IMAGENDO®



Revolutionising Endometriosis Diagnosis with Machine Learning and Imaging



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The Problem: Diagnostic Delay

- Endometriosis: affects 11% of reproductive aged women (190 million) globally:
 - incurable chronic inflammatory disease
 - severe pain, heavy menstrual bleeding, bleeding between periods, abdominal bloating, fatigue, anxiety, infertility
 - consequential annual work loss productivity worth \$30,900 per patient
- Lack of specialised imaging capability amongst sonographers and radiographers (eTVUS and eMRI):
 - confirmatory diagnosis for endometriosis has been through laparoscopic surgery for visual identification
- Normalisation of symptoms which are non-specific:
 - lack of awareness of specialist endometriosis imaging by General Practitioners,
 - 6.4-year delay from first symptoms to diagnosis by gynaecologist







The Solution: IMAGENDO®

- Machine Learning Model Learnable Cross-Modal Knowledge Distillation (LCKD)
 - detects important markers of endometriosis
 - uses either a magnetic resonance imaging (MRI) scan or a transvaginal ultrasound (TVUS) scan video clip
 - Pouch Of Douglas: 95% accuracy, 98.8% specificity, 65.0% sensitivity for eTVUS;
 85% accuracy for eMRI
 - Bowel Nodules: 86% accuracy for eTVUS;
 70% accuracy for eMRI
- IMAGENDO® will be sold as a diagnostic support tool
 - to imaging clinics as a "plug in" picture archiving and communications system (PACS) analytical software
 - highlights definitive signs of endometriosis on MRIs and TVUS
 - enables the imaging clinic to provide a non-surgical confirmatory diagnosis service.
- This diagnostic approach aligns with the European Society of Human Reproduction and Embryology's (ESHRE) Guidelines for Endometriosis

Are medical technologies reliable in diagnosing endometriosis and establishing the extent of the disease?

Clinicians should not use measurement of biomarkers in endometrial tissue, blood, menstrual or uterine fluids to diagnose endometriosis (Mol et al., 1998; May et al., 2010; May et al., 2011; Liu et al., 2015; Cosar et al., 2016; Gupta et al., 2016; Hirsch et al., 2016; Nisenblat et al., 2016a; Vanhie Jl., 2019; Moustafa et al., 2020).

Clinicians are recommended to use imaging (ultrasound (US) or MRI) in the diagnostic work-up for endometriosis, but they need to be aware that a negative finding does not exclude endometriosis, particularly superficial peritoneal disease (Bazot et al., 2009; Manganaro et al., 2012; Guerriero et al., 2014; Thomeer et al., 2014; Nisenblat et al., 2016b; Moura et al., 2019).

cal treatment was unsuccessful or inappropriate, the GDG recommends that clinicians consider offering laparoscopy for the diagnosis and treatment of suspected endometriosis.

The GDG recommends that laparoscopic identification of endometriotic lesions is confirmed by histology although negative histology does not entirely rule out the disease.

Strong recommendation

Strong recommendation

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IMAGENDO® Advantage







- First non-surgical diagnostic system for endometriosis.
- Highlights an endometriosis marker in 0.5 seconds
 - time effective aid for imaging clinics
- IMAGENDO® diagnostic platform trained on 2 modalities
 - adapts to either modality input
- No additional safety considerations beyond current exposures to existing commercially used MRI and ultrasound machines.
- Will grow service offering of imaging clinics by 30% in Australia
- IMAGENDO® Team clinical end-user driven development
- Recognition:
 - Australian Museum / Australian Nuclear Science and Technology Organisation Eureka Award for **Innovative Use of Technology 2023**







• IEEE International Symposium on Biomedical Imaging, Columbia 2023, Best Oral Presentation







IMAGENDO® Commercial Considerations

2020

Seed Funding, AGES, Endometriosis Australia

June 2021

Patient recruitment website to collect and collate scans https://imagendo.org.au/ **Initial MRFF Funding.**

Oct 2022 Regulatory Strategy Plan completed by Kd&A

Sept 2023 **Provisional Patent - multimodal and distillation** capability – filed

Sept 2024

2025

Patent Cooperation Treaty (PCT)

Action plan for regulatory pathway, governs our current development plan Business Model:

- Customer: diagnostic imaging clinics
- Revenue model:
 - Annual subscription fee of \$4,000 for TVUS and \$6,000 for MRI machines
 - User licence @\$400 per user
- Australian addressable market: \$27.7 million annually based on 2774 clinics
- US addressable market: \$60 million annually based on 6000 clinics
- Public Reimbursement status quo

medicare • *55065* Medicare Fee: \$106.45 Benefit: 75% = \$79.85 85% = \$90.50

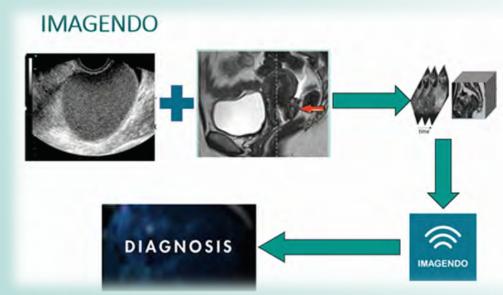
• *63563* Medicare Fee: \$426.50 Benefit: 75% = \$319.90 85% = \$362.55

IMAGENDO® Development Plan & Investment Proposal

IMAGENDO® trained on a dataset of 9000 MRIs & 1200 TVUS video clips.

What's next?

- Grow datasets through new global recruitment nodes to cover various populations for regulatory robustness and increased endometriosis markers.
- New national and international nodes lined up:
 - Australia: Epworth Health (Vic), King Edward Memorial Hospital (WA) Haven Ultrasound (QLD)
 - New Zealand: Advanced Gynaecology Auckland and Mercy Radiology Group
 - United States: Cleveland Clinic (Ohio), Mayo Clinic (Minn.), UCLA, University of Southern Florida, Brigham and Women's Hospital (Mass.)
 - United Kingdom: University of Cambridge
 - Indonesia: the University of Indonesia (Jakarta)
 - The Netherlands: Erasmus Medical Centre
 - Brazil: Chamie Clinic, Sao Paulo
- Investment required to
 - accommodate a global privacy-preserving Federated Learning AI system, and the cost of the recruitment nodes' upskilling and scanning amounts to A\$2,995,795







Contact: IMAGENDO®

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and the Lions Club.

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Results: POD Obliteration Classification

Method	Training Modality	Testing Modality	AUC mean±stddev
3D ViT	MRI	MRI	0.650±0.102
3D ViT + MAE Pretraining	MRI	MRI	0.872±0.094
3D ViT + Knowledge Distillation	MRI, TVUS	MRI	0.667±0.107
3D ViT + MAE Pretraining + Knowledge Distillation	MRI, TVUS	MRI	0.772±0.087
3D ViT + MAE Pretraining + Fine Tuning + Knowledge Distillation	MRI, TVUS	MRI	0.906±0.099

