

PACIFIC EDGE ANNUAL SHAREHOLDERS MEETING PRESENTATION

DUNEDIN, New Zealand – Cancer diagnostics company Pacific Edge (NZX, ASX: PEB) is today holding its Annual Shareholders Meeting at LINK Market Services offices in Auckland, commencing at 10.00am.

It attaches presentations given by Chairman Chris Gallaher, Chief Executive Dr Peter Meintjes, President Pacific Edge Diagnostics USA David Levison, and Chief Medical Officer Dr Tamer Aboushwareb.

In the presentation Pacific Edge notes, it expects to manage cash reserves - in the event of an adverse Medicare coverage decision - until it regains coverage, a process it would expect to take around 4 years.

Shareholders and other interested parties can also join the meeting online at:

www.virtualmeeting.co.nz/peb23

Released for and on behalf of Pacific Edge by Grant Gibson Chief Financial Officer.

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OVERVIEW

Pacific Edge: www.pacificedgedx.com

Pacific Edge Limited (NZX/ ASX: PEB) is a global cancer diagnostics company leading the way in the development and commercialization of bladder cancer diagnostic and prognostic tests for patients presenting with hematuria or surveillance of recurrent disease. Headquartered in Dunedin, New Zealand, the company provides its suite of Cxbladder tests globally through its wholly owned, and CLIA certified, laboratories in New Zealand and the USA.

Cxbladder: www.cxbladder.com

Cxbladder is a urine-based genomic biomarker test optimized for the detection and surveillance of bladder cancer. The Cxbladder evidence portfolio developed over the past 14 years includes more than 20 peer reviewed publications for primary detection, surveillance, adjudication of atypical urine cytology and equivocal cystoscopy. Cxbladder is the focal point of numerous ongoing and planned clinical studies to generate an ever-increasing body of clinical utility evidence supporting adoption and use in the clinic to improve patient health outcomes. Cxbladder is reimbursed by CMS and has been trusted by over 4,400 US urologists in the diagnosis and management of more than 100,000 patients, including the option for in-home sample collection. In New Zealand, Cxbladder is accessible to 75% of the population via public healthcare and all residents have the option of buying the test online.



Pacific Edge
Annual Shareholders Meeting

Link Market Services
Auckland
27 July 2023



PACIFIC EDGE
CANCER DIAGNOSTICS COMPANY

*Pacific Edge's ordinary shares trade on the NZX and
the ASX under the ticker code: PEB*



CHRIS GALLAHER
Chairman



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DIRECTORS



SARAH PARK



ANATOLE MASFEN



BRYAN WILLIAMS



ANNA STOVE



MARK GREEN



TONY BARCLAY

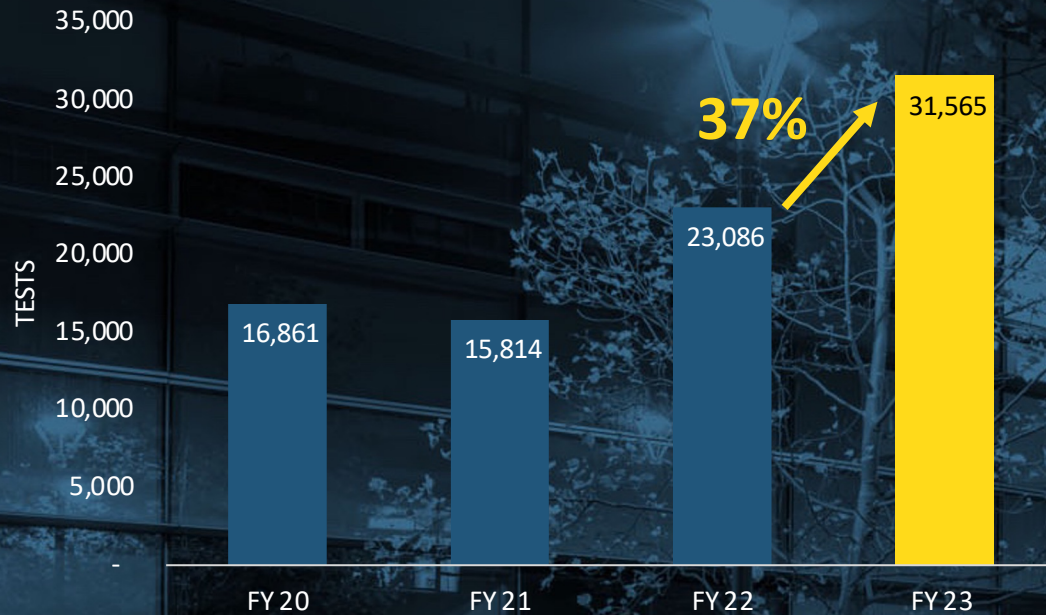
MEETING AGENDA

1. PRESENTATIONS
2. SHAREHOLDER DISCUSSION
3. RESOLUTIONS
4. ORDINARY BUSINESS
5. MEETING CLOSE

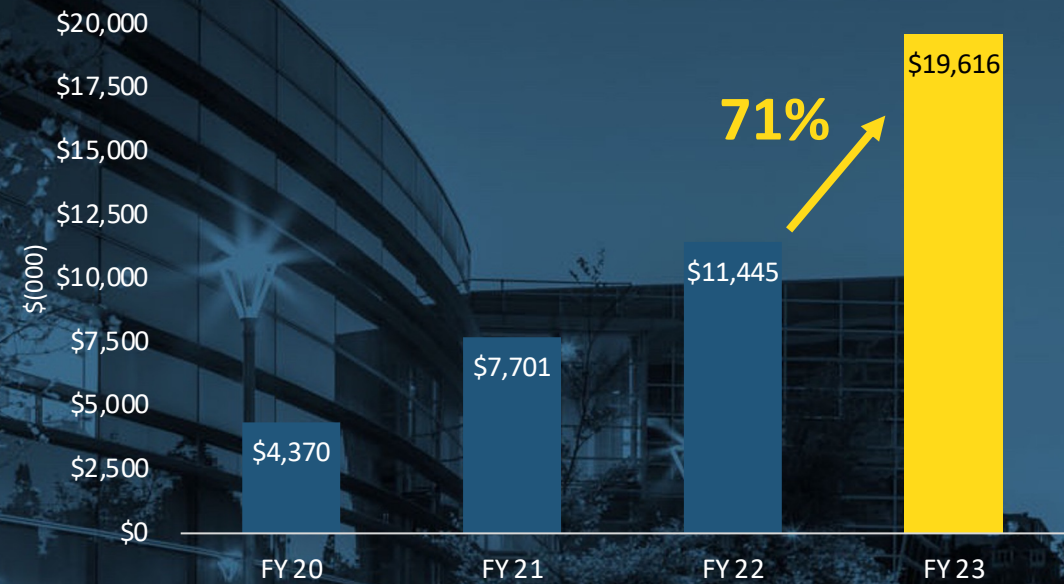


FY 23 HIGHLIGHTS: STRONG PERFORMANCE FOLLOWS STRATEGIC EXECUTION

PACIFIC EDGE GLOBAL TEST VOLUMES¹



PACIFIC EDGE OPERATING REVENUE



▲ 44%

US TEST VOLUMES¹
(27,217 TESTS)

▲ 46%

US ORDERING CLINICIANS²
(1,150 CLINICIANS)

\$27.0M
NET LOSS AFTER TAX

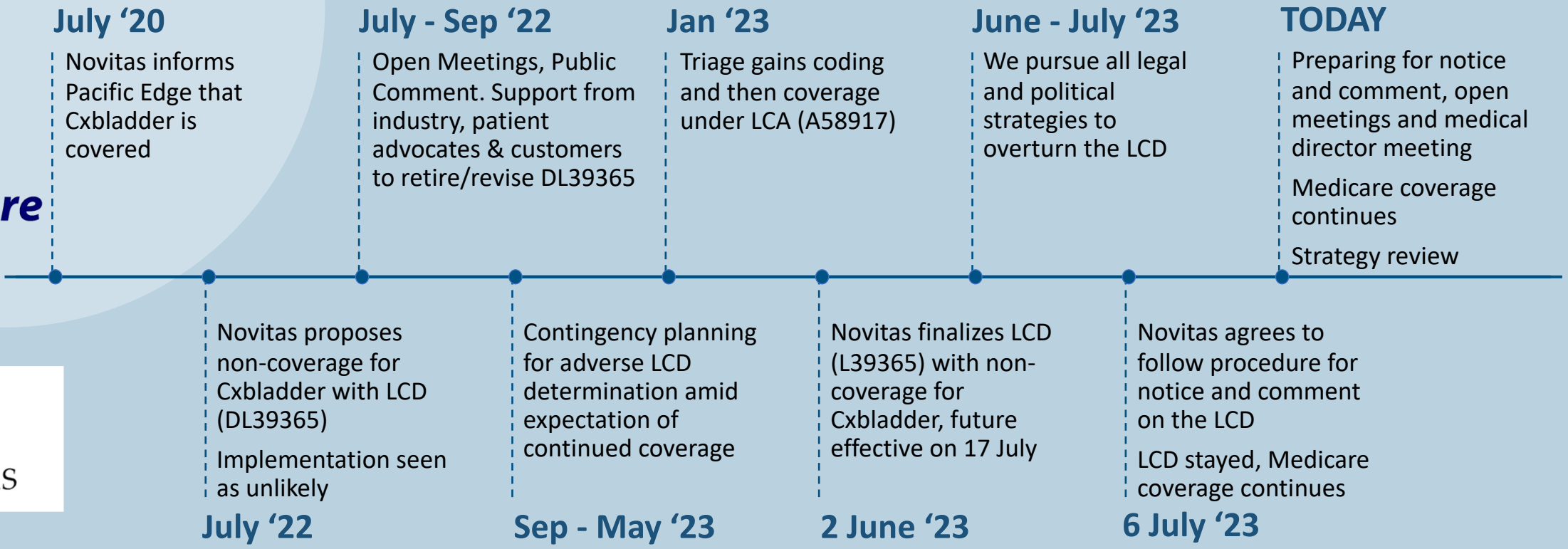
\$77.8M
CASH, CASH EQUIVALENTS³

¹ Testing volume is measure by Total Laboratory (TLT) Throughput including commercial, pre-commercial and clinical studies testing

² Unique ordering clinicians in Q4 23 vs Q4 22

³ Cash, cash equivalents and short-term deposits as at 31 March 2023

PACIFIC EDGE'S MEDICARE JOURNEY



Novitas is the Medicare Administrative Contactor (MAC) with jurisdiction for Pacific Edge's US laboratory.



PRESERVING CAPITAL AND CONTINUING TO CREATE SHAREHOLDER VALUE

Pacific Edge is continuing to review scenario planning, strategy and our risk management framework

COMMITTED TO MAINTAINING A STRONG BALANCE SHEET

- Pacific Edge expects to manage cash reserves - in the event of an adverse Medicare coverage decision – until it regains coverage, a process we would expect to take around 4 years.

STRATEGIC RESPONSE TO THE DETERMINATION

- Strategies:
 - Legal challenges; alternative paths to coverage; an alternative MAC; changed billing practices; other strategic options.
- Response so far:
 - Continue to promote Cxbladder and process all tests ordered by US clinicians with the current team
 - Enhanced patient responsibility rolling out in stages from July 17
 - Refocusing of evidence development, coverage and guidelines for increased coverage certainty

DECISION CRITERIA

- Impact on revenue, expenditure and cash reserves, the time and resources, the expected likelihood of success; and shareholder value.





Dr PETER MEINTJES
Chief Executive Officer



NOVITAS DETERMINATION IS A COMPANY DEFINING MOMENT

An unexpected, unprecedented and flawed decision

NOVITAS SUMMARY CONCLUSIONS

Finalized LCD 'Genetic Testing for Oncology' (L39365) noted Cxbladder tests 'not considered medically reasonable and necessary', the threshold required for coverage under the US Social Security Act, based on:

- Insufficient validation in confounding clinical circumstances
- Population and gender biases
- High numbers of false positives
- Questions credibility of Pacific Edge funded research
- L39365 is focused on diagnostic, prognostic and predictive tests following or as an adjunct to a confirmed pathological diagnosis of cancer



MEDICARE IS OUR LARGEST CUSTOMER

- Cxbladder has a majority Medicare and Medicare Advantage population; average age of 73 for presentation with hematuria
- In FY23, Medicare and Medicare Advantage delivered ~13,800 tests (~60%) of US commercial Cxbladder tests generating ~\$15.3m in total operating revenue (~77.3%)

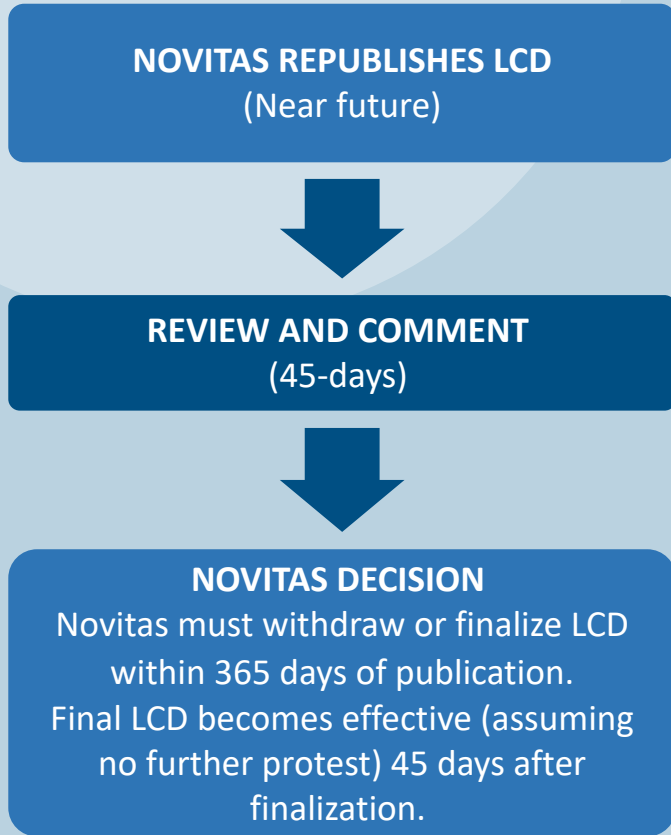


Pacific Edge's objections to the process leading up to the finalization of the LCD and the LCD itself have received overwhelming support from industry and the urological community.

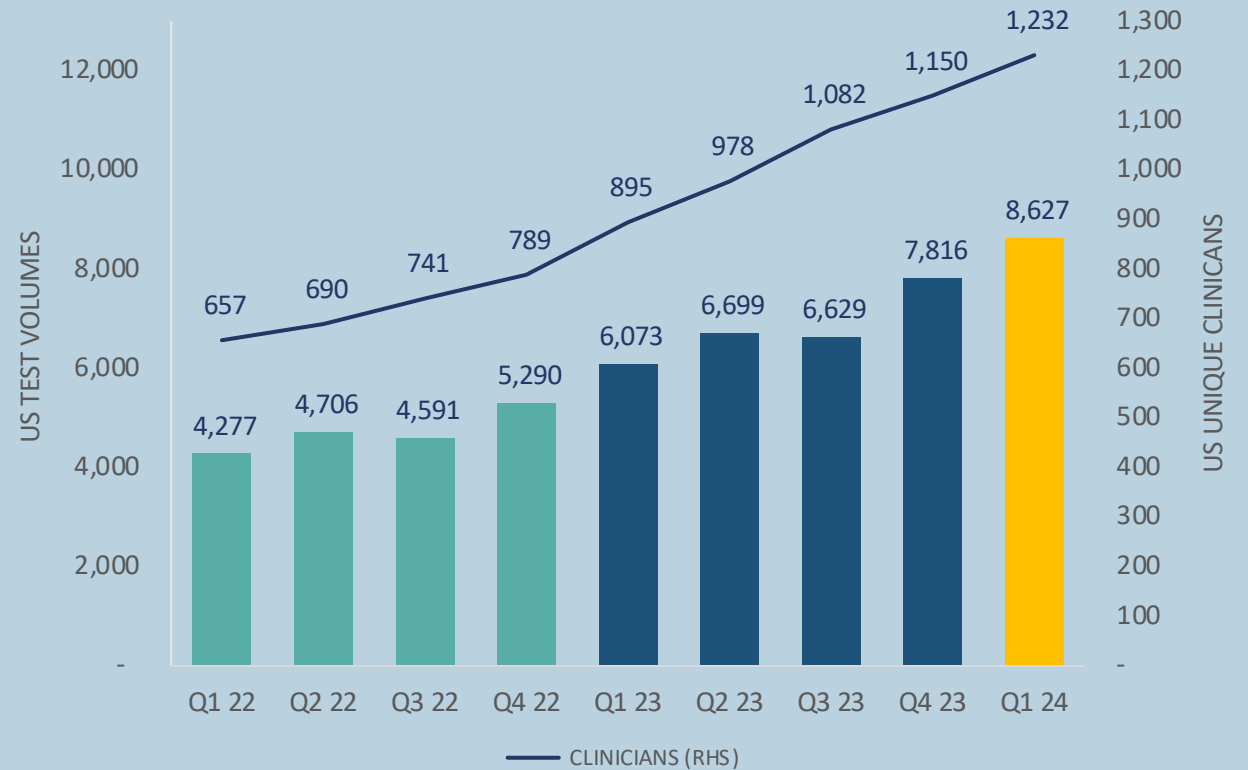
NAVIGATING COVERAGE UNCERTAINTY

Clinical evidence development remains a priority

LCD TIMELINE



Cxbladder is well supported by the US urological community with >1,200 separate clinicians (representing >10% of practicing US urologists¹) ordering >8,600 tests² in the US in Q1 24



¹ American Urological Assn 2021 Census

² Total Laboratory Throughput including commercial, pre-commercial and clinical studies testing

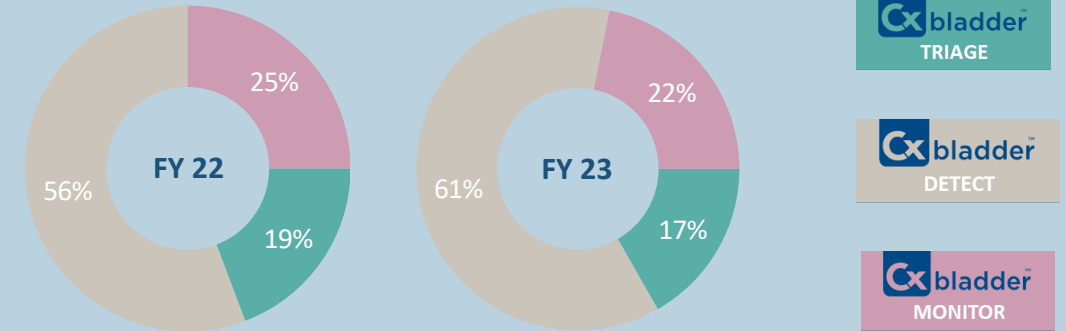
DESPITE LCD UNCERTAINTY IN FY 23 WE DELIVERED STAND-OUT GROWTH

WE HAVE SHOWN ABILITY TO EXECUTE DESPITE CHALLENGING MARKET CONDITIONS

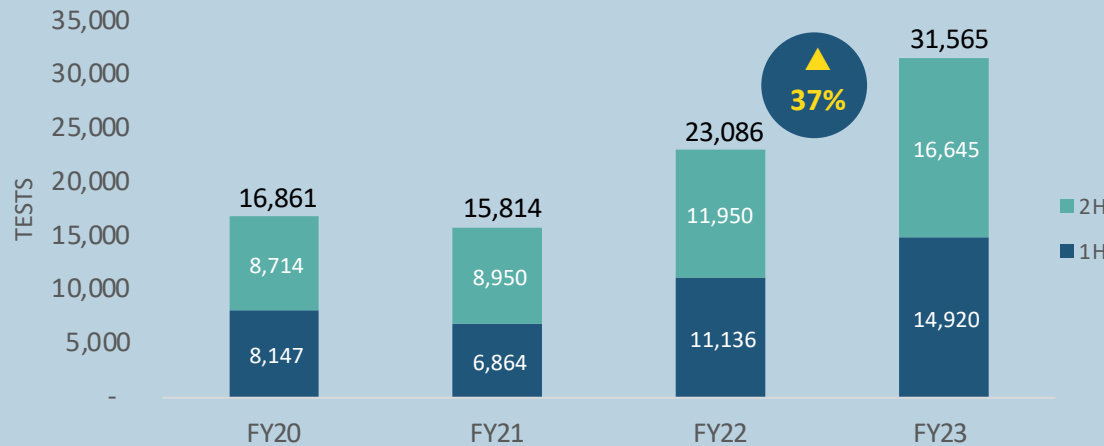
FY 23 TOTAL LAB THROUGHPUT (TLT*)

- Global TLT increased 37% to 31,565 tests
- Global Commercial test volumes increased 39% to 26,691
- Global TLT is driven by US growth in the US (predominantly Detect)
- Hematuria evaluation (Triage & Detect) is the **largest market** opportunity, ~3x the size of bladder cancer surveillance (Monitor)

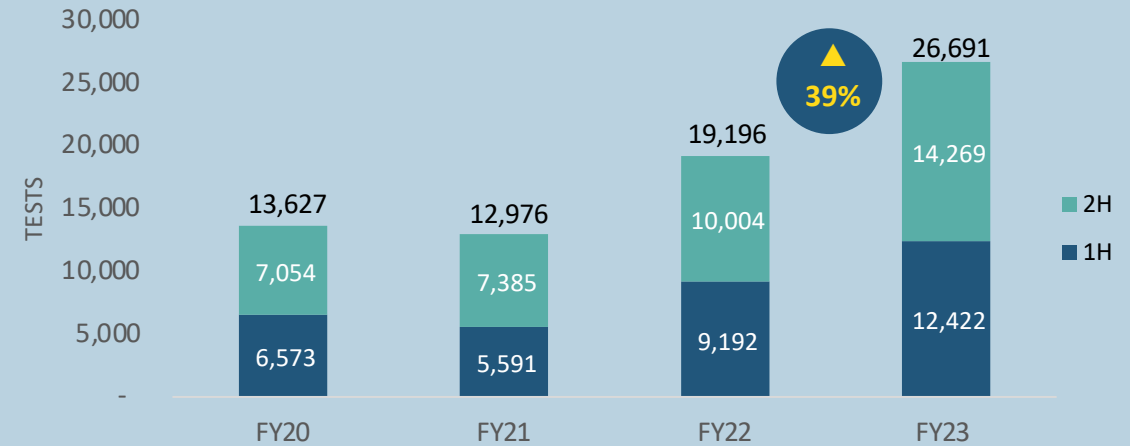
TEST VOLUMES BY TYPE (TLT*)



GLOBAL TEST VOLUMES (TLT)



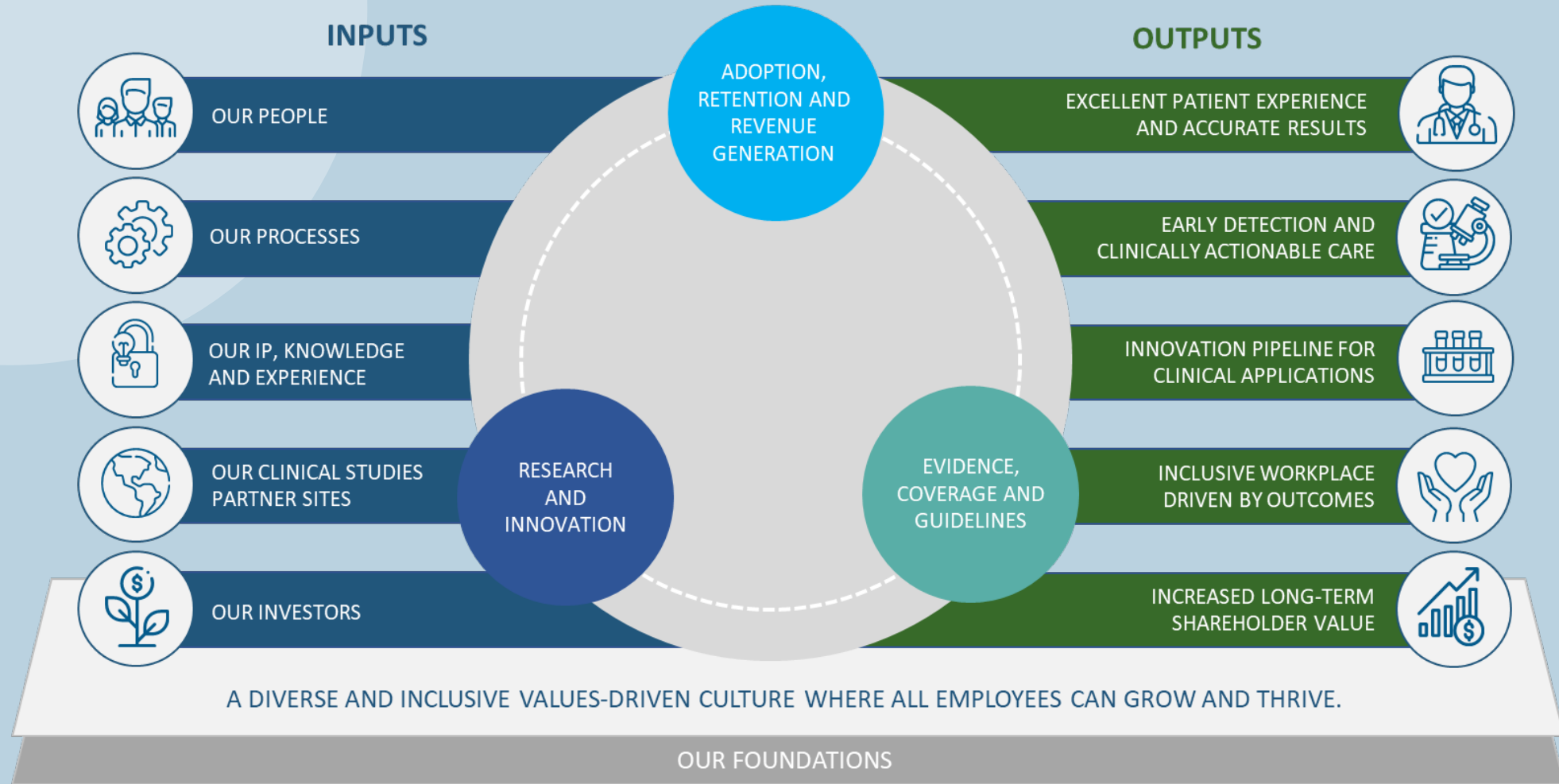
GLOBAL COMMERCIAL TEST VOLUMES (TLT)



*TLT is the Total Laboratory Throughput including commercial, pre-commercial and clinical studies testing

COVERAGE UNCERTAINTY HAS AFFIRMED OUR STRATEGY

CLINICAL EVIDENCE AND STRONG UROLOGICAL RELATIONSHIPS ARE FUNDAMENTAL TO SUCCESS



REFINING OUR FOCUS: ADOPTION, RETENTION AND REVENUE GENERATION



FOCUS AREAS:

- 1. NEW:** Dimensioning the US business to reflect increased probability of future adverse Medicare determination
 - I.** National Accounts and Virtual Teams to support Kaiser, VA, Capitated Systems
 - II.** Enhanced Patient Responsibility with positive gross margin per test
- 2. NEW:** Expansion of APAC and Ex-US opportunities through distribution agreements
- 3.** Internal digitalization and Performance Excellence (PerfEx) initiatives to improve the effectiveness and efficiency of our operations
- 4.** Marketing to amplify our clinical development program within the urology and oncology communities with events, sponsorship, communication and collateral
- 5.** Empower patients through patient awareness and patient advocacy initiatives through established societies and our Cxbladder website





DRIVING GROWTH IN ASIA PACIFIC AND CONSOLIDATING NEW ZEALAND

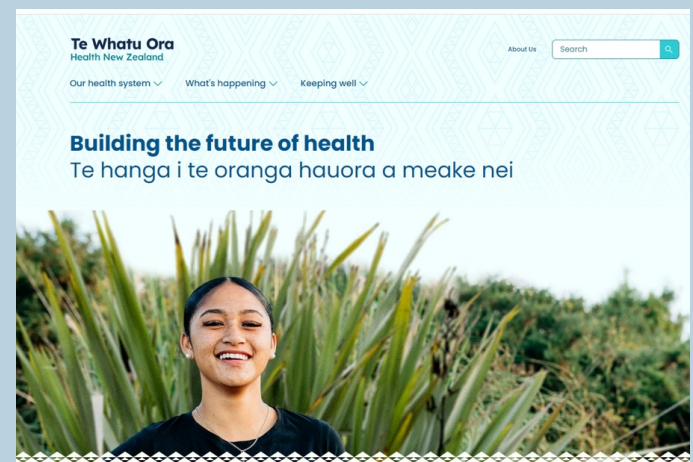
APAC GENERATING ~14% OF TEST VOLUME¹

NEW ZEALAND IS A MATURE MARKET

- Cxbladder is covered in 15 of the 20 new Te Whatu Ora, Health New Zealand, representing >75% of the population
- Seeking national contract

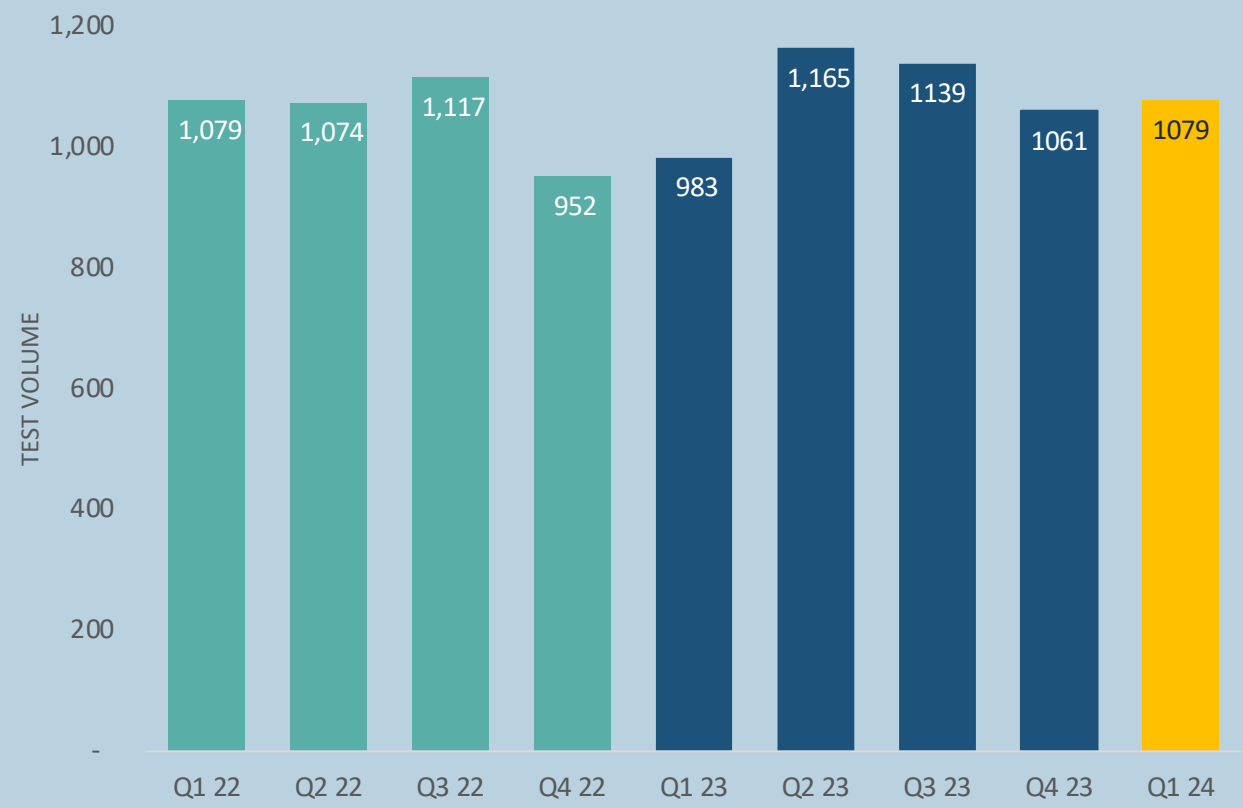
AUSTRALIA & ASIA PACIFIC

- Australia and Southeast Asia still in business development
- New APAC President recruited in March 2023
- Transviet (Vietnam) and Hi-Precision (Philippines) distribution agreements signed. Test shipments in progress



APAC TEST VOLUMES¹

Commercial tests represent 83% of TLT in FY 23 for APAC



¹ FY 23 Total Laboratory Throughput including commercial, pre-commercial and clinical studies testing

² CAGR compares Q4 21 to Q4 23



EVIDENCE, COVERAGE AND GUIDELINES: CHANGING CLINICAL PRACTICE



FOCUS AREAS:

1. Generate high-quality clinical validity and utility evidence through clinical studies
2. **NEW:** Reconfigure evidence program to focus on:
 - I. Hematuria evaluation and surveillance (Detect⁺ and Monitor⁺)
 - II. The end points that matter most to guidelines committees
3. Use Clinical Utility evidence to drive the adoption of Cxbladder by clinicians, insurers and hospitals ahead of guideline inclusion
 - I. Pursue inclusion of Cxbladder in globally-relevant standards and guidelines of clinical care across the breadth of patient pathways
 - II. Foster trusted relationships with key opinion leaders, relevant Urologic centers of excellence, professional societies and patient advocacy networks to drive a broader awareness and demand for Cxbladder
 - III. Develop the scientific and clinical credibility of the Cxbladder brand
4. **NEW:** Consider merits of MolDX program



RESEARCH AND INNOVATION:

UNDERSTANDING THE ENTIRE COMMERCIALISATION PATHWAY



FOCUS AREAS:

1. **NEW:** Ensure R&D, Digital and Lab Operations focus on the launch of Detect+ and Monitor+
2. **NEW:** Working to ensure Cxbladder is ready for the anticipated US Food and Drug Administration (FDA) regulation of laboratory developed tests (LDTs)
3. Evaluate 'product concepts' to address unmet clinical needs through market research and scientific/clinical advisory boards
4. Evaluate cutting-edge technologies to meet the market requirements of desired product concepts
5. Continue to build a patent portfolio for novel clinical applications of cutting-edge molecular technologies
6. Turn patented technology into clinically-validated molecular diagnostic tools that address an unmet clinical need

ESG: PACIFIC EDGE IS FOUNDED ON IMPROVING SOCIAL OUTCOMES

Pacific Edge is delivering actionable information that can contribute to clinically meaningful improvements in cancer treatment, improving lives, improving healthcare equity across populations and healthcare outcomes for patients

GOVERNANCE

- Integrating oversight of Environmental, Social and Governance (ESG) matters, including carbon reporting, into the Audit and Risk Committee Charter

AOTEAROA NEW ZEALAND CLIMATE STANDARDS

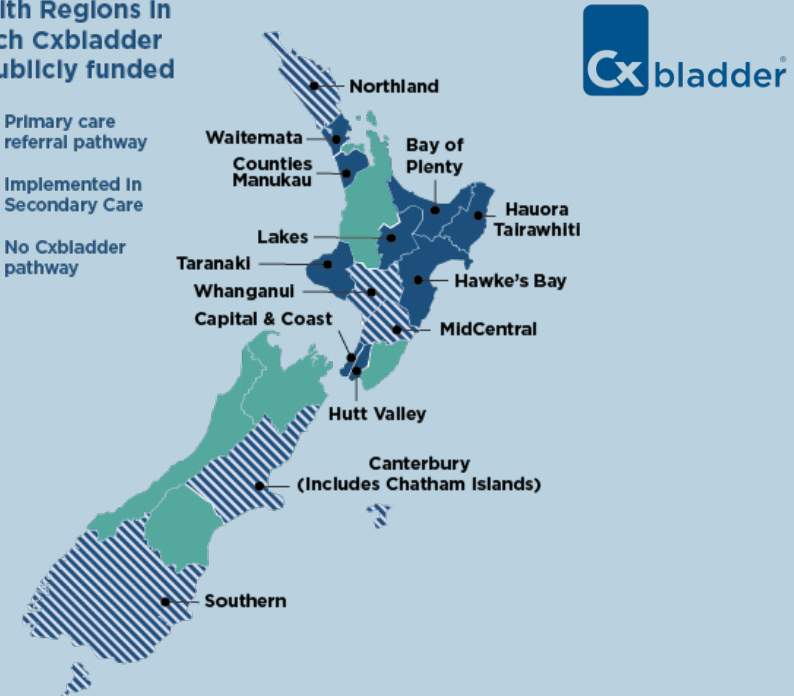
- Measured carbon emissions (Scope 1, 2, 3) in FY 23 and positioned to provide base year data in FY 24
- Working closely with Toitū Envirocare to accurately audit and measure our greenhouse gas emissions, as we work towards achieving certification in respect of FY 24
- Developing strategies and policies and evolving our risk management framework to meet our reporting requirements.

ATTRACTING AND RETAINING TALENT AT PACIFIC EDGE

- We actively promote diversity, inclusion, engagement and fair remuneration

Health Regions In which Cxbladder is publicly funded

- Primary care referral pathway
- Implemented In Secondary Care
- No Cxbladder pathway



PROMOTING HEALTH CARE EQUITY

Following the introduction of Cxbladder into primary care in Te Whatu Ora Canterbury, referrals to urologists were safely reduced, urological waiting lists fell by 25%¹

1. Davidson, Peter; [Presentation to Urofair, 2022](#), time to first specialist assessment.

OUTLOOK: FOCUSED ON FY24 EXECUTION

- Pacific Edge expects to manage cash reserves - in the event of an adverse Medicare coverage decision - until it regains coverage, a process we would expect to take around 4 years.
- We expect to re-focus the business on clinical development for guidelines inclusion and increased coverage certainty for Detect+ & Monitor+
- Selling focus on clinical value as the driver of higher throughput/headcount and throughput/clinician
- **HEADWINDS:**
 - Possible non-coverage determination from Novitas on a new proposed LCD after following appropriate procedure
 - Possible negative physician or patient response to 'balance billing' on commercial insurance
- **CATALYSTS:**
 - Possible re-coverage determination from Novitas on new proposed LCD after following appropriate procedure
 - Kaiser EMR integration "go live" in Southern California
 - Possible NCCN Guidelines inclusion after August submission
 - *Te Whatu Ora* national contract
 - New clinician-generated CU evidence as studies completed
- We have world-leading technology, a strong balance sheet and we are building momentum in the US and establishing footholds in new markets



DAVID LEVISON
President
Pacific Edge Diagnostics USA



PEDUSA – ADOPTION RETENTION AND REVENUE GENERATION

FOCUSED ON MEDICARE COVERAGE AND SELLING THE CLINICAL VALUE OF CXBLADDER



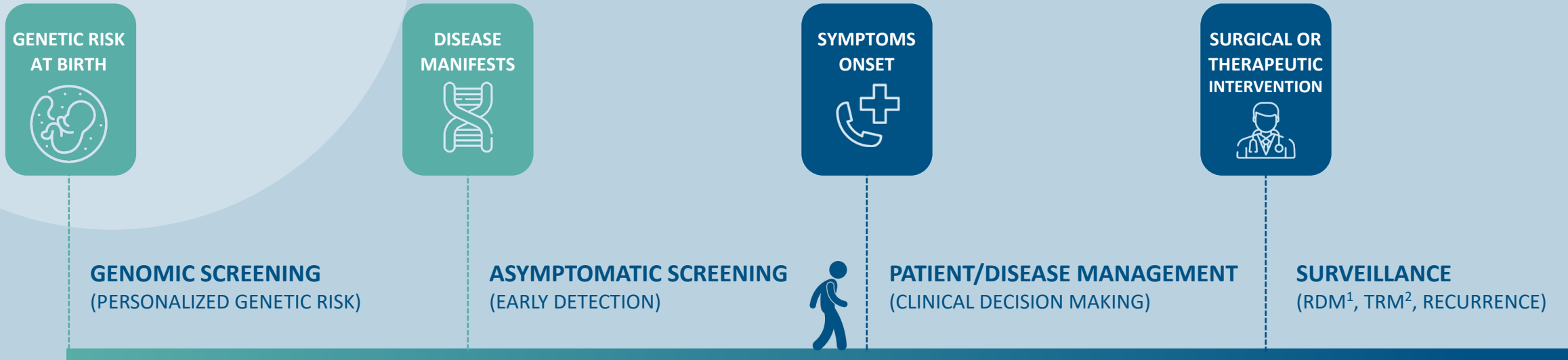
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2. Internal digitalization and Performance Excellence (PerfEx) initiatives continuing to improve the effectiveness and efficiency of our operations
3. Amplify our clinical evidence generation program within the urology and oncology communities with marketing, sponsorship and our medical affairs teams
4. Empower patients through patient awareness and patient advocacy initiatives through established societies and our Cxbladder website



Pacific Edge's offices and laboratory in Hershey, Pennsylvania.

MOLECULAR DIAGNOSTICS VALUE CHAIN: PATIENT JOURNEY



Cx INTENSIFY/DE-INTENSIFY WORKUPS



ADJUDICATE DIAGNOSTIC DILEMMAS

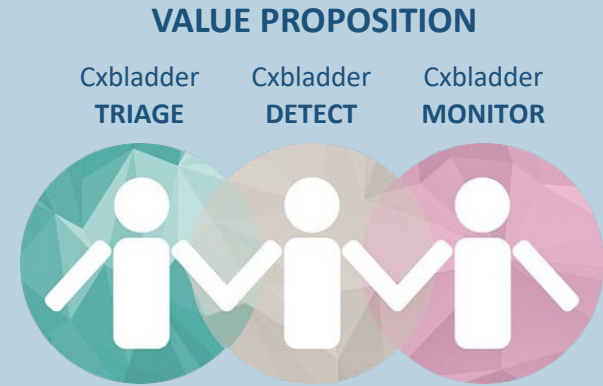


Cx MONITOR FOR RECURRENCE

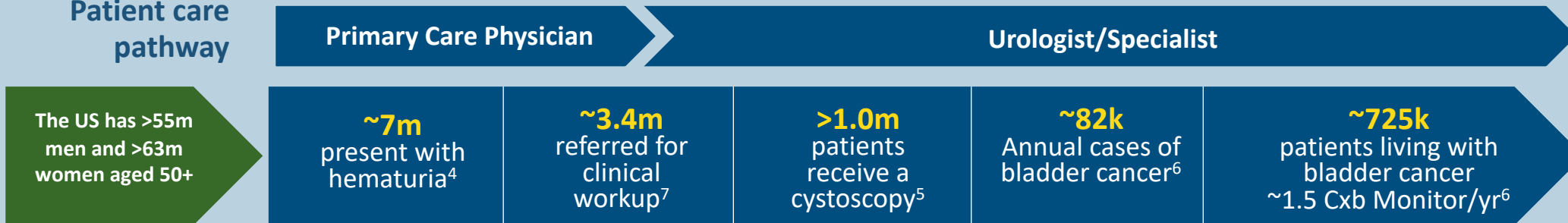


1. RDM: Residual Disease Monitoring
2. TRM: Therapeutic Response Monitoring.

HEMATURIA EVALUATION AND SURVEILLANCE IN THE US MARKET



Patient care pathway

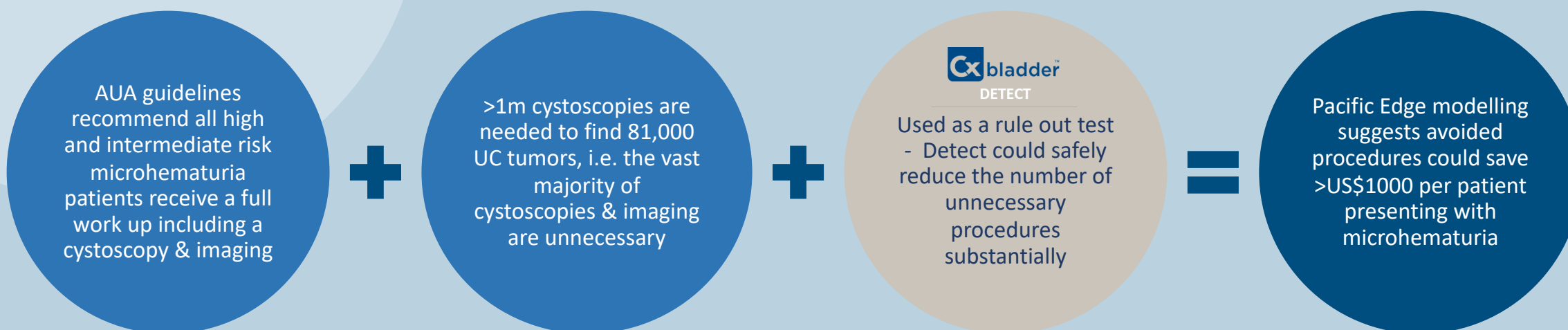


>4.5M **TEST OPPORTUNITIES**

1. National Cancer Institute SEER.
2. Aly A et al. (2020) The Real-World Lifetime Economic Burden of Urothelial Carcinoma by Stage at Diagnosis. J Clin Pathw. 2020 May; 6(4):51-60
3. National Cancer Institute: Cancer Progress Trends Report
4. Journal of the American Medical Association
5. Kenigsberg, A, et al. The Economics of Cystoscopy: A Microcost Analysis, Urology 157: 29–34, 2021.
6. National Cancer Institute SEER.
7. Pacific Edge Estimate, opportunity estimated at US\$760/Per test

HEALTH ECONOMICS – THE ECONOMIC VALUE OF CXBLADDER DETECT

Cxbladder Detect offers substantial total cost savings/patient when used to intensify or de-intensify hematuria evaluation in patients presenting with microhematuria¹



ASSUMPTIONS

- US health expenditure on microhematuria evaluation using the 2020 AUA Guidelines vs Cxbladder Detect test (sensitivity 82%, specificity 94% for UC).
 - Detect test positive results proceeded with cystoscopy and imaging
 - Detect test negative results were re-evaluated for hematuria in 6 months.
- Performance of cystoscopy, CT Urogram and renal ultrasound were based on the published literature and the costs of visits and procedures from the Medicare allowable fee schedule.
- Patients false positive (Cxbladder Detect or imaging) all had cystoscopy and all-positive cystoscopies led to Transurethral resection of bladder tumor (TURBT)
- Pacific Edge is working to publish this theoretical Budget Impact Model (BIM) over the coming months

1. Pacific Edge has developed a detailed budget impact model to understand costs to private practice, healthcare institutions and payers, over and above the Cxbladder test price of \$760/test focused on microhematuria patients

DIFFERENTIATED SALES ROLES FOCUSSED ON DIFFERENT CUSTOMER TYPES



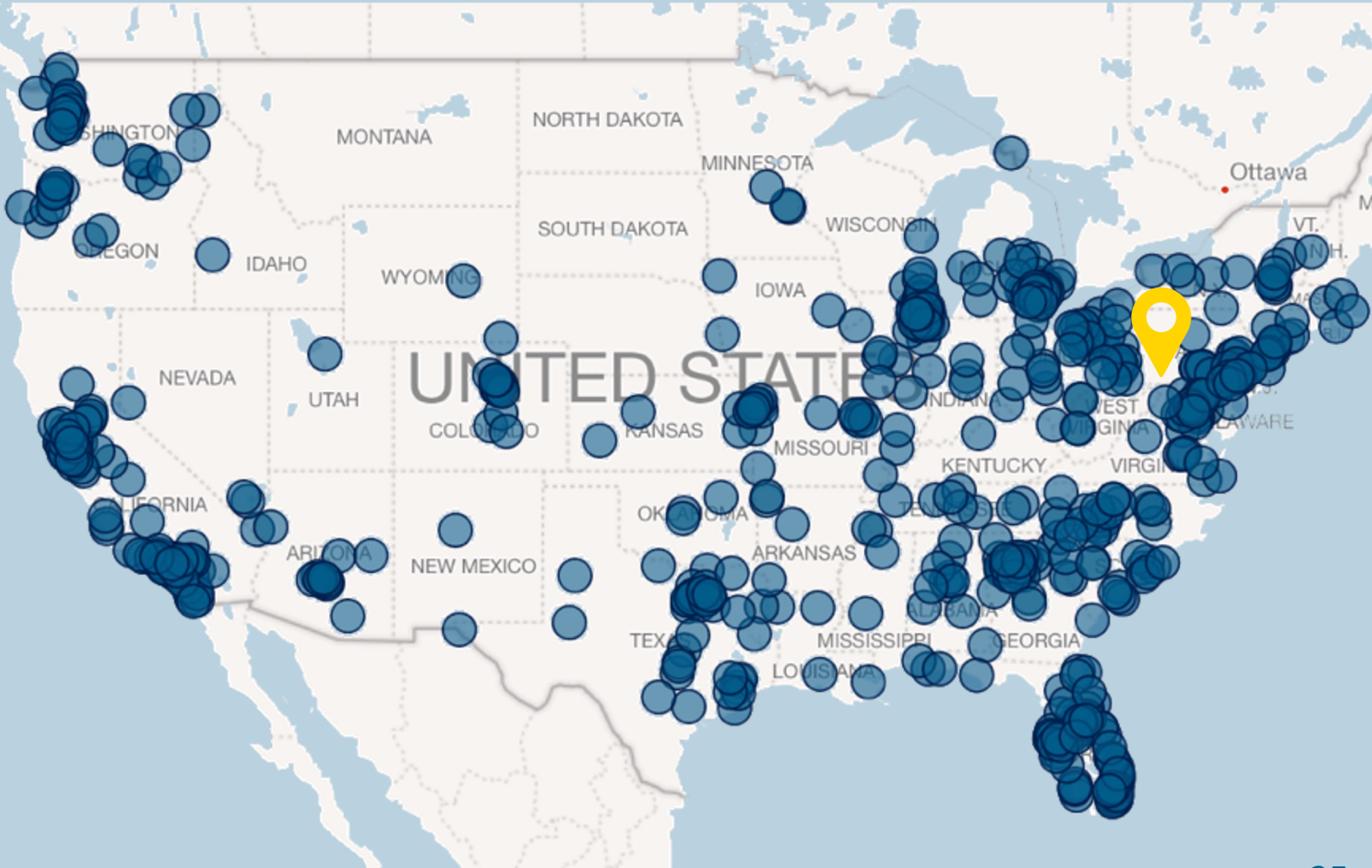
Regional Sales Director
Role: Manager
Target: Key clinicians and users
Focus: Escalation, coordination

National Account Manager
Role: Strategic sale
Target: KOL's, large institutions
Focus: Clinical value, execution

Account Executive
Role: Hunter
Targets: Urology networks and Urologists
Focus: Value selling, ordering

Medical Science Liaison
Role: Medical Expert
Targets: KOLs
Focus: Clinical use

- Distribution of Current U.S. Customers
- 📍 Pacific Edge Diagnostics USA, Hershey, Pennsylvania



REDIMENSIONING OUR SALES FORCE WITH STRATEGIC CHANGE

IMPACT ON TEST DEMAND AND REVENUE UNKNOWN



REVIEWING OUR APPROACH TO MARKET

- Focus on larger or value-based institutional accounts
- Sales initiatives focused on clinical value, economic value and patient value
- Increase expectations of throughput per sales force headcount
- Amplify our clinical evidence generation program within the urology and oncology communities with medical education

ENHANCED PATIENT RESPONSIBILITY AND SALE FORCES EFFICIENCY

- Patients with private insurance (non-Kaiser) to submit patient responsibility notice
 - Provides Pacific Edge with the means to collect payment from the patient, as the patient acknowledges liability
- Patient Assist Program will offer customers discounts based on income benchmarked against US federal policy guidelines
- Rolling out since mid-July, and expected to improve collections in the event of insurer denial



ENHANCED CUSTOMER EXPERIENCE AND GROWING GLOBAL FOOTPRINT



DIGITALIZATION & CUSTOMER EXPERIENCE

- EMR integrations and Customer Portal
- Investment to upgrade older hardware and IT systems
- Performance Excellence: Lab Operations and Customer Service
- Commercially-led product management for end-to-end customer experience, supported by digital workflows



The Kaiser Health Plan covers >12.5m members

- 2 Kaiser sites in PEB's Top 20 Accounts. 14 Kaiser sites across Southern California ordering in FY23
- EMR software development and integration testing complete; KP and PE working towards "go live"

EX-US DISTRIBUTORS SUPPORTED BY PEDUSA

- ProGenetics (Israel) and SouthGenetics (LATAM) distribution agreements
- Other geographies considered on a case-by-case basis where appropriate distributors exist



The US Veterans Administration serves >9m veterans each year

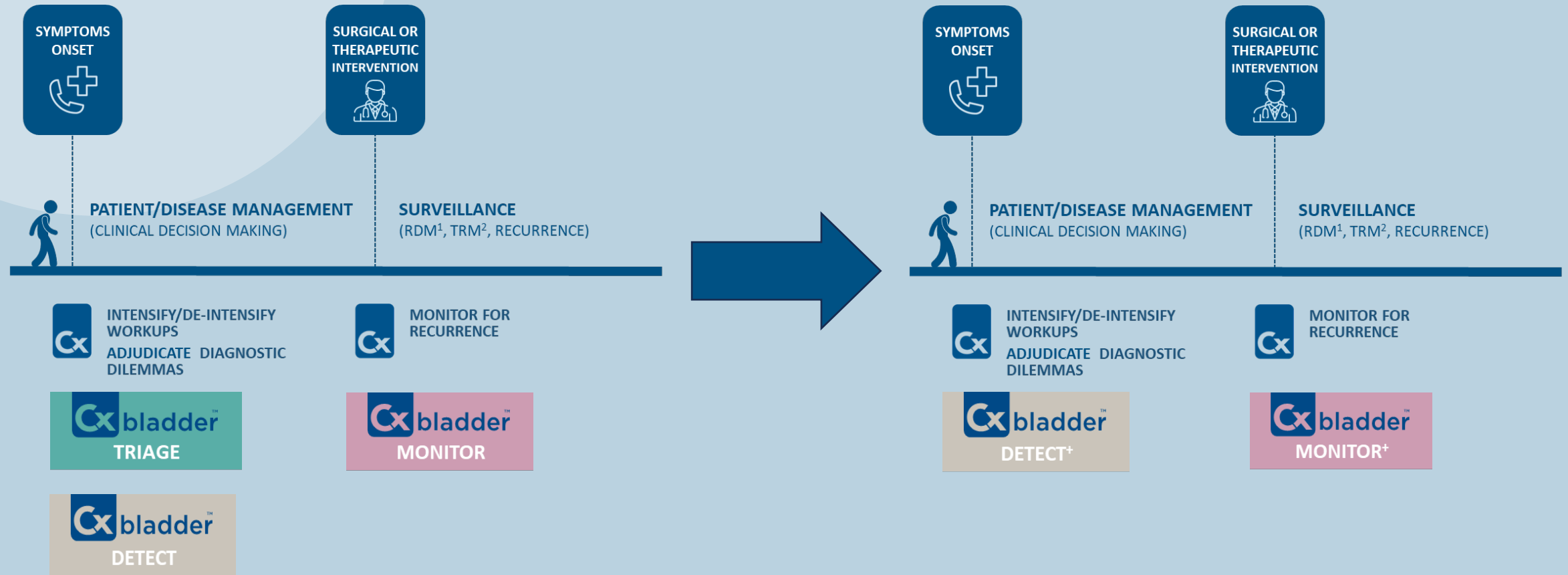
- DRIVE study is a key engagement with VA urologists to determine clinical validity in a cohort of VA patients

¹Total Laboratory Throughput including commercial, pre-commercial and clinical studies testing

²CAGR compares Q4 21 to Q4 23

SIMPLIFYING THE CXBLADDER PROPOSITION – DETECT+ AND MONITOR+

LEVERAGING EVIDENCE SHOWING THE ADDITION OF DNA BIOMARKERS ENHANCES TEST PERFORMANCE



1 RDM: Residual Disease Monitoring,

2. TRM: Therapeutic Response Monitoring

3. Lotan et al 'Urinary Analysis of FGFR3 and TERT Gene Mutations Enhances Performance of Cxbladder Tests and Improves Patient Risk Stratification'



Dr Tamer Aboushwareb, MD, PhD
Chief Medical Officer
Pacific Edge Diagnostics USA

DRIVE EVIDENCE-BASED CLINICAL PRACTICE CHANGE AND MAINTAIN LEADERSHIP



FOCUS AREAS:

1. **NEW:** Reconfigure evidence program to focus on:
 - I. Hematuria evaluation (Detect⁺) and surveillance (Monitor⁺)
 - II. The clinical end points that matter most to guidelines committees
 - III. Specific patient populations relevant to clinical utility
2. Use Clinical Utility evidence to drive the adoption of Cxbladder by clinicians, insurers and hospitals ahead of guideline inclusion.
3. **NEW:** Consider merits of MolDX program



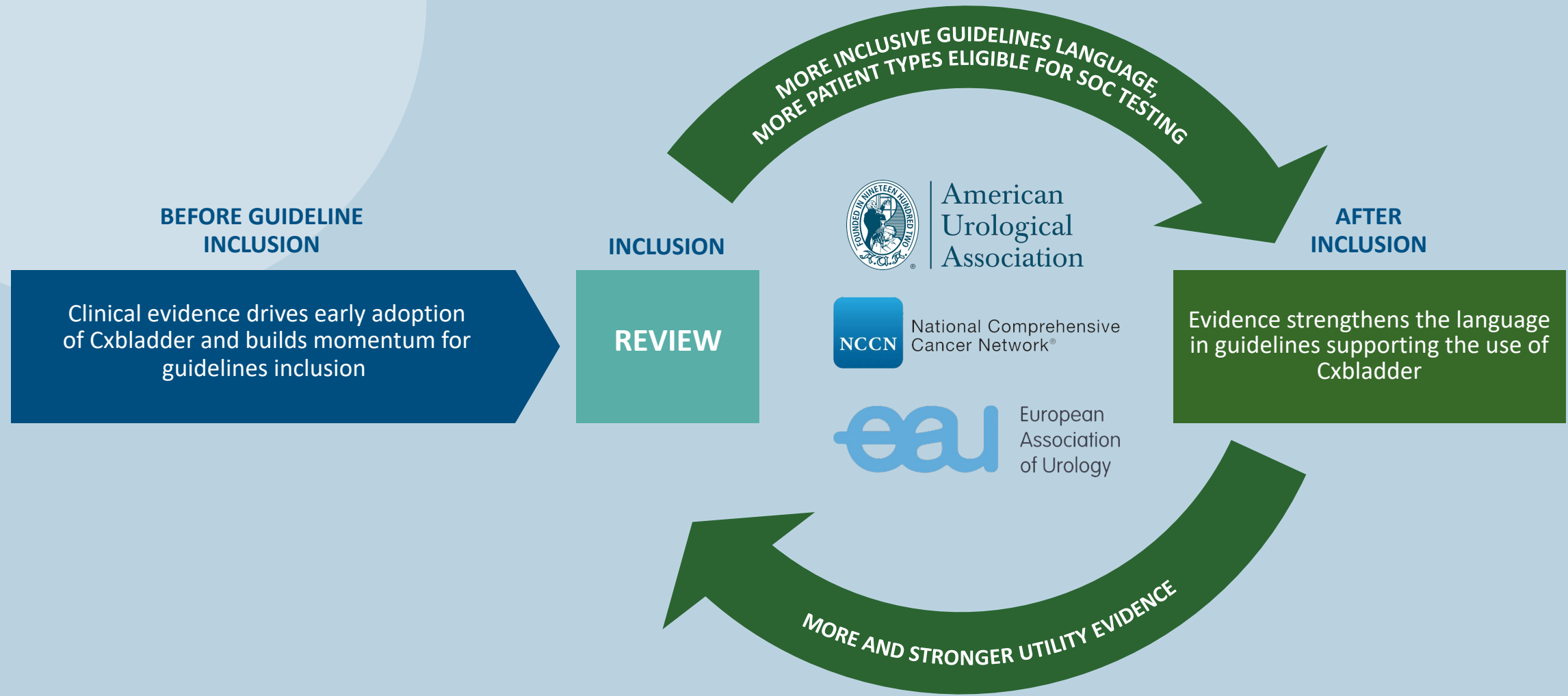
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HOW CLINICAL EVIDENCE GENERATES SHAREHOLDER VALUE

CLINICAL EVIDENCE GENERATION IS A CORE ELEMENT OF OUR STRATEGY AND WILL CONTINUE TO BE



CLINICAL EVIDENCE UNDERPINS COVERAGE AND GUIDELINES DECISIONS



Recognition in national guidelines is the best way to entrench Medicare coverage of Cxbladder and its use and adoption by other independent contracted healthcare systems.



American
Urological
Association

www.auanet.org

- Globally the most influential and largest urological association.
- **Relevant standards of care:** Hematuria, microhematuria management and non-muscle invasive bladder cancer (NMIBC).
- **Review period:** with new evidence



National Comprehensive
Cancer Network®

www.nccn.org

- US-based not-for-profit alliance of 32 leading US cancer centres
- **Relevant standards of care:** High-risk non-muscle-invasive bladder cancer
- **Review period:** annually



European
Association
of Urology

www.uroweb.org

- Leading urologic authority in Europe and globally influential
- **Relevant standards of care:** non-muscle invasive bladder cancer
- **Review period:** with new evidence

PACIFIC EDGE'S CLINICAL STUDY PROGRAM

STRATA

Safe Testing of
Risk for
AsymptomaTic
Microhematuria

DRIVE

Detection and
Risk Stratification
in Veterans
Presenting with
Hematuria

AUSSIE

Australian
Urologic risk
Stratification of
patientS wlth
hEmaturia

microDRIVE

Detection and
Risk Stratification
in Veterans
Presenting with
Microhematuria

POOLED ANALYSIS

Pooled-analysis of
Detect+ from
multiple studies

LOBSTER

Longitudinal
Bladder Cancer
Study for Tumor
RecurRence





THE PRINCIPLES OF PACIFIC EDGE'S CLINICAL STUDY DESIGN PROGRAM

We will attempt to gain guideline inclusion (and coverage) with every new piece of clinical or economic evidence, and through reframing our evidence with urology key opinion leaders

- Studies developing Clinical Validity (CV) evidence and Utility (CU) in patients presenting with microhematuria (the largest market).
- Inclusion of a population of gross hematuria in two studies (AUSSIE, DRIVE) to simultaneously achieve CV in gross hematuria patients, offering the prospect of a different clinical utility pathway for these patients
- Multiple studies (three) to demonstrate CV of Detect⁺ due to the low prevalence of cancer in microhematuria patients (need a sample with a statistically significant number of tumors).
- One large multicenter study for surveillance (LOBSTER)
- All studies offer endpoints supportive of NCCN and AUA guideline inclusion
- Temporarily ceasing further investment in registries and investigator-initiated trials

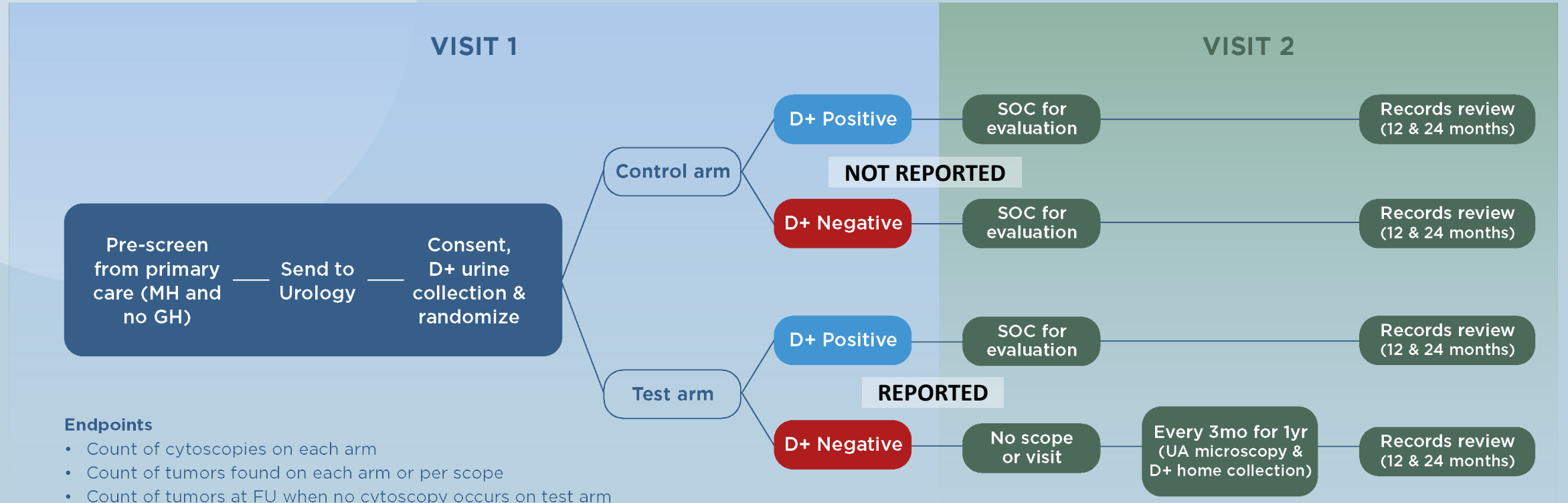
STUDY	GOAL	USE CASE	POPULATION
STRATA	<ul style="list-style-type: none"> • CU for Triage • CU for Detect⁺ (retrospective) 	<ul style="list-style-type: none"> • Risk stratification 	<ul style="list-style-type: none"> • Microhematuria
DRIVE	<ul style="list-style-type: none"> • CV for Detect⁺ • CV for Triage and within a Veterans' cohort • Data for pooled-analysis 	<ul style="list-style-type: none"> • Risk stratification 	<ul style="list-style-type: none"> • Microhematuria and gross hematuria
AUSSIE	<ul style="list-style-type: none"> • CV of Detect⁺ with an Australian cohort • Data for pooled analysis 	<ul style="list-style-type: none"> • Risk stratification 	<ul style="list-style-type: none"> • Microhematuria and gross hematuria
microDRIVE	<ul style="list-style-type: none"> • CV of Detect⁺ • Data for pooled analysis 	<ul style="list-style-type: none"> • Detection 	<ul style="list-style-type: none"> • Microhematuria
POOLED ANALYSIS	<ul style="list-style-type: none"> • CV of Detect⁺ 	<ul style="list-style-type: none"> • Risk stratification 	<ul style="list-style-type: none"> • Microhematuria
LOBSTER	<ul style="list-style-type: none"> • CV of Monitor/Monitor⁺ 	<ul style="list-style-type: none"> • Risk stratification 	<ul style="list-style-type: none"> • Surveillance

Clinical Utility (CU) - Evidence a test that can usefully change patient management within the context of care for the defined population and indication

Clinical Validity (CV) - Evidence a test works in the same way on an independent eligible population for a given indication.

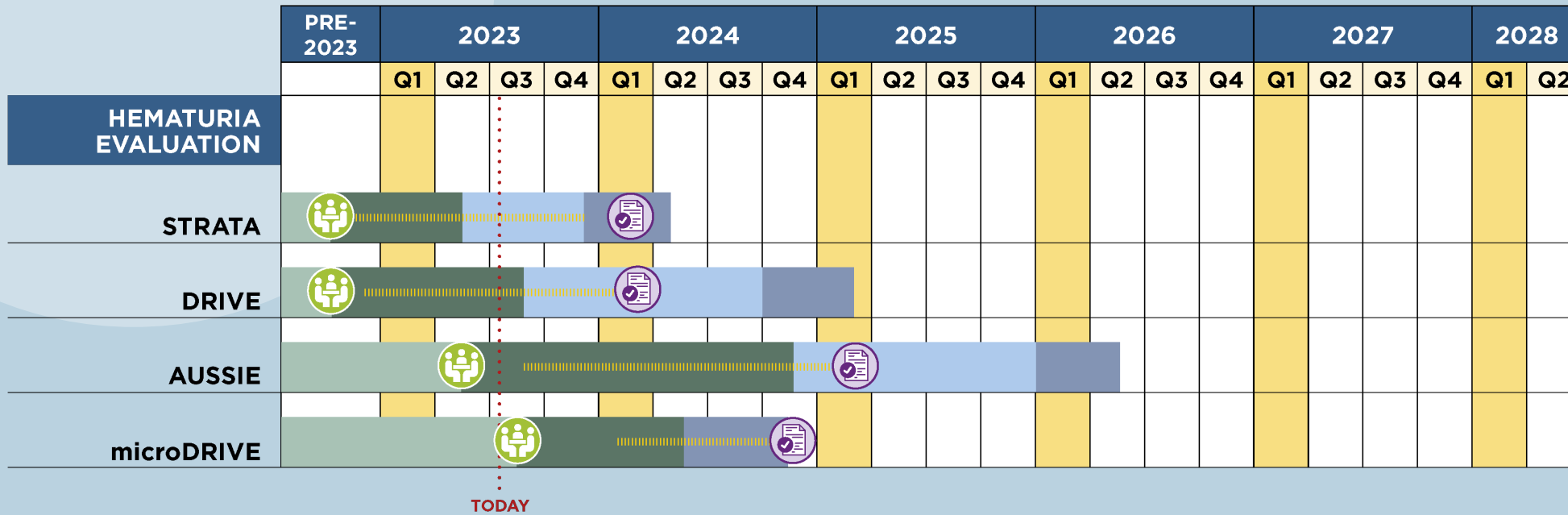
Analytical validity (AV) - Evidence a test is repeatable in the lab for a given indication and population

PROPOSED STUDIES FOR CLINICAL UTILITY OF DETECT⁺



- **US CU study-hem** – will focus on producing clinical utility data for Detect⁺ in microscopic hematuria patients (ABOVE)
- **US CU-surveillance** – will follow the CU for hematuria and focus on clinical utility of Monitor⁺

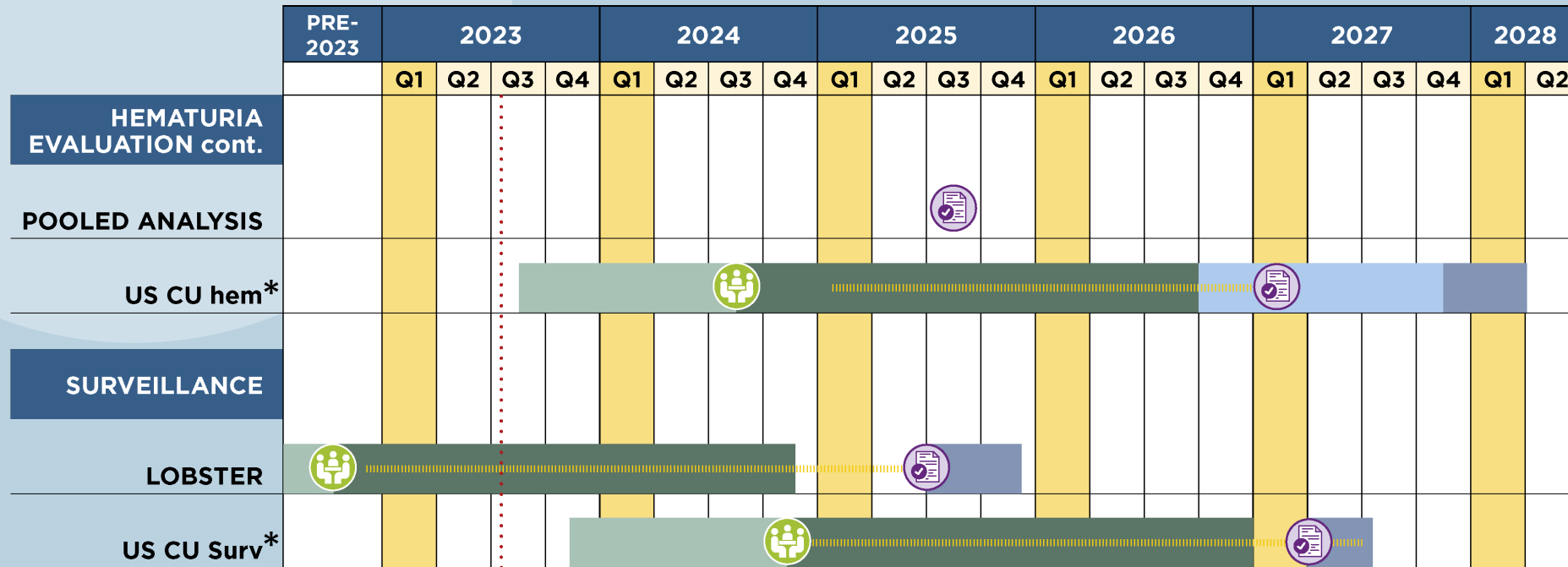
FIVE YEAR CXBLADDER CLINICAL STUDY ROAD MAP



Note: AUSSIE - Interim analysis for primary objective occurs Q4-2024. Post follow-up analysis for secondary objective occurs

- Pre-activation (docs, CTA, etc)
- Data cleaning
- Records review follow-up
- Site Initiation Visit (SIV)
- Publication submitted
- Close-out
- Enrolment

FIVE YEAR CXBLADDER CLINICAL STUDY ROAD MAP (continued)...



*Proposed studies

TODAY




- Pre-activation (docs, CTA, etc)
- Data cleaning
- Records review follow-up
- Site Initiation Visit (SIV)
- Publication submitted
- Close-out
- Enrolment

INCREASING COVERAGE INDICATIONS WITH DETECT+ AND MONITOR+



FOCUSING RESOURCES DETECT+ AND MONITOR+

- **HEMATURIA EVALUATION**
 - Detect and Triage tests to be superseded by Detect+ as single product for hematuria evaluation
 - Clinical development resources directed to generating evidence for Detect+
 - Every new publication on Detect+ would necessitate a reconsideration request and NCCN submission.
- **SURVEILLANCE OF UC**
 - Monitor test to be superseded by Monitor+ (inclusion of DNA markers)
 - Analytical validations and algorithm development already underway with clinical samples collected for development of the test.
 - LOBSTER would develop the evidence for clinical validation
 - A future multi-site Randomized Control Trial (RCT) would develop the evidence for clinical utility
 - Submission for coverage of Monitor+ would happen with every new publication

TEST	SUPPORTING EVIDENCE
	<p>Ongoing studies</p> <ul style="list-style-type: none"> - DRIVE - AUSSIE - microDRIVE - Pooled analysis <p>Future studies</p> <ul style="list-style-type: none"> - RCT with pre-specified clinical pathway for the use of Detect+ in micro-hematuria population
 	<p>Completed studies</p> <ul style="list-style-type: none"> - Li K, Chu C, Patel M, Meng M, Morgan T, Porten S. Cxbladder Monitor testing to reduce cystoscopy frequency in patients with bladder cancer. Urol Oncol. 2023 <p>Ongoing studies</p> <ul style="list-style-type: none"> - LOBSTER - RWE evidence supporting the utility of Cxbladder Monitor <p>Future studies</p> <ul style="list-style-type: none"> • RCT with pre-specified clinical pathway for the use of Monitor+ in surveillance population

AMPLIFYING OUR EVIDENCE WITH UROLOGY OPINION LEADERS



CLINICAL DOSSIER DEVELOPMENT

- Contains all published Cxbladder data; externally reviewed
- Used to engage with guideline committees, private payors, government payers, value-based clinician groups, ex-US distributors, etc.
- Annual NCCN submission of new evidence

PODIUMS, PRESENTATIONS, POSTERS AND PUBLICATIONS

- Increase “share of voice” by presenting data on Cxbladder utility in multiple forums (AUA, SUO, ASCO GU), clinicians, academic institutions
- Publications – support for data generated and published by our users and KOLs
- Speakers Bureau – trained, external KOLs and senior MSL team members

BUILDING KOL RELATIONSHIPS

- Academics, clinical leads in private practice, guidelines committees and other influential clinicians
- Educational events, journal clubs, and resident training for large institutions



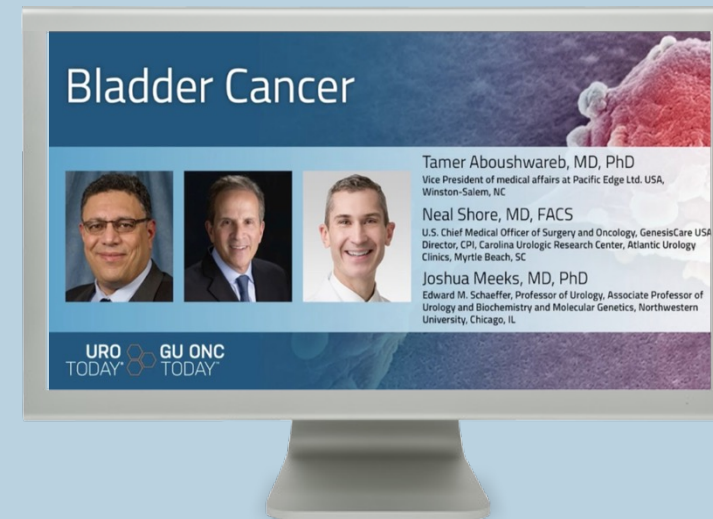
American
Urological
Association



National Comprehensive
Cancer Network®



European
Association
of Urology



VIDEO VIEWS

4102

PUBLISHED

12/2/22

RESEARCH & INNOVATION – FOCUSED ON COMMERCIALISATION



READYING FOR THE LAUNCH OF DETECT+ AND MONITOR+

- Ensure R&D, Digital and Lab Operations focus on the launch of Detect+ and Monitor+
- Develop higher level of documentation associated with product development and analytical validation of our next generation tests
- Continued engagement with industry and academic research and development collaborations to address unmet clinical needs in bladder cancer diagnosis and management



FDA REGULATION OF LABORATORY DEVELOPED TESTS (LDTs)

- FDA has stated they will regulate LDTs
- Tests like Cxbladder that are performed within a “single lab” as a CLIA/LDT are expected to be included
- Announcement on regulatory path in August





CHRIS GALLAHER
Chairman

SHAREHOLDER QUESTIONS



APPENDIX



Mission

To help improve people's lives and patient outcomes by providing leading solutions for the early detection and management of cancer.



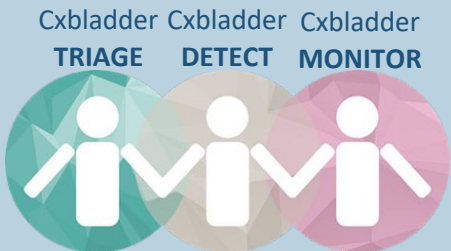
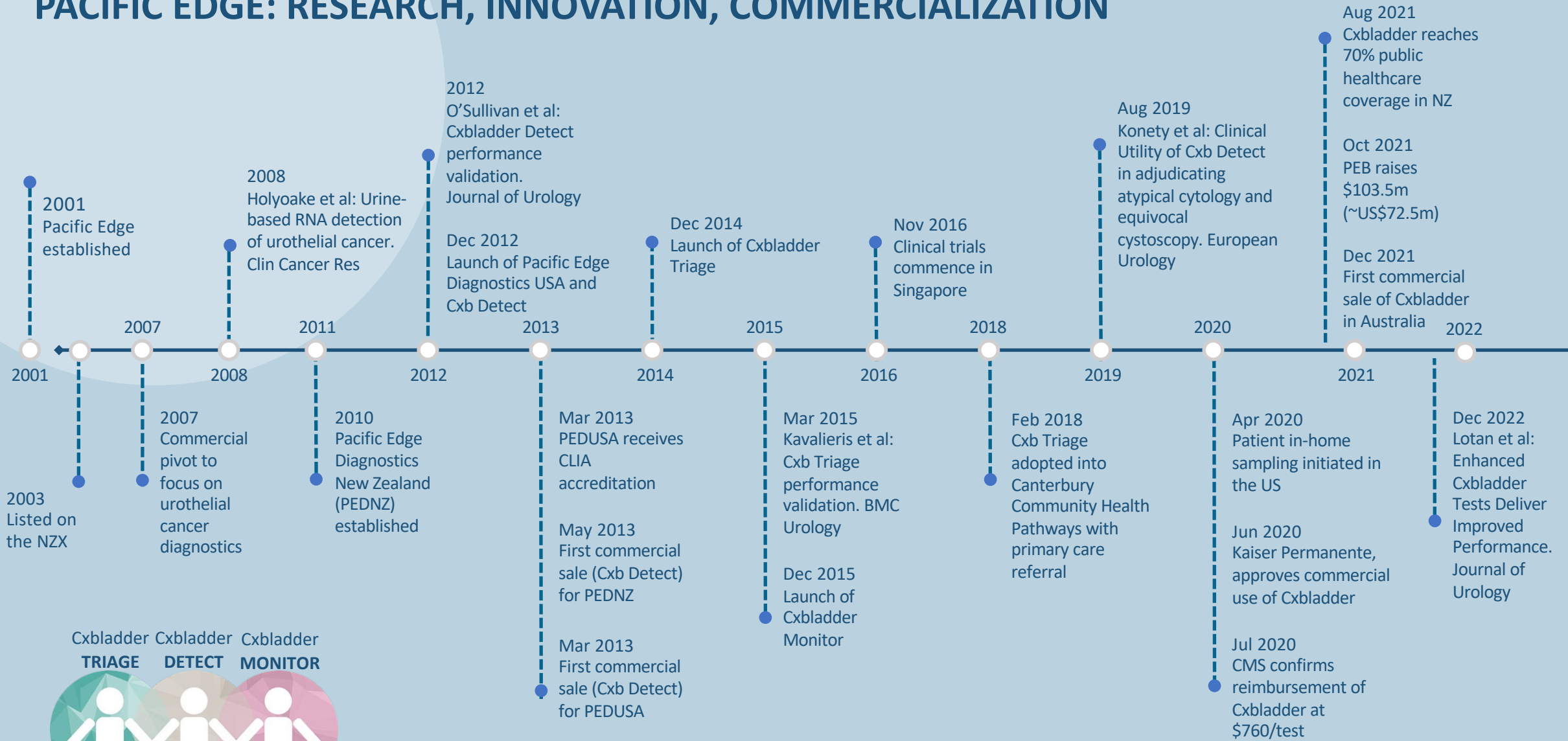
Vision

A world where the early diagnosis and better treatment of cancer is within reach of everyone.

"Nobody should die of cancer"



PACIFIC EDGE: RESEARCH, INNOVATION, COMMERCIALIZATION



PACIFIC EDGE: OUR GLOBAL FOOTPRINT



CLINICAL EVIDENCE GENERATION TOWARDS GUIDELINE INCLUSION (1/2)

STUDY	AIM	LOCATIONS	ENROLLED SITES*	STATUS**
STRATA	<p>Safe Testing of Risk for Asymptomatic Microhematuria</p> <p>Demonstrate the clinical utility (CU) of Cxbladder using a prospective, two-arm randomized design to risk stratify patients and rule out from cystoscopy</p> <ul style="list-style-type: none"> Establish CU for Cxbladder Triage in Micro Hematuria (MH) populations to identify patients at low risk of bladder cancer that can safely avoid cystoscopy Retrospective analysis with Cxbladder Detect+ to show equivalent or greater CU in MH populations with the improved performance characteristics CU evidence supports AUA/NCCN guidelines inclusion using Cxbladder Triage and/or Cxbladder Detect+ to risk stratify MH populations 	USA Canada	12 / 13	<ul style="list-style-type: none"> Enrolment total is 545 Target enrolment: ~600 patients, including 120 low risk subjects (now 131) Last patient in: Q3 2023 Data monitoring underway and expected to be completed Q1 2024 Follow up: until Q3 2024
DRIVE	<p>Detection and Risk Stratification in Veterans Presenting with Hematuria</p> <p>Prospective recruitment of patients to a single-arm observational study to demonstrate the Clinical Validity (CV) of Cxbladder tests in risk stratifying Veterans presenting with hematuria</p> <ul style="list-style-type: none"> CV evidence for Cxbladder Triage in MH and Gross Hematuria (GH) patients supplementing NZ Studies Demonstrate CV of Cxbladder Detect+ within a Veterans cohort Retrospective analysis with Cxbladder Detect+ to demonstrate CV evidence supporting AUA/NCCN Guidelines inclusion in MH & GH patients Contribute data to pooled-analysis to establish CV for Detect+ in MH patients 	VA Sites (USA)	11 / 11	<ul style="list-style-type: none"> Enrolment total is 601 Target enrolment: ~600 patients Last patient in: Q3 2023 Follow up: until Q2 2025
AUSSIE	<p>Australian Urologic risk Stratification of patients with hematuria</p> <p>Prospective recruitment of patients to a single-arm observational study to demonstrate CV in an Australian healthcare setting for patients presenting with MH and GH</p> <ul style="list-style-type: none"> Demonstrate CV of Cxbladder Detect+ with an Australian cohort Demonstrate accurate risk stratification of hematuria patients to intensify or de-intensify evaluation Contribute data to pooled-analysis to establish CV for Detect+ in MH patients 	Australia	1 / 2	<ul style="list-style-type: none"> Target enrolment: 600 patients Enrolment due to start July 2023

*Estimated number of enrolled sites

**All dates are best-case estimates and subject to change

CLINICAL EVIDENCE GENERATION TOWARDS GUIDELINE INCLUSION (2/2)

STUDY	AIM	LOCATIONS	ENROLLED SITES*	STATUS**
Microhematuria Pooled-analysis	<p>Pooled-analysis of Cxbladder Detect+ performance from multiple studies involving prospectively recruited patients from single-arm observational studies including eligible microhematuria patients</p> <ul style="list-style-type: none"> CV of Cxbladder Detect+ with MH patients Combines data from DRIVE, AUSSIE and a future MH-focused clinical trial Supports AUA/NCCN guidelines inclusion using Cxbladder Detect+ to risk stratify MH populations 	USA, Aus	N/A	- DRIVE underway, AUSSIE and microDRIVE projected to start in 2023
microDRIVE	<p>Detection and Risk Stratification in VEterans Presenting with MIcrohematuria</p> <ul style="list-style-type: none"> Demonstrate the CV of Cxbladder Detect+ in detecting urothelial cancer in patients presenting with MH. MicroDRIVE will compare the performance of Cxbladder Detect+ against the current gold-standard for the detection of urothelial cancer, diagnostic cystoscopy and pathology. 	USA	0/1	<ul style="list-style-type: none"> Projected to start recruitment Sep/Oct 2023 Target is 1000 patients and 50 tumour confirmed Last patient in: March/April 2024
LOBSTER	<p>Longitudinal Bladder Cancer Study for Tumor RecurRence Prospective recruitment of patients to a single-arm observational study to evaluate CV of Cxbladder Monitor and Monitor+</p> <ul style="list-style-type: none"> To safely risk stratify patients under surveillance for recurrence of UC To demonstrate that it is safe to alternate Cxbladder Monitor and Monitor+ with cystoscopy for intermediate and high-risk patients under surveillance for recurrence of UC Targeting AUA/NCCN guidelines inclusion for biomarkers as an alternative to cystoscopy in a surveillance setting 	USA (including some VA sites) Australia	5 / 10	<ul style="list-style-type: none"> Enrolment is now 100 patients with 157 samples collected to date Each site will enroll 100 patients within 12 months and follow up for another 12 months

*Estimated number of enrolled sites
**All dates are best-case estimates and subject to change



SUMMARY OF CLINICAL EVIDENCE

		Study	Pop. Type	Sensitivity (Sn)	NPV	Specificity (Sp)	Comment
Detect+	AV	Lotan et al., 2022	MH + GH*	97%	99.7%	90%	Pooled data from US and Singapore cohorts (n=804)
	CV	DRIVE (unpublished) (1)	MH + GH*				Study in progress
		AUSSIE (unpublished) (4)	MH + GH*				Study to start this year
		microDRIVE (unpublished) (5)	MH*				Study to start this year
Triage	AV	Kavalieris et al., 2015	MH + GH*	95.10%	98.50%	45%	Sn, Sp, NPV values when test-negative rate is 40%
	CV	Davidson et al., 2019	MH + GH*	95.5% (1)	98.6% (1)	34.3%	GH only: Sn (95.1%), NPV (98%), Sp (32.8%); MH only: Sn (100%), NPV (100%), Sp (42.6%)
		Konety et al., 2019	(2)	100%			Cxbladder (3) correctly adjudicated all UC confirmed patients (n=26) with atypical urine cytology results (n=153, 4)
		Lotan et al., 2022	MH + GH*	89%	99%	63%	Pooled data from US and Singapore cohorts (n=804)
	CU	Davidson et al., 2020	MH + GH*	89.4% (5)	98.9% (5)	59% (5)	39% of patients testing negative for Cxb Triage & imaging did not get cystoscopy & were managed at primary care (6)
		STRATA (unpublished) (7)	MH + GH*				Study in progress
Detect	AV	O'Sullivan et al., 2012	GH*	81.8%	97%	85.1%	Cxb Detect detected 97% of HG tumors & 100% of Stage 1 or greater tumors.
	CV	Lotan et al., 2022	MH + GH*	74%	97%	82%	Pooled data from US and Singapore cohorts (n=804)
		DRIVE (unpublished) (1)	MH + GH*				Study in progress
Monitor	AV	Kavalieris et al., 2017	(1)	88% (2)	97% (2)	N/A	(3)
	CV	Konety et al., 2019	(4)	100%			Cxbladder (5) correctly adjudicated all UC confirmed patients (n=26) with atypical urine cytology results (n=153, 6)
	CU	Koya et al., 2020	(7)				Integration of Cxb Monitor into the surveillance schedule reduced annual cystoscopies (39%) (8,9)

* Referred

MH: Microhematuria, GH: Gross Hematuria. For definitions of Sensitivity, NPV and Specificity please see the glossary on page 61 of this presentation

FOOTNOTES FOR CLINICAL EVIDENCE SUMMARY

Footnotes		
Detect+	1	Observational study to validate performance characteristics and clinical utility of Cxbladder tests (Cxb Triage, Cxb Detect, Cxb Detect*).
	2	Observational study to validate performance characteristics of Cxb Detect* in patients with UC of the upper tract.
	3	Patients with suspected upper tract UC (UTUC) or surveillance patients with a history of UTUC.
	4	Observational study to validate performance characteristics and clinical utility of Cxbladder tests (Cxb Triage, Cxb Detect, Cxb Detect*).
	5	Observational study to validate performance characteristics of Cxb Detect* in microhematuria (MH) patients.
Triage	1	Cxb Triage performance; Cxb Triage & imaging combined performance had a Sn of 97.7% & NPV of 99.8%.
	2	Patients included hematuria evaluation ($n=436$) or surveillance previously diagnosed with UC ($n=416$) with both Cxbladder & urine cytology results.
	3	Cxbladder includes Cxbladder Triage & Cxbladder Monitor.
	4	This included $n=70$ for patients with hematuria & $n=83$ for patients with previously diagnosed UC and overall test negative rate of 30.7%.
	5	Cxb Triage performance; Cxb Triage & imaging combined performance had a Sn of 98.1%, NPV of 99.9% & Sp of 98.4%.
	6	Cxb Triage negative rate was 53%; Follow-up period of 21-months showed no missed cancers, demonstrating safety.
	7	The intent of STRATA is to show that it is safe to risk stratify low risk microhematuria patients and not undertake cystoscopy.
Detect	1	Observational study to validate performance characteristics and clinical utility of Cxbladder tests (Cxb Triage, Cxb Detect, Cxb Detect*).
Monitor	1	Surveillance patients previously diagnosed with primary or recurrent UC.
	2	Cxb Monitor performance characteristics on surveillance patients diagnosed with primary UC; Cxb Monitor had a Sn of 93% and NPV of 94% on patients with recurrent UC.
	3	Using Kavalieris et al., (2017) data set, Lotan et al., (2017) compared relative performance of Cxb Monitor against NMP22 ELISA, NMP22 BladderChek and urine cytology.
	4	Patients included hematuria evaluation ($n=436$) or previously diagnosed UC ($n=416$) with both Cxbladder & urine cytology results.
	5	Cxbladder includes Cxbladder Triage & Cxbladder Monitor.
	6	This included $n=70$ for patients with hematuria & $n=83$ for patients with previously diagnosed UC; test negative rate of 30.7%.
	7	All patients were being evaluated for recurrence of UC ($n=309$ providing 443 samples).
	8	Cxb Monitor identified all seven confirmed recurrence events identified on the first cystoscopy.
	9	Patients returning negative Cxb Monitor results ($n=235$) had no pathology-confirmed recurrence at 1st cystoscopy

REFERENCES SUMMARY OF CLINICAL EVIDENCE

References	
Detect+	Lotan et al., (2022). Urinary Analysis of FGFR3 and TERT Gene Mutations Enhances Performance of Cxbladder Tests and Improves Patient Risk Stratification. <i>The Journal of Urology</i> , 10-1097.
Triage	Davidson et al., (2019). Inclusion of a molecular marker of bladder cancer in a clinical pathway for investigation of haematuria may reduce the need for cystoscopy. <i>NZ Med J</i> , 132(1497), 55-64.
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	Kavalieris et al., (2015). A segregation index combining phenotypic (clinical characteristics) and genotypic (gene expression) biomarkers from a urine sample to triage out patients presenting with hematuria who have a low probability of urothelial carcinoma. <i>BMC urology</i> , 15(1), 1-12.
	Konety et al., (2019). Evaluation of cxbladder and adjudication of atypical cytology and equivocal cystoscopy. <i>European urology</i> , 76(2), 238-243.
	Lotan et al., (2022). Urinary Analysis of FGFR3 and TERT Gene Mutations Enhances Performance of Cxbladder Tests and Improves Patient Risk Stratification. <i>The Journal of Urology</i> , 10-1097.
Detect	Lotan et al., (2022). Urinary Analysis of FGFR3 and TERT Gene Mutations Enhances Performance of Cxbladder Tests and Improves Patient Risk Stratification. <i>The Journal of Urology</i> , 10-1097.
	O'Sullivan et al., (2012). A multigene urine test for the detection and stratification of bladder cancer in patients presenting with hematuria. <i>The Journal of urology</i> , 188(3), 741-747.
Monitor	Kavalieris et al., (2017). Performance characteristics of a multigene urine biomarker test for monitoring for recurrent urothelial carcinoma in a multicenter study. <i>The Journal of Urology</i> , 197(6), 1419-1426.
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PACIFIC EDGE BOARD AND MANAGEMENT



CHRIS GALLAHER
Chairman

Chris has held senior positions in both CEO and CFO roles with large international companies and was a partner in Arthur Young, Chartered Accountants. Prior to retiring from full time corporate life, he was CFO of Fulton Hogan, a large New Zealand civil contractor.



DR PETER MEINTJES
Chief Executive Officer

Peter is a molecular diagnostics and genomics leader focused on nascent market development of disruptive innovations to drive commercial success. Prior to joining Pacific Edge, he was based in Boston in a succession of diagnostic leadership roles. Most recently he was the Chief Commercial Officer at Eurofins Transplant Genomics and before that CEO at Omixon.

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GLOSSARY

- **Sensitivity** - the frequency with which a test correctly identifies patients with a disease.
- **Specificity** - the frequency with which a test correctly identifies patients without a disease.
- **Negative Predictive Value (NPV)** - the percentage of negative tests being true negatives (by standard of care).
- **Positive Predictive Value (PPV)** - the percentage of positive tests being true positives (by standard of care).
- **Rule-out Rate (ROR)** - the percentage of tests that return a negative result.
- **Evidence definitions:**
 - **Analytical validity:** Evidence that a test is repeatable in the lab for a given indication and population.
 - **Clinical validity:** Evidence a test works in the same way on an independent eligible population for a given indication.
 - **Clinical utility:** Evidence that a test in the hands of a physician can usefully change patient management within the context of care for the defined population and indication.

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