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INOVIQ Ltd

Next-generation cancer
diagnostics and therapeutics

EXO-OC™ Test Investor Webinar
14 July 2026



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Retrospective clinical study outcomes [p6](#)

EXO-OC test and algorithm refinement [p20](#)

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Key Operational Q&As



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Why weren't the **samples quality** issues found earlier?

- All samples were sourced against **predefined criteria**, inspected on receipt in accordance with INOVIQ **QC procedures** and then stored for later sample processing and analysis in randomised batches under the HREC-approved Study Protocol. The provider-related sample quality issues could not be identified until sample analysis was complete, the study unblinded and initial data analysis completed on 27 June 2026. The unexpected differences in biomarker levels between biorepository providers were consistent with provider-specific pre-analytical factors.

What was the **test performance** in the samples?

- The samples were **unsuitable for a meaningful evaluation of the EXO-OC test performance** due to inconsistent provider-related miRNA biomarker levels. These differences are most likely attributable to variations in sample collection, handling and storage procedures prior to receipt by INOVIQ. Such pre-analytical factors affect extracellular vesicles and miRNA biomarker integrity and significantly impact test performance.

Will the **EXO-OC test** work in the real-world?

- Yes. The final LDT EXO-OC test will have a routine pathology **Biospecimen Collection Protocol** (to control sample collection, handling and storage) before the test is performed in a clinical-setting, real-world evaluation or prospective clinical trial. INOVIQ is committed to commercialising the EXO-OC™ test, initially as a LDT in the US for early detection of ovarian cancer, before further developing the test as an IVD for screening of ovarian cancer.

What are the **next steps**?

- Complete **technical review** to inform future validation studies, refine and validate the EXO-OC biomarkers and algorithm, and optimise the development pathway. INOVIQ is also progressing discussions with potential partners to support technology transfer, assay optimisation and final validation of EXO-OC in a CLIA-certified laboratory for initial commercialisation as a Laboratory Developed Test (LDT) in the US.

What did the **study cost**?

- The **cost of the 1255 case-control samples was \$849k** with FY26 project spend totalling \$1.216m, resulting in cash of \$9.35m at 30 June 2026. No sample acquisition costs were incurred for the previously scheduled high-risk and confounding disease groups. INOVIQ is funded into 2027 with a disciplined capital focus on advancing the EXO-OC diagnostic and CAR-exosome therapeutic programs.

What is the impact on **timelines**?

- INOVIQ aims to **minimise any impact on the development and commercialisation timelines** for EXO-OC. While it is too early to quantify the precise impact, our commercial strategy remains unchanged. We are undertaking a technical review and progressing discussions with CROs and potential partners to support the next phase of development and will update the market as key milestones and timelines are refined.

Key Governance Q&As



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What was the **Board and Management oversight** of the study?

- The study was managed under INOVIQ's established product development and governance processes including HREC-approved study protocols, structured project management and reporting processes, regular risk and progress reviews, and independent data analysis. Upon identification of the study issues, management escalated the findings to the Board, which is overseeing the technical review and actions to strengthen future study design, quality controls and governance processes.

Were the **development risks** adequately identified and managed?

- INOVIQ identified the key risks associated with retrospective case-control studies using biobanked samples, including sample quality and pre-analytical factors. Risk mitigation measures were implemented including supplier qualification, predefined sample requirements and inclusion criteria, temperature-controlled shipment monitoring, sample receipt inspections and QC checks. Consistent with standard diagnostic development practice, these risks were balanced against the stage of development, cost and timelines to efficiently advance the program to the next milestone.

What decision-making processes ensured **timely ASX disclosure**?

- The Board considers that decisions were made in accordance with the information available at each stage of the program and consistent with the Company's governance, risk management and continuous disclosure obligations.

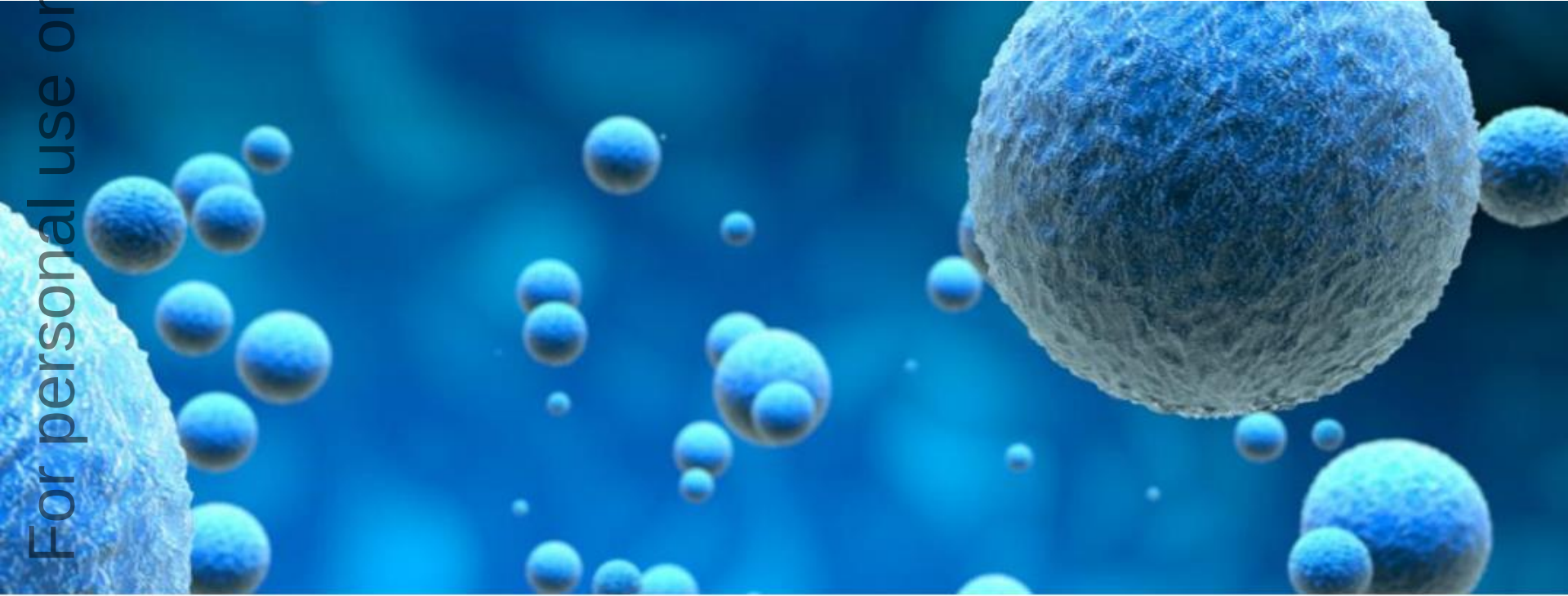
What are the **consequences for Management**?

- Management is accountable for delivering the companies strategic and operational objectives. This is regularly reviewed as part of performance management. No bonuses were paid in respect to FY25 as a result of the poor share price performance and it is anticipated that a similar bonus outcome will happen for FY26 when reviews are completed end of October. Other considerations outside of usual reviews on Management and Board renewal will be made after a full review has been completed of the current study.

How will the Board **restore shareholder value**?

- While the recent study outcome was disappointing, the Board believes the underlying scientific rationale remains strong. By addressing the key development risks identified, strengthening future study design and execution, progressing commercial partnering opportunities, and maintaining disciplined capital management, the Company aims to reduce risk, accelerate value-creating milestones and deliver sustainable long-term shareholder value.

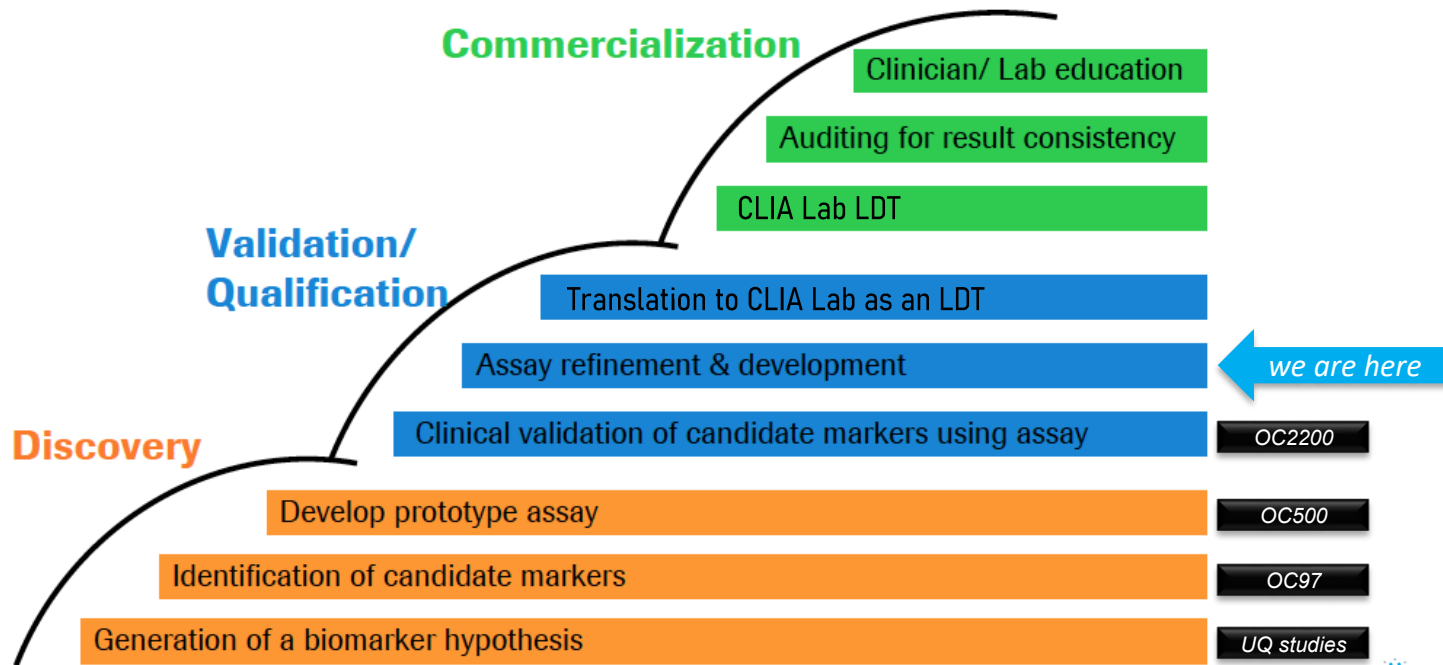
OC2200 Study Review





Biomarker Development – Required Capabilities

Significant challenges to establishing clinically viable and useful biomarkers



Source: Adapted from Roche corporate presentation "[Roche Diagnostics Driving Personalized Healthcare](#)" April 2008

EXO-OC™ | Ovarian Cancer Screening Test (OC500 Study)



Exosome-based blood test in development for early detection of ovarian cancer in asymptomatic average-risk women

- EXO-OC combines **multiple exosomal miRNA + CA125 biomarkers** in a **machine learning (ML) algorithm** enabling *early and accurate detection of ovarian cancer*

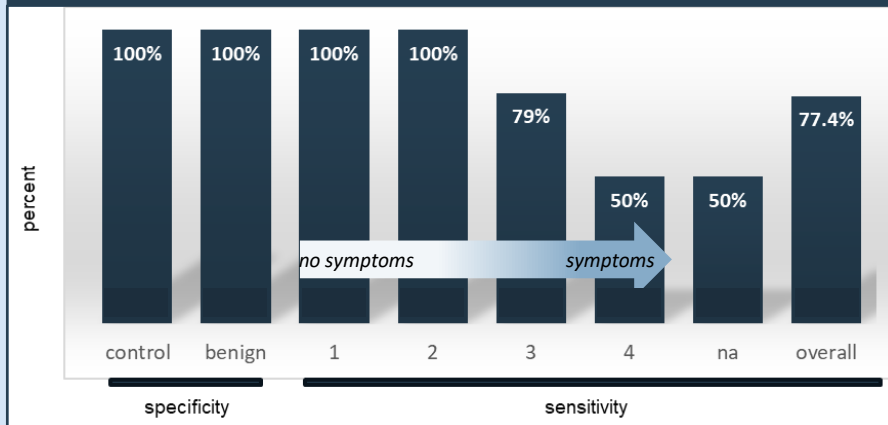
Study Design: Retrospective case-control study (n=498)

- Biobanked plasma samples from age-matched normal healthy women and benign masses vs ovarian cancers (stage I-IV)
- Proprietary ML algorithm developed and cross-validated using the Training set (n=372)¹
- Algorithm developed to **detect early-stage cases** and then tuned to achieve **≥99.6% specificity in controls**

Results: Meets screening performance criteria^{2,3,4}

- Cross-validated EXO-OC algorithm was applied to an independent Test set (n=125)
- Suitable for further development as an OC screening test for asymptomatic, average-risk women

Percent of Samples Correctly Identified by EXO-OC



Set	Control	Benign	Stage I	Stage II	Stage III	Stage IV	na	Total
Training	161	119	21	3	41	21	6	372
Test	59	35	6	3	14	6	2	125

100%
stage I/II
sensitivity

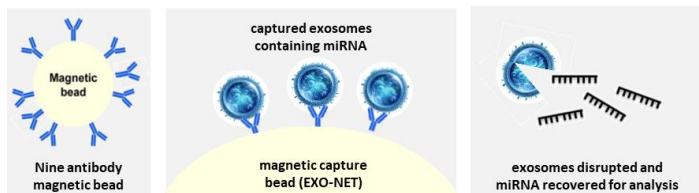
77%
all-stage
sensitivity

≥99.6%
specificity

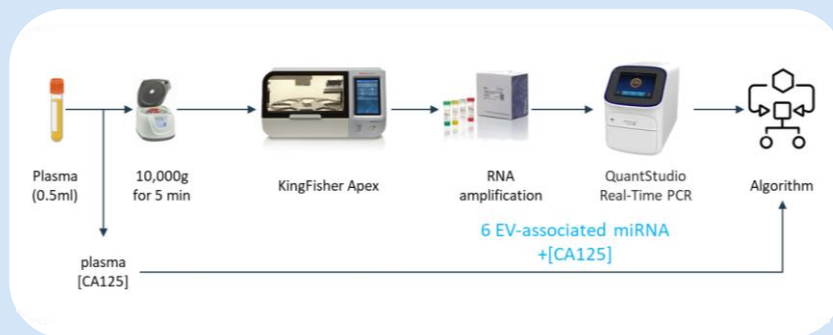




Assay Format



Lab Workflow



- EVs captured** from plasma using EXO-NET® immuno-affinity beads with capture antibodies targeting exosome-associated surface markers
- 6 exosomal **miRNAs biomarkers** are extracted and their abundance quantified using real-time **quantitative PCR (qPCR)**
- Plasma **CA125** concentration is independently measured by **immunoassay**
- AI/machine learning (ML) algorithm** integrates the 6 miRNA expression profiles plus CA125 value to generate a composite **EXO-OC test score**
- A **clinical report** is produced, returning a binary result of **cancer detected** or **cancer not detected**



Design control

a systematic process ensuring medical devices such as In Vitro Diagnostics (IVDs) meet user needs, intended uses and specified requirements

Clinical need: an accurate blood test for early-stage ovarian cancer with high specificity

>75% Sensitivity at 98% specificity

EXO-OC CA125 + 6 miR

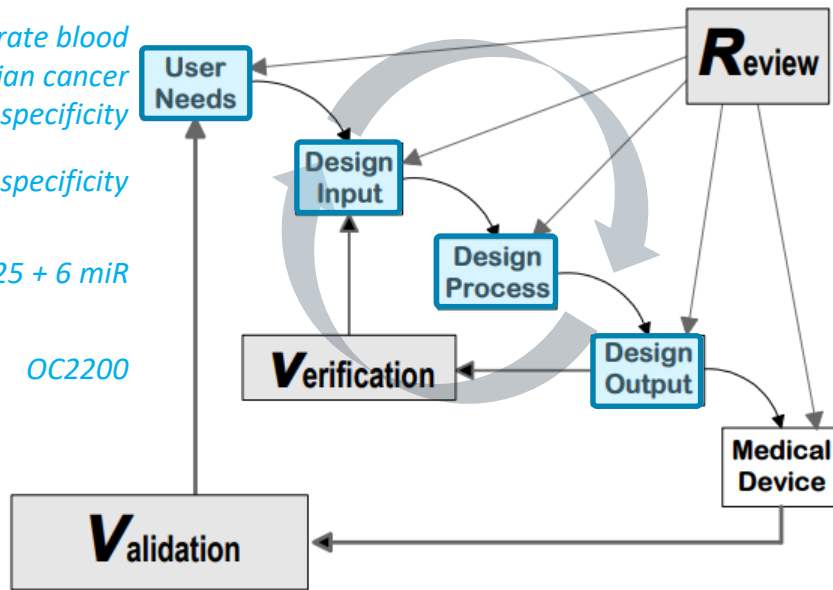
OC2200



Center for Devices and Radiological Health

DESIGN CONTROL GUIDANCE FOR MEDICAL DEVICE MANUFACTURERS

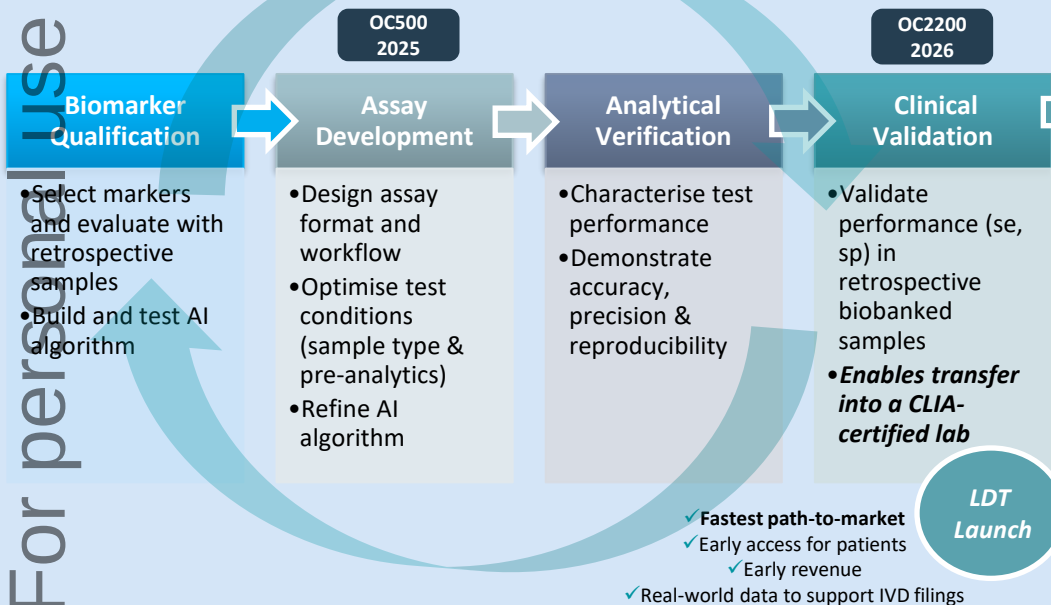
Guidance relates to FDA 21 CFR 820.30 and Sub-clause 4.4 of ISO 9001



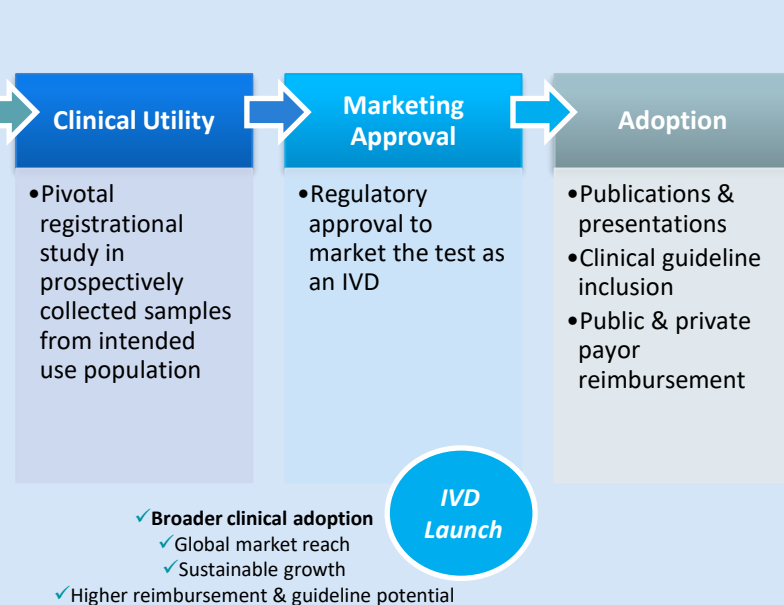


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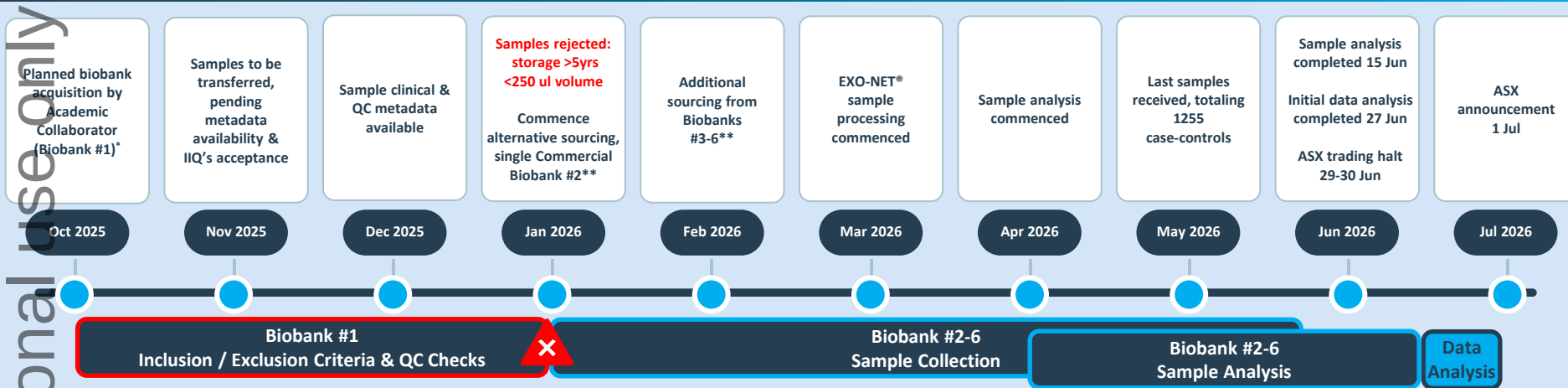
LDT Development



IVD Development



OC2200| Biobank sample acquisition & analysis timeline



All samples collected under individual biobank IRB-approval and applicable jurisdictional regulations

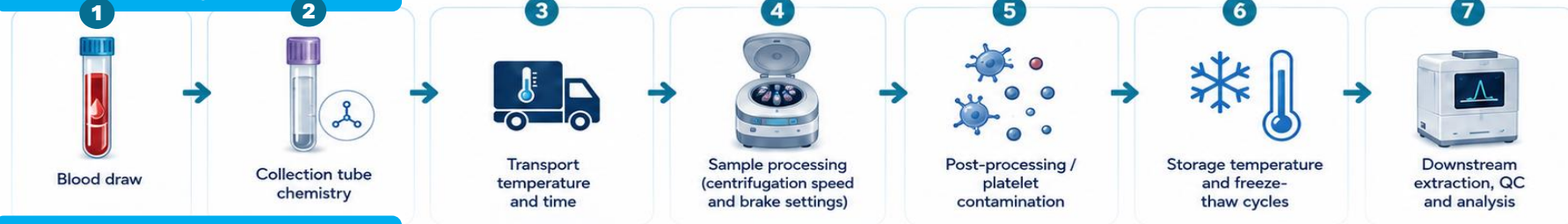
Study conducted under independent HREC approval and IIQ SOPs

Biobank	Total Samples	Outcome
1	2040	Pre-analytical Rejection Jan 2026: Did not meet IIQ inclusion criteria
2	284	Post-analysis review June 2026: Biomarker variability between biorepositories
3	191	Post-analysis review June 2026: Biomarker variability between biorepositories
4	109	Post-analysis review June 2026: Biomarker variability between biorepositories
5	15	Post-analysis review June 2026: Biomarker variability between biorepositories
6	656	Post-analysis review June: 616/656 low CA125 & miRNA biomarker levels consistent with degradation, excluded from model development
☒	800	Remaining samples not purchased for high-risk and confounding disease groups

Sample journey| Pre-Analytical factors impacting sample quality



The Sample Journey



What Can Go Wrong



IIQ Criteria for Biobanked Samples



IIQ QC Steps for Prospective Samples



In blood-based biomarker tests, including exosome-based tests, sample collection, handling and storage can impact test performance. These pre-analytical factors can only be fully controlled in prospectively collected samples.



Sample Requirements

- Female donors aged 40-75 years collected under appropriate IRB/HREC protocols and appropriate consent
- De-identified plasma and metadata supplied for each sample
- Plasma collected in EDTA anticoagulation tubes
- Biospecimen <5-year storage
- No haemolysed or grossly lipaemic plasma flagged by vendor QC
- Total usable plasma volume >1 mL
- No more than 1 freeze-thaw cycle before shipment
- Proper storage or handling, rejecting samples storage above -70°C, unmonitored storage, or unresolved freezer excursions

Clinical Criteria

Inclusion

- Healthy controls
- Benign gynaecologic conditions
- High-grade OC Stage I–IV
- Non-high-grade epithelial OC histotypes

Exclusion

- Infection, inflammatory/metabolic conditions or pregnancy
- Serious uncontrolled comorbidities
- Prior diagnosis of cancer or anti-cancer therapy
- Prior surgical removal of both ovaries

Part 2 Study - Additional Cohorts

- High-risk: high-risk individuals (BRCA1/2 or Lynch)
- Confounding diseases: non-ovarian cancers, inflammatory / metabolic conditions



Sample receipt and manifest QC

- Inspect container, dry ice status, and shipment temperature logs
- Reconcile IDs against the locked manifest
- Inspect vials for leakage, breakage, thawing, and quarantine deviations
- Visual inspection for haemolysis & lipaemia

Whole process & miRNA controls

- QC – WPC pooled human plasma standard
- QC – RT amplification, qPCR QC

miRNA Microarray Kits & Reagents

Universal miRNA Reference Kit ULUC

The Universal Human miRNA Reference RNA is an ideal reference control for miRNA microarray or miRNA-targeted qPCR experiments. The Agilent miRNA Kit may also be used as an optimization or standardization reagent for human miRNA analysis. It is available in industrial lots for high-throughput applications.

The product is composed of total RNA from nine human tissues or cell lines specifically selected and formulated for optimal miRNA representation. The kit is carefully screened to ensure no detectable DNA is present and contains several forms of RNA for robust analysis.

Agilent Research Use Only. Not for use in diagnostic procedures.

PRODUCT DETAILS



Precision checks RT-qPCR

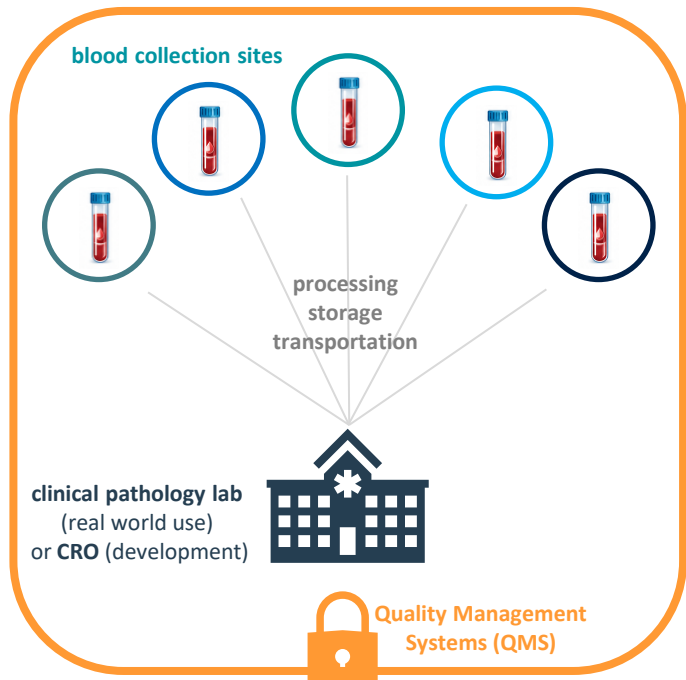
- Duplicate samples included for precision.
- qPCR SOP defines amplification-curve quality and NTC behaviour thresholds.
- Data quality review includes Ct range/distribution and standard-curve fit.



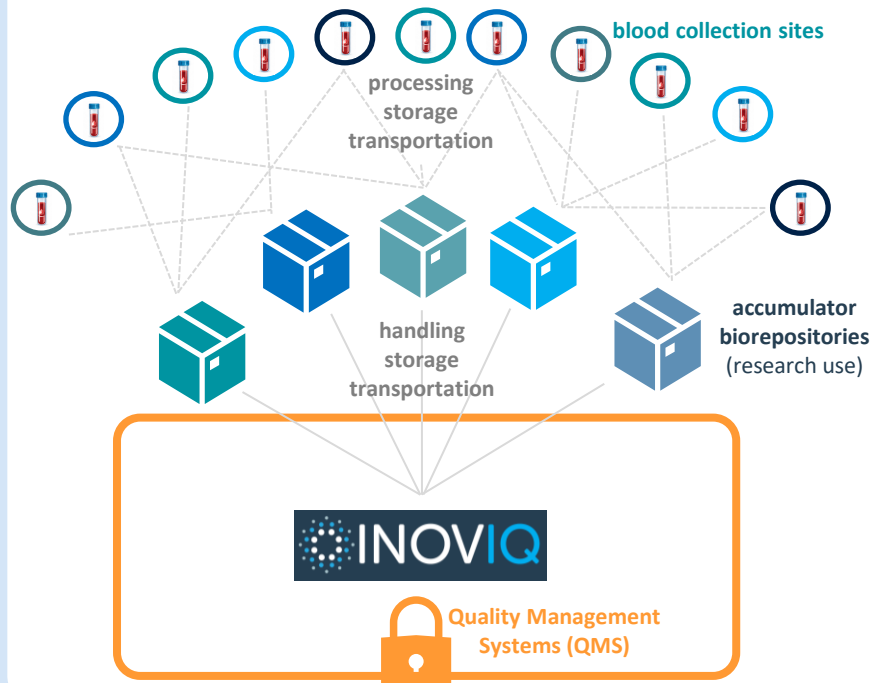
Samples accepted based on predefined criteria



Clinical Setting, Multi-site Prospective or Single-provider Retrospective Study (OC500*)

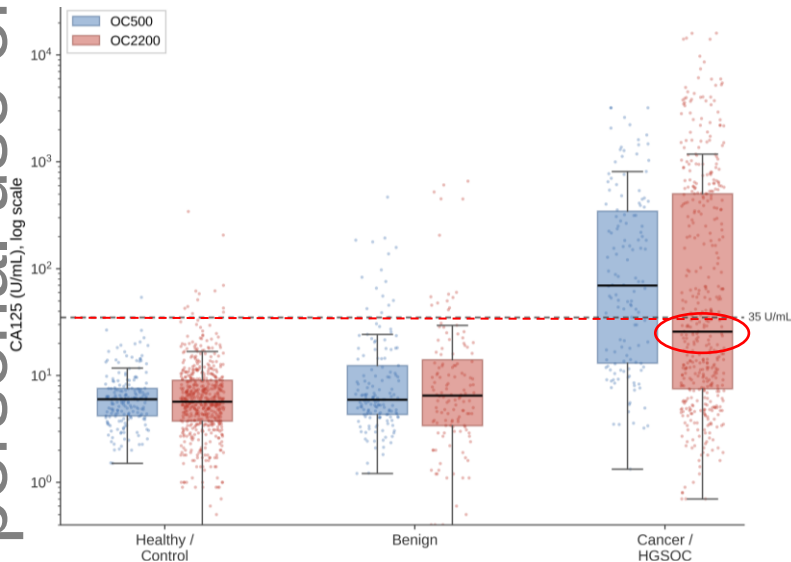


Multi-provider, Retrospective Study (OC2200*)



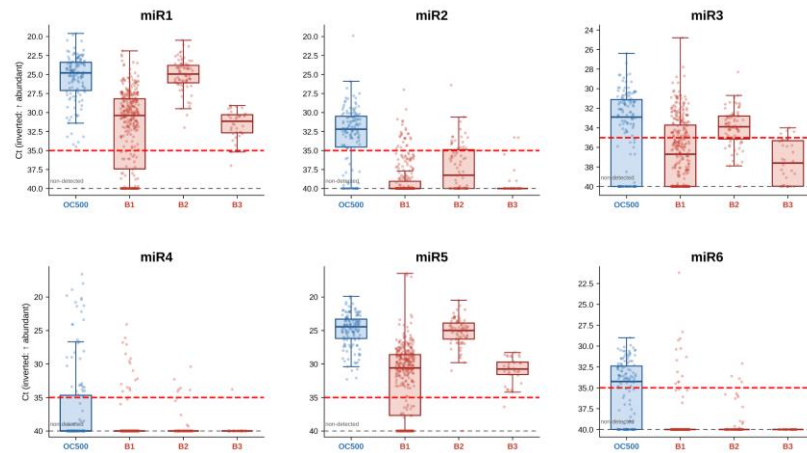


CA125 Protein Biomarker By Clinical Group



Key finding 1: CA125 lower in OC2200 cancer samples, consistent with protein degradation

miRNA Biomarkers in OC Samples By Biorepository



Key finding 2: miRNA levels vary by biorepository indicating provider-specific pre-analytical variation



Findings

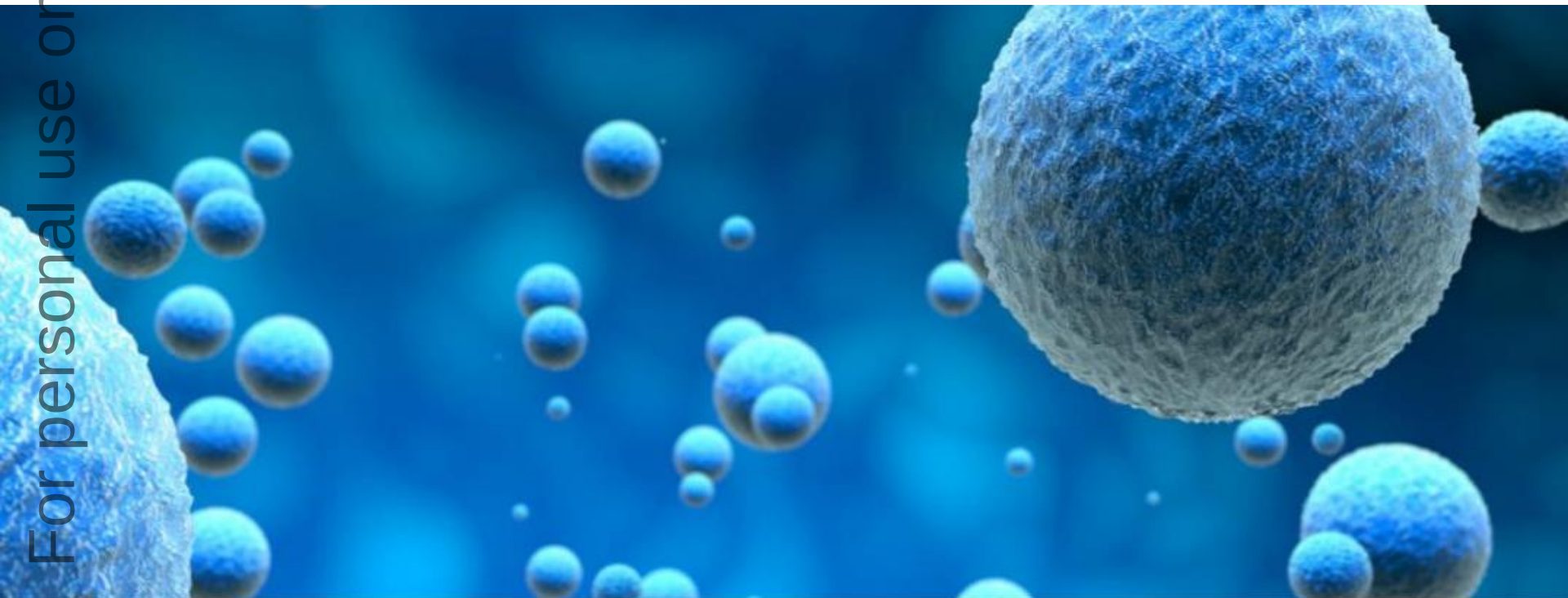
- 1 CA125 protein varies x biorepository and is less than in OC500 samples
- 2 miRNA varies x biorepository and is less than in OC500 samples
- 3 Provider-related variability in sample collection and processing by the biorepositories is the primary cause of low miRNA biomarker signal available for meaningful test evaluation

Recommendations

- Complete technical review to inform further validation studies
- Ongoing refinement of biomarkers and algorithm
- Sample sourcing from a single-site biobank, nested prospective or real-world samples with collaborator, CRO or partner
- Progress pre-analytical studies
- Update analytical and clinical validation studies

Correct sample collection = Correct test result

Next Steps

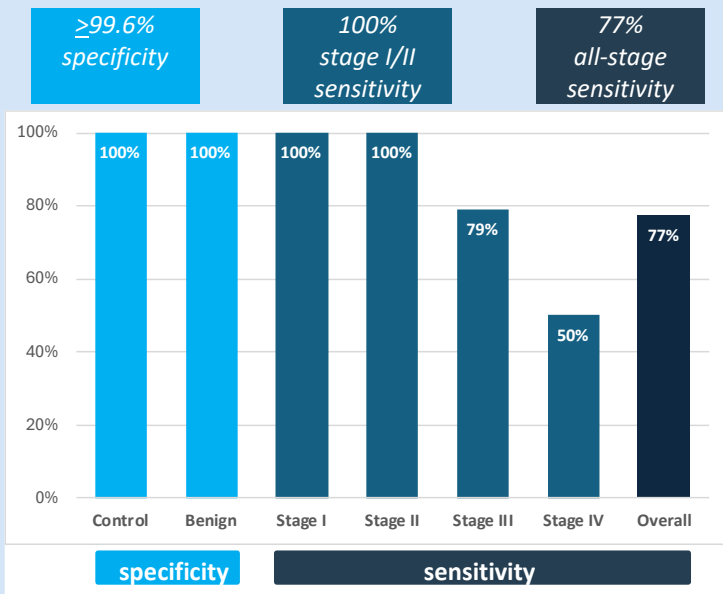




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✓ Model 1 – Screening, average-risk asymptomatic

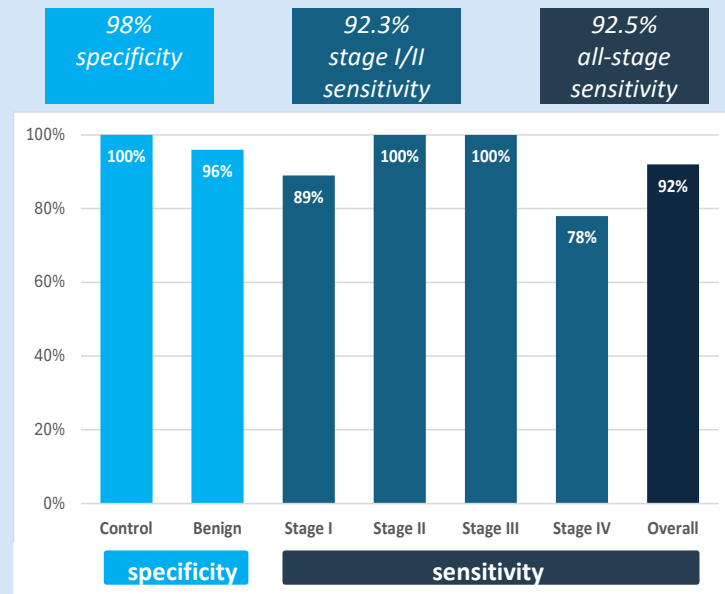
Designed to meet screening performance criteria for **general population**, **sensitivity >75% and specificity >99.6%**¹ and to preferentially detect early stage cancers^{2,3}



Objective: minimal false positives

✓ Model 2 – Early detection, high-risk

Tuned to improve **sensitivity across all stages** to meet the clinical needs for **early detection in women at high risk** of developing ovarian cancer, a defined population with higher disease prevalence reducing specificity requirements⁴



Objective: increase sensitivity across all stages



Clinical validation studies to evaluate performance of EXO-OC for early OC detection

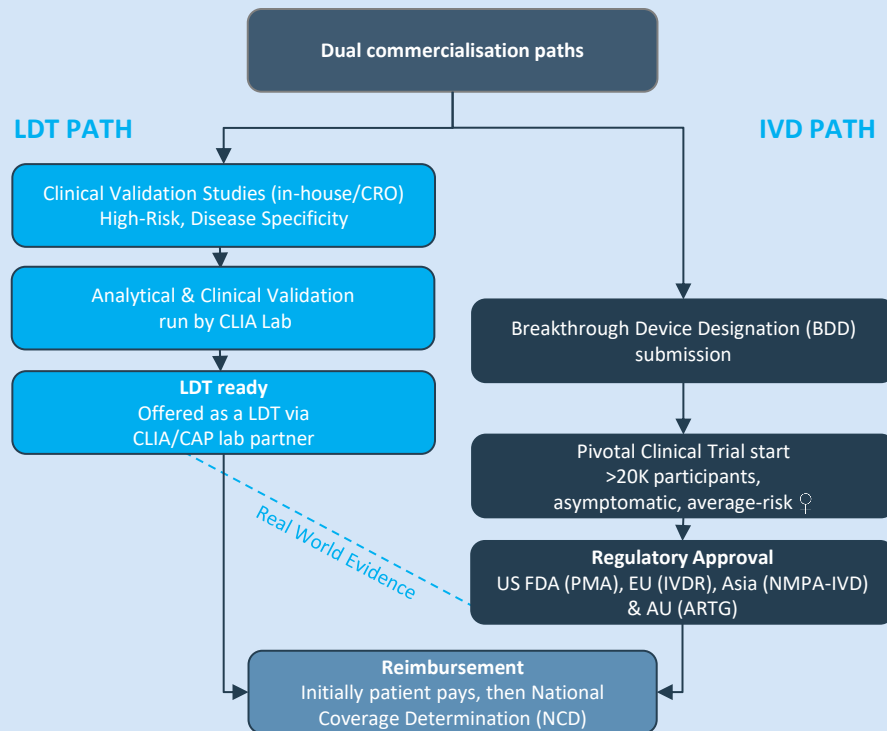
- **Objective:** Evaluate EXO-OC in healthy controls + benign compared to cancer across both average and high-risk groups
- **Study design:** retrospective analysis of biobanked samples from single provider or previous prospective study or real-world study with lab partner or CRO

LDT validation studies for OC early detection in high-risk women via US Laboratory Partner

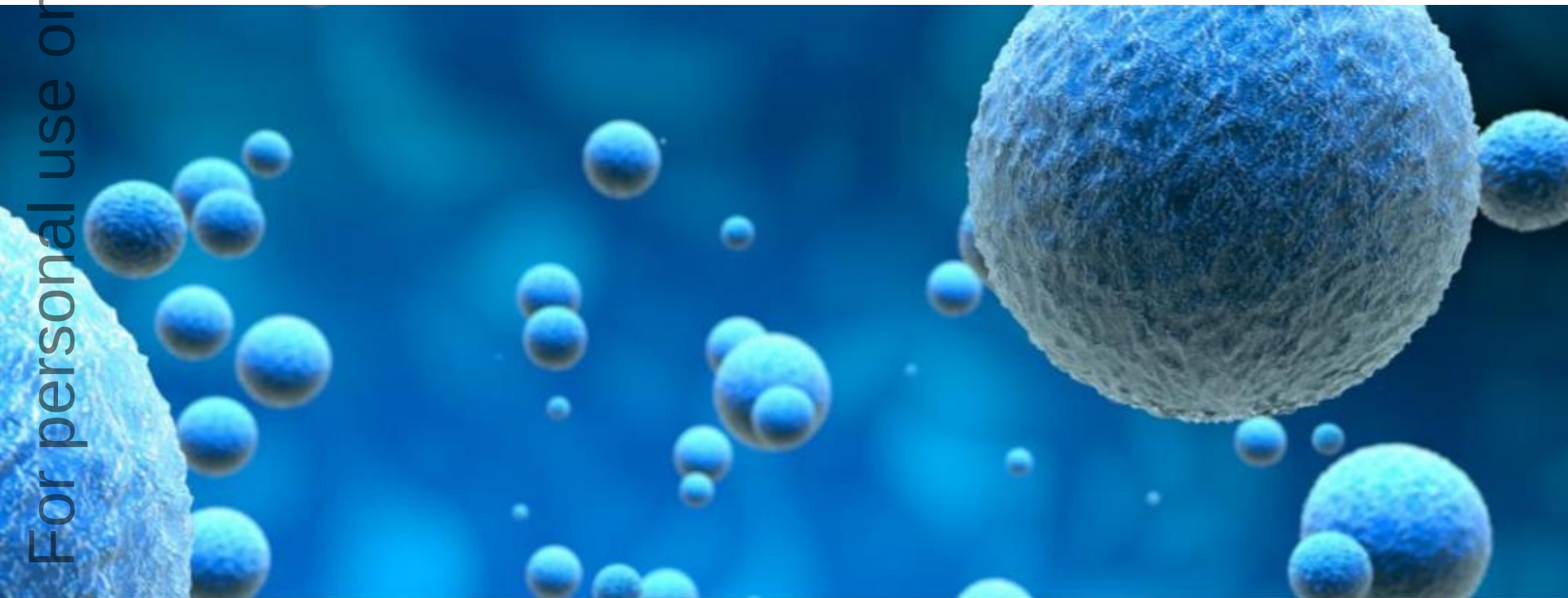
- **Intended use:** Early detection of Ovarian Cancer in *high-risk women with BRCA1/2, Lynch syndrome or family history*
- **Analytical validation** to show accuracy & reproducibility
- **Clinical validation** to demonstrate sensitivity & specificity in intended use population

IVD development for OC screening in post-menopausal women via PMA pathway with US FDA

- **Intended use:** Screening of Ovarian Cancer in *asymptomatic, average-risk, post menopausal women*
- Gain **BDD** to expedite development, enable FDA consultation & priority review
- Large-scale, prospective, **Pivotal Clinical Trial** to demonstrate clinical sensitivity, specificity and utility in intended use population



Summary and Q&A





Dual-path commercialisation strategy to maximise speed, access and value for patients, clinicians & investors

	Laboratory Developed Test (LDT)	In Vitro Diagnostic (IVD)
Partner	Laboratory partner to offer testing service via single CLIA/CAP lab	Large diagnostics company for global scale to distribute EXO-OC kits & deliver through pathology networks
Intended use	Early detection of OC in high-risk women with <i>BRCA1/2, Lynch syndrome or family history</i>	Screening of OC in <i>asymptomatic, average-risk, postmenopausal women</i>
Regulatory Path to Launch	LDT (US – CLIA states first)	IVD post regulatory approvals (US, UK, Europe, China, Asia, Australia)
Adoption	Peer reviewed publications & presentations Build KOL network	+ Pivotal Clinical Trial (prospective, multi-centre) + Health economic modelling & HTA + Clinical guideline inclusion (USPSTF, NICE, NCCN, ACOG)
Reimbursement	Patient-Pay initially Build evidence for PLA code & reimbursement	Public & Private payers Medicare & Medicaid, Others
Advantages	Fastest path-to-market Early access for patients Early revenue Real-world evidence to support IVD filings	Broader clinical adoption Global market reach Sustainable growth Higher reimbursement & guideline potential



IN VITRO DIAGNOSTIC (IVD)

Screening in Asymptomatic, Average-risk Women

Targeting same cohort of women as screened ~1-2 yrs for breast cancer as per clinical guidelines

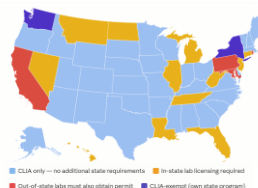
Average 60% mammography screening uptake across major markets

Market	Eligible Population (45-74yo) ¹	Screening Participation	Addressable Population ¹¹
China	282,713,102	51.4% ²	145,201,449
USA	60,689,385	75.7% ³	45,941,864
Japan	24,907,722	46.9% ⁴	11,681,721
Germany	17,197,363	51.0% ⁵	8,770,655
UK	12,639,038	64.6% ⁶	8,164,818
Italy	12,968,521	43.0% ⁷	5,576,464
France	12,674,444	60.0% ⁸	7,604,666
Spain	10,279,808	74.7% ⁹	7,676,961
Australia	4,636,304	54.2% ¹⁰	2,512,877
TOTAL	438,705,684	57.9% ²⁰	243,131,475

potential to reach **~243M women every 2yrs** across 9 major markets

LABORATORY-DEVELOPED TEST (LDT)

Early Detection in High-risk Women



Initial launch in states requiring CLIA certification only (light blue)¹²

1-2 tests p.a. for high-risk women¹³

Estimated US\$1000 per test¹⁴

Estimated Adult Women (30+) In High Risk Categories	Population Rate	Total US Women	CLIA-Only States
Family History of Ovarian Cancer	5.00%	5,300,019	2,107,085
BRCA1 or BRCA2 Mutations	0.25%	265,001	105,354
Lynch Syndrome	0.36%	381,601	151,710
Total Estimated High Risk Adult Women		5,946,622	2,364,150

Potential for double-counting across high-risk groups e.g. BRCA positive women likely to have a family history

Total number of women in the US: 167M all ages, 106M 30yrs & over

US\$2.4 – 4.8B annual TAM in CLIA states

¹ [United Nations, Data Portal, Population Division, 2024 data](#); 2-11 refer to appendices for country-specific mammography uptake figures; 12. CLIA certification is the minimum laboratory requirement, labs located in CLIA-only jurisdictions without additional state requirements potentially offer the fastest path to market; 13. Assumes testing 1 to 2x per year; 14. Indicative price based on US list price and reimbursement for early cancer detection LDTs ranging from US \$600-3000. Pricing analogue is ClearNote Health Avanteck® Ovarian Cancer Test with CMS reimbursement recommendation of US \$1,160; 15. [Lighthouse Lab Services State-By-State Laboratory Licensing Information](#) – visualisation by Claude; 16. US census data 2024; 17. Family history default 5%: commonly cited for first-degree FH per NCCN/ACS, range from literature: ~1.5% (strict first-degree, BRFS) to ~10% (incl. second-degree), other high risk categories internal modelling based on various literature sources; **TAM** = Total Addressable Market.



INOVIQ is developing next-generation exosome-based diagnostics and therapeutics that transform cancer care

Our strategy is to provide integrated diagnostic and therapeutic solutions that enable earlier detection and more targeted treatment of solid tumours to improve patient outcomes

DIAGNOSTICS	INDICATION	USE	DISCOVERY	ASSAY DEVELOPMENT	CLINICAL	IN-MARKET
EXO-OC LDT	Ovarian Cancer	Early detection, high risk				
EXO-OC IVD	Ovarian Cancer	Screening, average risk				
THERAPEUTICS	INDICATION	USE	DISCOVERY	PRE-CLINICAL	CLINICAL	APPROVAL
EEV-001	Breast Cancer	CAR-Exosome therapy	<i>in vivo</i>			
EEV-002	Lung Cancer	CAR-Exosome therapy	<i>in vitro</i>			
EEV-003	Ovarian Cancer	CAR-Exosome therapy	<i>in vitro</i>			

Summary | Focus remains on progressing our high-value exosome pipeline



Exosome leader

Leading exosome company with platform technology developing advanced cancer diagnostics and therapeutics



Critical unmet need for OC screening

Clinical-stage EXO-OC test addressing critical unmet need for ovarian cancer screening in 243m women globally



Early detection saves lives

Early detection of ovarian cancer with potential to improve diagnosis, treatment and outcomes



High-value therapeutics pipeline

Preclinical CAR-exosome platform with potential cost, safety & efficacy advantages over cell therapy



Partnering underway

Active LDT partner discussions for validation and commercialisation in US



Multiple value triggers

Funded to deliver upcoming catalysts in 2026

Priorities

1. Complete **EXO-OC™ development & validation** in case-control and high-risk groups
2. Progress EXO-OC™ toward **LDT-ready status** and **US laboratory partnering**
3. Accelerate **CAR-exosome therapeutics program**, including manufacturing readiness and preclinical data generation in solid tumours
4. Continue disciplined **capital allocation**, prioritising programs with the strongest near-term value potential
5. **Enhance shareholder value**



Dr Leearne Hinch BVMS MBA
Chief Executive Officer

e. lhinch@inoviq.com



Dr Rebecca Lim PhD
Chief Scientific Officer

e. rlim@inoviq.com



Dr Emma Ball PhD MBA GAICD
Chief Commercial Officer

e. eball@inoviq.com



Prof Gregory Rice PhD MHA
Founding Scientist & Advisor

e. grice@inoviq.com



Mark Edwards BAcc CA
CFO & Company Secretary

e. medwards@inoviq.com