



PacificEdge®
CANCER DIAGNOSTICS

INVESTOR CONFERENCE

Dr Peter Meintjes
Chief Executive Officer

PRESENTING TODAY



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Chief Executive Officer



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PACIFIC EDGE – THE FIRST MOVER AND LEADER IN BLADDER CANCER DIAGNOSTICS

	Pacific Edge is a world-leading cancer diagnostics company that develops and commercializes a suite of urine-based, non-invasive tests for bladder cancer
	The primary symptom of bladder cancer is hematuria (blood in the urine) which impacts ~7m patients per each year in the US driving a global market opportunity of US\$10.6 billion ¹
	Our proprietary Cxbladder tests are patented, non-invasive urine tests that have demonstrated analytical, clinical, and economic value to clinicians, hospitals, payers and patients.
	Cxbladder tests are supported by a robust portfolio of clinical evidence , and the AUA ² has recognized Cxbladder Triage with a ‘Grade A’ evidence rating – the only urine biomarker to achieve that rating
	Novitas, our Medicare contractor, issued positive coverage for Cxbladder Triage and Triage Plus in May 2026. We expect a final LCD ³ from Novitas by Jan 2027 ⁴
	Novitas issued favorable pricing of US\$1,328/test for Triage Plus . Pacific Edge is targeting long-term gross margins consistent with leading molecular diagnostic companies ⁵

1.

See slides 36-38 for assumptions

2.

AUA = American Urological Association,

3.

LCD = Local Coverage Determination.

4.

Novitas must publish the final LCD or retire the draft LCD within 365 days after publishing a draft LCD

5.

Requires testing volumes to scale and reimbursement coverage to broaden - Actual margins may differ

INTRODUCTION TO PACIFIC EDGE

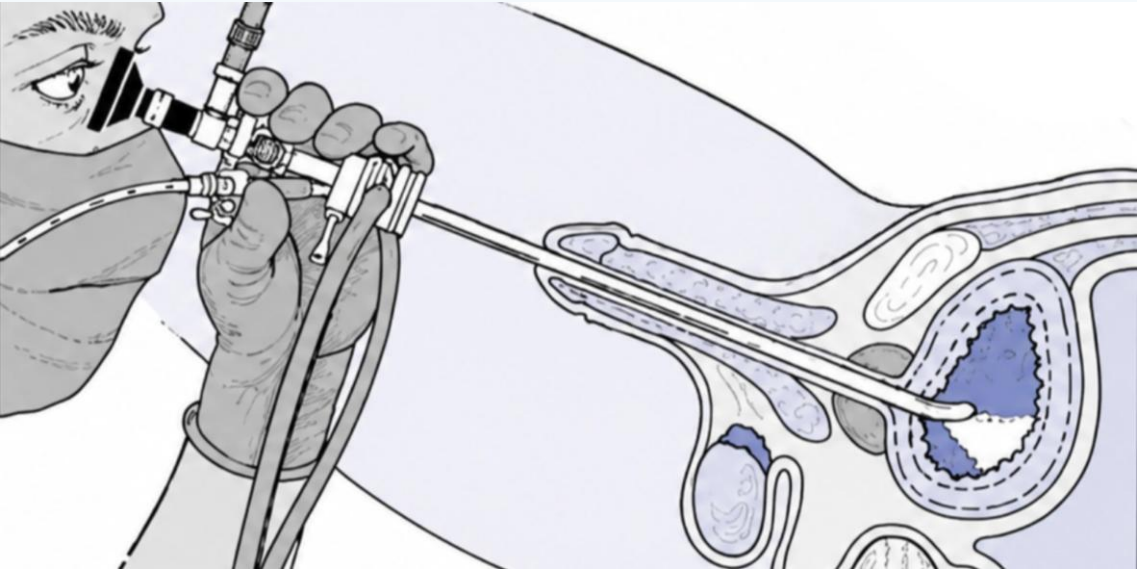


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CANCER DIAGNOSTICS

BLADDER CANCER – A SIGNIFICANT GLOBAL HEALTHCARE CHALLENGE

THE STANDARD OF CARE – CYSTOSCOPY – IS HIGHLY INVASIVE, UNCOMFORTABLE AND COSTLY

CYSTOSCOPY



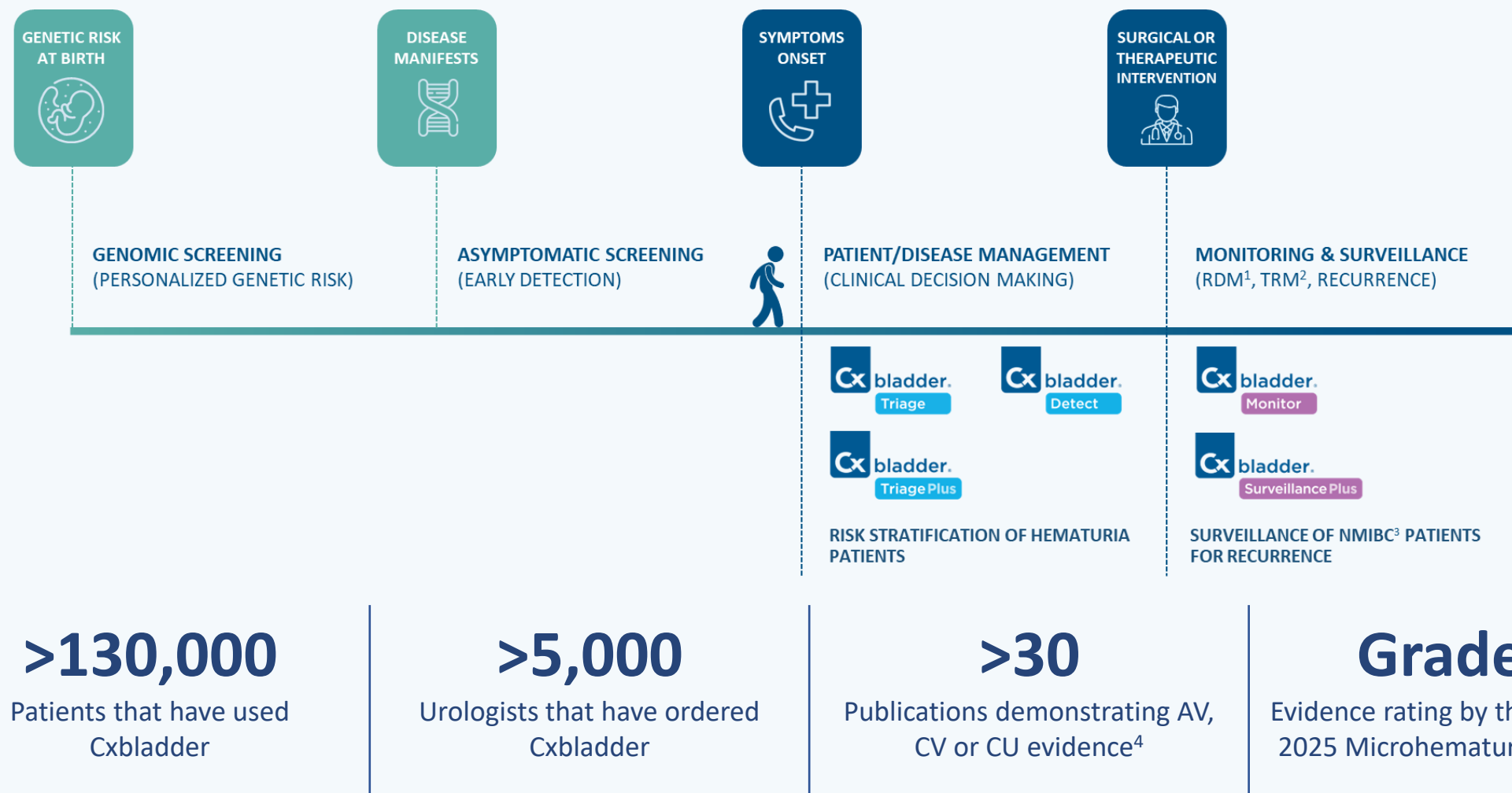
Cystoscopy is a procedure for men and women that inserts a camera on the end of a scope up the urethra for a visual inspection of the lining of the bladder wall for signs of bladder cancer and other diseases⁵

1 st	6 th	9 th
Costliest cancer to treat on a per-patient basis ¹	Most common cancer in men ²	Most common cancer world-wide ²
~614K	>220K	>50%
Cases per year and growing ²	Deaths per year ²	Recurrence ³
4.9m		
Annual cystoscopies avoided globally if Cxbladder tests were used to evaluate intermediate risk patients presenting with hematuria ⁴		

1. Sievert et al (2009) Economic aspects of bladder cancer: what are the benefits and costs? World J Urol. 2009 Mar 7;27(3):295–300. doi: 10.1007/s00345-009-0395-z
2. World Cancer Research Fund. Statistics are from 2022. Growth due to aging population.
3. Average recurrence for low grade non-muscle invasive bladder cancer as published in Palou J et al (2012); Eur Urol 2012; 62: 118.
4. Company estimate
5. Source: Nursing Skills

CXBLADDER: TESTS TO RULE OUT CANCER OR PRIORITIZE PATIENTS

THE PATIENT CARE PATHWAY: HEMATURIA EVALUATION AND CANCER RECURRENCE SURVEILLANCE



1. RDM: Residual Disease Monitoring
2. TRM: Therapeutic Response Monitoring
3. NMIBC: non-muscle invasive bladder cancer
4. AV, CV, CU are Analytical Validity, Clinical Validity, and Clinical Utility which are required for medical policy and guidelines
5. AUA: American Urological Association

THE CXBLADDER SUITE: TRIAGE AND TRIAGE PLUS FOR HEMATURIA EVALUATION

TESTS TO RULE OUT BLADDER CANCER AND IDENTIFY THOSE MOST NEEDING SPECIALIST CARE

HEMATURIA EVALUATION			
NEGATIVE RESULT	RULE OUT BLADDER CANCER The test combines a High Negative Predictive Value with High Sensitivity (it picks up most cancers)	✓	✓
POSITIVE RESULT	PRIORITIZE SPECIALIST CARE The test combines a High Positive Predictive Value with High Specificity (it delivers few false positives)		✓
PERFORMANCE		Kavalieris et al. (2015) ¹ • Sensitivity: 95% • Specificity: 45% • Negative Predictive Value: 99% • Positive Predictive Value: N/A	Harvey et al. (2025) ² • Sensitivity: 93.6%* • Specificity: 98.2%** • Negative Predictive Value: 99.4%* • Positive Predictive Value: 74.6%**
WHEN IT IS USED:		Prior to cystoscopy	Prior to cystoscopy / as an adjunct / 3 weeks post cystoscopy
COMMERCIALLY AVAILABLE		Globally available	Globally available
AUA GUIDELINE		Grade A Evidence	Assessment expected in 2027
MEDICARE		US\$760 (draft coverage)	US\$1,328 (draft coverage)

* When lower 0.15 cut point on test report is used

** When higher 0.54 cut point on test report is used

1. 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 Urol 2015;15:23.
2. Harvey et al. (2025) Analytical Validation of the Cxbladder® Triage Plus Assay for Risk Stratification of Hematuria Patients for Urothelial Carcinoma. Diagnostics. 2025; 15(14):1739. <https://doi.org/10.3390/diagnostics15141739>



THE CXBLADDER SUITE: MONITOR AND SURVEILLANCE PLUS

ALTERNATIVE TO CYSTOSCOPY FOR NMIBC¹ PATIENTS UNDERGOING SURVEILLANCE FOR RECURRENCE

NMIBC¹ CANCER SURVEILLANCE RECURRENCE



NEGATIVE RESULT	RULE OUT BLADDER CANCER RECURRENCE The test combines a High Negative Predictive Value with High Sensitivity (it picks up most cancers)	✓	In development, showing improved performance
PERFORMANCE		- Sensitivity: 93%^{2,3} - Specificity: N/A - Negative Predictive Value: 97%^{2,3} - Positive Predictive Value: N/A	- Sensitivity: not yet published - Specificity: not yet published - Negative Predictive Value: not yet published - Positive Predictive Value: not yet published
WHEN IT IS USED:		At any surveillance time point 9 months after the most recent cancer diagnosis	At any surveillance time point after the first surveillance cystoscopy (6 weeks)
COMMERCIALLY AVAILABLE		Globally available	- USA: CPT-PLA code targeted for Jun 2027, reimbursement from Jan 2028 - APAC: Soft launch from Q2 FY28
GUIDELINES		NCCN ⁴ 2b	Not yet available for assessment
MEDICARE		US\$760 (non-covered)	Seeking US\$1,800⁵ (not yet covered)

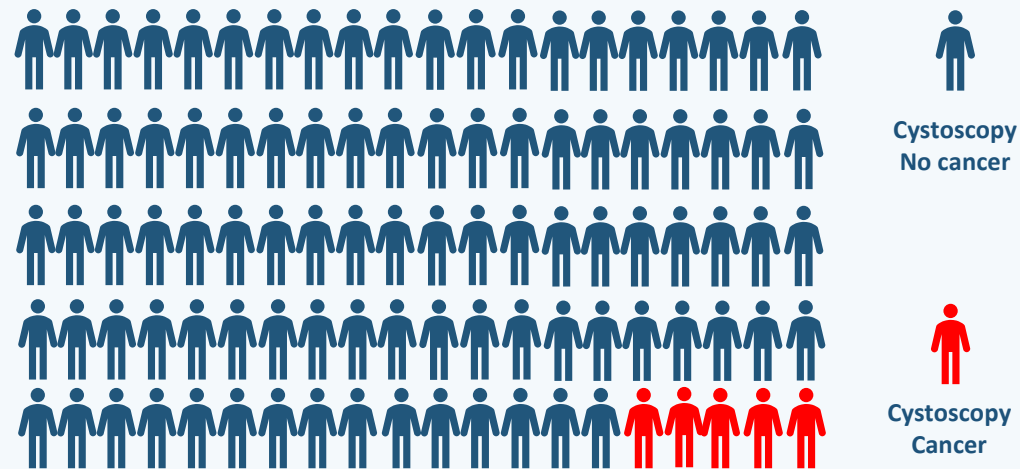
1. NMIBC: non-muscle invasive bladder cancer
2. Kavalieris et al. (2017) Performance Characteristics of a Multigene Urine Biomarker Test for Monitoring for Recurrent Urothelial Carcinoma in a Multicenter Study. J Urol 2017;197:6,1419-1426.
3. Lotan et al. (2017) Clinical comparison of noninvasive urine tests for ruling out recurrent urothelial carcinoma. Urologic Oncology: Seminars and Original Investigations. Elsevier; 2017; 1–8.
4. NCCN: National Comprehensive Cancer Network
5. Seeking pricing by way of crosswalk



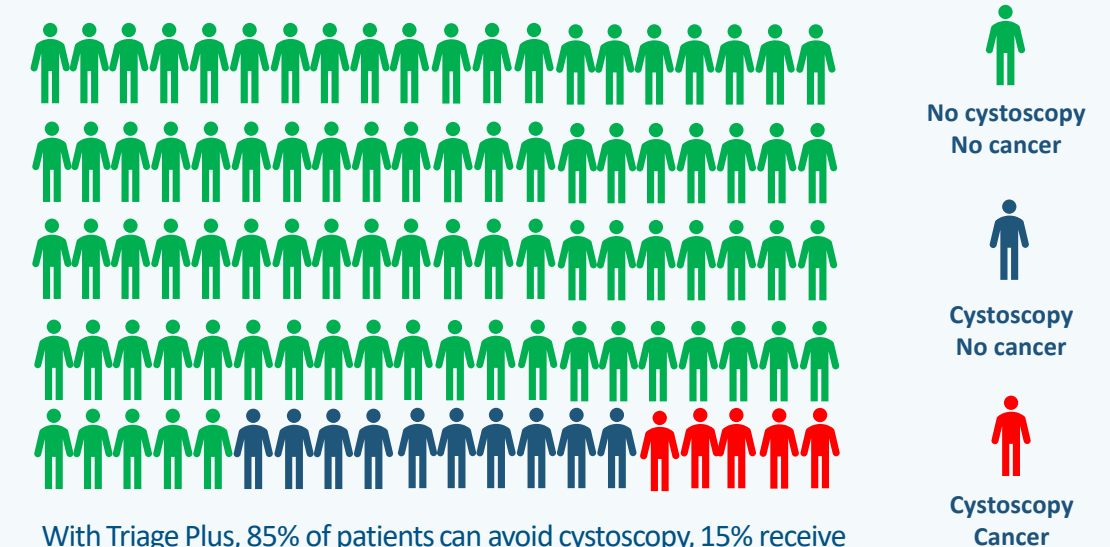
DRIVING ECONOMIC VALUE FOR PATIENTS, HOSPITALS AND PAYERS

CXBLADDER DELIVERS CLINICAL UTILITY, PATIENT SATISFACTION, IMPROVED ACCESS AND ECONOMIC VALUE

CANCER INCIDENCE IN MICROHEMATURIA PATIENTS



CYSTOSCOPIES SAFELY AVOIDED USING CXBLADDER



- Cxbladder avoids invasive, unnecessary procedures saving >US\$500/patient²
- Only 63% of counties in the US have a registered urologist³
- Only 13% of high-risk microhematuria patients receiving a cystoscopy⁴
- The number urologists per person over 65 is falling⁵ potentially delaying diagnosis
- Medicare reimbursement is declining⁶

1. AUA Guidelines cite incidence of bladder cancer in microhematuria risk categories from 0.4-6%. 5% is an example

2. Tyson et al (2024) Budgetary Impact of Including the Urinary Genomic Marker Cxbladder Detect in the Evaluation of Microhematuria Patients - PubMed (PMID: 37914255)

3. <https://www.auanet.org/research-and-data/aua-census/census-results>

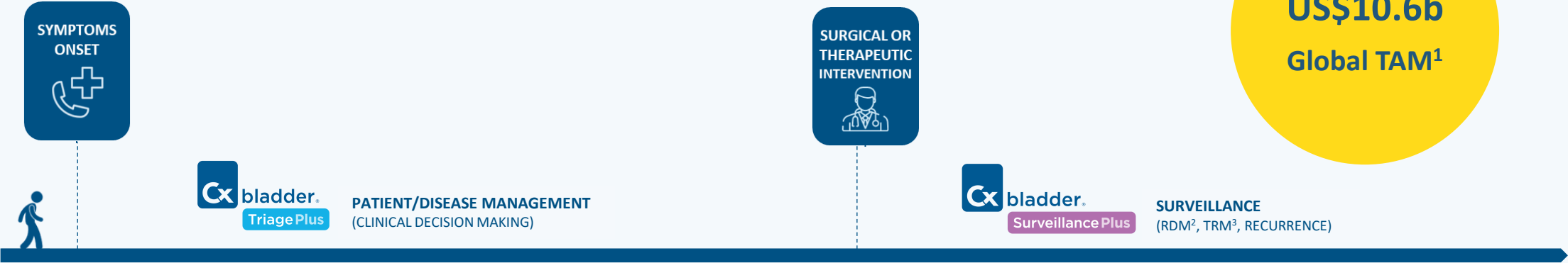
4. <https://acsjournals.onlinelibrary.wiley.com/doi/full/10.1002/cncr.25048>

5. Nam et al. (2021) Projected US Urology Workforce per Capita, 2020-2060 JAMA Network Open Published Online: November 16, 2021

6. <https://www.cms.gov/medicare/physician-fee-schedule/search>

CXBLADDER MARKET OPPORTUNITY

CXBLADDER OFFERS A SIGNIFICANT ADDRESSABLE GLOBAL MARKET ANNUALLY

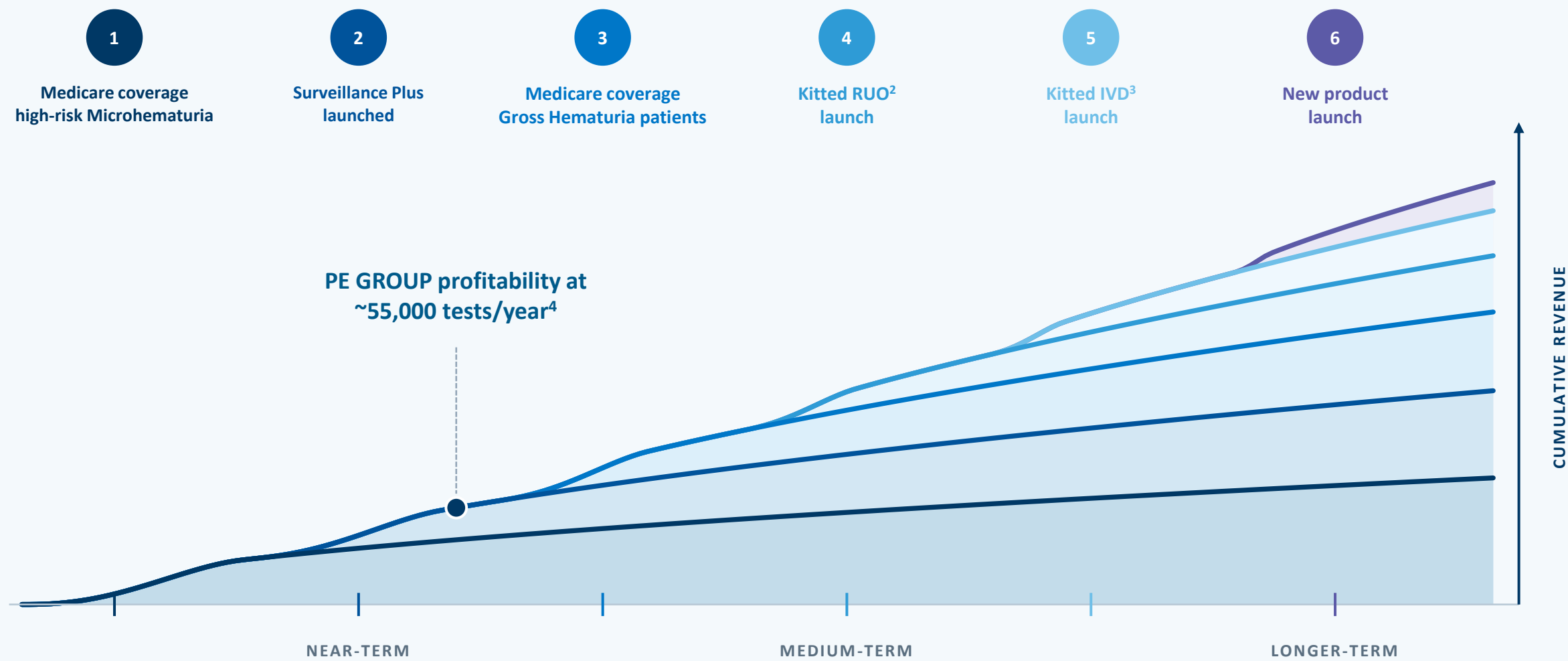


	Population	All hematuria	Microhematuria ⁴ Low Intermediate High	Gross ⁴ Hematuria	Annual cases of bladder cancer	Living with bladder cancer	TAM	
	340m	~7m	0.20m 1.14m 1.46m	0.7m	~90k	~750k	US\$6.7b	Primary growth focus due to higher CMS pricing
	830m	~17m	0.47m 2.71m 3.46m	1.7m	~58k	~300k	US\$2.0b	NZ market mature. Australia and SEA in business development
	600m	~12m	0.34m 1.96m 2.5m	1.7m	~180k	~1m	US\$1.9b	New market accessed via IVD / kitted tests

1. Pacific Edge estimate combining US, APAC and Europe. See slides 36-38 for details.
2. RDM: Residual Disease Monitoring
3. TRM: Therapeutic Response Monitoring
4. Management estimates derived from referred hematuria data in Woldu et al (2021), so do not add to ~7m figure for total incidence. See slides 36-38 for details.

PACIFIC EDGE CATALYSTS FOR LONG-TERM SUSTAINABLE GROWTH¹

AN EXPANDING SERVICEABLE MARKET AND REVENUE



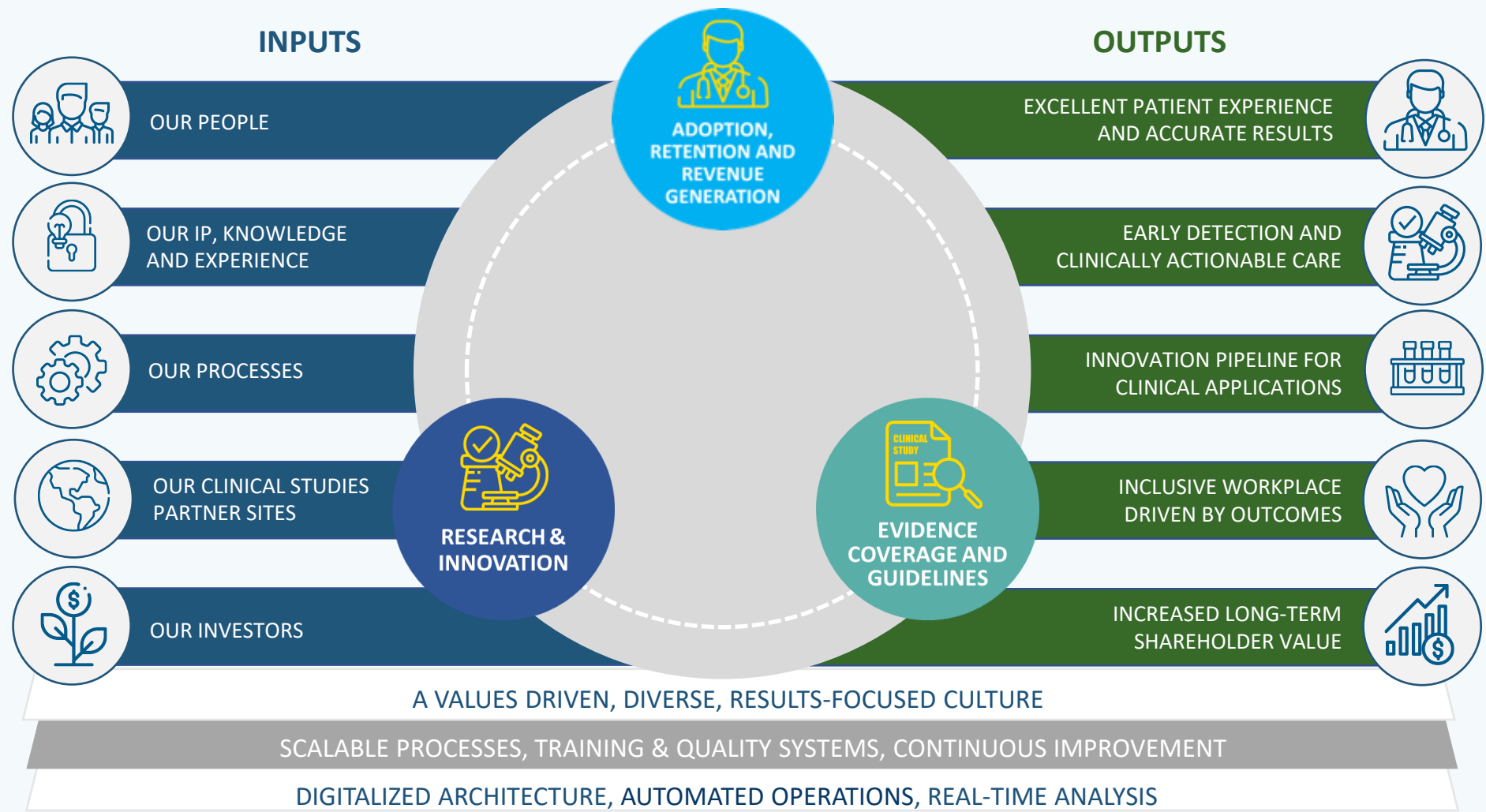
1. Illustrative only. The curves indicate the sequence and relative scale of expected market expansion, not forecast revenue
2. RUO is for “research use only” and limits the clinical claims that can be made and the payment options
3. IVD is an in vitro diagnostic and subject to country-specific product registrations, regulations and reimbursement processes
4. Profitability threshold determined on an annualized basis across all products with a blended ASP >\$NZD 1,450

STRATEGY AND PROGRESS



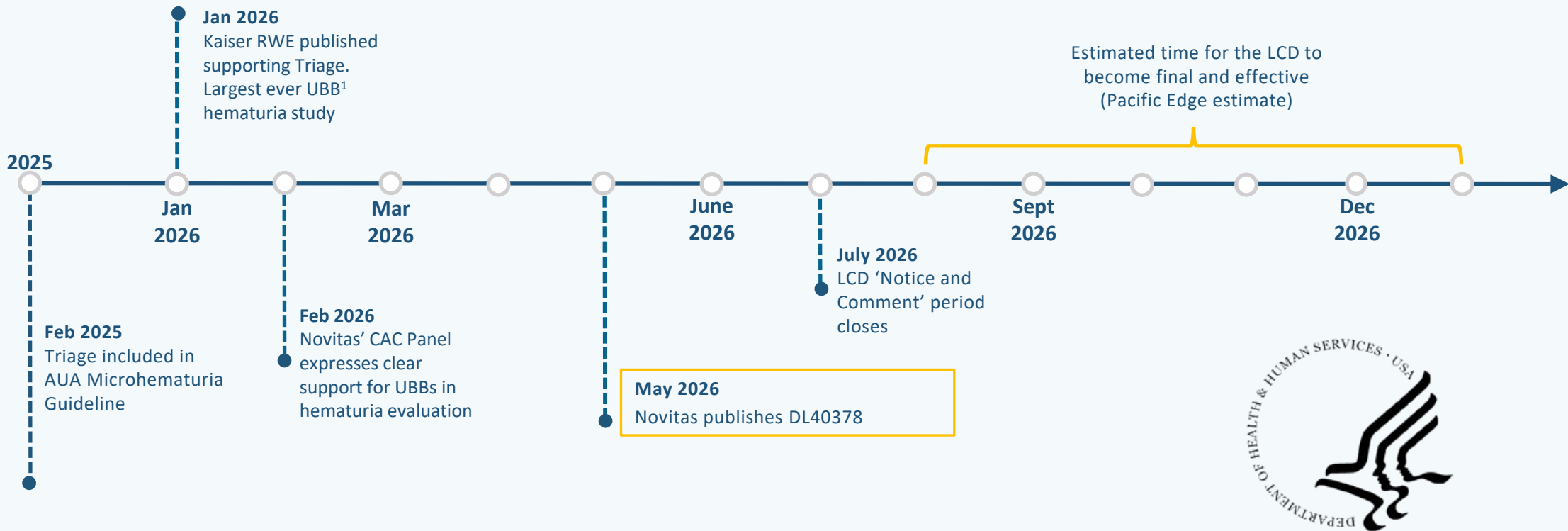
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VALUE CREATION THROUGH THREE PILLARS



TRIAGE AND TRIAGE PLUS – THE ONLY TESTS COVERED UNDER THE DRAFT LCD

MEDICARE COVERS ~71M PEOPLE - THE LARGEST SINGLE REIMBURSEMENT DECISION GLOBALLY



“Use of validated multi-analyte UBBs may be reasonable and necessary to support risk-stratification in appropriately counseled, intermediate-risk patients with MH who are considering deferral of cystoscopy.”

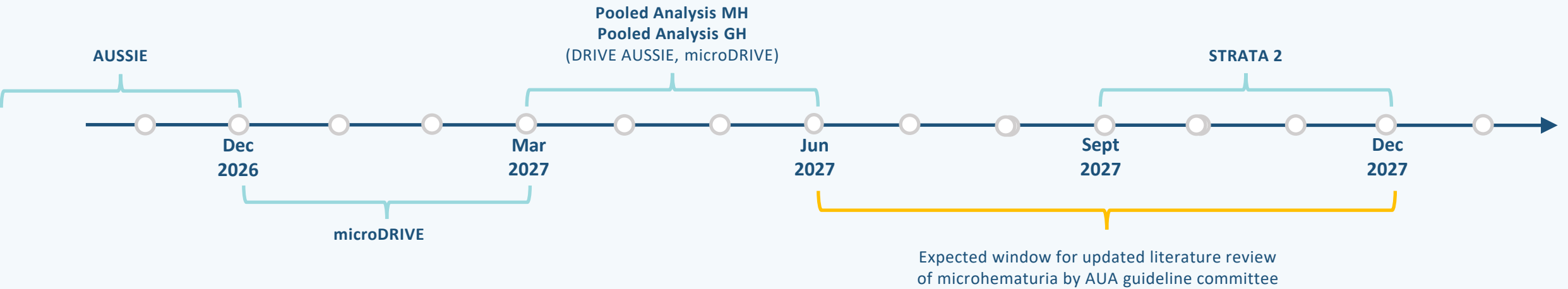
DRAFT LCD: ‘Urine-based Biomarkers in Patients with Microhematuria’ (DL40378)

Medicare

1. UBB is urine-based biomarker

EXPANDING COVERED INDICATIONS WITH OUR CLINICAL EVIDENCE PROGRAM

VALIDATION STUDIES SEEKING TO REDEFINE AUA RISK THRESHOLDS



Key Supporting Studies

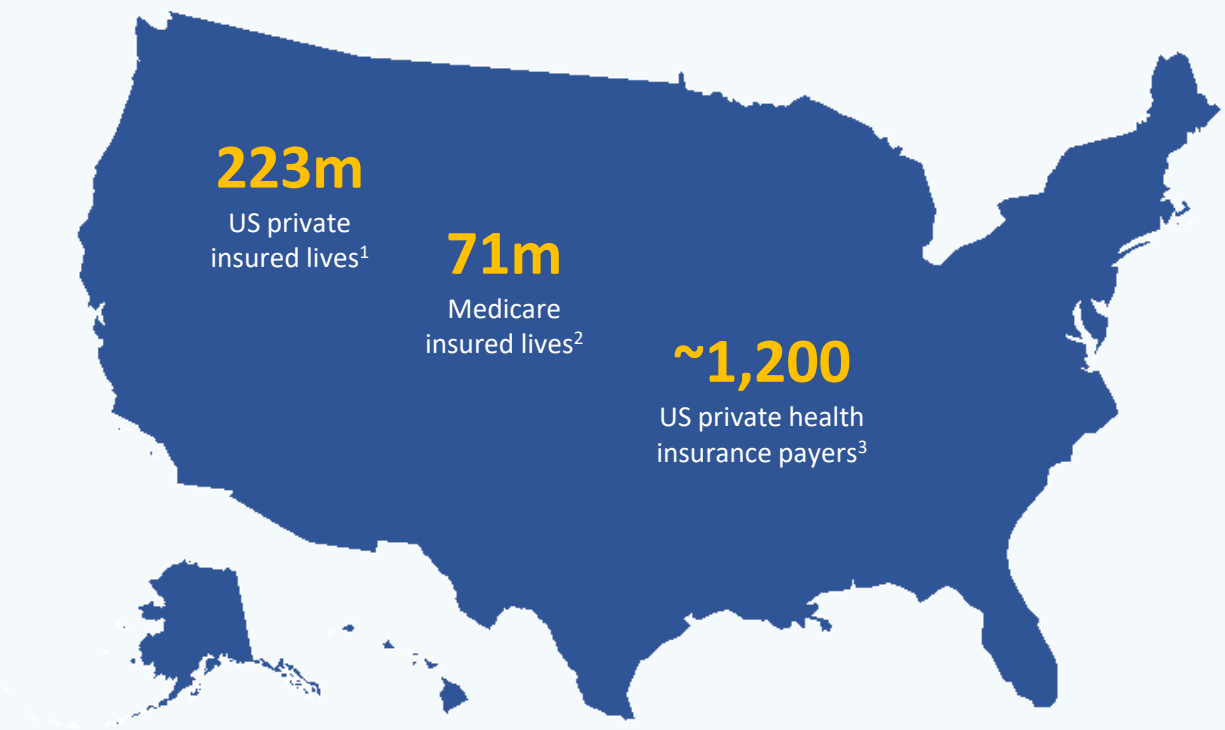
STRATA second publication	- CU of Triage
AUSSIE Clinical Validation	- CV of Triage Plus
microDRIVE Clinical Validation	- CV of Triage Plus
Pooled Analysis MH Clinical Validation ²	- CV of Triage Plus
Pooled Analysis GH Clinical Validation ²	- CV of Triage Plus



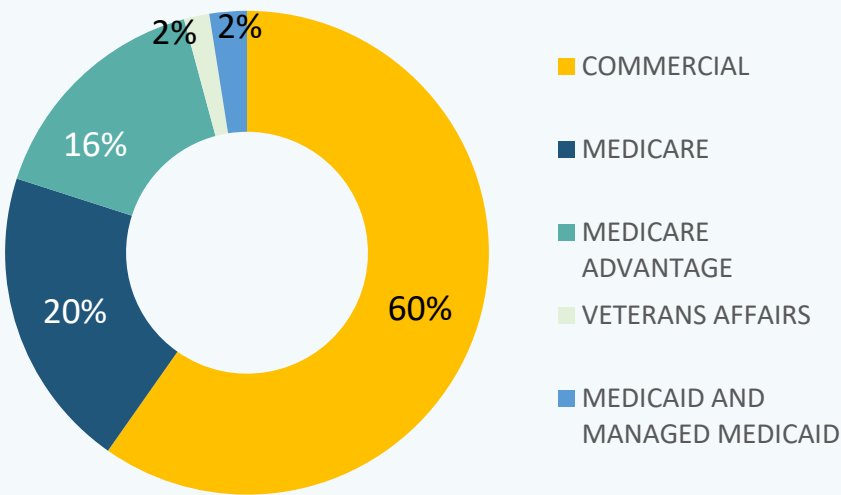
American
Urological
Association

US COMMERCIAL PAYERS: MEDICARE COVERAGE EXPECTED TO UNLOCK VOLUMES

LEVERAGING COVERAGE TO DIVERSIFY CUSTOMER BASE TO PRIVATE INSURERS



PACIFIC EDGE PAYER MIX (2H 26)



1. <https://www.census.gov/library/publications/2025/demo/p60-288.html>
2. <https://data.cms.gov/summary-statistics-on-beneficiary-enrollment/medicare-and-medicare-reports/medicare-monthly-enrollment>
3. <https://content.naic.org/sites/default/files/2024-annual-health-industry-commentary.pdf>

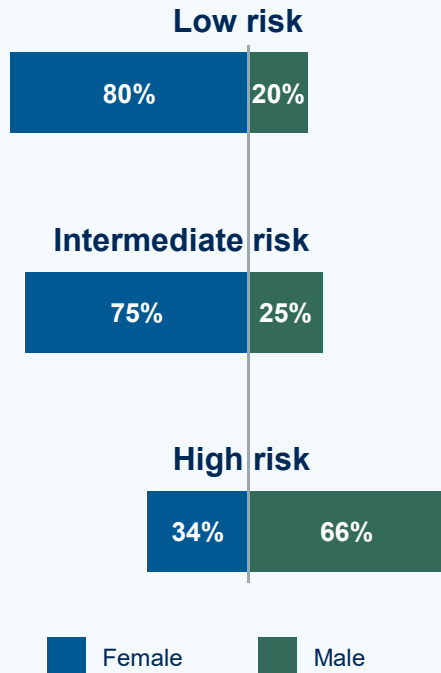
US COMMERCIAL STRATEGY WITH DRAFT MEDICARE COVERAGE

INTEGRATED DELIVERY NETWORKS ARE THE TOP TARGET FOR INTERMEDIATE RISK MICROHEMATURIA



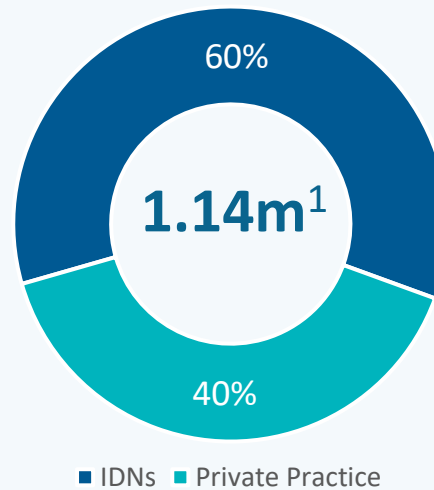
AUA RISK CATEGORY BY SEX (AT BIRTH)

(PERCENTAGE OF PATIENTS)¹



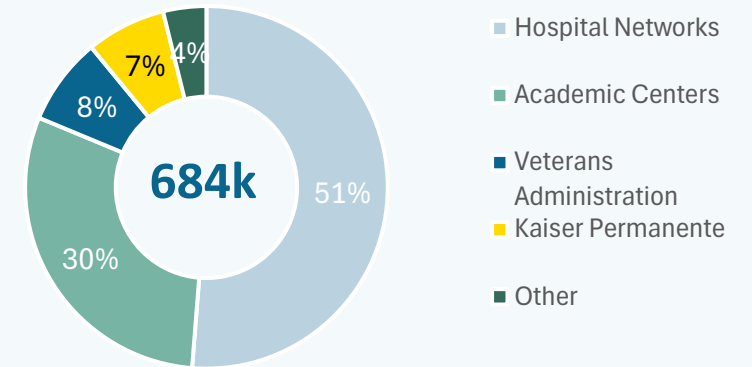
HEALTHCARE PROVIDER TYPE

(SHARE OF PATIENT VOLUME)²



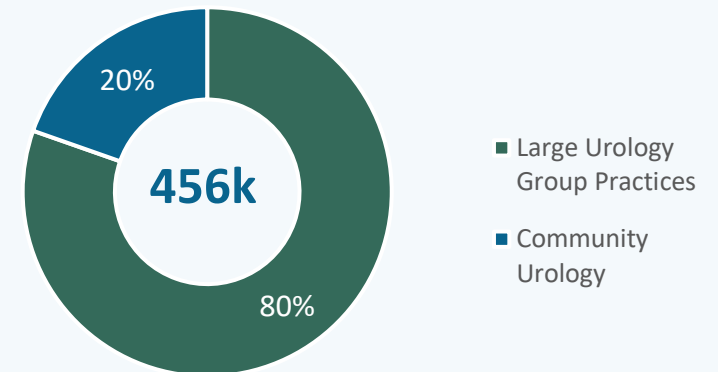
INTEGRATED DELIVERY NETWORKS

(SHARE OF PATIENT VOLUME)²



PRIVATE PRACTICE

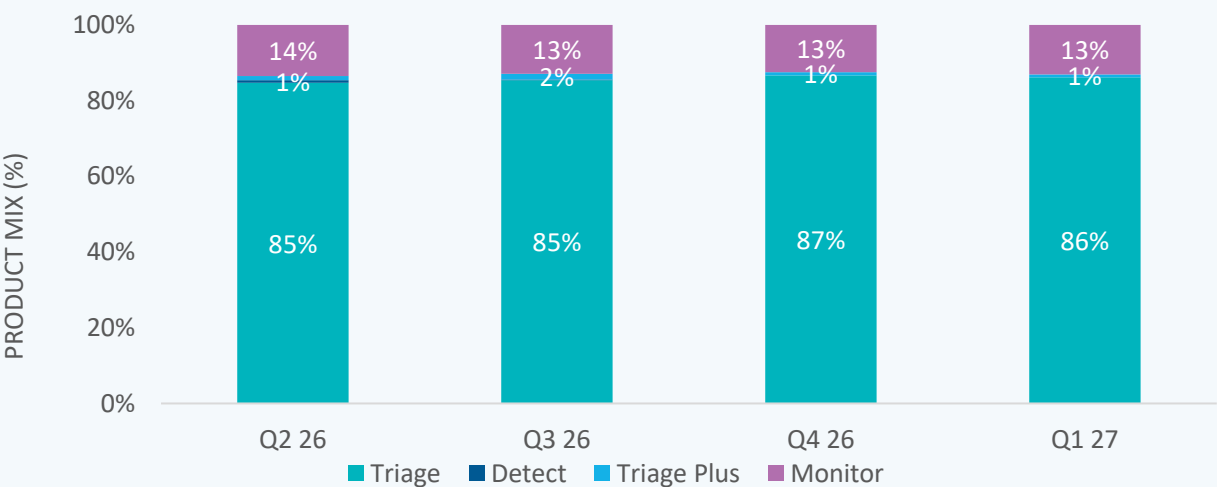
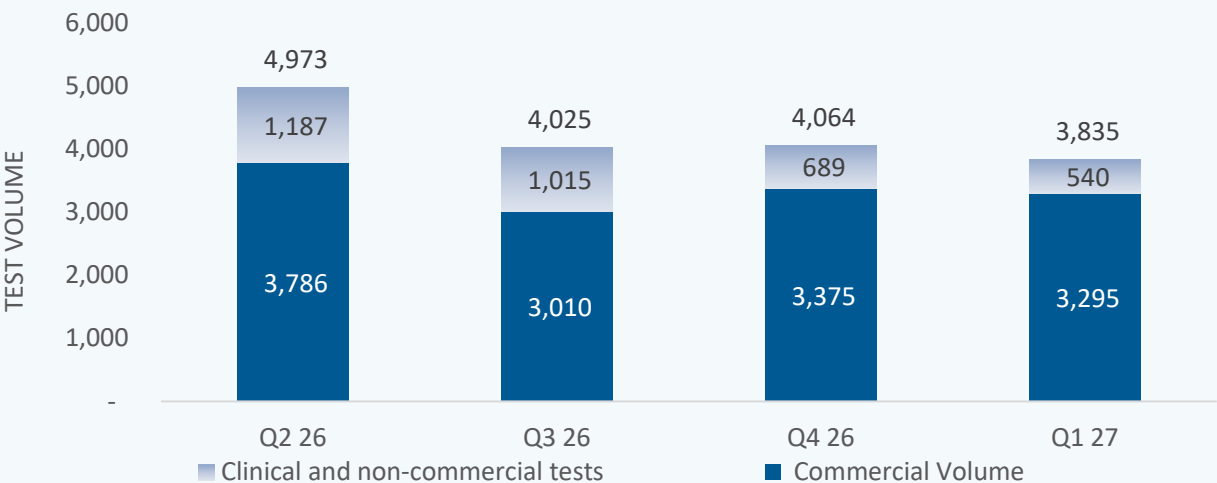
(SHARE OF PATIENT VOLUME)³



COMMERCIAL TESTS STABILIZED; SET TO RISE WITH FINAL COVERAGE



US TOTAL TEST VOLUME¹ AND COMMERCIAL PRODUCT MIX



COMMERCIAL AND TOTAL THROUGHPUT STABILIZED

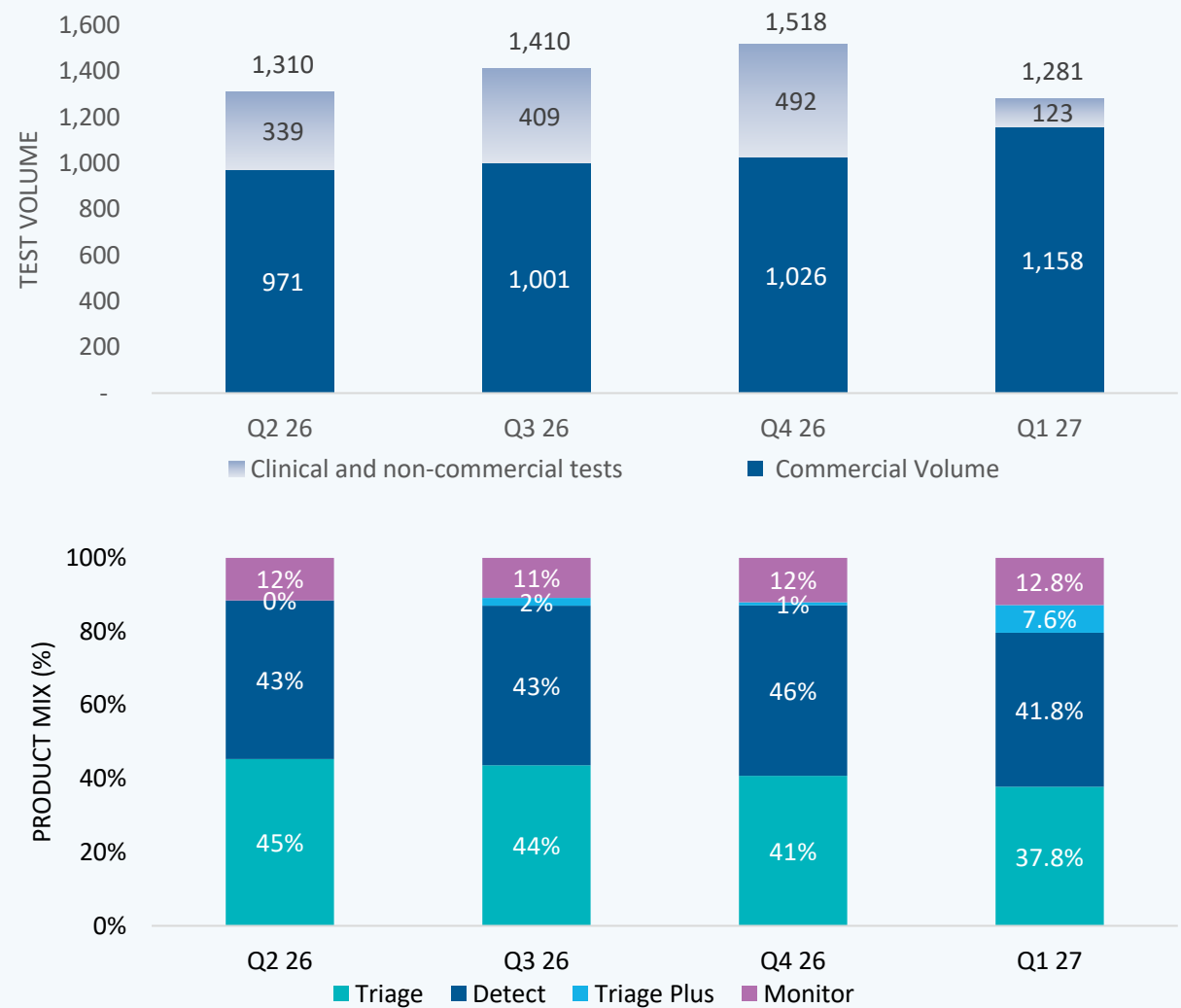
- Commercial and total throughput stable over last three quarters
- Sales efficiency improved as sales FTE lowered to address cash burn
- Seeking to shift commercial product mix towards Triage Plus (US\$1,328) on every eligible patient

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

APAC CHARTING A PATH TO PROFITABILITY



APAC TOTAL TEST VOLUME¹ AND COMMERCIAL PRODUCT MIX



TRIAGE PLUS DRIVING IMPROVED UNIT ECONOMICS

- Commercial testing volumes growing for four consecutive quarters
- Triage Plus volumes growing; potential for ~20% more revenue per test
- APAC contributed 19% of operating revenue in 2H 26 with \$2.0m in FY26; cash burn rate² of \$0.17m in Q1 FY27
- Repricing in 2025 created on average 25% more revenue per test

1. Total Laboratory Throughput in Asia and Pacific including commercial, pre-commercial and clinical studies testing
2. APAC Commercial and Clinical Operations cash burn figure is calculated on a direct cost basis and excludes R&D costs

NEXT GENERATION PRODUCTS ALREADY DELIVERING STRATEGIC VALUE

TRIAGE PLUS AND SURVEILLANCE PLUS OFFER SUPERIOR PERFORMANCE, PRICING AND MARGIN



ADVANCING IVD DEVELOPMENT FOR INTERNATIONAL MARKETS

- Triage Plus and Surveillance Plus will be offered as CAP/CLIA-approved LDTs¹ providing service to the entire USA
- International markets require a different approach in which Pacific Edge seeks to create a 'kitted' IVD medical device
- Pacific Edge is simplifying its tests to create Triage Plus IVD for decentralized lab deployment and international market expansion.
- Key objectives:
 - Establishing IVD regulatory framework for our next generation tests that includes IVD-R (Europe), FDA (USA) and ISO-13485² (International)
 - Prototype development plans are in place and ready to be implemented subject to budget approval

FY 26 FINANCIAL PERFORMANCE: POSITIONING FOR MEDICARE RE-COVERAGE

COST SAVINGS MINIMIZE CASH BURN; \$36.1 MILLION CAPITAL RAISE IN MAY 2026 STRENGTHENS BALANCE SHEET

Financial Period (NZ\$M)	1H 26 (Unaudited)	2H 26 (Unaudited)	FY 26 (Audited)	FY 25 (Audited)	2H 26 vs 1H 26	FY 26 vs FY 25
Operating Revenue	\$5.9	\$5.6	\$11.5	\$21.8	(6.4%)	(47.4%)
Total Revenue	\$7.1	\$6.5	\$13.6	\$24.6	(9.3%)	(44.8%)
Operating Expenses	\$26.2	\$23.1	\$49.4	\$54.6	(11.9%)	(9.5%)
Net Loss After Tax	(\$19.1)	(\$16.7)	(\$35.8)	(\$30.0)	(12.8%)	19.5%
Cash Receipts from Customers	\$8.0	\$5.2	\$13.2	\$21.6	(34.3%)	(38.7%)
Net Cash Flows to Operating Activities	(\$19.0)	(\$12.9)	(\$31.9)	(\$24.7)	(32.1%)	29.1%
Net Cash¹	\$22.1	\$7.8	\$7.8	\$22.6	(64.8%)	(65.5%)
Monthly Cash Burn	\$3.3	\$2.4	\$2.9	\$2.3	(27.7%)	23.4%

OUTLOOK

POSITIONED TO UNLOCK VALUE THROUGH UPCOMING COMMERCIAL, CLINICAL AND INNOVATION MILESTONES

NEAR-TERM VALUE CREATION COMMERCIAL CATALYSTS

- Case-by-case reimbursement expected for Triage and Triage Plus under draft LCD
- Final LCD published by end of 2026
- US customers adopt Triage Plus at US\$1,328/test
- Building US Commercial payer medical policy momentum

MEDIUM-TERM VALUE CREATION CLINICAL EVIDENCE GENERATION

- Evidence generation program delivers sustained strategic value
- US commercial payer policy for Triage and Triage Plus drives test adoption
- AUA guideline review (2027/28) expected to expand serviceable market
- Investigator initiated trials (IITs) generate novel evidence for new indications

LONG-TERM VALUE CREATION RESEARCH INNOVATION

- Triage Plus and Surveillance Plus deliver better patient outcomes at higher margin pricing for improved unit economics
- Surveillance Plus CPT-PLA coding submission in June 2027 and claim-by-claim revenue after 1 Jan 2028
- US\$1,800 CMS pricing for Surveillance Plus in FY28
- Product simplification and kitted IVD products enable de-centralized deployment in international markets

APPENDIX



PacificEdge®
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PACIFIC EDGE IS FOUNDED ON DELIVERING POSITIVE OUTCOMES FOR SOCIETY

WE CREATE VALUE BY PRIORITISING OUR PATIENTS, OUR PHYSICIANS AND OUR PEOPLE

Our Mission

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

Our Vision

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

WE PUT PATIENTS FIRST IN EVERYTHING WE DO

- **WE are committed to customer success**
- **WE are guided by data and evidence**
- **WE are trusting and transparent**
- **WE support our teammates**
- **WE celebrate successes, large and small**



PACIFIC EDGE – THE FIRST MOVER AND LEADER IN BLADDER CANCER DIAGNOSTICS

A GLOBAL COMPANY WITH A GLOBAL OPPORTUNITY

US\$10.6b¹

Global Market Opportunity



1. See slides 44-46 for assumptions

TIMELINE: COMPANY MILESTONES



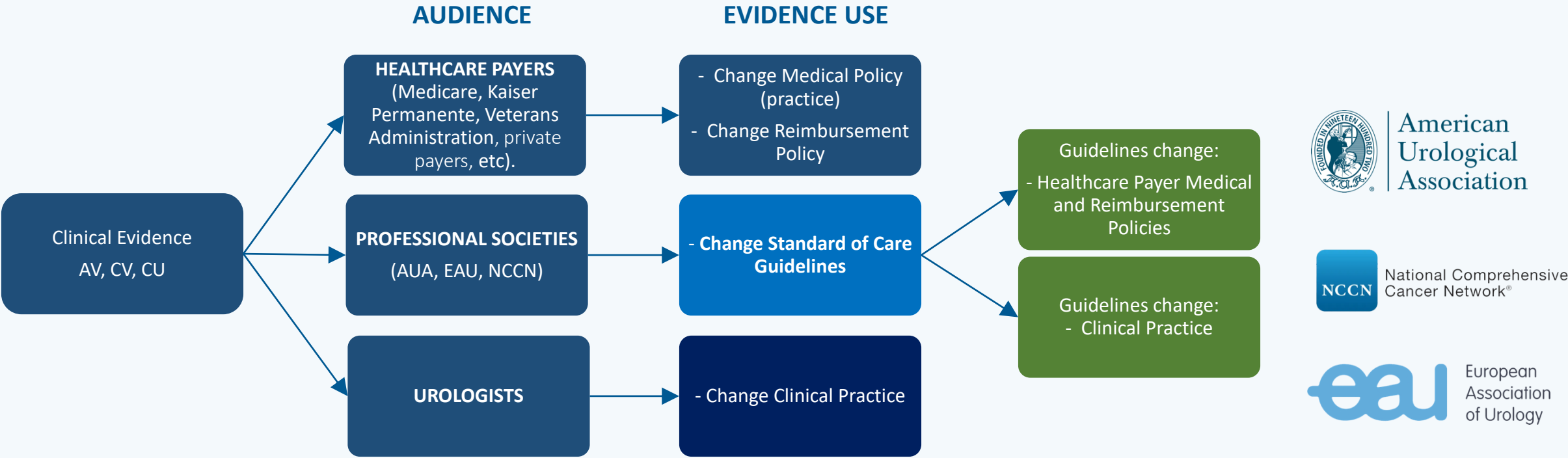
1. UBBs are urine-based biomarkers – a term adopted by AUA in their guidelines

FINANCIAL PERFORMANCE OPERATING EXPENSES

ALL COSTS REDUCED WITH LARGEST REDUCTION IN SALES AND MARKETING

Financial Period (NZ\$M)	1H 26 (Unaudited)	2H 26 (Unaudited)	FY 26 (Audited)	FY 25 (Audited)	2H 26 vs 1H 26	FY 26 vs FY 25
Laboratory Operations	\$5.9	\$5.7	\$11.6	\$12.5	(2.8%)	(7.1%)
Research	\$7.1	\$6.4	\$13.4	\$14.6	(9.9%)	(8.2%)
Sales and Marketing	\$8.5	\$6.8	\$15.2	\$17.5	(20.0%)	(13.2%)
General Administration	\$4.8	\$4.3	\$9.1	\$9.9	(11.8%)	(8.1%)
Total operating expenses	\$26.2	\$23.1	\$49.4	\$54.6	(11.9%)	(9.5%)

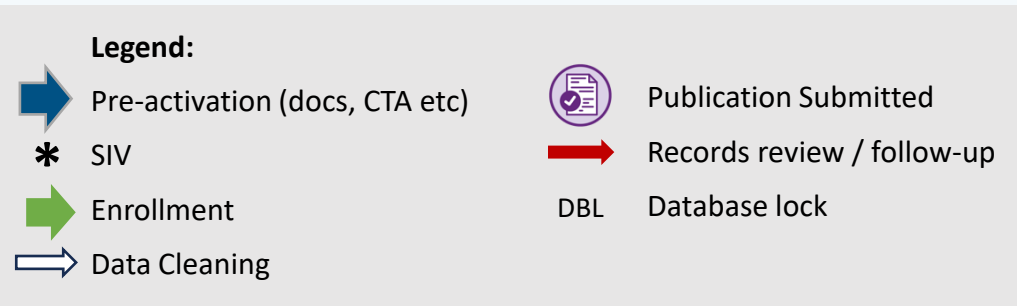
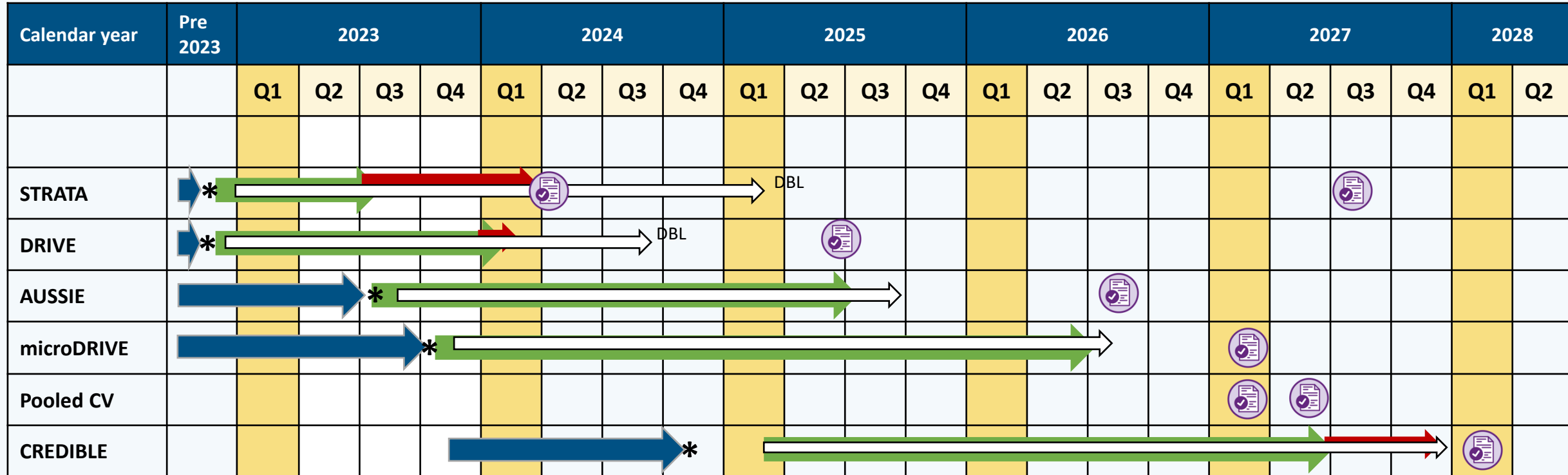
PACIFIC EDGE'S EVIDENCE PROGRAM SEEKS TO CHANGE CLINICAL PRACTICE



EVIDENCE DEVELOPED IN A STRUCTURED FRAMEWORK:

- **Analytical Validity (AV):** Evidence that a test is repeatable in the lab for a given indication and population
- **Clinical Validity (CV):** Evidence a test works in the same way on an independent eligible population for a given indication
- **Clinical Utility (CU):** Evidence that a test changes clinical practice in the hands of a physician; CU evidence obtained through randomized control trials is required to change standard of care guidelines (in addition to AV and CV evidence)
- **Real World Evidence (RWE):** CU verification of the real-world use of the test in clinical practice, usually through regular use of the test by physicians

HEMATURIA EVALUATION FIVE-YEAR CLINICAL STUDIES ROADMAP



SURVEILLANCE FIVE-YEAR CLINICAL STUDIES ROADMAP

Calendar year	Pre 2023	2023				2024				2025				2026				2027				2028	
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2
"The 1800" ¹																							
LOBSTER	➡*	➡												➡								📄	
OCTOPUS													CAB ²										

Legend:

➡

Business case approved

*

SIV

➡

Enrollment

➡

Data Cleaning

📄

Publication Submitted

➡

Records review / follow-up

DBL

Database lock

➡

Scheduled surveillance visits

1.

"The 1800" is the Surveillance Plus development dataset

2.

CAB is the Pacific Edge Clinical Advisory Board. It was convened at SUO in Arizona to review and confirm the clinical study trial design for OCTOPUS

DRIVING CLINICAL VALUE FOR PHYSICIANS, HOSPITALS AND PAYERS

COMPELLING CLINICAL EVIDENCE CHANGES CLINICAL PRACTICE, MEDICAL POLICY AND GUIDELINES

STUDY	TEST AND EVIDENCE	PUBLICATION DATE ⁽¹⁾
1. STRATA Clinical Utility	- CU of Triage	Published May 2024
2. Automated RNA & DNA extraction	- AV of Triage, Detect and Monitor	Published September 2024
3. Triage Plus Analytical Validation	- AV of Triage Plus	Published July 2025
4. DRIVE Clinical Validation	- CV of Triage Plus	Published October 2025
5. STRATA second publication	- CU of Triage	Q3 2027
6. AUSSIE Clinical Validation	- CV of Triage Plus	Q3 2026 (+1Q)
7. microDRIVE Clinical Validation	- CV of Triage Plus	Q1 2027 (+1Q)
8. Surveillance Plus Analytical Validation	- AV of Surveillance Plus	Q2 2027 (+3Q)
9. Pooled Analysis MH Clinical Validation ²	- CV of Triage Plus	Q2 2027 (+1Q)
10. Pooled Analysis GH Clinical Validation ²	- CV of Triage Plus	Q2 2027 (+1Q)
11. LOBSTER Clinical Validation	- CV of Monitor/Surveillance Plus	Q3 2027 (+3Q)
12. CREDIBLE Clinical Utility	- CU of Triage Plus	Q1 2028 (at risk)
13. OCTOPUS Clinical Utility	- CU Surveillance Plus	No timeline at this point

¹ All dates are calendar year and our best current estimates

² The MH and GH pooled analysis brings together data from DRIVE, AUSSIE and microDRIVE

Already published evidence

Expected to be published before AUA microhematuria guideline committee initiates next literature review in Q3 2027

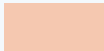
1. Clinical Utility (CU) - Evidence a test that can usefully change patient management within the context of care for the defined population and indication Clinical Validity (CV) - Evidence a test works in the same way on an independent eligible population for a given indication. Analytical validity (AV) - Evidence a test is repeatable in the lab for a given indication and population

INDEPENDENT STUDIES SUPPLEMENT OUR EVIDENCE PORTFOLIO

HIGH IMPACT RESEARCH AT LOW COST

INDEPENDENT STUDY FOCUS	INSTITUTION	TEST AND EVIDENCE TYPE	PUBLICATION DATE ¹
Real World Utility of Triage in MH: A Matched Cohort Study	Kaiser Permanente, US	CU Triage (RWE)	Q1 2026 ²
Patient preference and satisfaction of “biomarkers vs cystoscopy”	Mayo Clinic, US	CU Monitor	Q3 2026
NZ Hematuria Pathway comparing T/D with Triage Plus on AUSSIE samples	Canterbury DHB	CU of Triage Plus	Q3 2026
Retrospective concordance of Triage and Triage Plus in the Kaiser System	Kaiser Permanente, US	CU Triage Plus	2027
Test utility in screening patients at risk for bladder cancer	UT Southwestern, US	CU Triage Plus	2027
Test utility in assessing therapy success in a reduced chemotherapy protocol for upper tract tumors	Israel Institute of Technology, Israel	CU Monitor CU Surveillance Plus	2027
Test utility in assessing response to BCG ³ in high-grade bladder cancer patients	University of Miami, US	CU Monitor CU Surveillance Plus	2027
Test utility for the surveillance of MIBC ⁴ treated with bladder sparing methods (PRESERVE Trial)	Cleveland Clinic, US	CU Monitor CU Surveillance Plus	2028
A Randomized Trial of Apalutamide in Non-Muscle Invasive Bladder Cancer	National Institutes of Health, US	CU Monitor CU Surveillance Plus	2029

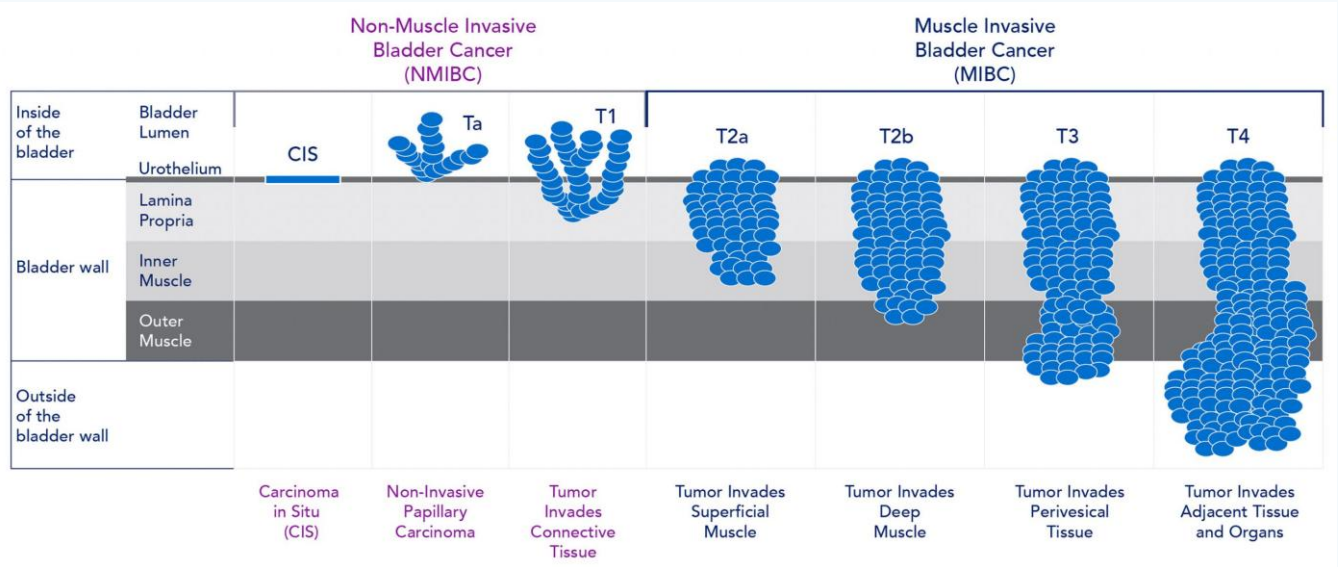
- Investigator initiated trials (IITs) are independent studies in which Pacific Edge typically provides free testing, so provide significant value at low cost
- IITs extend the evidence portfolio for new indications of existing tests and may inform new ‘core’ clinical trials
- IITs are an important part of Key Opinion Leader (KOL) engagement and generate publications or podium presentations that give profile to Cxbladder and Pacific Edge

 Already published evidence

1. All dates are calendar year and our best current estimates
2. Filson et al (2026); Real-World Utility of Cxbladder Triage for Patients with Microhematuria: A Matched Cohort Study, Urology Practice[®] (2026), doi: 10.1097/UPJ.0000000000000972.
3. BCG: Bacillus Calmette–Guérin is a bacterium instilled into the bladder that triggers an immune response that targets and destroys cancer cells.
4. MIBC: Muscle Invasive Bladder Cancer

BACKGROUND ON NMIBC AND MIBC

- Bladder Cancer
 - An estimated 83,190 patients were diagnosed with bladder cancer in the USA in 2024 at an average age of 73¹
- Non-muscle invasive Bladder Cancer (NMIBC)
 - NMIBC tumors represent approximately 75% of the bladder cancer diagnoses each year (CIS, Ta and T1)
 - NMIBC tumors *are localized* and present on the lining of the bladder wall and shed cancer cells and cell-free DNA/RNA into the urine in the bladder
 - NMIBC tumors are highly treatable with surgery/resection and deemed *cancer free* after surgery/resection
 - NMIBC patients are placed on a *surveillance protocol* after surgery/resection, because *recurrence can be 50-70% within the first two years*²
 - **NMIBC → TURBT → Surveillance**
- Muscle-invasive Bladder Cancer (MIBC)
 - MIBC tumors represent approximately 25% of the bladder cancer diagnoses each year (T2-4)
 - MIBC tumors differ from NMIBC tumors, because they shed cells/nucleotides to the blood
 - MIBC patients have advanced/serious disease, require high-levels of intervention (radical cystectomy followed by multiple therapies)
 - MIBC patients are *not deemed cancer free* after cystectomy and *frequently monitored for residual and metastatic disease*
 - **MIBC → Cystectomy → Monitoring**



1. American Cancer Society. *Cancer Facts & Figures 2024*
2. Holzbeierlein J, Bixler BR, Buckley DI, et al. Diagnosis and treatment of non-muscle invasive bladder cancer: AUA/SUO guideline: 2024 amendment. J Urol. 2024;10.1097/JU.0000000000003846.



NMIBC STANDARD OF CARE: INTERVENTION AND SURVEILLANCE

- NMIBC Standard of Care – Intervention
 - After NMIBC diagnosis, the standard intervention is a Trans-Urethral Resection of a Bladder Tumor (TURBT)
 - TURBT involves inserting a camera into the urethra and the use of small instruments like a wire loop or laser to cut or burn away the tumor tissue
 - Patients are deemed *cancer free post TURBT when muscles and tumor margins are confirmed free of disease by pathology*
 - A resection biopsy taken during surgery is used to stage the tumor (T0, Ta, CIS, T1-4) and determine the grade (low or high grade) which also provides the risk of recurrence.
 - All NMIBC patients are then classified into risk categories based on this information (low, intermediate and high risk).
- NMIBC Standard of Care - Surveillance
 - BCG (bacillus calmette guérin) is administered for several weeks after TURBT to initiate an immune response towards the tumor. Some patients are 'non-responders'
 - A cystoscopy at 3 months is recommended for every patient
 - Following the 3-month cystoscopy, patients are recommended for routine surveillance protocols involving cystoscopy and imaging among others based on their risk category
 - Due to the high burden of these protocols, the average patient only stays on surveillance for 1.8 years not 5¹ as recommended by most guidelines

SOURCES AND ASSUMPTIONS - TOTAL ADDRESSABLE MARKET (US)

REGION	STATISTIC		SOURCE
UNITED STATES	Population	341,762,685	https://www.census.gov/popclock/
	Incidence of hematuria	7,000,000	Presentation from Dr Sia Daneshmand (Director of Urologic Oncology and Clinical Research, USC) July 2019
	Referred for clinical workup	3,500,000	Presentation from Dr Sia Daneshmand (Director of Urologic Oncology and Clinical Research, USC) July 2019
	Proportion of gross hematuria amongst those referred for clinical workup	700,000	Pacific Edge estimate
	Proportion of microhematuria amongst those referred for clinical workup	2,800,000	Pacific Edge estimate
	Proportion of low-risk microhematuria	200,000	Woldu, S, et al. Evaluation of the New American Urological Association Guidelines Risk Classification for Hematuria; Pacific Edge estimates to account for AUA 2025 guidelines
	Proportion of intermediate-risk microhematuria	1,140,000	Woldu, S, et al. Evaluation of the New American Urological Association Guidelines Risk Classification for Hematuria; Pacific Edge estimates to account for AUA 2025 guidelines
	Proportion of high-risk microhematuria	1,460,000	Woldu, S, et al. Evaluation of the New American Urological Association Guidelines Risk Classification for Hematuria; Pacific Edge estimates to account for AUA 2025 guidelines
	Annual cases of bladder cancer	84,870	National Cancer Institute
	Patients living with bladder cancer	744,044	National Cancer Institute
	Test opportunities	4,616,066	Pacific Edge estimate
	Price of Cxbladder (US\$)	\$1,328 for Cxbladder Triage Plus, \$1,800 for Cxbladder Surveillance Plus	
	TAM (US\$billion)	\$6.7	

SOURCES AND ASSUMPTIONS - TOTAL ADDRESSABLE MARKET (EUROPE)

REGION	STATISTIC		SOURCE
EUROPE (EXCLUDING RUSSIA)	Population	600,000,000	World-population - Europe World-population - Russia
	Incidence of hematuria	12,000,000	Science Direct
	Referred for clinical workup	6,000,000	Presentation from Dr Sia Daneshmand (Director of Urologic Oncology and Clinical Research, USC) July 2019
	Proportion of gross hematuria amongst those referred for clinical workup	1,200,000	Pacific Edge estimate
	Proportion of microhematuria amongst those referred for clinical workup	4,800,000	Pacific Edge estimate
	Proportion of low-risk microhematuria	340,000	Woldu, S, et al. Evaluation of the New American Urological Association Guidelines Risk Classification for Hematuria; Pacific Edge estimates to account for AUA 2025 guidelines
	Proportion of intermediate-risk microhematuria	1,960,000	Woldu, S, et al. Evaluation of the New American Urological Association Guidelines Risk Classification for Hematuria; Pacific Edge estimates to account for AUA 2025 guidelines
	Proportion of high-risk microhematuria	2,500,000	Woldu, S, et al. Evaluation of the New American Urological Association Guidelines Risk Classification for Hematuria; Pacific Edge estimates to account for AUA 2025 guidelines
	Annual cases of bladder cancer	180,000	Uroweb
	Patients living with bladder cancer	900,000	Pacific Edge estimate - 5 years of annual cases
	Test opportunities	7,350,000	Pacific Edge estimate
	Price of Cxbladder EURO	€245	Pacific Edge estimate
	TAM (US\$billion)	\$2.0	

SOURCES AND ASSUMPTIONS - TOTAL ADDRESSABLE MARKET (APAC)

REGION	STATISTIC		SOURCE
APAC (EXCLUDING INDIA AND CHINA)	Population	830,000,000	World population - Southeast Asia Population Pyramid - Japan Population Pyramid - Hong Kong
	Incidence of hematuria	16,600,000	Science Direct
	Referred for clinical workup	8,300,000	Presentation from Dr Sia Daneshmand (Director of Urologic Oncology and Clinical Research, USC) July 2019
	Proportion of gross hematuria amongst those referred for clinical workup	1,660,000	Pacific Edge estimate
	Proportion of microhematuria amongst those referred for clinical workup	6,640,000	Pacific Edge estimate
	Proportion of low-risk microhematuria	470,000	Woldu, S, et al. Evaluation of the New American Urological Association Guidelines Risk Classification for Hematuria; AUA 2025 guidelines
	Proportion of intermediate-risk microhematuria	2,710,000	Woldu, S, et al. Evaluation of the New American Urological Association Guidelines Risk Classification for Hematuria; AUA 2025 guidelines
	Proportion of high-risk microhematuria	3,460,000	Woldu, S, et al. Evaluation of the New American Urological Association Guidelines Risk Classification for Hematuria; AUA 2025 guidelines
	Annual cases of bladder cancer	58,000	WHO Hong Kong
	Patients living with bladder cancer	290,000	Pacific Edge estimate - 5 years of annual cases
	Test opportunities	3,494,000	Pacific Edge estimate
	Price of Cxbladder (US\$)	\$550	Pacific Edge estimate
	TAM (US\$billion)	\$1.9	

KEY CLINICAL ADVISORS AND CONSULTANTS



Professor Yair Lotan, MD

Institution: UT Southwestern Medical Center
Relationship: Consultant, CAB member, IIT PI, CT PI
Brief Bio: Published >500 articles. Contributor to AUA/ASCO/ASTRO MIBC and Hematuria Guidelines. Chair of AUA Core Curriculum. BCAN Adboard



Professor Sam Chang, MD, MBA

Institution: Vanderbilt Cancer Center
Relationship: Consultant, CAB member
Brief Bio: Published >200 articles. Chair of AUA NMIBC Guidelines, SUO Executive Board, ABU/AUA Examination Committee, BCAN Adboard, AUA representative to the AJCC



Assistant Professor John Sfakianos

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Relationship: Consultant, CAB member
Brief Bio: Published >20 articles. Reviewer for J Urol and Urologic Oncology



Professor Dan Barocas, MD, MPH, FACS

Institution: Vanderbilt University Medical Center
Relationship: Consultant, CAB member
Brief Bio: Published >100 articles. AUA Guidelines panel for microscopic hematuria. Reviewer for AUA educational materials



Associate Professor, Siamak Daneshmand, MD

Institution: Keck School of Medicine at USC
Relationship: Consultant, CAB member, CT PI
Brief Bio: Published >200 articles. Editorial board of the J Urol, Bladder Cancer Journal, Current Opinions in Urology, BCAN Adboard, AUA/SUO Guideline Committee on NMIBC



Associate Professor Katie Murray, DOMS, FACS

Institution: NYU Langone
Relationship: Consultant, CAB member,
Brief Bio: Published >80 articles. Deputy Editor for J Urol.
Leadership roles for SUO Young Urologic Oncology Clinical Trials



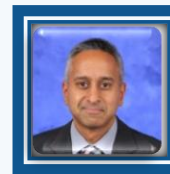
Professor Jonathan Wright, MD, MS, FACS

Institution: Fred Hutchinson Cancer Center at UW
Relationship: Consultant, CAB member, CT PI
Brief Bio: Member of ACS, SUO, AUA



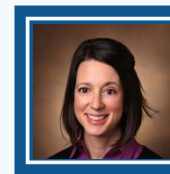
Professor Wade Sexton, MD

Institution: University of South Florida & Moffitt Cancer Center
Relationship: Consultant, CAB member
Brief Bio: Published >100 articles. NCCN Bladder Cancer Guidelines, AUA Annual Board Review Course



Professor Jay Raman, MD

Institution: Penn State and Hershey Medical Center
Relationship: Consultant, CAB member, CT PI
Brief Bio: Published >350 articles. Chair of AUA Office of Education and Past-President of the Mid-Atlantic AUA section. Urology Advisory Council for ACS, Hematuria Guidelines member



Associate Professor Kristen Scarpato, MD, MPH, FACS

Institution: Vanderbilt University Medical Center
Relationship: Consultant, CAB member, CT PI
Brief Bio: SUO Education Committee, AUA Core Curriculum, Urology Practice Editorial Committee

ASCO: American Society of Clinical Oncology
ASTRO: American Society of Radiation Oncology
AUA: American Urological Association
BCAN: Bladder Cancer Advocacy Network
CAB: Clinical Advisory Board
CT PI: Clinical Trials Principal Investigator

FACS: Fellow of the American College of Surgeons
IIT PI: Investigator Initiated Trial Principal Investigator
J Urol: Journal of Urology
KOL: Key Opinion Leader
MPH: Master of Public Health
SUO: Society of Urologic Oncology



PacificEdge®
CANCER DIAGNOSTICS

PACIFIC EDGE BOARD AND MANAGEMENT



SIMON FLOOD
Chairman

Simon has spent more than 25 years in the global investment management industry having held senior Investment and Business Leadership roles in some of the world's pre-eminent investment management firms including Merrill Lynch Investment Managers Lion Global Investors and AXA Investment Managers



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 he was CEO at Omixon

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