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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ANATOLE MASFEN

BRYAN WILLIAMS

ANNA STOVE

MARK GREEN

TONY BARCLAY

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MEETING AGENDA

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

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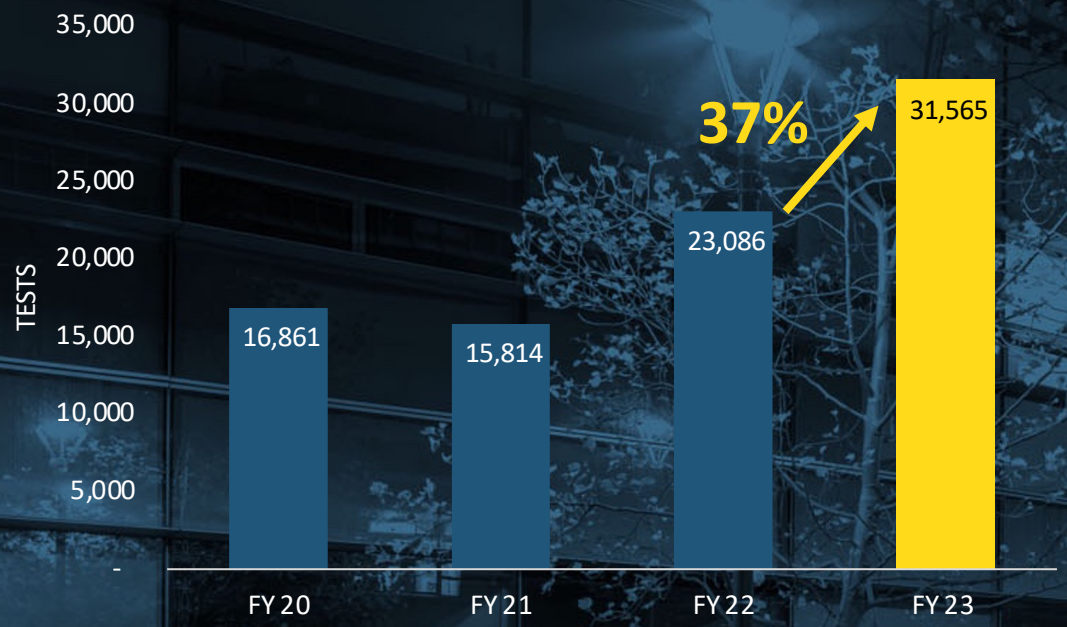
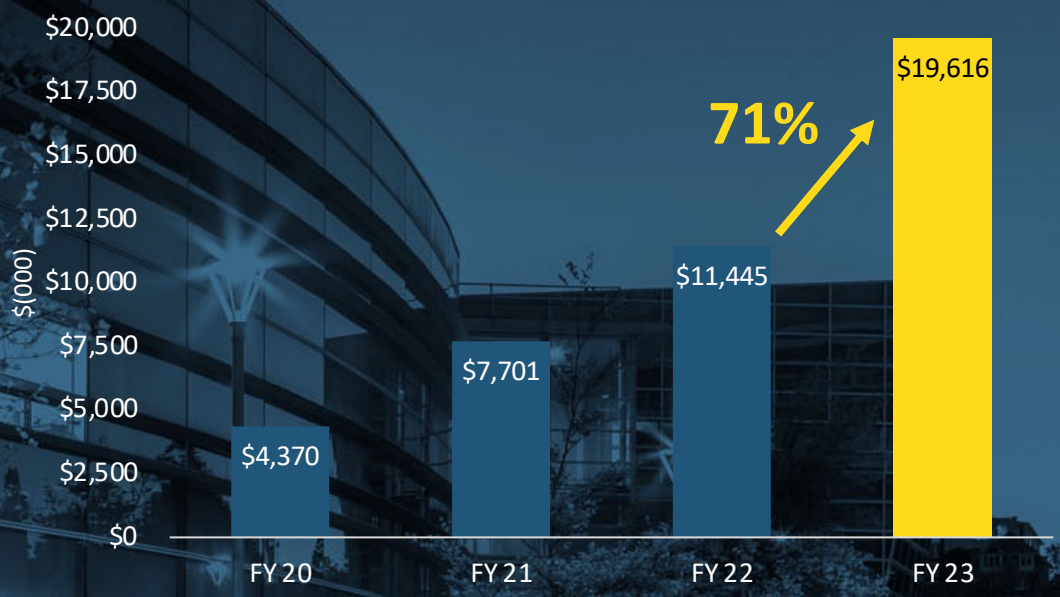
FY 23 HIGHLIGHTS: STRONG PERFORMANCE FOLLOWS STRATEGIC EXECUTION

PACIFIC EDGE GLOBAL TEST VOLUMES[1]



PACIFIC EDGE OPERATING REVENUE



▲44%
US TEST VOLUMES[1]
(27,217 TESTS)

▲46%
US ORDERING CLINICIANS[2]
(1,150 CLINCIANS)

$27.0M
NET LOSS AFTER TAX

$77.8M
CASH, CASH EQUIVALENTS[3]

[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

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PACIFIC EDGE'S MEDICARE JOURNEY

Medicare

July '20

Novitas informs Pacific Edge that Cxbladder is covered

July - Sep '22

Open Meetings, Public Comment. Support from industry, patient advocates & customers to retire/revise DL39365

Jan '23

Triage gains coding and then coverage under LCA (A58917)

June - July '23

We pursue all legal and political strategies to overturn the LCD

TODAY

Preparing for notice and comment, open meetings and medical director meeting

Medicare coverage continues

Strategy review

NOVITAS SOLUTIONS

July '22

Novitas proposes non-coverage for Cxbladder with LCD (DL39365)

Implementation seen as unlikely

Sep - May '23

Contingency planning for adverse LCD determination amid expectation of continued coverage

2 June '23

Novitas finalizes LCD (L39365) with non-coverage for Cxbladder, future effective on 17 July

6 July '23

Novitas agrees to follow procedure for notice and comment on the LCD

LCD stayed, Medicare coverage continues

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

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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.

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Dr PETER MEINTJES
Chief Executive Officer

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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

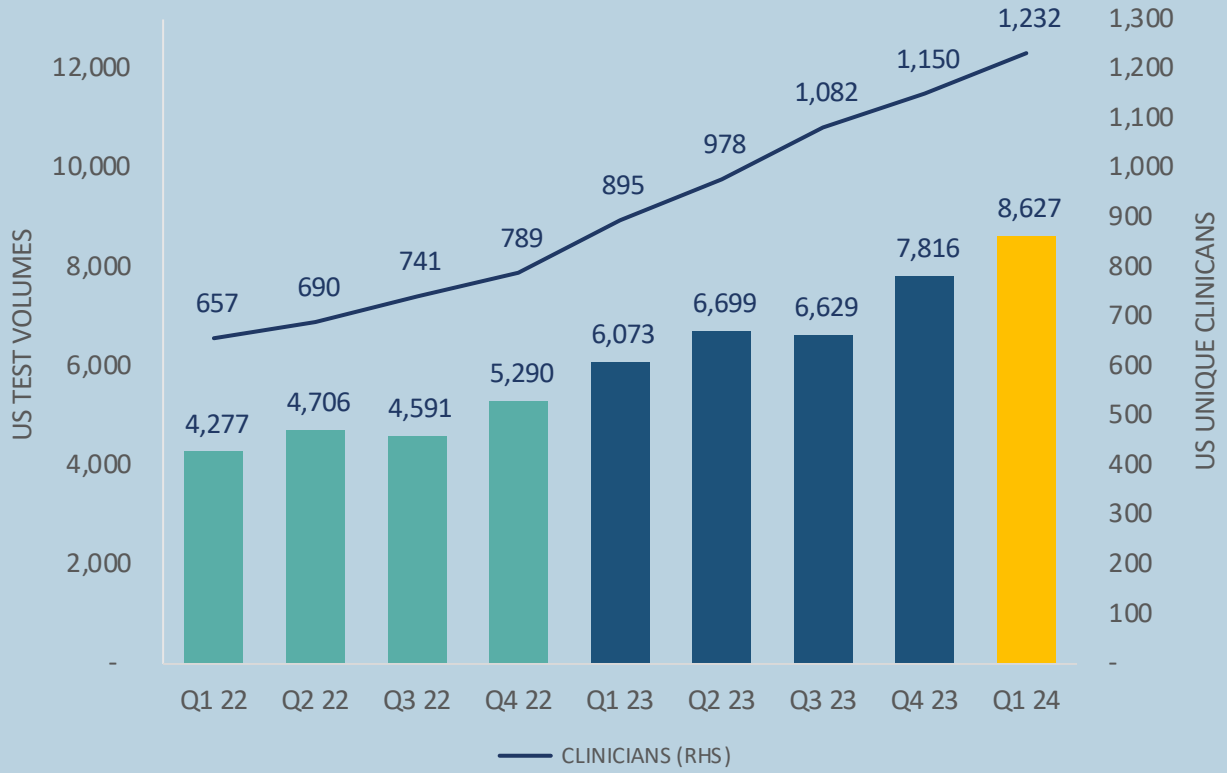
LCD TIMELINE

NOVITAS REPUBLISHES LCD
(Near future)

REVIEW AND COMMENT
(45-days)

NOVITAS DECISION
Novitas must withdraw or finalize LCD within 365 days of publication.
Final LCD becomes effective (assuming no further protest) 45 days after finalization.

Cxbladder is well supported by the US urological community with >1,200 separate clinicians (representing >10% of practicing US urologists[1]) ordering >8,600 tests[2] in the US in Q1 24



[1] American Urological Assn 2021 Census
[2] Total Laboratory Throughput including commercial, pre-commercial and clinical studies testing

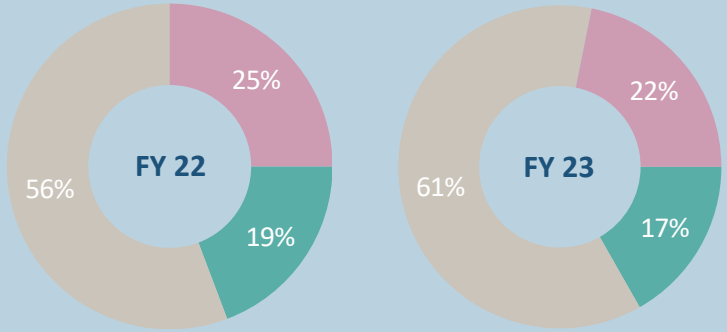
DESPITE LCD UNCERTAINTY IN FY 23 WE DELIVERED STAND-OUT GROWTH

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*)

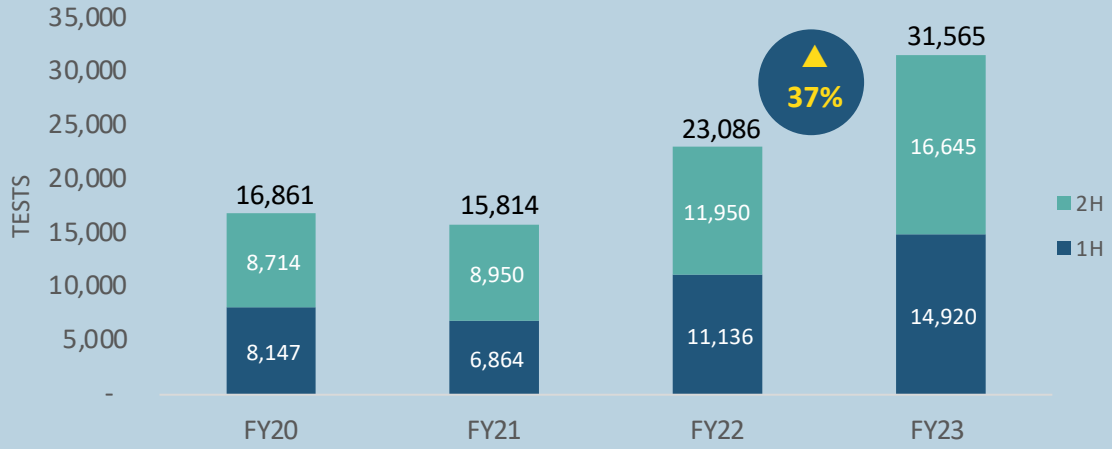


Cxbladder TRIAGE

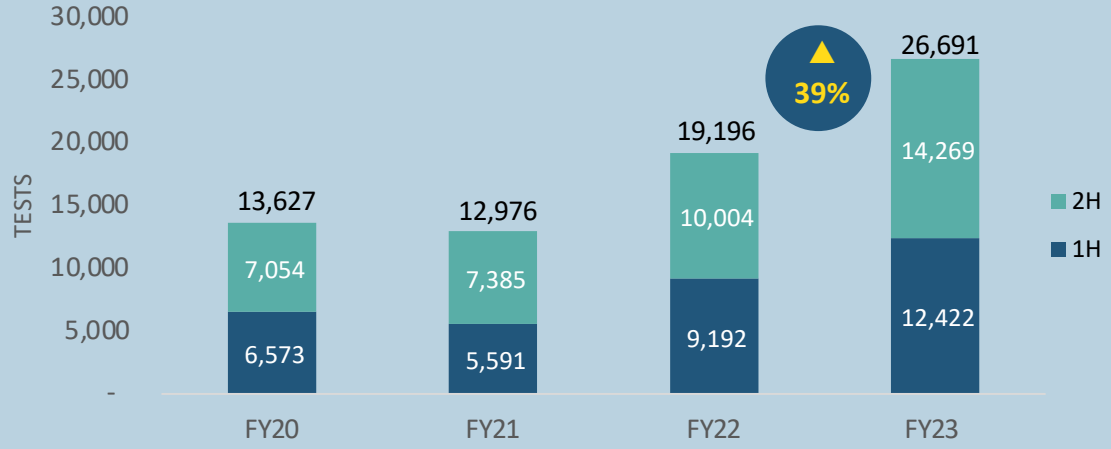
Cxbladder DETECT

Cxbladder MONITOR

GLOBAL TEST VOLUMES (TLT)



GLOBAL COMMERCIAL TEST VOLUMES (TLT)



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

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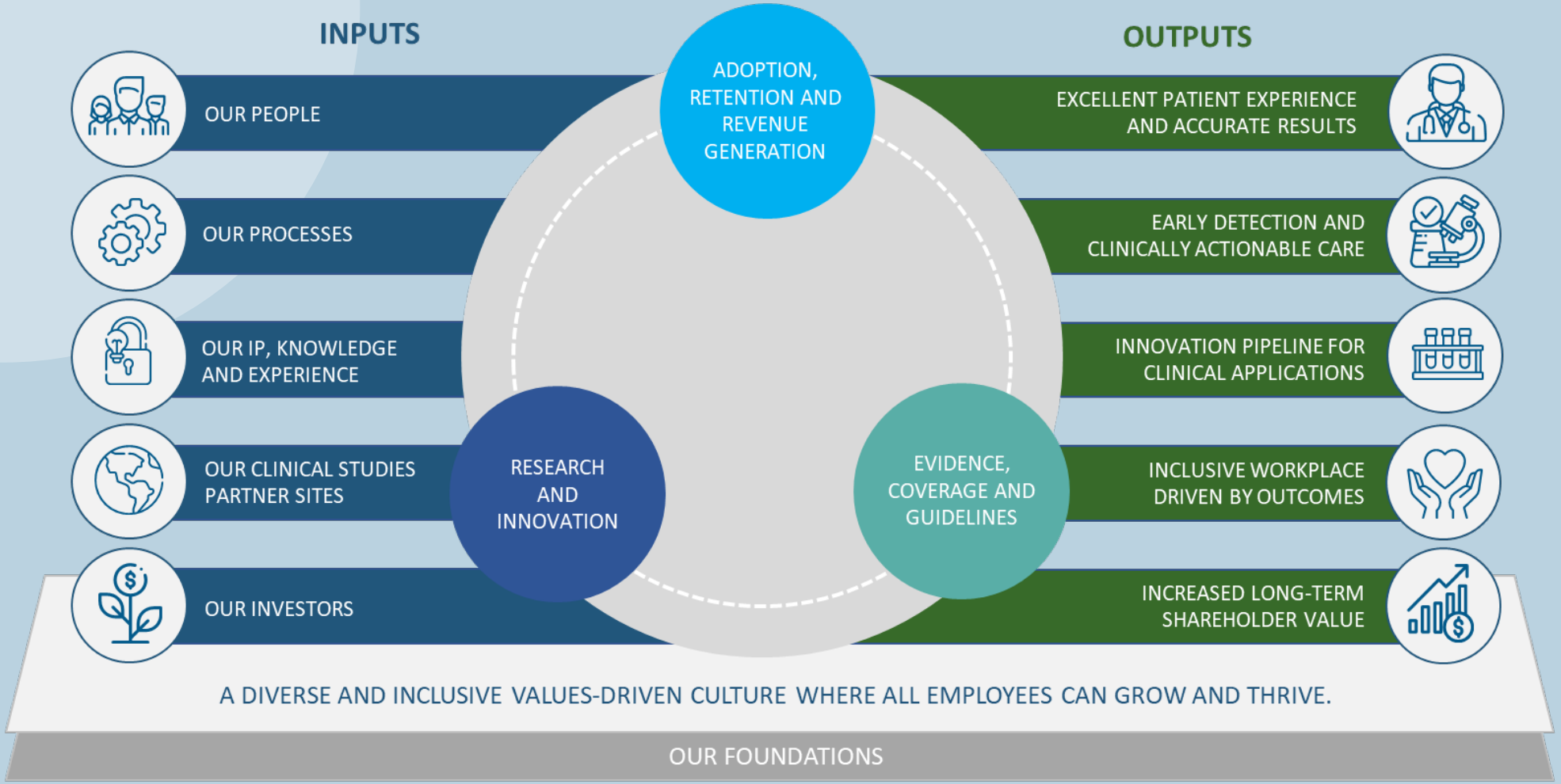
COVERAGE UNCERTAINTY HAS AFFIRMED OUR STRATEGY

CLINICAL EVIDENCE AND STRONG UROLOGICAL RELATIONSHIPS ARE FUNDAMENTAL TO SUCCESS



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REFINING OUR FOCUS: ADOPTION, RETENTION AND REVENUE GENERATION

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 VOLUME[1]

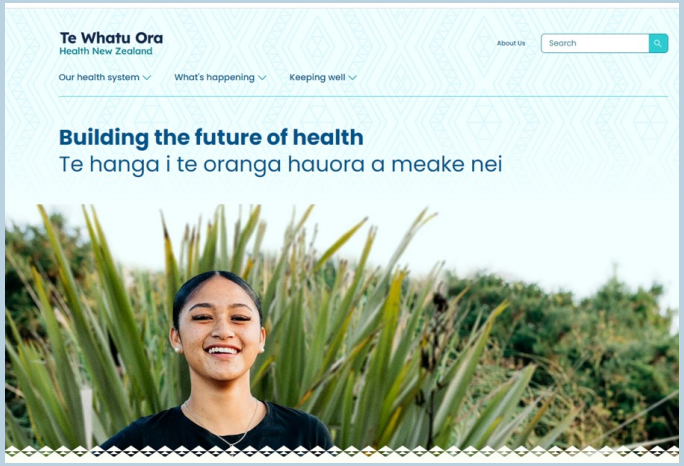
ADOPTION, RETENTION AND REVENUE GENERATION

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

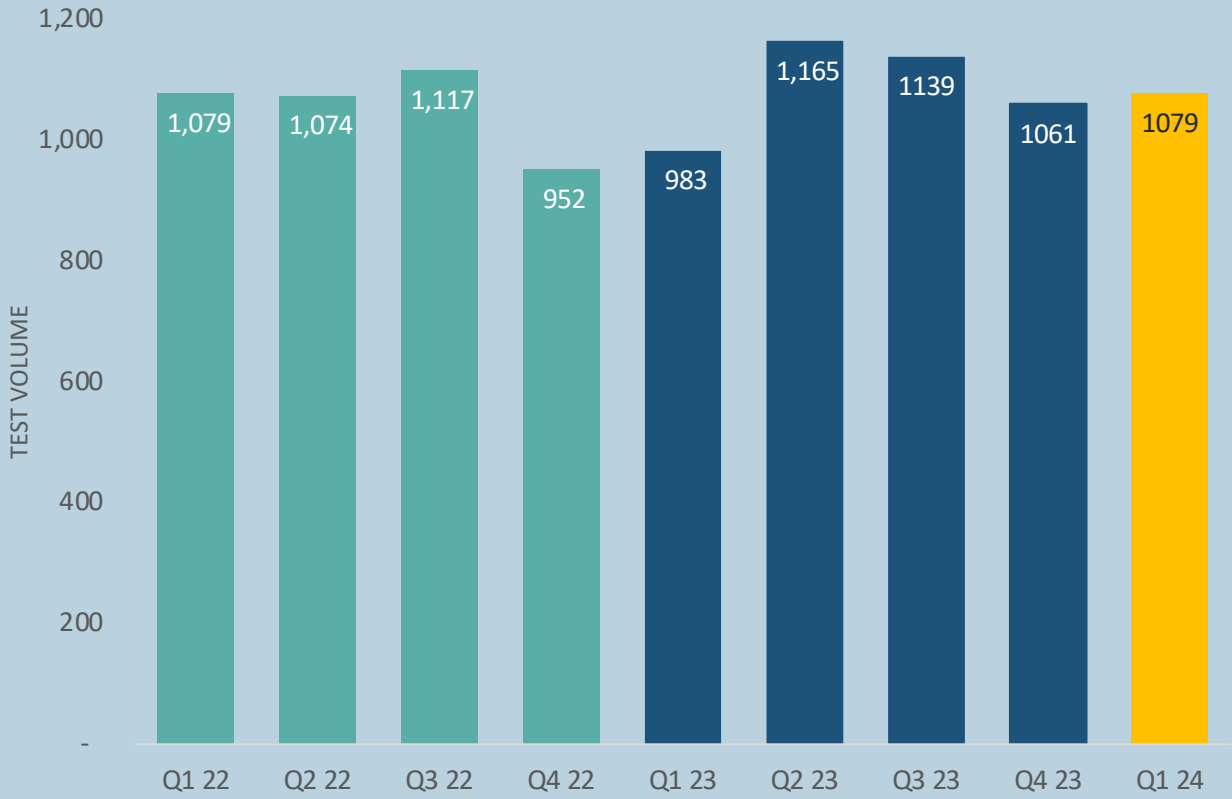
AUSTRALIA & ASIA PACIFIC

- 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 VOLUMES[1]

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

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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

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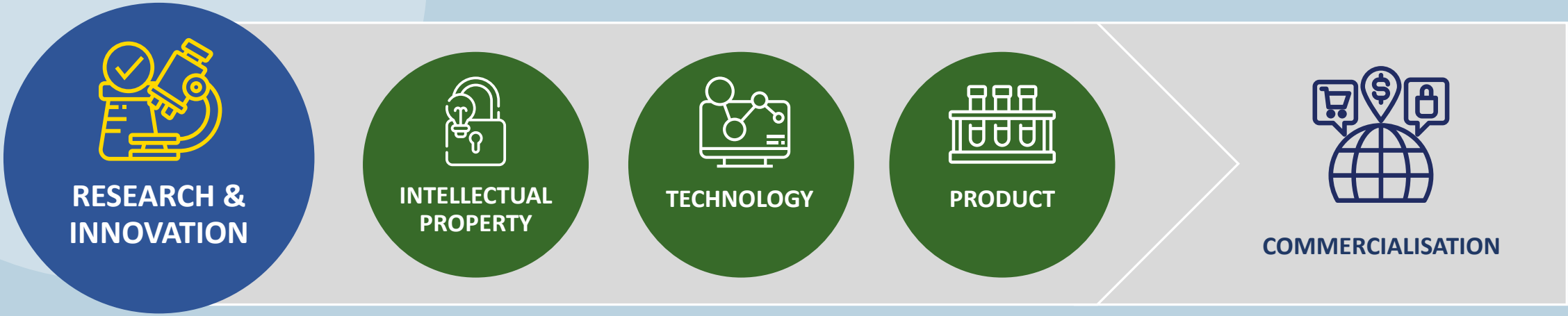
RESEARCH AND INNOVATION:

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

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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

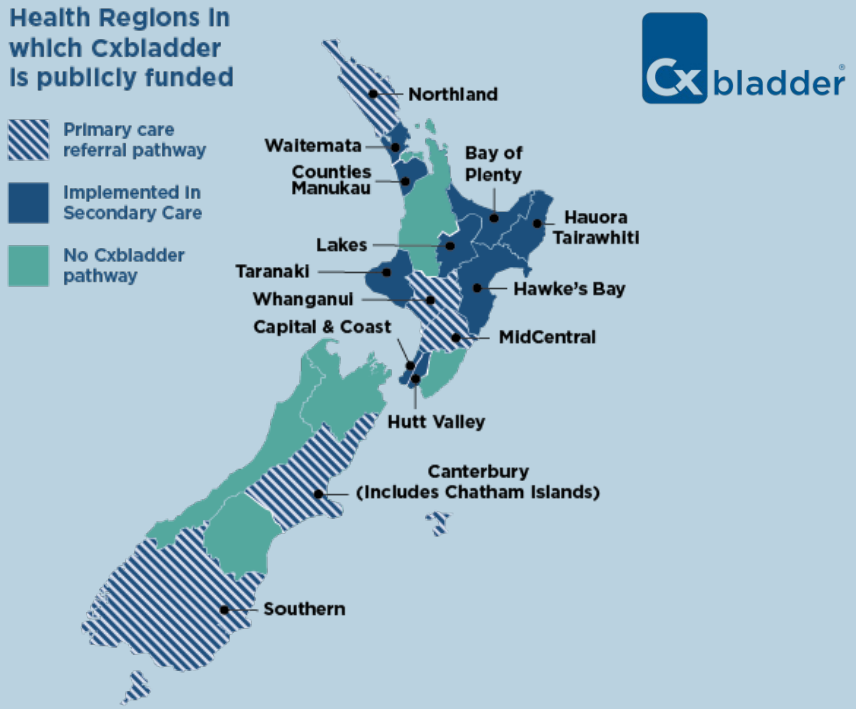
- Integrating oversight of Environmental, Social and Governance (ESG) matters, including carbon reporting, into the Audit and Risk Committee Charter

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



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

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PEDUSA – ADOPTION RETENTION AND REVENUE GENERATION

FOCUSED ON MEDICARE COVERAGE AND SELLING THE CLINCAL VALUE OF CXBLADDER

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 improved gross margin per test
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.

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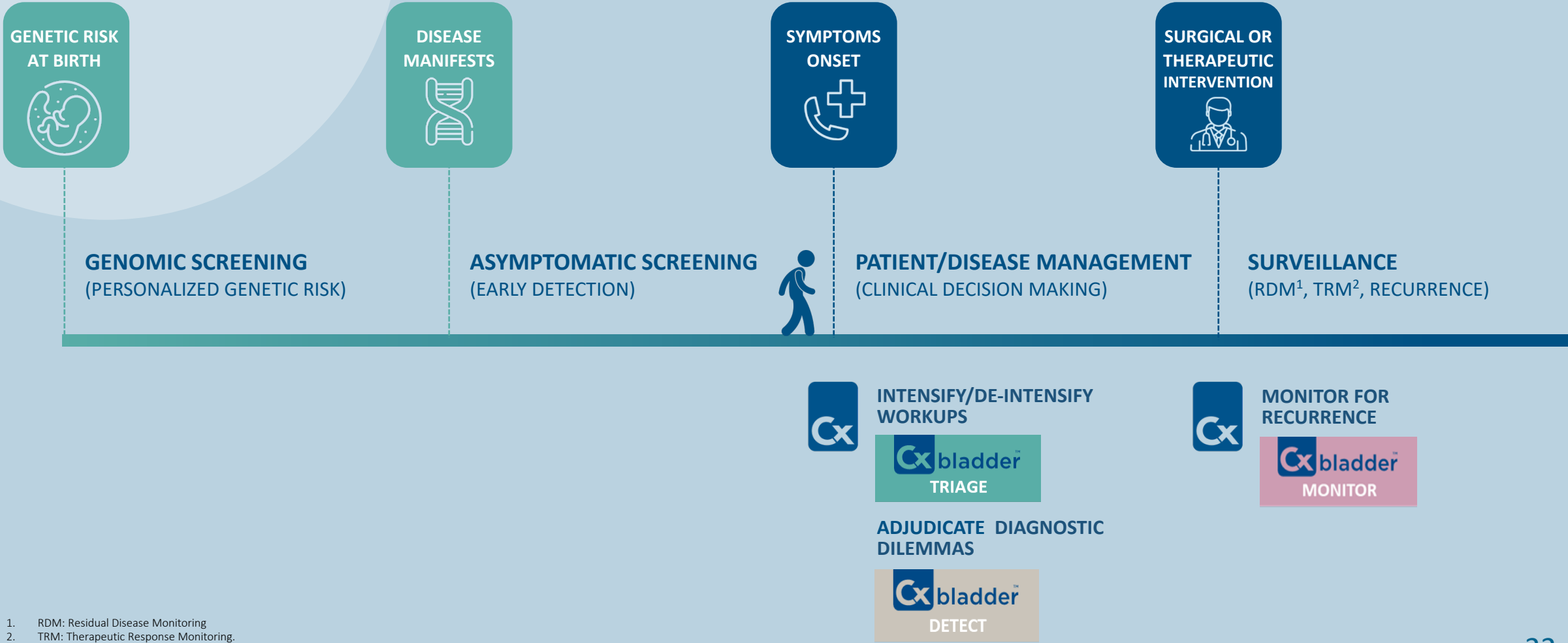
MOLECULAR DIAGNOSTICS VALUE CHAIN: PATIENT JOURNEY



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

HEMATURIA EVALUATION AND SURVEILLANCE IN THE US MARKET

ADOPTION, RETENTION AND REVENUE GENERATION

90%
Five-year survival rate for NMIBC if detected early[1]

US$191K
Average lifetime cost per patient[2]

US$9.4B
Annual US spend on bladder cancer[3]

VALUE PROPOSITION

Cxbladder **TRIAGE** | Cxbladder **DETECT** | Cxbladder **MONITOR**

Patient care pathway

Primary Care Physician → **Urologist/Specialist**

The US has >55m men and >63m women aged 50+

- **~7m** present with hematuria[4]
- **~3.4m** referred for clinical workup[7]
- **>1.0m** patients receive a cystoscopy[5]
- **~82k** Annual cases of bladder cancer[6]
- **~725k** patients living with bladder cancer ~1.5 Cxb Monitor/yr[6]

US$3.5B opportunity[7] (hematuria, surveillance)

>4.5M Cxbladder **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

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HEALTH ECONOMICS – THE ECONOMIC VALUE OF CXBLADDER DETECT

ADOPTION, RETENTION AND REVENUE GENERATION

Cxbladder Detect offers substantial total cost savings/patient when used to intensity or de-intensify hematuria evaluation in patients presenting with microhematuria[1]

AUA guidelines recommend all high and intermediate risk microhematuria patients receive a full work up including a cystoscopy & imaging

+

>1m cystoscopies are needed to find 81,000 UC tumors, i.e. the vast majority of cystoscopies & imaging are unnecessary

+

Cxbladder DETECT

Used as a rule out test - Detect could safely reduce the number of unnecessary procedures substantially

=

Pacific Edge modelling suggests avoided procedures could save >US$1000 per patient presenting with microhematuria

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

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DIFFERENTIATED SALES ROLES FOCUSSED ON DIFFERENT CUSTOMER TYPES

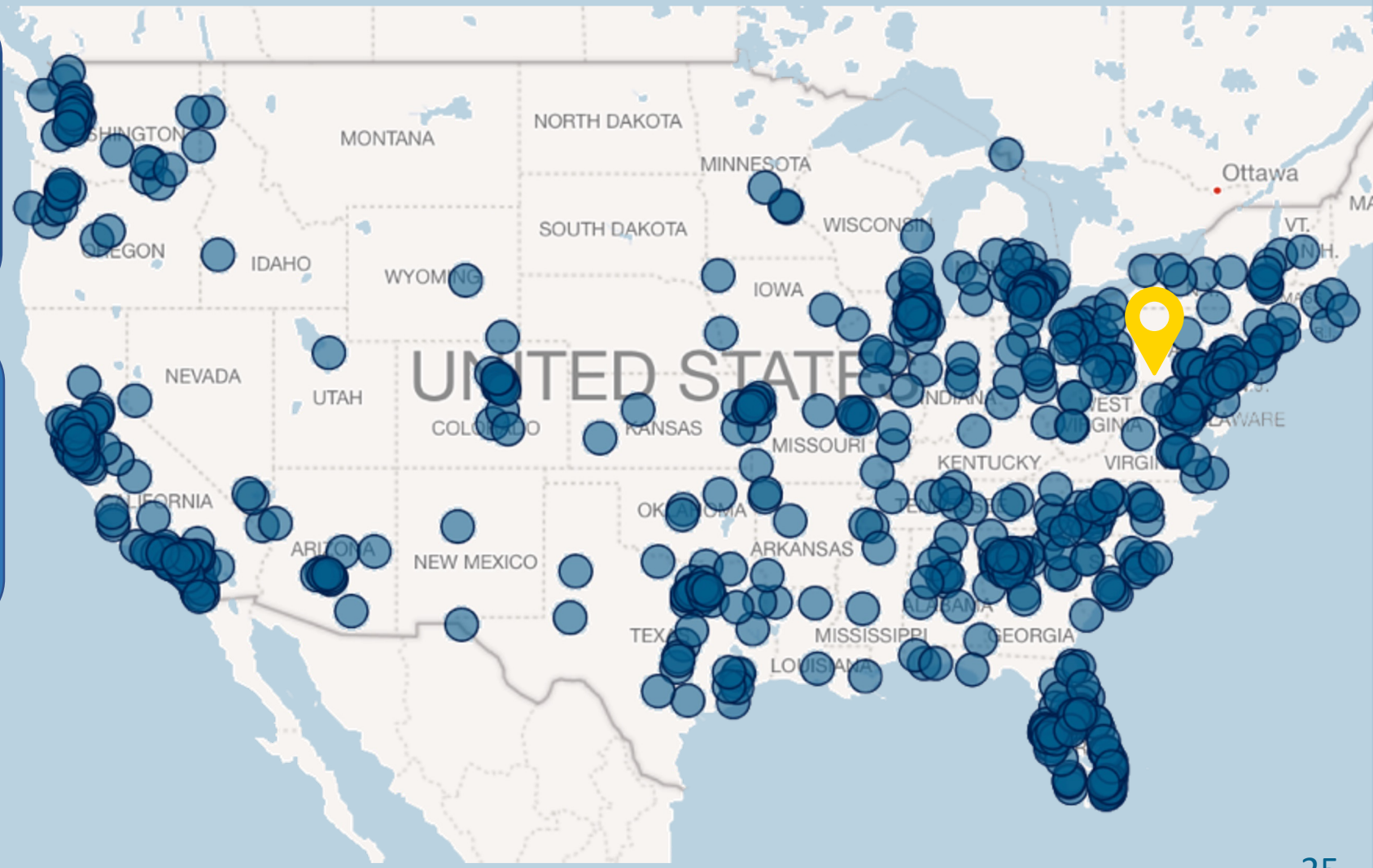
ADOPTION, RETENTION AND REVENUE GENERATION

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

ADOPTION, RETENTION AND REVENUE GENERATION

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

ADOPTION, RETENTION AND REVENUE GENERATION

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

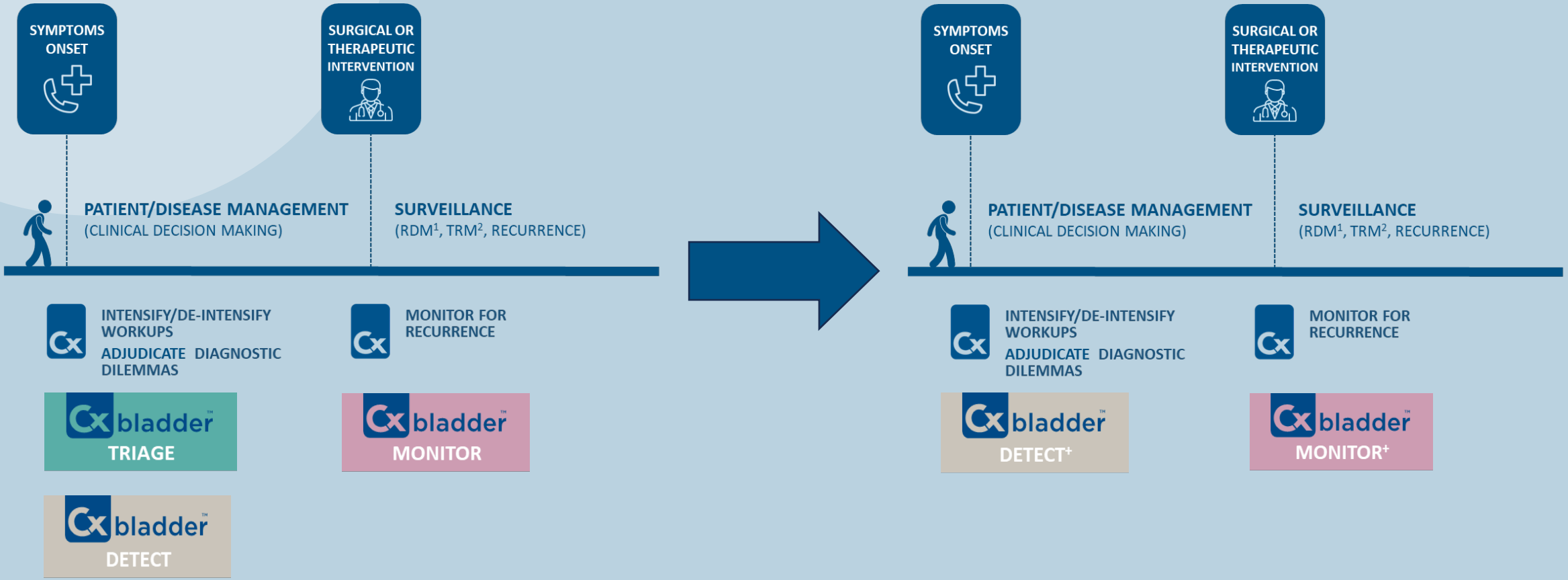
- DRIVE study is a key engagement with VA urologists to determine clinical validity in a cohort of VA patients

[1] Total Laboratory Throughput including commercial, pre-commercial and clinical studies testing
[2] CAGR compares Q4 21 to Q4 23

SIMPLIFYING THE CXBLADDER PROPOSITION – DETECT+ AND MONITOR+

LEVERAGING EVIDENCE SHOWING THE ADDITION OF DNA BIOMARKERS ENHANCES TEST PERFORMANCE

ADOPTION, RETENTION AND REVENUE GENERATION



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 Stratificationn

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

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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

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)

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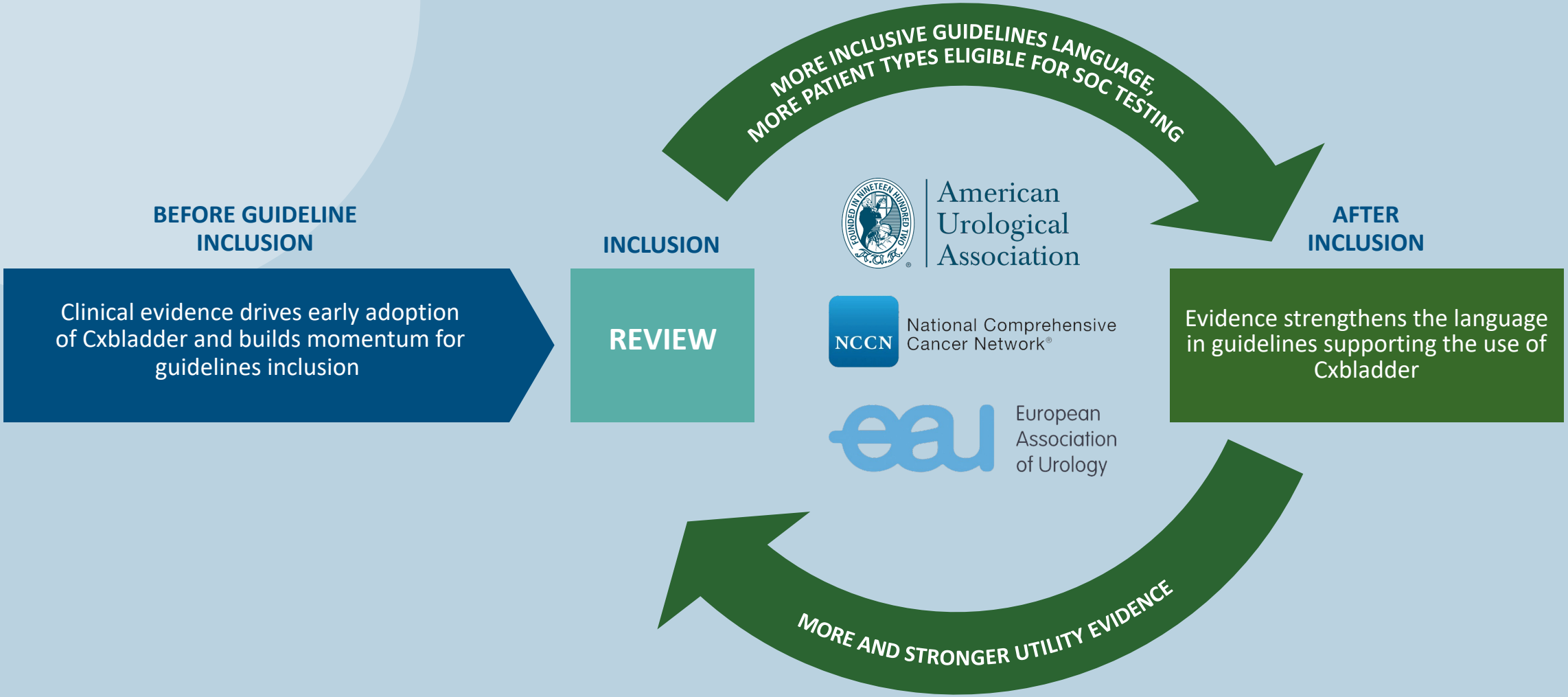
HOW CLINICAL EVIDENCE GENERATES SHAREHOLDER VALUE

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

EVIDENCE COVERAGE AND GUIDELINES



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CLINICAL EVIDENCE UNDERPINS COVERAGE AND GUIDELINES DECISIONS

EVIDENCE COVERAGE AND GUIDELINES

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

NCCN 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

eau 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 **T**esting of **R**isk for **A**symptoma**T**ic Microhematuri**A**

DRIVE
Detection and **RI**sk Stratification in **VE**terans Presenting with Hematuria

AUSSIE
Australian **U**rologic risk **S**tratification of patient**S** w**I**th h**E**maturia

microDRIVE
Detection and **RI**sk Stratification in **VE**terans Presenting with **Micro**hematuria

POOLED ANALYSIS
Pooled-analysis of Detect+ from multiple studies

LOBSTER
LOngitudinal **B**ladder Cancer **S**tudy for **T**umor R**E**cur**R**ence

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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	• CU for Triage • CU for Detect$^+$ (retrospective)	• Risk stratification	• Microhematuria
DRIVE	• CV for Detect$^+$ • CV for Triage and within a Veterans' cohort • Data for pooled-analysis	• Risk stratification	• Microhematuria and gross hematuria
AUSSIE	• CV of Detect$^+$ with an Australian cohort • Data for pooled analysis	• Risk stratification	• Microhematuria and gross hematuria
microDRIVE	• CV of Detect$^+$ • Data for pooled analysis	• Detection	• Microhematuria
POOLED ANALYSIS	• CV of Detect$^+$	• Risk stratification	• Microhematuria
LOBSTER	• CV of Monitor/Monitor$^+$	• Risk stratification	• 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

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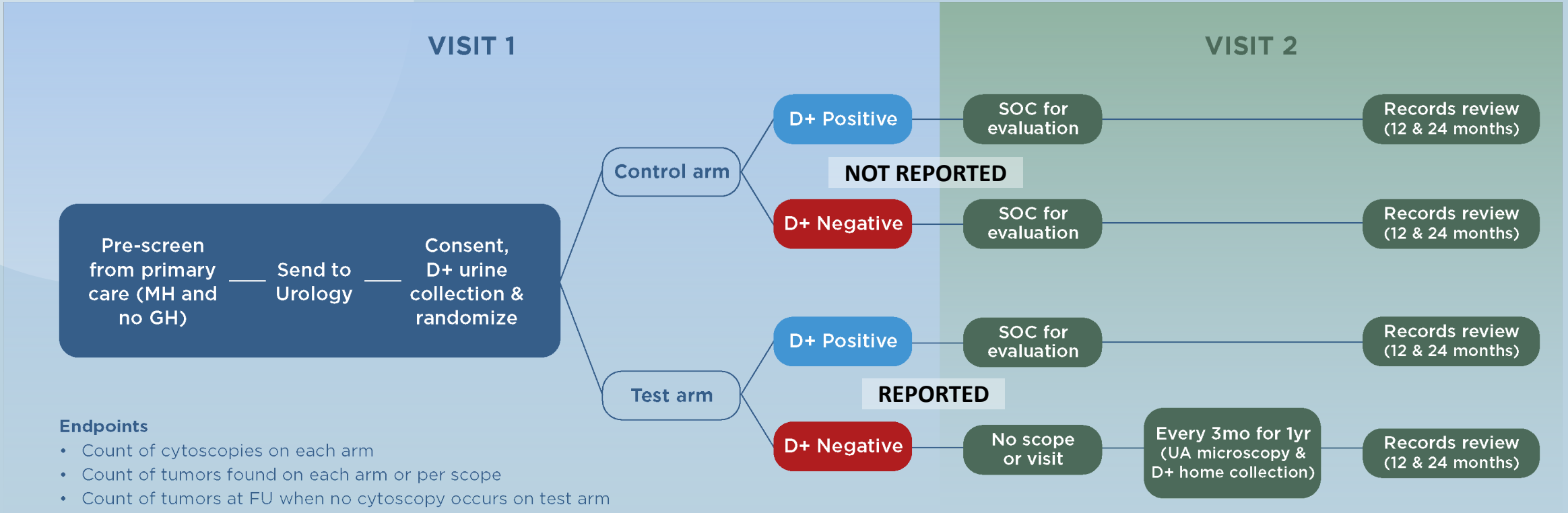
PROPOSED STUDIES FOR CLINICAL UTILITY OF DETECT+

EVIDENCE COVERAGE AND GUIDELINES



- **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+

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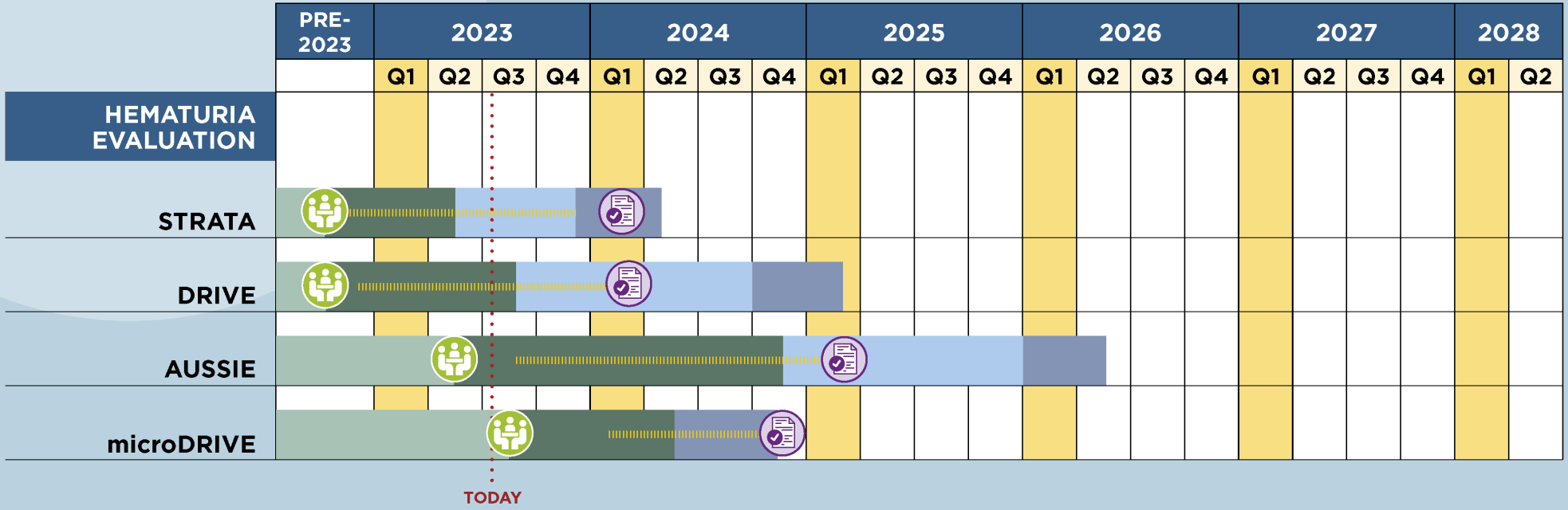
FIVE YEAR CXBLADDER CLINICAL STUDY ROAD MAP

EVIDENCE COVERAGE AND GUIDELINES



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

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

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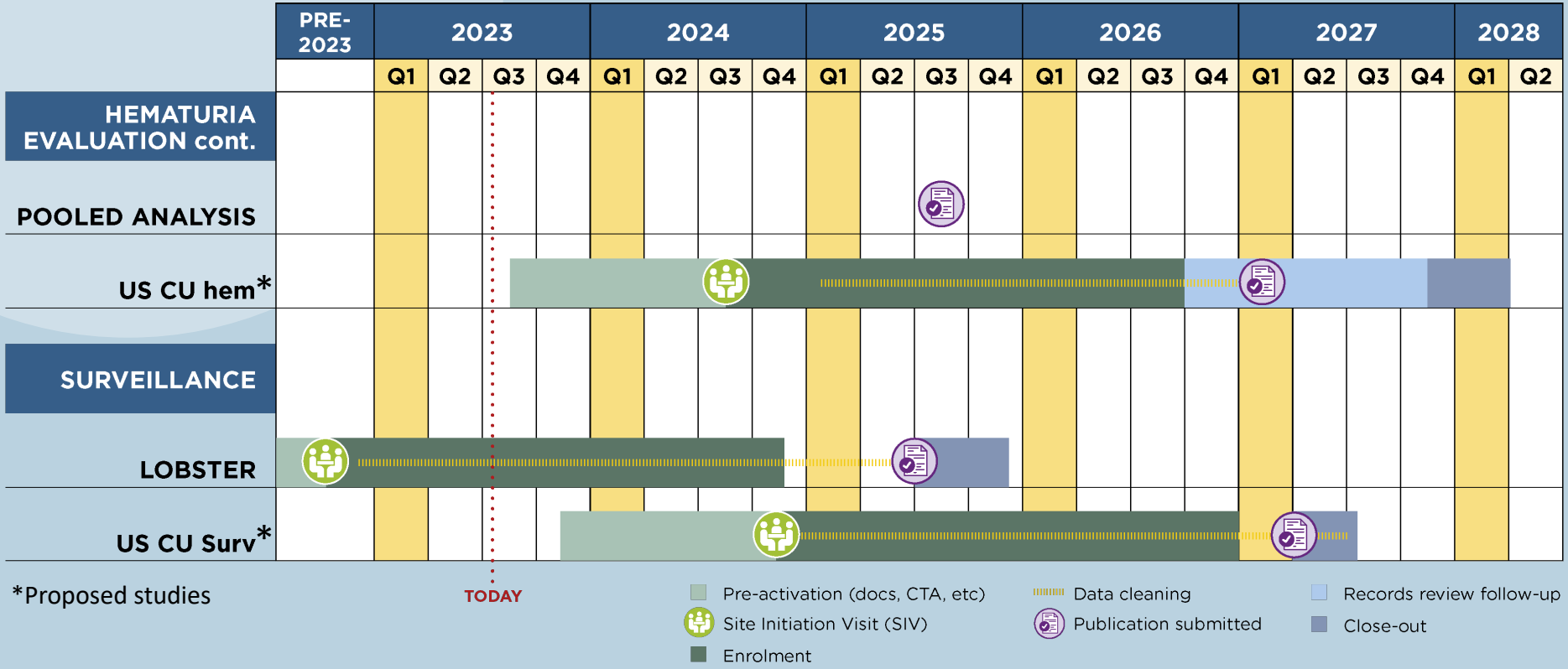
FIVE YEAR CXBLADDER CLINICAL STUDY ROAD MAP (continued)…

EVIDENCE COVERAGE AND GUIDELINES



*Proposed studies

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INCREASING COVERAGE INDICATIONS WITH DETECT+ AND MONITOR+

EVIDENCE COVERAGE AND GUIDELINES

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
Cxbladder DETECT+	**Ongoing studies** - DRIVE - AUSSIE - microDRIVE - Pooled analysis **Future studies** - RCT with pre-specified clinical pathway for the use of Detect+ in micro-hematuria population
Cxbladder MONITOR Cxbladder MONITOR+	**Completed studies** - 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 **Ongoing studies** - LOBSTER - RWE evidence supporting the utility of Cxbladder Monitor **Future studies** • RCT with pre-specified clinical pathway for the use of Monitor+ in surveillance population

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AMPLIFYING OUR EVIDENCE WITH UROLOGY OPINION LEADERS

EVIDENCE COVERAGE AND GUIDELINES

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

NCCN National Comprehensive Cancer Network®

European Association of Urology

VIDEO VIEWS
4102

PUBLISHED
12/2/22

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RESEARCH & INNOVATION – FOCUSED ON COMMERCIALISATION

RESEARCH & INNOVATION

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

FDA

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CHRIS GALLAHER
Chairman

SHAREHOLDER QUESTIONS

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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

2001
Pacific Edge established

2003
Listed on the NZX

2007
Commercial pivot to focus on urothelial cancer diagnostics

2008
Holyoake et al: Urine-based RNA detection of urothelial cancer. Clin Cancer Res

2010
Pacific Edge Diagnostics New Zealand (PEDNZ) established

2012
O'Sullivan et al: Cxbladder Detect performance validation. Journal of Urology

Dec 2012
Launch of Pacific Edge Diagnostics USA and Cxb Detect

Mar 2013
PEDUSA receives CLIA accreditation

May 2013
First commercial sale (Cxb Detect) for PEDNZ

Mar 2013
First commercial sale (Cxb Detect) for PEDUSA

Dec 2014
Launch of Cxbladder Triage

Mar 2015
Kavalieris et al: Cxb Triage performance validation. BMC Urology

Dec 2015
Launch of Cxbladder Monitor

Nov 2016
Clinical trials commence in Singapore

Feb 2018
Cxb Triage adopted into Canterbury Community Health Pathways with primary care referral

Aug 2019
Konety et al: Clinical Utility of Cxb Detect in adjudicating atypical cytology and equivocal cystoscopy. European Urology

Apr 2020
Patient in-home sampling initiated in the US

Jun 2020
Kaiser Permanente, approves commercial use of Cxbladder

Jul 2020
CMS confirms reimbursement of Cxbladder at $760/test

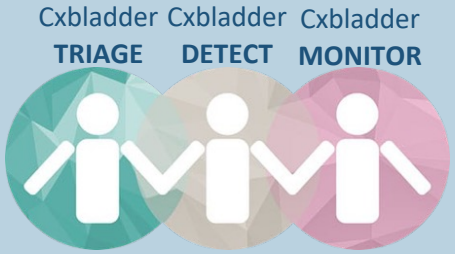
Aug 2021
Cxbladder reaches 70% public healthcare coverage in NZ

Oct 2021
PEB raises $103.5m (~US$72.5m)

Dec 2021
First commercial sale of Cxbladder in Australia

Dec 2022
Lotan et al: Enhanced Cxbladder Tests Deliver Improved Performance. Journal of Urology

2001 2007 2008 2011 2012 2013 2014 2015 2016 2018 2019 2020 2021 2022



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PACIFIC EDGE: OUR GLOBAL FOOTPRINT

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CLINICAL EVIDENCE GENERATION TOWARDS GUIDELINE INCLUSION (1/2)

STUDY	AIM	LOCATIONS	ENROLLED SITES*	STATUS**
STRATA	**S**afe **T**esting of **R**isk for **A**symptoma**TI**c Microhematuri**A** Demonstrate the clinical utility (CU) of Cxbladder using a prospective, two-arm randomized design to risk stratify patients and rule out from cystoscopy • 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	- 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	**D**etection and **RI**sk Stratification in **VE**terans Presenting with Hematuria 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 • 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	- Enrolment total is 601 - Target enrolment: ~600 patients - Last patient in: Q3 2023 - Follow up: until Q2 2025
AUSSIE	**A**ustralian **U**rologic risk **S**tratification of patient**S** w**I**th h**E**maturia 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 • 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	- 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	Pooled-analysis of Cxbladder Detect+ performance from multiple studies involving prospectively recruited patients from single-arm observational studies including eligible microhematuria patients • 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	**D**etection and **RI**sk Stratification in **VE**terans Presenting with **Micro**hematuria • 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	- Projected to start recruitment Sep/Oct 2023 - Target is 1000 patients and 50 tumour confirmed - Last patient in: March/April 2024
LOBSTER	**LO**ngitudinal **B**ladder Cancer **S**tudy for **T**umor R**E**cur**R**ence Prospective recruitment of patients to a single-arm observational study to evaluate CV of Cxbladder Monitor and Monitor+ • 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	- 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

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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 idnetified 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. The Journal of Urology, 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. NZ Med J, 132(1497), 55-64.
	Davidson et al., (2020). Assessment of a clinical pathway for investigation of haematuria that reduces the need for cystoscopy. The New Zealand Medical Journal (Online), 133(1527), 71-82.
	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. BMC urology, 15(1), 1-12.
	Konety et al., (2019). Evaluation of cxbladder and adjudication of atypical cytology and equivocal cystoscopy. European urology, 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. The Journal of Urology, 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. The Journal of Urology, 10-1097.
	O'Sullivan et al., (2012). A multigene urine test for the detection and stratification of bladder cancer in patients presenting with hematuria. The Journal of urology, 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. *The Journal of Urology*, *197*(6), 1419-1426.
	Konety et al., (2019). Evaluation of cxbladder and adjudication of atypical cytology and equivocal cystoscopy. European urology, 76(2), 238-243.
	Koya et al., (2020). An evaluation of the real world use and clinical utility of the Cxbladder Monitor assay in the follow-up of patients previously treated for bladder cancer. *BMC urology*, *20*(1), 1-9.
	Lotan et al., (2017). Clinical comparison of noninvasive urine tests for ruling out recurrent urothelial carcinoma. *Urologic Oncology: Seminars and Original Investigations*, 35 (8), 531-539.

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.

INDEPENDENT DIRECTORS

SARAH PARK
ANATOLE MASFEN
BRYAN WILLIAMS
ANNA STOVE
MARK GREEN
TONY BARCLAY

SENIOR LEADERSHIP TEAM

GRANT GIBSON
Chief Financial Officer
GLEN COSTIN
President Asia Pacific
ANDY MCINTOSH
Chief Digital Officer
DAVID LEVISON
President Pacific Edge USA
DARELL MORGAN
Chief Operating Officer
DR TAMER ABOUSHWAREB
Chief Medical Officer
DR JUSTIN HARVEY
Chief Technology Officer

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.

FOR MORE INFORMATION:

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Chief Financial Officer
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