CLEO DIAGNOSTICS

PIONEERING THE TRANSFORMATION OF OVARIAN CANCER DETECTION

Corporate Presentation

JUNE 2025

ASX: COV

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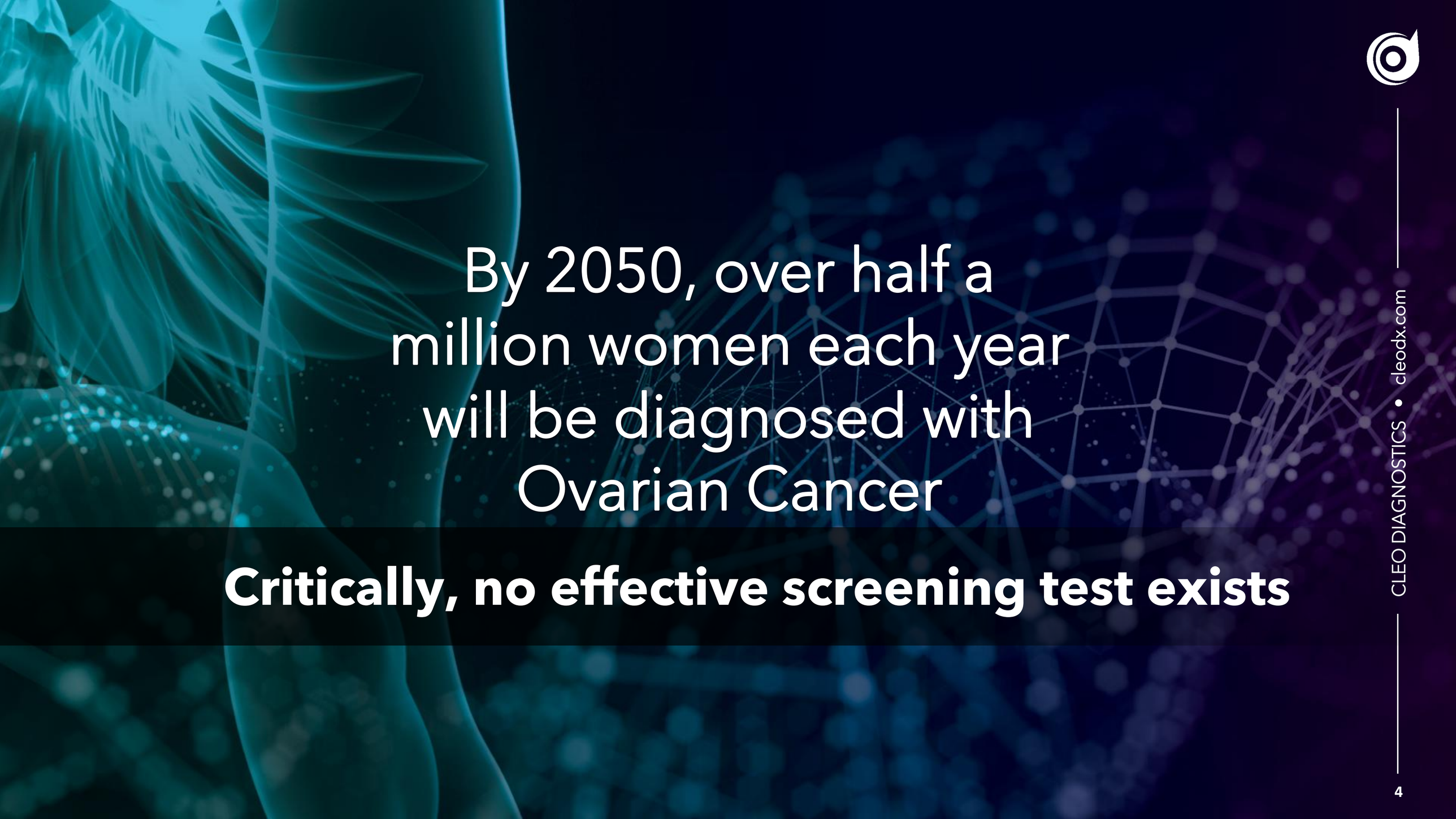
INVESTMENT HIGHLIGHTS

- Addresses a critical unmet need on a global scale
- Disruptive patented technology for the early detection of Ovarian Cancer
- Significant addressable market with initial focus on the U.S.
- Near term revenue potential with a staged execution strategy

Capital Structure	
ASX Ticker	COV
Share Price (10 June 2025)	$0.375
Shares on Issue	128.5M
Options	15.25M
Performance Options	1.5M
Market Capitalisation (fully diluted)	~$54.5M
Cash (as at 31 March 2025)	~$6.4M



By 2050, over half a million women each year will be diagnosed with Ovarian Cancer

Critically, no effective screening test exists

THE SILENT KILLER – WHY EARLY DETECTION IS KEY

Currently, the only way to diagnose Ovarian Cancer is after surgery

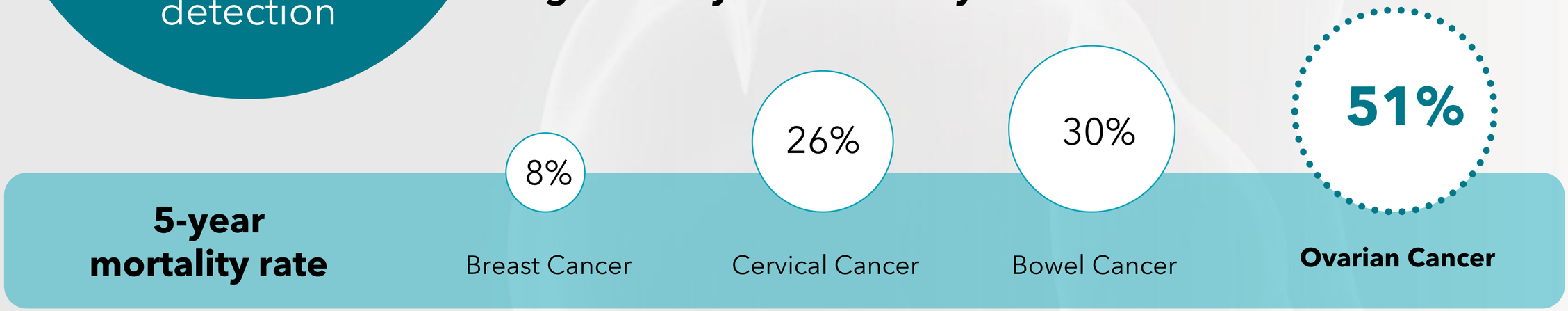
Ovarian Cancer is one of the deadliest of all cancers affecting women, primarily due to late detection

The clinical unmet need for a screening solution is urgent.

51% of women continue to die within 5 years of an Ovarian Cancer diagnosis.

That's 6 times higher than Breast Cancer.

For other cancers, accurate and early detection through screening programs and fit-for-purpose diagnostic tests has significantly increased 5-year survival rates.



Source: World Health Organisation, Australian Institute of Health and Welfare supplemented by American Cancer Society. World Ovarian Coalition

LIMITATIONS OF CA125 AS A SCREENING TOOL

A biomarker with clinical value, but insufficient for early detection or population screening

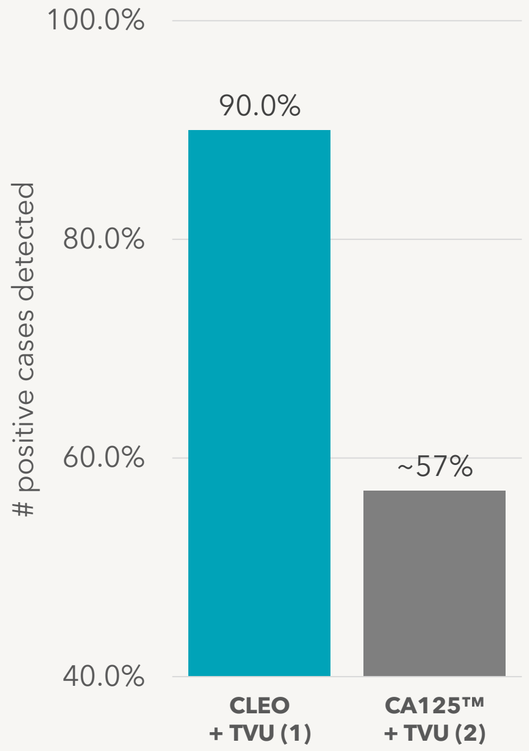
Key limitations of CA125

Low sensitivity in early disease	Misses up to 50% of early-stage ovarian cancers
Poor specificity	Elevated in benign conditions e.g. endometriosis, menstruation
No proven mortality benefit	Large trials (e.g. UKCTOCS) show no significant reduction in deaths
Biological variability	Some patients with advanced disease never show elevated CA125
Not viable for average-risk women	High false positives lead to overdiagnosis and unnecessary interventions

How CLEO's test overcomes the shortfalls of CA125

Solves the Early Detection Gap	Detects ovarian cancer earlier than CA125, addressing the key clinical shortfall
High specificity	Not elevated in benign conditions, reducing false positives & downstream costs
Strong Early-Stage Detection	Offers sensitivity where it matters most – improving potential survival outcomes
Subtyping Strength	Potential to detect across a broader range of ovarian cancer types
Novel Mechanism	Inflammatory chemokine linked directly to tumour biology, not just presence of a mass
Mass Market Opportunity	Unlocks potential for population-level or risk-based screening in average-risk women
Commercial Edge	Positioned to disrupt a stagnant diagnostics space with a high-need solution

CLEO's Test vs CA125 Test for Early Detection[1]



[1] Stephens AN et al DOI: 10.3390/cancers16112048
[2] Burke W et al DOI: 10.1097/AOG.0000000000005211

CLEO’s disruptive patented technology offers superior performance to current clinical tests

CLEO's PATENTED NOVEL BIOMARKER: CXCL10

CXCL10 is a biological marker that is highly expressed in Ovarian Cancer from an early stage

Over 15 years of funded research confirm it to be a robust indicator across all stages of Ovarian Cancer

Superior performance with 95% sensitivity and 95% specificity compared to current CA125 test (94% / 82%)[1]

CLEO's technology discriminates benign from malignant

Dr Andrew Stephens

Biomarker founder &
CLEO Chief Scientific Officer

Research and Development originally funded by

HUDSON INSTITUTE OF MEDICAL RESEARCH

OVARIAN CANCER RESEARCH FOUNDATION

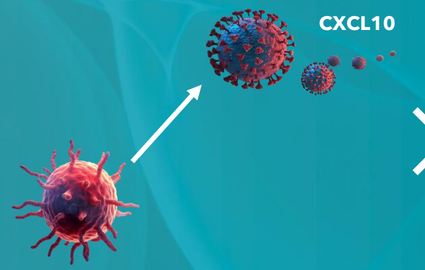
Australian Government
National Health and Medical Research Council

[1] Davenport, C., et al., DOI:10.1002/14651858.CD011964.pub2, Stephens, AN., et al., DOI: 10.3390/cancers16112048, Stephens, AN., et al., DOI:10.3390/cancers 15215267

ROLE OF CXCL10 IN OVARIAN CANCER DEVELOPMENT

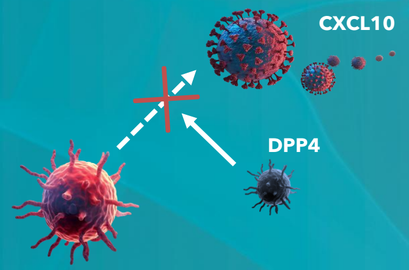
CLEO's biomarker, CXCL10, plays a pivotal role in the immune system's ability to recognise and attack Ovarian Cancer in its early stages

1. Tumour Initiation



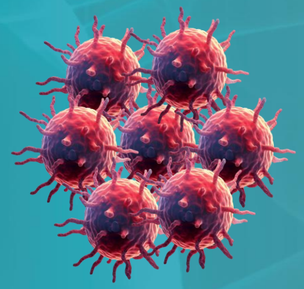
Ovarian cells begin to form early lesions and release CXCL10 to call for immune system help

2. Immune Disruption



Another molecule (DPP4) interferes with CXCL10 by breaking it down, weakening the immune alert system.

3. Immune Suppression



Without a strong immune response, the tumour can grow unchallenged. By the time symptoms appear, the cancer is often at a more advanced stage.

Why CXCL10 Matters

- Early Warning System:
  CXCL10 appears early—before symptoms arise—making it ideal for early detection
- Reliable Marker:
  It's stable and measurable, even when the cancer is still silent.
- Smart Detection Tools:
  Cleo's technology identifies this early immune signal, even when the tumour tries to hide it—helping doctors catch the disease sooner

DISRUPTIVE PATENTED TECHNOLOGY

CLEO has developed a proprietary algorithm underpinned by its novel biomarker, CXCL10, which can be used to detect the presence of Ovarian Cancer from a patient's blood sample

BLOOD SAMPLE

Doctor orders blood test. No additional process required

PATHOLOGY LAB

CLEO's test can be run on standard pathology equipment, making it highly accessible

CLEO's TECHNOLOGY

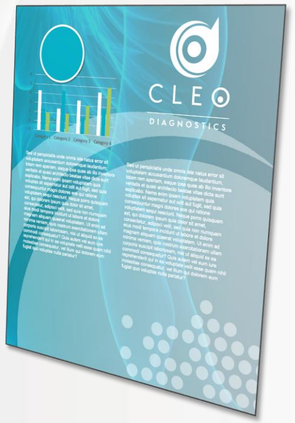
Multi-biomarker panel combined with a proprietary algorithm to produce a highly accurate risk of malignancy score that is assessed by a doctor to determine appropriate treatment

Highly accurate

Differentiates malignancy

Identifies early stage

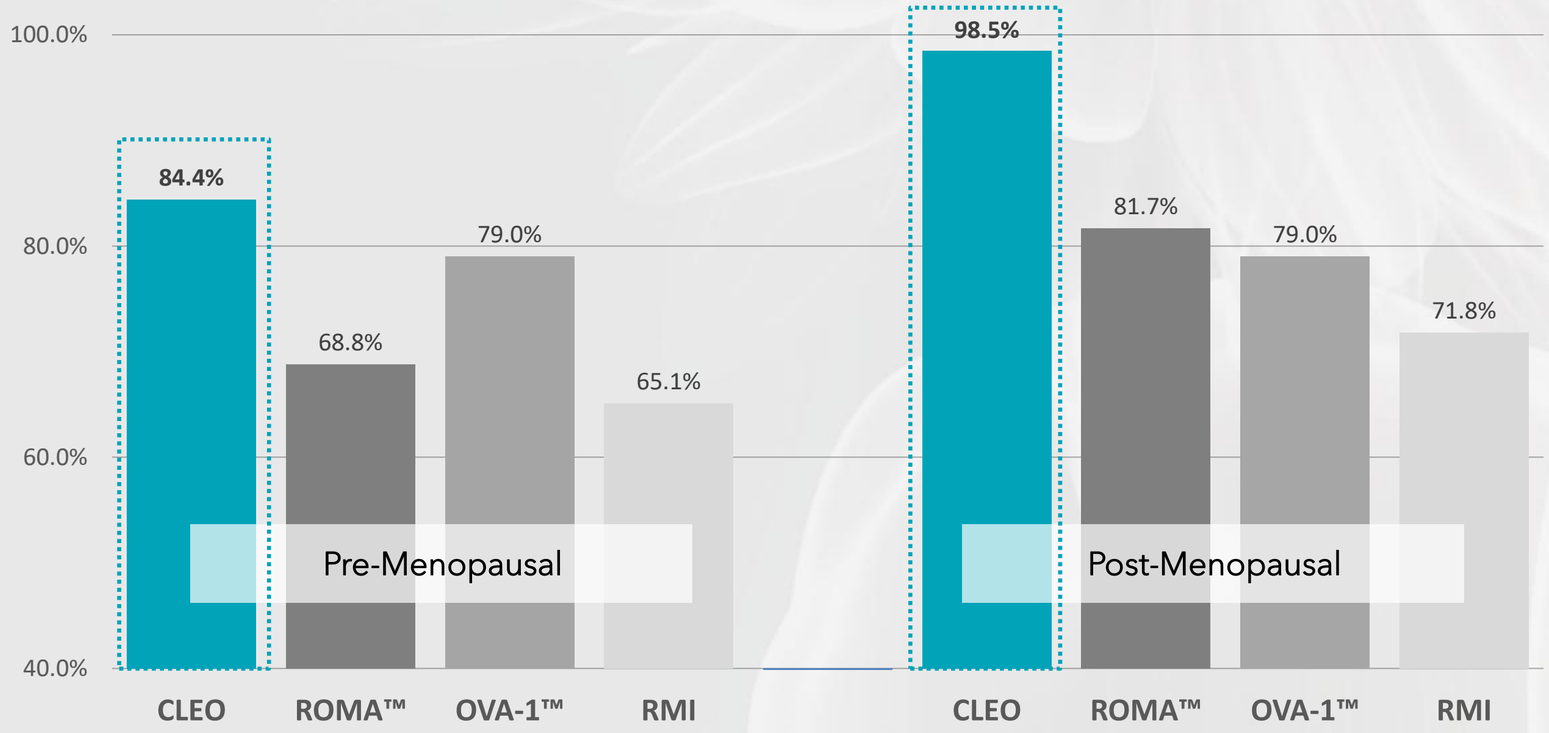
RESULT



MATERIALLY OUTPERFORMS EXISTING PRE-SURGICAL TESTS

CLEO's test outperforms all other clinical tools currently in-use, regardless of menopausal status

Sensitivity of CLEO's Pre-Surgical Test vs Other Tests[1]



**Specificity fixed at 90% for comparative purposes*

CLEO's Competitive Advantage

Superior performance regardless of menopausal status, making it universally easier to adopt

Greater accuracy increases potential to receive higher reimbursement

[1] Stephens, AN., et al., DOI:10.3390/cancers 15215267 Davenport, C., et al., DOI:10.1002/14651858.CD011964.pub2 D Fritsche, H.A. DOI: 10.1002/ijgo.14733. Bristow, R.E DOI: 10.1016/j.ygyno.2012.11.022

UKCTOCS: THE LARGEST OVARIAN CANCER SCREENING TRIAL

Collaboration Agreement a Major Step Forward for CLEO's Screening Test Development Program

- UK Collaborative Trial of Ovarian Cancer Screening (UKCTOCS) was conducted at University College London (UCL) with the aim to evaluate if population screening using existing tools can save lives
- The trial ran for over 20 years, involving 200,000 postmenopausal women aged 50-74 in the UK, and collected over 500,000 samples
- **The trial determined that current clinical tools, such as CA125, did not reduce mortality and cannot be recommended as a screening test in the general population.**

The UCL collaboration will accelerate test development and ultimately deliver a screening test for early Ovarian Cancer detection

CLEO has secured access to 2,000 highly sought after UKCTOCS blood samples

Two clinical studies to be conducted aimed at validating performance

Provides credible and independent endorsement of CLEO's technology

> *The performance data and evidence behind CLEO's technology are very encouraging, and we are excited to work with CLEO to assess how its tests can potentially be used in detection and screening strategies to reduce mortality from the disease.*

– Professor Usha Menon
World-leading gynaecological oncology expert

Ovarian Cancer is known as "*the silent killer*" due to its non-specific symptoms which often go untreated

SIGNIFICANT TOTAL ADDRESSABLE MARKET

CLEO is strategically targeting three key markets in phased execution, with the goal to establishing a transformative mass screening market where none currently exists today

PRE-SURGICAL MARKET

1M
women[1]

Blood test to distinguish benign from malignant disease in women with a pelvic mass prior to surgery.

Near-Term

RECURRENCE MARKET

1.2M
tests[2]

Regular blood test to monitor women post surgery and/or Cancer diagnosis to identify relapse early.

Mid-term

SCREENING MARKET

148M
women[2]

A blood test to identify early-stage ovarian cancers in patients WITHOUT symptoms.

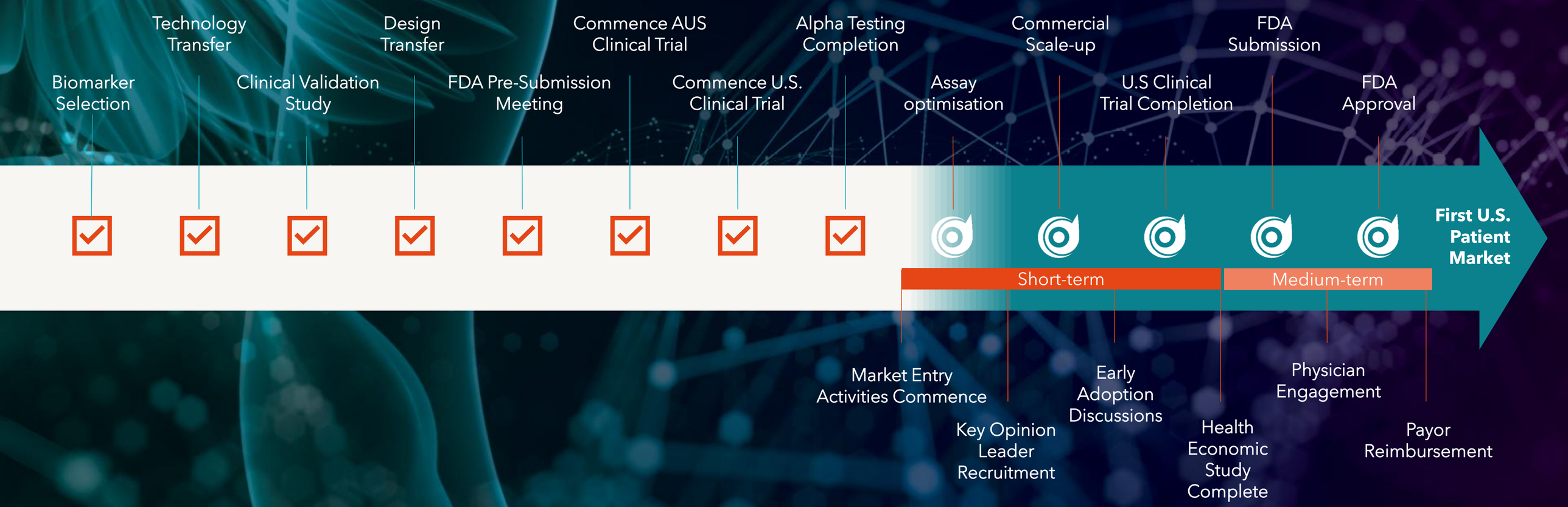
Long-Term

CLEO is initially targeting the existing pre-surgical market via a 510(k) submission under substantial equivalence. Success in the initial pre-surgical market will unlock the pathway to a mass screening market

[1] Refers to the U.S. [2] Refers to worldwide. Access to addressable markets is limited by items such as patent protection, regulatory approvals and access to distribution, amongst other factors. There are no guarantees that CLEO will be able to receive approval to distribute its products in its target addressable markets or adequately enforce its intellectual property in such markets.

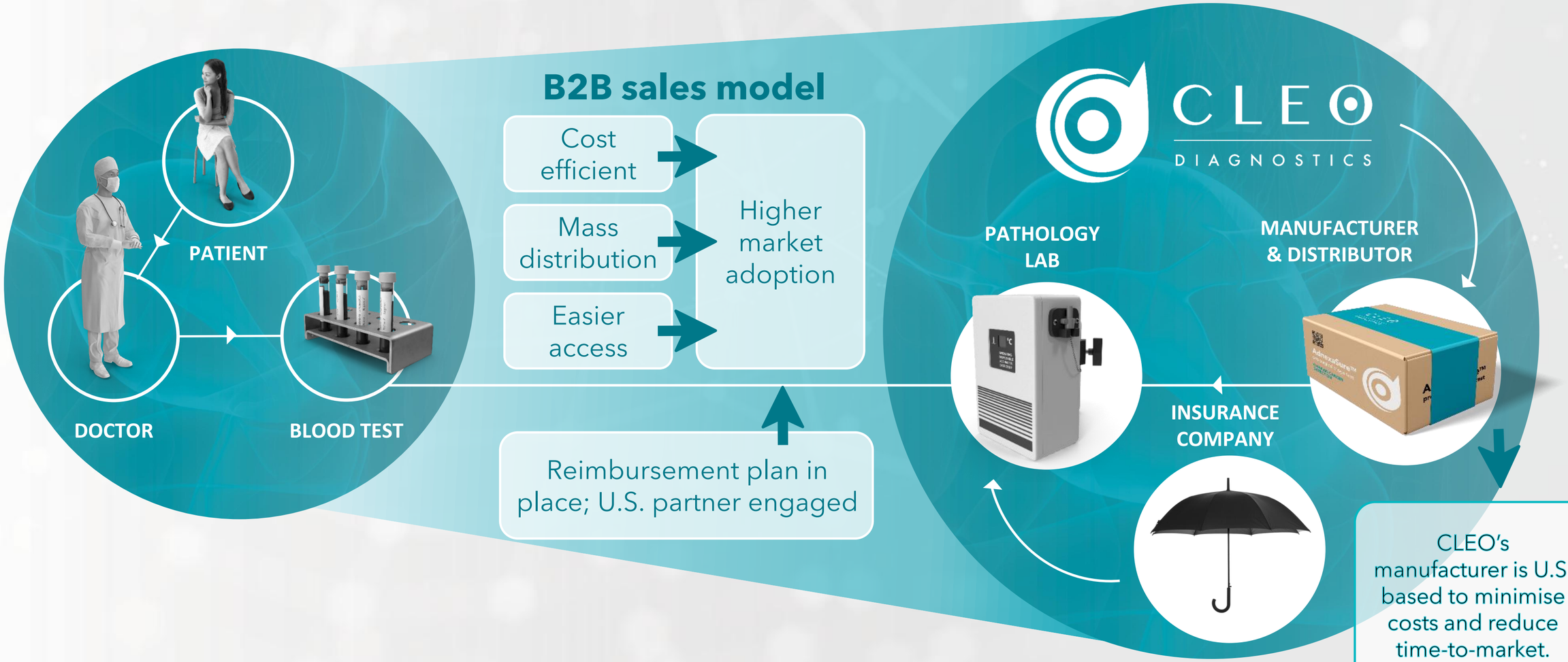
PATHWAY TO MARKET

CLEO has advanced-stage Ovarian Cancer detection technology with line of sight to first revenue



COMMERCIAL MODEL

CLEO will operate out of the U.S. through a B2B sales model to maximise patient accessibility, increase market adoption and maximise margins



INVESTMENT SUMMARY

- Disruptive patented technology for the early detection of Ovarian Cancer
- Significant opportunity to deliver a much-needed solution to women globally
- Superior performance to existing tests supported by published clinical studies
- Staged execution strategy with experienced team to deliver.

MANAGEMENT TEAM

Highly experienced team focused on execution

Board of Directors

ADRIEN WING

Non-Executive Chairman

Mr Wing is CPA qualified with over 25 years of experience in the corporate sector, particularly in ASX small-cap companies, he has led numerous IPOs, reverse takeovers, and acquisitions across various industries and jurisdictions.

Bachelor of Business (Accountancy) from Royal Melbourne Institute of Technology (RMIT) and Certified Practicing Accountant (CPA).

DR RICHARD ALLMAN

Executive Director and CEO

Dr. Allman has wide experience in research leadership, innovation management, and intellectual property strategy, covering oncology, diagnostics, and product development.

PhD (Microbiology) from The University of Wales.

DR ANDREW STEPHENS

Executive Director and CSO

Career research scientist and inventor of the CLEO's core technology. Dr Stephens has over 60 academic publications and numerous patents (pending and provisional) in the cancer therapeutic and diagnostic space.

PhD (Molecular Biology) from Monash University Australia.

LUCINDA NOLAN

Non-Executive Director

Ms Nolan was most recently the CEO of the Ovarian Cancer Research Foundation. Notable as the first female CEO of the Country Fire Authority and Deputy Commissioner of Victoria Police. She is an alum of the Advanced Management Programme at Harvard University.

Master of Arts from Melbourne University, Batchelor of Arts with Honours from Melbourne University, Alumni of the Advanced Management Programme at Harvard University.

PROFESSOR TOM JOBLING

Executive Director and Medical Advisor

Dr Jobling is a surgeon who has been treating ovarian cancer for more than 30 years. Dr Jobling is the head of gynaecological oncology at Monash Health and visiting medical officer at the Peter MacCallum Cancer Centre and the cofounder and former chairman of the OCRF.

Bachelor of Medicine, Bachelor of Surgery, Fellow of the Royal College of Obstetricians and Gynaecologists, Fellow of Royal Australian and New Zealand College of Obstetricians and Gynaecologists, Certificate of Gynaecological Oncology.

Core Team

DAYNA LOUCA

Head of Corporate Development

NATHAN HODGSON

Head of Operations

EMMA LESTER

Quality and Regulatory Manager

LEONA CHAN

Project Manager

SIMON HOBBS

Data Scientist

NAHO KAWASE

Laboratory Scientist

PAULINE MOFFATT

Company Secretary

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APPENDIX ONE: Evidence Base

RESEARCH PAPERS

1. Stephens AN, Hobbs SJ, Kang S-W, Oehler MK, Jobling TW, Allman R (2024). **Utility of a Multi-Marker Panel with Ultrasound for Enhanced Classification of Adnexal Mass**. *Cancers* doi: 10.3390/cancers16112048
2. Stephens AN, Hobbs SJ, Kang S-W, Bilandzic M, Rainczuk A, Oehler MK, Jobling TW, Plebanski M, Allman R (2023). **A Novel Predictive Multi-Marker Test for the Pre-Surgical Identification of Ovarian Cancer**. *Cancers* doi: 10.3390/cancers 15215267
3. Stephens AN, Hobbs SJ, Kang S-W, Oehler MK, Jobling TW, Allman R (2024). **ReClassification of Patients with Ambiguous CA125 for Optimised Pre-Surgical Triage**. *Cancers* doi: 10.3390/diagnostics14070671
4. Kampan NC, Kartikasari A, Deceneuux C, Madondo MT, McNally OM, Flanagan KL, Aziz NA, Stephens AN, Reynolds J, Quinn MA, Plebanski M (2023). **Combining TNFR2-Expressing Tregs and IL-6 as Superior Diagnostic Biomarkers for High-Grade Serous Ovarian Cancer Masses.** *Cancers* doi: 10.3390/cancers15030667
5. Sung-Woog Kang S-W, Rainczuk A, Oehler MK, Jobling TW, Plebanski M, Stephens AN (2021). **Active Ratio Test (ART) as a Novel Diagnostic for Ovarian Cancer. *Diagnostics*** doi.org/10.3390/diagnostics11061048
6. Wilson AL, Moffitt LR, Wilson KL, Bilandzic M, Wright MD, Gorrell MD, Oehler MK, Plebanski M, Stephens AN (2021). **DPP4 inhibitor sitagliptin enhances lymphocyte recruitment and prolongs survival in a syngeneic ovarian cancer mouse model**. *Cancers* doi.org/10.3390/cancers13030487
7. Moffitt LR, Bilandzic M, Wilson AL, Chen Y, Gorrell MD, Oehler MK, Plebanski M, Stephens AN (2020). **Hypoxia Regulates DPP4 Expression, Proteolytic Inactivation, and Shedding from Ovarian Cancer Cells.** *Int J Mol Sci* doi: 10.3390/ijms21218110
8. Kampan NC, Madondo MT, McNally OM, Stephens AN, Reynolds J, Quinn MA, Plebanski M (2020). **Pre-operative sera interleukin-6 in the diagnosis of high-grade serous ovarian cancer.** *Scientific Reports* doi: 10.1038/s41598-020-59009-z.
9. Rainczuk A, Rao JR, Gathercole JL, Fairweather NJ, Chu S, Masadah R, Jobling TW, Stephens AN (2014). **Evidence for the Antagonistic Form of CXC-motif Chemokine CXCL10 in Serous Epithelial Ovarian Tumours.** *Int J Cancer* 134 530-41
10. Rainczuk A, Rao J, Gathercole J, Stephens A.N. (2012). **The emerging role of CXC chemokines in epithelial ovarian cancer.** *Reproduction* 144 pp. 303-317

APPENDIX TWO: Clinical Trials for Pre-Surgical Test

ONGOING TRIALS

U.S. Clinical Trial

Multi-site validation study

9 active trial sites

Lindus Health appointed CRO

Expected completion in 2025

AUS Clinical Trial

Multi-site prospective observational study

3 active trial sites

Expected completion in 2025

Completion of U.S. clinical trials will enable

510(k) submission

through substantial equivalence to the FDA

TRIAL OBJECTIVES & END POINTS

Primary Objectives

1. Determine the CLEO adnexal mass score in patients identified with an adnexal mass requiring surgery, but who have not undergone surgery.
2. Correlate post-surgical pathology findings with the CLEO adnexal mass score and evaluate the performance metrics (including primary endpoints) of the CLEO adnexal mass assessment scoring system.
3. Demonstrate superiority of the CLEO adnexal mass scoring system compared to standard clinical workflows including ROMA (predicate device).
4. Collect robust clinical performance data to support a 510(k) submission to the FDA, demonstrating the effectiveness of the pre-surgical triage test for its intended use.

Primary End Points	Secondary End Points
1. **Sensitivity** 2. **Specificity** 3. **Positive Predictive Value (PPV)** 4. **Negative Predictive Value (NPV)**	To assess the accuracy of the test when used alongside physician assessment (PA), which incorporates clinical evaluation and radiological findings, compared to PA alone. The dual assessment will be considered successful if it demonstrates a statistically significant improvement in diagnostic accuracy over PA alone, as indicated by higher sensitivity and/or specificity.

https://clinicaltrials.gov/study/NCT06566716?cond=ovarian%20cancer&term=diagnostic&aggFilters=sex:f,status:rec,studyType:obs&rank=6

APPENDIX THREE: Current Standard of Care

Currently, no diagnostic or screening test exists for Ovarian Cancer

Research shows most women with Ovarian Cancer were seeing their doctor about symptoms for *more than six months* before they received a diagnosis

Unexplained weight fluctuation

Abdominal pain or pressure

Indigestion, gas and nausea

Changes in bladder patterns

Low back ache or cramps

Abnormal vaginal bleeding

CA125
Protein Biomarker Blood Test

TVU
Transvaginal Ultrasound

ROMA™
Risk of Ovarian Malignancy Algorithm

OVA1™
Protein Biomarker Blood Test

RMI
Risk Malignancy Index

Late-stage diagnosis

High recurrence

Low survival rate

Patient presents with multiple non-specific symptoms

Doctors use a range of tools to try to diagnose but ultimately, surgery must be performed

Diagnosis is made AFTER surgery