Danae
UROGENOMICS

Science in Urology, precision in care

Enabling Precision Therapy Selection in Bladder Cancer

A urine-based molecular biomarker platform for companion diagnostics and treatment optimization

Science in Urology, Precision in Care

THE PROBLEM

Bladder Cancer Patients Spend Years in Painful, Unreliable Follow-Up

Despite transformative advances in immunotherapy and targeted oncology, treatment decisions in bladder cancer remain largely empirical. **Clinicians still lack reliable, validated predictive biomarkers to guide therapy selection at the individual patient level.**

78%

Highest recurrence rate in oncology
Patients monitored for 5+ years

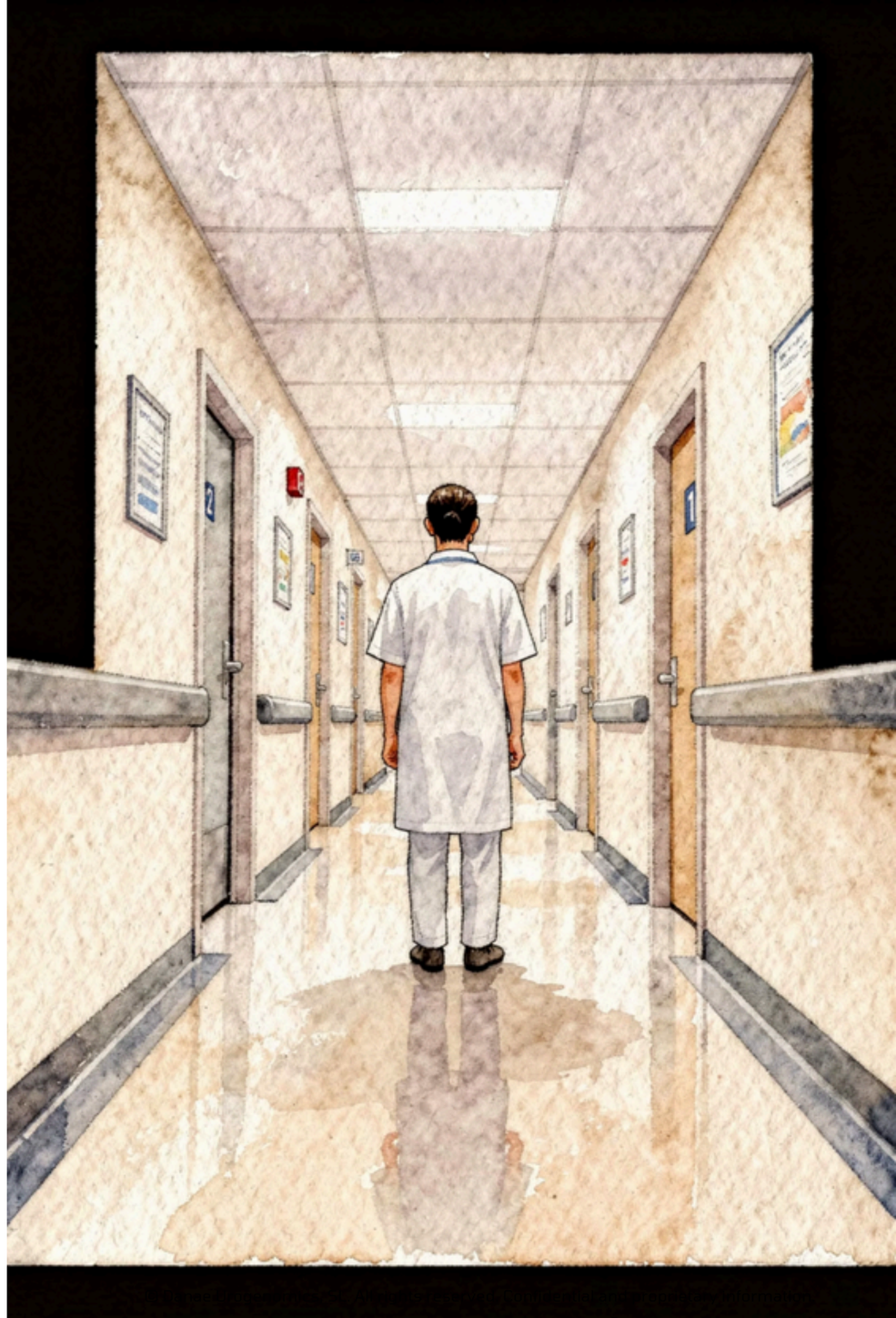
40–50%

BCG non-response
Patients do not respond with no molecular tools to predict failure in advance

€120–150K

Lifetime cost per patient
Driven by repeated invasive procedures

⚠ **Today, clinicians still cannot predict who will respond.**



THE PROBLEM

The Diagnostic Challenge Is Solved. The Therapy Selection Challenge Is Not.

The frontier challenge in bladder cancer is precision therapy selection, identifying, before treatment begins, which patients will respond and which will not.

CURRENT STANDARD OF CARE

- Trial-and-error treatment sequencing with no molecular guidance
- Delayed identification of non-responders, exposing patients to avoidable toxicity
- Repeat cystoscopies imposing procedural burden
- Escalating costs from inefficient, empirical therapy cycles

BIOMARKER-GUIDED PATHWAY

- Pre-treatment molecular stratification into responder and non-responder cohorts
- Rapid reallocation to alternative therapies for predicted non-responders
- Non-invasive, repeatable longitudinal monitoring throughout treatment
- Stronger health economics and value-based evidence for payers and partners

THE SOLUTION

BlaDimiR®

BlaDimiR is not a test.
It is a platform.

One urine sample.
Over 90% accuracy.

A non-invasive molecular diagnostic platform built on proprietary urine-based biomarkers, ***engineered from the ground up for companion diagnostic co-development and pharmaceutical partnership.***

- Replaces inefficient follow-up procedures
- Guides treatment decisions
- Aligns clinicians, patients and payers

THE SOLUTION

The Platform

3 PRODUCTS. 3 UNMET NEEDS. 1 PLATFORM.

Three products. One molecular engine. Built to replace inefficient procedures, guide treatment decisions, and scale globally through licensing.

BlaDimiR DIAGNOSTIC

Diagnosis & Follow-up

- Replaces cytology. >90% accuracy.
- ~100% low-grade detection.
- Reduces 1–2 cystoscopies per patient per year.

BlaDimiR PLUS

BCG Response Prediction

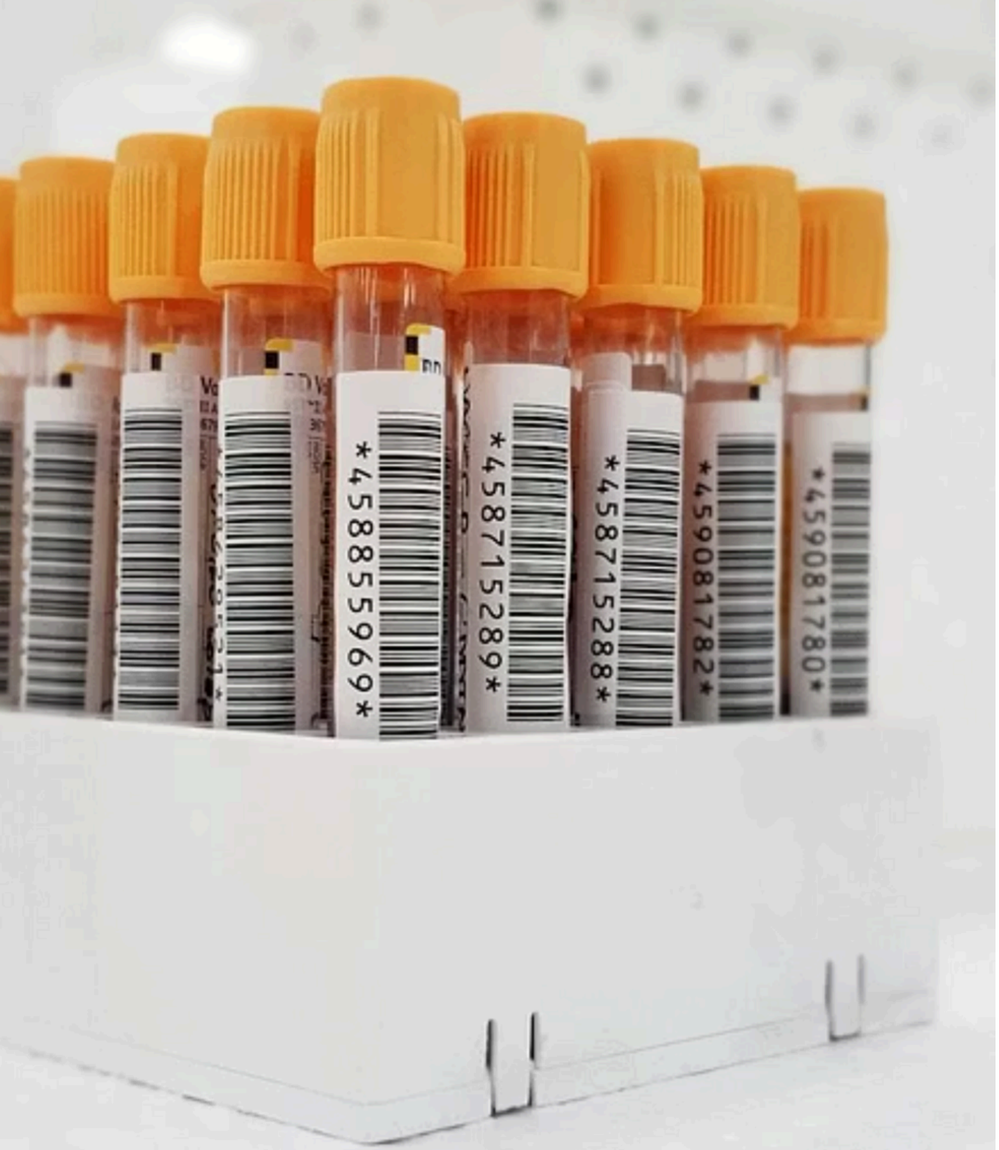
- The world's first urine test predicting BCG treatment response.
- Protects patients from toxic, ineffective therapy.

BlaDimiR IO®
Predicting response. Personalizing immuno-oncology

Immuno-oncology Selection

- Predicts immunotherapy response.
- Designed as a Companion Diagnostic (CDx): ***the gateway to major pharma partnerships.***

Each application layer generates clinical evidence that compounds value across the therapeutic pipeline.



Urine provides direct, non-invasive access to tumor-derived molecular signals → **enabling continuous biological monitoring at scale.** This fundamentally redefines what is clinically and commercially feasible in bladder cancer precision medicine.

THE ADVANTAGE

Why Urine Changes Everything

Attribute	Tissue Biopsy	BlaDimiR (Urine)
Invasiveness	**High**: cystoscopy or surgical resection required	Non-invasive → patient-collected urine sample
Repeatability	**Limited**: procedural risk and cost barrier	Unlimited → feasible at every clinical visit
Longitudinal Monitoring	**Impractical** at scale	Native capability → continuous treatment tracking
Clinical Practicality	Requires specialist setting; scheduling delays	Deployable in standard outpatient workflow
Cost Efficiency	**High** procedural and pathology cost	Low per-test cost scalable globally

CLINICAL EVIDENCE

Clinical Evidence

BlaDimiR is advancing through a structured, multicenter clinical validation program. Performance data represent current interim results → full validation cohort data available for scientific review and due diligence under CDA.

Diagnostic Performance

Sensitivity: 93% | **Specificity:** 86 %
AUC: 0.96 | **NPV:** 92 %
Cohort: 225 patients

BCG Response Prediction

Sensitivity: 100 % | **Specificity:** 92.9 %
AUC: 0.95 | **NPV:** 92.9 %
Cohort: 143 BCG-naïve NMIBC patients

Immunotherapy Response Prediction

Sensitivity: 94.4 % | **Specificity:** 87.5 %
AUC: 0.92 | **NPV:** 75 %
Cohort: 57 anti-PD1/PD-L1 treated patients

Multicenter Validation

Total Enrollment: 692 patients
Sites: 6 academic and community centers
Prospective validation study underway — designed to support IVDR and CDx regulatory submissions

✓ Full clinical data package and analytical validation dossier available under CDA for scientific and regulatory review.

COMPANION DIAGNOSTIC OPPORTUNITY

BlaDimiR as a Treatment Selection Companion Diagnostic

BlaDimiR is architected to stratify patients before therapy initiation and monitor molecular response longitudinally → purpose-built for **CDx co-development and regulatory co-submission**.

Patient Presents
Initial clinical evaluation and referral for therapy

BlaDimiR CDx Analysis
Urine-based companion diagnostic assay performed

Molecular Stratification
Classified as Responder or Non-Responder

Optimized Therapy
Treatment selected based on molecular stratification result

BCG Therapy
Predict response before initiation; avoid delayed escalation in non-responders

Anti-PD1 / PD-L1
Identify checkpoint inhibitor candidates and monitor on-treatment molecular dynamics

Emerging Therapeutics
Platform-ready for co-development with next-generation NMIBC and MIBC agents

Combination Regimens
Multi-biomarker signatures to support selection in complex combination therapy protocols

STRATEGIC VALUE

Strategic Value for Pharmaceutical Companies

BlaDimiR creates measurable value across the full pharmaceutical drug lifecycle from clinical development through post-market evidence generation and commercial differentiation.

Development Challenge	Value Created by BlaDimiR
Variable and unpredictable response rates in unselected populations	Pre-identified responder enrichment improves trial power and reduces sample size requirements
High cost of failed or underpowered pivotal trials	Biomarker-stratified enrollment increases probability of regulatory success
Market access and reimbursement challenges	Companion diagnostic generates companion health economics evidence for payer submissions
Post-launch label differentiation	Longitudinal monitoring data supports supplemental indications and label expansion
Competitive market positioning	CDx co-branding reinforces precision medicine leadership in oncology portfolio

Potential Partnership Pathways

Danae is structured for modular, milestone-driven pharmaceutical collaboration from retrospective evidence generation through full CDx co-development and regulatory co-submission.

Each pathway is designed to compound toward a long-term strategic relationship.

Phase I — Retrospective Biomarker Validation

Apply BlaDimiR biomarker signatures to existing partner clinical trial biobank samples. Generate initial analytical and clinical performance data within existing datasets → low cost, high strategic signal.

Phase II — Prospective Clinical Studies

Integrate BlaDimiR prospectively into ongoing or planned partner clinical trials.
Co-generate companion evidence in real time, with shared data ownership and publication rights.

Phase III — Companion Diagnostic Co-Development

Full CDx co-development agreement encompassing joint regulatory strategy, FDA/EMA submission planning, commercial deployment, and long-term lifecycle management of the combined therapeutic-diagnostic product.

Clear Path from Validation to Commercial Adoption

Danae has designed BlaDimiR from inception for regulatory-grade clinical deployment and international scalability with a quality management infrastructure aligned to the demands of a global CDx partner.

Clinical Validation

Multicenter analytical and clinical performance validation; prospective study completion

1

IVDR Readiness

2

ISO 13485-certified QMS; IVDR technical documentation and conformity assessment pathway

CDx Partnerships

Co-development agreements; joint regulatory strategy with pharmaceutical partner(s); FDA PMA/510(k) planning

3

International Expansion

4

Partner-deployed licensing model; centralized lab and decentralized deployment options; CE-IVD and global market access

Quality & Regulatory Infrastructure

- ISO 13485 Quality Management System
- IVDR-aligned technical file in development
- FDA CDx regulatory pathway scoped

Commercial Model

- Licensing and royalty model for partner deployments
- Central laboratory and kit-based decentralized options
- White-label and co-branded CDx configurations available

Why Danae

Danae Urogenomics occupies a uniquely defensible position at the intersection of molecular diagnostics and precision oncology therapeutics → **built on proprietary science, clinical rigor, and CDx-native architecture.**

Proprietary Biomarkers

Novel urine-based miRNA and molecular signatures developed and owned by Danae → not licensed, not repurposed from tissue-based platforms. Defensible IP with freedom-to-operate.

Clinical Validation

Structured, multicenter validation program designed to publication and regulatory submission standards → generating the evidence base required for CDx co-submission and payer acceptance.

Companion Diagnostic Architecture

Platform purpose-built for CDx co-development. BlaDimiR was designed for this role from the first clinical study → not retrofitted.

Scalable Global Deployment

Non-invasive sample collection, centralized processing capability, and a licensing model designed for rapid international scale → compatible with partner commercial infrastructure worldwide.

A multidisciplinary team united by *science and purpose.*

Deep expertise in **bladder cancer**, **molecular diagnostics** and **innovation**.

Marta Dueñas, PhD

CEO & SCIENTIFIC FOUNDER

- Molecular oncology
- Translational research
- Precision diagnostics

Félix Guerrero, MD-PhD

CLINICAL FOUNDER

- KOL in Urology
- Bladder cancer clinical practice
- Hospital adoption

Cristian Suárez, PhD

CO-FOUNDER & MOLECULAR BIOLOGY LEAD

- Clinical validation
- Biomarker platform
- Molecular diagnostics IP

Deep clinical expertise

Led by a world-class urologist with deep clinical experience.

Strong scientific IP

Proprietary biomarkers and robust validation create a defensible moat.

Built for licensing and global scale

Designed from day one for international expansion.

CORE TEAM

Jesús M. Paramio, PhD

Scientific Advisor

Cancer biology & molecular oncology

María López, PhD

IP & Tech Transfer

Licensing strategy & International IP

Carolina Rubio, PhD

QC & Regulatory Affairs

Quality systems & regulatory compliance

Daniel Castellano, MD

GU Oncologist

Clinical strategy & medical insight

Álvaro Martín

PhD Student

Research & data analysis

Health Economics & Regulatory Support

Value, reimbursement & market access

ADVISORS & STRATEGIC SUPPORT

Marta Palicio
Innovation R&D Director Werfen
Caixa Impulsa Mentor

Elena Rivas
Pinnacle Biopartners
Strategy partner

Rosario Cospedal
Regulatory Affairs

Xavier Velasco
Pinnacle Biopartners
Finantial partner

Oscar Alegre
RCD Legal
Legal Mentor

The Strategic Opportunity

Danae is building the first urine-based precision medicine platform for treatment selection and companion diagnostics in bladder cancer — a category-defining asset for the right pharmaceutical partner.

The Disease

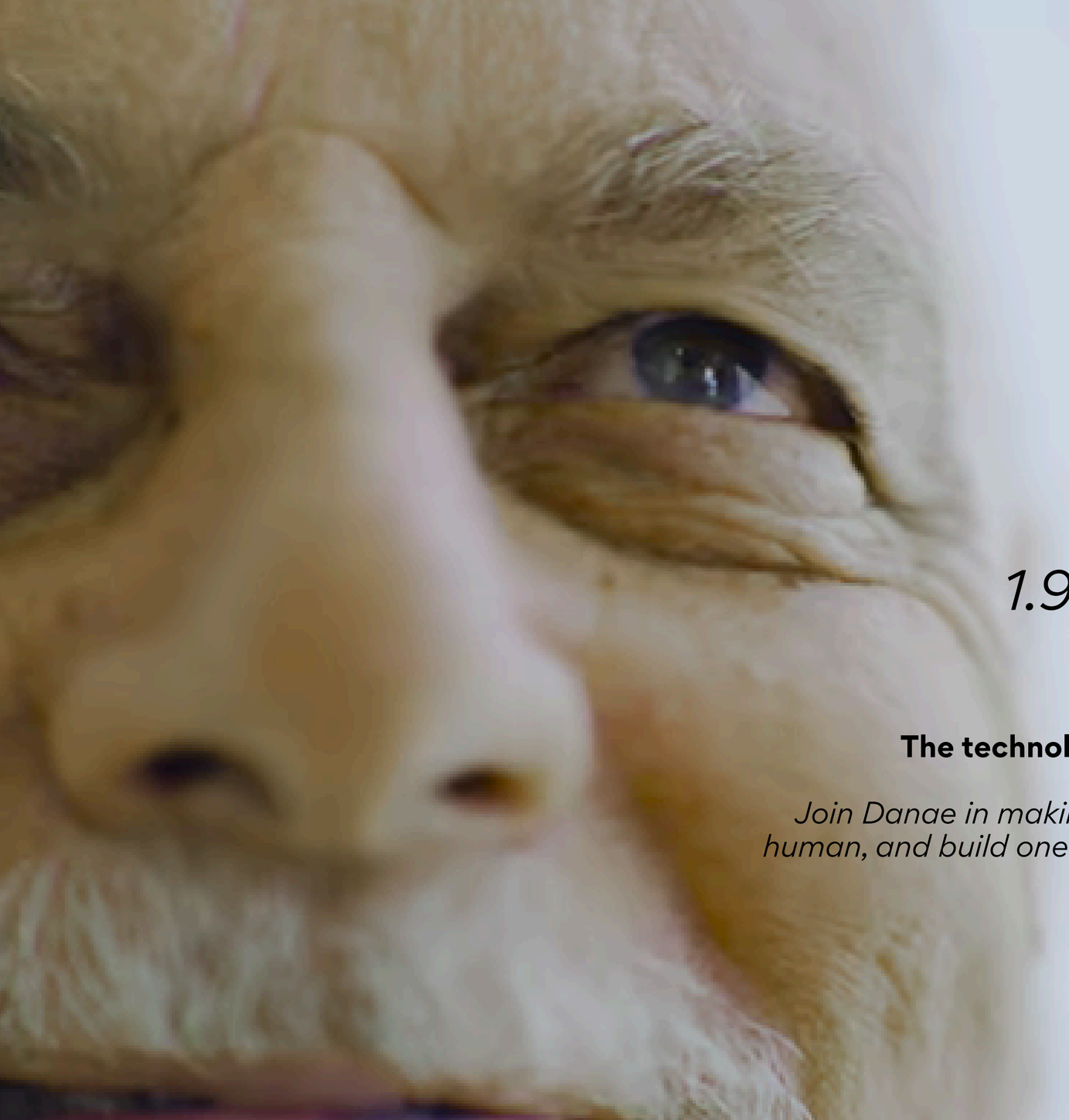
Bladder cancer: high recurrence, high unmet need, major treatment variability, and a growing immunotherapy market demanding **precision patient selection**

The Platform

BlaDimiR: proprietary urine-based molecular biomarkers with **diagnostic, predictive, and companion diagnostic** applications across the treatment pathway

The Partnership

A modular collaboration framework from retrospective validation through CDx co-development and regulatory co-submission **designed to accelerate mutual clinical and commercial value**



Danae
UROGENOMICS

1.95 Million Patients Are Waiting. The Window Is Now.

The technology exists. The team is ready. The market is enormous.

Join Danae in making bladder cancer monitoring non-invasive, precise, and human, and build one of the most impactful diagnostics companies in Europe.

Marta Dueñas, CEO at Danae urogenomics
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