



Market Presentation

24 OCTOBER 2024

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Executive Summary



Overview

- Rhythm Biosciences is developing and commercialising novel clinical cancer diagnostics.
 - ColoSTAT® is a 2nd generation multiplex assay designed to detect bowel cancer in a patient blood sample that is in the final stages of development ahead of commercialisation in 2025.
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Key Investment Highlights

- Accelerated market entry strategy into a multi \$bn global market.
 - RHY Cancer diagnostic solutions are clearly differentiated from competition: reduced invasiveness, ease of use, patient preferred and cost.
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Transformed Business

- Building on valuable Company learnings with new internal and external capabilities and enhanced commercial focus.
 - Complete re-engineering of core assay technology delivers customer requirements.
 - Pragmatic, quicker and lower risk path to market identified.
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Why Rhythm Biosciences?

Rhythm Biosciences is committed to saving lives through early detection of cancers using simple and accurate diagnostic technology.

Developing novel screening solutions for specific cancers via patient friendly blood tests is our primary focus.

Patent protected; fully characterised technology that can be readily adopted in all laboratories.

Targeting large global markets heavily supported by public and private health care systems.

Competitive product design that supplements and potentially improves current standard cancer testing methods used around the globe.

ColoSTAT®: A novel product with anticipated commercial launch in 2025.



Corporate overview



CORPORATE SNAPSHOT

ASX Code	RHY
Share Price (at 23 Oct 2024)	\$0.11
Shares on Issue	248.5M
Unlisted Options	21M
Market Capitalisation	\$27.35M
Top 20 Shareholders	42%

SHARE PRICE CHART - ASX:RHY



BOARD AND MANAGEMENT

David Atkins, PhD

Chief Executive Officer and Managing Director



Former CEO of Congenica (UK) & Synevo Diagnostics, Sr. Executive at Johnson & Johnson and Danaher.

Founder of Veridex – cancer molecular and cellular diagnostics (USA).

Significant experience in fund raising and VC investing. Currently adviser and board member for several private oncology businesses in UK and EU.

Otto Buttula

Non-Executive Chairman



Extensive financial, investment, IT & biotech experience.

Co-Founder and CEO of IWL (ASX: IWL); Founder / former CEO of Investors Mutual.

Formerly a Director of Imugene (ASX:IMU), Chairman of Investorfirst, now HUB (ASX: HUB), HITIQ (ASX: HIQ) & Oncosil Medical (ASX: OSL).

Sue MacLeman

Non-Executive Independent, Deputy Chair



30 years in Pharma, Biotech and Medtech including Amgen, BMS and Merck.

Experienced Board member, former CEO of NASDAQ, ASX, & AIM entities. Currently NED at Planet Innovation, Viral Vector Manufacturing Facility, Smartways Logistics, ATSE & OMICO & member of various government & academic advisory committees.

Trevor Lockett, PhD

Non-Executive Director



Former Theme Leader Colorectal Cancer and Gut Health CSIRO.

Leader – Personalised Health Group CSIRO.

Inventor on seven commercially-licensed patent families.

Lou Panaccio

Non-Executive Director



Chairman of Avita Medical (ASX: AVH) and Adherium Ltd (ASX:ADR).

Non-Executive Director Sonic Healthcare (ASX: SHL) and Unison Housing.

Former CEO Melbourne Pathology & Monash IVF.

Our Clinical Advisory Board



**Sally
Benton**

Consultant Clinical Biochemist and Clinical Lead for Clinical and Specialist Biochemistry Services at Berkshire and Surrey Pathology Services, a pathology network that serves 6 acute hospitals. Sally is also Director of the Bowel Cancer Screening South England Hub based at the Royal Surrey County Hospital, Guildford, serving a total population of about 16 million people across the South of England.



**Prof
Jon Emery**

Herman Professor of Primary Care Cancer Research at the University of Melbourne, and the Victorian Comprehensive Cancer Centre (VCCC) Primary Care Research and Education Lead. He is a National Health and Medical Research Council (NHMRC) Leadership Fellow, and Director of the Cancer Australia Primary Care Collaborative Cancer Clinical Trials Group (PC4).



**Prof
Finlay Macrae**

Head of Colorectal Medicine and Genetics at The Royal Melbourne Hospital, he is a lead clinician in the Familial Cancer Clinic and is engaged in research into Colorectal Cancer genetics and new therapies for Inflammatory Bowel Disease (IBD).

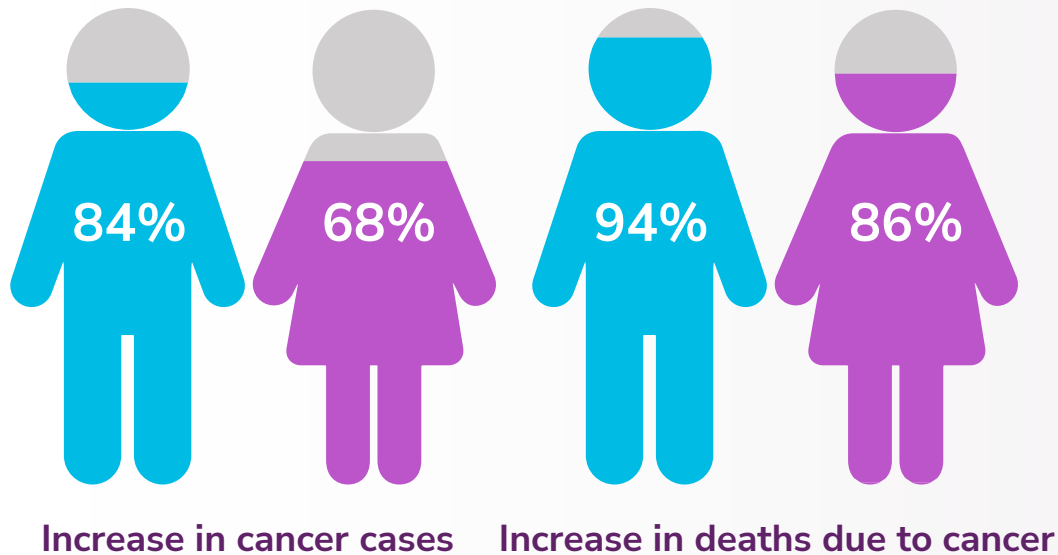
He trained in London with the world's leading colonoscopist at the time (St Mark's Hospital) and brought this skill to Australia and his practice.

Cancer is an increasing burden on global healthcare systems

Detecting and diagnosing cancer remains critical to public health

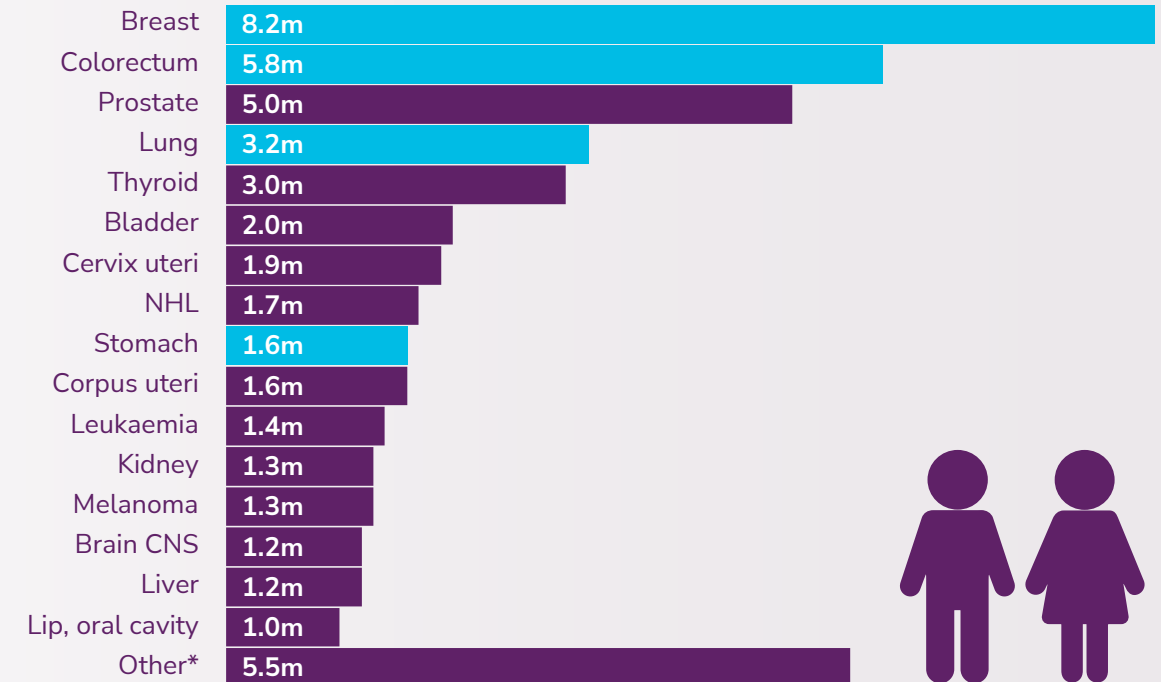
Estimated % rise in all cancers 2022 to 2050

Males and Females, Age 0-85+



Estimated number of worldwide prevalent cases in 5 years from 2022

RHY focus

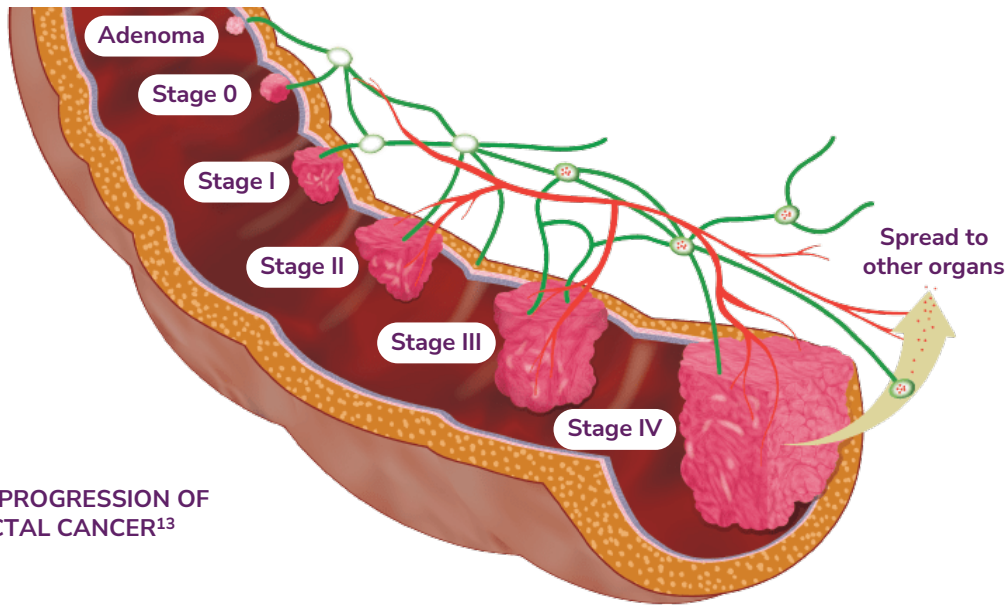


Source: <https://gco.iarc.who.int/>

* Ovary, Oesophagus, Larynx, Multiple myeloma, Pancreas, Nasopharynx, Oropharynx, Testis, Hodgkin lymphoma, Salivary glands, Gallbladder, Hypopharynx, Vulva, Penis, Kaposi sarcoma, Vagina, Mesothelioma

Colorectal cancer (CRC) is the 2nd leading cause of cancer death globally

CRC is a progressive disease in which epithelial cells in the colon or rectum grow out of control²



DISEASE PROGRESSION OF COLORECTAL CANCER¹³





CRC is generally asymptomatic; in over **50%** of cases it is diagnosed when already at an advanced stage⁹⁻¹¹

CRC grows slowly over many years and has the potential to be detected early¹²

When localised to the bowel, CRC is highly treatable and often curable⁸

GLOBAL BURDEN IN 2020

1.93 million new cases
~940,000 deaths¹







	RANK: MOST COMMON CANCER	ESTIMATED NEW CASES OF CRC	DEATHS FROM CRC IN 2020-21
 EUROPE: EU27 ⁷	2	341,419	156,105
 UNITED STATES ³	3	155,000	54,443
 UNITED KINGDOM ⁴	4	52,128	21,682
 AUSTRALIA ⁵	4	15,713 ⁶	5,326 ⁶

1. 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
2. Center for Disease Control and Prevention (CDC). Colorectal cancer, available at: https://www.cdc.gov/cancer/colorectal/basic_info/what-is-colorectal-cancer.htm#:~:text=Colorectal%20cancer%20is%20a%20disease,the%20colon%20to%20the%20anus.
3. Colorectal Cancer Statistics | CDC
4. Bowel cancer incidence statistics | Cancer Research UK
5. Bowel cancer (Colorectal cancer) in Australia statistics | Cancer Australia
6. Bowel cancer (Colorectal cancer) in Australia statistics: <https://www.canceraustralia.gov.au/cancer-types/bowel-cancer/statistics#:~:text=In%202019%2C%20there%20were%205%2C255,2%2C836%20males%20and%202%2C459%20females.>
7. Colorectal cancer burden in EU-27, 2020. Available at: https://ecis.jrc.ec.europa.eu/pdf/Colorectal_cancer_factsheet-Mar_2021.pdf
8. National Cancer Institute. Colorectal Cancer. Available at: Colon Cancer Treatment (PDQ®)—Health Professional Version – NCI
9. Australia colorectal cancer statistics. Available at: <https://nci.canceraustralia.gov.au/diagnosis/distribution-cancer-stage/distribution-cancer-stage>
10. ACS. Colorectal cancer facts and figure. Available at: <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>
11. Cancer Research UK. Early Diagnosis Data Hub. Available at: <https://crucancerintelligence.shinyapps.io/EarlyDiagnosis>
12. Better Health Channel. Bowel Cancer. Available at: Bowel cancer - Better Health Channel
13. Kuipers EJ, Grady WM, Lieberman D, Seufferlein T, Sung JJ, Boelens PG, et al. Colorectal cancer. Nat Rev Dis Primers. 2015 Nov 5;1:15065.

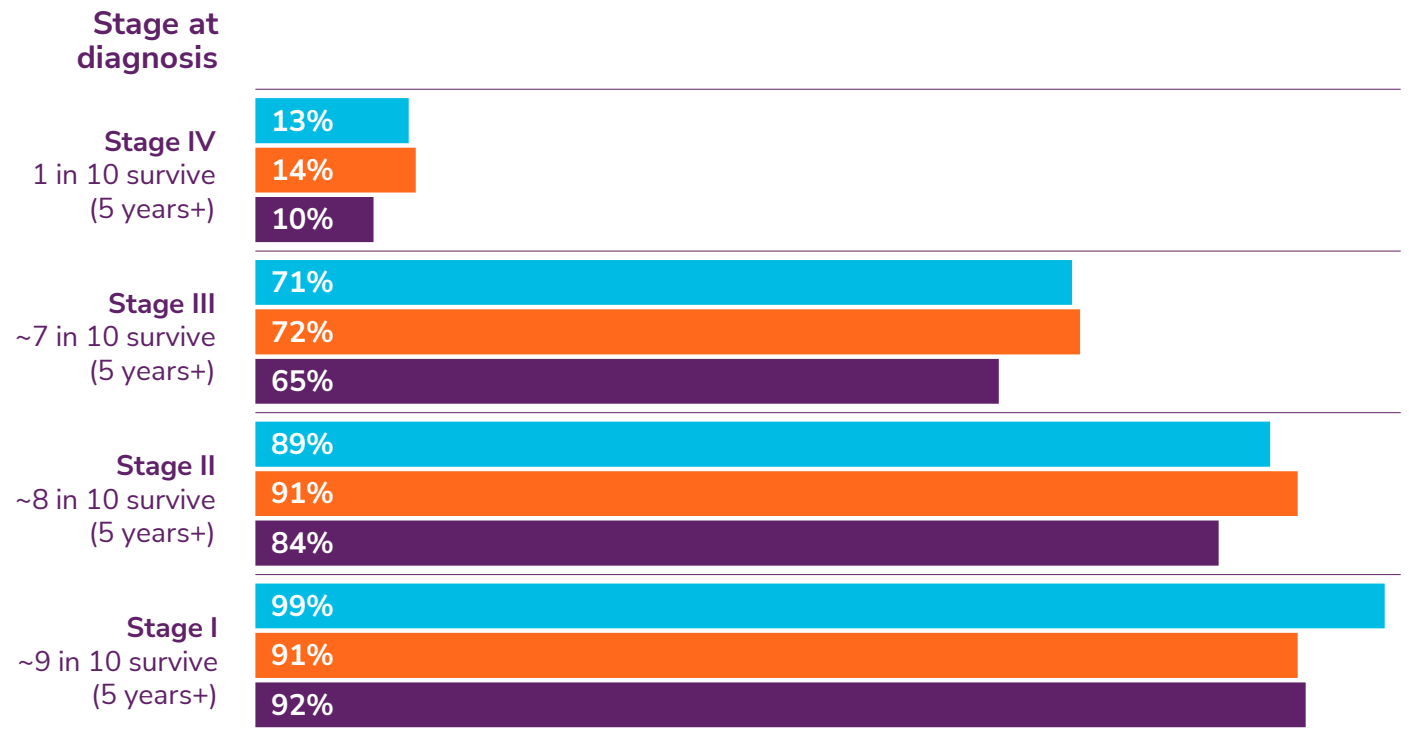
When diagnosed early, CRC can be successfully treated

Disease stage at diagnosis is the key predictor of survival in patients with CRC

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

	Stage I	Stage II
● AUSTRALIA	22% 	23% 
● US	37% 	37% 
● UK	16% 	21% 

Missed detection of early-stage CRC results in poor survival rates



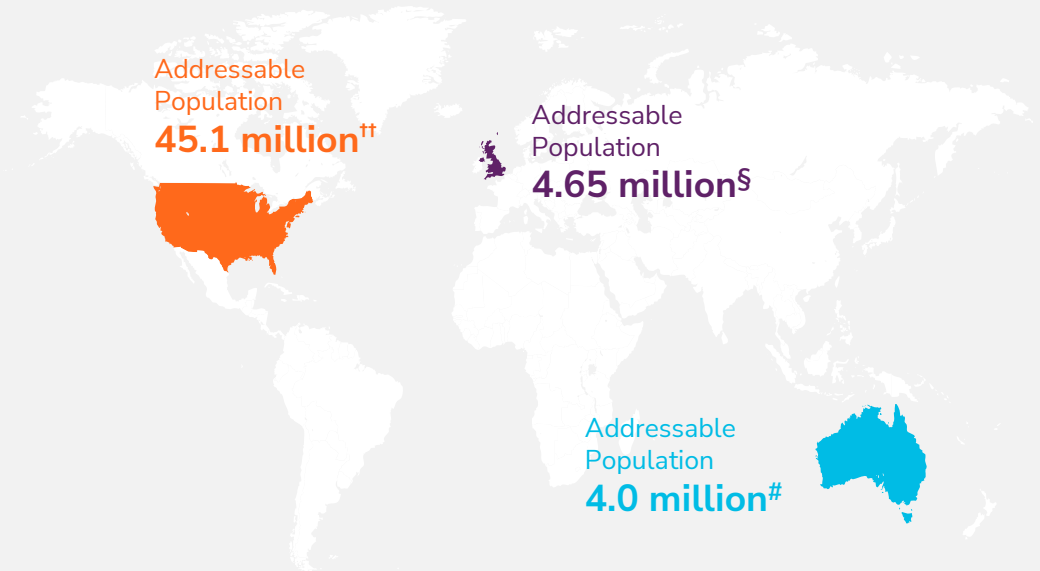
5-year survival rates in patients with CRC in US, UK and Australia

Abbreviations: CRC, colorectal cancer; US, united States
References: can be provided

Participation in CRC screening programs needs improvement

Based on current participation rates to CRC screening, **33–56% of the eligible population** across Australia, Europe, UK and US **remains unscreened**.

Participation rates in CRC screening programmes in UK, US, Europe and Australia (2018/2019/2021).



As many as **53.7 million** eligible people across US, UK and Australia **remain unscreened** for CRC.

Abbreviations: CRC, colorectal cancer; FIT, faecal immunochemical test

[†] Percentage of adults aged ≥50 years who had colonoscopy in the past 10 years (2018 data).

[‡] Percentage of people aged 60–74 year screened for CRC with FIT in 2020/2021.

[¥] Percentage of people screened for CRC with FIT in 12 European Union Member States in 2018.

[§] Based on 2020 UK population aged 60–74 years of 10.57 million and on 33.2% of the eligible population not been screened for CRC (participation rate: 66.8%).

^{††} Based on 2021 US population aged ≥50 years of 115.62 million and on 39.0% of the eligible population not been screened for CRC (participation rate: 61.0%).

[#] Based on 2021 Australia population aged 50–74 years of 7.08 million and on 56.5% of the eligible population not been screened for CRC (participation rate: 43.5%).

Blood tests, such as ColoSTAT[®], are preferred by patients over stool-based tests currently used in screening

Blood-based tests are preferred over faecal tests (FIT) by **78–93%** of people who are offered CRC testing, with ease and convenience being the main reasons for their preference



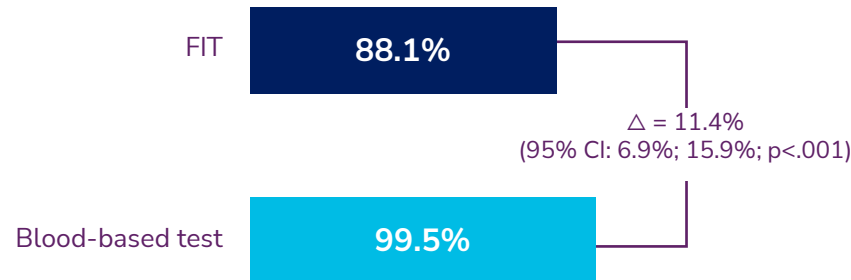
In an observational study among 460 people in the US who were offered CRC testing:



Opted for a blood-based test[†] over FIT

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

Test uptake (%) in people who were offered CRC testing in the US (n=413).



Patient-reported reasons for preferring blood-based options

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

Ioannou S, Sutherland K, Sussman DA, Deshpande AR. Increasing uptake of colon cancer screening in a medically underserved population with the addition of blood-based testing. BMC Cancer. 2021 Aug 28;21(1):966.

Liles GL, Coronado GD, Perrin N, Howel Harte A, Nungesser R, Quigley N, et al. Uptake of a colorectal cancer screening blood test is higher than of a fecal test offered in clinic: A randomized trial. Cancer Treatment and Research Communications. 2017;10:27-31.

Lamb YN, Dhillon S. Epi proColon((R)) 2.0 CE: A Blood-Based Screening Test for Colorectal Cancer. Mol Diagn Ther. 2017 Apr;21(2):225-32.

Adler A, Geiger S, Keil A, Bias H, Schatz P, deVos T, et al. Improving compliance to colorectal cancer screening using blood and stool-based tests in patients refusing screening colonoscopy in Germany. BMC Gastroenterol. 2014 Oct 17;14:183.

Osborne JM, Wilson C, Moore V, Gregory T, Flight I, Young G. Sample preference for colorectal cancer screening tests: Blood or stool? Open Journal of Preventive Medicine. 2012;2(3):326-31.

There are >250 million people who could benefit from an improved blood test

MARKET	POPULATION	AGE – SCREENING POPULATION	SCREENING METHOD	SCREENING PARTICIPATION RATE	UNSCREENED POPULATION/ OPPORTUNITY	INCIDENCE OF CRC (cases per year)	% OF TOTAL ADDRESSABLE MARKETS
Europe (EU-27)	746.4 m	231.0 m (50 -74 yrs)	FIT, Colonoscopy [†]	38%	143.0m	341,419	62%
UK (England, Scotland, Wales and Northern Ireland)	67.6 m	10.6 m (60 -74 yrs)	FIT	67%	3.5m	52,128	33%
USA	331.9 m	161.5 m (45 – 75+ yrs)	FIT, Colonoscopy, Cologuard	61%	62.9m	153,020	
Japan	125.7 m	60.2 m (> 40 yrs)	FIT	20% [¥]	48.0m	148,505	80%
South Africa	59.4 m	9.3 m (50 -74 yrs)	FIT	NA		8,671**	
Australia	25.7 m	7.1 m (50 – 74yrs)	FIT	43%	4.0m	15,713	56%
New Zealand	5.1 m	1.1 m (60 -74 yrs)	FIT	57%*	0.5m	> 3,000	
TOTAL		480.8m			262.1m		

* Based on pilot project, recent data not available - <https://www.health.govt.nz/our-work/preventative-health-wellness/screening/bowel-screening-pilot/bowel-screening-pilot-results>

** https://journals.lww.com/ajg/Fulltext/2021/10001/S342_Evaluating_Trends_of_Colorectal_Cancer.342.aspx

¥ Needs further investigation

† Every 10 years

FIT; faecal immunochemical test, NA; not available

First major clinical performance evaluation

Prospective, multi-centre study to evaluate the clinical performance of the first generation ColoSTAT[®] for the detection of CRC¹

STUDY DESIGN

Blood-based assay

N= 989 patients, aged 40 to <85.

PRIMARY ENDPOINT

The primary endpoint was to evaluate ColoSTAT[®] performance compared to gold standard, colonoscopy.

RESULTS

ColoSTAT[®] met the primary endpoint and showed a high-sensitivity blood test for CRC detection.

ColoSTAT[®] may provide an alternative test for people who cannot or will not take the FIT test.

Sensitivity¹

81%

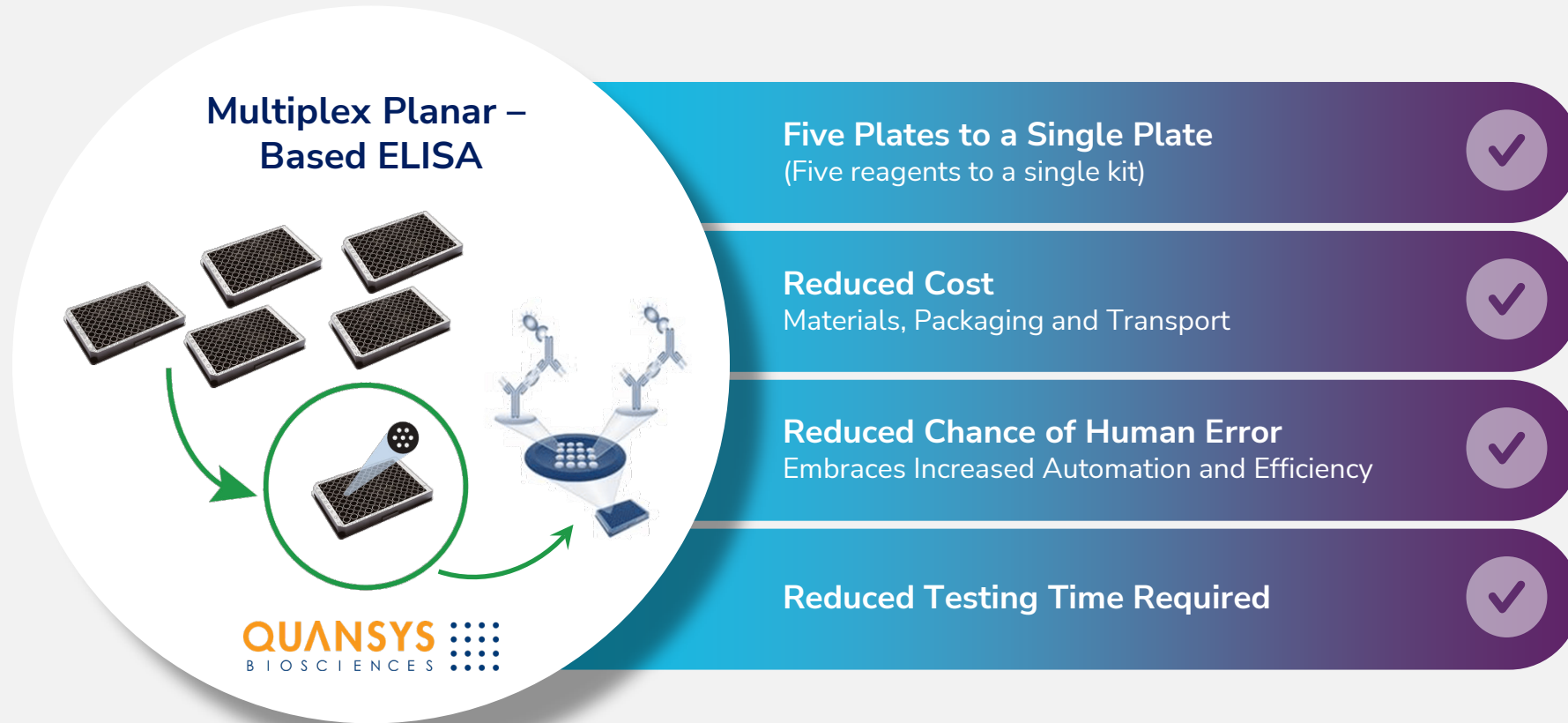
Specificity¹

91%



CRC; colorectal cancer, FIT; faecal immunochemical test
1. He et al DOI: 10.1200/JCO.2023.41.16_suppl.3529

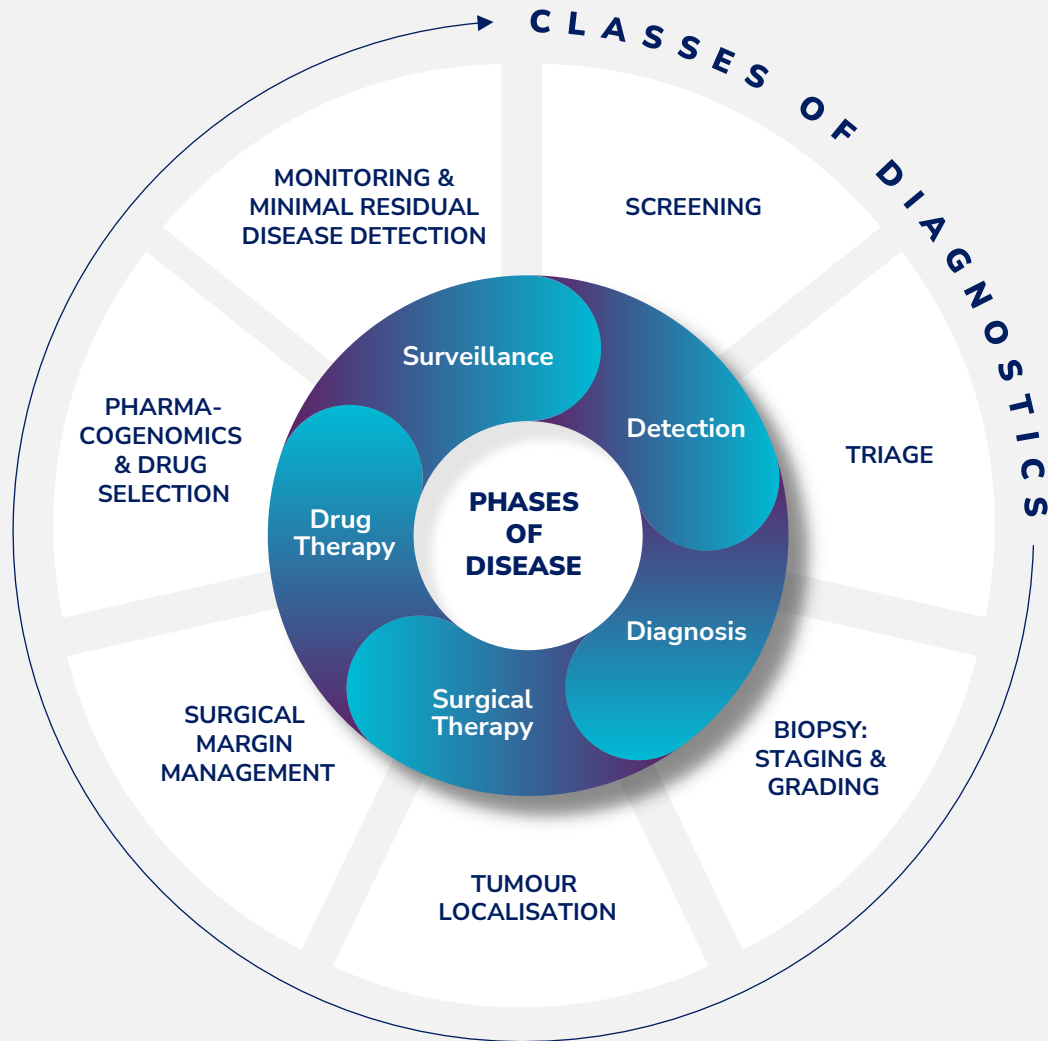
Second generation ColoSTAT[®] clinical assay: Standardised, simpler, faster turnaround time and lower cost



Laboratory customers prefer the design of the new ColoSTAT[®] assay design.

Cancer diagnostic interventions

Multiple Diagnostic decisions support an individual through the patient journey

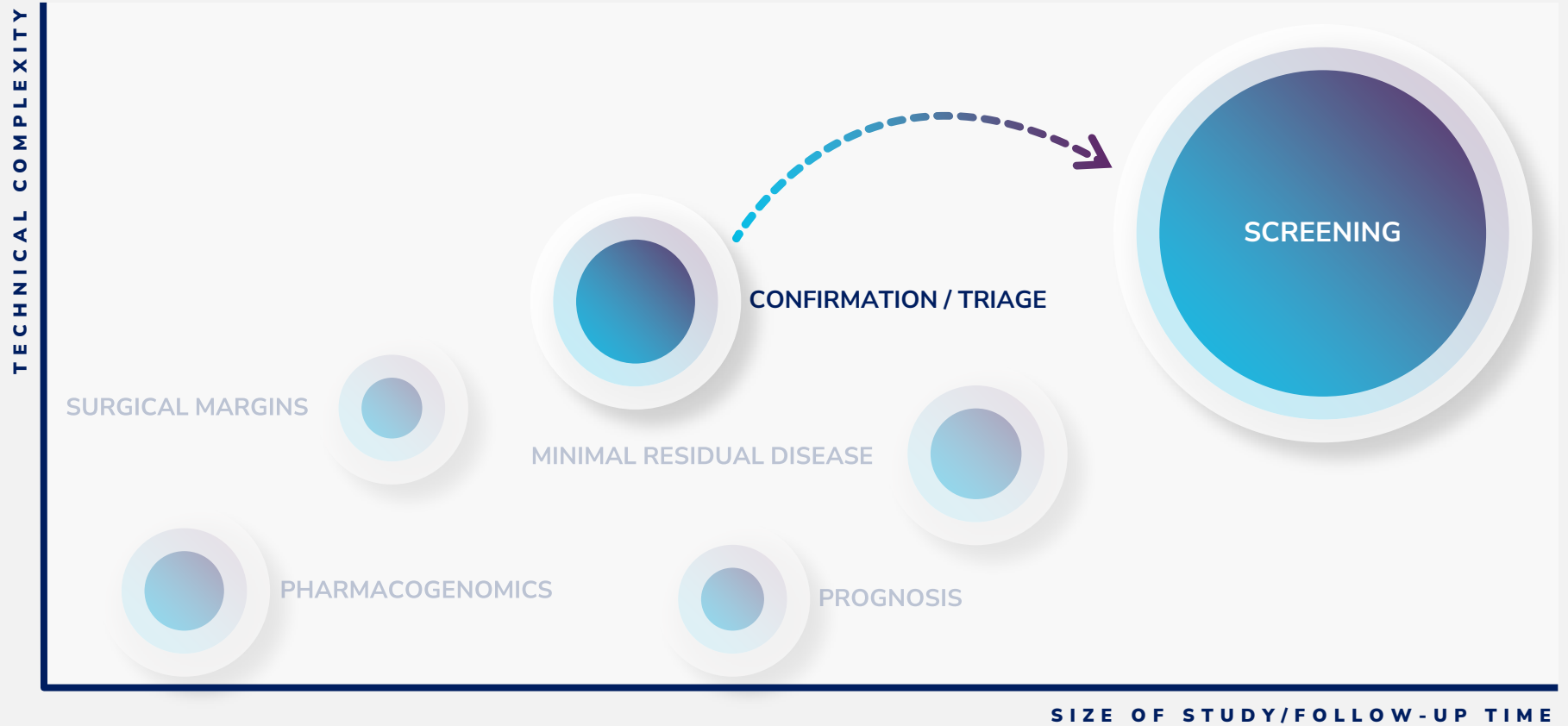


General population screening for CRC remains the ultimate goal

Targeting “intermediate” applications represent valuable intermediate steps towards the end goal

‘Intermediate’ Means

- Higher prevalence of cancer.
- Greater flexibility around current standard of care.
- Clear economic benefit.
- An opportunity to insert the new assay into the current SoC.



Note: Size of circles and relative position is not quantitative, and positions are for the purpose of illustration






Upcoming value inflection points

ITEM	DESCRIPTION	ESTIMATED DELIVERY DATE
<i>Alpha Assay Ready</i>	Arrival of Alpha kits for testing	✓
<i>Beta Release Candidate</i>	Beta Kits ready for verification	2H CY24
<i>Kit Validation Ready</i>	Kit Verification completion, Production Kits Ready.	1H CY25
<i>Commercialisation</i>	Partner's In House IVD launch	2H CY25

Platform technology expansion pipeline

Biomarker analysis complete in significant patient sample study for 3 major cancers



STAGE 1 PROGRESSION		THEORETICAL ANALYSIS OF BIOMARKER POTENTIAL	SERUM AND ALGORITHM ANALYSIS	RISK ANALYSIS → ENTER STAGE 2
CANCER TYPE	COLLABORATOR			
Breast	Agilex Biolabs			
Lung	Baker Institute			
Gastric	Nexomics			
Cervical	ON HOLD			
Pancreatic	ON HOLD			

Lung cancer blood-based assays will be the next priority.

Conclusion



Overview

Final stages of developing a potential “blockbuster” diagnostic product targeting a multi-\$billion global market.

Key Investment Highlights

An attractive and comparatively simple investment proposition / business model.

Transformed Business

A business with huge potential that has gone through a significant and productive business transformation.
