# DRIVING AUSTRALIAN MEDTECH INNOVATION FORWARD

## IMPACT OF MTPCONNECT'S CLINICAL TRANSLATION AND COMMERCIALISATION MEDTECH PROGRAM (2021–2025)

MTPConnect

Australia's Life Sciences
**Innovation Accelerator**

CTCM

Clinical Translation
& Commercialisation
Medtech

Powered by MTPConnect

# Contents


| | |
|---|---|
| MTPConnect CEO Foreword | 1 |
| Steering Committee Message | 2 |
| Executive Summary | 4 |
| Driving Australian Medtech Innovation Forward | 10 |
| Unlocking Capacity and Capability Building Through the CTCM Program | 12 |
| Right Funding at the Right Time | 16 |
| • Clever Culture Systems | 17 |
| • Navi Medical Technologies | 20 |
| • Ventora Medical | 23 |
| Future-proofing Australia's Medtech Capability | 26 |
| • CathRx | 27 |
| • OncoRes Medical | 30 |
| • VitalTrace | 32 |
| User-centric Innovation | 34 |
| • ARIA Research | 35 |
| • Medical Developments International | 38 |
| • VividWhite | 40 |
| Building an Ecosystem of Support | 43 |
| • 4DMedical | 44 |
| • Eudaemon Technologies | 47 |
| • REX Ortho | 50 |
| Appendix | Inside back cover |


In partnership with

CICADA INNOVATIONS

MEDICAL DEVICE PARTNERING PROGRAM

MTAA Medical Technology Association of Australia

THE BRIDGETECH PROGRAM

THERAPEUTIC INNOVATION AUSTRALIA

# MTPConnect CEO Foreword

Medical technologies – a broad range of products used in the diagnosis, prevention, treatment and management of disease and disability – cover everything from life-saving diagnostic tests and monitoring systems to through to wearables, therapeutic devices and tools for improving surgical outcomes.

Australia's 'medtech' sector also happens to be one of the nation's most innovative and research-intensive, producing more than 3,500 patent filings each year and ranking second only to pharmaceuticals in intellectual property generation.

This impact report for MTPConnect's **Clinical Translation and Commercialisation Medtech (CTCM)** program showcases exciting new technologies being developed by some of Australia's most innovative emerging medtech companies.

It also details how MTPConnect's unique accelerator model is getting these technologies to patients quicker, supporting a pipeline of new technologies to improve the health and wellbeing of Australians and setting companies on a path for commercialisation success.

The CTCM program was established in November 2021 with funding support provided by the Medical Research Future Fund.

The program had a key focus on accelerating first-in-human clinical trials and provided structured, wrap-around support and access to deep technical and commercial expertise, all with a view to encouraging company growth.

Through two open and highly competitive funding rounds, the CTCM program has supported 12 standout projects on their journey to first-in-human trials. These efforts have led to the recruitment of nearly 400 participants for these trials.

The program has played a pivotal role in guiding companies to navigate the challenging 'valley of death'. By de-risking product development, the program has significantly enhanced the appeal of these projects to private investors.

**The results speak for themselves. Through the delivery of the $19.75 million program we have seen $91 million injected into Australia's medtech sector, with more to come.**

One of the strengths of the CTCM program is its ability to bring the power of industry to the table; to mentor, guide and support our companies and the development of their technologies. Our sincere thanks to program partners Cicada Innovations, the Medical Device Partnering Program, the Medical Technology Association of Australia, the BridgeTech Program and Therapeutic Innovation Australia for their invaluable contributions.

The success of the CTCM program is also a testament to the dedication of its Steering Committee and the expertise and passion of the MTPConnect team. I would like to especially acknowledge Danielle Shand, Dr Michelle Lam and Dr Andionne Parlade. Former team members Dr Duncan Macinnis and Kevin Rajasekaran also contributed mightily to the program's success.

Most significantly, my congratulations to the teams behind the CTCM-supported projects. Your perseverance in navigating the complexities of advancing from preclinical studies to first-in-human trials – turning groundbreaking ideas into viable medical technologies – is an inspiration.

I invite you to explore the insights and case studies featured in this report and celebrate with us the remarkable milestones achieved by these companies and the CTCM program. Together, we have made a significant contribution to shaping the future of healthcare and delivering tangible health benefits to communities.

As always, MTPConnect is proud to play a role in helping these medtech projects thrive, and more broadly to strengthen Australia's ability to translate world-class science into investable and scalable medtech companies.

**Stuart Dignam**
Chief Executive Officer
MTPConnect

# A Message from the CTCM Steering Committee

## As CTCM Program Director and Co-Chair of the Steering Committee for the CTCM program, I am proud to reflect on its success as a collaborative effort to bridge the gap between medtech innovation and clinical application.

From its inception, the CTCM program was designed to address one of the most critical challenges faced by early-stage medtech innovators: bringing promising technologies to clinical trials. During this crucial phase – indeed, at every stage of an innovator's translation and commercialisation journey – success is impossible without the support of industry and the broader 'medtech village.' These support systems need to be complementary rather than competing, to further ensure a project's success.

Recognising this, MTPConnect leveraged its unique position as a connector and relationship broker within the medtech ecosystem to bring together our dedicated program partners to deliver the CTCM program successfully through MTPConnect's leadership. Our partnership model has fostered a strong strategic oversight, and met the program's objectives with efficiency and impact.

### Mentorship and project support

Beyond the funding, the partnership offered invaluable opportunities for knowledge sharing and access to extensive networks. Our funded companies benefited not only from MTPConnect's resources but also from the mentorship and connections of our medtech specialist partners, all well-established organisations with complementary strengths and a nationwide reach:

- **Cicada Innovations (CI)**: With its world-class deep tech incubator, Cicada Innovations has provided cutting-edge labs, expert mentorship, and commercialisation training, helping companies navigate the complexities of scaling medtech innovations.
- **Medical Device Partnering Program (MDPP)**: MDPP has brought its extensive experience in fostering medtech innovation, uniting researchers, industry, and end users to assess ideas, complete R&D projects, and drive commercial opportunities.
- **Medical Technology Association of Australia (MTAA)**: As the national voice of the medtech industry, MTAA has provided critical connections between researchers, industry, and government, ensuring the funded companies have access to the expertise needed to address clinical and technical challenges.

The funded companies have greatly valued and appreciated the Program Partners' support, which is sure to cultivate enduring relationships that extend far beyond the program.

### Capacity and capability building

The CTCM program also enabled capability building and infrastructure access within the sector. Through our partnership with **Therapeutic Innovation Australia (TIA)**, companies gained access to essential engineering, fabrication, and prototyping facilities, facilitated via the broader NCRIS network and beyond. TIA supports national research infrastructure in biologics, cell and gene therapies, and small molecule pharmaceuticals. Since 2008, TIA has helped researchers and industry advance discoveries through the development pipeline, enabling readiness for Phase I trials and beyond, driving innovation in Australia's therapeutic landscape.

This initiative not only fostered strong connections within industry, but also strengthened the research infrastructure of these SMEs, giving them greater capacity to undertake translational research.

At the individual level, the CTCM program also supported upskilling and networking through our educational partner, **The BridgeTech Program**. Delivered by the Queensland University of Technology (QUT) and led by a consortium of leading industry partners, the BridgeTech Program provides industry-led commercialisation training for researchers and entrepreneurs in the medtech sectors in partnership with key industry partners, Australian universities, sectoral representatives, and industry associations.

Through this invaluable program, CTCM enabled capability building for its participants and provided support for the medtech ecosystem.

## Acknowledgements

I extend my heartfelt gratitude to the CTCM Operations team, comprising the dedicated MTPConnect team and representatives from our valued Program Partners, both past and present. Special thanks to Stephen Blakeney, MDPP (including past team members Andrew Milligan and Dr Kerstin Schuetz), Gordon Malouf, Cicada Innovations (with past team members Dr Dharmica Mistry and Hebbat Manhy), Stuart Anderson, MTAA, Kate Nelson, QUT's BridgeTech Program (including past team member Joel Spotswood), and Stuart Newman, TIA. Their collaboration has been instrumental in guiding our funded companies and driving the program's success. Delivering an impactful program truly required a collective effort, and the outstanding results outlined in this impact report speak volumes about the value of this partnership.

A special thank you also goes to all members of the CTCM Steering Committee, both past and present, for their unwavering dedication and expertise. Their commitment has been vital in ensuring the program's objectives were met, with a shared vision of accelerating medtech innovation and commercialisation across Australia.

The CTCM journey has not been without its challenges, but the progress we've made together is undeniable. We've been on a journey together delivering incredible support for these companies that will certainly propel them forward. We are on the right track and have driven meaningful change in Australia's medtech sector.

**Danielle Shand**
CTCM Program Director and Co-Chair of the CTCM Steering Committee

"The CTCM program is a leading example of successful ecosystem collaboration; its partners work seamlessly together to deliver the tangible commercial outcomes that are critical for advancing Australia's deep tech sector. Cicada Innovations is proud to contribute to the commercial endeavours of so many medical device companies and can see the accelerated growth that comes with expert coaching and guidance."

**Sally-Ann Williams, (previously Chief Executive Officer, Cicada Innovations)**

"CTCM has greatly benefited Australia's medtech sector by supporting several companies through first-in-human studies with great outcomes that will have real impact both for patients and economically. MDPP has been a huge supporter of MTPConnect-led grant initiatives, and the involvement of partnering organisations helps to bring the sector together to deliver better national outcomes."

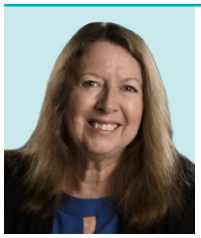
**Professor Karen Reynolds, Director Medical Device Partnering Program**

"The CTCM program has had a significant impact, enabling our most promising innovators to bring life-changing technologies to patients more rapidly. As the national MedTech association, MTAA is proud to have contributed to the commercialisation of home-grown innovations and to the strengthening of Australia's sovereign MedTech capabilities."

**Ian Burgess, Chief Executive Officer, Medical Technology Association of Australia**

"TIA has worked with MTPConnect for some years and we remain greatly impressed by the management and delivery of the CTCM program by them and also the program partners. The benefits to the companies are extremely clear and are a testament to the strong and focussed strategy of this initiative – the medtech industry in Australia has unarguably been pushed forward by this scheme."

**Stuart Newman, Chief Executive Officer, Therapeutic Innovation Australia**



"The BridgeTech Program has proudly collaborated with MTPConnect since 2018, most recently as a value-add partner of the CTCM program. CTCM has been an impactful initiative and a transformative force in the Australian medtech industry, championing medtech commercialisation. The tangible benefits to the companies through funding, mentorship, guidance and broad-reaching supportive networks have elevated the sector's ability to show real medtech translational outcomes, reinforcing our country's strength of solving unmet needs for patients."

**Distinguished Professor Lyn Griffiths AM, Director, Bridge and BridgeTech Programs**

# Executive Summary

## The $19.75 million CTCM program is an initiative of the Medical Research Future Fund's (MRFF) 2020 Early Stage Translation and Commercialisation Support grant and has been delivered by MTPConnect over four years (2021 – 2025).

Established to identify and nurture high-quality Australian medical device projects with significant commercial potential, the CTCM program was designed to support their translation through early clinical trials and is guided by the following core objectives:

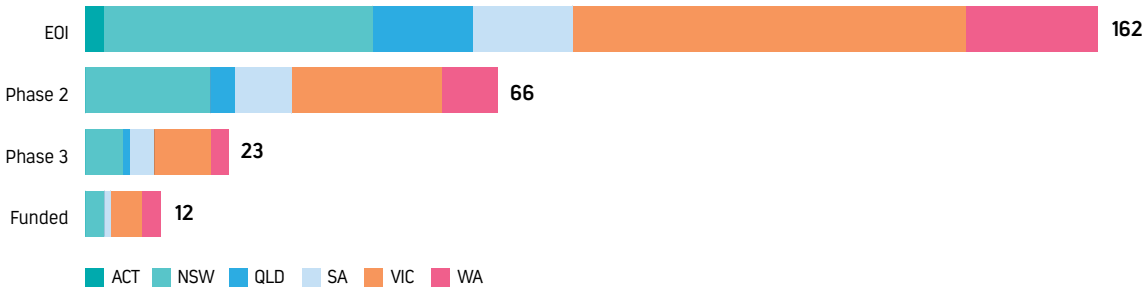
1. Improve the health and wellbeing of Australians by enabling faster access to latest technology
2. Enable Australian Small to Medium Enterprises (SMEs) to generate commercial returns and create high-paying jobs in the medical products sector
3. Create access to more clinical trials
4. Help Australian technology reach global markets
5. Support local design and manufacturing expertise
6. Strengthen the Australian medtech ecosystem

### Delivering success

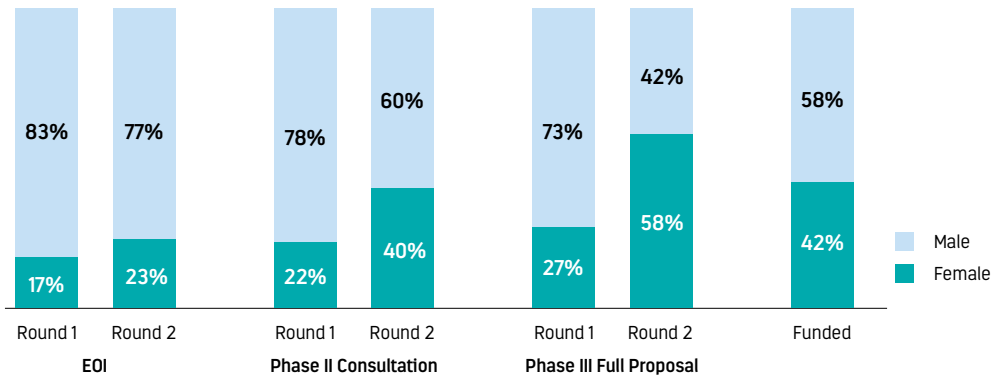
The CTCM program integrates expertise in governance, project administration, clinical research, and stakeholder engagement for both pre- and post-award phases. The operational team was composed of industry experts from MTPConnect and partnering organisations - Cicada Innovations, MDPP, MTAA, TIA, and The BridgeTech Program. Leveraging the diverse strengths, this collaboration has led to the successful execution of two highly competitive funding rounds.

Projects were selected through an open and contestable process. Each funding round consisted of three distinct phases: Expression of Interest (EOI), Consultation and Full Proposal. MTPConnect received over 170 applications from around Australia with strong interest from WA, QLD, SA, NSW and VIC. There were no applications received from NT or TAS. Interestingly, while applications that reached full proposal stage in Round 1 were predominantly submitted by male lead applicants, Round 2 saw a significant shift, with the majority of the strongest proposals coming from female leads - a testament to the growing diversity in the medtech innovation space and the quality of female led applications.

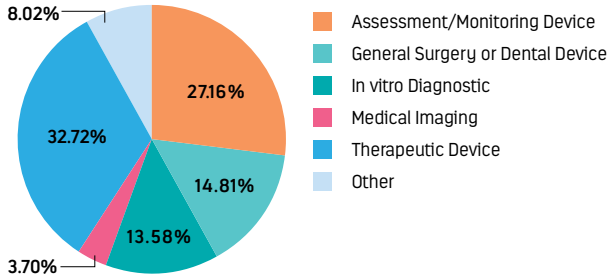
**Numbers of applications per stage with distribution by state**




**Gender distribution of project lead per stage**



**Type of medical device approach in applications received**




> **Australia is not a big country – we need all of us collaborating together to help Australian innovation grow into sustainable and thriving businesses.**
> Hebbat Manhy, Cochlear's Director of Global Manufacturing Operational Excellence, (formerly Cicada Innovations CTCM Program Partner)

Applications were evaluated at each stage by independent assessment panels comprising national and international experts within the medtech industry. Twelve strong applications that demonstrated project feasibility, technical proof-of-concept, product validation and commercial potential were selected to enter the program. Each SME was awarded non-dilutive funding ranging from $500,000 to $1.5 million to support their device through to clinical trial within a two year period.

In addition to funding, the program provided bespoke wrap-around *'value-add'* support including mentorship with medtech Program Partners, a voucher scheme, and other targeted opportunities. Combined, this made the CTCM program the 'best value for money compared to other government grants' – a deliberate strategy to derisk early-stage projects to attract further funding.

## Achievements and impact

Over two funding rounds, the CTCM program committed **$12.5 million** in funding to the 12 selected projects, with an additional **$13.6 million** in matched cash and in-kind contributions from industry, bringing the sector investment to **$26 million**. This investment helped companies attract **$65 million** in additional flow-on funding, through other grants and capital raises, injecting a total **$91 million** into Australia's medtech sector.

**36**
New technologies invented or progressed

**50**
New jobs created in funded companies (FT or PT)

**392**
Patients access clinical trial

**17**
Interactions with regulatory authorities

**75%**
Funded companies boosting in-house manufacturing

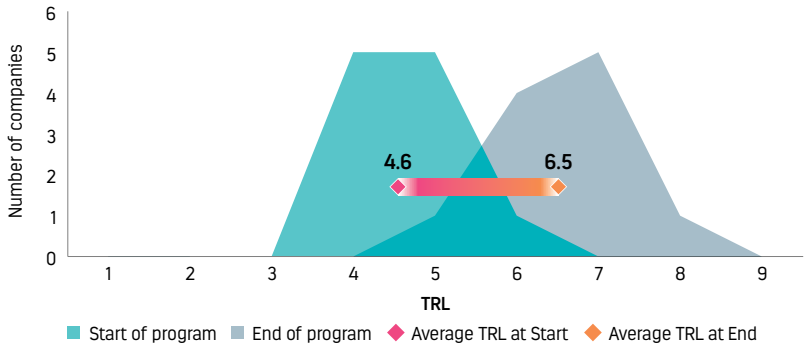
**$91m**
Total investment generated by the program

# Executive Summary continued

The CTCM-funded companies commenced their clinical studies within a median time of 16 months of starting their project. A total of 392 participants were enrolled in 12 studies ranging from First-In-Human, investigational and feasibility studies to pivotal studies in preparation for regulatory submission, conducted nationally and internationally. During the program, 36 new technologies were invented or progressed, including novel medical device components, software and algorithms, and manufacturing processes.

The companies also conducted a self-assessment of their Technology Readiness Levels (TRLs) at the start and end of the CTCM program. In two years, funded companies reported a change of average product maturity by two levels of Technology Readiness, moving from 4.6 (Technical proof of concept in lab/animal models) to 6.5 (Safety in humans demonstrated in clinical trial).

### Progress against Technology Readiness Levels

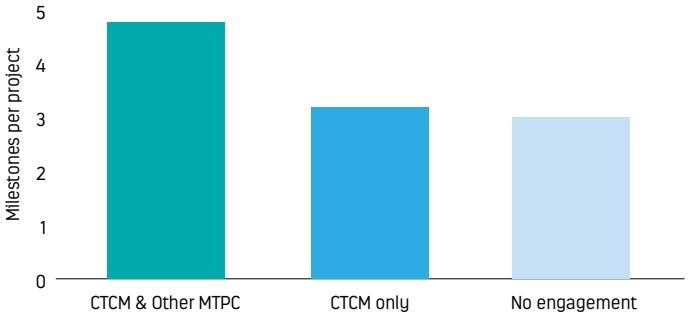



Utilising publicly available data collected by Horiz-in, comparisons were made between the CTCM-funded companies and those that had submitted full applications into the program but were unsuccessful. Both groups of companies were at a similar stage at the time of application and were all medical device companies meeting the same eligibility criteria (See Appendix). Compared to this cohort, CTCM-funded companies have on average commenced 1.6 times more clinical trials within two years of the application. These companies also:

- Received 1.25 times more flow-on funding
- Published supporting evidence 1.4 times more
- Communicated news about research and strategic collaborations 1.2 times more

This positive effect was further amplified for projects that secured funding through the CTCM program, as well as through other MTPConnect accelerator initiatives in the past, such as BTB, BMTH, or TTRA. Horiz-in's analysis showed that the CTCM-funded companies that engaged with other MTPConnect programs achieved an average of 2.5 times more critical developmental milestones compared to companies that have not been funded by MTPConnect.

### Previous engagement with MTPConnect programs helped projects achieve more milestones




This showcases the impact of MTPConnect's accelerator funding programs and underscores the importance of consistent funding throughout development stages to maintain momentum.

## Program resilience

In the four year delivery of the program, the CTCM-funded companies have had to navigate challenges including:

- Unforeseen project delays complicating the completion of the project within the timeline stipulated by the program. Delays were observed in obtaining ethics approval, contracting with clinical trial sites, patient recruitment, and manufacturing due to supply chain issues or production faults. One company terminated their project after challenges extended their project timeline beyond the maximum two year allocation. Funding was redeployed to the next highly ranked application after a due diligence process.
- Loss of funding or dissolution of partnerships, impacting operational continuity.
- Strategic pivots necessitated by evolving market demands.
- Technical risks realised during prototyping and validation.

Recognising that these hurdles are an unavoidable part of medical device development, MTPConnect provided the companies flexibility to navigate these obstacles, through close guidance and mentoring, strategic resource reallocation and timeline adaptability, all the while ensuring that the projects remained aligned with their original scope and objectives. This adaptive approach enabled medtech innovators to achieve their project goals without being limited by rigid program constraints.

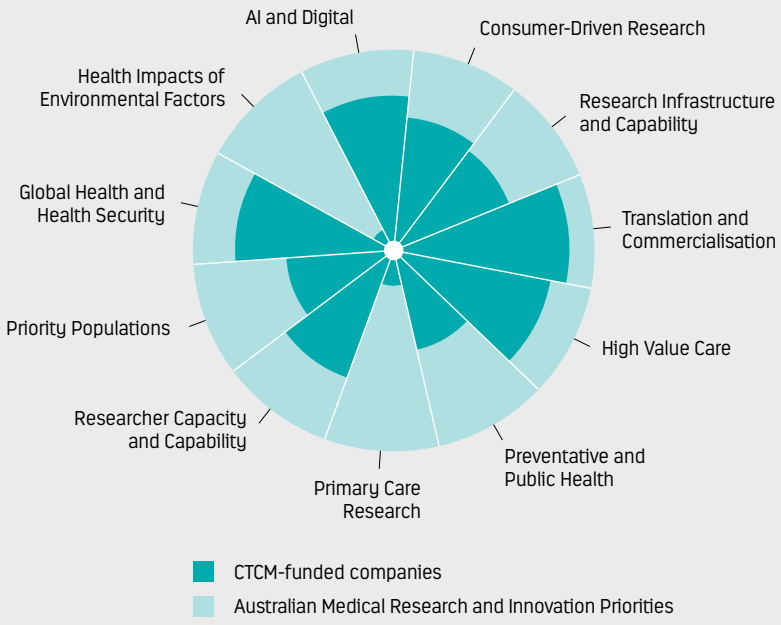
## Alignment to MRFF priorities

Beyond the program's measures of success, the CTCM program also demonstrated strong alignment with the MRFF's overarching goals, as outlined in the Australian Medical Research and Innovation Strategy 2021-2026.

Horiz-in conducted a strategic alignment analysis using the Australian Medical Research and Innovation Priorities updated for 2024-2026. Each CTCM-funded project was evaluated and scored using Horiz-in's proprietary algorithm to assess how effectively it addressed these priorities.

Across the board, the funded companies showed significant alignment with the priorities of Translation and Commercialisation, as well as High Value Care. They also made meaningful contributions towards advancing Consumer-Driven Research, strengthening Research Infrastructure and Capability, building Research Capacity, and addressing Global Health and Health Security challenges.

**Visualisation of CTCM-funded companies fit within the Australian Medical Research and Innovation Priorities**



# Executive Summary continued

A few examples of how the CTCM-funded companies demonstrated strong alignment across several priorities include:

- **Ventora Medical, Navi Medical Technologies** and **VitalTrace** are developing devices for improved neonatal healthcare, working towards providing high value care for a priority population.
- **Clever Culture Systems** exemplified advancing research in AI and digital health technologies through its development of an AI-powered analysis tool for culture plate readings, while addressing the global health and health security challenge of antimicrobial resistance.
- **Eudaemon Technologies'** work on next-generation hydrogel condoms is a strong step forward in preventive and public health research, as well as strengthening manufacturing capability within Australia with their strong Industry 4.0 focus.
- **ARIA Research's** strong consumer focus and co-design of their AI-powered smart glasses together with the blind community.

Supporting these innovations demonstrate MTPConnect's dedication to advancing Australian health and medical research, directly supporting broader Commonwealth priorities.

## Notable achievements

The program has been marked by remarkable achievements from the funded companies. Here are some of the standout successes:

- 75 per cent of the funded companies attracted further grant and accelerator funding during their CTCM project.
- **4DMedical** received FDA 510(k) approval for their CT:VQ ventilation analysis software, which paves the way for the approval of their perfusion analysis software supported by the CTCM program. The company has also partnered with Philips to install their XVD lung scanner in government funded hospitals across the US, collaborating towards improving veteran lung health.
- **ARIA Research** conducted their pilot clinical trial, meeting the primary safety endpoint of their non-invasive bionic vision system, and have been awarded a $2 million NSW Medical Device Fund grant to further develop their device.
- **CathRx** has recently published results of their first-in-human study for the ElectroPulse PFA system supported by the CTCM program. They also signed a new distribution partner agreement for their diagnostic cardiac catheters with a Korean distributor, with a high interest in distributing their new PFA catheters once approved by regulators.
- **Clever Culture Systems** strategically pivoted their microbiology plate reading technology towards the pharmaceutical manufacturing market and launched a new AI module for pharmaceutical environmental monitoring developed in the CTCM program, celebrating major contract sales and partnerships with major companies such as Pfizer, AstraZeneca, Bristol Myers Squibb and NovoNordisk. The company has raised $4.5 million capital to support future commercialisation efforts in the pharmaceutical market.
- **Eudaemon Technologies** successfully completed their clinical trial demonstrating the safety of their novel hydrogel condoms in humans, and have progressed their manufacturing and scaling plan.
- **Navi Medical Technologies** completed their pilot clinical trial for their breakthrough catheter tip location device, and recently received an FDA 510(k) approval, paving the way for their groundbreaking technology to enter the US market.
- **OncoRes Medical** has completed a multi-site pilot clinical trial for their QME imaging system for breast cancer detection and completed their dossier in preparation for TGA submission, attracting a $2.5 million CUREator+ grant as well as $27 million in private funding to conduct their pivotal clinical trial.
- **Ventora Medical** has taken their airway pressure monitor for critically ill neonates through clinical feasibility and useability studies, and recently partnered with AusHealth Ventures to support their ongoing clinical study at the Royal Women's Hospital.
- **VitalTrace** have commenced their first-in-foetus clinical study for their DelivAssure continuous lactate sensor to monitor foetal distress during labour. Building on its 2022 FDA Breakthrough Device designation, the company has undertaken breakthrough sprint discussions with the FDA to refine its clinical evidence and validation plans, strengthening the pathway toward regulatory approval. They recently were awarded a WA FHRI Innovative Solutions – Precision Health grant for further development of their device.
- **VividWhite** has now completed recruitment for their pivotal clinical trial for their glaucoma implant, having already established the safety of the device through a pilot trial prior to the CTCM project. Findings from this pivotal trial will guide the company's future regulatory submissions.

## Projects by therapeutic area

| COMPANY NAME | THERAPEUTIC AREA | MEDICAL DEVICE TYPE | CTCM ROUND |
|---|---|---|---|
| CathRx | Cardiovascular | Therapeutic Device | Round 2 |
| Clever Culture Systems Ltd (ASX:CC5) | Infectious Disease Diagnostics | In Vitro Diagnostic | Round 1 |
| Ventora Medical | Neonatal Care | Assessment/Monitoring Device | Round 2 |
| Navi Medical Technologies | Neonatal Care | Assessment/Monitoring Device | Round 1 |
| VitalTrace | Neonatal Care, Obstetrics | Assessment/Monitoring Device | Round 2 |
| OncoRes Medical | Oncology | Medical Imaging | Round 1 |
| REX Ortho* | Orthopaedics | Surgical Implantable | Round 2 |
| Medical Developments International** | Pain Management | Therapeutic Device | Round 2 |
| Eudaemon Technologies | Preventive Sexual Health | Preventive | Round 1 |
| 4DMedical Ltd (ASX:4DX) | Respiratory Disease | Medical Imaging | Round 2 |
| ARIA Research | Vision | Wearable | Round 1 |
| VividWhite | Vision | Surgical Implantable | Round 2 |

* Project terminated in January 2026 due to time constraints with the CTCM program.

** Project self-terminated in March 2024.

# DRIVING AUSTRALIAN MEDTECH INNOVATION FORWARD

CTCM Clinical Translation & Commercialisation Medtech
Powered by MTPConnect

## Accelerating progress

**12**
Medical device projects started

**$91m**
Total sector investment

**$65m**
Total flow-on funding attracted

**392**
Patients in clinical trials

**12**
Clinical trials commenced

**51**
Active clinicians involved

**36**
New technologies invented/ progressed

**16** Research publications

**17** Interactions with regulatory authorities

**39** Patents and trademarks

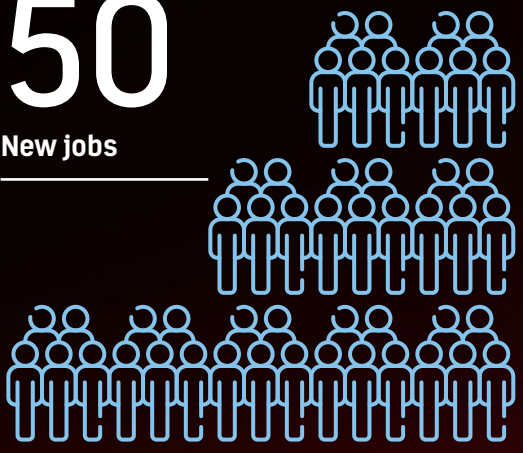
## Advancing technological readiness

**4.6**
Proof-of-concept

**6.5**
Clinical safety and effectiveness

## Strengthening medtech sector

**50**
New jobs



**49**
Australian manufacturing activities

**75%**
Boosting in-house manufacturing capability

**247**
End users engaged in co-design

**23**
Partnerships formed

**16**
Collaborative research agreements

# Unlocking Capacity and Capability Building Through the CTCM Program

CTCM Partnering Summit 2023

The CTCM program, powered by MTPConnect, has emerged as a transformative initiative for its funded companies, unlocking a wealth of value-add opportunities that have significantly enhanced their medtech journeys. By leveraging MTPConnect's expertise, extensive stakeholder network, and tailored support offerings, CTCM companies have maximised their potential for success in the competitive medtech landscape.

## Tapping into expertise and networks

Participation in the CTCM program has unlocked a swathe of value-add opportunities that have enriched the experience and extracted as much value from MTPConnect's expertise as possible. Through the program, companies have been able to tap into the Company's stakeholder network, bounce ideas with a dedicated industry-based, medtech Program Partner, grown their networks with leading sector experts and peers who have shared similar journeys.

Additionally, companies have benefited from CTCM's tailored offerings, including one-on-one advisory consultations, regular summits and discounted access to major conferences. These resources have empowered participants to navigate the medtech landscape with greater confidence and strategic insight.

## Value-add vouchers: 'A game-changer'

Throughout the life of each CTCM project, MTPConnect deployed $800,000 in value-add vouchers to support activities that complemented CTCM projects. These vouchers addressed critical needs such as research infrastructure access as well as commercialisation gaps and areas of opportunistic growth identified through a bespoke needs analysis process.

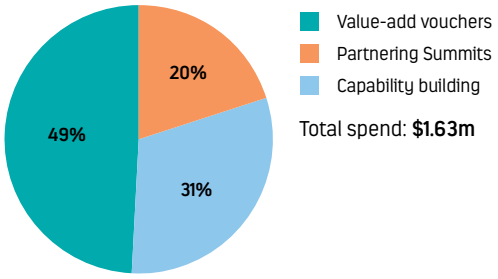
Described as 'perfectly timed,' these value-add vouchers, combined with MTPConnect's suite of offerings, have elevated the CTCM program to the 'top of the pile' of game-changing, non-dilutive Federal funding initiatives. Working closely with program partner, Therapeutic Innovation Australia, the breadth of activities undertaken ranged from tapping into the National Collaborative Research Infrastructure Strategy (NCRIS) network for research infrastructure, tooling, and prototyping to bringing in Go-to-Market specialists to optimise appropriate market strategies.

## Building skills and relationships

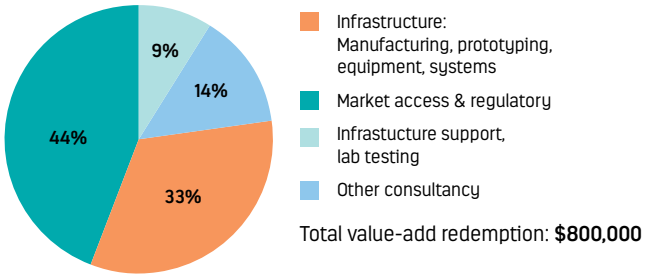
One of MTPConnect's remit is to support sector capability and capacity and while this has been achieved through formal training via The BridgeTech Program, further opportunities have been built into the CTCM program through value-add offerings, including additional training programs covering leadership skills, intensive commercialisation bootcamps and manufacturing workshop series as well as annual CTCM Summits and tours. These in-person events and training programs have given Companies the opportunity to build stronger teams by investing in their staff development, while expanding the medtech industry network with new up-and-coming talent.

CTCM's Design to Manufacturing Tours, annual Partnering Summits and dedicated face-to-face networking opportunities have seen over 400 delegates build relationships and expand their networks over the four years of the program. With three major events originally scheduled during the life of the program, CTCM has instead delivered six major events. These are highly regarded by participating organisations as worthwhile opportunities to learn and share experiences with peers and medtech leaders. Companies also dipped into the expertise of MTPConnect's three specialist medtech program partners, who have worked collaboratively to address specific company challenges through intensive and targeted workshops.

**Total spend on value-add activities**




**Value-add voucher redemption by value**




## Consulting and advisory services

Beyond regular touchpoints with dedicated program partners, MTPConnect has opened the door for companies to access specialist expertise, offering tailored guidance to overcome challenges and strategise for success. A total of 13 consultants and subject-matter experts were engaged to deliver 44 one-on-one consultation sessions, providing personalised support to address each company's unique commercialisation and development needs.

These consulting and advisory services have been instrumental in helping companies overcome technical and commercial hurdles, refine their strategies, and unlock new opportunities for growth and success in the medtech sector.

## PARTNERING SUMMITS: BUILDING CONNECTIONS

The CTCM program's Partnering Summits have been a standout feature, fostering collaboration and knowledge sharing across the medtech sector. These events have achieved an impressive Net Promoter Score (NPS) of 76 per cent, reflecting their value and impact.

**6**
Partnering Summits

**400+**
Delegates

**76%**
Average NPS (Excellent)

These summits have not only strengthened connections within the medtech community but have also provided participants with a platform to share experiences, discuss challenges, and collaborate on solutions, further solidifying the CTCM program's reputation as a game-changing initiative.

> "I appreciate the warmth and enthusiasm of the MTPConnect team. I feel like there are individuals who care what I'm doing in my small corner who can answer questions, help me critically evaluate and improve, as well as giving me the sense of being part of something much bigger in Australia."

> "Great event, really helpful to talk with teams from other projects to discuss similar challenges we're all having (e.g. finding and selecting local CROs, where to physically move teams as we grow etc)."

# Unlocking Capacity and Capability Building Through the CTCM Program continued

CTCM Partnering Summit 2025

## The BridgeTech Program: Driving impact

The CTCM program supported the delivery of The BridgeTech Program, enabling representatives from CTCM-funded companies to participate in its industry-led commercialisation training. The program proved highly successful and impactful in strengthening the commercialisation capabilities of participating companies.

Participants have reported significant improvements in their commercialisation skills and networks, with 73 per cent rating their skills as excellent or very good and 100 per cent noting stronger connections post-summit.

## Deep connections and tailored support

CTCM-funded companies have also benefited from MTPConnect's deep connections to medtech and commercialisation experts. Through facilitated introductions to industry leaders such as Bosch Australia Manufacturing Solutions (BAMS) and CSIRO, companies were able to work through complex problems and unlock new opportunities. These efforts have resulted in tangible outcomes, such as ongoing partnerships with manufacturing giants and refined market entry strategies.

The CTCM program has set a new benchmark for non-dilutive Federal funding, combining financial support with a comprehensive suite of value-add offerings. By fostering collaboration, building skills, and addressing commercialisation challenges, MTPConnect has empowered companies to achieve their medtech ambitions and drive innovation in the sector.

## Testimonials

The impact of the CTCM program is best captured through the voices of participants:

> **Met BOSCH during a CTCM organised tour, resulting in an ongoing valuable relationship.**

> **The (Partnering Summit's) networking components provided fantastic opportunities to learn and share experiences. More such opportunities would be beneficial.**

> **The voucher for a go-to-market strategy plan was perfect timing and very useful.**

BridgeTech Symposium 2024

Design to Manufacturing tour 2023 - BAMS

1:1 consultations

Design to Manufacturing tour 2024 - CSIRO

VitalTrace Kickoff meeting


Eudaemon Technologies Kickoff meeting

# RIGHT FUNDING AT THE RIGHT TIME


**7**
Regulatory dossiers developed

**17**
Interactions with regulatory authorities

**24**
National phase patent applications

**7**
Provisional patents

**8**
Trademarks

Access to timely and targeted funding can be the difference between a promising technology and a fully commercialised medical innovation. The CTCM program provided non-dilutive funding to help companies navigate the 'Valley of Death' and reach critical inflection points – one of the most pivotal being early clinical trials. This allows them to de-risk their technology and generate substantial evidence to attract further investment.

The CTCM funding and support accelerated the timeline for reaching key milestones, while also giving companies the flexibility to make transformative strategic decisions. For example, Clever Culture Systems leveraged the program to pivot into the pharmaceutical market, achieving significant commercial success.

As the companies navigated their clinical trials, they also advanced their regulatory readiness with dossier preparations and direct engagement with authorities such as the TGA and the US FDA. Notably, three of the funded companies already achieved FDA Breakthrough Device Designation prior to the program, with one, Navi Medical Technologies, obtaining their US FDA 510(k) approval soon after project completion. Alongside regulatory progress, the companies also strengthened their IP assets through new patent applications and trademarks.

The CTCM program actively accelerates the commercialisation journey, giving companies the tools, guidance, and confidence to rapidly bring new medical technologies to market.

# CCS expands AI-powered culture plate analysis technology into the pharmaceutical manufacturing market

CLEVER CULTURE SYSTEMS

START DATE:
9 Nov 2022

END DATE:
28 Feb 2025

STATUS:
Complete

DELIVERABLES COMPLETED:
100%

TOTAL CTCM EXPENDITURE:
$1,409,918

TOTAL CASH CO-CONTRIBUTION:
$1,409,918

TOTAL IN-KIND CONTRIBUTION:
$444,927

TOTAL PROGRAM:
$3,264,763

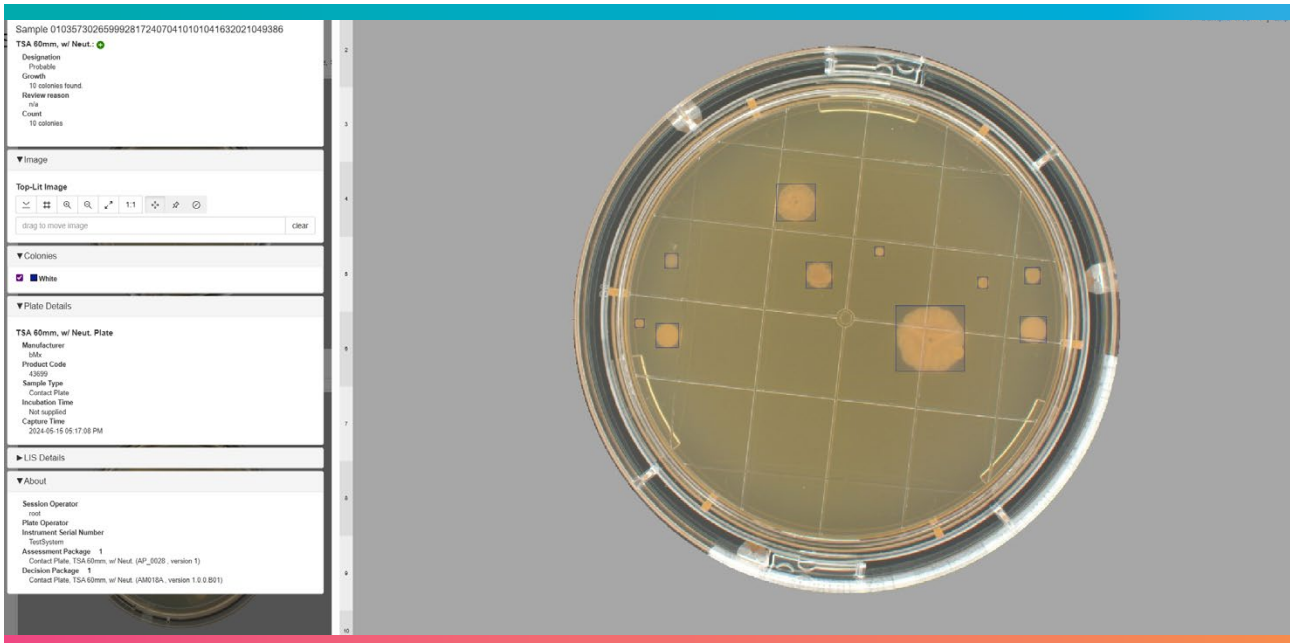
| | |
|---|---|
| Total additional investment secured | $4,500,000 |
| New job opportunities created as a result of the CTCM project | 7 |
| New technologies progressed | 2 |
| New database curated and annotated | 1 |
| New research publications including posters, publications and oral conference presentations | 10 |
| New collaborative research agreements signed with registered research providers | 2 |
| New product launched as a result of the CTCM project | 1 |
| Product sales as a result of CTCM project | $3,000,000 |

Image: APAS Independence at CCS product development facility.

Adelaide-based company Clever Culture Systems (CCS, ASX: CC5) has established itself as a key player in the clinical microbiology space since 2004. By utilising artificial intelligence (AI) and automation, CCS has revolutionised how culture plates are screened and interpreted, targeting a long-standing challenge of traditionally manual, time-consuming processes that strain laboratory resources.

The company's Automated Plate Assessment System (APAS®) was the first AI technology approved by the US Food and Drug Administration (FDA) for automated culture plate reading, cleared as a Class II in vitro diagnostic device for the reading of urine and MRSA cultures, now serving as the predicate device for all other equivalent technologies. The APAS Independence instrument can automatically image, detect and interpret bacterial growth at a rapid rate of 200 culture plates per hour, and is already improving efficiency in clinical laboratories around the world.

# CCS expands AI-powered culture plate analysis technology into the pharmaceutical manufacturing market continued




APAS Contact Plate Reporting.

During the research and development (R&D) of its technology, CCS established a strong partnership with global analytical instrument and diagnostics leader Thermo Fisher Scientific. Thermo Fisher is currently the exclusive distributor of CCS's APAS Independence across the US and select European markets. This strategic collaboration has enabled CCS to service clinical customers worldwide, reinforcing its position as a trailblazer in microbiology automation.

Building on its growing momentum, CCS was awarded $1.4 million by MTPConnect's Clinical Translation and Commercialisation Medtech (CTCM) program – supported by program partner Cicada Innovations – to develop the APAS Compact, a smaller, more economical and accessible benchtop version of the APAS Independence. Reflecting CCS's industry-driven approach, this initiative included a comprehensive market research report that incorporated insights from approximately 75 end users to shape the device's user requirements.

## A strategic pivot

Simultaneously, CCS identified a critical industry need that its technology was uniquely equipped to address: detecting contamination during the routine manufacture of sterile drug products.

Input from microbiologists is essential to ensuring the safe production of pharmaceuticals. Typically, two microbiologists are needed to review each environmental monitoring culture plate, as errors can result in significant costs – potentially up to $1 billion in lost revenue due to batch failures[1]. Moreover, a 116 per cent increase in FDA regulatory observations[2] regarding environmental monitoring has added new compliance challenges for drug manufacturers. A shortage of microbiologists further compounds this issue, with microbiologist job vacancy rates averaging 8 to 10 per cent in developed regions such as the US, Australia and the EU[3].

CCS recognised these challenges as an opportunity to enter and expand into the pharmaceutical monitoring market. As already demonstrated within the clinical pathology market, its APAS technology automatically triages positive plates from negative plates. In sterile production environments, approximately 98 per cent of environmental monitoring culture plates are negative, so this technology would free up a significant portion of a microbiologist's time to focus on positive results and deviations.

This efficiency boost can lead to laboratory productivity gains of 60 to 90 per cent. Recognising the potential of this innovation, pharmaceutical giant AstraZeneca partnered with CCS to develop an APAS analysis module software tailored for sterility monitoring during drug manufacturing.

1. www.researchandmarkets.com Global Pharmaceuticals Market Report 2021: COVID-19 Impact and Recovery to 2030.
2. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspection-observations
3. Medical Laboratory Observer 2021 Annual Salary Survey of laboratory professionals; Feb. 22, 2021.

APAS Independence in use at HSL, UK.

## Accelerating hardware and software development

CCS was able to leverage the hardware and software it was developing for the APAS Compact device to support its expansion into this new market.

Through its CTCM project, CCS developed a new plate-handling system capable of processing both standard 90mm culture plates and smaller ~55mm contact plates used for pharmaceutical environmental monitoring. The team prototyped the APAS Contact Plate System in collaboration with engineering partner Planet Innovation.

Additionally, CCS enhanced its in-house capabilities in 3D printing, significantly reducing costs and accelerating timelines for hardware development. The final prototype has now been delivered to Planet Innovation to begin manufacturing the device in preparation for sale.

CCS also developed a new APAS analysis module for the contact plates, which it shared with customers for feedback and evaluation.

> **The CTCM program has allowed us to accelerate the development of our AI application for contact plates, ensuring we are delivering a complete solution for pharmaceutical environmental monitoring applications. The use of AI in this area is changing the way quality control microbiology laboratories are operating, freeing up resources to support the safe manufacture of drug products for patients, said CCS's Corporate Development Director Jack Brown.**

CCS conducted a formal validation study to gauge the performance of both the APAS Contact Plate Analysis Module against a panel of qualified microbiologists in assessing more than 20,000 culture plate images. All the data from the validation study has been collected and is now in the final stage of analysis, with final performance data expected in mid-2025.

## Preparing for launch and global expansion

The company's strategic pivot has proven highly successful – driving growth, increasing sales and establishing new relationships within the pharmaceutical sector. The work done within the CTCM project helped CCS foster valuable partnerships with global pharmaceutical companies, including AstraZeneca and Bristol Myers Squibb, for future technology development. Recently, NovoNordisk has also purchased an APAS Independence unit for evaluation, marking another milestone in CCS's growing presence in the pharmaceutical sector.

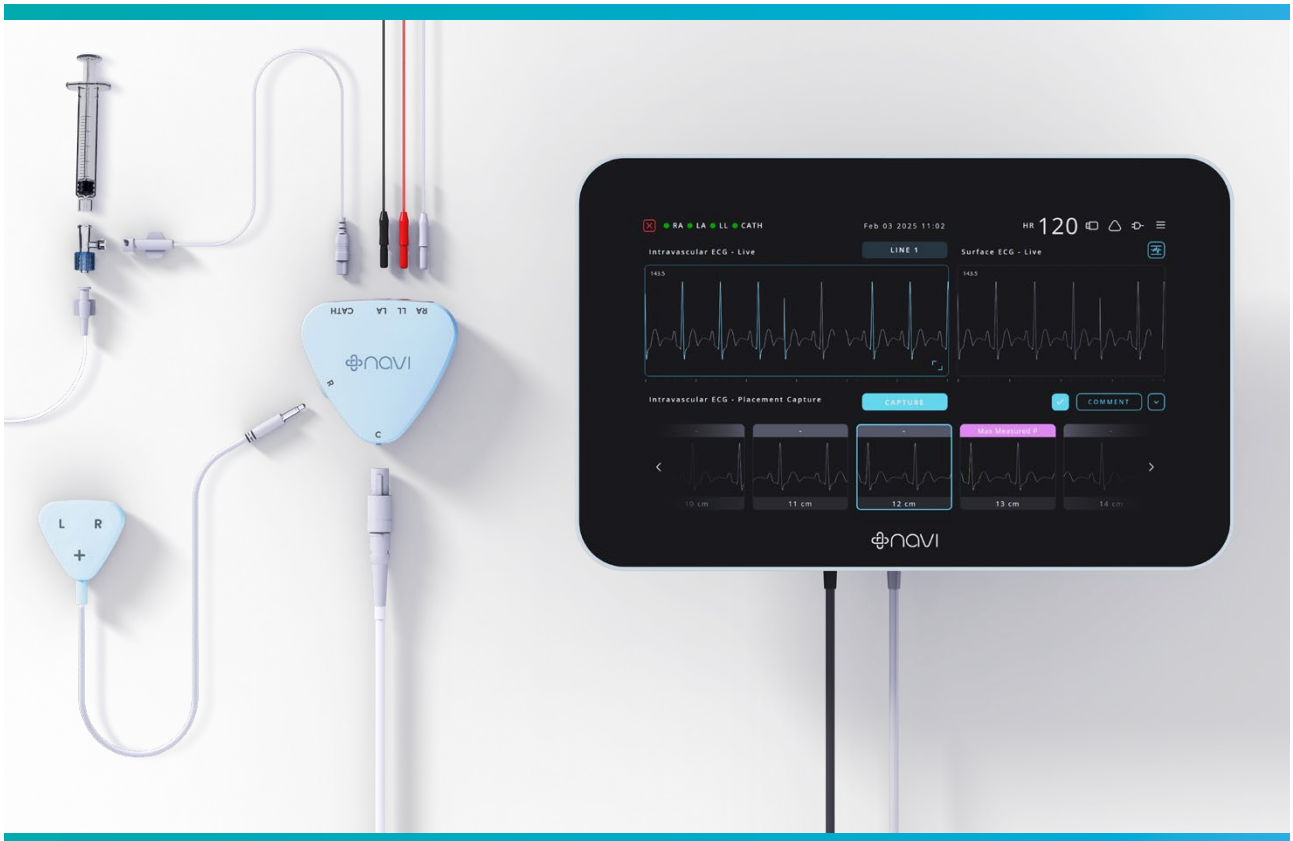
"The development completed under the CTCM program has delivered a unique solution for pharmaceutical culture plate reading," said CCS CEO and Managing Director Brent Barnes.

"The APAS technology is the only fully automated and validated system in the market able to read both 90mm and contact culture plates, providing us with a compelling differentiator for customers. We are already seeing the benefits of this and expect this to be a key commercial driver for the company over the next 12 months," said Barnes.

The developmental leaps achieved by CCS during participation in the CTCM program have been instrumental in supporting the company's transition from an R&D focus to a direct sales model.

CCS is currently focused on finalising its performance data and launching the new APAS Contact Plate System in mid-2025. This milestone marks a crucial step forward in commercialising the technology within the pharmaceutical manufacturing sector and is expected to drive substantial sales growth and accelerate the company's path to profitability.

# Breakthrough newborn medical device gains FDA clearance in US




START DATE:
31 Oct 2022

END DATE:
29 Nov 2024

STATUS:
Completed

DELIVERABLES COMPLETED:
100%

TOTAL CTCM EXPENDITURE:
$1,239,187

TOTAL CASH CO-CONTRIBUTION:
$687,010

TOTAL IN-KIND CONTRIBUTION:
$174,940

TOTAL PROGRAM:
$2,101,138

| | |
|---|---|
| New job opportunities (FTE) created | 6 |
| New digital infrastructure and research tools created | 3 |
| Number of patents filed | 1 |
| Number of local manufacturers supporting the project | 2 |
| New partnerships commenced | 11 |
| Number of end users engaged in co-design | 40+ |
| Number of clinical trial participants recruited | 41 |

## Australian-designed and developed technology is poised to revolutionise the treatment of critically ill newborns and children with a safer and more efficient means of placing central line catheters in veins near the hearts of the tiniest patients.

In little more than a year, start-up company Navi Medical Technologies went from proof-of-concept to receiving clearance from the US Food and Drug Administration (FDA) regulator for its innovative device, the Neonav®, which helps clinicians accurately track the placement of catheters in critically ill newborn babies and children. This remarkably fast approval turnaround for a medical device of this complexity has been partly attributed to the granting of a Breakthrough Device Designation by the US Food and Drug Administration (FDA) in 2022, and the impact of 'company-changing funding' provided by MTPConnect's Clinical Translation and Commercialisation Medtech (CTCM) program.

Image: Neonav® Tip Location System showing Neonav® Console, Neonav® Acquisition Unit, Neonav® Remote Unit, ECG adapter, Adapter Cable and catheter.

Navi Founders: (left to right: A/Prof Christiane Theda, Brad Bergmann, Shing Yue Sheung, Mubin Yousuf, Wei Sue, Alex Newton.

Tens of thousands of central venous catheters are inserted into the veins of newborns and children in Australian Intensive Care Units every year to deliver fluids and administer life-saving medications and nutrients. Current techniques can be hit and miss when it comes to correct positioning of the catheters.

"Clinicians are really trying their best, but the current system is difficult. Around 40 per cent of the time, the catheter tip is placed in the wrong spot." said co-founder and Chief Operating Officer Shing Yue Sheung.

The consequences of misplaced catheters can be severe, potentially causing tissue damage if infusions are delivered to the wrong area. Catheter migration once inserted is also another concern.

## Designed for the smallest of patients

Navi's groundbreaking device uses techniques that have been proven in adult treatment but never in neonatal care.

"For the correct positioning of a catheter in an adult procedure, we're talking about a 'landing zone' of two to three centimetres," said Sheung.

"But when the procedure is for a sick baby, that is only around 0.5 centimetres, with much greater consequences for a misplaced catheter. The way that we have designed our system is very accurate for newborn patients."

The catheters themselves are tiny – a third of a millimetre in diameter, little bigger than a human hair.

"It's very thin, it's extremely flexible, and even the slightest misplacement can cause some complications. Placement is based on a blind insertion and the current standard of care is to use X-ray, which is post-procedure, exposes patients to radiation and causes a lot of frustration to the clinicians because they're waiting for an X-ray to be called over and they can't confirm the tip position until the X-ray is performed."

"Sometimes it can take a long time for an X-ray to be taken – maybe 30 to 45 minutes – especially in the middle of the night," said Sheung.

## Safe insertion and surveillance

Navi's device uses sensors and the patient's own heart signals. As the catheter gets closer to the source of those electrical impulses there is a specific change in the heart signal.

The information is used to provide real-time feedback to clinicians on the location of the catheter tip, so they know exactly where the catheter is located, both during and after the placement procedure.

"We display this information on a screen and clinicians can make any kind of adjustments in real time," said Sheung.

Navi began developing the new device in 2018 and credits strategic decisions, strong clinical demand, and critical funding and support from the CTCM program as key drivers of this accelerated timeline.

> **MTPConnect's funding was company-changing for us. It allowed us to complete essential studies, finalise our device design, grow our team, and even start manufacturing – all in just two years, said Shing Yue Sheung.**

"MTPConnect's connections and advice on regulatory, manufacturing, and commercial strategy were invaluable."

During the CTCM-funded project the Navi team progressed the device from Technology Readiness Level (TRL) 5 to TRL 7 over 24 months. Through the CTCM program they were matched with Cicada Innovations as a program partner to assist with this challenge by providing strategic guidance.

The company has been able to refine the device's design with extensive clinician and end-user engagement to ensure optimal performance in clinical settings. Navi worked closely with neonatal and paediatric healthcare professionals conducting 200 clinical interviews across Australia and the US and conducting more than 100 product demonstrations to build product awareness among healthcare professionals.

# Breakthrough newborn medical device gains FDA clearance in US continued

These interviews provided valuable feedback. The Neonav® underwent six device iterations, requiring a dedicated multi-disciplinary team that expanded from 8 to 12 staff making improvements based on feedback from users and data collected during testing and studies. Each iteration allowed the team to resolve technical issues, enhance the user experience, and improve the accuracy of catheter tip placement detection.

## Developed for clinicians by clinicians

Collaborating with the University of Melbourne, and the Royal Women's Hospital as well as D+I and Entech helped to foster a successful culture of innovation, making sure the technology could eventually be adapted for use in various healthcare systems around the world to improve neonatal care.

Trials have shown that not only does Neonav® make clinicians work more efficient, and less stressful, it reduces risks of complications, leading to improved health outcomes and potentially shorter hospital stays for these young and vulnerable patients.

This also translates to less stress for families and lower healthcare costs.

The Neonav® device has the potential to enable more hospitals to offer effective specialist care for critically ill children, especially for families requiring neonatal intensive care.

The device is also open source in that, unlike many of the adult devices, Neonav® is not tied to one brand of catheter.

"We try to be agnostic to all brands of catheters so that hospitals can choose their own, which is actually something that the users have asked us to do," Sheung said.

For the Navi team who came together originally from The University of Melbourne and Melbourne Business School's Biodesign Innovation Subject to work with senior neonatologist Associate Professor Christiane Theda, this exciting journey is about to take on a new dimension.

## FDA clearance paves the way for use in global paediatric care

With FDA clearance in hand, the company is now gearing up for its first commercial launch in the US, aiming to get the device in hospitals as soon as possible. This breakthrough technology promises to transform the standard of care for some of the most vulnerable patients in neonatal and paediatric intensive care.

Since initiating their CTCM project, the company has won the Victorian Premier's Design Award – 'Best Product Design' (2024) and won 2025 Australian Good Design Awards for Best In Class (Medical & Scientific Design) and Gold Winner (Medical & Scientific Design) for their device. The company also attracted significant further investment including funding from the Victorian Government's Breakthrough Victoria Fund, a CRC-P Round 14 Grant (2023), a City of Melbourne Small Business Grant (2023), the Victorian Government's Medtech Manufacturing Growth Program Grant (2024) and the FDA funded Midwest Pediatric Device Consortium Fall Grant (2024).

Exciting times for a Melbourne startup with big ambitions to create brighter, healthier futures for children.

Neonatologist A/Prof Christiane Theda with Navi Medical's Shing Yeu Sheung operating the Neonav® Tip Location System at Royal Women's Hospital, Melbourne.

# Improving respiratory support for newborns

ventora


START DATE:
1 Aug 2023

END DATE:
30 Jun 2025

STATUS:
Completed

DELIVERABLES COMPLETED:
100%

TOTAL CTCM EXPENDITURE:
$500,000

TOTAL CASH CO-CONTRIBUTION:
$130,111

TOTAL IN-KIND CONTRIBUTION:
$20,000

TOTAL PROGRAM:
$650,111

| | |
|---|---|
| Trademark applications related to CTCM project | 2 |
| National phase patent applications | 8 |
| Interaction with regulatory authorities | 1 |
| Patients recruited to clinical feasibility study | 22 |
| Clinicians recruited to the clinical study | 6 |
| Collaborative research agreement with a registered research provider | 1 |
| Number of end users engaged in co-design | 38 |
| Number of end users engaged as participants in market research | 80 |

## Ventora Medical is developing an Airway Pressure Monitor that delivers non-invasive respiratory treatment for premature babies requiring neonatal intensive care support.

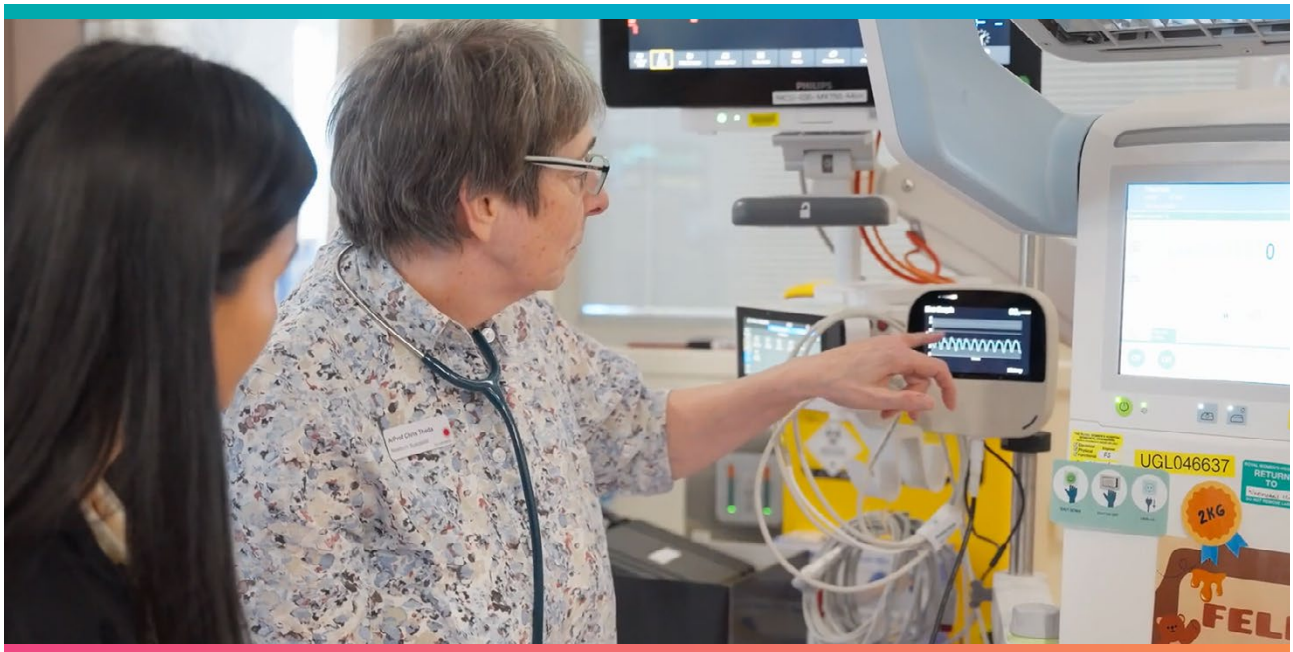
In 2023, almost one in five babies were admitted to a special care nursery or neonatal intensive care unit (NICU) in Australia, with about 20 per cent of those infants requiring respiratory support[1]. In the US, about 300,000 infants are admitted to NICUs annually[2].

Newborns receive respiratory support through two main methods. The first method, mechanical ventilation, is highly invasive, requiring a tube inserted into the airway. For an infant, intubation carries extra risk, including airway trauma, lung injury, delayed oral feeding and neurological impairment. The second, and preferred method is non-invasive breathing support, such as Positive Airway Pressure (CPAP) or High-Flow Nasal Cannula (HFNC), which uses a non-invasive nasal mask or prong interface.

Image: Ventora's Airway Pressure Monitor clinical prototype in use in a clinical feasibility study at the Royal Women's Hospital in Melbourne.

1. https://www.aihw.gov.au/reports/mothers-babies/australias-mothers-babies/contents/baby-outcomes/admission-to-a-special-care-nursery-or-neonatal-in
2. https://www.cdc.gov/nchs/products/databriefs/db525.htm

# Improving respiratory support for newborns continued




Co-founders A/Prof Christiane Theda and Amy Yu, using Ventora's Airway Pressure Monitor clinical prototype in a clinical feasibility study at the Royal Women's Hospital.

For non-invasive methods, there is no way to accurately measure the pressure inside the airway in real time. This poses a problem as adequate pressure is needed to ensure that the treatment is effective and achieving good oxygen and carbon dioxide exchange, while too little or too much pressure could also cause injury to the babies' fragile lungs. Even miniscule pressure errors can cause underventilation or lung injury, and the target pressure needs to be adjusted continuously based on the infant's developing lungs and as their condition improves or worsens.

Recent studies have shown that improving the consistency of pressures delivered through CPAP leads to better clinical outcomes: less need for intubations, and less time on the ventilator[3,4]. However, it comes with additional challenges: the interface can leak air, newborns often have obstructed nasal passages, and the required pressure may dissipate before reaching the airways. Importantly, the existing methods of optimising neonatal CPAP are resource-intensive, requiring one-on-one nursing care and manual support, and making it impractical for long-term or widespread adoption.

Seeking a better solution, Ventora Medical is transforming neonatal care with a world-first Airway Pressure Monitor that accurately monitors airway pressure to support breathing, reduce clinician uncertainty, enable tailored treatment, and improve clinical outcomes for newborns. This solution aims to reduce respiratory complications by decreasing NICUs' reliance on mechanical ventilation. Ventora also expects its device to result in shorter hospital stays for families and significant cost savings for hospitals.

## Leveraging existing clinical workflows

Ventora's device is compatible with all non-invasive respiratory support systems, including CPAP and HFNC. This means the device has minimal impact on NICU workflows, reducing staff burden and lessening the potential for infection.

With $500,000 funding and support from MTPConnect's Clinical Translation and Commercialisation Medtech (CTCM) program, Ventora Medical set out to develop and manufacture its clinical prototype and conduct a clinical feasibility study.

"Ventora is incredibly grateful to MTPConnect and its industry partners for supporting the development of Ventora's clinical prototype," said Ventora Medical Chief Executive Officer and Co-Founder, Mr Edward Buijs.

## Compelling data propels progress

With wraparound support from MTPConnect during its CTCM project, including mentoring and guidance from their program partner Cicada Innovations, Ventora Medical progressed its technology from demonstrated safety in pre-clinical and one-hour clinical pilot studies to demonstrating safety and feasibility in its clinical feasibility study, marking a significant uplift in technology readiness.

Within two years, the team has delivered a clinical prototype and conducted a clinical feasibility study involving 22 patients receiving CPAP and/or HFNC respiratory treatments for an extended period between three and eight days.

3. https://pubmed.ncbi.nlm.nih.gov/31572894/
4. https://www.upmcphysicianresources.com/news/032719-bubble-cpap-and-preterm-neonates-a-noninvasive-ventilation-approach-to-quality-improvement

Ventora Medical Chief Technology Officer, Co-Founder and Project Lead, Ms Amy Yu, explained the study successfully demonstrated technical and clinical proof of concept by using "the prototype device in a real-world clinical environment for a representative clinical-use duration".

The team collected more than 2,000 hours of airway pressure data – combining this data with insights from a separate formative usability study to inform the next product design iteration including hardware, electronics, software, and algorithms.

The usability study, a CTCM project milestone, saw Ventora Medical partner with Sento Solutions over two days at the Epworth HealthCare Clinical Education and Simulation Centre, where neonatologists and neonatal nurses tested the prototype device in a representative clinical setting. The Airway Pressure Monitor received a System Usability Scale (SUS) score of 87, well above average, demonstrating strong user understanding of how to use the device safely and effectively.

Throughout the clinical trial, families were at the forefront of the team's decision-making to ensure the device could function in a family-centred environment. Participant parents actively caring for their children, neonatal nurses, clinicians and respiratory therapists were all engaged in the design and study, providing feedback on how the device fit into or impacted their routines, which was incorporated into the final design.

The Ventora Medical team also received support in making key strategic decisions – determining which skills and capabilities to keep in-house and which to outsource. The team's main learnings from the CTCM program were to engage manufacturers early, explore all options and remain flexible in design and manufacturing choices to reduce production costs without compromising performance or quality.

Ventora Medical has now completed the design of its Airway Pressure Monitor hardware, identified suitable manufacturing partners, and is preparing for transfer to manufacturing and pilot production.

## Market positioning

While Ventora is looking to set a new gold standard in non-invasive ventilation for newborns, the economic benefits of its Airway Pressure Monitor are also compelling. Analysis conducted as part of the CTCM program projects that an average NICU in Australia could save $2–5 million annually through reduced mechanical ventilation use and shorter hospital stays.

Ventora's intellectual property portfolio has also strengthened with the support of the CTCM program's value-add vouchers; providing an opportunity to conduct additional activities that complement the objectives of the CTCM project. Under this MTPConnect scheme, Ventora Medical was able to work on its IP strategy with FB Rice to coordinate and progress its existing patent applications. Three national-phase patents were granted for Australia, New Zealand and India, with applications in key jurisdictions the US, China and Europe still pending as of publication. This sets the scene for Ventora's next objectives as it strategically positions itself in priority markets and explores potential manufacturing sites.

## Looking beyond CTCM

The Ventora Medical team has worked steadily to attract $3 million in private investment and non-dilutive funding. Through an exciting new partnership with AusHealth, Ventora Medical expects to conduct a larger clinical study using its refined product. The timing of the Ventora Airway Pressure Monitor's development aligns perfectly with growing global calls to use airway pressure monitoring in infants receiving non-invasive respiratory support.

In assessing the prototype performance in the clinical feasibility study, Ventora reassessed the prototype design, made adjustments and is now ready to proceed to production as part of its next steps beyond the CTCM program.

> **"The CTCM program has supported Ventora through a critical stage of development. It has accelerated the development of a clinical prototype and commencement of an ongoing clinical feasibility study, said Amy Yu."**

Ventora Medical's proven technology and scalable business model, combined with the team's dedication, openness to guidance and clear focus, position the company for future opportunities as it moves forward.


Ventora's Airway Pressure Monitor clinical prototype, developed as part of their CTCM project.

# FUTURE-PROOFING AUSTRALIA'S MEDTECH CAPABILITY

**9**
Companies developing in-house manufacturing

**49**
Manufacturing activities supported locally

**14**
Digital infrastructure projects developed

**9**
Databases created or curated

Strengthening Australia's sovereign manufacturing capability and supply chain resilience is critical to ensuring long-term national security, economic strength, and global competitiveness. The CTCM program shares this mission by building the capacity and capability of Australian companies through investment in research infrastructure, skills, and local industry engagement.

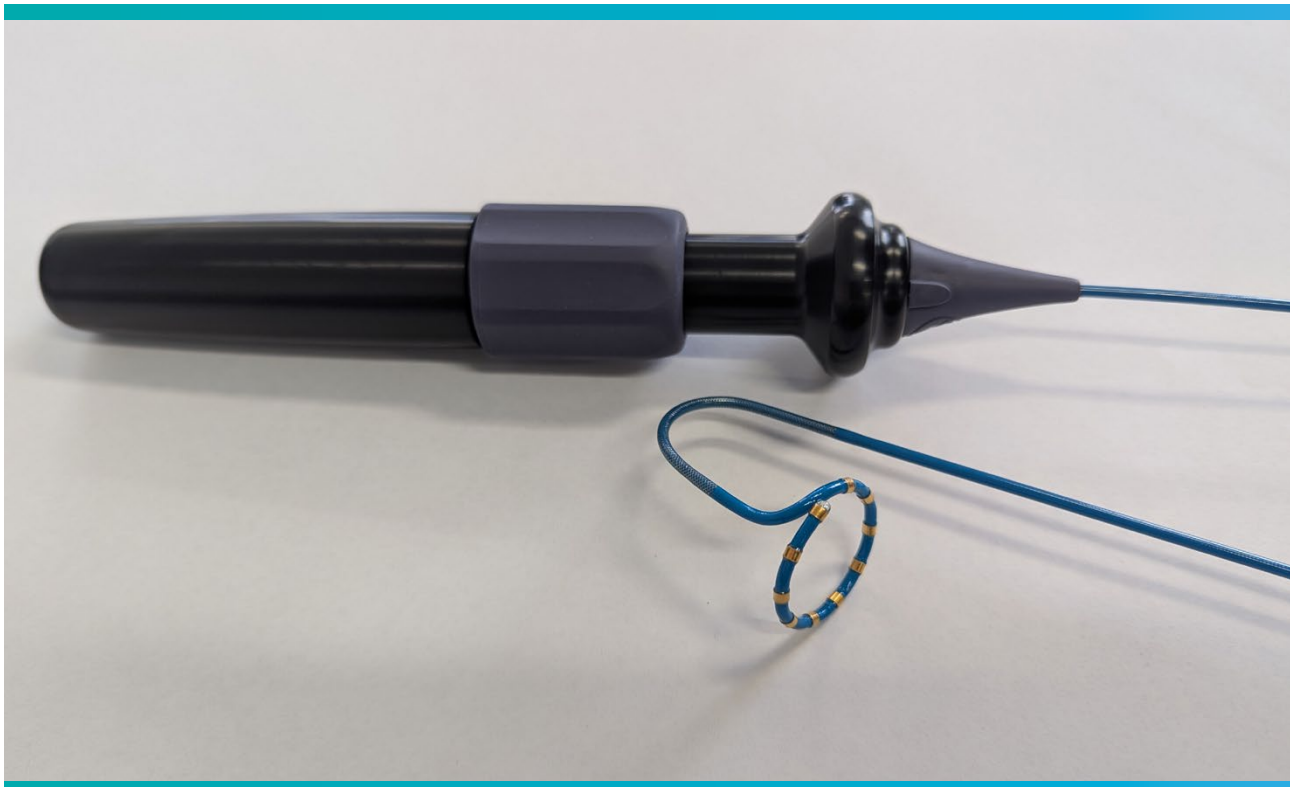
Of the 12 funded companies, nine are developing their own in-house manufacturing capability, with the goal of keeping aspects of their manufacturing activity within Australia.

Each company also collaborated with other local manufacturers, supporting a wide range of manufacturing activities across the country, including activities conducted within the National Collaborative Research Infrastructure Strategy (NCRIS) network.

Alongside manufacturing, the program strengthened digital capabilities through digital infrastructure development and database creation or curation. Coupled with upskilling team members through The BridgeTech Program, these initiatives equipped companies with the expertise and tools to continue innovating, ensuring that the benefits of the program extend well beyond its duration.

Together, these achievements highlight how the CTCM program is equipping Australia's medtech sector to remain resilient, competitive, and ready for the challenges ahead.

# Transforming atrial fibrillation treatment with innovative pulsed field ablation technology



**START DATE:**
1 Sep 2023

**END DATE:**
30 Jun 2025

**STATUS:**
Completed

**DELIVERABLES COMPLETED:**
100%

**TOTAL CTCM EXPENDITURE:**
$1,500,000

**TOTAL CASH CO-CONTRIBUTION:**
$1,500,000

**TOTAL IN-KIND CONTRIBUTION:**
$1,602,644

**TOTAL PROGRAM:**
$4,602,644

| | |
|---|---|
| New job opportunities (FTE) created as a result of the CTCM project | 4 |
| International-level research publications | 2 |
| Trademark applications related to the CTCM project | 3 |
| New technologies invented or progressed during the CTCM project term | 7 |
| Number of clinical trial participants recruited | 75 |
| New partnerships commenced during the project term | 4 |
| New distribution partner agreement | 1 |
| Manufacturing activities supported locally | 18 |

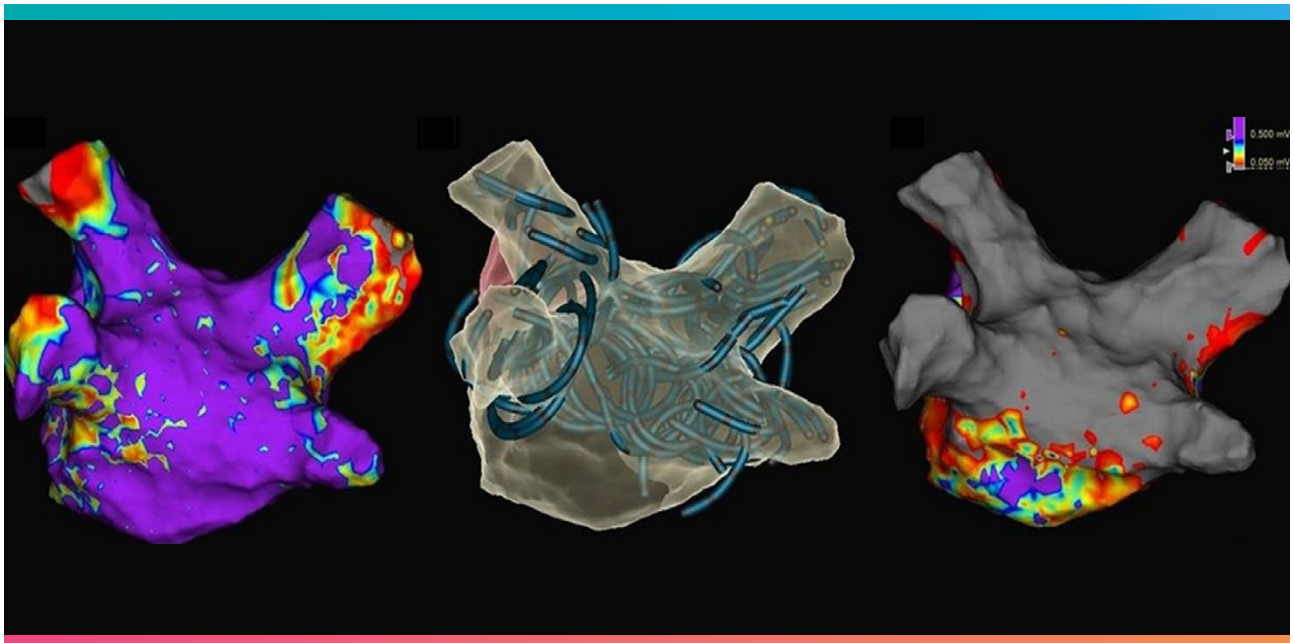
Atrial fibrillation (AF) is the most common heart rhythm disorder, impacting more than 59 million people globally[1]. Its prevalence continues to rise, driven by ageing populations, modern lifestyles and increased detection worldwide[2]. One in 10 adults is at risk of developing AF during their lifetime, with more than 500,000 Australians currently living with this condition[3].

AF occurs when the heart's electrical network become unsynchronised, resulting in an irregular heartbeat. This can trigger a range of distressing symptoms, including palpitations, chest discomfort, fatigue, dizziness and shortness of breath, all of which can significantly disrupt daily life and emotional wellbeing. In severe cases, AF can lead to serious complications such as blood clots, stroke, heart failure, dementia or even death. The condition also imposes a financial burden, driven by hospital stays and expensive treatment options.

Image: The ElectroPulse Variable Loop Ablation Catheter.

1. https://www.thelancet.com/journals/lanepe/article/PIIS2666-7762(23)00205-3/fulltext
2. https://www.sciencedirect.com/science/article/pii/S1098301524000354
3. https://www.aihw.gov.au/reports/heart-stroke-vascular-diseases/hsvd-facts/contents/all-heart-stroke-and-vascular-disease/atrial-fibrillation

# Transforming atrial fibrillation treatment with innovative pulsed field ablation technology continued



3D electro anatomical maps – pre ablation (left), post ablation (right), catheter placement shadows (middle).

Catheter ablation is a common treatment for AF, particularly for a proportion of patients whose symptoms are inadequately controlled by medication, with success rates ranging between 50 and 70 per cent[4]. The process involves inserting a small catheter into the heart to target and destroy cardiac tissue, typically using thermal or cryo energy. Although complications are relatively rare, they can be severe, with an early mortality rate of 1 in 200 patients within the initial admission or 30-day readmission[5]. The procedure can also cause collateral damage to the healthy tissue and structures surrounding the target. Due to the risks involved, catheter ablation is typically only performed by highly skilled specialists using expensive, complex catheter devices. Repeat procedures are often necessary, further driving up costs and resource use.

Established in 1999, New South Wales-based company CathRx is Australia's only onshore designer and manufacturer of electrophysiology catheters. It is developing an innovative device to make catheter ablation safer, faster and more effective, setting a new standard for this life-changing procedure.

## Revolutionising catheter ablation with dual-function technology

CathRx operates with a robust Quality Management System and manufacturing facility which are ISO13485 and MDSAP-certified. The company manufactures a range of diagnostic catheters (Khelix™) with a modular design, that gives clinicians the flexibility to adapt them to match the procedure, the patient's anatomy and their own preferences.

CathRx has pioneered the development of reusable electrophysiology catheters, which have demonstrated the ability to reduce medical waste by up to 70 per cent compared to conventional single-use systems. CathRx's technology is also designed to be more affordable, saving the healthcare system up to 50 per cent per catheter use.

The company has built strong commercial relationships with global distributors, and its products are already available or approved in major markets such as the US, Europe, South Korea and Australia.

Leveraging the team's expertise, CathRx is developing ElectroPulse™, a non-thermal, tissue-selective pulsed electric field ablation (PFA) System. In contrast to thermal or cryo ablation procedures, which are non tissue selective, the ElectroPulse utilises short microsecond bursts of high-amplitude electrical pulses that ablate or destroy cardiac tissue while preserving surrounding tissue. The catheter is also designed to be one of the smallest catheters in its class for better handling and safety, and dual-function, combining diagnostic capabilities with therapeutic PFA delivery.

## Backing ElectroPulse technology

CathRx was awarded $1.5 million funding from MTPConnect's Clinical Translation and Commercialisation Medtech (CTCM) accelerator program in 2023 to progress its innovation from Technology Readiness Level (TRL) 5 to TRL 7. This included support and mentorship from program partner, the Medical Technology Association of Australia (MTAA). The project spanned the small-scale manufacture of CathRx's trial device and design improvements, as well as the completion of its first-in-human clinical study.

4. https://pmc.ncbi.nlm.nih.gov/articles/PMC5135164/
5. https://www.jacc.org/doi/10.1016/j.jacc.2019.08.1036

This all-in-one solution enables clinicians to perform real-time mapping and ablation seamlessly, enhancing patient safety, with no disruption to existing clinical workflows, and reducing costs. Combining both functions into a single device eliminates the need for a separate mapping catheter, resulting in a simpler quicker procedure and approximate savings of $2,300 per procedure in equipment costs.

A simple and faster procedure also allows for same day discharge significantly improving patient outcomes and reducing cost to the healthcare system. There's also the potential for additional savings from fewer hospital admissions and repeat procedures.

## Cross-sector collaboration delivers clinical validation

CathRx took a highly collaborative approach to this project, bringing industry, clinical and research sectors together in a highly integrated way. The clinical trial was conducted in partnership with the Centre for Heart Rhythm Disorders (CHRD) and University of Adelaide. Additionally, a steering committee comprising top electrophysiologists from six hospitals across Australia and New Zealand provided strategic oversight. This cross-sector collaboration exemplified a progressive way of working in the Australian medtech ecosystem, combining sovereign manufacturing capability with world-class clinical research.

The first-in-human study successfully achieved its primary objectives, including demonstrating acute procedural success, confirming safety in human subjects, and laying the foundation for long-term efficacy.

Over the course of the program, 75 patients were treated with the ElectroPulse system, and a comprehensive clinical trial report was produced, confirming long-term procedural success. The trial's initial results have been published and showcased at prominent conferences, including the Heart Rhythm Society's annual meeting, earning widespread peer recognition for the project.

The device likewise garnered positive feedback from clinicians, who are the intended users of the device.

"The ElectroPulse PFA system has performed exceptionally well in our clinical experience," said Professor Prash Sanders, Director of the CHRD in Adelaide and member of CathRx Medical Advisory Board.

"It's intuitive to use, delivers consistent results, and has shown a strong safety profile with promising efficacy. As a second-generation product, it brings meaningful improvements and is well-positioned to compete in the global market."

## CTCM support accelerates journey towards global commercialisation

The CTCM program played a pivotal role in enhancing CathRx's manufacturing capabilities and research infrastructure. By facilitating the purchase of a laser cutter, the program ensured seamless continuity in catheter production. Additionally, upgrades to the company's IT infrastructure have further strengthened operations. These advancements provide a solid foundation for future scalability and drive CathRx's journey towards digital transformation.

> **Support from MTPConnect through the CTCM grant has been instrumental for CathRx. It enabled us to upgrade essential infrastructure and fast-track the development of our ElectroPulse PFA system. We've successfully demonstrated the safety and effectiveness of the system in a large first-in-human study – something rarely achieved at this scale without dedicated funding like that provided through the CTCM program, said CathRx CEO Ian Fong.**

CathRx is making significant strides towards bringing the ElectroPulse system into the hands of more clinicians and electrophysiologists. Through its CTCM project, the company has developed invaluable in-house expertise in conducting clinical trials, paving the way for the next phase: multi-centre clinical trials. These trials will generate robust clinical data to support regulatory submissions.

CathRx is fully prepared and eager to take this next step, having secured ethics approval for the multi-centre trial and recently receiving new funding from MTPConnect's Targeted Translation Research Accelerator (TTRA) Drugs and Devices program.

"Over the next year, we expect strong results from our multi-centre clinical trial, which will be a major step towards global commercialisation," said Ian Fong.

The company has also expanded its manufacturing capabilities through a partnership with a contract manufacturer in Taiwan, allowing for increased product supply once regulatory approval is obtained. CathRx is also actively pursuing new distribution partners in regions beyond its current reach, such as Latin America and South-East Asia, while remaining open to strategic investors that can support its global expansion efforts.

The ElectroPulse PFA system represents a promising breakthrough in the treatment of AF, offering a safer, faster and more effective solution. Backed by robust clinical data and growing interest from international distributors, CathRx is well-positioned to bring this innovation to market.

The CathRx team performing a device demonstration for the CTCM team at the project's kick-off meeting.

# Real-time imaging device designed to get breast conserving surgery right the first time

OncoRes Medical


START DATE:
3 Nov 2022

END DATE:
31 Oct 2024

STATUS:
Completed

DELIVERABLES COMPLETED:
100%

TOTAL CTCM EXPENDITURE:
$1,500,000

TOTAL CASH CO-CONTRIBUTION:
$851,883

TOTAL IN-KIND CONTRIBUTION:
–

TOTAL PROGRAM:
$2,351,883

| | |
|---|---|
| New job opportunities (FTE) created | 2 |
| New database curated from prior clinical data | 1 |
| Regulatory Dossier developed | 1 |
| New partnerships commenced | 2 |
| Number of local manufacturers supporting the project | 1 |
| Number of end users engaged in co-design | 16 |
| Number of clinical trial participants recruited | 30 |

Image: Dr. Simon Graindorge (COO) and Dr. Katharine Giles (CEO)

OncoRes Medical is developing a hand-held diagnostic imaging system used during breast cancer surgery that could dramatically improve outcomes for patients.

Breast cancer is the most common cancer among women globally, with 2.3 million women diagnosed annually[1]. For those undergoing breast-conserving surgery (BCS), success hinges on removing all cancerous tissue during the first procedure. Yet, up to 35 per cent of patients face the physical and emotional toll of repeat surgeries due to residual cancer being left behind.

A significant challenge surgeons face is ensuring 'clear margins' – that no microscopic cancer is left behind at the edge of the removed tissue. Currently, finding these margins relies on the surgeon's sense of touch, a highly subjective approach with limited precision. Outcomes are only confirmed by post-operative pathology, in the week after surgery. This limitation most often results in a higher risk of cancer recurrence, costly repeat surgeries, significant delays in commencing post-surgery cancer treatments, and emotional stress for patients and their families.

1. https://www.who.int/news-room/fact-sheets/detail/breast-cancer

Perth-based medical technology company, OncoRes Medical, is tackling this critical issue head-on by developing an innovative imaging system designed to give surgeons real-time, microscopic feedback directly in the operating theatre.

## A better way of imaging cancer in real time

OncoRes's proprietary Quantitative Micro-Elastography (QME) imaging system combines micro-elastography with optical coherence tomography[2]. By combining these techniques, the system can produce high-resolution cross-sectional images of tissue micro-architecture such as cancer tissue margins, surpassing the capabilities of existing intraoperative tools like ultrasound or specimen radiography. Most importantly, this vital information is available to surgeons in real-time, using a device conveniently operated by hand within the operating room, enabling them to make faster, more informed decisions.

Since its founding in 2016, OncoRes has had impressive traction in advancing its technology from concept to clinic. The company has secured multiple successful funding rounds, alongside receiving Australian government grants from the CRC-P, Modern Manufacturing Initiative and WA State Investment Attraction Fund. OncoRes was also awarded funding from MTPConnect's BioMedTech Horizons (BMTH) accelerator program, to support the pre-clinical development of its device.

The company conducted first-in-human clinical trials in WA and demonstrated early clinical feasibility of the QME imaging System, and the device was granted Breakthrough Device Designation by the US Food and Drug Administration in October 2020.

Reflecting on the company's progress, Deputy Chief Medical Officer, Dr Bridget Ryan, says one of OncoRes's strongest advantages is the workplace culture the firm has created.

"I'm a big fan of the concept of 'psychological safety' – the capacity to ask questions of seniors, in a supportive environment, without fear of retribution," she said.

"This kind of culture is embraced and encouraged, which is a testament to the company's leadership and managers, for leading by example. We have a common goal to improve patient outcomes, and that's pretty awesome."

## Nationwide clinical trials open regulatory pathways

Building on its momentum, OncoRes received $1.5 million in funding from MTPConnect's Clinical Translation and Commercialisation Medtech (CTCM) program, enabling the company to complete its first nationwide, multi-centre clinical trial with support from CTCM Program Partner, the Medical Device Partnering Program.

The 'OPTICS' pilot trial aimed to establish the device's safety profile and demonstrate seamless integration into surgical workflows. This involved shipping the devices across the country, and training surgeons, theatre nurses and sterilisation staff to use the imaging system.

The device successfully met its primary safety endpoints and allowed OncoRes to prepare a robust technical file for regulatory and market approval from authorities such as the TGA and the FDA, once pivotal trial data is available.

> **For us, producing great data and understanding it deeply, is one of our superpowers. The better our data, the more we can learn from it, and the more we can help the surgeons achieve better outcomes for their patients, said OncoRes' Chief Operating Officer Dr. Simon Graindorge.**

The funding also supported the implementation of the company's Quality Management System, ensuring it is well-equipped for future manufacturing processes.

During the clinical trial, OncoRes built strong relationships with clinicians, with many surgeons showing deep interest in the QME Imaging System and expressing eagerness to be involved in future trials. The company also actively engaged with the broader community, gathering feedback on patient preferences and attitudes, while observing real-world scenarios involving breast cancer and breast conserving surgery firsthand.

This engagement is crucial in providing OncoRes valuable insights into the needs of both surgeons and patients, identifying gaps in the market, and enabling the development of their technology to optimise outcomes for patient and end users.

MTPConnect's CTCM program also enabled OncoRes to upskill its existing team in conducting medical device clinical trials. OncoRes staff received subsidised ISO13485 training and participated in multiple networking events hosted by MTPConnect and the CTCM program, fostering valuable industry connections. This funding also allowed the company to grow its team, including bringing on a dedicated project manager to support regulatory submissions. This strategic addition increased the capabilities within the company and was instrumental in finalising a TGA dossier.

## Building a future of world-class Medtech in WA

OncoRes has successfully advanced its device from a Technology Readiness Level (TRL) of 5 at the start of the project to TRL 7 by its conclusion.

The company has not only demonstrated its potential to improve the success rate of cancer surgery, but has also made a considerable impact to Australia's Medtech sector, particularly in Western Australia. By conducting all manufacturing at its Nedlands facility, the company is creating high-value jobs in engineering, clinical research, and manufacturing, and helping to retain and attract specialised talent to the state. OncoRes's workforce has grown to over 40 professionals from diverse industry sectors. Fostering good relationships with local and Australian based suppliers, the company is proud to say that their device is truly Australian-made.

Following the completion of its CTCM project, OncoRes secured a $2.5 million CUREator+ grant from Brandon BioCatalyst as well as $27 million in private funding.

OncoRes is well-prepared to launch large-scale pivotal clinical trials necessary for regulatory approval of the device and to scale up manufacturing efforts, marking a significant step forward in their commercialisation journey.

2. https://www.oncoresmedical.com/science

# Safer Childbirth: How VitalTrace is revolutionising foetal monitoring to keep mothers and babies safe

**START DATE:**
8 Aug 2023

**END DATE:**
30 Jun 2024

**STATUS:**
Partially completed

**DELIVERABLES COMPLETED:**
96%

**TOTAL CTCM EXPENDITURE:**
$656,666

**TOTAL CASH CO-CONTRIBUTION:**
$503,615

**TOTAL IN-KIND CONTRIBUTION:**
$148,585

**TOTAL PROGRAM:**
$1,308,865

| | |
|---|---|
| New job opportunities (FTE) created as a result of the CTCM Project | 6 |
| Preclinical studies commenced | 3 |
| Number of local manufacturers supporting the CTCM Project | 10 |
| Databases curated/created | 1 |
| Number of patients recruited to First-in-Foetus Clinical Study | 7 |
| Interactions with regulatory authorities | 2 |

Image: The CTCM team with Dr Lee Hubble, Celine Royet, and Dr Julian Shapley with the prototype DelivAssure™ device at VitalTrace's facility in Perth.

## Childbirth remains one of the most high-risk medical events for both mother and child.

During active labour, numerous factors can lead to foetal hypoxia-ischaemia, a condition where the foetus has an inadequate supply of blood or oxygen. Approximately 1,110 Australian babies are born each year with preventable foetal hypoxia[1]. Early detection is critical, as it can prevent lifelong, incurable disabilities such as developmental delay, epilepsy, vision and hearing impairment, and cerebral palsy (CP). With 20 per cent of CP cases caused during childbirth[2], there is a significant opportunity for prevention. To prevent hypoxic birth injury, it is routine to monitor the foetal wellbeing during labour. The standard of care, the cardiotocography (CTG), measures foetal heart rate (FHR), a subjective, inaccurate, unreliable biomarker for foetal hypoxia. This can lead to missed or delayed diagnoses.

1. https://www.ajog.org/article/S0002-9378(08)00776-X/fulltext
2. https://www.sciencedirect.com/science/article/abs/pii/S1521693415001017#

Foetal heart rate monitoring has an inherent 70 per cent false positive rate resulting in an estimated 16,000 unnecessary C-sections in Australia each year. These procedures are linked to higher maternal mortality, longer recovery times and hospital stays, an increased risk of infection, and a greater chance of postpartum depression compared to vaginal delivery. A more accurate and objective method for monitoring foetal distress is urgently needed to improve health outcomes for both mother and child.

## A world-first sensor design

Perth-based SME VitalTrace is developing DelivAssure, a continuous lactate sensor to address this critical unmet need. Foetal blood lactate has been used to determine the presence of life-threatening foetal hypoxia in clinical practice for decades. Lactate rises as oxygen supply decreases, and is a robust indicator of foetal hypoxia, with numerical, clinically validated cut-offs to manage labour.

While there are current methods to measure lactate to monitor foetal distress, they are underutilised as they require an invasive, time and skill intensive in-utero blood test which results in a single data point, often outdated by the time it is received. The potential for lactate monitoring has remained unrealised, until now. DelivAssure utilises biosensor placed on the foetus's scalp, connected to a small wearable monitor to measure foetal lactate continuously and less invasively.

This will help clinicians make informed decisions based on precise and objective measurements, allowing early intervention in cases of foetal hypoxia before permanent brain damage occurs, while also reducing the number of avoidable C-sections.

The device's wireless design enables maternal mobility to alleviate pain compared to the traditional wired CTG. This world-first novel technology received a Breakthrough Device Designation from the US Food and Drug Administration (FDA) in 2022, recognising its potential to transform perinatal care.

In 2023, VitalTrace was awarded $656,666 in funding through MTPConnect's Clinical Translation and Commercialisation Medtech (CTCM) program to further advance its technology through clinical testing, along with mentoring and support from program partner, Cicada Innovations.

## Design innovation meets local manufacturing expertise

Through the CTCM program, VitalTrace successfully conducted a study in healthy human adults, which, combined with outcomes from ongoing preclinical studies, informed crucial design and material choices for its First-in-Foetus clinical trial.

The company then finalised its design and material specifications, manufacturing its clinical prototype at its advanced facility in Perth. Extensive validation and verification testing was also conducted to ensure the prototype performed to expectations. This included robust studies to determine the optimal sterilisation doses for maintaining biosensor sterility and performance, as well as carrying out the sterilisation of the clinical prototypes themselves, supported through the CTCM's value-add voucher scheme.

Manufacturing the high-tech device proved challenging, requiring precision and quality from suppliers, deep technical expertise and strong supplier engagement. Expertly navigating these hurdles, VitalTrace's biosensors are manufactured in Western Australia, with components sourced both locally and internationally. Other components of the device are assembled in-house. This commitment to advanced domestic manufacturing delivers a tangible boost to Australia's sovereign manufacturing capability.

## Early results show promising accuracy

VitalTrace successfully commenced its feasibility clinical studies, collaborating with King Edward Memorial Hospital (WA), Monash Health and Eastern Health (VIC) and Royal North Shore Hospital (NSW). The clinical trial is ongoing, with early results showing promising sensor accuracy. Valuable feedback from patients and clinicians is also being gathered to guide further design improvements.

> **"Our greatest achievement is seeing this DelivAssure progress to our First-in-Foetus clinical trial. We were able to generate continuous lactate data from a human foetus for the first time in history. This milestone brings us one step closer to transforming obstetric care, reducing avoidable C-sections, neonatal death and lifelong brain injury, said Dr Arjun Kaushik, CEO and Founder."**

The support of the CTCM program has been instrumental in accelerating our development.

## Building clinical evidence towards regulatory approval

With its clinical evidence data growing, VitalTrace is moving a step closer to regulatory approval and future market entry. Clinical validation will enable further conversations with strategic investors, commercial partners and research collaborators. Throughout the process, the company has also engaged in Breakthrough Device Sprint discussions with the US FDA to confirm its clinical evidence and validation plans, ensuring a clear path towards eventual regulatory approval.

Through the CTCM program, VitalTrace was also able to engage with a US medtech consultant to help develop its US and global go-to-market strategy. Their extensive experience bringing medical devices to market at major international medtech companies has proved invaluable to the team.

"In the next 12 months, VitalTrace will begin pivotal clinical studies and prepare for regulatory submissions in Australia, US and EU. I believe VitalTrace is on the cusp of moving closer to commercialising DelivAssure, a paradigm-shifting medical device that will provide clinicians with the objective, real-time and accurate data needed to make birth safer for mothers and babies," said Dr Kaushik.

The DelivAssure represents a promising advancement in perinatal care, with the potential to provide a safer, more precise way to monitor foetal health during labour. At the same time, the project highlights the strength of Australia's medtech sector, demonstrating local innovation, advanced manufacturing capability and the potential to compete globally while improving outcomes for mothers and babies.

# USER-CENTRIC INNOVATION

**247**
End users engaged in Co-Design

**313**
Participants in market research

**186**
End users engaged in data gathering/ analysis

**42**
End users on advisory boards

**51**
Active clinicians involved in trials/studies

Any medical device innovation, regardless of its technical quality, will struggle to achieve commercial success if adoption and implementation barriers persist. MTPConnect firmly believes that breakthrough products succeed when innovators develop solutions that align with the genuine need of target communities. This is best achieved through collaborative co-design with consumers and end users at every development stage.

The CTCM program placed strong emphasis on this approach in its selection processes, and this commitment is clearly reflected in the exceptional outcomes achieved by funded companies.

The companies actively engaged a wide range of end users in co-design through hands-on user focus groups, human factor studies, and feasibility analyses that directly influenced product design. Consumers also contributed to strategic market research initiatives, data gathering and analysis, while others provided input at the advisory board level. Clinician engagement was equally strong, with healthcare professionals actively involved in product design and clinical trials, empowering health professionals to adopt best practices early.

By embedding diverse stakeholder perspectives into product development, the CTCM program fosters the creation of high-value solutions that are user-centric and impact-driven – directly addressing real-world health challenges and benefiting the Australian healthcare system and beyond.

# ARIA's smart glasses co-designed by the blind community offer sight through sound

**START DATE:**
9 Nov 2022

**END DATE:**
31 Jan 2025

**STATUS:**
Complete

**DELIVERABLES COMPLETED:**
100%

**TOTAL CTCM EXPENDITURE:**
$1,500,000

**TOTAL CASH CO-CONTRIBUTION:**
$870,049

**TOTAL IN-KIND CONTRIBUTION:**
$574,254

**TOTAL PROGRAM:**
$2,944,303

| | |
|---|---|
| New job opportunities (FTE) created as a result of the CTCM project | 18 |
| New technologies progressed or invented | 6 |
| Databases created | 1 |
| New partnerships commenced during the project term | 2 |
| Pre-clinical trials completed | 2 |
| Clinical trial participants recruited | 11 |
| End users engaged in co-design | 22 |
| End users engaged on advisory board | 2 |

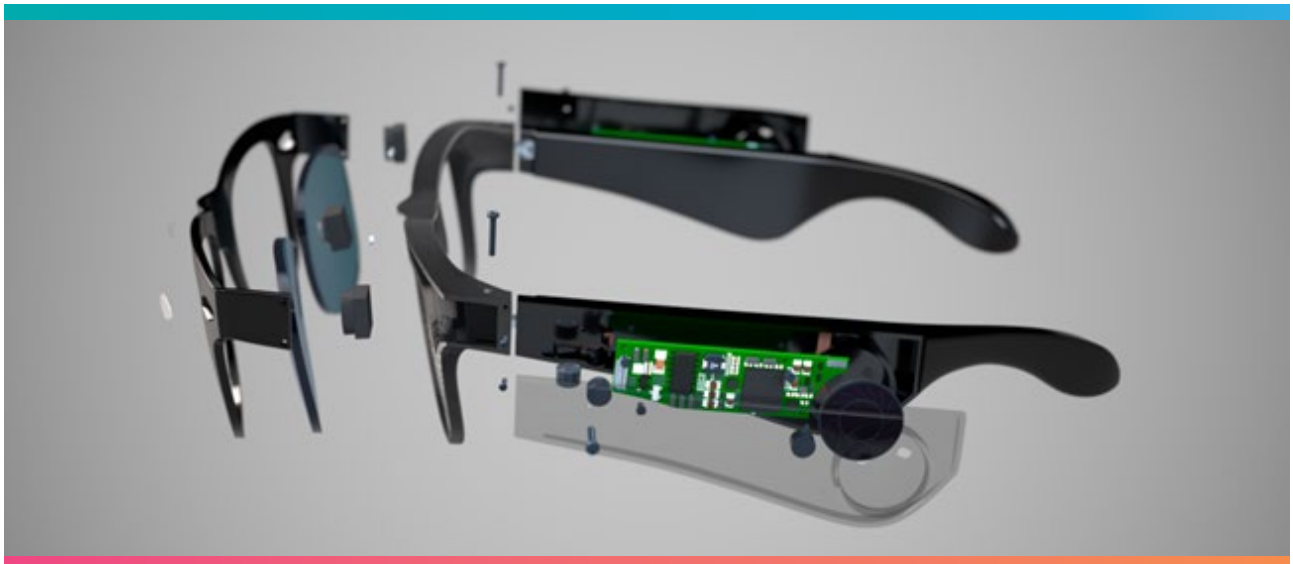
Image: Complete ARIA Crescendo Prototype developed during CTCM project and used in the Clinical Trial.

Globally, 338 million people live with blindness, or moderate to severe vision impairment[1], including 575,000 in Australia[2]. Beyond the economic burden – estimated at about US$411 billion each year in lost productivity[3]– vision impairment can significantly affect a person's quality of life, limiting their ability to work, make and maintain social connections, study and carry out everyday tasks independently.

While many companies are exploring solutions such as bionic implants, usually aiming for restoration of eyesight as an end goal, New South Wales-based company ARIA Research is looking at the problem in a different light – by first listening to those who live with vision impairment.

1. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3582742
2. https://www.vision2020australia.org.au/resources/a-snapshot-of-blindness-and-low-vision-services-in-australia/
3. https://pmc.ncbi.nlm.nih.gov/articles/PMC8528064/

# ARIA's smart glasses co-designed by the blind community offer sight through sound continued



The ARIA 'Vision via Sound' glasses for blind users - exploded view of 'Hollywood' model.

Rather than chasing visual restoration, ARIA Research has collaborated closely with the blind community to understand their needs and co-develop a bionic solution that is practical, affordable and broadly applicable.

The result is an optical device that is non-invasive and requires no recovery time, provides functional benefit within minutes, and works for most individuals regardless of their underlying vision pathology.

## Transforming images into sound

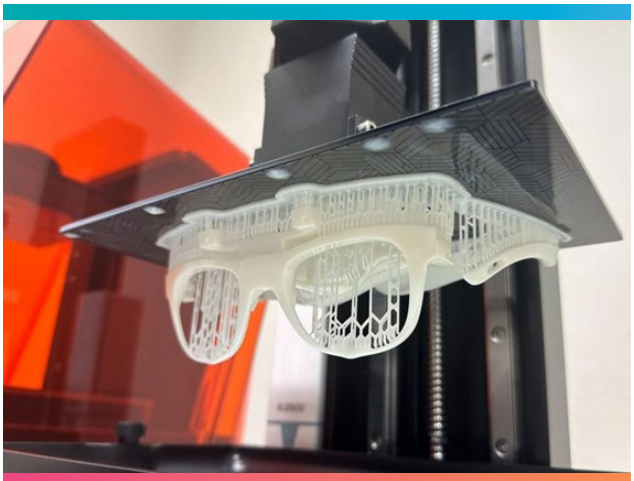
ARIA (Augmented Reality in Audio) is a non-invasive pair of glasses that leverages AI and machine vision to render the wearer's environment as a real-time soundscape. The glasses can detect objects, obstacles, faces and more, and relay this information to the user via audio cues, allowing them to successfully navigate and interact with their surroundings. This enables blind users to have greater functional independence and, as a result, contributes to improved mental wellbeing.

The device was designed with scalability in mind, leveraging existing consumer electronics supply chains to deliver a low-cost, easily accessible solution to vision disability on a global scale.

## Measuring what matters

In 2022, ARIA Research was awarded $1.5 million from the Clinical Translation and Commercialisation Medtech (CTCM) program, in addition to support and guidance from MTPConnect and the Medical Device Partnering Program (MDPP) as the program partner. This funding supported software development, prototype manufacture, preclinical validation and ultimately a pilot clinical trial.

The company encountered a unique challenge during this process: most existing outcome measures for competing bionic vision devices focused on visual improvements – metrics irrelevant to the ARIA's sound-based technology. Additionally, the team found that existing measures on functional task performance for implanted bionics were too specific to the device and not representative of real-world conditions. So, they set out to 'measure what matters' for blind users, devising test conditions that represented real world challenges faced by people living with blindness.



A 3D print of ARIA Crescendo Prototype Frame produced onsite for clinical trials, onsite 3D printing allowed rapid product iteration, and a ready supply of parts when needed, reducing supply chain risk.

This led to an extensive consultation and iterative co-design process, including 'friendly' trials with blind stakeholders interacting with the ARIA prototype hardware to identify 12 tasks that represent common daily living activities that are either significantly challenging or impossible for individuals with vision impairments to complete. These identified tasks formed the foundation for the functional measures used during the pilot clinical trial.

"The process of co-designing the measures with the end user was a significant investment, and it bore fruit with measures and a protocol that has been road-tested and that we felt confident in," said ARIA Research CEO and Co-Founder Robert Yearsley.

The pilot clinical trial met its primary endpoint of device safety with no adverse events or severe adverse events reported. It also enabled the company to validate the suite of functional clinical trial measures, which will be further refined and used in follow-up clinical trials.

> **"The support of MTPConnect has been key to advancing towards medical device commercialisation. The CTCM program has supported our pilot clinical trial, and helped advance ARIA prototypes, to bring life-changing agency and autonomy to people living with vision disability, said Robert Yearsley."**

## Co-design is key to success

The product's greatest strength is that it was created in collaboration with the blind community, including blind team members who led key aspects of development. Community involvement has been seamlessly integrated into every stage of the design process. This includes feedback from more than 300 expressions of interest and survey participants; interviews with more than 30 blind collaborators; and hands-on interactive testing with 20 blind participants.

ARIA Research also worked with disability support stakeholders such as the NDIS, US Department of Veterans Affairs, Vision Australia and Guide Dogs Australia to understand costs and service delivery systems within the disability space.

This strong focus on stakeholder engagement enables future users and payers of the device to have a say in what they want in a product and which outcomes matter to them in the service delivery and administration of disability support services.

## Advancing towards market readiness

ARIA Research is continually making progress to bring its device into the market and into the hands of its valued end users.

ARIA Research's commitment to this mission has earned significant recognition. At the 2023 Australian Technologies Competition, it won the Medtech & Pharma Award and was named Australian Technology Company of the Year. It was also selected as one of Australia's top deeptech start-ups by Cicada x Tech23 that year and received the inaugural Robert Pataki Award for Healthcare Design at the 2024 Good Design Awards.

Through its CTCM project, the company has developed a regulatory plan and begun consultations with US-based regulatory advisors, as well as informal discussions with the US FDA.

The project has also opened doors for ARIA Research to collaborate with the US Department of Veterans Affairs, which has shown strong interest in partnering on the design and implementation of a pivotal clinical trial in the US. To support this next phase, ARIA Research is currently raising capital and has made an impressive start by securing a $2 million investment from the NSW Health and Medical Research Medical Devices Fund.

With its user-led approach, cutting-edge technology and growing support, ARIA Research has great potential to improve the quality of life for individuals in the blind community.

ARIA Research team accepting the Australian Technologies Competition Medtech and Pharma Company of the Year and overall Australian Technology Company of the Year awards.

# Next generation non-opioid pain management device to deliver better flexibility and patient experience

Medical Developments International


**START DATE:**
21 Aug 2023

**END DATE:**
1 Mar 2024

**STATUS:**
Self-terminated

**DELIVERABLES COMPLETED:**
32%

**TOTAL CTCM EXPENDITURE:**
$178,405

**TOTAL CASH CO-CONTRIBUTION:**
$178,405

**TOTAL IN-KIND CONTRIBUTION:**
–

**TOTAL PROGRAM:**
$356,810

| | |
|---|---|
| Number of end users engaged in co-design | 5 |
| Number of interactions with regulatory authorities | 1 |

The Penthrox™ inhaler, known as the 'green whistle,' is used across Australia for rapid emergency pain relief as a safe alternative to opioids. Medical Developments International, the company behind the product, attracted funding from the Clinical Translation and Commercialisation Medtech program to accelerate the development of the next iteration inhaler.

In Australia, pharmaceutical opioids are responsible for more deaths and poisoning hospitalisation than heroin. Every day, three Australians die from opioid use and nearly 150 hospitalisations are opioid-related. Meanwhile in the US, the opioid epidemic has been declared a national public health emergency with overdoses killing more than 80,000 people each year.

Image: Side profile of the Selfie device prototype.

Given the adverse effects the drugs can have on both individuals and society, there is a worldwide move towards non-opioid alternatives for acute pain relief.

Australian firm Medical Developments International (MDI) is answering the movement as a leader in non-opioid emergency pain relief and respiratory products.

Its fast-acting trauma and emergency pain relief product Penthrox™, administered via an inhaler nicknamed the 'green whistle,' is widely used in Australian hospitals, ambulance services, the Australian Defence Forces, in sports medicine and for analgesia during short surgical procedures, and is a safe, effective alternative.

Currently registered and used in 28 countries, Penthrox™ is non-addictive and, in Australia, is classified as a Schedule 4 – prescription only medicine. This makes its use more flexible as it is not as restricted as controlled drugs such as opioids (Schedule 8).

## Developing a new all-in-one design inhaler

With support of the Clinical Translation and Commercialisation Medtech (CTCM) program and the valuable advice and guidance of its program Partner, Medical Device Partnering Program (MDPP), MDI's aim for the project was to speed up development of the next generation inhaler by 18-24 months – to finalise development and validate and clinically test the new design.

This new version of the 'green whistle,' dubbed 'the selfie', is designed to build on the original device's success by eliminating the 8-step assembly process only a trained healthcare professional may complete, before patients can self-administer pain relief as needed.

The all-in-one design significantly reduces the resource burden on the healthcare system as patients administered standard pain relief, including opioids, often spend lengthy periods of time in the emergency department, requiring significant hospital resources in terms of staff administration, monitoring and recording.

Under supervision, the selfie also improves the patient experience as the time to delivery is reduced from 30 seconds to within five seconds.

## Drug delivery design challenges

While MDI chalked up several milestones in its first seven months working on the project, the company encountered some design challenges and technical hurdles when developing the product as a combination drug delivery device, leading to significant time constraints. This meant the firm was unable to start its clinical trial within the CTCM program timeline. MDI consequently decided to self-terminate its project.

Nevertheless, MDI is in a good position as it considers its strategy to replace the current Penthrox™ device in existing markets and explores new ones.

## CTCM support helped progress device development

It successfully completed a toxicological evaluation of the device and cleared initial FDA hurdles in the US, where there is no similar device. Some challenges remain in the product design, including appropriate storage now that the drug is incorporated into the device.

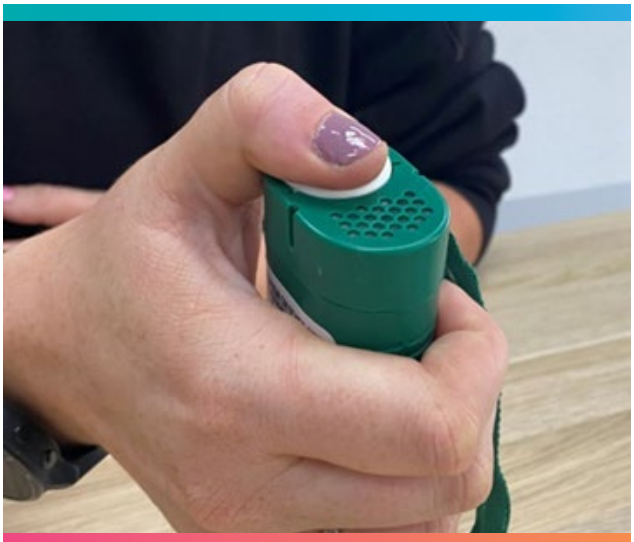
Market research – conducted by MDI as part of the project – showed promising results for the Australian market. Responses to questions about the device's usability were extremely positive, particularly in comparison with the existing device. End users loved the design, ease of use and the rapid activation time from healthcare professional to patient.

Despite the challenges the project experienced, MDI has advanced the device from Technology Readiness Level (TRL) 4 to TRL 5.

MDI CEO Brent MacGregor said "MDI was very grateful to have been one of only a few companies to have received funding under this government initiative."

"It is testament to the innovation we are driving from our base here in Australia out to global markets. As well as being an exciting prospect for existing markets, the next generation Penthrox device will play a crucial role in our ambition to bring Penthrox to the US market."

> **"Although we were not able to deliver on all the program milestones within the funding timelines, the funding, insightful support and value-add from MTPConnect's CTCM program over the initial six-months enabled MDI to significantly progress the development phase of the next generation Penthrox device. This has provided us with the confidence that the new device will be the 'device of choice' to enter the US market when the right time comes, said Brent MacGregor.**



MDI employee demonstrating actuation of the Selfie device by pressing down on the plunger.

# VividWhite set to transform surgical glaucoma management and vision care

START DATE:
1 Jul 2023

END DATE:
30 Jun 2025

STATUS:
Complete

DELIVERABLES COMPLETED:
100%

TOTAL CTCM EXPENDITURE:
$1,000,000

TOTAL CASH CO-CONTRIBUTION:
$536,094

TOTAL IN-KIND CONTRIBUTION:
$164,065

TOTAL PROGRAM:
$1,700,159

| | |
|---|---|
| National phase patent applications as a result of CTCM funding | 6 |
| PCT patent application as a result of the CTCM funding | 1 |
| Number of patients recruited to pivotal clinical trial | 65 |
| Number of active clinicians recruited to clinical study | 10 |
| End users engaged on advisory boards | 18 |
| End users engaged in data gathering/analysis | 15 |

Investment of $1 million from MTPConnect's Clinical Translation and Commercialisation Medtech (CTCM) program has helped propel VividWhite's novel surgical implant, VividFlo, towards becoming an improved long-term treatment option for people with glaucoma. A debilitating and progressive eye disease, glaucoma diminishes vision and requires ongoing management to slow its progression.

Glaucoma is a group of eye diseases affecting more than 300,000 Australians, yet over half remain undiagnosed. This can lead to impaired vision and vision loss, reduced quality of life, a higher risk of injury and increased patient isolation and psychological distress[1]. Traditional treatments such as eye drops and laser therapy are often limited by poor patient compliance or may not be sufficient or suitable for everyone.

Image: Surgical insertion of VividFlo in the eye.

1. https://glaucoma.org.au/news-details/treatment/glaucoma-update-2024-the-treatment-landscape

CERA's Professor Keith Martin, VividWhite CEO Andrew Batty, CSO Dr Craig Ross, CERA's Principal Investigator Dr Jennifer Fan Gaskin, VividWhite's CTO Christopher Smith and CMO Professor Michael Coote.

Surgically reducing intraocular (eye) pressure by allowing fluid to drain out of the eye is currently the most effective treatment. This includes procedures such as shunt placement, implant insertion and trabeculectomy. However, challenges persist around long-term efficacy, accessibility[2,3], complications[4] and integration into routine care[5]. With patients typically requiring an average of 17 specialist follow-up visits in the first year and facing a 30–50 per cent failure rate within five years[6,7], the need for more reliable and patient-friendly treatment solutions is increasingly urgent, especially for those in rural and remote regions.

Melbourne-based medical device company VividWhite is working to close these gaps and improve vision outcomes for people with glaucoma through its lead device, VividFlo (VW-51).

With CTCM funding, VividWhite has advanced VividFlo through an Australian multi-centre pivotal study and is producing promising data that address key challenges of current surgical treatments. It is hoped that the device will demonstrate improved reliability and a reduced post-surgery care burden, offering a significantly better treatment option to patients.

> **We're grateful for the support of MTPConnect and the CTCM program, which has been instrumental in advancing this work. As we move forward with local manufacturing and product registrations, our focus remains on delivering safe, effective, and accessible solutions for glaucoma patients, said VividWhite Co-founder and CEO, Andrew Batty.**

## Precision in pressure control

VividWhite's device, the VividFlo glaucoma implant, is designed for surgical placement at the side of the eye, connecting to the anterior chamber to establish a sealed pathway that maintains stable intraocular pressure and enables precise fluid-flow regulation. Unlike conventional devices that rely on a single fluid channel, VividFlo features a network of resistive microfluidic channels with 157 points of egress. This device distributes fluid more evenly, alleviating fluid stress, safely reducing internal eye pressure.

Engineered with flexible materials and ultra-small dimensions, VividFlo prioritises patient comfort and improves ease of use for surgeons. Its implantation technique is intentionally designed to be intuitive, closely mirroring existing 'tube and plate' procedures, making it easy for trained ophthalmologists to adopt.

## Overcoming barriers to clinical trial recruitment

When VividWhite joined the CTCM program, it had already achieved encouraging clinical results in efficacy and reduced post-operative care from a feasibility study involving 10 participants. The study also provided manufacturing insights that informed the product's design and the execution of the larger pivotal trial.

While the journey presented challenges, the team adapted quickly, supported throughout by MTPConnect and its program partner, the Medical Device Partnering Program (MDPP). The biggest hurdle during the two-year project was recruiting participants for the pivotal study, which progressed slower than expected.


2. https://pubmed.ncbi.nlm.nih.gov/22814041/
3. https://pubmed.ncbi.nlm.nih.gov/26664740/
4. https://www.aoa.org/assets/documents/EBO/931-016GEDDE-2007.pdf
5. https://pubmed.ncbi.nlm.nih.gov/25999687/
6. https://pubmed.ncbi.nlm.nih.gov/34715397/
7. https://onlinelibrary.wiley.com/doi/10.1155/2015/847439

# VividWhite set to transform surgical glaucoma management and vision care continued

In response, the team swiftly expanded the trial to additional sites, to eventually include six clinical and seven surgical sites, with 10 active clinicians involved in the study. This paved the way for more investigational teams to integrate the new treatment into existing clinical workflows. Although this required extensive communication and training, it provided valuable insights into the device. Throughout the ongoing pivotal trial, investigators have worked closely with the VividWhite team, providing insights into the device, its implantation and post-operative management requirements. Their feedback – particularly on surgical challenges and how best to convey key differences in handling between VividFlo and existing competitor devices – has been instrumental in developing the product dossier.

By expanding test sites, increasing the number of investigator teams and broadening testing parameters, VividWhite successfully recruited 65 participants – five more than originally planned – and, at the time of publishing, achieved promising trial outcomes. In overcoming this major hurdle, VividWhite's carefully tailored strategy and strong relationships with all investigational teams have paid off, laying a solid foundation for future trials.

"With the completion of recruitment for VividWhite's pivotal glaucoma trial, we've reached an important milestone in our efforts to improve vision care," said VividWhite Co-founder and CMO, Professor Michael Coote.

## Adding value on manufacturing, trial execution and regulatory strategy

As part of its strategic planning, VividWhite leveraged the CTCM's Value-Add Voucher scheme with infrastructure partner Therapeutic Innovation Australia to unlock targeted support ahead of its pivotal trial. This included engaging the Victorian node of the Australian National Fabrication Facility (ANFF), the Melbourne Centre for Nanofabrication, to produce specialised tooling for implant manufacturing. This allowed VividWhite's engineering team to deepen their expertise in commercial-scale production. These learnings have positioned the company to expand local manufacturing capabilities in future phases.

Further program support was directed towards clinical trial oversight, regulatory compliance, and clinical trial data integrity, delivered in partnership with Avania. This input directly shaped the structure and execution of the pivotal trial. A final collaborative activity with Commercial Eyes, facilitated through the CTCM program, helped strengthen VividWhite's regulatory strategy to enter the US market.

## Getting ready for market

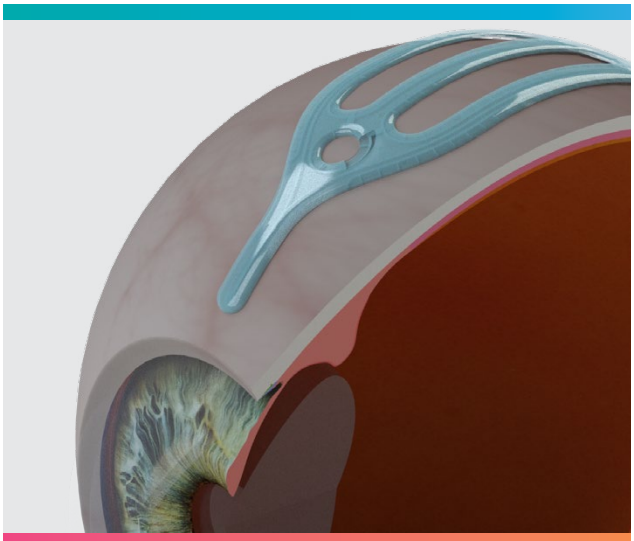
VividWhite successfully progressed its patent application to the national phase, securing review across key global jurisdictions including Australia, China, USA, EU, Canada and Japan. In addition, regulatory activity will reflect the market opportunity and alignment with the company's commercial road map.

As VividWhite continues to monitor patient safety, its fundraising efforts are now geared towards completing the pivotal trial, publishing the results and preparing to scale manufacturing. Ongoing engagement with the local community of ophthalmologists – particularly through presenting results from the feasibility trial at the Australian and New Zealand Glaucoma Society's 2024 and 2025 congress – is helping to keep VividFlo visible within the clinical community and is critical to supporting its transition from clinical validation to commercial readiness.

"It's quite a privilege to be part of this trial, based on such fantastic research and a design that has been entirely locally created," said Professor Keith Martin, Managing Director at the Centre for Eye Research Australia (CERA) and one of the surgeons participating in the study. "There are not many cases where a small team, without assistance from a major medical device or pharmaceutical company, has taken an idea like this all the way from the drawing board to clinical trial".

Recent funding milestones include a Gate 2 pre-seed investment from ANFF-C to support manufacturing and packaging development, and a LaunchVic Medtech Market Growth Program grant to advance VividWhite's market expansion plans.

Together, this flow on funding reflects growing momentum and validates the team's strategic execution across clinical and regulatory domains, signalling strong progress towards the company's next milestones in bringing this new implant to patients to save their vision.



Positioning VividFlo in the eye to relieve intraocular pressure.

# BUILDING AN ECOSYSTEM OF SUPPORT

**16**
Collaborative Research Agreements

**23**
Partnerships formed

**16**
Research publications

Collaboration is a cornerstone of innovation in the medtech industry, where the journey from concept to commercialisation is rarely a solo endeavour. For Australian innovators, creating a robust network of support is critical to navigating the complex pathway of medical device development.

Over four years, the CTCM program fostered its own medtech ecosystem, by bringing together the funded companies for valuable peer-to-peer learning, and opened the ecosystem into MTPConnect's wider network of industry experts, service providers, and potential partners.

This collaborative spirit is cultivated and shared across all the CTCM-funded projects. Companies established multiple collaborative research agreements and forged new national and international partnerships. This includes partnerships with various clinical trial sites and research service providers to conduct clinical trials, R&D partnerships with industry-leading medtech and pharmaceutical companies, relationships formed with key industry associations, as well as manufacturing and distribution partners. The companies also contributed to sector-wide knowledge sharing through publishing in academic journals and presenting their work at conferences, helping to strengthen the collective expertise of the medtech community.

These successes foster a supportive and interconnected medtech ecosystem, generating benefits not only for innovators but also for the wider Australian healthcare system.

# 4DMedical develops breakthrough imaging diagnostic technology for respiratory disease


START DATE:
1 Jul 2023

END DATE:
30 Jun 2025

STATUS:
Complete

DELIVERABLES COMPLETED:
100%

TOTAL CTCM EXPENDITURE:
$1,068,030

TOTAL CASH CO-CONTRIBUTION:
$1,233,882

TOTAL IN-KIND CONTRIBUTION:
$145,812

TOTAL PROGRAM:
$2,447,725

| | |
|---|---|
| Total grant funding as a result of the CTCM project | $5,800,000 |
| New job opportunities (FTE) created as a result of the CTCM project | 4 |
| Databases created/curated | 2 |
| New technologies progressed during CTCM project term | 2 |
| Collaborative research agreements with registered research providers | 3 |
| Distribution partner agreements during CTCM project term | 2 |
| Patients recruited to clinical trials | 73 |

Image: 4DMedical's CEO Andreas Fouras with clinical collaborators at Vanderbilt University.

Respiratory diseases are among the most common causes of severe illness and death worldwide. Chronic obstructive pulmonary disease (COPD), for example, is ranked as the third-leading cause of death in 2023, while lower respiratory infections and lung cancer ranked fourth and seventh respectively[1]. With 8.5 million Australians living with chronic respiratory conditions[2], the annual healthcare cost of lung conditions is significant, exceeding $5.4 billion[3] in 2022-2023.

1. https://www.healthdata.org/sites/default/files/2025-10/GBD_2023_Booklet_Final_2025.10.17.pdf
2. https://www.aihw.gov.au/reports/chronic-respiratory-conditions/chronic-respiratory-conditions/contents/summary
3. https://www.aihw.gov.au/reports/health-welfare-expenditure/health-system-spending-on-disease-and-injury-aus/contents/spending-australian-burden-of-disease-groups


Clinical trial collaborators at the University of Miami.

Patients with respiratory disease often experience breathlessness – a symptom they describe as urgent and highly distressing. Relieving breathlessness is a key treatment priority, and new or worsening symptoms are often what prompt patients to seek medical care. Early identification and accurate diagnosis of the underlying causes are essential for effective management and better patient outcomes. However, because breathlessness can result from many conditions – including cardiac problems, anaemia and various respiratory diseases – fewer than 30 per cent of breathlessness-related diagnoses made in primary care align with the final diagnosis made by a specialist[4].

Current lung diagnostic techniques have limitations: they are often insensitive for early detection of lung disease and ineffective for monitoring disease progression or treatment response. The key indicators for lung conditions are changes in the structure of the lung and how they perform their vital functions, specifically how air moves in and out (ventilation) and how blood flows through them (perfusion).

No single diagnostic technique currently available can provide definitive information on both these critical aspects simultaneously. Existing tests tend to focus either on the lung's physical structure or offer only an approximation of its functional changes. This forces clinicians to either order a battery of tests or rely on limited tests to inform diagnosis and management. These limitations can lead to delayed diagnoses, underdiagnosis and misdiagnosis, significantly affecting patients' health outcomes and quality of life.

Melbourne-based global medtech company 4DMedical is developing a solution for this diagnostic challenge.

## A frontrunner in functional lung imaging

Established in 2013, 4DMedical has created a portfolio of Software-as-a-Service (SaaS) technology to derive functional lung health insights from conventional X-rays and computerised tomography (CT) scans without the use of radioactive tracers or contrast agents.

These software products have been approved by the Therapeutic Goods Administration (TGA) and the US Food and Drug Administration (FDA), with nine FDA cleared and three already achieving reimbursement in the US.

4DMedical is a significant contributor to Australia's medtech ecosystem, with all core research and development (R&D) performed at its Melbourne headquarters. The company employs 92 of its 124 staff in Australia, fostering local talent and ensuring its innovative technology is designed, developed and manufactured locally. It has also expanded operations to the US with an office in Los Angeles, California.

Supported by a Medical Research Future Fund (MRFF) Frontier Health and Medical Research grant in 2021, 4DMedical has advanced its four-dimensional lung imaging technology by developing a dedicated lung scanner – the XV Scanner™. This device uses X-ray velocimetry (XV) to visualise ventilation in lung tissue, allowing clinicians to observe airflow with higher detail, greater accuracy and a lower radiation dose than existing methods. A clinical trial is currently underway at the University of New South Wales to evaluate the scanner.

In 2023, 4DMedical was awarded $1.1 million in funding from MTPConnect's Clinical Translation and Commercialisation Medtech (CTCM) program to further enhance this lung scanner device, specifically to integrate perfusion measurement functionality into the same scan (XVD), expanding its diagnostic utility.

4. https://lungfoundation.com.au/health-professionals/clinical-tools-and-training/breathlessness/

# 4DMedical develops breakthrough imaging diagnostic technology for respiratory disease continued

## Clinical validation through global collaboration

With guidance and support from MTPConnect and its program partner, Medical Technology Association Australia (MTAA), 4DMedical successfully demonstrated technical proof-of-feasibility of utilising the novel XVD technology to measure perfusion through preclinical large animal studies at the South Australian Health and Medical Research Institute (SAHMRI).

4DMedical also achieved clinical validation of its device's perfusion scanning capability through a pivotal collaboration with Vanderbilt University Medical Center. This first-in-human clinical trial has successfully scanned 69 human volunteers, including both healthy controls and participants with a range of respiratory diseases.

"We're now able to see the invisible," said Dr Bradley Richmond, Pulmonologist and Co-Lead Investigator at Vanderbilt University alongside Dr Michael Lester. "(This) technology gives us a window into parts of the lung we've never been able to assess so precisely before. It could transform care for patients whose symptoms were previously a mystery."

Building on this momentum, 4DMedical has also initiated a clinical trial at a second US site, at the University of Miami. While the clinical trials are ongoing, the dataset generated has already proven valuable. 4DMedical used the XVD images to develop a statistical model for a 'lung mask' – a 3D map of the lung region previously derived from a paired CT scan. Using this statistical model, the team has developed a software prototype that generates a lung mask to analyse XVD scans without requiring an additional CT scan. This innovation has the potential to lower costs for patients and significantly reduce their radiation exposure.

> **This CTCM project has generated a world first: the ability to see and measure regional lung perfusion, said Dr Tim O'Meara, Director of Government and Research Strategy at 4DMedical.**

"When combined with regional lung ventilation measured from the same scan, we can see and measure, for the first time, how well a patient's lungs are functioning, without exposing them to toxic contrast agents or radioactive tracers."

## Partnerships driving a shared mission

4DMedical also gained a valuable partner in global healthcare company Philips. In September 2024 the company signed a comprehensive distribution agreement with Philips, leveraging the company's long-established and significant commercial partnerships with both the US Department of Veterans Affairs and the US Department of Defense. Under this agreement, Philips holds exclusive distribution rights to 4DMedical's suite of products for US government customers and non-exclusive rights for all other US customers.

In a similar vein, Vanderbilt University Medical Center, a US Veterans Affairs clinical site, has also proven to be a strategic partner in 4DMedical's efforts to advance non-invasive lung diagnostic technologies for US veterans, particularly those exposed to airborne toxins.

These partnerships pave the way for 4DMedical to expand healthcare accessibility for veterans, underscoring a shared commitment to improving cardiothoracic imaging and addressing the unique needs of this vulnerable population.

## Building momentum towards widespread adoption

Support from the CTCM program has enabled 4DMedical to undertake a comprehensive Australian market access feasibility assessment with Pulse Economics to determine the best way forward for market entry and reimbursement success. This assessment evaluated patient populations, market dynamics, reimbursement pathways and economic value proposition of 4DMedical's technology. The findings have helped refine the company's commercialisation strategy including the prioritisation of target markets, the design of future clinical studies to support adoption, and the identification of potential partners to facilitate market access.

Looking ahead, 4DMedical is advancing at full pace, driving forward its entire portfolio of lung imaging hardware and software. During the CTCM funding period, the company raised $47.5 million through two capital raises and secured a $1.9 million Cooperative Research Centres Projects (CRC-P) grant to conduct clinical trials for its new CT:VQ™ software, which measures perfusion directly from CT scans.

For the XV Scanner™, 4DMedical's next steps focus on completing and publishing ongoing clinical studies, with promising preliminary data already presented at several international conferences. In parallel, the company is pursuing a licensing agreement with a global healthcare or imaging partner to support large-scale manufacturing and commercialisation of the device.

With a clear road map, growing clinical evidence base and strong investor and partner support, 4DMedical is well placed to translate its innovative lung function scanner technologies into widespread clinical adoption, impact respiratory healthcare and secure commercial availability.


XVD Scanner at University of Miami clinical trial site.

# High tech materials deliver world-first condoms that feel like skin

Eudaemon TECHNOLOGIES


**START DATE:**
8 Nov 2022

**END DATE:**
30 Sep 2024

**STATUS:**
Completed

**DELIVERABLES COMPLETED:**
100%

**TOTAL CTCM EXPENDITURE:**
$1,500,000

**TOTAL CASH CO-CONTRIBUTION:**
$1,911,880

**TOTAL IN-KIND CONTRIBUTION:**
–

**TOTAL PROGRAM:**
$3,411,880

| | |
|---|---|
| New job opportunities (FTE) created | 3 |
| Number of countries in which PCT was approved | 40+ |
| Number of end users engaged in co-design | 100+ |
| Number of clinical trial participants | 68 |
| Number of collaborative research agreements | 5 |
| Number of local manufacturers supporting the project | 5+ |
| Number of Research Publications | 1 |

1. https://www.who.int/news-room/fact-sheets/detail/condoms
2. https://www.safeabortionwomensright.org/news/unfpa-seeing-the-unseen-the-case-for-action-in-the-neglected-crisis-of-unintended-pregnancy-state-of-the-worlds-population-2022/
3. https://www.grandviewresearch.com/industry-analysis/condom-market

Eudaemon Technologies has developed a next-generation condom designed to feel more natural and be more appealing to use as protection. Support from the CTCM program has helped the company complete a key pilot clinical trial paving the way for a commercial release that would change lives, improve public health outcomes and save healthcare agencies millions of dollars.

Condoms are effective both as a contraceptive and for preventing sexually transmitted infections (STIs) – but only if they are used, and there remains resistance to doing so. Condom avoidance results in more than 120 million unintended pregnancies and more than 365 million STI cases each year[1,2].

Eudaemon Technologies was founded in 2018 with the aim of disrupting the US$11 billion market[3] in condoms by using a proprietary platform technology to develop a world-first, superior-feeling condom made from tissue-like materials called tough hydrogels.

Image: Engineers at Eudaemon Technologies working with robotic dipping systems to optimise the precision manufacturing of hydrogel-based barrier products.

# High tech materials deliver world-first condoms that feel like skin continued

Dr Cook examines the form and clarity of a medical-grade hydrogel condom designed to enhance comfort, safety, and sensation.

This innovative hydrogel condom has the potential to overcome fundamental issues with current condoms, like feel, allergies, odours and tastes while saving healthcare agencies millions of dollars.

"In the past we have approached condom manufacture as just putting a raincoat on, as opposed to wearing a cashmere sweater," Nick Northcott, the Executive Chairman of Eudaemon Technologies, said.

"What we're now producing is something that feels like skin and has a better outcome for women's health. If you can make the experience better for both partners, then you are increasing the likelihood that condoms will be used."

## CTCM support boosts commercialisation efforts

Eudaemon was awarded $1.5 million funding from MTPConnect's Clinical Translation and Commercialisation Medtech (CTCM) Program to further develop their innovative solution. This support helped Eudaemon on its path to commercialise the condom through completion of a pilot clinical trial in 2023, a key step for regulatory approval.

The project objectives included achieving manufacturing readiness of prototypes using Eudaemon's proprietary systems, ensuring pre-clinical verification of devices to ISO standards, and executing the Phase 1 trial.

> **"This CTCM project helped us show strong and compelling evidence of our product's potential and demonstrated the benefits, features and performance for the consumer in real life in a clinical trial, said Nick Northcott.**

## Pilot clinical trial overcomes hurdles

The Phase 1 trial faced several challenges, some specific to Australia, primarily due to a limited number of providers capable of conducting specialised condom product trials.

"This led to a slower process compared to markets like the US and Europe, where more established networks for condom product testing creates smoother pathways," the company reported.

Recruiting participants for a condom-related clinical trial also proved more difficult than anticipated. Specific inclusion criteria, such as requiring couples who had regularly used condoms in the past 12 months, combined with other contraception methods, significantly narrowed the recruitment pool.

"The challenge was balancing recruitment timelines against the risk of cost and time overruns. We adapted by slightly expanding the inclusion criteria to include couples with partners just outside the initial age range, allowing us to complete recruitment in a timely manner," the company said.

Co-founder Professor Robert Gorkin, Eudaemon's Executive Director of Innovation says the project is at the cutting edge of medical device innovation.

"Condoms are unique, serving as both medical devices and fast-moving consumer goods, and rarely seeing major innovation. Completing our Phase 1 clinical trial marks one of the most significant advancements in condom materials in decades."

## Disruptor mindset

The trial has also taken the company closer to meeting the challenge of disrupting an established consumer market dominated by a few major brands, as well as an underserved public health sector.

Introducing a new product in this global market poses a risk, as resistance could arise not only from consumers accustomed to existing products, but also from retailers and distributors who prioritise established brands. Throughout the process, the company has addressed concerns by conducting thorough stakeholder consultations to understand user wants, needs, and expectations.

"We collected and analysed feedback to guide the design and specifications of our product. This iterative process was crucial in refining our technology, ensuring the condom met the highest standards of user satisfaction and performance," the company reported.

The evidence gathered in the clinical trial and deep investigation into scaled manufacturing risks, coupled with ongoing discussions with industry experts, has given Eudaemon the confidence to move forward into the next stage of commercialisation.

"It's been a great outcome for the business that we have proven that our product has passed through that pilot clinical trial," Northcott said.

"We've got really strong signals around the response of the consumer and preference for our product. From a marketing point of view, having that strong consumer signal is really valuable."

## Scaling manufacturing

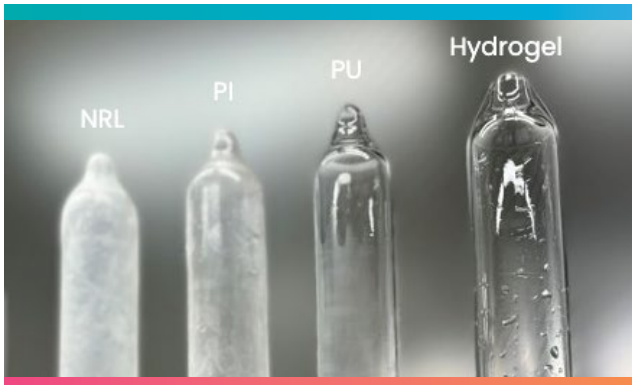
Through the CTCM program, Eudaemon established some key relationships including a notable collaboration with Bosch, enhancing its technical concepts, particularly in scaled manufacturing systems.

The relationship was initiated through an event in Melbourne organised by MTPConnect, where members of the Eudaemon team toured Bosch's advanced manufacturing solutions facility (BAMS) in Clayton. It has led to a series of projects focused on reviewing manufacturing processes and assessing the company's readiness for scaling up to the next level of plant design.

"Robust discussions with Bosch senior engineers helped refine our understanding of the necessary technical requirements and business strategies for scaling production, which is essential for the next stage of commercialisation," the company said.

The company has now created a comprehensive plan for scaled Industry 4.0 manufacturing, which will also strengthen Australia's manufacturing ecosystem.

This plan includes final design, commissioning, verification, and validation of a scaled manufacturing plant, which can produce condoms for their upcoming pivotal clinical trial involving more than 200 couples and 1,000 uses.




Comparison of condom materials: natural rubber latex (NRL), polyisoprene (PI), polyurethane (PU), and Eudaemon's transparent, skin-like hydrogel.

"It's great that we can manufacture our condoms, and we can make them at small scale, but we've got to manufacture at huge scale. That's been another part of this project, thinking about what does that pathway look like and how do we execute to take the risk out of scale manufacturing," Northcott said.

## Collaborations drive success

During the project, Eudaemon also leveraged CSIRO's decades of expertise in advanced materials characterisation of medical polymers. Their insights deepened the understanding of critical material properties, ensuring medical-grade suitability. This collaboration reinforced the confidence in the material platform, supporting both ongoing innovation and a long-term scaled manufacturing strategy.

Another partnership that Eudaemon gained through the program is with the Medical Technology Association of Australia (MTAA), of which it is now a member.

As a CTCM program partner, MTAA was on hand to provide valuable guidance and support for the project's progress and to address any emerging issues promptly. The company described it as "a significant factor in the project's success and our overall business objectives."

The CTCM project also helped to strengthen the company's intellectual property position with patent approval in over 48 jurisdictions, including a recent milestone in China – enhancing its global commercial position and providing strong protection across key markets.

Throughout the project, Eudaemon developed, identified, and documented substantial new patentable IP across its technologies including materials, manufacturing processes, product features, and quality control.

This new IP holds direct value for the new condom product and indirect value for other medical and wellness devices, forming the basis for new products to be added to the company's portfolio.

## Next steps to pivotal trial and funding raise

The company's next steps are to advance towards the final stages of commercialising its technology, while developing and refining its Quality Management System (QMS) to ensure that the product meets the necessary regulatory standards.

"We are just in the process of closing a funding round and preparing manufacturing for the final pivotal clinical trial. After that, we'll be able to submit for regulatory approval to different regulators around the world to launch our product on the market," Northcott said

The company is seeking new collaborators and partners who can bring additional expertise and resources and welcomes interest from those who share its vision and are eager to contribute to the future development of this pioneering technology.

Co-founder and Eudaemon's Executive Director Operations Dr Simon Cook summed up the company's journey through the CTCM program.

"The technology we've developed will have a profound impact on the world, by improving the accessibility and performance of sexual health products, and this grant has played a vital role in turning that vision into reality."

# New orthopaedic screw aims to reduce hip fracture surgery complications


**START DATE:**
6 Jun 2024

**END DATE:**
22 Dec 2025

**STATUS:**
Terminated

**DELIVERABLES COMPLETED:**
75%

**TOTAL CTCM EXPENDITURE:**
$490,380

**TOTAL CASH CO-CONTRIBUTION:**
$410,940

**TOTAL IN-KIND CONTRIBUTION:**
$15,000

**TOTAL PROGRAM:**
$916,320

| | |
|---|---|
| Total additional investment secured | $200,000 |
| New job opportunities created as a result of the CTCM project | 3 |
| New technologies progressed | 1 |
| No. of end-users engaged in co-design | 15 |
| No. of interactions with regulatory authorities | 4 |
| New partnerships commenced during the CTCM project term | 3 |
| New distribution partner agreements during CTCM project term | 1 |
| New licence agreements established during CTCM project term | 1 |

Image: REX Ortho Pegasus Hip Fracture System - in situ illustration.

WA-based company REX Ortho is advancing a novel removable and expandable orthopaedic screw to reduce complications in hip fracture surgery. Despite not achieving all the objectives of its CTCM project due to timing constraints, support from the program has laid the foundations for future clinical and commercial success.

## A growing challenge

Hip fracture is a major and growing global health challenge, affecting an estimated 14.2 million people each year, predominantly adults over the age of 70[1]. As populations continue to age worldwide, the burden of hip fractures is increasing for patients, families, and health systems. Over 90 per cent of all first hip fractures are managed with surgery[2], typically using implants such as metal rods, screws, plates, or prostheses to stabilise the damaged joint.

1. https://pmc.ncbi.nlm.nih.gov/articles/PMC10194687/
2. https://www.aihw.gov.au/reports/chronic-musculoskeletal-conditions/hip-fracture-care-pathways-in-australia/summary

A major complication in hip fracture surgery is failure of the orthopaedic screw used to secure the implant, leading to implant migration, further bone damage, and the need for revision surgery. In Australia, the average cost of a primary hip fracture admission is approximately $38,000 per patient, while revision surgery can cost up to three times more, compounding the already significant personal toll on patients and families[3]. The consequences are profound: up to 25 per cent of affected patients become wheelchair-dependent, and 40 per cent never regain their pre-fracture mobility, resulting in lasting loss of independence and quality of life[4].

To address this challenge, REX Ortho is developing the F-REX, a removable and expandable screw designed to integrate seamlessly with existing intramedullary (IM) nailing systems, with the aim of reducing complications and improve outcomes for patients undergoing hip fracture surgery. Combining the novel screw with Radio Stereometric Analysis (RSA), a highly sensitive and precise measurement technique, enables direct quantification of implant migration, avoiding reliance on long-term revision surgery as a surrogate endpoint. This approach may facilitate earlier identification of implant instability and may reduce associated complications.

REX Ortho was awarded $500,000 through the CTCM program for the manufacture and design verification of the device, and the commencement of a first-in-human clinical trial within an 18-month timeframe. Targeted support from MTPConnect and program partner MTAA enabled the company to make significant progress despite the accelerated delivery schedule.

## Progress through strategic partnerships

REX Ortho's project is underpinned by high-value partnerships with the University of Adelaide and Sahlgrenska University Hospital in Sweden, enabling the transfer of a highly specialised clinical trial technique into Australia and strengthening sovereign capability in advanced orthopaedic research and clinical translation. During this CTCM project, REX Ortho also secured a strategic agreement with a commercial partner to license and commercialise their F-REX screw in the US, packaged with the partner's existing intramedullary nailing system as the investigational PEGASUS system, comprising of the F-REX Screw, an intramedullary nail and instrumentation. This partnership will allow the company access to a well-established customer base, potentially reducing barriers to adoption, once the device/system is commercialised.

REX Ortho successfully completed verification and validation testing of the PEGASUS system, reaching design freeze, finalising its technical dossier and submitting an ethics application. In parallel, the team commenced clinical trial preparations, including manufacturing sufficient device units. However, extended review timelines and additional testing requirements requested by the ethics body delayed approval, pushing the anticipated trial start beyond the CTCM program timeframe.

## Growing momentum beyond the CTCM program

REX Ortho continues to work closely with its clinical trial collaborators to ensure a smooth trial commencement, now anticipated in the first half of 2026. Importantly, participation in the CTCM program also strengthened the company's commercialisation readiness, enabling engagement of a US-based consultancy to undertake a market feasibility assessment. This work delivered actionable commercial roadmaps and identified priority future clinical trial sites and key opinion leaders.

REX Ortho has also attracted additional support through state funding, securing a WA Biomedical Industry Commercialisation Bridge Grant.

While this project could not be completed in the CTCM program timeframe, REX Ortho is well placed to continue developing this novel orthopaedic innovation toward clinical translation and commercialisation, underpinned by strong technical validation, clinical and commercial partnerships, and a strengthened go-to-market strategy.

REX Ortho Pegasus Hip Fracture System.

3. https://www.aihw.gov.au/reports/injury/hip-fracture-incidence-in-australia-2015-16/summary
4. https://pmc.ncbi.nlm.nih.gov/articles/PMC5010762/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30 - 32


CTCM


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Clinical Translation

# Appendix

## Data analysis methodology

Horiz-in's proprietary tracking system was used to track the development of CTCM projects over time including before, during and after their CTCM tenure. Horiz-in used its Health Horizon data framework to detect 13 different types of publicly disclosed activity that indicate project progress, including milestones like regulatory applications, IP submissions, supporting scientific papers, funding, and more. Where companies had other products, only development activities related to the CTCM-supported products were included, with the exception of funding, which was tracked at the company level.

To provide a fair comparison, CTCM projects were compared to a control group – a selection of other CTCM project applications that reached the full application stage but were ultimately not selected for funding by the independent panel. These projects by definition were at a similar stage of development and faced similar challenges to those selected for CTCM. Horiz-in tracked the control group using the same public tracking system as the CTCM projects, allowing a systematic indicative comparison. Any impact measures were conservative estimates.

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