

## **Catalyst Partnership Grants**

**Investment Case** 

Message from the heart: a new solution to screen for blood vessel calcification

Professor Joshua Lewis, PhD, FASBMR School of Medical and Health Sciences Edith Cowan University





## Executive summary: A new solution to screen for blood vessel calcification, enabling earlier detection and prevention



#### **Current State**

- Cardiovascular Disease (CVD) is responsible for 11% of all hospitalisations, whilst 1 in 4 deaths had CVD as the underlying cause of death.<sup>1</sup>
- More than 1 in 4 Australians suffering a heart attack have no known risk factors for CVD.<sup>2</sup>
- CVD costs the Australian healthcare system \$12.7B per year.<sup>3</sup>
- Heart health checks and heart calcium scores only tell part of the story.
- In 2024, 209,025 Australians underwent a Heart Health Check – representing 2.14% of the population aged between 45-79 years of age.<sup>4</sup>
- Calcium is often detectable earlier in the abdominal aortic blood vessel than heart blood vessels, providing an opportunity for earlier detection.



We are seeking **\$4.0M** over the next **3 years** to enable us to deliver our solution to market.

#### Solution

- We have developed an **Al-driven solution** to automatically detect and estimate Abdominal Aortic Calcium (AAC) from low-cost, widely available Dual-Energy X-Ray Absorptiometry (DEXA) scans.
- Our solution can predict those patients which are **1.8 2x** more likely to have a future CVD event.
- AAC is a low cost, easily applied solution that allows early CVD risk detection and intervention, in addition to late-life dementia, falls and fractures.
- There are ~700,000 clinical DEXA scans performed per annum in Australia and ~3M scans performed per annum in the USA.
- We have access to >100,000 DEXA scans and a pipeline to develop solutions for non-regulated and regulated markets from these images.
- We have clinical validation and published our results in leading scientific journals.
- Obtained >\$6M in research grant funding from 2016 to date, used to understand why AAC occurs, develop and validate our solution.

## Cardiovascular disease is a leading cause of death, and many people don't know they have the disease



#### Cardiovascular disease (CVD) is Australia's – and the world's – number 1 killer<sup>1</sup>



Image: © blueringmedia/Getty Images

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**1 in 4 deaths** in Australia are CVD related.<sup>1</sup>

CVD is responsible for **11% of** all hospitalisations.<sup>1</sup>

CVD costs the Australian healthcare system **\$12.7** billion per year.<sup>3</sup>

More than **1 in 4** Australians suffering a heart attack have no known risk factors for CVD.<sup>2</sup>

### AAC facilitates the early detection of subclinical cardiovascular disease



- Current health check and blood tests do not tell the full story.
- Heart calcification (CAC) can be detected and quantified using Computed Tomography Calcium Scoring (CTCS) and is used as a screening tool to identify risk of future CVD events.
- In Australia, CTCS is not on the Medicare Benefit Scheme and patients are expected to pay an out-of-pocket cost ranging from \$200-\$300 depending on Radiology provider. The high out of pocket cost limits access to this test in patients unable or unwilling to pay.
- Abdominal Aortic Calcification (AAC) often occurs before CAC,<sup>5</sup> it predicts who will develop CAC,<sup>5</sup> predicts CVD events independent of CAC<sup>6, 7</sup> and predicts CVD events in people with no CAC.<sup>6</sup>
- Traditionally, AAC is detected by CT, but can be seen on low radiation, low-resolution lateral spine DEXA images.



From a cohort of 3,011 older men and women (mean age 50 years) with ECG-gated, non-contrast CT.<sup>6</sup>

# AAC is not being reported on DEXA scans due to the need for trained experts and inconsistencies in expert interpretation





- Lateral spine scans from low resolution DEXA machines contain CVD health information - AAC, which is currently not being reported on.
- AAC detection informs clinicians of subclinical CVD as well as risk of clinical events such as heart attacks, stroke, peripheral arterial disease and heart failure.<sup>8</sup>
- Providing people with AAC results improves CVD risk factor control over 12 weeks.<sup>9</sup>
- However, current detection of AAC and estimating extent is a time-consuming process and requires highly trained experts.



#### Solution: A clinically validated Al-driven AAC detection

- We have developed an AI algorithm to automatically screens for the presence and extent of AAC.
- Algorithm trained on >5,000 expertly annotated scans on 5 makes and models of commonly found DEXA machines.<sup>10</sup>
- We have >80% classification accuracy to identify those with low, moderate and high AAC.
- Our solution was externally validated in 8,565 people undergoing bone density testing without human assessment and strongly predicts future CVD events.<sup>10</sup>
- Moderate to extensive AAC was found in 1 in 2 people undergoing bone density testing (mean age 75 years, n=10,250)<sup>11</sup> and 1 in 4 people in the UK biobank (mean age 65 years, n=53,993)<sup>12</sup>.



Unlabelled VFA images captured at DXA assessment due to low BMD plus older age, height loss and/or glucocorticoid exposure, n=8,565

Machine learning

Incident CVD events (mean follow-up 4 years)	Low AAC n = 3,400	Moderate AAC n = 2,840	High AAC n = 2,325
MACE, Primary endpoint	7.9%	14.5%	21.2%
All-cause mortality	6.3%	11.4%	17.3%
Myocardial infarction	1.2%	2.9%	4.0%
Cerebrovascular disease	1.2%	2.6%	3.9%
Secondary endpoints			
Coronary artery disease	3.2%	5.9%	10.2%
Coronary revascularization	0.9%	1.8%	2.8%
Congestive heart failure	3.0%	5.9%	8.5%
Peripheral arterial disease	0.6%	1.5%	2.3%
Any secondary endpoint	5.6%	10.2%	16.1%

Fig. 3: Proportion with clinical outcomes stratified by machine-learning abdominal aortic calcification groups from dual-energy Lunar Prodigy and iDXA images captured at the time of bone density testing. "Created with BioRender.com."

Image taken from Sharif, N., Gilani, Z., 2023, eBioMedicine, volume 94, 104676

## Solution: AAC is predictive of future CVD events in middle aged people

- Our solution was tested on the scans from 30,830 people aged 45 to 70 years (mean age 60 years) in the UK biobank without human assessment.<sup>12</sup>
- The risk of heart attack, stroke or ASCVD event significantly increases with detection of AAC.
- AAC is strongly predictive of future CVD events, independent of traditional cardiovascular risk factors and another subclinical CVD measure.
- AAC was the most important predictor contributing to the statistical model compared to all other traditional CVD risk factors.
- Higher AAC = a higher risk of heart attack, stroke or ASCVD event (see appendix)

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### Our solution is unique in being able to identify and quantify AAC



Quick with results within seconds.



Captures multiple important disease processes earlier.

Works on multiple machines and can be done at the same time or on existing scans.



Allows for earlier detection and initiation of risk reducing behaviors.



Low cost of machines, scans & solutions.



Innovation equity – allows access to global expertise and scoring.



Allows for earlier detection and management of CVD.



Untapped potential for new uses & markets: screening, remote & rural communities and developing countries.



Ultra low radiation exposure: radiation dose from one DEXA scan is around the same as natural background radiation received in three days.



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# Our solution is differentiated against the standard of care and alternatives by early detection, speed and cost



	Current	broducts availa	able assessing po		
	Our AAC solution	Hologic IVA	CT Calcium Scoring	Carotid ultrasound	Heart Health Check
Availability of testing	$\checkmark$	$\checkmark$	×	$\checkmark$	$\checkmark$
Cost	$\checkmark$	$\checkmark$	×	$\checkmark$	$\checkmark$
Reproducible	$\checkmark$	×	$\checkmark$	×	$\checkmark$
Speed	$\checkmark$	×	×	×	$\checkmark$
Radiation/safety	$\checkmark$	$\checkmark$	×	$\checkmark$	$\checkmark$
Identifies Abdominal Aortic Calcification, enabling earlier detection	~	X	×	×	×

Current products available assessing potential CVD

## Early detection through AAC provides the information patients need to control their risk factors





- Providing AAC results once with education led to better 12-week CVD risk factor control (up to 5.3% better) and estimated CVD risk (AusCVD risk calculator) compared to education alone.<sup>9</sup>
- In the group that received their AAC results, the 70/121 (58%) people with AAC lost 0.9 kg more weight than those without AAC.

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#### Comments from people receiving AAC results

"The initial results for me have been life changing. I was most surprised to be informed of evidence of advanced blood vessel disease (my AAC). This was confirmed by a CT scan, and I've consulted with a specialist."

"I think anyone my age would want to know (their AAC). I came away with, okay I have an issue to sort out ... I've got a challenge and so I'm very grateful to know my AAC"

"I can go to my GP and have the annual cholesterol test and my blood pressure taken, but that only gives very small insight as to the health of my blood vessels.... during which time calcification can silently build up without any knowledge of it happening"

Imagine the impact if we could replicate these results in younger people

(45-60-year-olds)

#### ECU EDITH COWAN UNIVERSITY

#### Professor Joshua Lewis, PhD, FASBMR Lead Researcher in AAC Project

- Heart Foundation Future Leader Fellow.
- Leader of the disorders of mineralisation group and two global consortium on abdominal aortic calcification.
- Areas of expertise are cardiometabolic health and abdominal aortic calcification.

Our team combines a mix of highly experienced researchers and clinicians

• Named the 2023 WA cardiovascular researcher of the year.



#### Adjunct Professor John Schousboe MD, PhD

- Director of the Park Nicollet Bone Densitometry. services of HealthPartners, Inc.
- Past President of the International Society for Clinical Densitometry.
- Chair of the Vertebral Fracture Recognition course of ISCD.

#### Dr Zulqarnain Syed Gilani, PhD

- Raine Robson Fellow & Senior Lecturer in the School of Science.
- Leads the team carrying out abdominal aortic calcification research in computer vision and big-data analysis.
- Area of expertise are in machine learning, artificial intelligence, deep learning, biometrics and syndrome delineation.

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#### Professor William Leslie, MD

- Professor of medicine and radiology at University of Manitoba.
- Past president of the International Society for Clinical Densitometry.
- Past Chair of the Osteoporosis Canada Scientific Advisory Council.



#### Professor David Suter, PhD

- Professor of Computer Science.
- Deputy Director of the School of Science Centre for AI & ML (CAIML).
- Area of expertise includes robust statistical fitting, computational geometry and machine learning.

#### Rapid progress has been made to date



## Our progress is supported by clinical validation & results published in leading scientific journals



- Machine learning for abdominal aortic calcification assessment from bone density machine-derived lateral spine images. The Lancet • Discovery Science Journal eBioMedicine 2023, 94, Article number 104676. https://doi.org/10.1016/j.ebiom.2023.104676.
- Show, Attend and Detect: Towards Fine-Grained Assessment of Abdominal Aortic Calcification on Vertebral Fracture Assessment • Scans. Medical Image Computing and Computer Assisted Intervention – MICCAI 2022 (439-450). Springer Nature. https://doi.org/10.1007/978-3-031-16437-8 42.
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- A Hybrid CNN-Transformer Feature Pyramid Network For Granular Abdominal Aortic Calcification Detection From DXA Images. Medical Image Computing And Computer Assisted Intervention - MICCAI 2024, Springer Nature. https://doi.org/10.1007/978-3-031-72120-5 2.
- Machine-Learning Assessed Abdominal Aortic Calcification is Associated with Long-Term Fall and Fracture Risk in Community-Dwelling Older Australian Women. Journal of Bone and Mineral Research, Journal of Bone and Mineral Research. 2023 Dec 1;38(12):1867-76.

## We have a strong competitive advantage with high barriers to entry



Ř	First mover advantage	Despite the growing interest in identification of abdominal aortic calcification on DEXA, there are no other AI driven solutions that provide as comprehensive a solution for AAC.	
	Exclusive access to critical images and key collaborators	Exclusive access to some of the world's largest annotated datasets; over 17,000 expertly annotated images. Two global leaders in AAC, Adjunct Professor John	
~		Schousboe & Professor William Leslie are key members of our team.	
Ĩ <u></u>	Patent Protection	Provisional patent application lodged to protect our intellectual property.	

#### Use of DEXA scans can be broken into three market segments





#### Potential for early success in the Research & Health/Wellness markets



Research setting (Unregulated)

Researchers are currently paying \$10-15 AUD for evaluation of the AAC

Health & Wellness setting (Unregulated)

- Our AAC scores have been run on existing research study scans from more than 100,000 people globally (>150,000 images) and serve as a new research tool for researchers.
- This is expected to lead to a huge increase in the papers on AAC and our solution has led to further interest from cohorts around the world to apply for grant funding to run the solution on their existing scans or future scans.
- Two successful international grants awarded to run our solution on existing research images to provide AAC scores (>\$35,000 AUD) with three further grants currently in submission.
- There is growing interest within the Health & Wellness setting for individuals to learn about their body composition, lean and fat mass as they are wanting to be proactive if any lifestyle changes are required.
- This examination is performed using DEXA and in some settings within the USA and Australia can be performed without a physician's referral.
- Approximately 4% of global DEXA scanner sales are sold to the health and wellness market.<sup>13</sup>
- To capture a first mover advantage, there is the opportunity for early adoption of AAC within this market segment.
- We have interest from a US based group in our AAC solution as an adjunct to their existing body composition, lean and fat mass assessment. They estimate that they perform 120,000 scans per annum.

#### There are ~3.7M clinical DEXA scans performed across Australia and the USA each year



#### Clinical Setting (Regulated)

730,000 scans/annum in AU

AU Medicare schedule fee/exam: \$116.65<sup>14</sup>

3 million scans/annum in USA (US Fee for Service Medicare population only)

> Average US Medicare Rate USD \$57.25<sup>15</sup>



Source: http://medicarestatistics.humanservices.gov.au/statistics/mbs\_item.jsp

Item numbers: 12306, 12312, 12315, 12320, 12321, 12322

Excludes scans performed with private or Department of Veterans's Affairs reimbursement



Source: <u>https://data.cms.gov/summary-statistics-on-use-and-payments/physiciansupplier-proceduresummary</u>, CMS code: 77080

Excludes scans performed through private insurance or self-funding. Note approx. 18% of the population is covered by Medicare.

#### However, entry into the regulated market requires a longer-term approach



Australia: Therapeutic Goods Administration (TGA)

- We have received guidance that under current TGA regulatory guidelines, AAC as a diagnostic tool will be classified as a **Class IIa** medical device.
- Applying for assessment as a Class IIa medical device will require a Conformity Assessment to be submitted which will include:
  - A **full conformity assessment** to be submitted if no other regulatory approvals are in place.
    - Full technical dossier and supporting documentation.
    - Clinical evidence / results from clinical trials.
  - An **abridged conformity assessment** can be submitted when there are other regulatory approvals in place, for example a successful 510k or De Novo approval.

USA: Food and Drug Administration (FDA)

- We have received guidance that under current FDA regulatory guidelines, AAC as a diagnostic tool will be classified as a Class II medical device.<sup>15</sup>
- The FDA provides two key pathways for regulatory approval of a medical device:
  - The **510k** pathway will require demonstration that AAC is as safe and effective as an already legally marketed medical device; a predicate; or
  - The **De Novo** pathway is used when a device does not match already approved devices. In this case the developer will need to establish both safety and efficacy.
- Our current guidance is that there are current predicates that may be used for a 510k pathway, however further detailed research is required.

Currently, we expect the overall regulatory process to take approximately **18-24 months** from the time the commercial product development is completed and cost approximately **\$1.5M**, inclusive of all regulatory work and clinical trials.

#### Product development is key to support future revenue generating activities



- The current AAC solution is currently in a proof-of-concept format and work is required to transition to a solution ready for commercial customer usage.
- External review of the current state of the AAC solution has made key recommendations.
  - Transition to a cloud-based solution/Software as a Service (SaaS), and a high gross margin pay-per-use/exam pricing model.
  - Drive software efficiencies to minimise processing and hosting costs.
  - Integrate into current typical customer environments.
  - Need to meet all current healthcare privacy standards e.g., HIPPA.
  - Additional model development.

- Additional technical resources will allow this work to be completed as per the recommendations.
  - Front end developer 0.5 FTE.
  - Backend & API developer 1 FTE.
  - Machine Learning Engineer 1 FTE.

Currently, we expect the transition to a commercially ready product will take approximately **18 months** with a cost of approximately **\$0.5M**.

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#### A separate entity will allow us to be agile and execute our strategy swiftly



- Edith Cowan University (ECU) sees the best path forward for commercialisation is through a spin out company focused on bringing our product to market.
- The intellectual property underpinning the AAC algorithm will be assigned to the spin out entity by ECU in exchange for a negotiated consideration.
- The spin out entity will directly employ:
  - Senior Leadership.
  - Regulatory/Technical Support.
  - Business Development & Sales.
- Professors Lewis, Schousboe, Leslie, Suter and Dr Gilani will continue to provide research and clinical support to the spin out entity.
- Currently, we estimate that initial setup and operational costs of the spin out entity over a **3-year period** will be approximately **\$1.0M**

- Once the AAC solution is ready for commercial customer usage, we would commence our pilot program into the unregulated market segment:
  - Commence proof of concept program with customers in the health & wellness market.
  - Commence research only usage with key clinical stakeholders.
  - Aim to secure first contracts and customer revenue in unregulated markets.
- Currently we estimate that costs to run a comprehensive pilot program for target customers over a **12-month** period to be approximately **\$1.0M**

Currently, we estimate that initial setup, operational and pilot costs of the spin out entity over a **3-year** period will be approximately **\$2.0M**.



## AAC go to market approach & timeframes

Spin out entity & Commercial Product Development	Commercial Pilots & Scale Organisation	Regulatory activities in target markets	Drive usage in approved markets and pivot to new
~ 18 months (Commencing April 2025)	~12 months (Commencing November 2026)	~ 18 – 24 months (Commencing November 2026)	Ongoing (Commencing ~ June 2028)
<ul> <li>AIM: Develop a commercially ready solution for customer usage within the unregulated market.</li> <li>Set up new commercial entity to manage this process and appoint: <ul> <li>Senior Leadership.</li> <li>Regulatory/Technical Support.</li> <li>Business Development &amp; Sales.</li> </ul> </li> <li>Negotiate exclusive usage of AAC algorithm with ECU.</li> <li>Estimated cost: ~\$1.0M</li> <li>Develop commercially ready solution</li> <li>Estimated resources required: <ul> <li>Front end developer.</li> <li>Backend &amp; API developer.</li> <li>ML Engineer.</li> </ul> </li> <li>Total estimated cost to complete this stage: ~\$1.5M</li> </ul>	<ul> <li>AIM: Generate revenue through a successful pilot program into the unregulated market (Health/Wellness &amp; Research).</li> <li>Commence proof of concept pilot program with customers in the unregulated Wellness market.</li> <li>Commence research only usage with key clinical stakeholders in both Australia and USA.</li> <li>Secure first contracts and customer revenue in unregulated markets.</li> <li>Estimated cost to complete this stage: ~\$1.0M</li> </ul>	<ul> <li>AIM: Secure regulatory approvals for clinical usage of AAC in target markets of Australia and USA.</li> <li>Engage with regulatory consultants to identify the most suitable regulatory pathway (510k vs De Novo) for application success in USA.</li> <li>In collaboration with the FDA (through the Q-Sub process) and TGA, design suitable clinical trials to prove safety and efficacy of AAC within the target clinical population.</li> <li>Commence clinical trials to support FDA and TGA regulatory applications.</li> <li>Submit FDA (510k vs De Novo) and TGA (Class IIa) applications.</li> <li>Estimated cost to complete this stage: ~\$1.5M</li> </ul>	<ul> <li>AIM: Drive usage and adoption of AAC within approved markets and seek to capitalise with further regulatory applications to other markets.</li> <li>Work with special interest groups and charities in the CVD space (e.g., Heart Foundation) to investigate new uses of AAC within hospitals and private radiology practices: <ul> <li>Could DEXA &amp; AAC be used as a new low-cost, easy access screening method for CVD when referred by General Practitioners and Medical Specialists?</li> <li>To reduce the financial burden on patients and expand reach, how can we get a Medicare Benefit Schedule code?</li> <li>What would the impact be on existing clinical guidelines?</li> </ul> </li> <li>Future capital raise to drive ongoing rapid growth and enter additional markets (e.g., UK, EU).</li> </ul>



## Identifying and managing risk early is key to success

Risk	Likelihood	Impact	Mitigating actions
Unable to recruit suitable resources for commercial development of AAC solution.	Medium	Low	We can contract out this work to any number of independent 3rd party developers, but at a higher cost than originally estimated.
Changes in government requirements reduces the size of the addressable unregulated market.	Medium	Medium	We can pivot our focus to the research market and provide the AAC solution at a cost to clinical research, while accelerating our regulatory applications.
Results from clinical trials are not ideal and delay regulatory applications.	Low	High	We have access to over 17,000 annotated datasets to train our AI models and will not commence clinical trials until we are comfortable with the accuracy, sensitivity and specificity of our solution.
Regulatory approval is delayed or refused by TGA &/or FDA.	Low	High	We will be working with regulatory experts with strong TGA & FDA experience and will ensure that we effectively engage the regulators before and during the application process to minimise the risk of any delays or refusal.



## Our ask

We are seeking **\$4.0 million** over the next **3 years** to bring our AAC solution to market in Australia and the United States of America.

Join us to save lives globally through early identification of AAC and improved management of CVD risk factors. Using AAC screening to reduce the burden of cardiovascular disease and health inequities via improved access to screening and low-cost provision of critical health-related information.



### Nutrition and Health Innovation Research Institute

Strategic Research Institute

Supplementary slides



## References

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\*Figures on pages 1, 4, 5, 6, 7, 8, 10, 27 & 29 prepared using biorender.com

## The risk of a life changing event significantly increases with AAC



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## We are global leaders in AAC & aortovascular disease

- >100 publications and presentations on AAC, many in leading journals in the field such as the Journal of Bone and Mineral Research, Lancet family journals, Arteriosclerosis, Thrombosis and Vascular Biology & Nature Communications and conferences such as American Society for Bone and Mineral Research & European Calcified Tissue Society, Cardiac Society for Australia and New Zealand.
- Lead two international consortium on AAC (n >150,000 people).
- Run AAC training workshops for radiologists, clinicians and researchers e.g. 2024 Asia-Pacific 2-day workshop & masterclass Singapore.
- Present masterclasses, webinars and symposiums (Australia, Singapore, US, France, UK) at meetings/in conjunction with large professional societies such as IOF, ISCD, ECTS, ANZBMS & ASBMR.

## Number and source location of images as of February 2025\*





## Our work in AAC is supported by >10 years of published research

- Abdominal aortic calcification identified on lateral spine images from bone densitometers are a marker of generalized atherosclerosis in elderly women. Arteriosclerosis, thrombosis, and vascular biology 36.1 (2016): 166-173.
- **Prognostic value of abdominal aortic calcification: a systematic review and meta-analysis** of observational studies. Journal of the American Heart Association 10.2 (2021): e017205.
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- Abdominal aortic calcification on lateral spine images captured during bone density testing and late-life dementia risk in older women: a prospective cohort study. The Lancet Regional Health–Western Pacific 26 (2022).
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#### **Our collaborators**





Cheryl has over 20 years of senior strategic, operational, and HR management experience in the tertiary education and corporate sectors, Cheryl is the Strategic Initiatives and Operations Manager at the NHIRI ECU, she manages the day-to-day operations and commercial activities of the Institute.





#### John Barrington AM, BBus, MBA, HonDoc, FAICD, FAIMWA

John has more than 20 years' experience advising boards and senior executives on growth strategies and, prior to this, worked in the technology industry for 12 years. He brings considerable strategy, governance and commercialisation experience to organisations, pertinent to the translation of research, including co-founding and leading Artificial Intelligence medical technology company Artrya Ltd.



#### Janice Marcon, BA (Psych)

Janice is a strategic people professional with 20+ years of strategic human resources experience creating strong and productive cultures. She specialises in working closely with Boards and Executives providing operational and strategic advice and has experience in building businesses from the ground up having had experience in 3 start-ups.



#### Riaz Kingston, BRadMedImg, MBA

Riaz has more than 20 years of experience in medical devices, and brings extensive clinical, business development and sales experience to any project. He has unique insights into the marketing, business development and sales of novel AI driven medical software including software-as-a-service solutions.