

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Introduction



Rhythm's initial product, ColoSTAT® is a **simple, affordable** and **highly accurate** blood test for the detection of colorectal cancer for **global mass-market** screening.

IP protection **secured** in all major international jurisdictions.

Market-ready with operational revenues expected in FY'23.

Commenced **platform technology** program for multiple / pan cancer targets.

ColoSTAT® Highlights



Disruptive and transformative technology

More affordable and easier to administer

Globally addressable markets

Performance better than market standard

Manufacturing & Patents secured

Operational revenues expected in FY'23

Platform Technology Extension Underway



Company Overview



Capital Structure

ASX Code	RHY
Share Price (at 5 December 2022)	\$1.11
Shares on Issue	216.7 M
Unlisted Options	16.8 M
Market Capitalisation	\$241.1 M
Cash in bank (31 October 2022)	\$11.2M
Top 20 Shareholders	42%

Share Price Chart



Board and Management

Otto Buttula	Glenn Gilbert	Trevor Lockett	Lou Panaccio	Rachel David
Executive Chairman	CEO & Managing Director	Executive – Technical Director	Non-Executive Director	Non-Executive Director
<ul style="list-style-type: none"> Extensive financial, investment, IT and biotech experience. Co-Founder and CEO of IWL (ASX: IWL); Founder / former CEO of Investors Mutual. Formerly a Director of Imugene (ASX: IMU) and Chairman of Investorfirst, now HUB (ASX: HUB). Chairman of HITIQ (ASX: HIQ) and Oncosil Medical (ASX: OSL). 	<ul style="list-style-type: none"> Former Head of Global Sales, Marketing and BD at Medical Developments Int. (ASX: MVP). Various leadership positions at CSL (ASX: CSL). Strong Legal, IP & Operational management. Broad international business experience. 	<ul style="list-style-type: none"> Former Theme Leader Colorectal Cancer and Gut Health CSIRO. Leader – Personalised Health Group CSIRO. Inventor on seven commercially-licensed patent families. 	<ul style="list-style-type: none"> Chairman of Avita Medical (ASX: AVH). Non-executive Director of Sonic Healthcare (ASX: SHL). Chairman of NeuralDX. Non-executive Director of Adherium (ASX: ADR). Non-executive Director of Unison Housing. Former CEO Melb Pathology & Monash IVF. 	<ul style="list-style-type: none"> Currently the Chief Executive Officer (CEO) of Private Healthcare Australia (PHA). Previously: Senior Director Government Affairs, Policy and Market Access for Johnson & Johnson. Various senior roles with McKinsey, CSL and Pfizer (formally Wyeth).

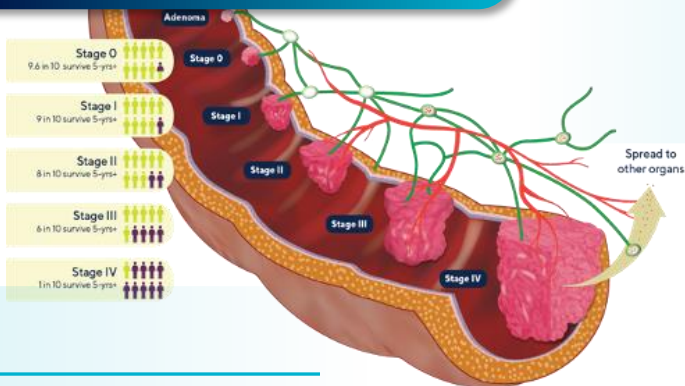
Colorectal Cancer (CRC)



Globally, Colorectal Cancer is currently the 3rd largest cancer by volume with 1.93 million new cases diagnosed annually and 2nd largest cause of cancer related deaths



DIAGNOSIS BY STAGE



COLORECTAL CANCER RISK FACTORS

50+

Aged over 50



Inherited genetic risk factor



Poor diet and lack of exercise



Smoking



A waistline of over 94cm for men and 80cm for women



A strong family history of bowel cancer



A serious inflammatory bowel disease for more than eight years

AUSTRALIAN OPPORTUNITY

“The National Bowel Cancer Screening Program could prevent 84,000 bowel cancer deaths by 2040 if participation rates were increased to 60%” *Cancer Council Australia^A*



CURRENT TESTING & SCREENING REGIME



In most countries, screening is recommended for those aged between 50-74 years old, with the primary method being a faecal test (FIT), which is designed to test only for blood in the stool.

Early detection is key to survival

>90%

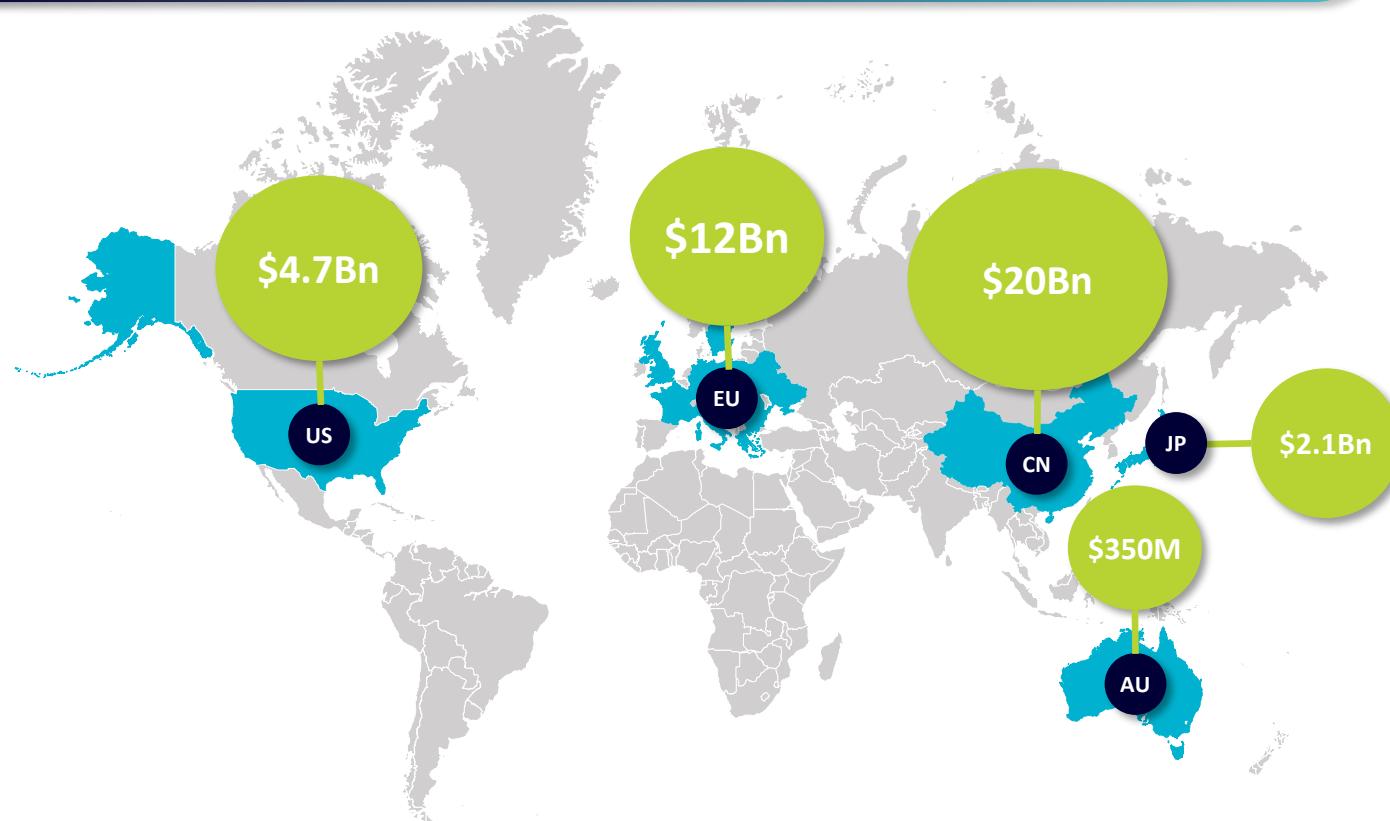
Source: Xi Y, Xu P (2021), Global colorectal cancer burden in 2020 and projections to 2040, Translational Oncology, 14(10), 101174, doi:10.1016/j.tranon.2021.101174 Epub 2021 Jul 6.

Source: ³Cancer Council 2021/22 Pre Budget Submission (page 6) - https://treasury.gov.au/sites/default/files/2021-05/171663_cancer_council_australia.pdf <https://www.aihw.gov.au/reports/cancer-screening/national-cancer-screening-programs-participation/contents/summary> <https://www.canceraustralia.gov.au/cancer-types/bowel-cancer/statistics#:~:text=In%202022%2C%20it%20is%20estimated,8%2C300%20males%20and%207%2C413%20females>

Market Opportunity / Addressable Market



US\$39 billion addressable screening value in priority markets¹



Colorectal Cancer Screening Market Population

Number of people over 50 years of age eligible for screening

Country	Screening participation	Addressable population
United States	63%	94 million ²
Europe	38%	231 million ³
China	19%	397 million ⁴
Japan	38%	42 million ⁴
Australia	41%	7 million ⁵
Total		771 million people

Potential to reach ~1 billion people
when the screening age is lowered to 45 years old

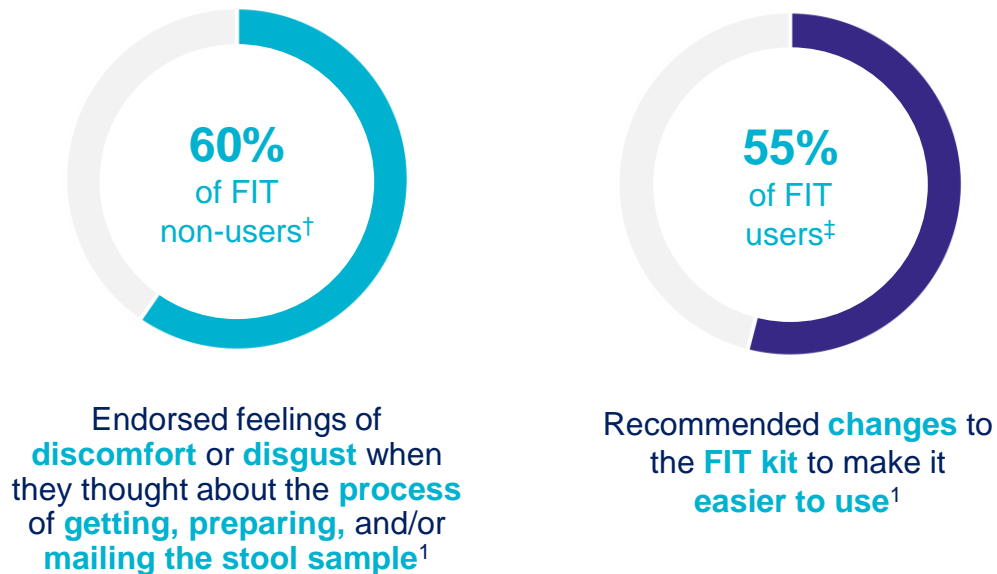
¹.Based on 2021 data calculated as Eligible Screening Population (771 million) x Example Test Cost (US\$50). RHY revenue may vary ². <https://doi.org/10.1158/1940-6207.CAPR-19-0527> ³<https://www.statista.com/statistics/253408/age-distribution-in-the-european-union-eu/>.
⁴. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5449420/> ⁵. <https://ncci.canceraustralia.gov.au/screening/colorectal-screening-rates/colorectal-screening-rate-participation>

Poor acceptability of faecal tests is a significant limitation to the performance of current CRC screening

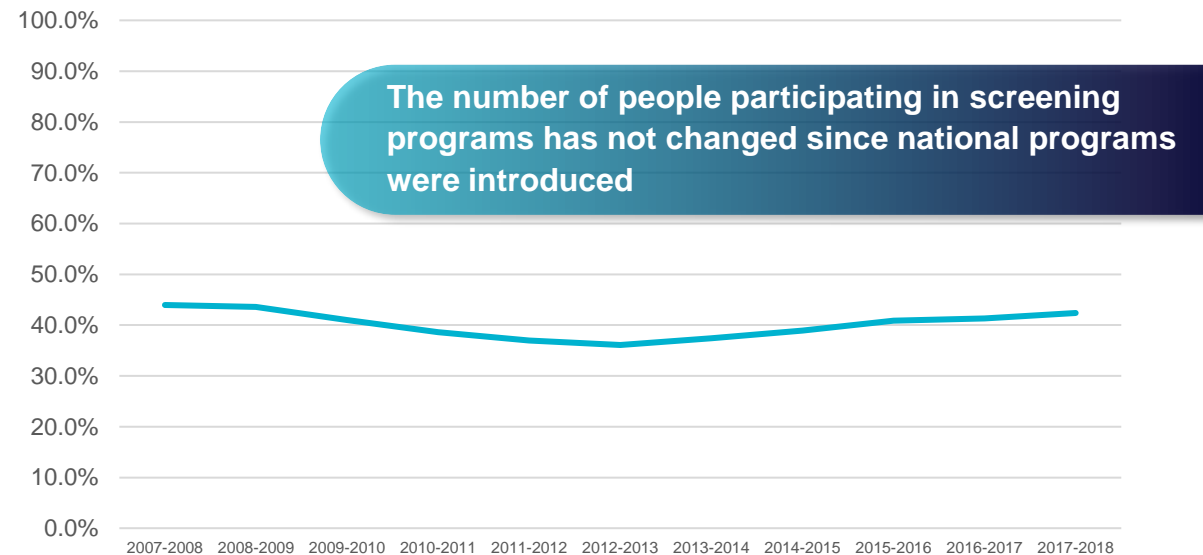


Patients report **inconvenience of sample collection**, **aversion with the procedure** and general **fear** as **significant barriers** to CRC screening¹⁻³

An observational study¹ in over 1,000 people in the US who received FIT kits reported that:



CRC Screening Participation in Australia⁴



Abbreviations: CRC, colorectal cancer; FIT, faecal test

[†]FIT non-users were defined as people who received the FIT but did not complete it.

[‡] FIT users defined as people who received and complete the FIT.

¹ Gordon NP, Green BB. Factors associated with use and non-use of the Faecal Immunochemical Test (FIT) kit for Colorectal Cancer Screening in Response to a 2012 outreach screening program: a survey study. BMC Public Health. 2015 Jun 11;15:546. 2. Osborne JM, Flight I, Wilson CJ, Chen G, Ratcliffe J, Young GP. The impact of sample type and procedural attributes on relative acceptability of different colorectal cancer screening regimens. Patient Prefer Adherence. 2018;12:1825-36. 3. Muthukrishnan M, Arnold LD, James AS. Patients' self-reported barriers to colon cancer screening in federally qualified health center settings. Prev Med Rep. 2019 Sep;15:100896.6

⁴ National Cancer Control Indicators - <https://ncci.cancer australia.gov.au/screening/colorectal-screening-rates/colorectal-screening-rate-participation>

Current CRC screening involves the use of a faecal test followed by colonoscopy



Abbreviations: CRC, colorectal cancer; FIT, faecal test



The FIT pathway consists of a cumbersome multi-step screening process which has a number of limitations¹⁻²:

- **Self-administered** test involving an **inconvenient** and **unpleasant** sample collection requiring faecal handling¹
- Sample collection and labelling **prone to error** as done by the patient
- **Mailing a stool sample** is required
- **Sample instability** imposes specific organisational constraints, and transport requirements²
- **Process** may need to be **repeated** for a subsequent round (e.g., in case of sample errors)³
- **Not specific** for CRC, may lead to unnecessary colonoscopies
- Unnecessary colonoscopies **increase burden** on healthcare systems, patients, insurers and government

¹. Gordon NP, Green BB. Factors associated with use and non-use of the Fecal Immunochemical Test (FIT) kit for Colorectal Cancer Screening in Response to a 2012 outreach screening program: a survey study. BMC Public Health. 2015 Jun 11;15:546

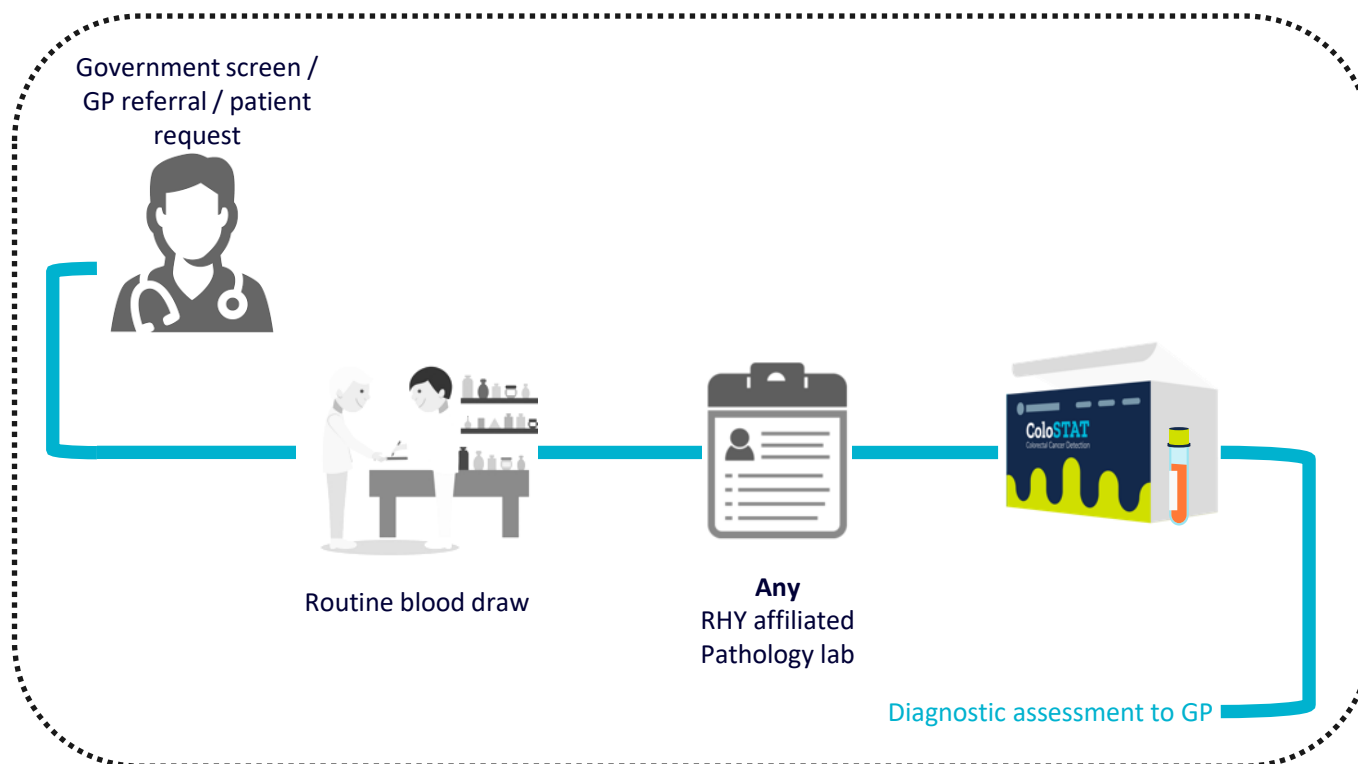
² Quintero E, Hassan C, Senore C, Saito Y. Progress and challenges in colorectal cancer screening. Gastroenterol Res Pract. 2012;2012:846985

ColoSTAT® - Patient Friendly, Increased Compliance



Early detection is the key to survival and reducing the cost of treatment

Simple & Routine Patient Journey With ColoSTAT®



ColoSTAT® has the potential to:

- ✓ Improve participation in screening and achieve early diagnosis.
- ✓ Improve patient outcomes and survival rates.
- ✓ Reduce healthcare resource use and unnecessary costly treatments.
- ✓ Improves the doctor/patient relationship.

Blood-based tests, such as ColoSTAT[®], are preferred by patients over FIT as they provide a more acceptable way to participate in testing



Blood-based tests are **preferred** over **faecal tests (FIT)** by **78–93%** of people who are offered CRT testing¹⁻⁵, with **ease** and **convenience** being the main reasons for their preference³⁻⁴

In an observational study among 460 people in the US who were offered CRC testing¹:

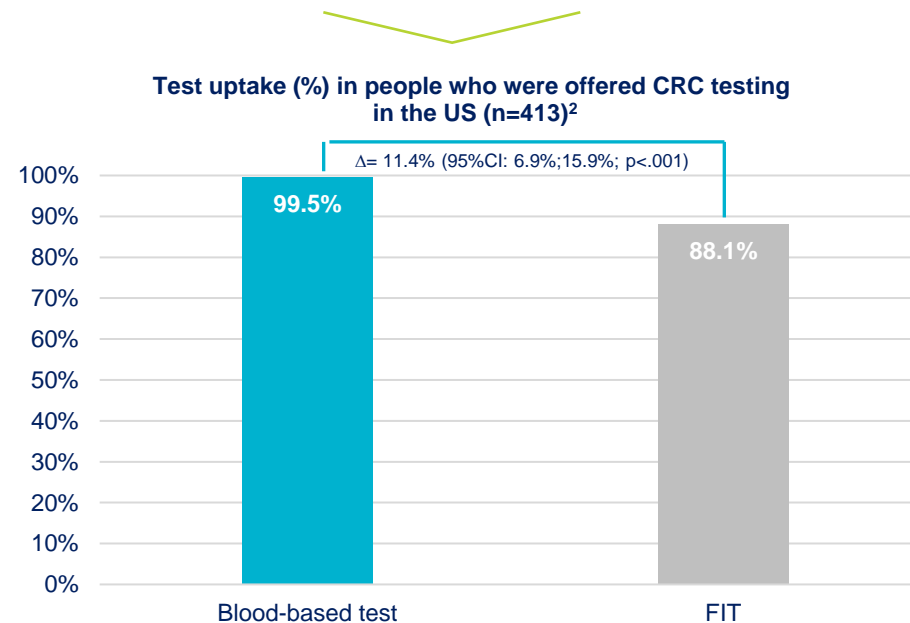


Opted for a **blood-based test**[†] over FIT¹

Abbreviations: CRC, colorectal cancer; FIT, faecal test

[†]Blood-based test offered was Septin9 DNA blood test (Epi proColon[®])

In a randomised controlled trial, **test uptake** was **significantly higher** with a **blood-based test**[†] than with FIT ($p < 0.001$)²



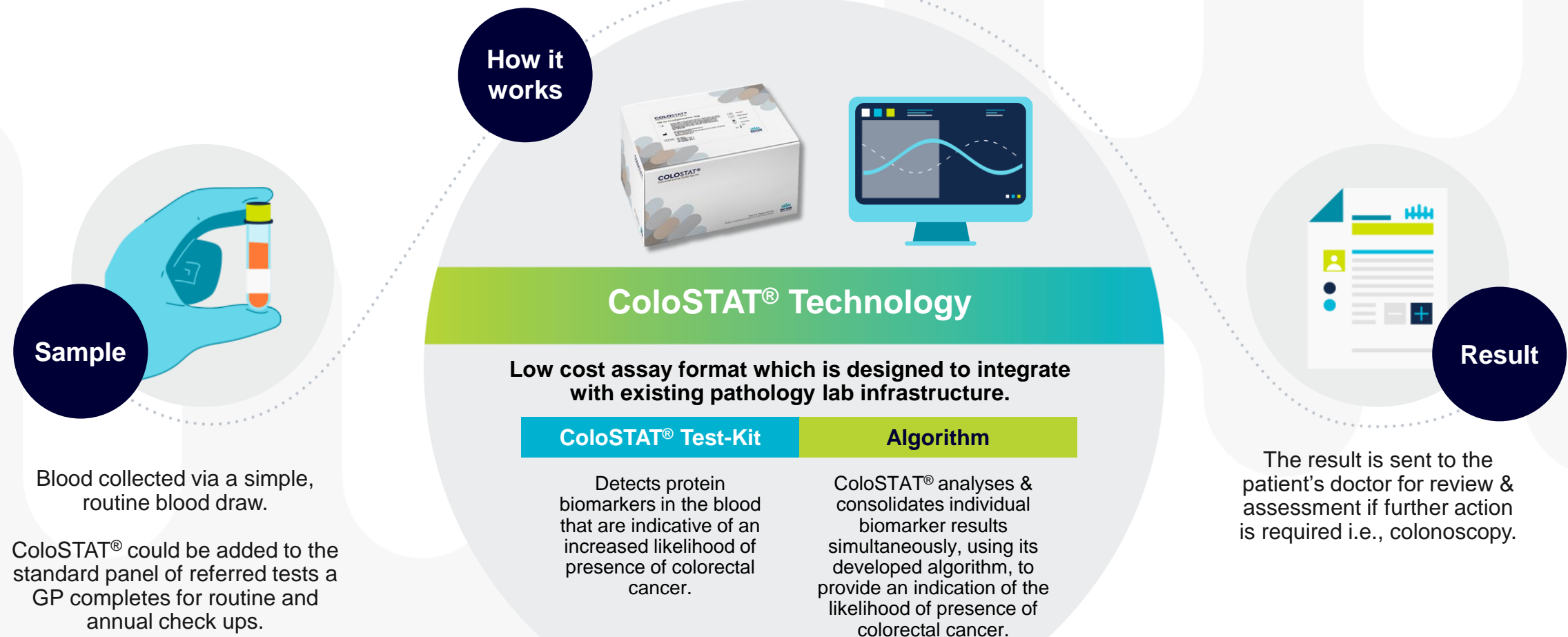
Patient-reported reasons for preferring blood-based options³⁻⁴:

- **Convenience of a blood draw** in the physician's office (74%; 67/90 patients)
- **Ease/comfort of a blood test** (78%; 71/90 patients)
- **Lower time requirement** vs FIT (48%; 43/90 patients)

ColoSTAT® - What Is It? How Does It Work?



Unlike the FIT, ColoSTAT® is specific for colorectal cancer – not just blood in faeces.

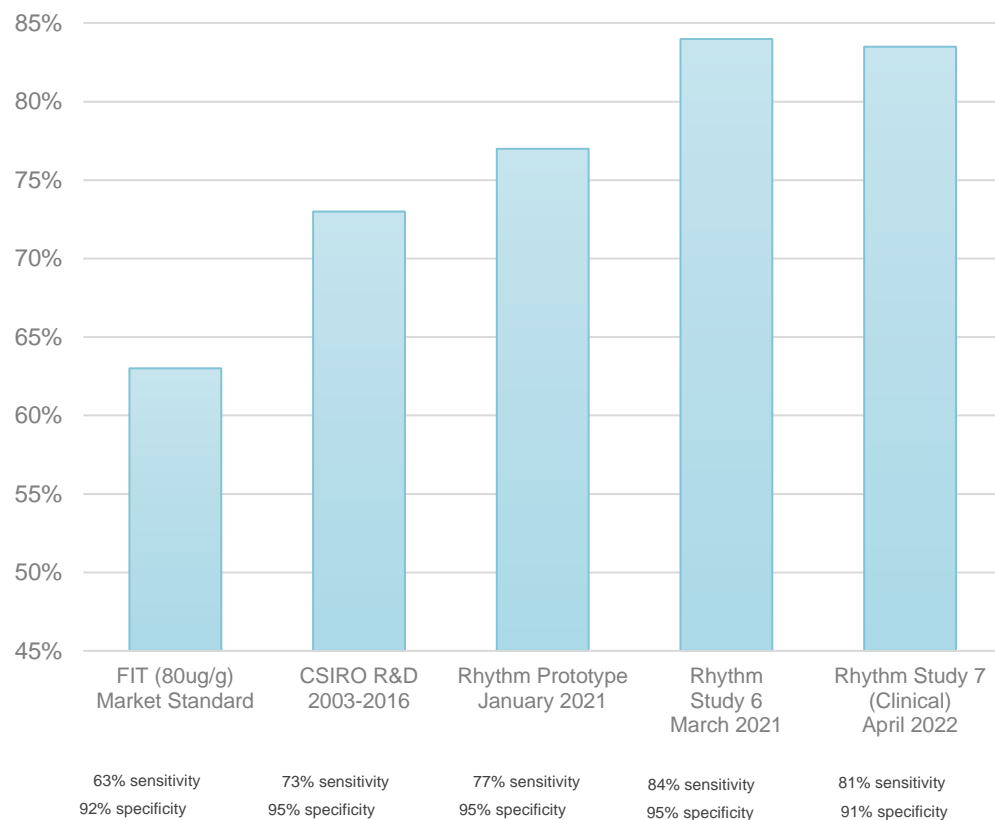


ColoSTAT® Performance



ColoSTAT® is expected to increase participation, leading to earlier detection and avoiding costly treatments

ColoSTAT® Sensitivity Performance Comparison



- **Highly Accurate**
ColoSTAT® was shown to be **35% more accurate** at detecting colorectal cancer than the current market standard Faecal Immunochemical Test (FIT).²

ColoSTAT® was shown to be **more accurate** at detecting advanced adenomas than the current market standard Faecal Immunochemical Test (FIT).²
- **Affordable and Simple**
Protein biomarker led delivers a cost-efficient simple blood test that is suited to global mass market screening programs.
- **Detects Cancer**
Disruptive technology that detects the presence of cancer in the blood whereas current FIT based testing regimes only detect the presence of blood in a stool sample.
- **Preferred**
A blood test is preferred as a more acceptable way to participate in testing.
- **Patient Friendly**
Convenient and can be part of routine health control.

¹ 9. Osborne, J. , Wilson, C. , Moore, V. , Gregory, T. , Flight, I. and Young, G. (2012) Sample preference for colorectal cancer screening tests: Blood or stool?. Open Journal of Preventive Medicine, 2, 326-331. doi: 10.4236/ojpm.2012.23047.

² Internal company data for Study 7.

Missed detection of early-stage CRC leads to the use of costly healthcare for advanced disease



Colorectal cancer is associated with **high healthcare costs which increase with advanced disease stage at diagnosis**¹⁻⁴

The **symptoms of CRC** only manifest at the **advanced stages**⁵

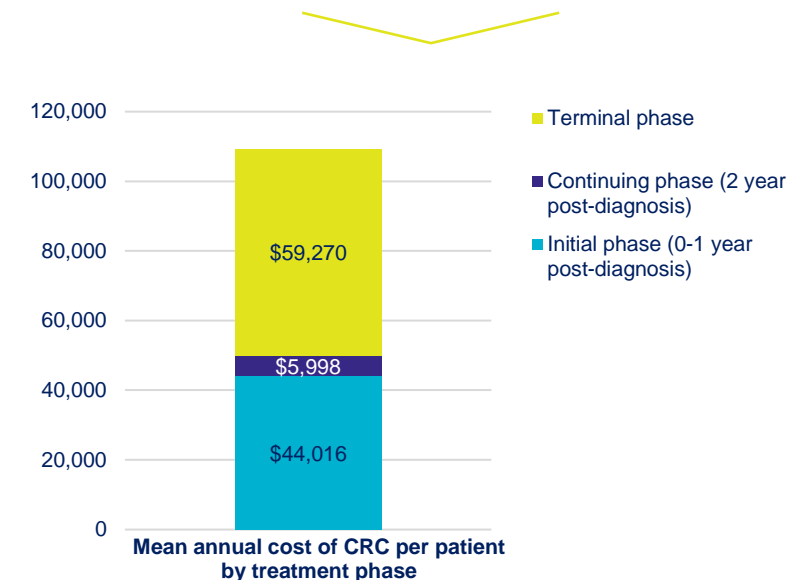
Diagnoses at Stage I or II only represent **less than half** of all CRC diagnosed in:



Total annual healthcare cost of CRC



In Australia, the estimated annual **cost of treating** a patient with CRC **increases** by **~35%** from **initial** phase to **terminal** phase³



When **diagnosed early**, CRC can be **successfully treated** and is associated with **5-year survival rates** of more than **90%**^{6,9-11}

Abbreviations: CRC, colorectal cancer

[†]2015 costs reported in Euros

[‡]Based on SEER_Medicare registry data set to estimate spending for patients with CRC enrolled in Medicare fee-for-service. Costs reported are in 2013 US\$.

[§] 2013 Australian dollars

1.Henderson RH, French D, Maughan T, Adams R, Allemani C, Miniccozzi P, et al. The economic burden of colorectal cancer across Europe: a population-based cost-of-illness study. *Lancet Gastroenterol Hepatol*. 2021 Sep;6(9):709-22. 2.Chen CT, Li L, Brooks G, Hassett M, Schrag D. Medicare spending for breast, prostate, lung, and colorectal cancer patients in the year of diagnosis and year of death. *Health Serv Res*. 2018;53(4):2118-2132. 3.Goldsbury 2018. 4.Mariotto AB, Robin Yabroff K, Shao Y, Feuer EJ, Brown ML. Projections of the cost of cancer care in the United States: 2010-2020. *J Natl Cancer Inst*. 2011;103(2):117-128. 5.Xi Y, Xu P (2021), Global colorectal cancer burden in 2020 and projections to 2040, *Translational Oncology*, 14(10), 101174, doi:10.1016/j.tranon.2021.101174 Epub 2021 Jul 6. 6.Australia colorectal cancer statistics. Available at: <https://ncpi.cancer.gov.au/diagnosis/distribution-cancer-stage/distribution-cancer-stage>. 7.<https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/colorectal-cancer-facts-and-figures/colorectal-cancer-facts-and-figures-2020-2022.pdf> 8.<https://crukancerintelligence.shinyapps.io/EarlyDiagnosis>. 9.UK colorectal cancer statistics. Available at: <https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/bowel-cancer/survival#heading=Three> 10.US colorectal cancer statistics. Available at: <https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/survival-rates.html> 11.US colorectal cancer statistics <https://www.cancer.net/cancer-types/colorectal-cancer/statistics>

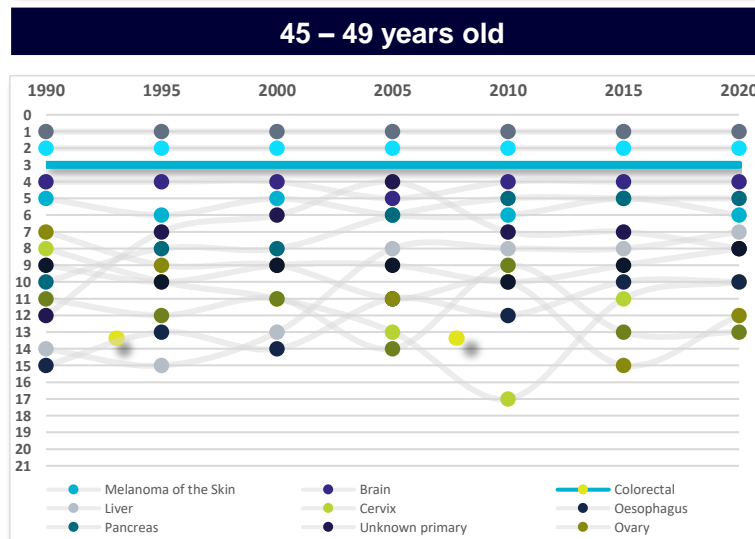
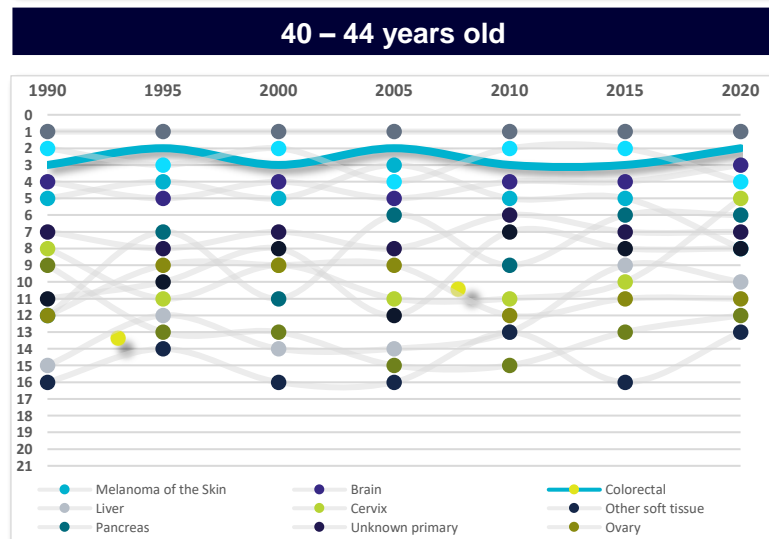
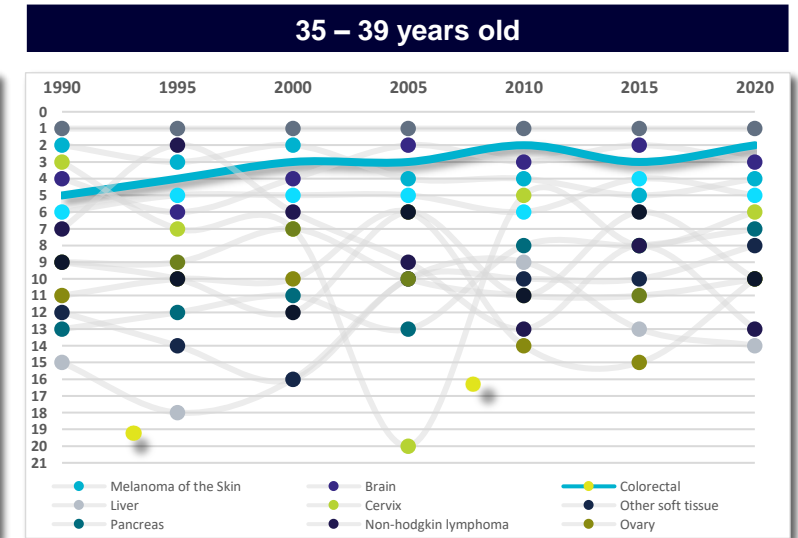
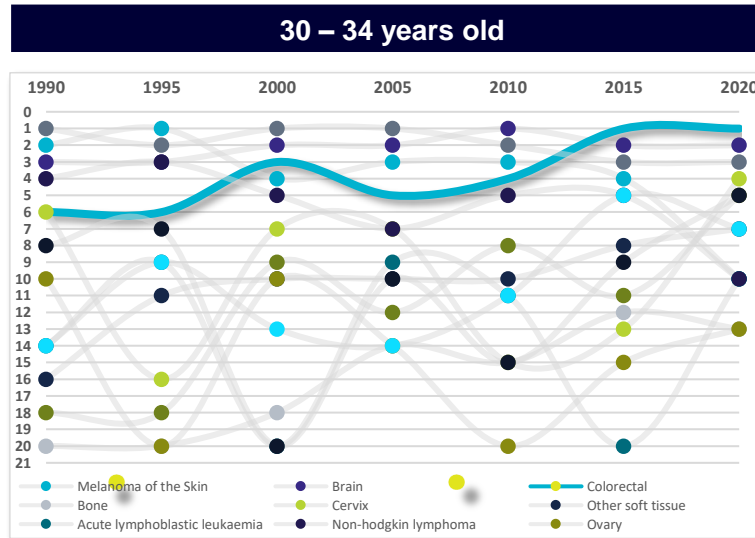
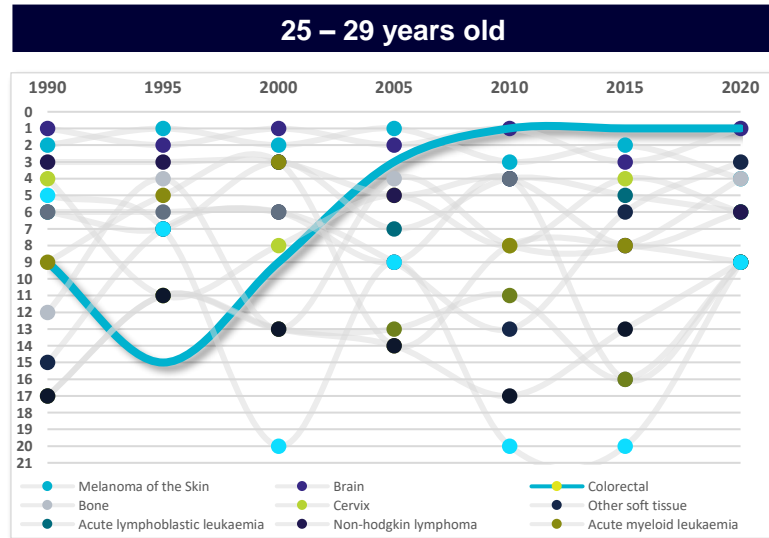
Market Likely To Expand Significantly



- ✓ USA Preventative Services Task Force recommends Colorectal Cancer Screening to commence at age 45. Five years younger than it previously recommended, adding circa 20 million patients to the screening population in the USA alone.
- ✓ Reduction of screening age under 50 years of age is expected to occur in all major global markets.
- ✓ The US Centres for Medicare and Medicaid Services released a draft decision outlining the criteria for the reimbursement of current and future blood-based colorectal cancer screening tests.
- ✓ Tests must demonstrate both sensitivity **greater than or equal to 74 percent** and specificity **greater than or equal to 90 percent**.

ColoSTAT® would meet the requirements in the US based on both the Study 6 and Study 7 (Rhythm's pivotal, prospective clinical trial) performance.

Australia – Growth of CRC in younger age groups



Colorectal Cancer is the #1 cause of death in 25–34-year-olds.

Top 2 cause of cancer related deaths below the age of 50.

Source: Australian Institute of Health and Welfare (AIHW). Cancer data in Australia - Cancer rankings data visualisation. <https://www.aihw.gov.au/reports/cancer/cancer-data-in-australia/contents/cancer-rankings-data-visualisation>

Unique Opportunity To Add Significant Value



Seamless alignment across the entire value chain providing broader benefits for the health system



Patients



Blood test is the preferred testing method.



Increased participation in screening.



Government



Cheaper testing leads to higher availability.



More lives saved. Reduced economic & social burden.



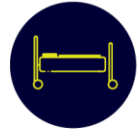
Health Insurers



Reduction in unnecessary colonoscopy procedures.



Reduced claims costs. Increased member engagement.



Health System



Reduction in unnecessary procedures.



More resources and beds available to prioritise urgent cases.



Laboratories



Technology fits existing pathology infrastructure.



No additional equipment or training required.



GP/Doctors

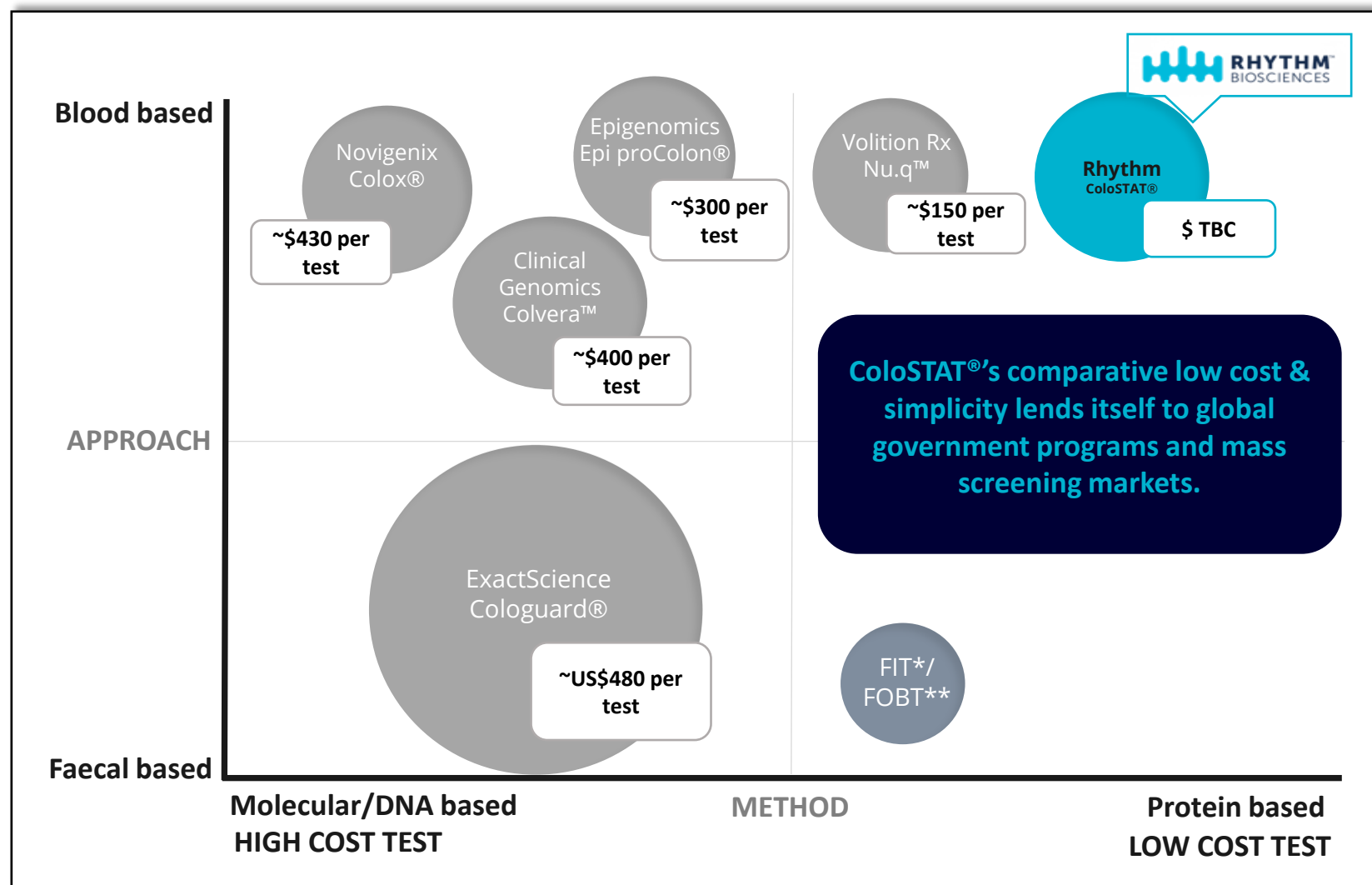


Test managed via a doctor referral.



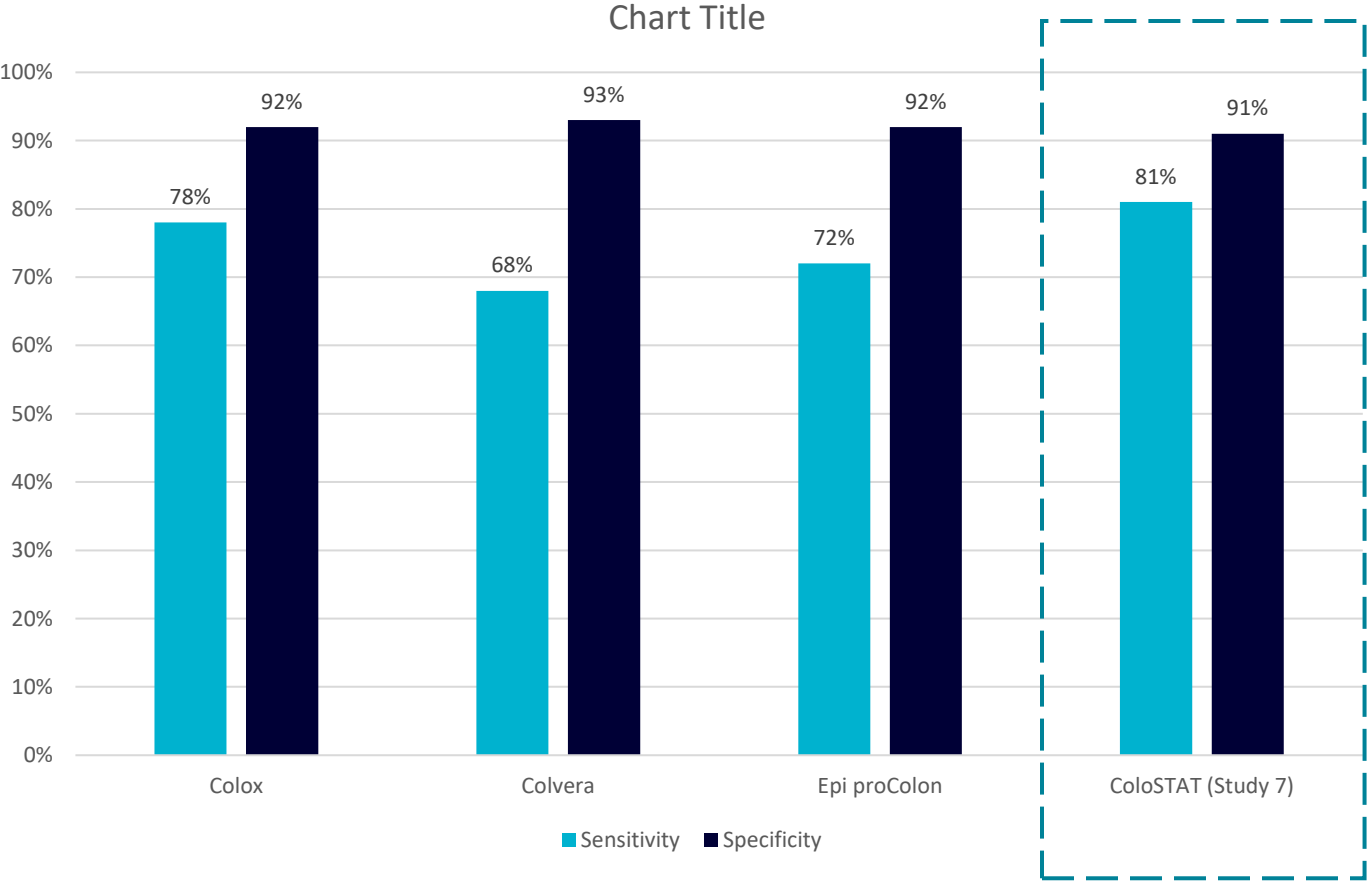
More relevant contact with patients for better health outcomes.

Competitive Landscape – ColoSTAT®'s Advantage



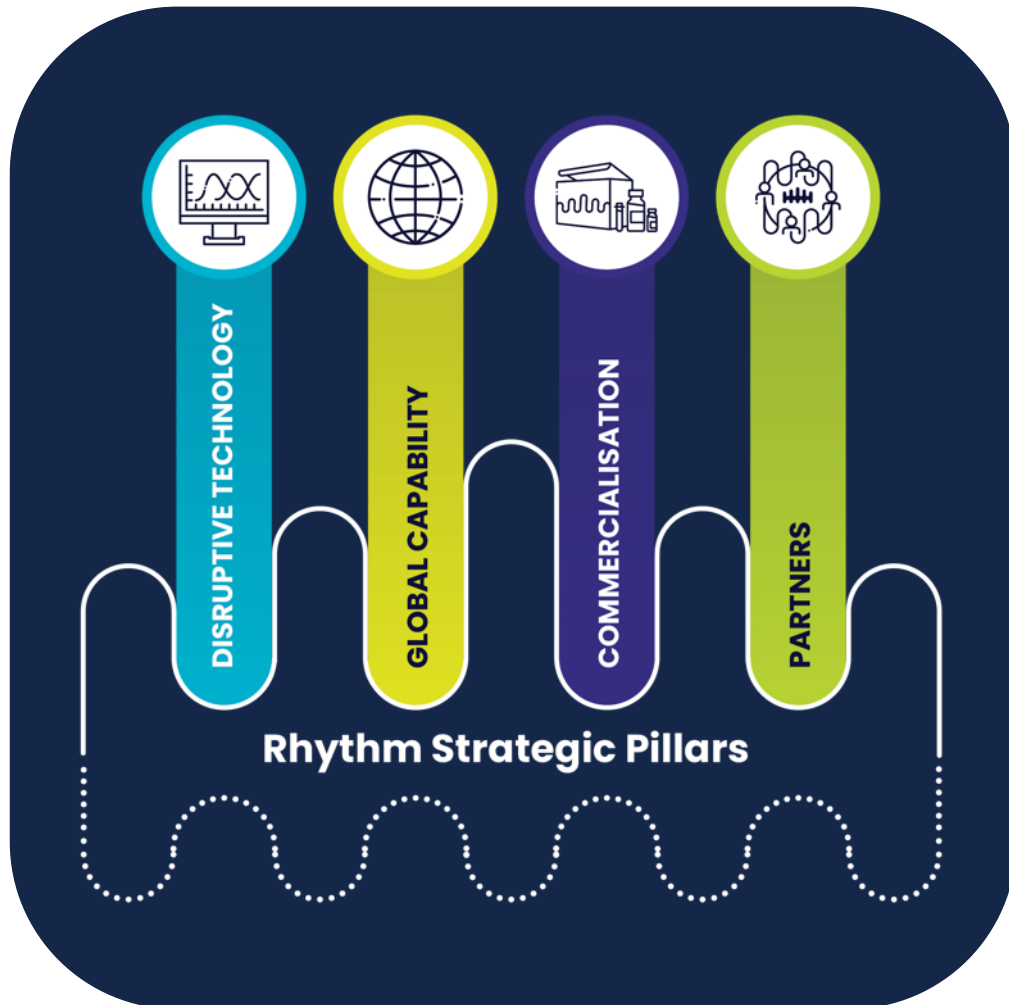
• FIT = Faecal Immunochemical Test
** FOBT = Faecal Occult Blood Test

Competitive Landscape – ColoSTAT[®]'s Advantage



**Performance / accuracy
of ColoSTAT[®] versus
other more expensive,
competitor, blood-based
tests**

Market Entry Strategy



Rhythm's strategy is underpinned by:

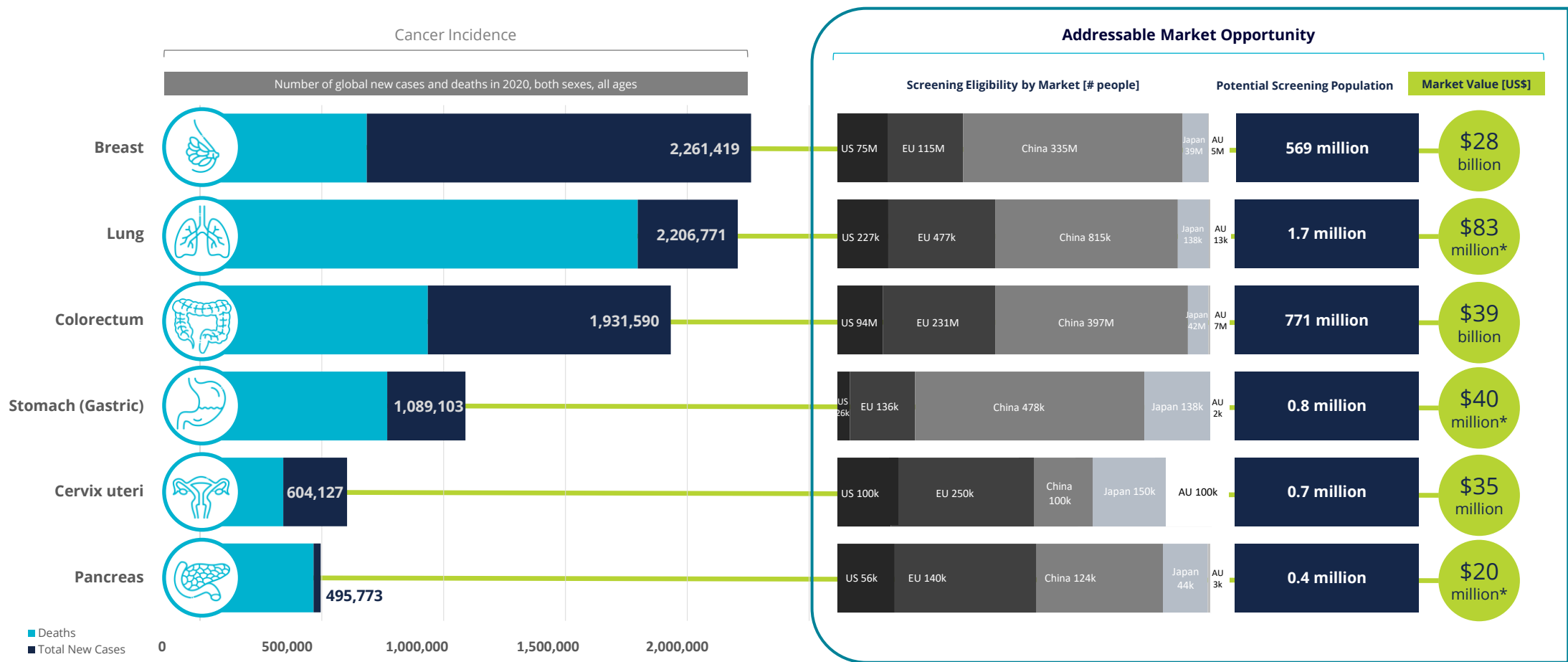
- ✓ **Proven technology**
- ✓ **Global manufacturing capability**
- ✓ **Establish partner networks**
- ✓ **Secure commercialisation pathway/s**
- ✓ **Partnerships in various global jurisdictions**
- ✓ **USA – Two mainstream pathways:**
 - ✓ Lab Developed Test (LDT) via a CLIA Lab;
 - ✓ FDA route.
- ✓ **Regulatory – Review additional country submissions for approval. Initially those that recognise the granting of a CE Mark and/or TGA approval.**

Platform Technology Expansion



- The expansion program is expected to be significantly shortened, leveraging the Company's lead biomarker which exhibits **pan-cancerous** properties;
- A platform expansion program identified a number of additional cancer target markets that have formed a new Research and Development program designed to follow a similar development pathway to ColoSTAT®;
- The initial five additional cancers to be targeted include:
 - ✓ Breast;
 - ✓ Cervical;
 - ✓ Lung;
 - ✓ Gastric; and
 - ✓ Pancreatic.
- Expedited program commenced, significant upside potential;
- Creates opportunity for collaboration and non-dilutive grants; and
- Complements Rhythm's affordable, global mass market cancer diagnostics strategy.

Global Market Opportunity – Platform Expansion



<https://www.wcrf.org/cancer-trends/worldwide-cancer-data/#:-:text=Find%20information%20about%20world%20cancer,and%208.8%20million%20in%20women.>

Example Test Cost (US\$50). RHY revenue may vary.

*No formal cancer screening program currently exists. This number reflects a base case view of new cases per annum as an initial market. It is expected that these potential populations will increase as the structure of new markets are developed for screening.

Milestones Delivered and Future Catalysts



Completion of the ColoSTAT® prototype test-kit



Core technology technically validated



CE Mark (Europe) and expanded to UK and Ireland



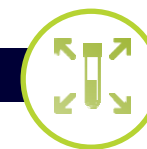
TGA Submission (Australia)



Inclusion of RHY into the All Ordinaries Index



Clinical trial (Study 7) successfully completed



Commenced Platform Technology Expansion



TGA Approval (Australia)



Operational revenues



Market Entry



Partners - Distribution / Labs



Additional international regulatory submissions



Further advance Platform Technology Expansion Program



Glenn Gilbert
CEO and Managing Director, Rhythm Biosciences
glenn.gilbert@rhythmbio.com
+61 3 8256 2880

www.rhythmbio.com

