MTP Connect

Australia's Life Sciences
Innovation Accelerator

REDI DEVELOPING AUSTRALIA'S MTP SECTOR WORKFORCE
Researcher Exchange & Development within Industry Initiative Program

Improving workforce skills in Australia's medical products sector

A summary of the impact of activities supported by the REDI initiative 2020-2024

May 2024

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MTPCONNECT CEO FOREWORD

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Australia's Life Sciences Innovation Accelerator

Medical science has quite rightly been designated as a priority sector of the Australian economy. The sector already supports more than 70,000 Australian jobs and contributes more than $5 billion in Gross Value Added, with rich potential for much more. However, its future growth is dependent on the skills and capacity of its workforce.

Stuart Dignam
Chief Executive Officer

The sector faces the ongoing challenge of developing, attracting and retaining world-class talent, particularly people with experience in research translation, clinical applications and commercialisation.

Australia also needs researchers, clinicians and industry to be closely linked if the sector is to create commercially viable medical products.

These are the challenges which MTPConnect's workforce initiative, Researcher Exchange and Development within Industry (REDI), has been comprehensively addressing, and in so doing, setting up Australian medical science SMEs for future success.

If medical science start-ups can get access to the staff they need, then they have every chance to grow and scale their businesses here in Australia, further building the capacity of the ecosystem to sustain jobs growth, investment and increased onshore economic activity.

The $32 million REDI initiative is delivered by MTPConnect for the Australian Government's Medical Research Future Fund.

Across three integrated pillars and three and a half years, REDI has focused on developing an industry-ready workforce with the skills necessary to keep pace with a rapidly changing medical products sector.

This impact report details the many successes of REDI.

We started with a target of delivering training, mentoring and industry placements to 4,700 participants and ended up almost doubling that to 8,423.

The industry-focused fellowship program was inundated with interest, ultimately seeing 49 professionals spending up to 12 months with research-intensive companies in Australia and around the world.

The program also delivered:

– three comprehensive skills gap reports

– training for 119 clinician entrepreneurs – nurses, allied health professionals and doctors

– 48 targeted training programs in sought-after skills like Good Manufacturing Practice and Quality Management Systems.

MTPConnect's REDI initiative has succeeded in providing researchers with a diverse range of industry experiences and exposure to entrepreneurism and enabling the formation of long-term, sustainable partnerships across the sector.

It has also succeeded in expanding the capacity and capability of the research community to drive translation and commercialisation outcomes and strengthen Australia's success in generating value from our health and medical research.

My thanks to all involved in making REDI such a success. This includes the Steering Committee comprised of experts from across academia, industry and government and the REDI partners who delivered such engaging and impactful training and development programs. It also includes MTPConnect's REDI team, led by Jarrod Belcher, including Dr Ashwin Dhanasekaran and Victoria (Tori) Mynard, as well as Dr Dan Grant, Dr Rebecca Tunstall and Dr Michelle Low, who were instrumental in establishing the initiative.

With REDI now concluded, the challenge remains to ensure growing and scaling SMEs can access the skilled staff they need, in Australia, to get their products to market and ultimately to patients.

Stuart Dignam
Chief Executive Officer
MTPConnect

A MESSAGE FROM DR ANDREW NASH

REDI STEERING COMMITTEE MEMBER AND CHIEF SCIENTIFIC OFFICER AT CSL LTD

CSL is an Australia-based global biotechnology company with extensive R&D and biotech manufacturing capability that supports a dynamic portfolio of lifesaving therapies.

Australia has world-class medical research, but we fall behind our global competitors for rates of research commercialisation and industry-academic collaboration. Building the personal and institutional capacity of Australian academic researchers and their institutes and increasing the interactions between industry and academia are key to driving improvement.

This is where MTPConnect's Researcher Exchange and Development within Industry (REDI) initiative has played such a critical role – and why CSL has been pleased to play an active role from day one.

Along with other sector leaders from industry and academia, we worked with MTPConnect to offer our insights and experiences to help develop the uniquely targeted program concept and support its governance as an industry member of the Steering Committee.

I believe the outcomes, as detailed in this report, speak for themselves. With the growing recognition of the importance of medical science as a designated priority sector of the Australian economy, capacity-building programs like this are needed now more than ever.

We need a strong and vibrant workforce with the skills to rise to the challenge of translating and commercialising research, manufacture high-value products, be compliant with strict quality practices, undertake clinical trials and take our innovations and products to the world through a number of different approval processes, regulatory agencies and reimbursement methods.

The role of education and training in supporting and developing researchers, clinician entrepreneurs, manufacturing staff, quality managers and clinical study leaders to drive the healthcare innovation system forward is significant and increasing.

I offer my congratulations to every one of the 8,423 REDI participants and am pleased to see the significant advancements they have achieved in developing their skills and careers.

My congratulations to the team at MTPConnect for delivering a highly effective initiative that engaged closely with the whole sector and has delivered real impact.

I urge the federal government to continue its support for the REDI program and look forward to supporting CSL's participation for many years to come.

Dr Andrew Nash
CSL Chief Scientific Officer
Senior Vice President and Head of Research

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CSL Chief Scientific Officer
Senior Vice President and Head of Research

EXECUTIVE SUMMARY

The $32 million Researcher Exchange and Development within Industry (REDI) program is an initiative of the Medical Research Future Fund (MRFF) delivered by MTPConnect.

The intended outcomes of the funding opportunity were to:

– provide researchers with a diverse range of experiences and exposure to entrepreneurism in the medical technologies, biotechnologies and pharmaceuticals (MTP) industries.

– develop meaningful and sustainable partnerships with the MTP industries, universities, registered training and government entities, that will form the foundation from which a variety of joint training, placement exchange and mentorship opportunities can be delivered.

– strengthen Australia's success in terms of translation and commercialisation of health and medical research.

– expand the capacity and capability of the research community to undertake translational health and medical research.

The REDI initiative has comprehensively addressed the funding opportunity objectives. It has provided researchers and industry with a diverse range of experiences and exposure to entrepreneurism and enabled the formation of long-term, sustainable partnerships across the sector and in Australia. The program has exceeded all its contracted objectives and outcomes.

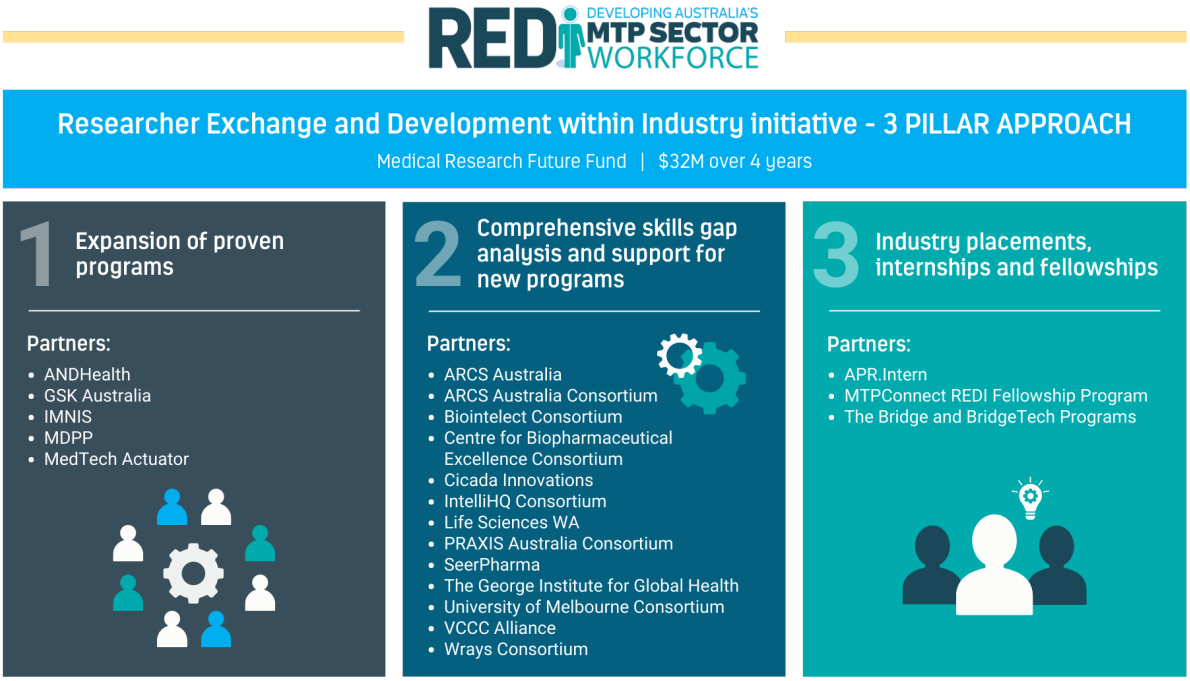
This workforce skills program was designed as a three-pillar approach:

– expansion of high quality existing programs

– skills gap analyses that identify skills gaps and then deployment of programs that close these skills gaps

– support for Fellowships, Internships and mentoring programs.

This approach enabled a fast start to rapidly address significant gaps and then nuancing programs to tackle the more impactful skills gaps. The MTPConnect REDI team was aware that long-term experiential support for fellowships and internships would be of particular benefit.

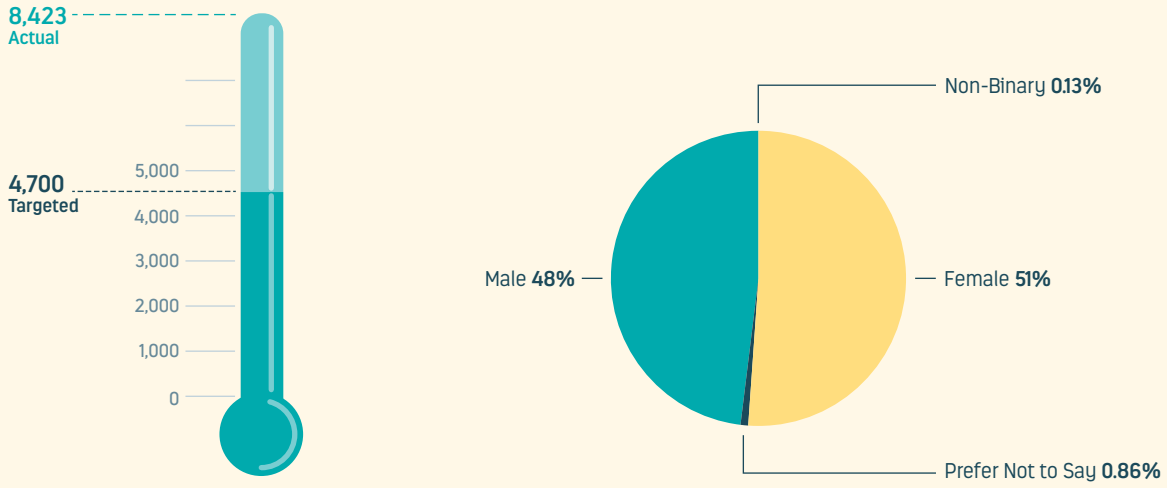


We would like to thank the REDI Steering Committee members from around Australia from industry, government and academia for their guidance into the skills gap reports and their work with us in selecting appropriate training to fill the skills gap needs of the sector. Thank you to Dr Stephen Palmer, Dr Andrew Nash, Anna Schulze, Greg Mullins, Dr Jason Coonan, Dr Antonio Penna, Anne O'Neill, Dr Dan Grant, Dr Rebecca Tunstall, Stuart Dignam, Lisa Dube, Dr Paul MacLeman, Ian Burgess, Lee Harvey, Professor Sir John Savill, Dr Peter Thomas, Dr Saraid Billiards, Professor Caroline McMillen, Dr Amanda Caples, Professor Kevin Pfleger and Leanne Kemp for their Steering Committee input.

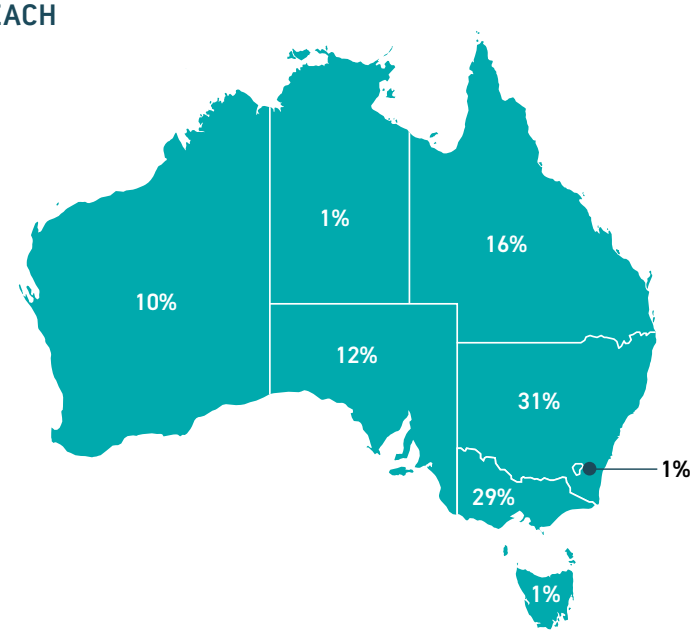
One of the early REDI activities undertaken was to determine the skill gaps in the life sciences sector. A series of three well-received reports were developed with over 145 stakeholder consultations, a workforce skills survey and external data analysis. The REDI Skills Gap report series identified a total of 81 skills gaps, which were categorised into seven themes with 24 most impactful opportunities comprehensively described. These represent a mixture of new and emerging gaps covering the full value chain from pre-production, production and post-production and focus on the most important skills for building a resilient and competitive medical products sector.

Since inception, REDI has delivered 8,423 new training, mentoring and industry placements. The program has exceeded – by 79 per cent – the 4,700 participants target set out in the Funding Agreement. We are particularly proud of the diverse participation in the training opportunities from both a gender and a state-based perspective. This truly is a program with national reach.

STAKEHOLDER PARTICIPATION



NATIONAL REDI REACH



REDI is directly addressing six of the 13 'Australian Medical Research and Innovation Priorities 2022-24' and will enable several more to be addressed. Of note is the priority area *'to achieve health equity and deliver health and economic benefits through transformative and innovative research and a health system that is responsive to health challenges and underpinned by a skilled and sustainable workforce'*. REDI is the only national program that is delivering the skills, expertise and knowledge to create this 'skilled and sustainable workforce'.

The REDI programs and graduates (our real outcomes) support the outcomes for many other MRFF programs nurturing the development of growing early-stage companies. REDI graduates create a strong pipeline of skilled staff to be employed by emerging companies – the companies that are growing Australia's MTP sector and delivering improved health outcomes through translation of research.

The REDI workforce skills initiative has delivered notable achievements including:

- 8,423 participants
- 890 companies accelerated
- 1,649 trainees in Good Manufacturing Practice and Quality Management Systems
- 49 REDI Fellows through the REDI Fellowship program
- 159 Clinical Trial trainees.

REDI Fellowships – different to any other government-funded Fellowship scheme

The REDI Fellowship program has been well received and strongly supported by industry. As an industry-led initiative, the REDI Fellowship program is different to any other government-funded Fellowship scheme. It has created real collaborations between academia and industry and surpassed expectations for giving researchers exposure to entrepreneurism across the MTP sector. Industry has embraced REDI Fellowships – it gives companies control over projects and allows them to collaborate and work with academia on terms they find favourable. Through REDI Fellowships, industry is gaining access to world-class research talent.

A testimony to the value of the Fellowship program was its extension with additional support from Department of Industry, Science and Resources (DISR) and CSIRO, allowing a total of 49 REDI Fellowships to be undertaken.

Feedback from REDI Fellows is that the experience is transformative, providing an opportunity to develop skills and understanding of working in a research-intensive industry setting while secure in their academic roles. These Fellowships have changed the way academics do their research and collaborate with industry. Academics feel more empowered to discuss their ideas and partner with industry and can see that they have something worthwhile to offer industry – changing their value proposition.

Examples of the Fellowship program's successes can be seen in the testimonies in each of the 48 Fellowship case studies from pages 62-159 in this report. Standout collaborations include Trajan Scientific and The University of Melbourne, which will continue to work together to develop the RPM2 microfluidic pump; Regeneus and Kolling Institute, which will continue their research collaboration for osteoarthritis medication; and Telix Pharmaceuticals (ASX: TLX, market cap $3.61 billion), which is continuing its research partnership with Central Adelaide Local Health Network.

The REDI Fellowships increase the porosity of the academia:industry barrier. This lack of porosity has been identified as a reason for our poor translational outcomes compared to other similar nations. To further enhance the value of the Fellowships and bring academia and industry closer together, the Fellows undertake post Fellowship activities to help their colleagues and research centres better understand industry drivers, language and ways. These activities have embedded the success of the program and employer support.

Expanding the capacity and capability of the research community

REDI has expanded the capacity and capability of the research community to undertake translational health and medical research and strengthen Australia's success in this area. The end-to-end commercialisation programs such as those delivered by REDI partners ANDHealth, MedTech Actuator, the Medical Device Partnering Program, TGI and the Australian Clinical Entrepreneur Program have encouraged researchers to innovate and provided support for translation of researchers' innovations. Kali Healthcare, for example, has used support from the Medical Device Partnering Program and ANDHealth and attributes successes in its product development and commercialisation to the advice and guidance provided by these organisations. Navi Medical Technologies has provided feedback that MedTech Actuator has been instrumental in its success, with many more similar examples. MedTech Actuator alumni such as VitalTrace, Nutromics, Navi Medical Technologies and Ventora have created more than 100 Australian jobs.

Fit-for-purpose training programs that meet the needs of the sector have also met the objectives of the REDI funding opportunity. The George Institute (TGI) 10x Global Health Pre-Accelerator and Accelerator programs have provided researchers with skills, knowledge and experiences to translate their innovations to address unmet medical needs globally and improve human health. The REDI funding enabled TGI to deliver the Accelerator program and create partnerships that are moving the program towards a more sustainable future. Its partnership with University of New South Wales has provided access to more subject matter experts and delivered a high-quality student learning system, and Virtus Health and Medical Angels partnerships have afforded greater access to capital for the Accelerator participants that have started to de-risk their innovations.

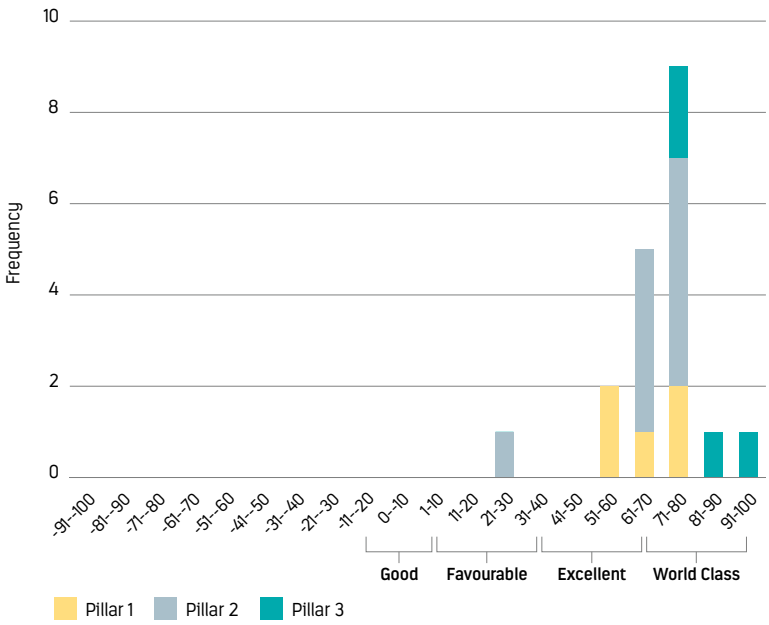
The REDI partners continue an ongoing relationship with these companies to keep on opening doors nationally and internationally to overcome obstacles in the notoriously challenging healthtech sector. They continue to increase and build new pathways to capital and lower barriers to market entrance, connect start-ups with potential customers and partners, and act as a platform for the more advanced entrepreneurs to feedback their knowledge and learning to new innovators earlier in the journey.

The VCCC Alliance and PRAXIS Australia are educating and developing new Clinical Trial Coordinators and Clinical Trial Associates through a program that includes online training, workshops, roundtables, bootcamps and work-integrated learning. These diverse teaching methodologies ensure all learners are catered for. In these programs, the REDI partners are working with government, hospitals, MTP industries and universities to deliver and accredit the program. When skills and knowledge can be developed in this way, participants can readily translate this into workplace environments.

APR.Intern has delivered 82 industry internships for PhD students from all around Australia with REDI support. These internships have had impressive outcomes for the intern, the sponsor and their academic institution. One intern who spent time at CSL directly attributes their subsequent employment at the Australian Proteome Analysis Facility to the demonstrable skills and knowledge they acquired during their internship. Another intern who spent time at Cortical Labs proved critical to advancing the company's innovation converting digital to physical signals with an injection of new concepts and approaches. This REDI-facilitated experience has driven Cortical Labs innovation forward in new ways not anticipated.

Feedback from industry and trainees on the REDI programs delivered has been exceptional, with a Net Promoter Score (NPS) across all programs of 63. For context, an NPS of 30 is considered to be a very good program.

NET PROMOTER SCORE



PROGRAM QUALITY – DELIVERY

This summary contains just a few examples of how the REDI initiative has met its objectives. There are many more examples in the case studies showcased in this report.

The programs, activities and events supported by the REDI initiative are bringing MTP industries, universities, RTO and government entities together to provide fit-for-purpose experiences and development programs for researchers and entrepreneurs. They are breaking down the industry-academia divide, bringing many parts of the sector together to leverage different skills sets and increase translation and commercialisation.

As the REDI initiative draws to completion, the overall funding objectives have been exceeded and the program has surpassed its objectives. Momentum has been built; REDI's 20 partners have delivered 46 programs; and the MTP sector can continue to benefit from these programs.

The outcomes detailed in this report are impressive, but if we are to see success continue in the sector – and to maximise the impacts of the Industry Growth Program, the National Reconstruction Fund, the Medical Research Future Fund and the National Health and Medical Research Council's funding – we need an experienced, skilled and sustainable workforce. This will allow us to translate and commercialise our Australian health and medical research to achieve health equity and deliver health and economic benefits.

SKILLS GAP REPORTS

MTPConnect
Australia's Life Sciences Innovation Accelerator

As part of the REDI initiative, three skills gap reports were published that examined current and future skills gaps. The focus of the study was on specific skills or skill sets rather than job roles which have been analysed in other reports, however a few job roles were included as skills gaps due to the overwhelming responses from stakeholders. The study was designed to examine skills gaps that could be closed through professional development activities.

The first REDI Skills Gap report was an interim report, published in November 2020, and identified three skills gaps as near-term priorities for the sector, addressable within 12 to 18 months. The second report, a thorough 'root and branch review' identified a comprehensive set of 76 skills gaps, including 20 priority gaps that need to be addressed to drive continued life sciences sector growth. The third report highlighted skills gaps in specific areas that have become more pronounced due to the COVID-19 pandemic.

The REDI Skills Gap report series identifies a total of 81 skills gaps, with detailed analysis provided on 24 of these. They represent a mixture of new and emerging gaps covering the full value chain from pre-production, production and post-production and focus on the most important skills for building a resilient and competitive medical products sector.

The skills gaps reports were developed through:

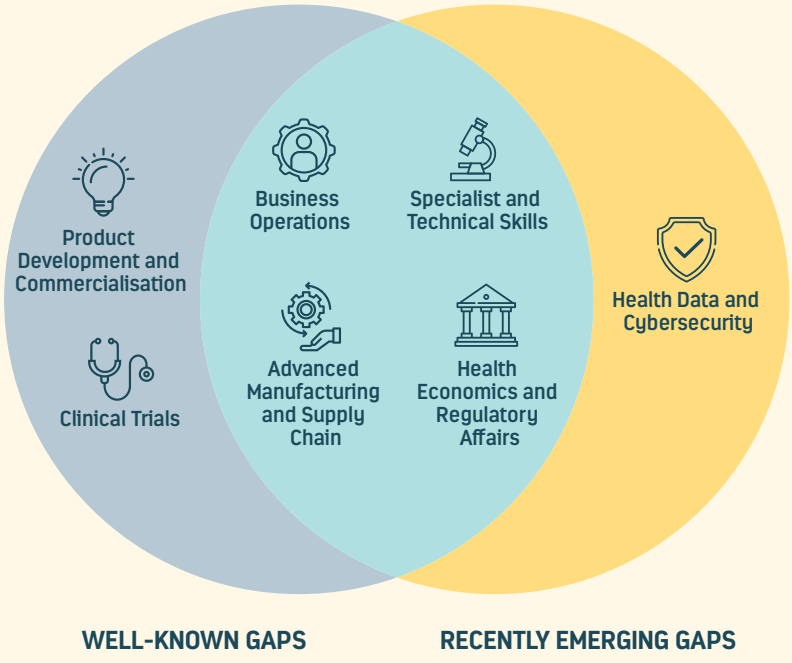
– stakeholder consultations (147 senior sector stakeholders)

– MTPConnect's 2020 workforce skills survey (121 respondents)

– analysis of MTP sector on SEEK job advertising platform

– desktop research and analysis.

The 81 skills gaps were categorised into seven themes, which can be further characterised into well-known and recently emerging skill gaps as per the diagram below.



All skills gaps were scored for:

– alignment of the skills gap with MTP sector priorities (from MTPConnect Sector Competitiveness Plan)

– alignment with skills gaps with nine global megatrends (from MTPConnect Sector Competitiveness Plan)

– breadth of impact across the MTP value chain

– depth of impact and estimated value from addressing the gap.

This analysis was used to determine the 24 most impactful skill gaps, i.e. those with the biggest impact on the MTP sector if they can be reduced. These skills gaps were characterised and defined as below:

CAPABILITY: Existing workforce requires upskilling or training **(50 PER CENT OF GAPS)**	**EXPERIENCE:** Lack of experience in the existing workforce **(29 PER CENT OF GAPS)**	**CAPACITY:** Lack of supply of workforce in the sector **(21 PER CENT OF GAPS)**

THE 24 MOST IMPACTFUL SKILL GAPS

CAPABILITY: Existing workforce requires upskilling or training

1. Understanding of QMS and protocols
4. Shortage of MTP-specific project managers to support start-ups and spin-offs
5. Strategic design of clinical trials to address regulatory and payer needs
8. Leadership awareness about the value of best-practice management in cybersecurity
10. Understanding of and expertise in big data capture, management and analysis
11. Expertise in the design and use of AI within MTP
13. Awareness and understanding of regulatory requirements amongst start-ups and SMEs
16. Identifying unmet market need and understanding the clinical context
17. Ability to secure investment, funding and/or industry collaboration
18. Identification of the payer and understanding of reimbursement pathways
21. Shortage of GMP-trained staff for advanced manufacturing
23. Lack of commercialisation competency framework/resource SMEs

50%

EXPERIENCE: Lack of experience in the existing workforce

2. Manufacturing expertise in high-tech and/or specialised medtech devices
3. Manufacturing expertise in high-value therapeutics
6. Shortage of experienced CRAs
14. Shortage of experienced health economists
15. Shortage of industry professionals with end-to-end translation and commercialisation experience
20. Shortage of pharmacologists and toxicologists with drug development expertise
22. Lack of process design expertise

29%

CAPACITY: Lack of supply of workforce in the sector

7. Shortage of CTCs
9. Shortage of cybersecurity professionals and IT infrastructure resilience skills within MTP
12. Shortage of skills in health informatics
19. Shortage of skills in Bioinformatics (particularly in genomics)
24. Lack of *in-silico* (computational) skills for drug and vaccine development

21%

The 24 skills gaps detailed directly impacted all stages of the MTP value chain. Many were also well-known existing skills gaps.

In some cases, it is positive that these continue to exist. For example, within clinical trials, the sector is growing and more staff are needed to service this demand – so skills gaps should be expected and wanted. There are also skill gaps in the capability category (numbers 13, 16, 17 and 18) that are related to knowledge of the commercialisation pathway predominantly by founders. This is a positive as it demonstrates we have new founders innovating and inventing and we need to focus on support to allow their innovations to be sufficiently de-risked in an efficient and focused manner.

Other skills gaps reflect the commercialisation pathway and the selected high-value manufacturing that has historically been done in Australia. Following COVID-19 there is a renewed focus on sovereign manufacturing and new technologies. This has created several emerging skills gaps, which demonstrates a clear need for a continued programmatic approach to identifying and closing skills gaps.

The sovereign manufacturing capability, because of major pillars such as automotive manufacturing closures, has created new skills gaps in the sector. There is now less training for these manufacturing skills in the ecosystem and many skilled workers are retiring. Skills such as plastic extrusion and blow moulding are becoming increasingly difficult to find in addition to the skills gaps created as we move to Industry 4.0.

Feedback on the skills gap reports has been very positive. Of note, feedback is that many of these skills gaps are international and not just impacting Australia. Therefore, it is not enough just to recruit internationally for certain roles, but these skills gaps need to be closed through upskilling and cross skilling within the Australian workforce. The REDI report series highlighted that there is an increase in complexity of the skills gaps, which require more nuanced approaches to close the skills gaps. Old-style education and training programs are insufficient to close these and encompassing professional development solutions are required.

The Skills Gap report series shows there are a lot more skilled and competent people in the life sciences sector now compared to previously[1] and demonstrates that there is a strong foundation to grow the sector, but there are still major constraints that need consistent effort to ensure Australia reaches its potential in life sciences.

1. 2007 Internal Report, Commercial in confidence.

PARTNERSHIPS SECTION 1: END-TO-END REDI PROGRAMS

Commercialising a medical product is a long and difficult process, with therapeutics commonly taking more than 12 years and devices more than eight years to enter the market. Regulated manufacturing, clinical trials, regulatory and reimbursement are all extra considerations for a life sciences entrepreneur and not one person has all this specialist knowledge. It takes a village.

Five of the seven skills gap themes identified in the REDI Skills Gap report must be considered by any new medical product start-up. These are:

– advanced manufacturing and supply chain

– business operations

– clinical trials

– health economics and regulatory affairs

– product development and commercialisation.

In addition, the founder or founding team must be able to provide clear answers on any of these to secure the all-important capital that allows medical product development, with the reported average cost for therapeutics being US$1.3 billion and medical devices US$30 million to reach the market.

The challenge – how to skill the sector with the greatest impact

There is a growing interest in creating and commercialising new medical products, so the challenge for REDI was how to skill the sector with the greatest impact. From reviewing applications to MTPConnect's funding programs, such as the Biomedical Translation Bridge (BTB) and BioMedTech Horizons (BMTH), it was clear that several potential products are already in the ecosystem and there needed to be a pipeline of developing these skills at different stages. REDI needed to complement this, and the training programs had to cover multiple skills and knowledge – hence the term end-to-end training programs – where a company's leaders could learn several skills critical for success.

The Bridge and BridgeTech programs were already funded by MTPConnect to help researchers and life sciences professionals learn about the process of commercialisation – and many universities and medical research institutes were helping their own research entrepreneurs.

Therefore, REDI looked further down the pipeline and focused on helping entrepreneurs and companies through the support of a number of accelerator-type programs delivered by the MedTech Actuator (biotechnology and medical devices), ANDHealth (digital health), The George Institute (global health) and the Medical Device Partnering Program (medical devices). REDI support allowed these effective programs to expand nationally and help start-ups across Australia.

REDI programs have accelerated the commercialisation journey

REDI also found that many clinicians and allied health professionals were not supported in developing their innovations and, after scouring the planet, settled on a program inspired by the NHS Clinical Entrepreneur Programme. The resulting 'Australian Clinical Entrepreneur Program' pilot managed to fund two cohorts across three states.

And finally, when the support for The Bridge Program from other MTPConnect programs ceased, REDI invested in this program, allowing another 100 researchers and life sciences professionals to learn skills to start their entrepreneur journey.

890 companies participated in these accelerator end-to-end type programs and these companies have since received over $52 million in funding and created hundreds of jobs. Several have even commenced clinical trials. The common feedback is that these programs truly accelerated their commercialisation journey – helping them de-risk their innovations and secure funding or a deal. Find out more in the following pages.

CONTENTS

The Bridge Program – training to successfully commercialise Australian pharmaceutical research

PARTNER:
The Bridge Program

NUMBER OF REDI SUPPORTED PROGRAMS:
1 Program:
– The Bridge Program

NUMBER TRAINED SUPPORTED BY REDI:
100

The Bridge Program launch in WA in 2023 L-R: Alumni and UWA's Dr Elizabeth Johnstone, MTPConnect's Jarrod Belcher; Pfizer's Anand Gautam; QUT's Distinguished Prof Lyn Griffiths, UWA's Prof Kevin Pfleger.

Despite having a strong infrastructure, market sophistication and placing ninth out of 36 economies in the Organisation for Economic Co-operation and Development (OECD) rankings for high-quality health and medical research outputs, Australia is still lagging in the translation (ranked 32nd) and commercialisation (ranked 25th) of medical research.[1]

MTPConnect's work showed that researchers often lack the skills and knowledge required to translate their ideas from bench to bedside. The commercialisation pathway is an unknown, making it simpler for a researcher to focus on securing publications and traditional funding to back their research. A scan of the training ecosystem showed a lack of courses in Australia designed for life science researchers wanting to commercialise a new regulated medical product. So, the Bridge Program was developed to equip researchers and entrepreneurs with the knowledge, skills and networks needed to commercialise new pharmaceuticals.

Funded by MTPConnect's Growth Centre Project and REDI to address critical skills gap

Launched in 2017 with support from MTPConnect's Growth Centre Project fund to address this critical skills gap, the Bridge Program is delivered by Queensland University of Technology (QUT) with a consortium of 10 pharmaceutical companies and universities. The program's 2023 cohort was consequently funded by REDI continuing the support.

Industry has had significant input into the design and development of the Bridge Program, which selects 100 participants annually from across Australia to take part in a 12-month program with online content, face-to-face seminars and a three-day symposium, covering the various components that contribute to the commercialisation of new medicines.

The industry knowledge behind the Bridge Program consortium makes the program unique with its venture capital and global pharmaceutical networks and its ability to share specific, detailed and practical know-how. Participants benefit from direct exposure to networking opportunities at the three-day symposium, which ties together the program's learnings and enables collaboration and commercialisation opportunities.

Understanding of commercialisation processes improved

After the most recent offering of the flagship event in late 2023, a survey revealed that the three-day symposium was a highlight for the cohort – with 100 per cent of respondents saying their understanding of commercialisation processes has improved, their networks have improved and their expectations were either met or exceeded.

Bridge Program graduate Daniel Fernandez Ruiz, from UNSW, said, "I spent many years unsuccessfully trying to understand how to connect my basic science with industry. Again and again, I feel I received poor advice and finding useful information was extremely hard.

1. Australian Government Department of Education: Discussion Paper – Boosting the commercial returns from research https://www.education.gov.au/download/5035/discussion-paper-boosting-commercial-returns-research/7564/document/docx

"The Bridge Program has completely solved this. Thank you! It is exactly what I had been looking for. I will recommend this program to any of my students or colleagues in academia interested in understanding what the pharmaceutical industry is about," Mr Fernandez Ruiz said.

Achieving multiple milestones for Kinoxis Therapeutics following the Bridge Program

Bridge Program graduate, Raymond Luong, completed the program in 2021 while working for Kinoxis Therapeutics, an Australian company developing first-in-class therapeutics to address the escalating demand for effective treatments for substance-use disorders and social dysfunction in neurological and psychiatric disorders.

Since Mr Luong took part in the Bridge Program, Kinoxis has achieved multiple milestones including establishing an active clinical program. A Phase I clinical trial for Kinoxis's lead compound, KNX100, was completed in 2023, demonstrating its safety and tolerability in healthy volunteers. With the successful completion of Phase I, Kinoxis is now poised to advance KNX100 into Phase II clinical trials in multiple indications, which will focus on further evaluating the efficacy and therapeutic benefits of the compound.

Mr Luong said the Bridge Program has had a momentous impact on his career development – supporting his progression from a Drug Development Associate to a Business Development Associate, in which role he now directly supports Kinoxis's CEO and senior leadership team in business development, systems/operation support and project management. He is also actively involved in supporting Kinoxis' collaboration with a global pharmaceutical company.

The Bridge Program – contributed to body of knowledge and directly influenced career trajectory

"The Bridge Program most definitely provided the broad fundamentals of the drug development process, which directly influenced my career trajectory.

"The knowledge I gained from the program contributed significantly to my own body of knowledge, which was extremely helpful when developing company presentations for business deals. I have been actively involved in a collaboration and licence agreement from initial contact through to deal finalisation," Mr Luong said.

As demonstrated by Mr Fernandez Ruiz and Mr Luong's experience, the Bridge Program is helping researchers demystify the commercialisation process and giving them the skills and knowledge to successfully translate their research into a viable product.

This pioneering education program is creating a new wave of research-based entrepreneurs that will help to drive Australia up the OECD rankings – fulfilling the nation's potential as a world leader in pharmaceutical innovation.

> **The Bridge Program most definitely provided the broad fundamentals of the drug development process, which directly influenced my career trajectory.**

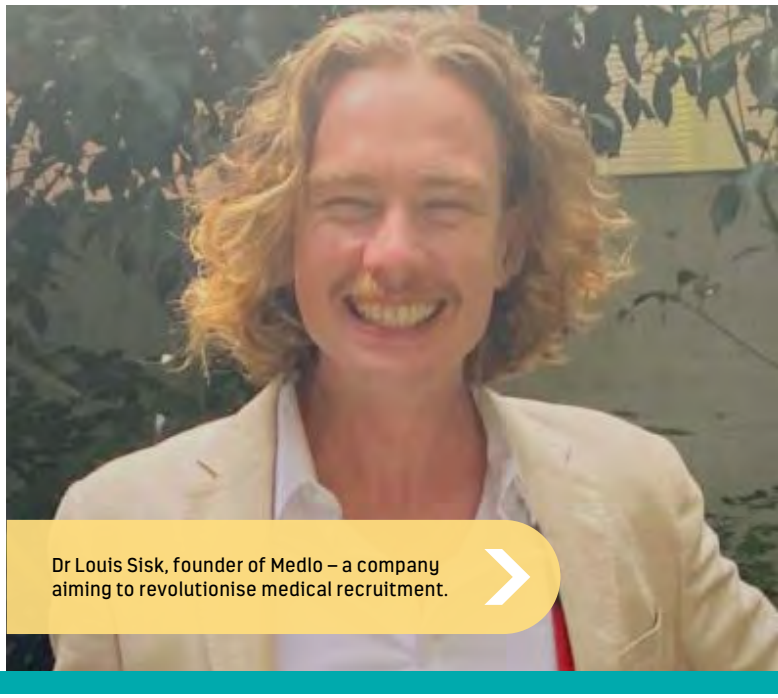
Upskilling entrepreneurs to advance digital health innovations

PARTNER:
ANDHealth

NUMBER OF REDI SUPPORTED PROGRAMS:
4 Programs:
– BRIGHT Ideate
– BRIGHT Innovate
– ANDHealth Masterclass: ACCELERATE Program
– Industry Education

NUMBER TRAINED SUPPORTED BY REDI:
676

COMPANIES ACCELERATED:
199



Dr Louis Sisk, founder of Medlo – a company aiming to revolutionise medical recruitment.

Australia's National Digital Health strategy outlines the strategic significance of the digital health industry and the benefits of digital health technologies in delivering a more efficient health system, greater healthcare access to rural/remote areas and improved patient experience through technology.[1]

The commercialisation of digital health technologies offers numerous health and economic opportunities, leveraging our international strengths in health and medical research alongside emerging capabilities in technology to create companies that can serve global populations, while remaining headquartered here at home.

Rapidly evolving and different commercialisation and valuation pathway

However, these companies face a commercialisation and valuation pathway that is distinctly different from the more established biopharmaceutical and medical device pathways. This pathway is rapidly evolving as regulators, health systems and payers adapt to these new types of technologies, meaning that real-world experience and proven track records from executives and innovators who have successfully navigated this environment are critical to enabling Australia's high-potential innovators and technologists in this sector.

To help the next generation of pioneers survive the challenges common to the sector, ANDHealth with support from Planet Innovation has designed three highly practical courses that give entrepreneurs the skills and foresight to successfully commercialise their innovations.

Supported by the REDI initiative, the integrated series of programs leverages ANDHealth's national and global network of digital health industry leaders, alongside Planet Innovation's award-winning BRIGHT Process framework, to facilitate early-stage idea generation and validation specific to digital health.

Ideate, Innovate and Masterclass: ACCELERATE

The first program in the series is Ideate – a one-day seminar designed for early-stage digital health innovators who are ideating or developing their prototype or seeking initial customers.

Next is Innovate – a three-day workshop for digital health companies with a technical or commercial proof of concept that are seeking practical skills and insights for achieving success.

Finally, Masterclass: ACCELERATE – an intensive six-day workshop, currently delivered as a two-day-per-week, three-week program, that brings proven industry expertise to digital health companies to address common pitfalls and knowledge gaps. This internationally unique program features more than 50 expert speakers per year, who provide participants with commercialisation-focused real-world advice, quality feedback and actionable answers and the ability to ask questions specific to their company.

1. https://www.digitalhealth.gov.au/national-digital-health-strategy

Tangible impact, key support, valuable leverage and high attendee satisfaction

To date, the project has impacted 676 participants, supported 199 digital health companies through the BRIGHT and Masterclass programs, and leveraged 545 hours of in-kind support from 270 industry experts. Attendee satisfaction has been high, with program NPS ranging from 65 to 96 across all programs, with the average NPS of Masterclass (including all four cohorts) of 95.

The results speak for themselves, with participating companies from cohorts 2020, 2021 and 2022 raising $12.30 of capital for every $1 invested and impacting 273 patients for every $1,000 invested through the program, according to a recent independent report by global consulting firm LEK Consulting.

The program has also successfully provided an important pathway into other programs that provide additional later-stage commercialisation support. Forty-seven per cent of companies selected in the first three MRFF-funded ANDHealth+ cohorts have completed the Masterclass program prior to applying for funding, underlining its benefits as a pipeline program.

One such participant was Dr Louis Sisk, Founder of Medlo – a tech company aiming to revolutionise medical recruitment in Australia with a digital platform that directly connects hospitals with locum doctors.

Masterclass – understanding business basics in the digital health space

Dr Sisk said taking part in Masterclass 2023 allowed him to explore areas such as business development, organisation mapping and client/candidate relationship building. The program's emphasis on risk and regulation, as well as the importance of creating the right team and raising capital, also proved valuable.

"Masterclass offered a perfect launch platform for me to understand the basics of business, as well as a full holistic view of the digital health space. Being a doctor, I understand medicine though business is obviously quite different. The ANDHealth Masterclass was a crash course spanning across an array of business topics, specifically in digital health, that would allow me to do a deeper dive into everything from marketing to cybersecurity.

"Using the Masterclass as the cornerstone, I hope to be pointed in the right direction of what a healthy business looks like," Dr Sisk said.

Since he completed the Masterclass program, Medlo has become operational and is now securing final investments for its next development phase. The company won the 2023 Victorian Healthcare Week Start-up of the Year award – an accolade Dr Sisk said would not have been feasible without ANDHealth's involvement.

Medlo – creating equity in Australian healthcare and defining the gold standard in this space

"We intend to bring Medlo to all allied health professionals across Australia … to create equity in Australian healthcare in rural and remote areas through an organised on-demand workforce, hardware and technology. Medlo aims to be an extension of every hospital administrator's toolbox and define the gold standard in this space," Dr Sisk said.

It is testimonials like these that demonstrate the significant impact initiatives such as ANDHealth's Masterclass can have on growing the capability and commercial understanding of Australian digital health companies. By supporting entrepreneurs to bring their innovations to life, these programs are securing the future of Australia's digital healthcare system – generating job opportunities and reinforcing the nation's standing as a leader in equity and healthcare outcomes in the process.

> **Masterclass offered a perfect launch platform for me to understand the basics of business, as well as a full holistic view of the digital health space.**

Technology platform uPaged attended the 2020 event, hoping to resolve several challenges relating to capital raising, compliance and business development/implementation strategies. As a national practitioner database that hospitals can tap into when seeking on-demand and permanent nursing staff, uPaged found the Masterclass invaluable.

Transforming ideas into early-stage ventures

PARTNER:
MedTech Actuator

NUMBER OF REDI SUPPORTED PROGRAMS:
3 Programs:
– MedTech Actuator Accelerator
– MedTech Actuator Origin
– Bespoke Training

NUMBER TRAINED SUPPORTED BY REDI:
1,986

COMPANIES ACCELERATED:
226

Screening genetic diseases before pregnancy at GenEmbryonics.

Commercialisation of medical products requires a specialist set of skills. Regulation, reimbursement and ongoing compliance are all issues challenging medical entrepreneurs, which entrepreneurs in other sectors do not face. As such, specialist training programs are required to help medical entrepreneurs accelerate their commercialisation journey.

REDI Skills Gap Stakeholder consultations highlighted that spin-offs, start-ups and emerging companies developing life sciences products can lack the skills and knowledge required along the commercialisation and product development pathway. The skill sets and knowledge required are dependent on the nature of the technology being developed (e.g. vaccines, stem cells, gene therapies, drugs and medtech) and the stage of development. There is a lot to learn and the appropriate context must be provided to help ideas become commercial successes.

Having access to a clear framework of the skills required to commercialise novel medical products successfully helps early-stage companies and SMEs recruit an appropriate workforce into their projects and identify training needs. This should lower the costs and timeframes needed to commercialise products and ultimately result in more innovations reaching the market.

Adults learn best when they can relate to the subject matter and see how new skills are applied

Though some education programs do cover topics relating to the commercialisation of medical products, MTPConnect's REDI program acknowledges that adults learn best when they can relate to the subject matter and see how new skills and knowledge are applied. As a result, REDI has supported the MedTech Actuator to expand delivery of its Accelerator program and develop its 'Origin' innovation intensive to train and develop the next generation of life sciences entrepreneurs across the country.

Over the past five years, the MedTech Actuator's Accelerator program has supported more than 75 early-stage healthtech start-ups to progress rapidly through the complex commercialisation process. Over a nine-month program, participants are supported to develop a complete commercialisation strategy in a global context, increase investment readiness and grow their skills as leaders within a growing international community of healthtech entrepreneurs. This focus on market success makes it possible to achieve in 12 months what can typically take three years or more.

To further help start-ups, REDI supported the MedTech Actuator to deliver the Origin program: an international innovation competition for early-stage medtech, healthtech and biotech entrepreneurs. The program starts with the cohort immersed into the MedTech Actuator for an 'intensive sprint' – three days of learning from industry experts and access to opportunities to pressure-test innovations, network and gain exposure to the start-up ecosystem. The winner of the Origin pitching competition also receives a cash and in-kind prize pack worth more than $20,000, as well as fast-tracked entry into the MedTech Actuator Accelerator. Sixty-one companies have accessed the Origin program through REDI support.

GenEmbryomics – identifying and refining its pathway to market through the Accelerator program

GenEmbryomics is one of many organisations that has completed the Accelerator program. The Melbourne-based biotech, founded in 2019, offers an unprecedented, complete whole genome sequencing solution for IVF embryos, significantly improving IVF success rates by using genome screening to optimise the chances of healthy embryo implantation.

While taking part in the Accelerator program, the GenEmbryomics team was able to identify and refine its pathway to market and better understand market dynamics and competitors, focusing on Australian and US market strategies.

Since joining the program, GenEmbryomics has raised $180,000 in equity-based capital and $680,000 in non-dilutive capital. The team has also commenced clinical trials in the US and Turkey, with plans to conclude clinical studies by early 2024.

Making a real-world difference and preventing unnecessary genetic diseases

Furthermore, the organisation has partnered with a financial advisor and investment banker to pursue a listing on a US stock exchange during 2024. An international board of directors is in place and the company is currently focusing on customer acquisition in the massive US IVF market.

According to Dr Nick Murphy, CEO and Founder of GenEmbryomics, the company will make a real-world difference to hopeful parents and prevent the unnecessary tragedies of genetic diseases – an ambition that is closer to being realised, thanks to the Accelerator program.

"The MedTech Actuator Accelerator is comprehensive and helped GenEmbryomics to develop in the specialist areas we needed. This support was crucial in preparing us for the reality of the life sciences industry," Dr Murphy said.

Diag-Nose.io – significant progress towards commercialising its work through the Accelerator

Healthtech start-up Diag-Nose.io likewise made significant progress towards commercialising its work by participating in the MedTech Actuator Accelerator. Taking part in the program's fifth cohort in 2020, the company solidified its focus for RhinoMAP – a diagnostic test kit that uses artificial intelligence (AI) and protein signatures to match chronic respiratory disorder (CRD) patients with appropriate treatment based on their biologic make-up.

Before joining the MedTech Actuator Accelerator, Diag-Nose.io was repurposing existing technology to address antibiotic resistance. Participation in the program helped the team test its hypothesis and uncover established intellectual property (IP) and companies already working in this crowded space.

As a result, the team conducted extensive market research with key opinion leaders, regulators, payers and pharmaceutical companies to better understand the clinical need. Consequently, Diag-Nose.io shifted its focus to CRD diagnostics and designed and validated RhinoMAP, launching a proof-of-concept clinical study with more than 70 patients.

Originally scheduled to conclude in 2022, the study was delayed due to COVID-19, deferring progress and the study's completion to 2023.

Partnerships, US-based investor and eight active patent filings

Following the Accelerator, Diag-Nose.io commenced a clinical partnership and received investment from a US-based speciality physician associate in Pennsylvania. Additional partnerships were formed, including with University of Florida, to look at lung transplant monitoring, and Canadian protein design company Proteic, to manufacture sustainable antibodies for diagnostic or research use.

Diag-Nose.io has now created the world's first device and platform to predict and monitor therapeutic responses for patients with CRDs, resulting in eight active patent filings across four patent families, with the potential for more as clinical trials and R&D continue. Underpinning this work is a growing workforce; Diag-Nose.io was founded by a team of four in 2020 and now employs 11 team members, with 55 per cent gender parity.

To date, Diag-Nose.io has raised $1.7 million in equity-based funding, supported by an additional $500,000 of non-dilutive funding. The team is actively raising and is in the process of closing a $3 million venture round in the first half of 2024.

CEO and Co-Founder of Diag-Nose.io, Eldin Rostom, has expressed his gratitude for the Accelerator program.

"As a participant in the MedTech Actuator Accelerator, my involvement has offered a clear perspective on the program's role in advancing the medical technology and pharmaceutical industries. At Diag-Nose.io, this experience has been integral to our progress.

"As guided by the program, we shifted our focus away from the antibiotic resistance market towards the respiratory immunotherapy market, recognising a more urgent and underserved market with a greater impact on patient outcomes and lowering healthcare costs," Mr Rostom said.

Addressing challenges, essential support, establishing significant partnerships and much more

The program's assistance proved crucial in refining the team's commercialisation pathway and enhancing its understanding of the market.

Mr Rostom added, "It also aided us in addressing various challenges, including unexpected roadblocks brought about by the COVID-19 pandemic. The support from the MedTech Actuator and MTPConnect have proved essential in establishing significant partnerships, conducting human clinical studies and acquiring necessary funding, which has been central to our path of innovation and expansion."

Specialist support for medical entrepreneurs, such as that afforded by the MedTech Actuator, is essential in the pursuit of innovation and a stronger healthcare sector for Australia.

Expanding clinician-led transformation across Australia's healthcare workforce

PARTNER:
The University of Melbourne with The University of Western Australia

AUSTRALIAN CLINICAL ENTREPRENEUR PROGRAM

NUMBER OF REDI SUPPORTED PROGRAMS:
1 Program:
– Australian Clinical Entrepreneur Program (AUSCEP)

NUMBER TRAINED SUPPORTED BY REDI:
119

COMPANIES ACCELERATED:
103

Among Australian researchers and entrepreneurs, there is a significant skills gap for clinician entrepreneurs (and intrapreneurs) across the whole product development and commercialisation theme. A clinical-based entrepreneur is perfectly positioned to clearly articulate unmet market needs and commercial potential in their proposals.

To support the development of clinical entrepreneurs in Australia, there is a great need to enhance the local pool of entrepreneurial and intrapreneurial clinicians and provide adequate mentoring and support through accelerator and incubator programs. In this endeavour, the nation can learn from successful international programs, including the US city Boston – a mecca for healthcare innovators and investors – and the NHS Clinical Entrepreneur Programme in the UK. The NHS initiative offers expert mentoring, networking opportunities and bespoke training to clinicians, enabling them to develop innovative ideas into products and businesses that benefit patients, without leaving their clinical careers.

Consequently, MTPConnect's REDI initiative partnered with The University of Melbourne and The University of Western Australia to establish the Australian Clinical Entrepreneur Program (AUSCEP), which has been inspired by the NHS Clinical Entrepreneur Programme and customised for the Australian environment. Launched in 2022 and supported by both REDI and the New South Wales, Victorian and Western Australian state governments, two 12-month pilot programs created a platform for professional development and accelerated a dynamic pipeline of clinician-led innovations to nurture the next generation of clinical entrepreneurs.

Over the course of the program, participants engaged in eight immersive in-person workshops ('pitstops') and 12 webinars that blended clinical expertise with entrepreneurial insights. They also benefitted from personalised guidance through one-on-one mentorship with industry experts, accessed AUSCEP's delivery team to refine their commercialisation path and gained access to a network of potential collaborators, investors and partners.

Identifying a clinical need and pioneering the Eating Disorder Waitlist

Clinical psychologist Dr Bronwyn Raykos was part of AUSCEP's first cohort. As Head of the Eating Disorders Program at the Centre for Clinical Interventions in Western Australia, she was motivated to address the long waitlists for specialist eating disorder treatment, which range from six to 12 months.

Along with her clinical team, she launched an electronic workbook containing the latest evidence-based cognitive behavioural therapy strategies and education for treating adult eating disorders. Within the first year of its release, the workbook was downloaded approximately 400,000 times. Having identified a clinical need, Dr Raykos then pioneered the Eating Disorder Waitlist Project – aiming to transform the workbook into a digital app that patients could download at the point of referral. Dr Raykos also wanted to conduct in-depth interviews with clients affected by waitlists for eating disorder treatment, to guide her towards finding additional solutions for supporting people at the time they first seek help.

From left: Prof Jane Gunn, Dean of Medicine, University of Melbourne; Dr Brandon Carp, AUSCEP Chief Clinical Entrepreneur; Juliana Addison MP, Member for Wendouree; Ken Jefferd, Executive Director of Research, Innovation and Commercialisation, University of Melbourne; and MTPConnect CEO Stuart Dignam at the Melbourne launch.
Image credit: @ carmenzammit

After joining AUSCEP, Dr Raykos formed a partnership with Innovation Unit's Jethro Sercombe, a specialist in the facilitation of inclusive and engaging co-design processes. Mr Sercombe provided human-centred coaching and helped to establish questions and processes for the interview component of the AUSCEP project. Dr Raykos also developed a first prototype for a 'recovery hug box' – a care package that members of the public can use, or clinicians can give to patients, to support their recovery.

Securing funding for the app, launching a website and hug boxes

Within the first six months of the program, Dr Raykos had secured funding for the app's development and its five-year implementation; created a project control group and consumer advisory panel; and formed several important partnerships. By the end of the 12 months, she had launched a website, started selling hug boxes to private practices and was exploring new opportunities to further support clinicians treating people with eating disorders.

Dr Raykos said the app eventuated as a direct result of her participation in AUSCEP.

"Before the program, an app solution such as the one we're building now wasn't within the remit of what we had resourcing or support to do and wasn't seen as a priority for the health service. We're now planning that the app will be ready for release at the end of 2024," Dr Raykos said.

AUSCEP has a way of making you truly believe in yourself

Through AUSCEP, she had the opportunity to engage with "every level of the healthcare system" in her efforts to ensure the app and other proposed solutions aligned with the priorities of the broader health service.

Reflecting on the value she gained from participating in the program, Dr Raykos said the pitstops, webinars and mentoring were highly beneficial, as was the opportunity to step outside the clinical setting and learn how entrepreneurs, founders and industries approach today's problems.

Summing up, Dr Raykos said, "The mentoring and the different workshops that I've been able to attend have been amazing. The AUSCEP program has a way of making you truly believe in yourself and enables you to take the leaps of faith needed to really drive change and impact within healthcare."

> **This is an industry-leading innovation program designed to advance clinician-led transformation across Australia's healthcare workforce.**

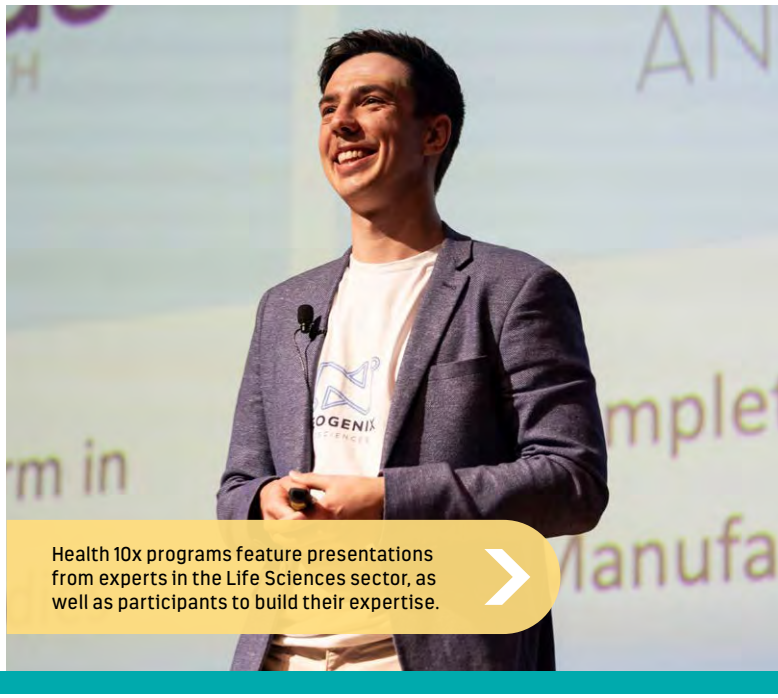
Backing the next wave of global health entrepreneurs through the Health 10x Accelerator

PARTNER:
The George Institute for Global Health

NUMBER OF REDI SUPPORTED PROGRAMS:
3 Programs:
– Health 10x Pre-Accelerator
– Health 10x Accelerator
– Disruptive Entrepreneurship and Innovation Training

NUMBER TRAINED SUPPORTED BY REDI:
700

COMPANIES ACCELERATED:
140



Health 10x programs feature presentations from experts in the Life Sciences sector, as well as participants to build their expertise.

Australia's medical products sector is experiencing a notable shortage of 'serial entrepreneurs' – individuals who have navigated the journey of innovation, potentially faced setbacks, adapted their strategies and ultimately achieved success in bringing their ideas to market. The fundamental issue lies in the insufficient number of entrepreneurs capable of assuming calculated risks and driving innovation within the market.

Recognising this gap, MTPConnect's REDI initiative supported The George Institute for Global Health and the University of New South Wales, to deliver the Health 10x Accelerator – an intensive program that supports start-ups to develop affordable and scalable solutions to some of the world's most pressing unmet medical needs. Health 10x is open to early-stage start-ups, researchers, students, clinicians and health innovators across Australia.

Health 10x Accelerator has supported more than 100 start-ups since 2019

Equipping health and medtech founders with the business expertise and resources they need to understand the health technology ecosystem, build their company and drive impact through commercialisation, the Health 10x Accelerator has supported more than 100 start-ups since its inception in 2019 and invested in 27 start-ups.

The Health 10x Global Health Accelerator has a specific focus on innovations that address major health challenges in emerging and underserved markets, particularly the burden of injuries and non-communicable diseases (such as cancer, diabetes and chronic respiratory illness) – leading causes of death and disability worldwide.

The Pre-Accelerator provides targeted global health modules and start-up education from leading industry experts and founders over four weeks. This can be followed by the Health 10x Accelerator, which provides 10 weeks of full-time learning from industry, health and start-up experts via workshops, mentoring and collaborative activities. It covers regulatory compliance, health economics and clinical trials, offers exclusive access to Entrepreneur-in-Residence support and provides funding of up to $90,000 SAFE investment.

Commercialising a breakthrough medical device to help people with mobility issues

One alumnus of the 2020 Health 10x Accelerator cohort, Walking Tall Health, is proof of the program's effectiveness.

The organisation is commercialising a breakthrough medical device to help people with mobility issues, such as Parkinson's disease, walk independently again. Its early prototype device, which attaches to users' ankles, has already demonstrated improvement in users', walking ability; the device can be used in conjunction with the Walking Tall app, which gives users walking exercises and audio cues for timing of steps.

The free Walking Tall app was released in August 2023 and can be used with or without the medical device.

In December 2023, Walking Tall Health was awarded a $1 million development grant from the National Health and Medical Research Council (NHMRC) to enable the team to advance beyond a prototype device. The proposed new device, dubbed a 'pacemaker for gait', will use the effects of synchronising neuronal stimulation across limbs, which is already proven to help people with spinal cord injury regain function. This has the potential to help people living with Parkinson's disease walk better and for longer, restoring quality of life and reducing hospital visits.

Making key industry connections, focusing the development pathway and much more

Medtech start-up MUVi was another of the five companies selected to join Health 10x in 2020. Its Melbourne-based team, led by Founder Murray McDonald, developed a mobile device that uses rapid ultraviolet (UV) disinfection, decontamination and monitoring technology to tackle the burden of healthcare-acquired infections, which are responsible for one death every three minutes globally. The MUVi device aims to safeguard against human cleaning errors in clinical environments, and consequently reduce the risk of complications or deaths from healthcare-acquired infections and 'superbugs'.

During and following its involvement in Health 10x, MUVi made key industry connections, successfully acquired non-diluted funding, focused its development pathway and ensured it was investment ready.

Mr McDonald said the device's potential to save lives was tested by the onset of COVID-19. At this time, the company launched trials of its UV technology, together with leading researchers from the University of New South Wales. He said it was later used in several hospitals in Wuhan, China – the site of the first confirmed coronavirus cases.

Innovations with the potential for life-changing and far-reaching impacts in healthcare systems

"Our team was addressing the risk of hospital-acquired infections through highly contaminated, frequently touched surfaces, in particular for vulnerable patients within healthcare facilities. Having a digital monitoring and alert system can help to ensure equipment and rooms are regularly and thoroughly disinfected," Mr McDonald said.

Both Walking Tall Health and MUVi's innovations have the potential to convey life-changing and far-reaching impacts in healthcare systems. As proven during the COVID-19 pandemic, it has never been more important to support companies that are endeavouring to deliver rapid, affordable and effective innovations for worldwide healthcare. Health 10x will continue to give these pioneers access to the knowledge and networks they need to succeed on their mission to create a healthier world.

The REDI support also allowed development of The Disruptive Entrepreneurship and Innovation Training Program – a short course designed for health researchers and health-focused professionals looking to develop foundational knowledge and skills in health commercialisation and the broader entrepreneurial ecosystem. The training modules focus on building capacity in ideation and identifying commercial ideas, market analysis, idea validation, planning for commercialisation, and communicating and presenting ideas effectively. This training is intended to help health professionals and academics understand why and how they can pursue commercialisation of research outcomes, the steps they need to take to do this, and how they can achieve impact through entrepreneurship.

> **Health 10x Accelerator has supported more than 100 start-ups since its inception in 2019 and invested in 27 start-ups.**

Participants in the TGI REDI supported programs value the intensive entrepreneurial and commercialisation focus these tailored programs provide.

Ideas incubator a boost for early-stage innovation for new medical devices

PARTNER:
Medical Device Partnering Program (MDPP)

NUMBER OF REDI SUPPORTED PROGRAMS:
4 Programs:
– Concept Workshops
– Concept Training
– R&D Medical Device Projects
– REDI Engagement Series

NUMBER TRAINED SUPPORTED BY REDI:
1,122

COMPANIES ACCELERATED:
222

The VentiWatch – a practical, simple and reusable ventilation management solution.

Formed in 2008 in South Australia, the Medical Device Partnering Program (MDPP) is an ideas incubator – an initiative that fosters dynamic collaborations between researchers, industry, end users and government to develop and progress innovative medical technologies with global market potential. The MDPP's primary goal is to accelerate the development and commercialisation of medical device start-ups in Australia, paving the way for increased investment in technology and entrepreneurship.

In 2019, a partnership with MTPConnect's REDI initiative empowered the MDPP to expand its reach and provide award-winning technical expertise to medical device start-ups around Australia. With REDI's backing, the MDPP has facilitated early-stage advice and assessed the eligibility of an additional 250 applications from around the country.

Connecting innovators with great ideas to the knowledge and resources they need

The MDPP connects innovators with great ideas to the knowledge and resources they need to bring their inventions to life. It selects projects that focus on industry-driven challenges with strong commercial potential, which aim to tackle a range of critical issues. This includes improving traditional procedures such as airway management and catheterisation and enhancing success rates in cardiac ablations and orthopaedic procedures.

After applicants pass an eligibility assessment, the MDPP arranges a technical workshop for them to showcase their project to a panel of experts, including academics, clinicians, manufacturers, end users and commercial professionals. This process provides the applicant with valuable industry feedback to guide the development of their product.

Upon approval, each approved project receives up to 250 hours of technical expertise, covering research, proof-of-concept, prototyping, product validation or small clinical evaluation. Additionally, applicants receive a Product Opportunity Assessment, including feedback from prospective end users and a market overview, as well as introductions to potential partners such as manufacturers and commercial entities.

At the project's conclusion, all results, data, prototype and intellectual property are released unencumbered to the applicant, together with a plan for further R&D.

Through collaboration with REDI, MDPP expands its successful approach nationwide

The collaboration between the MDPP and REDI has enabled the MDPP to not only expand its successful approach nationwide, but also provide new services. These include a series of seminars and events including 'MedTech Mondays', and an increased provision of Ideation workshops and R&D projects for approved participants.

Throughout REDI's support, the MDPP's Ideas Incubator program attracted 250 applicants, each granted a complimentary hour with an MDPP expert. They discussed their medical device ideas, received technical and commercial advice, and explored potential connections.

Out of these, 41 were selected for a two-hour Ideation workshop and then the MDPP chose 19 companies from this

pool to receive 250 hours of dedicated technical expertise. Many of these applicants have since advanced their ideas and formulated their go-to-market strategies.

Collectively, these 19 projects employ more than 65 full-time equivalents, have established more than 25 partnerships/collaborations, filed more than 10 patents, and secured more than $20 million in funding and investment.

With REDI's support, the MDPP has provided Australia's new medtech innovators more than 650 hours of expertise at no cost.

A more accurate, scalable and cost-effective prototype with a sophisticated processing algorithm

One successful alumnus of the program is Western Australian start-up company Abtulus – the brainchild of Dr Siavash Noor who invented VentiWatch: a practical, simple and reusable ventilation management solution to aid medical professionals and first responders in delivering precise and efficient ventilation during resuscitation.

Dr Noor presented his early, functioning Raspberry Pi-based prototype to the MDPP team and together with a project manager, software engineer, electronic engineer and mechanical engineer they worked to enhance the sensing method to achieve a more accurate, scalable and cost-effective prototype, with a sophisticated processing algorithm, providing real-time feedback on air delivery and ventilation timing.

Placed on the outside of a Bag Valve Mask (BVM), VentiWatch is a ventilation management device, which features a user-friendly interface, colour LCD screen, audible alarms and a rechargeable lithium-ion battery. First responders can use the system to obtain guidelines-compliant volume and timing for a successful resuscitation.

> **The MDPP connects innovators with great ideas to the knowledge and resources they need to bring their inventions to life.**

Refining the design, developing a low-cost prototype and achieving recognition

Dr Noor said the collective expertise of the MDPP team led to the development of a more reliable and accurate prototype, requiring less power and better suited to its intended environment.

In addition to technical guidance, Dr Noor said the MDPP connected him to resources and insights about commercialising his invention.

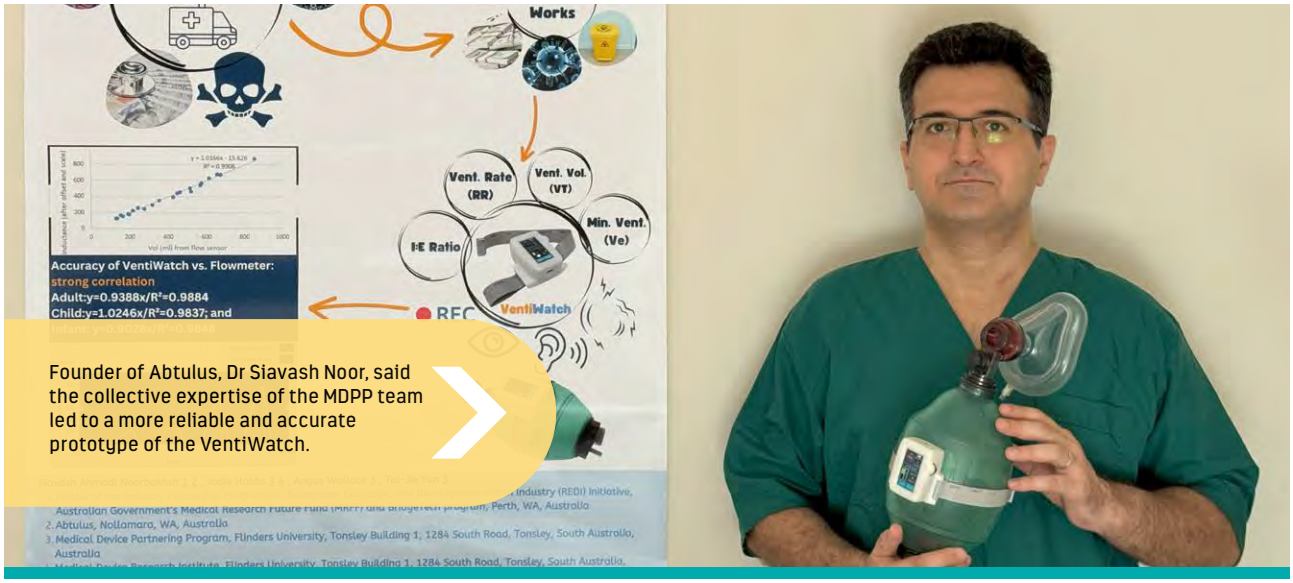
"MDPP connected me with many people in the medical device industry and advised me of opportunities for grant funding. They helped me to refine VentiWatch's design and develop the prototype at a low cost so I can show end users, get feedback and improve on it to achieve a tangible product," Dr Noor said.

Having progressed his innovation to a Level 2 prototype, Dr Noor has showcased the VentiWatch at several medical conferences and industry events. Abtulus achieved recognition as a finalist for 'Best New Idea' at the 2023 Startup Daily Best in Tech Awards, as well as being named a finalist in the 'Research & Innovation Project (Industry)' category of the 2023 INCITE Awards. Additionally, Abtulus was one of 20 teams selected nationwide for the MedTech Actuator Origin in 2023.

An enriching experience propelling the medtech device and the company to a whole new level

With a robust patented prototype, Dr Noor is ready to take Abtulus to the next level of testing and refinement and is actively seeking funding for this purpose.

"Overall, working with MDPP has been an enriching experience that has propelled my device and company to a whole new level. I'm incredibly grateful for the expertise, resources and support provided throughout the program. I look forward to a continued partnership as we bring this lifesaving technology to the world," Dr Noor said.



Founder of Abtulus, Dr Siavash Noor, said the collective expertise of the MDPP team led to a more reliable and accurate prototype of the VentiWatch.

Commercialisation competency framework: a road map for early-stage innovators

PARTNER:
Wrays Consortium

NUMBER OF REDI SUPPORTED PROGRAMS:
2 Programs:
– Start-Up Competency Framework
– Start-Up Competency Framework Training

NUMBER TRAINED SUPPORTED BY REDI:
307

Independent intellectual property specialist Wrays led a REDI initiative funded consortium to develop a life sciences competency framework. Pictured, Wrays team members presenting at Science on Swan 2022 in Perth, WA.

The development path of a life sciences start-up is daunting for a new entity. Founders are often cash constrained yet need to scale the business and bring in the right talent and advice at the right time.

Feedback gathered during MTPConnect's REDI Skills Gap analysis was that founders didn't know what skills they needed for their team and when these should be brought on. Many were also unsure about the remit of specific roles and responsibilities. In short, there was no handbook for scaling a start-up life sciences company.

A unique consortium with a wealth of knowledge and hands-on experience

Consequently, the REDI initiative awarded funding to a consortium, led by independent intellectual property (IP) specialist Wrays, to develop a life sciences competency framework. Administered by The University of Western Australia, the consortium also includes Biotech Recruitment Consultants, specialists in executive search and recruitment for the biotechnology industry; Biodesign Australia, which facilitates programs about biomedical entrepreneurship; and Yuuwa, a specialist life sciences commercialisation and investment firm.

This unique consortium brings with it a wealth of knowledge and hands-on experience relating to all issues of the commercialisation of therapeutic products and medical technology.

Drawing on expertise from various stakeholders, including policymakers, investors, recruitment consultants and industry professionals, the consortium has developed – and delivers training on – a commercialisation competency framework tailored to the unique needs of early-stage innovators in the life sciences field.

Helping founders and investors scale, grow and hire the best staff

This framework aims to help founders and investors scale, grow and articulate clear roles and responsibilities of staff that can be used in job descriptions – providing a skills road map for SMEs to enhance their commercialisation capabilities. Designed to bridge the gap between technical expertise, soft skills and commercial acumen, the framework encompasses a wide range of domains including team culture, technical skills, regulatory compliance, market requirements, funding pathways and more.

> One component of the program that has resonated particularly well with researchers has been case studies featuring real-world commercialisation of research.

To facilitate the dissemination of the framework, the Wrays consortium runs face-to-face and online training sessions nationally. The sessions are engaging and informative, using cartoons as a visual and memory-aid tool to educate professionals about the standards and practices required for successful commercialisation. The training program addresses the key areas of communication and collaboration, translation of laboratory research, business-focused outcomes, meeting investment criteria and leadership and management growth.

One component of the program that has resonated particularly well with researchers has been case studies featuring real-world commercialisation of research to demonstrate what is required to build a successful start-up team. This aggregation of multiple case studies has allowed learned experiences, good and bad, to be articulated in a highly illustrative and memorable manner.

Empowering SMEs to navigate commercialisation more effectively

Program themes are centred very much on building teams and asking the right questions from external suppliers – integrating, for instance, IP or regulatory and reimbursement strategies into an overall corporate strategy.

In addition to the training sessions, the Wrays consortium launched a dedicated website in 2023 – biotechcommercialisationskills.com.au – to assist companies with their commercialisation activities. The website serves as a resource hub, sharing a range of job description forms, soft skills and technical skills resources, and other useful tools for SMEs looking to expand their teams and enhance their capabilities.

By equipping early-stage innovators with the necessary skills and resources to build their start-up, the Wrays consortium has empowered SMEs to navigate the complexities of commercialisation more effectively. The training sessions and online resources provide important insights and guidance, enabling SMEs to build effective teams, identify key skills gaps and develop strategies for success in the market.

PARTNERSHIPS SECTION 2: SPECIALIST REDI TRAINING PROGRAMS

The REDI Skills Gap reports identified a number of skills that were holding the growth of the life sciences sector back that were specific and able to be filled through a targeted training program. These covered a number of themes from advanced manufacturing to clinical trials, product development, commercialisation and health data and cybersecurity. These also impacted different parts of the MTP value chain, from translation to sales and marketing.

Developing new skills and taking founders and leaders out of their comfort zone

Becoming a successful entrepreneur is difficult; training needs to develop both new skills and the confidence to take founders and leaders out of their comfort zone and equip them to tackle demanding tasks that are crucial for growth.

Manufacturing and quality systems skills gaps were reported to REDI as major impediments to growth of the sector. Manufacturing companies and investors highlighted the lack of quality systems in SMEs as a deterrent to investment decisions. REDI tackled these challenges head on, delivering supporting programs through SeerPharma and the Centre for Biopharmaceutical Excellence. These initiatives aimed to raise awareness of the importance of quality systems and offered more in-depth training to develop skills and knowledge in navigating regulated environments, understanding the significance of quality systems and implementing them effectively in the workplace.

Making a significant impact, the knowledge to ask the right questions and securing funding

Clinical trials emerged as another key area requiring attention and one where REDI could make a significant impact by addressing the skills gap in start-ups, understanding their clinical trial needs and improving their collaborations. A new program, delivered by ARCS Australia, was not about making company founders clinical trial experts, but giving start-ups the skills and knowledge to ask the right questions and the basic understanding to ensure that their clinical trials were able to answer the questions required by regulators and payers.

Securing funding is an issue affecting those looking to start a company, as well as SMEs and even more mature companies. Biointelect delivered a training program around Australia on grants, investments, government programs and incentives and how to secure these, as well as what different investors look for. On the flip side, REDI and Life Sciences Western Australia delivered programs to help demystify life sciences investment for Australian investors and give them the skills to evaluate and the confidence to invest in life sciences and medical product companies.

Big data and AI product development, scaling up start-ups and developing a skills framework

Tied to product development is making sure your product has a target market who will purchase and use the product once it is produced. Training from Cicada Innovations was delivered nationally on how to identify the customer and the payer, identify their needs and check that the product meets market needs.

REDI also found a significant gap relating to big data and AI product development (as opposed to commercialisation) and funded an introductory program to develop big data analysis and AI development skills.

CONTENTS

Boosting Australia's Good Manufacturing Practice capabilities for medicinal products

PARTNER:
Centre for Biopharmaceutical Excellence Consortium

NUMBER OF REDI SUPPORTED PROGRAMS:
2 Programs:
– CBE Essentials GMP Program
– CBE Advanced GMP Program

NUMBER TRAINED SUPPORTED BY REDI:
400

CBE GMP programs are specifically designed to provide participants with a real-world perspective.

The COVID-19 pandemic and the search for a vaccine shone a spotlight on sovereign capabilities in the medical technology, biotechnology and pharmaceuticals (MTP) sector in Australia, underscoring the critical importance of R&D of innovative technologies to address complex human health challenges. The pandemic also highlighted the need for Australian-based manufacturing and a robust supply chain to ensure the continuous provision of medical products.

Recognising the role of Good Manufacturing Practice (GMP) in supporting the healthcare sector, MTPConnect's REDI initiative had pinpointed GMP competency as a key skills gap in its needs assessment.

To address this gap, REDI engaged the Centre for Biopharmaceutical Excellence (CBE) to form a strategic partnership with ARCS Australia, CBE Pure Solutions, Merck Australia, Translational Research Institute and University of Technology Sydney to launch two different GMP training programs. The programs are specifically designed to provide participants with a real-world perspective and to enable the interpretation and application of GMP in practice.

GMP describes a set of principles and procedures that when followed helps ensure that therapeutic goods produced and tested are of high quality. Australian-based manufacturers of medicines and biologicals are required to hold a licence to manufacture, with different codes of GMP for medicines, human blood and tissues as well as medical devices. GMP also extends to legal components covering responsibilities for distribution, contract manufacturing and testing and responses to product defects and complaints.[1]

Regulatory oversight by bodies like the Therapeutic Goods Administration (TGA) ensures manufacturers uphold these standards, fostering consumer confidence in the safety and efficacy of therapeutic products in the Australian market.

The REDI initiative identified a shortage of GMP-competent staff

Many Australian SMEs require GMP skills for R&D and product development and the REDI initiative identified a shortage of GMP-competent staff. This is a skills gap for new hires, who need to understand how to be GMP compliant, and for senior staff, who need to maintain competence and knowledge of the latest GMP guidance from the many regulatory bodies worldwide.

As consortia lead, CBE brings strong technical credentials, from consulting services across the biopharmaceutical sector and GMP-related enterprise training. One of the programs – CBE's REDI GMP Uplift Essentials program – is a five-day equivalent course designed to upskill those new to the sector in the core principles of GMP. It takes the theoretical into practice through experiential learning.

CBE Director Steve Williams said the GMP Uplift Essentials program builds experience for those early in their GMP career journey, giving them foundational yet practical skills.

1. Therapeutic Goods Administration: Good Manufacturing Practice Overview https://www.tga.gov.au/good-manufacturing-practice-overview

"Growth across our biopharma sector presents both an opportunity and a challenge for companies trying to find staff. Start-ups and small enterprises face a real challenge to find GMP-trained staff and they aren't large enough to have their own training division.

"These REDI-supported training places are making a difference for start-ups and SMEs transitioning from development to manufacturing and enabling them to incorporate a compliance structure," said Mr Williams.

Aiming to equip its workforce with immediate practical skills, EnGeneIC has been training its staff through CBE's REDI GMP Uplift Essentials program.

Named by *Australian Financial Review* as the most innovative company in healthcare in 2022, Sydney-based clinical-stage biopharmaceutical company EnGeneIC has developed 'EDV (EnGeneIC Dream Vector) technology' – a nanocell platform enabling targeted delivery of cancer treatments to be far more potent and less toxic, while also stimulating an anti-tumour immune response. This technology has the potential to revolutionise cancer treatment – making the process simpler, quicker and more effective than existing options.

Growing organisations hampered by a shortage of GMP-trained staff

Yet, like many growing organisations in the life sciences sector, EnGeneIC's efforts are being hampered by a shortage of staff trained in GMP, which impacts the company's growth and scalability.

Recognising this, EnGeneIC found REDI's funded program a great opportunity not only for its own benefit, but also to help bridge the sector-wide skills gap in the industry and to enhance medical product sovereign capabilities across Australia.

EnGeneIC Senior Vice-President of Manufacturing, Juan Dux-Santoy, said the program has been extremely helpful in upskilling staff and introducing them to microbial controls and aseptic techniques – particularly as the company looks to scale up its technology.

"The benefit of this training is enormous for us, since it helps us to understand the critical parameters and steps in our manufacturing process and action any issues deficient in GMP," he said.

GMP training for EnGeneIC staff – particularly valuable at a pivotal moment

Mr Dux-Santoy added that the training has been particularly valuable at a pivotal moment in EnGeneIC's growth, as it designs a new manufacturing facility. As such, learning about clean room areas and layout optimisation – essential features of any facility manufacturing sterile medicine products – has proved very timely.

"Through the GMP Uplift Essentials program, the team has not only gained an understanding of what will be required in the new facility, but has also already implemented changes to existing workflows, in relation to gowning processes, record-keeping and microbial controls," he said.

Participating in the GMP Uplift Essentials program has underscored the immediate and practical impact training can have on workforce development for EnGeneIC, as well as contributing to the team's ongoing success and innovation in cancer treatment.

In December 2023, the company was granted US Food and Drug Administration (FDA) 'Fast-Track' designation for its Novel Armed Nanocell Drug Conjugate (ANDC) pancreatic cancer therapeutic and is now entering Phase IIa clinical trials in Australia and the US in patients with intractable, low survival cancers, including patients with metastatic pancreatic cancer.

> **Start-ups and small enterprises face a real challenge to find GMP-trained staff.**

Participants of the REDI-supported CBE GMP programs have found enormous benefit from the specialised training offered.

Regulatory education key to boosting commercialisation outcomes

PARTNER:
SeerPharma

NUMBER OF REDI SUPPORTED PROGRAMS:
4 Programs:
– Quality Systems Primer
– ISO 13485:2016 Preparation Workshop
– ISO 9001:2015 Bootcamp
– Good Laboratory Practice: Alignment Bootcamp

NUMBER TRAINED SUPPORTED BY REDI:
1,249

Widespread adoption of Quality Management Systems and other standards by start-ups and SMEs will drive greater commercialisation success

Products in the life sciences sector are highly regulated. Manufacturers must meet relevant quality standards before they are eligible to seek approval from government regulators, such as the Therapeutic Goods Administration (TGA) in Australia and the Food and Drug Administration (FDA) in the US.

Applicable international quality standards for manufacturers of medical products include Good Manufacturing Practice, Good Laboratory Practice and ISO 9001, ISO 13485, ISO 17025 and ISO 27001. The latter establishes requirements related to information security management systems, which is especially important for businesses that capture patient data.

Certification to relevant industry standards represents a mark of assurance

Being certified to relevant industry standards represents a mark of assurance regarding the competence of an organisation and the integrity, reliability and consistency of its products or services. It is therefore essential that researchers and companies in the medical products sector understand the relevant quality systems required for commercialisation.

Such groups likewise need to understand the steps required to implement a Quality Management System that meets the requirements for certification, as well as the related documentation and audit processes.

Large pharmaceutical and medical technology companies tend to have sufficient in-house capabilities in this space due to their scale and deep knowledge of the regulatory requirements of the sector. However, skills gaps in these areas are particularly evident within start-ups and SMEs. The emergence of digital health businesses has also brought to light the lack of understanding of ISO 27001 protocols, thus increasing exposure to potential data breaches.

An observed skills gap in mandated training and adherence to quality systems across research institutions

There is also an observed skills gap in mandated training and adherence to quality systems across research institutions (such as universities, medical research institutes and public research organisations), whereby some have more thorough training and protocols in place than others. According to former Chief Scientist, Dr Alan Finkel AO, training in research institutions "varies widely in quality and is often seen as a pro forma exercise".

Widespread adoption of Quality Management Systems and other standards by start-ups and SMEs will drive greater commercialisation success, as companies will have more robust business processes and therefore be better positioned in investor/partnership discussions and regulatory submissions.

Developing increased capabilities in quality management at the basic research level will also drive better commercialisation outcomes. Researchers will gain greater credibility among big pharmaceutical and medical technology companies and the licensing opportunities are likely to be higher if the asset and research data have been collated within a certified quality framework from early in the development pathway.

Increasing capabilities in quality management

To address these skills gaps and increase capabilities in quality management, as well as cultivate greater awareness of standards and protocols, MTPConnect's REDI initiative partnered with SeerPharma – Asia-Pacific's leader in quality assurance and compliance solutions – to deliver four new courses.

The first course was the Quality Systems Primer: a two-hour online course that was aimed at those considering translating their research to a commercialised product. The course outlined four highly relevant quality systems for life sciences commercialisation – ISO 13485, ISO 9001, ISO 17025 and Good Laboratory Practice – and the relevance of each.

The second course, the ISO 13485:2016 Preparation Workshop, ran over four days, and imparted the knowledge and processes that enabled participants to effectively implement a Quality Management System that meets the requirements for ISO 13485:2016 certification.

The third and fourth courses were both held as three-day bootcamps, and respectively covered ISO 9001:2015 Quality Management System and Good Laboratory Practice.

Moving towards an integrated state-wide service – rationalising, consolidating and standardising

Manufacturing Lead Pharmacist at SA Pharmacy, Nick Sharley, completed the ISO 9001:2015 Bootcamp. He said it brought together the various elements of Quality Management System into a structured format.

He explained that SA Pharmacy has four manufacturing facilities and associated Quality Control Services that have evolved as disparate units and are now moving towards an integrated state-wide service – rationalising the range of products, consolidating services and standardising practices.

"My approach has been through a quality/patient safety lens, cost-effectiveness and sustainability model. By attending the ISO 9001 training, I hoped to further consolidate my approach by putting the ISO 9001 into the context of our business model," Mr Sharley said.

Leveraging elements of the training and the focus SA Pharmacy's management now has on maintaining a sustainable growing service, Mr Sharley said obtaining approvals for resources, research and consultations has been more straightforward.

"I plan to have a Quality Management System that meets the requirements of ISO 9001," he said.

> **Widespread adoption of Quality Management Systems and other standards by start-ups and SMEs will drive greater commercialisation success.**

Training showed the factors you need to consider when implementing a Quality Management System

Like Mr Sharley, Associate Professor Amee George, Head of the ANU Centre for Therapeutic Discovery at The John Curtin School of Medical Research, participated in SeerPharma's ISO 9001:2015 Bootcamp.

Though she manages a research facility in an academic institution with primarily academic clients, she said an increasing number of industry clients are looking to work with facilities that have ISO 9001 certification – as well as Good Laboratory Practice frameworks – in place.

"Attending training provided an insight into what is required to implement ISO 9001 and what we need to consider when we implement this in our workplace. The training also opened my eyes to the factors you need to consider when implementing a Quality Management System.

"It was fantastic to meet others as part of the training – particularly those who have already implemented Quality Management Systems in their workplace – and hear about how they had done this and what they would have done differently. I would feel comfortable to contact some of the other participants again to ask for their opinions in our design process," A/Professor George said.

A Quality Management System opens doors to collaborate with industry partners and clients

Post-training, she said she now understands the basic principles of implementing a Quality Management System and has identified the resources required to ensure the system implemented is comprehensive.

Summing up, A/Professor George said, "Once we implement our Quality Management System, it will open a lot of doors for collaborating with industry partners and clients who require ISO 9001 accreditation to utilise our facility and/or services. As a result, our facility and the broader enterprise will benefit knowing that we provide a measurable 'quality' service to them."

Empowering medical innovators – impact of ARCS Foundations Bootcamp for clinical trial design

PARTNER:
ARCS Australia

NUMBER OF REDI SUPPORTED PROGRAMS:
2 Programs:
– Foundations Bootcamp: Medical Devices
– Foundations Bootcamp: Medicines

NUMBER TRAINED SUPPORTED BY REDI:
79

In the dynamic landscape of medical technology and pharmaceutical innovation, the ability to design and execute effective clinical trials is paramount for success. However, many early-stage companies and SMEs often lack the necessary skills and resources to navigate the complexities of clinical trial design. Recognising this challenge, MTPConnect, in collaboration with the REDI program, partnered with ARCS Australia to develop a series of bootcamps aimed at addressing the skills gap in clinical trial design.

The bootcamp series, facilitated by industry experts and regulatory professionals, focused on equipping participants with the knowledge and skills required to design clinical trials effectively. The workshops delved into various aspects of clinical trial design, including regulatory and reimbursement requirements, data collection and communication with investigators. Tailored to the specific needs of the medical products sector, the bootcamps provided attendees with practical insights and actionable strategies to optimise their clinical trial processes.

Bootcamp objectives:

- To provide relevant and targeted information to participants on the strategic development of pharmaceuticals and medical devices.
- Delivering practitioner-led programs anchored around the Target Product Profile (TPP) for pharmaceuticals and Concept and User Requirements (CUR) documents for medical devices.
- Providing participants with an understanding of the knowledge required to research and develop products for a global market.
- Fostering problem-solving skills through group/team activities, enabling participants to apply their learning in practical contexts.

Workshop outcomes:

The outcomes of the workshops were designed to empower Australian researchers, entrepreneurs and industry professionals with the knowledge and insights needed to navigate the complexities of clinical trial design. Over a span of two years, five workshops were delivered, focusing on medical devices or therapeutics.

Workshop highlights:

Market Expansion Discovery: One participant noted, "The standout for me is understanding what it takes, both from a time and a financial perspective, to get a medical device approved and to the market." This newfound understanding led to a breakthrough, as the participant identified a new market for their product, expanding its potential reach beyond initial projections.

Insights into Health Spending: Another participant shared, "I learned a lot about reimbursement and Health Technology Assessments, which was the topic I have the least experience of." This insight into government decision-making processes regarding health spending provided them with a fresh perspective on medical development, enriching their approach to product development.

Implementation of Learnings: This practical application of bootcamp teachings demonstrated the immediate impact of the program on one participant's workflow and decision-making processes, with them providing feedback as follows: "There are definitely teachings I have already applied, such as restructuring our requirements, tests and test results into a Requirements Specification format."

New Lens on Medical Development: Several participants highlighted the bootcamp's role in broadening their understanding of medical development. As one attendee expressed, "It was very interesting to understand how the government makes decisions on health spending. It gave me a new lens through which to look at medical development."

A catalyst for transformation

The ARCS bootcamp series has emerged as a catalyst for transformation within the therapeutics and medical devices sector. By empowering participants with the skills and knowledge needed to navigate the intricacies of clinical trial design, the bootcamps have facilitated market expansion, fostered insights into health spending decisions and inspired actionable changes in participants' approaches to product development.

As the industry continues to evolve, initiatives like these play a vital role in equipping innovators with the tools they need to bring life-changing medical products to market.

> **Providing practical education on incorporating regulatory and reimbursement needs for both domestic and international markets into the development plans can facilitate potential earlier market access of medical devices and medicines.**

Biointelect Venturer program delivers 'skills toolbox' to help researchers attract investment

PARTNER:
Biointelect Consortium

NUMBER OF REDI SUPPORTED PROGRAMS:
1 Program:
– Biointelect Venturer Program

NUMBER TRAINED SUPPORTED BY REDI:
178

Australia's life sciences investment industry is a niche and risk-averse landscape, one in which the challenges of securing financial investment underscore the critical need for innovation ventures to have the skills to navigate the investment environment effectively.

With the support of the REDI initiative, a consortium – led by Biointelect and supported by ARCS Australia and Biodesign Australia – introduced a training program for researchers and innovators to close this key skills gap.

The training equipped participants with a valuable understanding of the domestic and international life sciences investment climates. Through a blend of real-world insights, firsthand experiences and a focus on practical problem-solving, this national program aimed to enhance participants' abilities to attract funding and commercialise their innovations.

Consortium lead Biointelect is a renowned strategic planning and commercialisation advisory firm for the life sciences sector across the full innovation journey. With a deep knowledge of the life science ecosystem in Australia, Biointelect has a network of respected partners.

The consortium was selected as a partner of the REDI initiative to deliver the Biointelect Venturer program: a one-day course designed for life science organisations and entrepreneurs that are looking to leverage external funding to accelerate the commercialisation of their product or to take their start-up to the next level.

A real-world understanding of Australia's investment environment

Designed to ensure participants will be both partner and investor ready, the program provided a real-world understanding of the investment environment in Australia and other key markets and the different funding models and opportunities available. Critically, the Venturer program aimed to help bridge the gap in funding for academic research and start-ups – not only giving these groups the skills and knowledge needed for successful commercialisation, but also fostering partnerships and knowledge exchange within the dynamic life sciences sector. The popular program delivered 14 one-day workshops across five states to 178 participants.

Dr Jody Peters and colleagues Dr Henry de Malmanche and Ryan Johnston from The University of Queensland's School of Chemistry and Molecular Biosciences took up the training. In 2019, their arbovirus vaccine laboratory developed and patented a novel vaccine and diagnostics platform technology to combat mosquito-borne viral diseases. The technology has significant commercial potential, however, due to the novel nature of the technology – which harnesses cultivated mosquito cells to produce genetically modified viruses – it had been difficult to generate engagement or commercial investment.

Gaining insights and skills to engage with private equity and angel investors

Prior to attending the workshop, the team was hampered by a lack of knowledge of the commercial investment space. Through the program, the team gained insights into opportunities available for engaging with private equity investors and angel investors and acquired a toolbox of skills for pitching its technology as an investible proposition.

Following the workshop, the group was awarded a $500,000 CUREator biotech incubator grant in the health security stream, with the team crediting the knowledge gained from the Biointelect Venturer program for this momentous achievement. It was a pivotal endorsement of the team's potential and a funding injection that will play a significant role in advancing the Insect Specific Flavivirus Platform project towards commercialisation and, ultimately, making a meaningful contribution to the Australian biotech ecosystem.

The team has since submitted several more grant applications to various government and industry funding sources identified through the workshop, to advance development of both its vaccines and the diagnostic applications of its platform technologies.

Biointelect Venturer program imparted valuable lessons

Besides giving them the knowledge required to successfully attract investment, Dr Peters said the program imparted many valuable lessons: the importance of understanding opportunities for commercialisation and the various levels of investment funding, as well as the need to assemble the 'right' team – possessing the exposure and experience required to push forward the technology towards commercialisation.

"Importantly, the program also nurtured the team's skills in communication, relationship-building and sales – all essential 'tools' for stakeholder engagement.

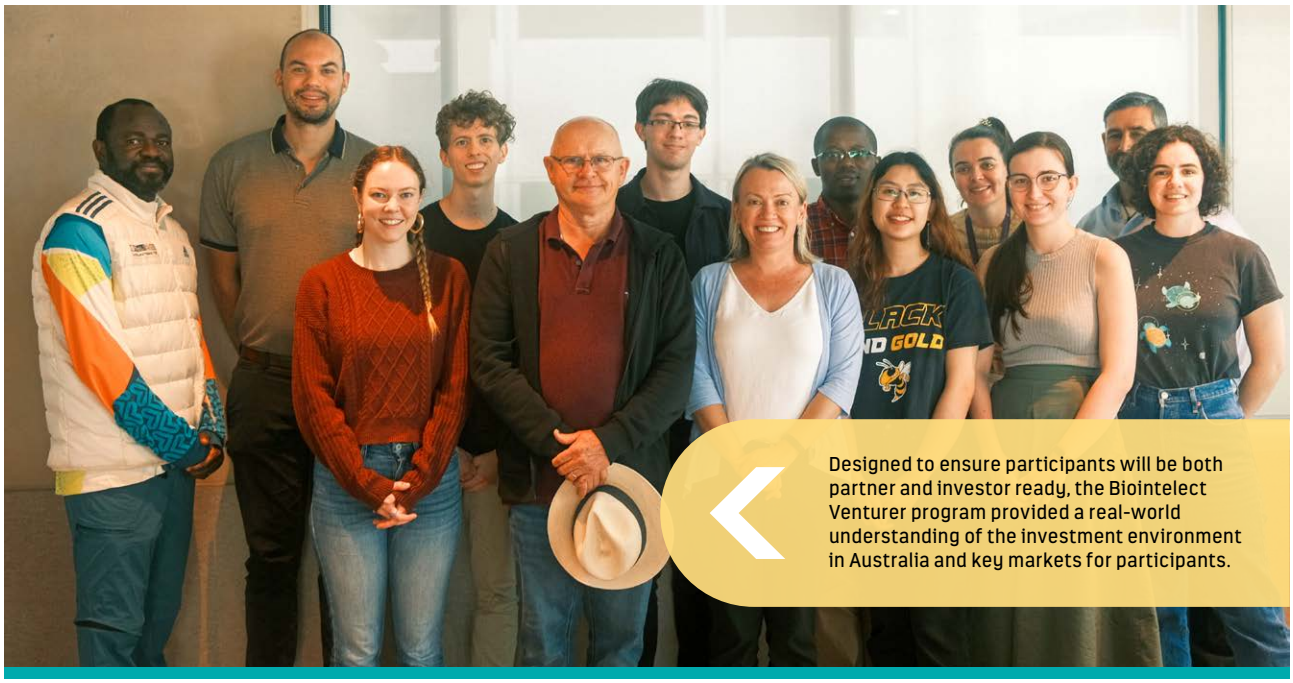
"The team from the Biointelect Venturer program delivered a highly engaging and eye-opening workshop on the strategies to facilitate commercialisation of biotechnological research in Australia," said Dr Peters.

Greater insight and confidence to engage with investors and funding bodies

"Our university research team now has greater insight and confidence to engage with investors and funding bodies, a better understanding of the motivations of key stakeholders, and a more nuanced awareness of the journey of taking a product to market. Our aim is to reach Phase I clinical trials for our arbovirus vaccine platform within five years.

"In the meantime, with the help of collaborators in both industry and academia and boosted by this investment training, we aim to conduct field trials and commercialise veterinary vaccines against Japanese encephalitis virus in pigs and West Nile virus in crocodiles within a one-to-two-year period," she said.

> **The team gained insights and skills into opportunities available for engaging with private equity investors and angel investors.**



Designed to ensure participants will be both partner and investor ready, the Biointelect Venturer program provided a real-world understanding of the investment environment in Australia and key markets for participants.

Commercialisation workshop sparks global first in contraceptive development

PARTNER:
Cicada Innovations

NUMBER OF REDI SUPPORTED PROGRAMS:
1 Program:
– MedLab: Commercialisation 101

NUMBER TRAINED SUPPORTED BY REDI:
148

Cicada Innovations workshops and training utilise the heritage building and deep tech space at the company's location in Sydney.

Australia has a strong health and medical research infrastructure, but falls behind other countries in the translation and commercialisation of medical research. The nation urgently needs to create an environment where budding entrepreneurs and start-up founders are equipped with requisite knowledge and guidance to nurture their ideas effectively.[1]

MTPConnect's REDI initiative engaged Cicada Innovations to develop the Commercialisation 101 workshops to equip entrepreneurs and start-ups in the health and medical sectors with essential skills for validating and advancing their ideas toward commercial success.

The Cicada MedLab: Commercialisation 101 workshop was a fast-paced, hands-on program that allowed participants to work on their healthtech idea – and receive personalised advice and feedback from Australia's leading deep-tech incubator to help them progress faster. Working alongside other innovators, participants worked through real examples of the commercialisation process and gained access to REDI partner Cicada's network of healthtech mentors and experts around the country.

The two-day workshop, delivered to 148 people, focused on practical, applied learning and targeted a diverse audience including researchers, scientists, clinicians, entrepreneurs and intrapreneurs, ensuring they were prepared to navigate the commercialisation pathway from concept to market.

This program is a pillar of a larger strategic effort to boost innovation across the Australian ecosystem, by fostering knowledgeable and skilled entrepreneurs who have a medical product wanted – and most likely to be accepted – by the market.

Creating an effective alternative and new contraceptive option

Dr Samson Dowland and Dr Kirsten Shankie-Williams from The University of Sydney's School of Medical Sciences took part in the program. They are developing a novel non-hormonal contraceptive, with the aim to create an effective alternative to current contraceptive options.

If successful, their innovation has the potential to deliver a major global impact. While there are currently 842 million users of contraception worldwide, with 407 million of these using an oral contraceptive pill, an intrauterine device and contraceptive implants or injections – 22 per cent discontinue use within three years due to adverse side effects.[2,3]

1. Boston Consulting Group: Realising Australia's Biomedical Potential with Targeted Capability Attraction https://www.bcg.com/publications/2023/realising-australias-biomedical-potential-with-targeted-capability-attraction
2. United Nations – Department of Social and Economic Affairs: Contraceptive Use by Method 2019, Data Booklet https://www.un.org/development/desa/pd/sites/www.un.org.development.desa.pd/files/files/documents/2020/Jan/un_2019_contraceptiveusebymethod_databooklet.pdf
3. National Library of Medicine – National Center for Biotechnology Information – PubMed Central https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3883041/#:~:text=Esfahany%20et%20al.-,2006).,2006).
4. Grand View Research: Contraceptive Market Size, Share & Trends Analysis Report By Product (Contraceptive Devices, Contraceptive Drugs), By Region (North America, APAC, EU, Latin America), And Segment Forecasts, 2023 – 2030 https://www.grandviewresearch.com/industry-analysis/contraceptives-market

Common oral hormonal contraceptive options require users to take their medication at the same time every day for the best effectiveness. If this is not done, the failure rate is between seven and nine pregnancies per 100 women.[2] At present, non-hormonal contraceptives tend to be implanted, which can be unsuitable for some women.

Despite the huge potential their non-hormonal contraceptive project presents, Dr Dowland and Dr Shankie-Williams had struggled to attract funding, to articulate their work's impact to stakeholders or find suitable collaborative partners.

Workshop re-energises participants and provides a dedicated project opportunity

Participation in the Cicada MedLab: Commercialisation 101 program not only re-energised Dr Dowland and Dr Shankie-Williams' excitement for their project, but also provided them with a dedicated opportunity to pull together their ideas, map out a pathway and concisely articulate critical points about the unmet need they are addressing, the problem they are trying to solve and how their solution directly addresses the problem and unmet need.

Dr Dowland said the opportunity to speak with people that had once been in their position was particularly beneficial.

"It was fantastic to learn about the commercialisation process from professionals who have previously traversed the pathway themselves and could provide insightful advice based on this personal experience," said Dr Dowland.

The workshop also gave them the opportunity to consider and identify relevant key stakeholders, analyse aspects of their market and establish transformative partnerships. Importantly, it inspired them to broaden their perspectives; having previously focused on women as the primary users of contraceptives, they began to investigate the perspectives of both clinicians and payers and to articulate the value proposition for those groups as well.

After participating in the workshop, Dr Dowland and Dr Shankie-Williams established a new collaborative partnership, which has allowed them to perform initial tests of their technology with promising results. This is a pioneering global first in contraceptive development.

Early-stage funding secured, next milestone developing initial minimum viable product

They have also secured early-stage funding to progress their project further, allowing them to create a new method of quantitatively testing side effects, which could be applied to all contraceptives. The team's next milestones include developing an initial minimum viable product and securing more funding for the project using their proof-of-concept data.

The duo's work has demonstrated the potential of their new non-hormonal contraceptive technology, which would be a game-changing development in women's healthcare worldwide. It could conceivably develop into an entirely new category of contraceptives in a market currently worth approximately US$28.3 billion annually.[4]

The outcomes achieved from attending the Cicada MedLab: Commercialisation 101 workshop demonstrate how important such programs are for delivering practical advice, forming critical partnerships and paving the way for teams to attract early-stage funding – all critical elements of creating a dynamic and pioneering medtech sector.

> **"Participants worked through real examples of the commercialisation process and gained access to Cicada's network of healthtech mentors and experts."**

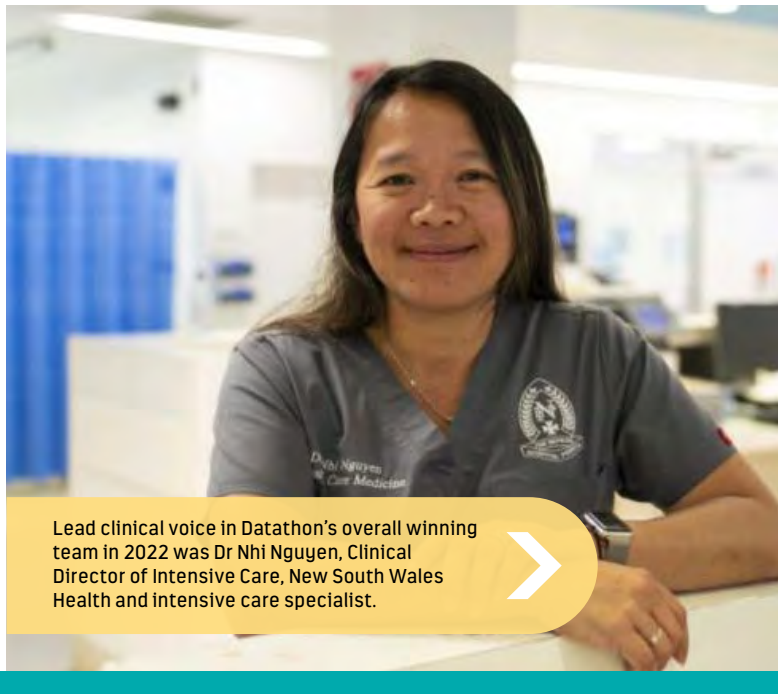
Dr Samson Dowland and Dr Kirsten Shankie-Williams from the University of Sydney's School of Medical Sciences took part in the MedLab: Commercialisation 101 program.

Upskilling the healthcare and research workforce in big data analytics and AI to fast-track innovations

PARTNER:
IntelliHQ

NUMBER OF REDI SUPPORTED PROGRAMS:
3 Programs:
– Big Data/AI Healthcare Leaders Bootcamp
– Big Data Analytics Workshop
– Healthcare: Datathon

NUMBER TRAINED SUPPORTED BY REDI:
476



Lead clinical voice in Datathon's overall winning team in 2022 was Dr Nhi Nguyen, Clinical Director of Intensive Care, New South Wales Health and intensive care specialist.

Artificial intelligence (AI) is playing a major role in the fourth industrial revolution. It is estimated that global gross domestic product (GDP) will be up to 14 per cent higher in 2030 because of AI, with the biggest sector gains to be seen in healthcare – as well as retail and financial services – due to increased productivity, product quality and consumption.[1]

Already, AI tools are rapidly moving from optional to essential within the sector. In Australia, about a quarter of total government spending is currently directed to health, age-related pensions and aged care. This is expected to rise to around half by 2049-50, mostly due to an ageing population.[2]

Radical changes to boost productivity and safety of healthcare workers and their patients are therefore required, and AI is seen as one of the few solutions that can deliver. Smart data interpretation from AI for clinical decision support is also becoming urgent and using AI to assist the workforce, particularly with mundane and repetitive tasks, will be both welcome and increasingly needed as we navigate ongoing worker shortages.

1. PriceWaterhouseCoopers, AI Analysis Report: Sizing the Prize – What's the real value of AI for your business and how can you capitalise? https://www.pwc.com.au/government/pwc-ai-analysis-sizing-the-prize-report.pdf
2. Australian Government, Treasury: Australia to 2050 – future challenges https://treasury.gov.au/sites/default/files/2019-03/IGR_2010_Overview.pdf
3. Science Direct: Pressure injuries in Australian public hospitals – A cost of illness study https://www.sciencedirect.com/science/article/pii/S0020748922000207?via%3Dihub

A national AI-in-healthcare business accelerator

Supporting the growth of the health industry in Australia and the AI to advance it, IntelliHQ was established with the goal to set up a national AI-in-healthcare business accelerator, based on the Gold Coast. The company is focused on promoting research, investment and commercialisation of next-generation technologies within AI and machine learning within the health sector.

MTPConnect's REDI initiative secured IntelliHQ to deliver courses that rapidly upskill clinicians, nurses, researchers, scientists and healthcare leaders on the use of big data and AI.

In July 2022, in partnership with Massachusetts Institute of Technology (MIT), IntelliHQ delivered two comprehensive 'masterclasses' on big data analytics and AI tailored specifically for healthcare executives, clinicians and researchers, engaging 476 participants. Presenters for the masterclasses came from a wide range of top international institutes of research, data, health and AI including MIT, Harvard University, NASA, Phillips Healthcare and Google Cloud.

Groundbreaking event in Australia – delivering multiple clinical breakthroughs

In October 2022, REDI supported IntelliHQ and the Australian and New Zealand Intensive Care Society (ANZICS) in its inaugural National Healthcare Datathon – the first event of its kind in Australia.

This event saw more than 200 participants across Australia join forces over two days to solve unique healthcare challenges using expansive, de-identified healthcare

datasets and machine learning tools. Datathon hosted workshops in Brisbane, Melbourne, Perth and Sydney, where 15 pressing medical issues came under intense data-led scrutiny.

Both in terms of national reach and the use of real-world patient data, this groundbreaking event in Australia delivered multiple clinical breakthroughs.

Lead clinical voice in Datathon's overall winning team was Dr Nhi Nguyen. An intensive care specialist at Sydney's Nepean Hospital, Dr Nguyen and her team tackled the prevalence of pressure injury.

This issue cost Australian public hospitals approximately $9.11 billion in 2020, of which treatment cost was $3.59 billion, with the remaining cost being increased length of hospital stay and loss of productivity.[3] Reducing preventable pressure injuries and stopping the progression of Stage 1 pressure injuries will result in an immense cost saving for Australia.

During the Datathon, Dr Nguyen's team developed a natural language processing (NLP) algorithm able to extract information surrounding pressure injuries from text-based clinical progress notes.

Potential to improve patient outcomes and optimise resource allocation

If used in ICU settings, the algorithm would enable clinicians to mitigate risk and adapt to different patient needs immediately based on automatically detected, relevant documentation. This has the potential to improve patient outcomes, as well as optimise resource allocation – thus minimising costs and strain within ICUs.

By implementing the capabilities of platform partner Datarwe's Clinical Data Nexus, the team was able to explore, visualise and test potential algorithms and models in a frictionless intertwining of clinical capabilities and AI.

Dr Nguyen said that this highlights one of the greatest benefits of the Datathon: that it gave people from vastly different backgrounds – clinicians, data scientists, researchers and technologists – the opportunity to work together.

A medical and data lens – applying expertise from both sides to real problems

"There are very few individuals that approach problems with both a medical and data lens. The Datathon format allows experts from both sides to apply their expertise in real time in a rapid problem-solving cycle," Dr Nguyen said.

IntelliHQ Director Steve Woodyatt said further clinical opportunities will emerge from these types of collaboration.

"The first National Healthcare Datathon proved that opening up access of real-world patient data to clinical and data-science professionals can produce dynamic evidence-based changes in modern medical practice," he said.

Dr Nguyen agreed, noting that the potential for Datathon-like collaborations and data is endless.

"Things in the medical world need to happen faster now than ever before – we can't just sit around and wait. Bringing the right voices and brains together is crucial to moving forward at a rate that benefits all patients and clinicians in Australia," she said.

Contemporary medicine relies on programs like Datathon

Fellow Datathon participant Dr Sebastian Quezada, a data scientist, biotechnology engineer and neuroscientist at RMIT University, developed a clinical decision tool to analyse a patient's recent blood records to determine if it was necessary for their blood to be drawn and tested again. Dr Quezada believes the evolution of contemporary medicine relies on programs like the Datathon, which give ideas a chance to grow, be heard and eventually be applied.

"These programs offer a purpose and a pedestal that stimulates professionals to get involved with the data and put their expertise to work. They enable people to connect and liaise with the right organisations with the right resources that help ideas be explored in the real healthcare world," Dr Quezada said.

In addition to accelerating the idea-generation and development process, Datathon was designed to champion and present potential medical breakthroughs on a national scale.

By encouraging people to connect and liaise with organisations and resources normally outside their network, events like this can foster groundbreaking ideas and ongoing evolution in healthcare solutions for Australia and globally.

After close deliberation, the first place in the inaugural Datathon went to 'Sydney Team 9' – who developed an algorithm to combat the lack of universally recorded pressure injury incidence.

Investor education delivers a boost to Western Australia's life sciences sector

PARTNER:
Life Sciences Western Australia (LSWA)

NUMBER OF REDI SUPPORTED PROGRAMS:
1 Program:
– LSWA Investment Series

NUMBER TRAINED SUPPORTED BY REDI:
90

The LSWA Expo booth with the Hon Stephen Dawson MLC, Minister for Medical Research (centre); and MTPConnect's Director Stakeholder Engagement WA, Dr Tracey Wilkinson, third from left, front row.

The Western Australian Government has identified the human and medical life sciences sector as a priority sector in the state's economic development framework. Yet, feedback from the state's life sciences community indicates that raising funds locally is challenging due to the focus on the resources industry. As a result, entrepreneurs tend to source capital elsewhere – often outside the state, culminating in lost job opportunities and economic benefits from these ventures.

Recognising the need to address this issue and promote better understanding among local investors about life sciences throughout the state, Life Sciences WA (LSWA) has initiated Western Australia's first dynamic, life sciences-focused investor education and engagement program. MTPConnect's REDI initiative supports the program, acknowledging that the best way to direct funds towards the life sciences sector is by educating investors about investment opportunities.

Over the past several years, LSWA has held a series of in-person education sessions, starting with its Investment Series launch in June 2022. The event featured presentations from ANDHealth and the Perron Institute for Neurological and Translational Science, as well as a fireside chat with growing successful companies like VeinTech and Biotome.

Educating investors and connecting them with up-and-coming innovators

LSWA Chairperson Gary Cox said the series delivered on its objective to educate investors and connect them with up-and-coming innovators.

"Despite the challenges of COVID-19, the Investment Series delivered a dynamic opportunity for investors to connect, learn and understand the immense investment opportunities which exist in the Western Australian life sciences industry," Mr Cox said.

Focusing on biotechnology as an investment opportunity

Subsequently, LSWA collaborated with Brandon Capital – Australasia's leading life sciences venture capital firm – to host an education event at AusBiotech 2022 in Perth.

Western Australia-based Investment Manager at Brandon Capital, Helga Mikkelsen, partnered with LSWA to organise the event, explaining that it was attended by more than 30 investors and family offices and focused on biotechnology as an investment opportunity.

The session included a presentation by members of Brandon Capital's leadership team, who spoke about why (and how) they invest in biotechnology, the financial opportunity it presents and why Australia is a good place to invest in the life sciences sector. This was followed by a panel discussion with Founder and Managing Director of Brandon Capital, Chris Nave; OncoRes Medical Chief Operating Officer, Dr Simon Graindorge; and ANDHealth CEO, Bronwyn Le Grice, during which the audience could ask questions followed by networking.

The importance of experience and understanding the risk

Ms Mikkelsen believes many people do not feel comfortable investing in biotech unless they have spoken with investors who have experience with, and understand, the risk.

"I think it's yet to be determined what the format should be to get more people to look at life sciences, but going in together with other investors who have been there before and know what they're looking for will be key.

"The other thing we're waiting for is some real local success stories in biotech; that would be my top wish, to see some of these companies succeed, since I believe that would galvanise a much broader investor base," Ms Mikkelsen said.

Based on feedback, LSWA's in-person events pivoted to a virtual format in late 2022, at which point LSWA commenced the *Life Sciences WA Investment Series* podcast. Like the in-person events, it explored various aspects of life sciences investing – outlining the mutual benefits for innovators and investors to work together. The series offered insights into high net-worth, venture capital and public investing, as well as some of the key considerations for investing in vaccine and drug development and digital heath life science innovations. Investors listening to the podcast also learned about working with innovators, including founders, researchers and commercialisation offices.

WA focus to podcast and in-person events enables local investors and boosts confidence

A total of 14 episodes were created, culminating in 2,855 downloads, of which almost half were attributed to Western Australian listeners. Most episodes featured local speakers, who shared both innovator and investor perspectives.

The Western Australian focus of both the podcast series and LSWA's in-person events has enabled local investors to identify key contacts within the sector that they can connect with when seeking additional context about investing.

Though direct attribution of increased investment cannot be quantified, anecdotally LSWA's events have laid the foundation for at least one family office to make investments in the sector. With support from the Department of Jobs, Tourism, Science and Innovation, and building on the momentum provided by MTPConnect, LSWA has since delivered the 'Western Australian BioInnovation Symposium', connecting local companies with industry partners and investors and the 'Broker Meets Biotech' event, showcasing opportunities in the life sciences sector to brokers, financial advisors and investors.

The success of the *Life Sciences WA Investment Series* podcast and LSWA's live events underscores the demand for targeted education and engagement initiatives between the life sciences and investment communities. By demystifying the sector and facilitating connections, LSWA's program has not only boosted investor confidence but also contributed to the overall development of Western Australia's life sciences industry.

> **Life Sciences WA has initiated Western Australia's first dynamic, life sciences-focused investor education and engagement program.**

REDI Investor Series focuses on demystifying the life science sector to promote investment

PARTNER:
REDI Investor Series

NUMBER OF REDI SUPPORTED PROGRAMS:
1 Program:
– REDI Investor Series

NUMBER TRAINED SUPPORTED BY REDI:
60

Business Transformation Leader and Innovation Activist, Duncan Jones, is a member of the Melbourne Angels and presented at the REDI Investor Series.

REDI delivered a training program focused on local investors in Adelaide, Melbourne and Sydney. This was developed adjacent to the training for investors delivered by Life Sciences Western Australia, which was supported by REDI and focused on Western Australia.

The program delivered information to a sold-out audience of 20 investors in each of the three states and was supported by a pre-reading guide – *Guide to Life Sciences Investing* – that was developed by a consortium led by AusBiotech as an MTPConnect Industry Growth Centre Fund project.[1,2]

Explaining opportunities and discussing ways to invest in the sector for non-experts

The half-day workshops focused on explaining the opportunities to invest in health technologies and discussed ways to invest in the sector for non-experts. Types of products in the life sciences sector were discussed, the timelines from basic research to customer sales explained and the risks and benefits detailed.

The two presenters for the Investor Series were Richard Dale and Rob McInnes.

Mr Dale works with Sydney Angels and has his own advisory service. He has more than 30 years' experience in top-tier management consulting, new venture development, venture capital and R&D engineering, and has invested in life sciences over many years. He provided insights he has developed through his investing experience and shared case studies of Sydney Angels' life science investments.

Mr McInnes also works with Sydney Angels and has his own intellectual property (IP) advisory service. He provided tools for robust due diligence, especially around IP and discussed negotiation techniques.

What to look for when investing in life science companies and case study examples

Following the presentation, venture capital firms Brandon Capital and Artesian covered what they look for when investing in life science companies and gave case study examples. All the presenters were then joined by local investors with extensive life science investment experience for a facilitated panel session.

Following the training, a networking event allowed state-based connections to be made for furthering investment discussions.

1. https://www.ausbiotech.org/documents/item/451
2. https://www.mtpconnect.org.au/Category?Action=View&Category_id=119

Learning from presenters' investment journeys and an appetite for more advanced training

Feedback from the attendees was that they left the event a lot more confident about investing in life science companies. Attendees appreciated the experience of the presenters, that they were willing to share case studies and the lessons they had learned along their investment journey, and that they approached the training in a practical and systematic way that aligns with how investors assess opportunities in other sectors.

Strong feedback revealed that there is an appetite for more specific advanced training in this area, such as a specific IP due diligence masterclass and a health economics masterclass now that the potential investors feel more confident in the life sciences sector.

> The half-day workshops focused on explaining the opportunities to invest in health technologies and discussed ways to invest in the sector for non-experts.

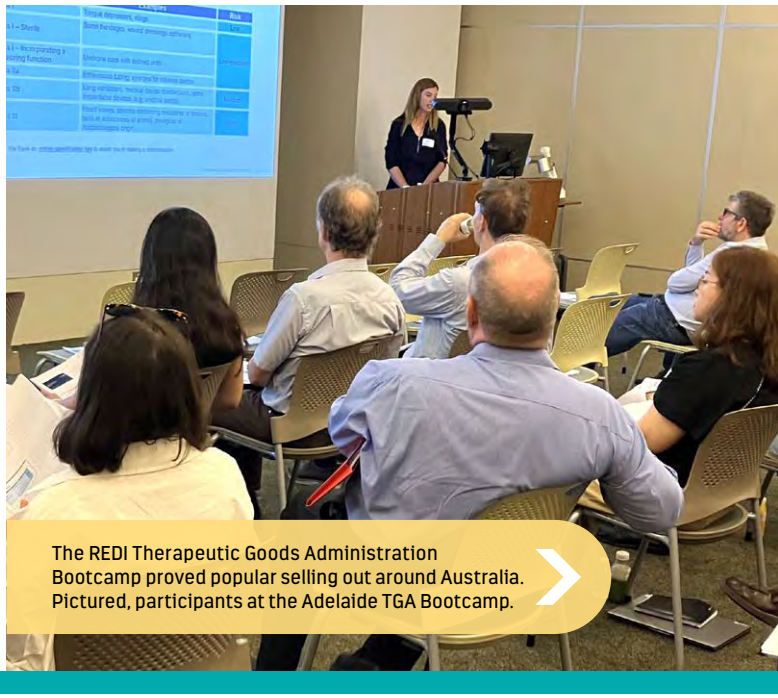
The main presenters for the REDI Investor Series: from left, Rob McInnes and Richard Dale both members of the Sydney Angels.

Empowering medical device companies through Australian regulatory pathways bootcamp

PARTNER:
REDI & TGA Learn

NUMBER OF REDI SUPPORTED PROGRAMS:
1 Program:
– Australian Medical Device Registrations Bootcamp

NUMBER TRAINED SUPPORTED BY REDI:
132



The REDI Therapeutic Goods Administration Bootcamp proved popular selling out around Australia. Pictured, participants at the Adelaide TGA Bootcamp.

Navigating the regulatory pathways for medical devices is a complex and often daunting task for start-ups and SMEs in Australia. With stringent requirements set by the Therapeutic Goods Administration (TGA), the process of obtaining regulatory approval can be lengthy, costly and filled with uncertainties. Recognising the need to bridge the skills gap and provide practical guidance, REDI partnered with TGA Learn to develop and deliver a series of bootcamps, aimed at empowering medical device companies to navigate the regulatory landscape with confidence.

The skills gap

Start-ups and SMEs in the medical device industry face numerous challenges, particularly when it comes to understanding and complying with regulatory requirements. Many companies lack the necessary expertise and resources to effectively navigate the regulatory pathway, resulting in delays and setbacks in bringing their products to market. Recognising this skills gap, MTPConnect's REDI sought to address the concerns and questions of these companies by providing tailored support and guidance through a series of national bootcamps, focused on Australian medical device registration. The aim was to empower companies with the knowledge and skills necessary to better understand the regulatory pathway and obtain TGA approval for their products.

Collaboration with the TGA

Understanding the importance of collaboration, MTPConnect and REDI reached out to the TGA to help facilitate a workshop aimed at explaining the intricacies of regulatory submissions. As the experts, the TGA Learn department developed the content and provided the subject matter specialists for an intensive half-day designed to address the specific questions of medical device companies. This collaboration allowed participants to gain insights directly from regulatory experts and engage in meaningful discussions to address their own concerns and questions. The TGA experts answered questions in the room and provided answers to online questions posed by the audience.

The bootcamps were tailored for two main categories of medical device companies:

- Companies planning for regulatory approval – those intending to submit their medical device products for regulatory approval in the next two years.
- Companies expanding to Australia – those with products registered outside Australia and looking to expand their market presence in the country.

> **The bootcamp provided them with new skills and knowledge useful for regulatory applications.**

The insights and practical guidance provided by TGA experts at the Bootcamps including strategies to ensure a smooth submission process were valued by participants. Pictured, the TGA Bootcamp in Perth.

The objectives of the bootcamps were to provide participants with:

- insights into the regulatory approval process
- strategies to ensure a smooth submission process
- practical guidance on new product registrations and post-registration follow-up
- opportunities to engage in discussions with TGA experts and address specific queries.

Bootcamp delivery and impact

The bootcamps were delivered in five major cities across Australia: Adelaide, Perth, Sydney, Melbourne and Brisbane. Demand was high – with sell-out events in the last three cities – highlighting the significance of the initiative. Participant feedback was overwhelmingly positive:

- 86 per cent of participants found the program had a good balance of relevant content.
- 94 per cent confirmed that the bootcamps provided them with new skills and knowledge useful for regulatory applications.
- 80 per cent expressed gaining a better understanding and confidence required to make their regulatory applications.

Valuable tools to navigate the regulatory landscape

The Australian Medical Device Registration bootcamps proved to be a valuable initiative in addressing the skills gap and empowering start-ups and SMEs in the medical device industry by providing practical insights, guidance and opportunities for engagement with regulatory experts. The bootcamps equipped participants with the necessary tools to navigate the regulatory landscape with confidence.

PARTNERSHIPS SECTION 3: FELLOWSHIPS, INTERNSHIPS AND MENTORING

Moving from study or academia to industry can be a difficult process. Employers generally want to employ staff with experience and a common question is, "How do I get the experience?" This makes for a shallow talent pool and slows down MTP sector growth as companies wait for the perfect candidate.

REDI's Skills Gap analysis showed 29 per cent of the top 24 skills gaps were experience skills gaps – gaps that were difficult (and sometimes impossible) to fill with 'normal' training programs. We needed to focus on developing experiential learning programs, where people learn by doing and developing skills that 'de-risk' them for potential future employers.

The REDI Fellowships are probably the best-known example, however, they are described in detail in their own chapter – see page 62.

PhD graduates transferring to industry

Many life sciences companies have programs for Bachelor' degree graduates, but not for PhD graduates – who have been finding it very difficult to transfer to industry, even with extra learning and skills. Hence, the GSK Graduate Program for PhD graduates was born.

Also supporting PhD graduates to explore our industry and jobs therein is APR.Intern. The REDI support of this program allowed a focus on life sciences and encouraging companies to provide internships for high calibre PhD students.

REDI also looked at what currently active programs could be leveraged with internships. The Bridge and Bridgetech programs were already engaging the next generation of entrepreneurs and researchers who wanted to work with industry. REDI doubled down on these students and, with QUT, worked to create the REDI Bridge and REDI Bridgetech Fellowships for short internships in industry.

Clinical trial workers require an underpinning of scientific knowledge, but many of the additional skills and attributes are considered 'soft skills' such as teamwork, negotiation and attention to detail. Also important are privacy and confidentiality and, due to this, internships are an eloquent solution to develop new clinical trial workers, either as Clinical Trial Coordinators, study coordinators or clinical research associates. REDI developed internship programs for this sector.

The importance of networks

And finally in this area, the REDI team kept hearing of the importance of networks and networking when exploring roles in industry and having the confidence to meet industry to learn about roles that, coming from academia, researchers are unaware of. Therefore, REDI supported IMNIS to expand its mentoring programs for specific growth in life sciences, including in clinical trials and the growing area of cell and gene therapy.

The Fellowships, Internships and Mentoring programs supported by REDI have changed hundreds of lives and the following pages provide details of some of those who have benefitted from these valuable programs.

CONTENTS

ARCS Grow program prepares trainees for the clinical trials sector

PARTNER:
ARCS Australia Consortium

NUMBER OF REDI SUPPORTED PROGRAMS:
2 Programs:
– ARCS Grow
– CRA Supervisor Train the Trainer Program

NUMBER TRAINED SUPPORTED BY REDI:
119

REDI Director Jarrod Belcher, speaking about the impact of the REDI initiative at the 2023 ARCS Conference.

The creation and execution of clinical trials for therapeutics and medical devices in Australia is a growing industry, which has led to increased demand for a skilled clinical trials workforce.

There are no specific courses available where entrants graduate qualified to work in clinical trials. New entrants into the clinical trials workforce usually qualify through a science or medical degree with the required scientific knowledge, but then need to learn the specific skills of a Clinical Research Associate (CRA) or Clinical Trial Coordinator (CTC) on the job – such as good clinical practice, medical terminology, clinical operations, negotiation and communication.

The perfect storm for a growing industry

Compounding the issue is the fact that experienced clinical trial workforce professionals are highly sought after. This has created the perfect storm, whereby there is a shortage of skilled workers entering the sector with the onus on the employer to upskill them, while experienced staff are leaving due to excellent career opportunities in allied areas.

Seeking to overcome this skills gap, MTPConnect's REDI initiative contracted ARCS Australia as a specialist training provider. Since 2022, ARCS Grow – a targeted web-based modular training program – has equipped 79 new CRAs with the in-demand skills and experience requisite to the clinical trials sector.

Operated as a traineeship-style model, ARCS Grow works with Clinical Research Organisations (CROs) that employ trainees directly. These new employees are trained through a webinar-based program over a one-year period. The training program is purpose built to bridge academic knowledge with practical skills, promote ongoing professional development and emphasise the critical importance of ethical and regulatory standards in the field. This approach reduces the training burden on CROs, incentivises the trainee to stay with the CRO for longer – to complete the ARCS Grow program – and the trainee is ready for work on clinical trial projects in a shorter timeframe.

Strong theoretical foundations, but lacking hands-on experience

Seasoned CRO Mobius Medical was one of the first organisations to join the program. Though already committed to fostering talent in the life sciences sector, it had encountered several challenges throughout its 16 years of operation when training incoming clinical research professionals.

Like other CROs, Mobius Medical found the gap between academic knowledge and practical application was often significant among new university graduates. Graduates typically possessed strong theoretical foundations, but many lacked the hands-on experience required to navigate the complexities of clinical research such as medical terminology and therapeutic knowledge in addition to the practical application of good clinical practices and regulatory requirements.

It also found that the fast-paced and ever-evolving nature of clinical research demanded continuous learning and adaptability and could be overwhelming for those just entering the field. Fostering a balance between independence and supervision is considered crucial; while new graduates need guidance and mentorship, they must also develop the ability to work autonomously.

A profoundly positive impact on career development – from CTA to CRA

Further challenges were associated with the need to instill a deep understanding of ethical considerations and regulatory compliance, and to cater for individual learning styles and professional goals – all of which require resources and time that are typically limited.

Consequently, when Mobius Medical hired Natasha Donald as a Clinical Trial Assistant (CTA), the company enrolled her in ARCS Grow to give her the best start.

The training program has had a profoundly positive impact on Ms Donald's career development and has enabled her to transition from a CTA to a CRA. These two roles require different knowledge and skill sets. Her initial role as a CTA typically provides administrative support during a clinical trial, while a CRA acts as the eyes and ears of the study sponsor, ensuring that the study adheres to strict regulatory guidelines. CRAs are responsible for tasks including monitoring investigator sites, ensuring data integrity and reporting any issues or deviations from the protocol.

As an ARCS Grow trainee, Ms Donald gained an in-depth understanding of clinical trial protocols, regulatory compliance and data management. Through the program, Ms Donald learned the fundamental basics of good clinical practice and its application and was taught a variety of other important skills that will stand her in excellent stead to be a highly knowledgeable, confident and professional CRA for Mobius Medical. Effective communication and negotiation skills are essential in this field, facilitating collaboration among diverse stakeholders including sponsors, investigators, research coordinators and regulatory bodies.

Pivotal skills to address unique challenges and complexities

Additionally, the ARCS Grow program emphasised the importance of ethical considerations and patient safety in clinical research, which resonated deeply with Ms Donald. These skills are all pivotal in addressing the unique challenges and complexities of a career in clinical research.

Ms Donald said the program enhanced her technical abilities and boosted her confidence and professional network – setting her on track for a successful career.

"Participating in the REDI ARCS Grow program has elevated my professional knowledge of not only the clinical trials industry holistically, but also specific CRA roles and responsibilities.

"The interactive webinars on a diverse range of topics, coupled with real-world case studies really deepened my theoretical knowledge and gave me simulated experience of monitoring and problem solving. The program's emphasis on staying abreast of industry trends, regulatory changes and fostering a collaborative learning environment has not only expanded my expertise but has also empowered me with the skills and confidence to navigate the dynamic landscape of clinical trials," Ms Donald said.

REDI's ARCS Grow program welcomed by industry

Co-Founder and Clinical Director of Mobius Medical, Suzanne Williams, said REDI's ARCS Grow program has also been welcomed by industry.

"The ARCS Grow CRA program is rapidly propelling Natasha and our junior team members towards becoming highly proficient, knowledgeable and confident clinical research professionals," Ms Williams said.

A robust clinical research sector fosters an environment conducive to R&D, attracting more investments and collaborations. These investments are not just financial; they also include the sharing of knowledge and resources, which are essential for groundbreaking discoveries.

A dynamic clinical research industry can significantly contribute to better health outcomes by accelerating the development and early access of new treatments and therapies. The presence of skilled and enthusiastic clinical research professionals ensures that Australia remains at the forefront of medical research and innovation, enhancing the country's reputation as a leader in healthcare and scientific innovation. Encouraging young scientists and researchers to join the industry is not just beneficial for the sector itself, but also for the broader Australian economy and the global scientific community.

Internship program builds clinical trial workforce and supports regions

PARTNER:
VCCC Alliance

NUMBER OF REDI SUPPORTED PROGRAMS:
2 Programs:
– SKILLED Clinical Trials Internship – Clinical Trials Assistant
– SKILLED Clinical Trials Internship – Study Coordinator

NUMBER TRAINED SUPPORTED BY REDI:
68

Northeast Health Wangaratta Supervisor, Nicole Humphreys with Deakin University graduate Jacqueline Lake who took part in the SKILLED Internship program at NEHW.

More than 90,000 Australians participated in clinical trials in 2022. That same year, the nation spent $1.6 billion on clinical trials, around 1,850 trials commenced and the sector employed 8,000 skilled workers.[1]

These are compelling figures – with participants in clinical trials gaining early access to potentially lifesaving new therapies, while at the same time advancing medical knowledge. Multiple reports, including MTPConnect's Australian Clinical Trials Sector reports and REDI Skills Gap Analysis reports have identified workforce shortages in this sector.[2,3] However, the rapid growth of the medical technology, biotechnology and pharmaceuticals sector is causing serious shortages of skilled workers, especially in clinical trial operations and pharmaceutical manufacturing.[4]

The VCCC Alliance SKILLED Internship program is building a future workforce to support the growth of clinical trials in cancer and non-cancer research as part of the REDI initiative.

A pathway for scientists to build role-specific knowledge, skills and more

The VCCC Alliance's pilot program was expanded to provide a pathway for scientists to build role-specific clinical trial knowledge, experience and skills in a clinical trials unit through theoretical and on-the-job training. The program trains clinical trial Study Coordinators and Clinical Trial Assistants and has since helped many regional health services develop their clinical trial workforce and units' capability and capacity, increasing access to clinical trials for regional patients.

Regional Victorians have a 10 per cent higher likelihood of a cancer diagnosis and their survival rate is 16 per cent lower than their urban counterparts. Although there are many reasons for these differences – including the types of cancers, the stage of detection and risk factors, compounded by access to medical practitioners and diagnostic services – better access to clinical trials improves these outcomes.[5] Understandably, there is a focus from the health sector to decentralise clinical trials and use technology to achieve equitable access.

Developing skills needed to forge careers in the clinical trials sector

From 2021 to 2023, the VCCC Alliance trained 38 Clinical Trial Assistants and 30 Study Coordinators through its competency-based internship program, which combines face-to-face and online training, action-learning projects and on-the-job experience to help science-based graduates develop the skills required to forge careers in the clinical trials sector.

1. https://www.health.gov.au/sites/default/files/documents/2022/03/biotechnology-in-australia-strategic-plan-for-health-and-medicine.pdf
2. https://www.mtpconnect.org.au/reports/clinicaltrialsreports2021
3. https://www.mtpconnect.org.au/images/Interactive%20MTPConnect%20REDI%20Skills%20Gap%20Second%20Report.pdf
4. https://www.ausbiotech.org/documents/item/698
5. https://www.cancervic.org.au/research/vcr/annual-report-2022#:~:text=Cancer%20diagnoses%20in%20Victoria%20in%202022%20are%20lower%20than%20in,bowel%2C%20lung%2C%20and%20melanoma.

To date, the VCCC SKILLED Internship program has placed interns at eight regional clinical trial units, and regional interns made up almost half of the VCCC Alliance SKILLED placements in 2023. The VCCC Alliance SKILLED Internship program offered extra support to these regional sites through resource provision and additional training opportunities for novice clinical trial staff to grow their capability in facilitating clinical trials. The program also ensured that interns gained a well-rounded experience by providing opportunities at the Parkville Cancer Clinical Trials Unit (PCCTU) in specialty areas not covered by host sites. This strategic approach not only benefits the interns but also enriches the regional clinical trial units with additional resources, such as standard operating procedures (SOPs), processes and expertise in various phase trials.

In 2021, Jacqueline Lake, a graduate of Deakin University's Bachelor of Health and Medical Science, secured a place in the VCCC Alliance SKILLED Internship program – embarking on her internship journey at Northeast Health Wangaratta (NEHW) as the first intern hosted by the hospital site. NEHW is the major referral facility in regional Victoria for people with complex health needs from Bright, Mansfield, Beechworth, Myrtleford, Yarrawonga, Euroa and Benalla.

Groundbreaking project for regional health patients

At NEHW, Ms Lake took the initiative to address the lack of a cancer-specific clinical trials unit by focusing her quality improvement 'learning project' on developing a teletrial process for the clinical trials unit. This groundbreaking project aimed to enable regional patients to participate in clinical trials closer to their homes, providing greater access to trials held in larger centres via telehealth.

The next phase of development involves establishing cancer clinical trials based at NEHW with opportunities for collaboration with Border Medical Oncology – the leading cancer service in Albury, Wodonga and the Victoria-New South Wales border region.

Ms Lake's outstanding contributions to clinical trials enabled her to secure a position as a Clinical Trial Assistant and then a Study Coordinator at NEHW, demonstrating her dedication to improving healthcare standards in regional communities.

Reflecting on her journey, Ms Lake remarked, "The VCCC Alliance SKILLED Internship presented an opportunity for me to see whether my love for research and my yearning for patient care could be met in a way that I had not previously considered. Once I began my internship, I very quickly realised that what I wanted from a career and my life could be found in clinical trials."

Significant impacts and growth and acceleration in quantity of trials

Her supervisor at NEHW, Nicole Humphreys, expressed her gratitude for the VCCC Alliance SKILLED program.

"The impacts to our unit since becoming involved in the program in 2020 have been significant and have formed a critical component of our operational planning. The VCCC Alliance SKILLED program has definitely contributed to our growth both in quantity of trials and the acceleration of our progress to date," Ms Humphreys said.

Ms Lake's pioneering work, which has ultimately increased the opportunities to access clinical trials for both cancer and non-cancer treatments for NEHW's 90,000 patient population across regional north-east Victoria, exemplifies the significant impact of the VCCC Alliance SKILLED Internship program.

Award-winning initiative setting a new standard

The VCCC Alliance's SKILLED Internship program is a pioneering venture, establishing a flexible, immersive and comprehensive training pathway that fosters a robust talent reservoir for the nation's clinical trials sector, as well as providing prestigious career opportunities for science graduates.

This award-winning initiative enhances patient access to clinical trials, resulting in positive health outcomes for regional patients. With its holistic approach to training and education, the program is setting a new standard for integrating academic excellence with impactful healthcare solutions.

> **Once I began my internship, I very quickly realised that what I wanted from a career and my life could be found in clinical trials.**

Internships are key to solving the clinical trials skills gap

PARTNER:
PRAXIS Australia Consortium

NUMBER OF REDI SUPPORTED PROGRAMS:
1 Program:
– Clinical Trials Coordinator Internship Program

NUMBER TRAINED SUPPORTED BY REDI:
14

PRAXIS Australia CEO, Sally Armstrong (right) and Senior Projects Manager Mel Goldman promoting PRAXIS Australia programs including the Clinical Trial Coordinator Internship Program.

Over the past few years, demand for skilled clinical trial professionals in Australia has skyrocketed. As reported by MTPConnect in 2021, the annual growth rate of clinical trials across the country sat at seven per cent, which led to a four per cent annual increase in the workforce. This rapid expansion put significant pressure on the sector to scale effectively and keep pace with rising demand.

Typically, new entrants to the clinical trials workforce come from a science or medical degree background and thus possess scientific knowledge; however, they acquire the specific skills relevant to a Clinical Trial Associate (CTA) or Clinical Trial Coordinator (CTC) while on the job. This skill set covers areas such as good clinical practice, medical terminology, clinical operations, negotiation and communication.

MTPConnect found there is a shortage of CTCs – and industry agrees

Through its REDI Skills Gap Analysis reports, MTPConnect found – and industry agrees – that there is a shortage of CTCs.

Consequently, REDI partnered with PRAXIS Australia to create the CTC Internship Program – an innovative initiative undertaken by a consortium of seven strategically aligned partners working across the Australian clinical trials ecosystem. This consortium led by PRAXIS Australia includes ARCS Australia, The George Institute for Global Health, South Australian Health and Medical Research Institute (SAHMRI), SPHERE, Sydney Health Partners and The University of Queensland.

Run over a 10-month period from January 2023, PRAXIS Australia's CTC Internship Program addressed critical skills gaps by providing interns with expert training and education from sector leaders. This immersive, flexible and competency-based training model allowed interns to implement what they learned directly into the workplace setting.

Representing the broad clinical trials landscape in Australia, with a wide range of clinical settings

Host organisations from metropolitan and regional areas of Queensland, New South Wales and South Australia employed the interns as 'trainees'; and they, in turn, received additional intermittent training from a specialist provider. The diversity of host locations represented the broad clinical trials landscape in Australia, giving interns exposure to a wide range of clinical trials settings.

The internship program required a part-time commitment of 0.6 full-time equivalent (three days per week) over the 10-month period. This schedule allowed the interns to develop practical workplace skills through hands-on experience, while also giving them the flexibility to maintain or seek other employment. This approach aimed to enhance inclusivity for participants with family responsibilities and those from regional, rural and remote areas.

PRAXIS Australia delivered a total of 14 CTAs and CTCs through the internship pilot program. PRAXIS Australia designed and delivered the training, sourced hospital placements for the interns and assisted participants' progress through final assessments.

Demand for skilled clinical trial professionals in Australia has skyrocketed, so REDI partnered with PRAXIS Australia to create the Clinical Trial Coordinator Internship program.

The CTC Internship Program was exactly what registered nurse Gemma Barker needed when she was looking for a pathway into the clinical trials field.

CTC Internship Program – a positive, supportive and stimulating experience

Upon her acceptance into the program, Ms Barker was placed at SAHMRI with the Clinical Trials Platform team in Adelaide. She said her host site was extremely supportive and encouraging and facilitated the development of her learning.

"My experience in the CTC Internship Program was a really positive, supportive and stimulating one. I developed a whole new set of skills, knowledge and experience in clinical trials. I feel that the internship is a great pathway into the sector," said Ms Barker.

Through the program, Ms Barker gained practical experience in clinical research, together with background theoretical training. Her placement led to an ongoing role at SAHMRI, where she now works as a Research Nurse, coordinating clinical trials.

Ms Barker said she is excited about the possibilities of her new career and the opportunities available to her because of her participation in the program.

"The PRAXIS CTC Program provided an invaluable experience and one that I hope to use as a platform for my future career," she said.

Immersive training programs are key to solving Australia's clinical trials skills gap

CEO of PRAXIS Australia, Sally Armstrong, said immersive training programs such as this are key to solving the clinical trials skills gap.

"We are delighted to have helped Gemma and many others like her to pursue the careers they've always aspired to through this innovative program," Ms Armstrong said.

Given the overwhelmingly positive feedback received for the program, and significant need identified by participating host organisations, it is critical that investment continues in workforce capacity-building projects such as this to ensure the success of the clinical trials sector into the future.

By equipping interns with the necessary skills and experience for successful careers in the clinical trials sector – and bridging the gap between theoretical knowledge and practical application – the CTC Internship Program plays a pivotal role in strengthening Australia's clinical trials workforce and ensuring the continued advancement of medical research and healthcare outcomes.

> "I developed a whole new set of skills, knowledge and experience in clinical trials."

Opening doors for graduate researchers to move into the pharmaceutical industry

PARTNER:
GSK Australia

NUMBER OF REDI SUPPORTED PROGRAMS:
1 Program:
– GSK Australia Graduate Researcher Program

NUMBER TRAINED SUPPORTED BY REDI:
19

Pictured, from left: GSK Australia Graduate Researchers from the 2022 cohort – Dr Anushi Rajapaksa and Dr Anitha Yates – with Patrick Desbiens (centre) Senior Vice-President and General Manager, GSK Australia and New Zealand.

The transition from academia to industry is a common challenge in medical research, with many aspiring professionals facing barriers to gaining industry experience. Recognising this need, MTPConnect's REDI initiative supported multinational biopharma GSK Australia to develop and pilot the GSK Australia Graduate Researcher Program (GRP) over three years.

The GRP was a one-year program designed to provide a hands-on understanding of the pharmaceutical sector for postdoctoral researchers through immersion into specific roles in work areas including medical affairs, regulatory affairs and new product development. Participants apply their skills to the translation and commercialisation of new medical products, gaining invaluable hands-on industry experience including mentoring and access to sessions with GSK Australia's leadership team to develop new knowledge, skills, aptitude and business confidence.

Many participants have transitioned into industry since 2021

Since 2021, the GRP has been opening doors for PhD science graduates and postdoctoral research academics interested in pursuing careers in the vaccines and pharmaceutical industry. Many participants have gone through the program and transitioned into industry across Australia. In addition, GSK Australia has found that the development time to transition a candidate from academia to the level required for certain roles is lower than expected, thus opening the door for future hires direct from academia where previously they have waited for an experienced candidate.

GSK Australia Country Medical Director and the Australian leadership team's program sponsor, Dr Alan Paul, said the GRP has helped numerous emerging talents expand their horizons as future leaders and step into the pharmaceutical industry, while simultaneously fostering collaboration between academia and industry.

"Our GSK Australia Graduate Researcher Program has helped to expand the capacity and capability of the research community by creating opportunities for researchers to gain experience and skills in the pharmaceutical industry. Greater collaboration between these sectors can strengthen Australia's success in terms of translation and commercialisation of health and medical research that has the potential to beneficially impact society."

Over the past three years, the GRP has provided 19 early-career researchers with the opportunity to step into the pharmaceutical industry and gain professional and practical hands-on experience.

This has included Dr Catherine Cochrane and Dr Terence Tieu, who have both taken significant steps forward in their careers by building on the experience they gained through the program.

Exploring different areas of the pharmaceutical industry

During the GRP, Dr Cochrane, an RMIT postdoctoral research scientist in HIV, joined the ViiV Healthcare Australia team as a Medical Affairs Associate. She applied for the program to explore different areas of the pharmaceutical industry and to have a positive impact on the lives of Australian patients.

Dr Cochrane said taking part in the GRP was a unique opportunity to apply her academic skill set in a practical setting.

"The skills and knowledge I gained while in academia were directly transferable to my role at GSK. Programs like the GRP are incredibly valuable, as many researchers are looking to get their foot in the door of the pharmaceutical industry, yet do not know where to go to make this career shift a reality."

Across the 12 months of the program, Dr Cochrane was involved in various projects including managing a compassionate access program, shadowing sales representatives and attending business strategy meetings.

Gaining valuable experience for industry roles and further opportunities

At the end of the year, Dr Cochrane transitioned to a role as a Scientific Advisor at the Therapeutic Goods Administration (TGA). She said the experience she gained through the GRP was not only valuable in helping her make the transition to her new role, but also made her more aware of her interest areas and how her skill set could be transferred to other opportunities in industry.

"My time in the GSK Graduate Researcher Program allowed me to gain an in-depth understanding of the pharmaceutical industry, which helped me increase my comprehension of the different skills required for other career opportunities in industry," she said.

"The experience I gained at GSK/ViiV helped me become more employable, as it equipped me with new skills and knowledge that I could then transfer to my TGA role."

GRP provided building blocks for a budding career in pharma

Similarly, the experience and networking connections Dr Tieu gained through the GRP provided the building blocks for his budding career in the pharmaceuticals sector. He completed a PhD in Pharmaceutical Sciences at Monash University and worked researching cancer treatments before he decided to shift his career focus. After completing the program in 2021, he successfully applied for a role in the respiratory team at GSK Australia as Associate Brand Manager and stayed on to work in the company.

During the program, Dr Tieu was part of GSK Australia's new product team, working on various assets within GSK's pipeline across multiple therapy areas. He built business cases for three assets, which were all approved as opportunities to bring new medicines to the Australian market.

After 12 months, Dr Tieu commenced face-to-face conversations with doctors in the clinic. He said it was incredible to see how his work in the program was having a meaningful impact on patients.

A move to industry to impact patients' lives

"In the program, I was at the frontline of innovation with the new products team. It was fulfilling to see positive clinical trial results and feedback from healthcare professionals who had witnessed firsthand the impact these trials had on patients. For me, this is the pinnacle of impacting patient lives and why I made the move to industry," he said.

Dr Tieu loves being a part of the 'behind-the-scenes' work that ultimately brings new medicines to patients who need them.

"GSK Australia's GRP enabled me to establish a strong foothold in the pharmaceutical industry and envision a long, meaningful career in this space.

"It also provided me with wonderful industry mentors who have empowered me to continuously explore and understand the end-to-end process of bringing medicines to improve outcomes for patients," said Dr Tieu.

Transformative impact shaping the future of Australia's pharma and medtech industry

These results are testament to the power of strategic collaborations in addressing industry challenges and fostering talent development. By providing a structured pathway for academia-to-industry transitions, the GRP has allowed participants to make meaningful contributions to the pharmaceutical sector while driving advancements in healthcare outcomes for Australian patients.

Both Dr Cochrane and Dr Tieu's GRP journeys serve as inspiring examples of the program's transformative impact and the role programs like this one can have in shaping the future of the pharmaceutical and medtech industry in Australia.

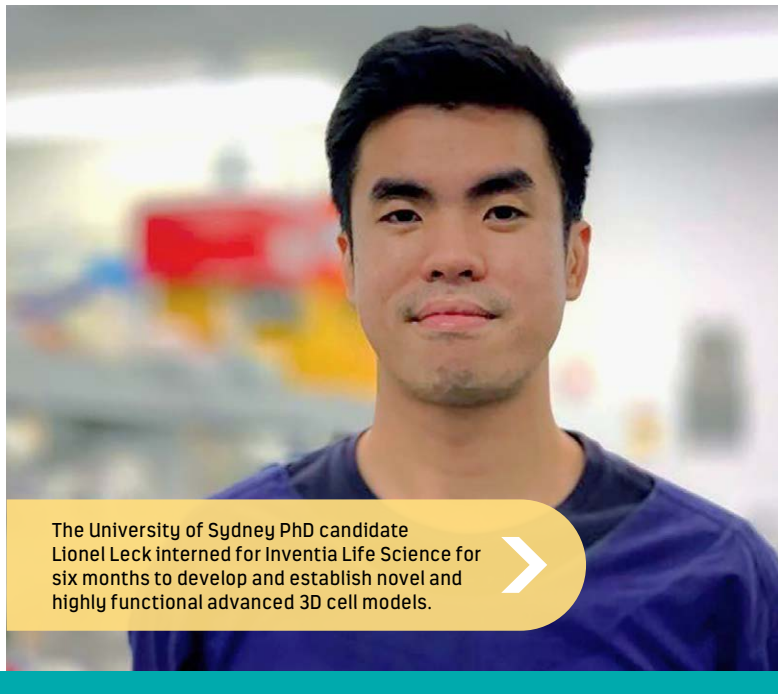
> **Many researchers are looking to get their foot in the door of the pharmaceutical industry, yet do not know where to go to make this career shift a reality.**

Internship program delivers mutual benefits in 3D cancer cell models

PARTNER:
APR.Intern

NUMBER OF REDI SUPPORTED PROGRAMS:
1 Program:
– APR.Intern PhD Industry Placement program

NUMBER TRAINED SUPPORTED BY REDI:
82



The University of Sydney PhD candidate Lionel Leck interned for Inventia Life Science for six months to develop and establish novel and highly functional advanced 3D cell models.

Collaborations between industry and academia are essential to the growth of R&D in Australia. Currently, this accounts for only 1.8 per cent of gross domestic product (GDP) – well behind the Organisation for Economic Co-operation and Development (OECD) average of 2.7 per cent. Meanwhile, the US and South Korea attribute 3.5 and 4.9 per cent of their respective GDPs to R&D initiatives.[1]

Australian Postgraduate Research Intern (APR.Intern) is Australia's only national internship program for PhDs and Master by Research degrees spanning all sectors and disciplines. It plays a crucial role in accelerating STEM innovation, working with all universities nationally to streamline pathways for postgraduate research students to be industry-literate and career-ready; expand university research collaborations; and connect businesses with the country's brightest emerging research talent.

Impactful internship opportunity supported by REDI initiative with benefits all round

This impactful internship opportunity was supported by MTPConnect's REDI initiative, which awards eligible businesses a $10,000 rebate towards the cost of engaging a PhD student intern. There are benefits for both students and participating organisations; the three-to-six-month placements help businesses fast-track R&D, while students develop their skills and knowledge in a practical, industry setting. Eighty-two internships were supported by REDI.

1. OECD Data: Gross domestic spending on R&D https://data.oecd.org/rd/gross-domestic-spending-on-r-d.htm

One of the key advantages of these placements is that they facilitate greater interactions and understanding between academia and industry. PhD students bring cutting-edge research skills and specialised knowledge from their academic training and the internships provide the opportunity to apply this expertise to real-world industry challenges. This facilitates the transfer of knowledge and expertise between academia and industry, fostering collaboration and mutual learning.

The hands-on experience that the students gain is invaluable, giving them a deeper understanding of industry practices, priorities and constraints. By addressing industry challenges, they contribute to driving innovation and economic growth in key STEM sectors.

Access to valuable networking opportunities with industry professionals and potential employers

In addition, the internships give PhD students access to valuable networking opportunities, allowing them to establish connections with industry professionals, researchers and potential employers. PhD students gain comprehension of the commercialisation process and the pathways for translating research outcomes into marketable products and technologies, leading to the creation of partnerships, start-ups and spin-off companies that contribute to Australia's innovation landscape.

Biotech start-up Inventia Life Science – a specialist in 3D cell culture bioprinting technology for drug discovery and biomed research company – has so far engaged eight PhD students through the APR.Intern program.

One former intern is Lionel Leck from The University of Sydney. During his placement at Inventia, he worked primarily with the

R&D team, actively engaging with institutions and industry partners to develop and establish novel and highly functional advanced 3D cell models.

APR.Intern's expertise and insights proved highly valuable to the team

Over a six-month period, Mr Leck played a key role in developing numerous cell models for Inventia's clients, which were made available to customers during his internship. His expertise in cancer stem cells and his researcher-focused product insights proved highly valuable to the team. In addition to his primary role, he pitched and established a joint collaborative research project between Inventia and his PhD host institute, which was instrumental in conducting experiments for a research manuscript.

Mr Leck said the internship was an excellent learning platform that enhanced his adaptability, communication, problem-solving and project-management skills – all of which he considers to be essential for success in both academic research and industry settings.

"My most significant learning outcomes from this internship experience have been the substantial improvement of my communication skills and the ability to collaborate within multidisciplinary teams effectively. This internship has also provided me with opportunities to engage with stakeholders from diverse backgrounds, where I could actively contribute my ideas and experiences to the team," Mr Leck said.

> **"The hands-on experience that the students gain is invaluable, giving them a deeper understanding of industry practices, priorities and constraints."**

He also found the focus on creating solutions with real-world applications to be highly rewarding.

"The opportunity to conduct a product- and customer-focused approach to research and development vastly different from an academic setting, has also been a valuable aspect of my learning journey," Mr Leck said.

Head of Life Science at Inventia, Dr Marie Besnier, said that during the six-month period with the company's multidisciplinary R&D team, Mr Leck was instrumental in developing Inventia's most advanced model.

"This model was made available to customers before the end of his internship. Lionel's expertise in cancer stem cells and customer-centric product insights significantly contributed to our work," Dr Besnier said.

Collaborating with universities nationally and engaging with high-end academic resources

The short-duration, results-driven nature of APR.Intern projects has allowed Inventia to collaborate with universities nationally and engage with high-end academic resources.

Access to research talent has likewise enabled the organisation to identify suitable interns who have an interest in joining industry and, following their graduation, Inventia has made seven full-time hires resulting from successful internship projects.

As demonstrated by Inventia's experiences with the program, initiatives like APR.Intern contribute to a more robust R&D sector, which in turn delivers far-reaching economic benefits and ensures Australia remains a leader in nurturing innovation.

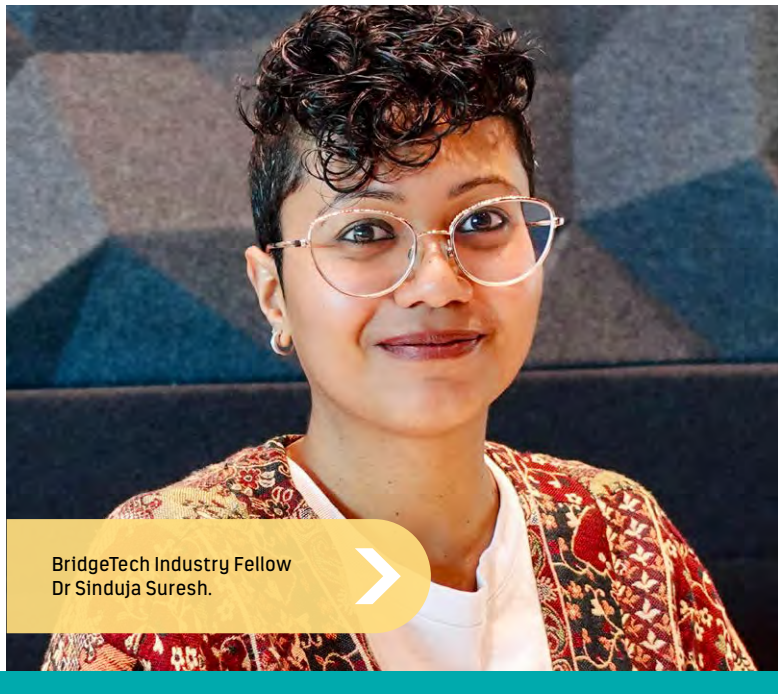
Biotech start-up Inventia Life Science is a specialist in 3D cell culture bioprinting technology for drug discovery and biomed research.

Industry placement turbocharges researchers' commercialisation skills and networks

PARTNER:
The Bridge Program/
The BridgeTech Program

NUMBER OF REDI SUPPORTED PROGRAMS:
2 Programs:
– Bridge Industry Fellowship Program
– BridgeTech Industry Fellowship Program

NUMBER TRAINED SUPPORTED BY REDI:
80



BridgeTech Industry Fellow Dr Sinduja Suresh.

Each year throughout the REDI initiative, 20 leading pharmaceutical and medtech researchers, clinicians and innovators from around Australia were awarded short-term industry placements via the Bridge and BridgeTech Industry Fellowships Program.

Open to participants and alumni of the Bridge Program and BridgeTech Program, the initiative was created to boost researchers' skills and advance the collaborations and networks needed to push their research into therapeutics or medical devices, including digital health, towards commercialisation.

Giving academics a 'peek' behind the door of industry to obtain valuable experience

Delivered by Queensland University of Technology and funded by MTPConnect's REDI initiative, the Bridge and BridgeTech Industry Fellowships Program offered $10,000 per Fellow – funds to directly support a three to six-week placement with a key industry partner. These placements gave academics a 'peek' behind the door of industry, allowing them to obtain valuable industry experience. They could also make important connections with industry and grow these relationships throughout the placement.

In addition to teaching Fellows about the workings of the life sciences sector and nurturing the skills and relationships they will need along the commercialisation pathway, the Fellowships were also a way to assist participants to transition from academia to industry or to generate new ideas and innovations that can be used to secure future collaborations.

One recipient of a BridgeTech Industry Fellowship is Dr Sinduja Suresh, a Postdoctoral Research Fellow in the Biomechanics and Spine Research Group and the ARC Training Centre for Multiscale 3D Imaging, Modelling and Manufacturing.

In 2022, Dr Suresh undertook her industry placement with Stryker, a global leader in medical technologies, to support her work improving orthopaedic trauma care through rapid additive manufacturing.

Visiting Stryker facilities in Germany and Ireland during the Fellowship program

During her placement, Dr Suresh visited Stryker facilities in Germany and Ireland. In the former, she learned about the processes involved in the design and manufacture of intramedullary nails – implants used to treat fractures of long bones through sitting inside the bone cavity – while in the latter she explored how the company is transitioning from conventional to additively manufactured products and the challenges this presents.

At both facilities, Dr Suresh had the opportunity to speak with employees about their roles and projects and where their processes fit into the manufacturing pipeline. Through these interactions, she gained insights into areas spanning custom design, industrial design, polymer 3D printing, marketing, commercial and advanced operations, business management, software development, quality control, regulatory clearance, intellectual property (IP) and entering the market with a new product.

Dr Suresh also delivered presentations about her project to the local teams, who provided feedback and raised issues that she had not previously considered. Through Stryker, she was able to meet with surgeons – her target customer – and gain a deeper understanding of the solutions they were looking for.

Hugely informative – making connections, learning from others and collaborating

The experience was hugely informative, with Dr Suresh emphasising the importance of making connections and learning from others to progress her work.

"Life will be easier if you just collaborate with people in different fields. You'd be surprised how many people are happy to teach you a thing or two about their jobs and give free advice," Dr Suresh said.

Meeting so many people in different roles was the perfect way to broaden her understanding of medical device development and the logistics of the industrial supply chain.

"It was enlightening, to say the least. It was the sort of low-pressure networking and learning process that absolutely suited me," she said.

In 2023, Dr Thomas Meikle likewise undertook a Bridge and Industry Fellowship placement to lead a collaborative project between Trajan Scientific and Medical (Trajan) – a leader in the supply of pathology consumables and histology products – and his employer, the Baker Heart and Diabetes Institute (the Baker). The project focused on the development of a clinical lipidomics platform – the commercialisation of research assays for lipid concentrations in blood and plasma. This assay is to be used alongside large datasets available to the Baker to predict cardiometabolic risk and provide measures of general metabolic health.

Fellow made substantial progress towards developing a commercial clinical assay

Dr Meikle's placement at Trajan enabled him to make substantial progress towards developing the clinical lipidomics platform in line with the requirements of a commercial clinical assay. He acquired valuable skills relating to automation design and meeting regulatory requirements and participated in a collaborative project focusing on adapting Trajan's plasma microsampling technology for lipidomics.

Since completing the placement, Dr Meikle has presented some of the research output generated during his time with Trajan at the academic conference 'Precision Medicine Symposium 2023'. He also participated in a collaborative think tank, organised to advance industry collaboration with the Baker, with a specific focus on clinical lipidomics. This was attended by high-level staff from both the Baker and Trajan, as well as other major industry figures.

Throughout his time at Trajan, Dr Meikle said he secured access to important industry networks and learned many transferrable skills.

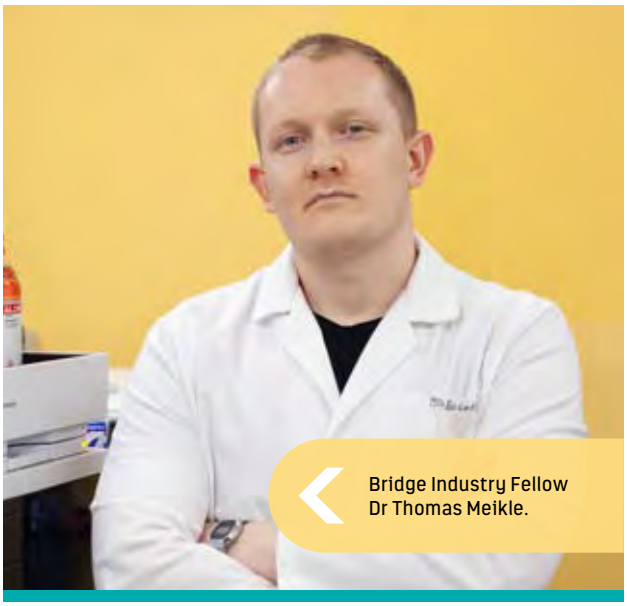
> "These placements gave academics a 'peek' behind the door of industry, allowing them to obtain valuable industry experience."

The importance of communicating complex scientific concepts to make them accessible

"The Fellowship honed my project management skills, particularly in managing timelines, resources and various team members. Additionally, it's highlighted the importance of communicating complex scientific concepts in a manner that is accessible to non-scientific stakeholders including investors, clinical staff and regulatory bodies. Improving my communication skills will thus be a focus in my career.

"Importantly, it has given me experience working in a commercial, industry-focused position and how the dynamics and values of such a workplace differ from those found in academia or research-focused jobs," Dr Meikle concluded.

For both Dr Suresh and Dr Meikle, the Bridge and BridgeTech Industry Fellowships Program expedited their understanding of the complexities of commercialising a therapeutic or medical device in a rapidly changing sector. Thanks to the skills, knowledge, experience and relationships they gained through the program, they are now in a strong position to successfully translate their research and, in doing so, bolster Australia's life sciences sector and deliver better outcomes to the intended recipients of their work.



Bridge Industry Fellow Dr Thomas Meikle.

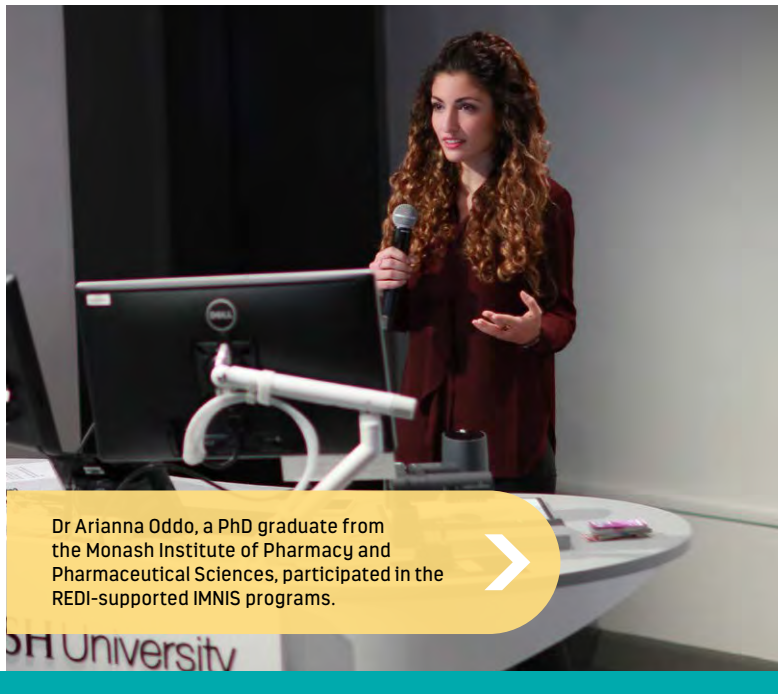
THE BRIDGE AND BRIDGETECH INDUSTRY FELLOWSHIPS
Supported by MTPConnect's REDI Program

IMNIS unlocks the career potential of STEM researchers

PARTNER:
Industry Mentoring Network in STEM (IMNIS)

NUMBER OF REDI SUPPORTED PROGRAMS:
4 Programs:
– IMNIS Medtech-Pharma Program
– IMNIS Clinical Health Program
– IMNIS International Program
– IMNIS Catalyst

NUMBER TRAINED SUPPORTED BY REDI:
170



Dr Arianna Oddo, a PhD graduate from the Monash Institute of Pharmacy and Pharmaceutical Sciences, participated in the REDI-supported IMNIS programs.

In the medical technology, biotechnology and pharmaceuticals sector, academia and industry are seen as two separate circles on a Venn diagram, despite several initiatives having drawn the two areas closer together in recent years. This is particularly problematic for the incoming generation of future clinical and medical sector leaders, PhD students and early-career researchers, who want to learn more about industry, but are unsure where to turn.

Seeking to bridge this gap, Industry Mentoring Network in STEM (IMNIS) is an award-winning initiative of the Australian Academy of Technological Sciences and Engineering (ATSE) that connects PhD students at the forefront of clinical and healthtech-related research with high-calibre industry champion mentors. Its purpose is to help mentees develop the skills and knowledge needed to succeed in industry, create connections to extend their professional network and learn about different career opportunities, so they can determine their career direction accordingly.

With IMNIS covering all STEM disciplines and a real and continuing need within the life science sector for better understanding of industry, the REDI program has supported IMNIS to create 170 life science-specific relationships through its sub-programs. This has included creating mentee-mentor relationships in emerging areas such as regenerative medicine, clinical trials and digital health technologies. The REDI support has likewise enabled the creation of relationships with internationally based mentors to develop mentees' understanding of the global STEM environment, international career pathways and the economic, political, legal and socio-cultural nuances to the domestic STEM market.

Given that the MTP sector needs to attract the best talent, REDI has also supported the development of IMNIS Catalyst, an ambassador-style program which assists IMNIS mentee alumni to promote STEM benefits and careers across Australia's schooling system. Participants receive public communication training, with opportunities to interact with senior-level high school students about careers and opportunities in life sciences.

The medical technology, biotechnology and pharmaceuticals sector is ultimately about helping people – whether through the creation of new therapeutics or devices, helping people better understand and manage their health condition, or to help medical professionals better care for their patients. The job roles for STEM experts in this industry are truly limitless.

Dr Arianna Oddo, a PhD graduate from the Monash Institute of Pharmacy and Pharmaceutical Sciences, completed the IMNIS program in 2021, then participated in the IMNIS Catalyst program the following year.

She opted to undertake the program because she recognised the importance of commercialisation of research and the huge role industry plays in this for better health outcomes. She also realised that her understanding of industry was limited due to a lack of exposure.

Progressing careers and facilitating dynamic opportunities

IMNIS was instrumental in helping Dr Oddo progress her career. Not only did it pair her with a mentor who was an accomplished

industry leader, but it also facilitated networking opportunities and guidance on translating academic skills into practical applications in the medtech sector. Dr Oddo joined IMNIS with the intention of transitioning to industry post-PhD, but IMNIS recalibrated her goal, and Dr Oddo is now involved in the commercialisation of medical research within the business development team at The University of Melbourne.

Through IMNIS, Dr Oddo gained exposure to valuable industry perspectives and connections. The program helped her understand the drivers and requirements of industry and how to overcome challenges in applying her skills in commercialisation as well as how highly these skills are valued by both academia and industry.

Shaping career trajectories, providing diverse career pathways and more

Since completing IMNIS, Dr Oddo's career has been marked by significant experiences, including participation in industry events such as the 2023 Automation Fair in Boston. She was also selected to join the ATSE Emerging Leaders Network in 2024, highlighting her contributions to shaping Australia's technological landscape.

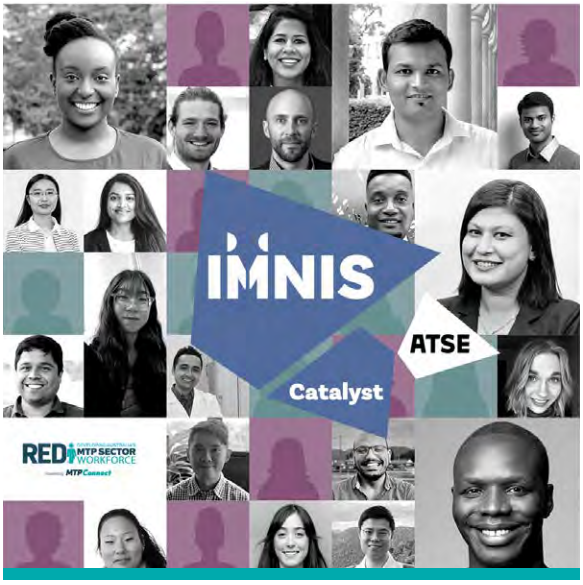
Reflecting on the program's impact, Dr Oddo said her career trajectory has been shaped by the IMNIS experience, which exposed her to diverse career paths and provided access to expert advice and mentorship.

"Like many PhD students, I struggled to envision what 'industry' really meant outside sophisticated R&D labs and how to apply my specialised skills more broadly. Conversations with my IMNIS mentor helped me explore alternative paths," said Dr Oddo.

Empowering early-stage researchers to drive innovation and commercialisation

Dr Oddo's journey showcases the transformative impact of IMNIS on shaping the careers of Australia's medical technology, biotechnology and pharmaceuticals workforce. By providing mentorship, networking opportunities and guidance on career transitions, IMNIS has empowered early-stage researchers like Dr Oddo to become active agents driving innovation, research translation and commercialisation in the sector.

> The REDI program has supported IMNIS to create 170 life science-specific relationships through its sub-programs.



REDI FELLOWSHIP PROGRAM

Australia punches above its weight in medical research, but it is widely accepted that we are less successful in the translation and commercialisation of that research.

There has been significant effort to increase our success in translation and commercialisation, but it is a complex issue and not an easy fix. It has been suggested that this is because of the differences in academic and industry goals and the lack of porosity and synergy between the two groups. Movement from research to industry is generally a one-way ticket in Australia and this only exacerbates the divide.

A unique opportunity and program in Australia

The REDI Fellowship Program provides industry with the opportunity to access academics, clinicians and public organisation life sciences professionals for distinct medical research projects involving discovery, translation and commercialisation. It is a unique program in Australia as it is led by industry to solve industry problems and allows academics, clinicians and life sciences professionals to spend time in industry and return to academia at the end of their Fellowship. Fellowships could be taken internationally or within Australia and were focused on the professional development of the REDI Fellow in an industry setting.

Forty-nine REDI Fellows undertook Fellowships in Australia, Asia, North America and Europe where salary, relocation, travel, training and professional development costs were covered by the program. These were contracted with the substantive employer or industry to ensure porosity and job security. Feedback on the program from Fellows, sponsors and employers was exceptional. Over 50 per cent of REDI Fellowships ended with formal contracts for further collaboration between the sponsor and employer, with above 80 per cent continuing collaboration relationships. Near universal feedback from Fellows reveals that it has changed the way they interact with industry.

A groundbreaking program that has progressed inventions and changed lives

The REDI Fellowships have nucleated an Austrian company to set up research facilities in Australia, accelerated many REDI Fellows' careers, progressed many inventions and changed the lives, minds and ways of working of the REDI Fellows who have taken part in this groundbreaking program. To find out how, read on.

CONTENTS

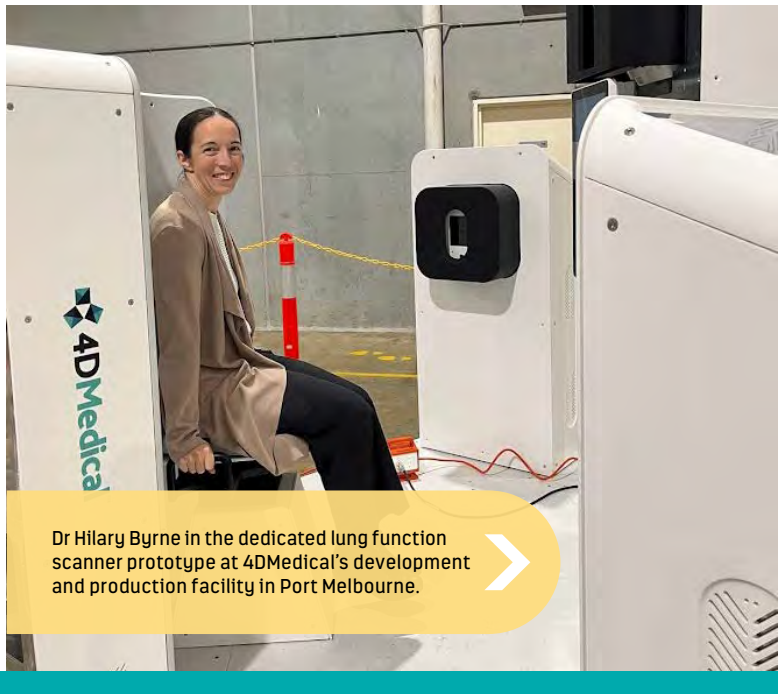
Breakthrough lung mapping technology invention accelerated in Australia

SPONSOR:
4DMedical

FELLOW:
Dr Hilary Byrne

EMPLOYER:
The University of Sydney

KEY FOCUS:
Medical technology, clinical validation, regulatory applications and clinical trial management



Dr Hilary Byrne in the dedicated lung function scanner prototype at 4DMedical's development and production facility in Port Melbourne.

Recent regulatory approvals for 4DMedical's Computed Tomography Lung Ventilation Analysis Software (CT LVAS) for mapping lung tissue will provide a lifesaving breakthrough for thousands of patients with pulmonary disorders including asthma, COPD, cystic fibrosis and cancer, and was accelerated by a well-timed REDI Fellowship with The University of Sydney.

In 2019, 5.3 million diagnostic lung procedures were carried out in Australia, representing a spend of $285 million.[1] The addition of a new dimension to diagnostic lung imaging, Computed Tomography (CT) ventilation imaging, has potential benefits in diagnosis, treatment and maintenance of nearly all lung diseases, especially lung cancer.

Lung cancer is one of the most diagnosed cancers and one of the most difficult to treat. Although three out of four lung cancer patients benefit from radiation therapy, many experience serious side effects, which can be reduced by preserving healthy, functional lung tissue. Since 2000, researchers at The University of Sydney's Image X Institute have been developing a novel 3D imaging software called CT Ventilation, which shows oncologists how well different areas of the lungs are performing and helps them protect healthier lung tissue during radiation therapy.

REDI Fellowship instrumental in expanding software's application

Through a REDI Fellowship, pulmonary imaging specialist Dr Hilary Byrne was embedded with the global medtech developer 4DMedical, which has been working with Image X to develop a clinic-ready prototype of its Lung Ventilation Analysis Software (LVAS).

4DMedical products provide clinicians with lung health metrics and information, using images from existing hospital fluoroscopy or CT scanners, across various pulmonary disorders including asthma, COPD, cystic fibrosis and cancer. Shortly after the Fellowship, in November 2023, 4DMedical's CT LVAS product line secured both FDA approval in the US and TGA approval in Australia – making it available to thousands of patients with lung diseases.

According to 4DMedical's CEO, Dr Andreas Fouras, Dr Bryne's Fellowship was instrumental in expanding the software's application from its original focus on radiation therapy only to much broader applications of lung diagnostics, which proved vital to its regulatory success.

"Our ability to draw on the expertise of Dr Byrne as an industry ready and 'in-house' resource definitively advanced our research translation efforts. She added a very human dimension to our work, and our mission of improving the lives of people impacted by respiratory compromise.

"We value this investment by MTPConnect towards commercialising Australian medical technology research," Dr Fouras said.

1. https://4dmedical.com/

The REDI Fellowship built upon the existing collaboration between 4DMedical and The University of Sydney's clinical imaging group, to which Dr Byrne had contributed findings from her radiation therapy research. However, the REDI Fellowship experience of the documentation and clinical validation reporting required for regulatory applications, clinical trial management and liaising with clinicians as a commercial trial sponsor was all new.

Following Dr Byrne's Fellowship, 4DMedical released a commercial, TGA-approved version of its CT LVAS product line in Australia, in partnership with radiology provider i-Med. The new software produces detailed ventilation reports from CT scans, enabling access to lung function imaging for patients with lung disease.

A significant milestone – enabling transformative lung imaging for more patients

In the US, 4DMedical's commercial CT LVAS product has been included in the government rebate scheme for diagnosis of small airway disease in US veterans. This allows an alternative to an invasive and risky biopsy procedure for the diagnosis of lung conditions developing from burn pit practices during overseas conflict.

"The CT LVAS product line is a significant milestone for 4DMedical, enabling our transformative functional lung imaging to be accessed by more patients, clinicians and researchers through widespread availability of Computed Tomography imaging infrastructure," said Dr Fouras.

During her Fellowship, Dr Byrne visited 4DMedical's laboratories in Melbourne and Adelaide, and presented work on CT-based lung imaging at the 2023 Annual Meeting of the American Association of Physicists in Houston.

Work continues under an NHMRC grant and larger Phase III trial planned

Today, she is continuing to work on the radiation therapy applications of LVAS under a NHMRC Development Grant, in conjunction with two newly appointed Image X pulmonary researchers. A larger Phase III trial is planned, which should demonstrate the use of 4DMedical's product in identifying and avoiding healthy lung tissue and quantifying the resulting patient benefits in the radiation therapy workflow.

A commercialisation group has also been formed within The University of Sydney clinical imaging group, which aims to offer specific advice and tailored expertise to help its researchers develop relationships and follow steps to commercialise their imaging research.

Dr Bryne said: "I am incredibly excited to be able to say 4DMedical has publicly released the CT LVAS product, representing the culmination of years of research and bringing to the public the assessment of lung health via widely available CT scans.

"During my REDI Fellowship, I have learned a lot about working with industry, about what it takes to prove an idea is worthwhile and about perseverance. I hope to use these learnings to guide my future research to faster, clinic-ready innovations to make a real difference for patients afflicted with lung conditions," Dr Byrne concluded.

> "We value this investment by MTPConnect towards commercialising Australian medical technology research."

From left, Dr Nina Eikelis, 4DMedical Director, Medical and Clinical Affairs and REDI Fellow Dr Hilary Byrne at 4DMedical's Melbourne offices.

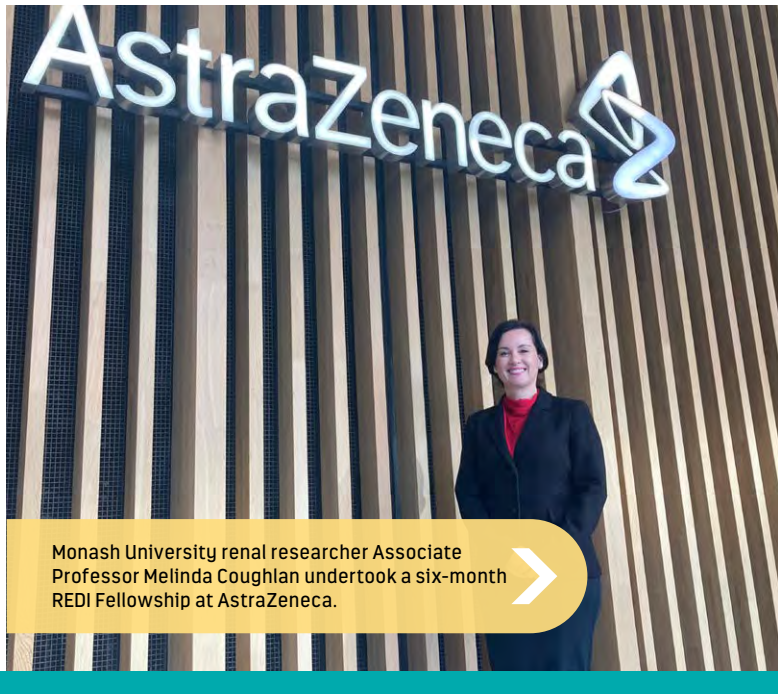
New partnerships help accelerate vital kidney metabolism research

SPONSOR:
AstraZeneca

FELLOW:
Associate Professor Melinda Coughlan

EMPLOYER:
Monash University

KEY FOCUS:
Pharmaceutical, commercialisation pipeline, global collaboration



Monash University renal researcher Associate Professor Melinda Coughlan undertook a six-month REDI Fellowship at AstraZeneca.

A six-month immersion in the Renal and Metabolism teams at AstraZeneca provided diabetic kidney disease expert Associate Professor Melinda Coughlan a unique opportunity, to explore new research pathways and technologies and build the foundations for a partnership with major therapeutic potential.

A REDI Fellowship gave leading Monash University kidney researcher A/Professor Coughlan the chance to be immersed in a variety of drug discovery work that broadened her clinical perspectives and will revolutionise her future research.

An understanding of the early-stage pipeline

The Fellowship also gave her an understanding of the early-stage pipeline – bringing projects from target identification to clinical trial – to give her the best chance to have her research in novel therapeutics approved as medicines.

AstraZeneca is a global biopharmaceutical company committed to developing innovative medicines in areas such as oncology, respiratory, renal and cardiovascular diseases.

The REDI Fellowship with AstraZeneca focused on chronic kidney disease. Kidney diseases represent a high unmet medical need, affecting hundreds of millions of people, and are the sixth most common cause of death worldwide. Around two million Australian adults were living with chronic kidney disease in 2021. The annual cost of chronic kidney disease was estimated to be $9.9 billion in Australia in 2021.[1]

1. Kidney Health Australia, Changing the chronic kidney disease landscape: The economic benefits of early detection and treatment. Deloitte Access Economics 2023. (https://www.deloitte.com/au/en/services/economics/analysis/changing-chronic-kidney-disease-landscape.html)

Much of A/Professor Coughlan's work to date has focused on mitochondria, the tiny energy-conversion structures in our cells. Mitochondrial dysfunction is implicated in a wide range of pathologies – including kidney damage associated with diabetes. While her team at Monash has done groundbreaking work in understanding some of the factors driving mitochondrial dysfunction in kidney cells, most of their research to date has been restricted to the earliest stages of drug discovery.

Exploring a variety of cutting-edge analytical technologies

During her Fellowship at AstraZeneca, A/Professor Coughlan covered processes of target identification and validation, and explored a rich variety of cutting-edge analytical technologies, from multiomics and functional genomics, to advanced molecular imaging and sample management.

A/Professor Coughlan established the foundations of a strong new partnership between Monash and AstraZeneca, presenting her work on diabetic kidney disease to AstraZeneca's Renal team (located across Cambridge, UK and Gothenburg, Sweden), as well as her partners at Nestle Health Sciences – which resulted in a partnership on a new project related to nutritional science, and the University of Cambridge – where she collaborated with the world-renowned developmental endocrinologist Professor Susan Ozanne.

She also travelled to Germany to present her work at a meeting of the European Association for the Study of Diabetes and delivered two invited presentations at the American Society of Nephrology's Kidney Week – the most prestigious event on the renal medicine calendar.

Upon her return to Melbourne, Associate Professor Melinda Coughlan directly applied her REDI Fellowship learnings to a new area of research.

A raised international profile and meeting potential new collaborators

These presentations strongly raised her international profile and enabled her to meet several potential new collaborators including Professor Maryam Afkarian at UC Davis, who is planning to visit The University of Melbourne to work on a research project with A/Professor Coughlan in 2025.

Senior Director of Renal Bioscience at AstraZeneca, Dr Kevin Woollard, said it was a pleasure to host A/Professor Coughlan within Renal Biosciences, Early Cardiovascular, Renal and Metabolism and R&D Biopharmaceuticals at AstraZeneca.

"With the Renal team at Cambridge, UK, we explore the biology of renal dysfunction in diabetic kidney disease, and her passion and experience in mitochondrial biology and oxidative stress contributed to experimental design to uncover novel mechanisms of renal cell stress in diabetic kidney disease. We look forward to following up on this work and publishing high-impact papers together," Dr Woollard said.

> "Through my REDI Fellowship placement at AstraZeneca, I've gained a much deeper understanding of early-stage projects from target identification to validation.

Due to the broad reach of AstraZeneca's networks, A/Professor Coughlan was able to engage with multiple teams at the pharmaceutical company, including the Metabolism team where she embarked on a new project to define a new biological mechanism leading to chronic kidney disease.

New perspective of scientific and technical capabilities within pharma sector

This enabled A/Professor Coughlan to gain new insights into mechanisms of disease biology as well as new technical skills in the laboratory. Upon her return to Melbourne, she directly applied these skills to a new area of research in her home lab, which has led to the award of an NHMRC Ideas Grant for which she will be Chief Investigator for the next five years.

"Through my REDI Fellowship placement at AstraZeneca, I've gained a much deeper understanding of early-stage projects from target identification to validation. I also gained a new perspective of the scientific and technical capabilities within the pharmaceutical sector, and of how collaborative efforts are better utilised to generate results.

"I've been really motivated by all the new insights I've received into innovation in the field of kidney diseases and novel technologies we can harness to deliver impact on our research outcomes. I am looking forward to the continuing discussions we'll be having about extending our research activities through this exciting new collaboration between Monash University and AstraZeneca," A/Professor Coughlan said.

Bringing research experience into the mix to identify a high-quality life science investment

SPONSOR:
Brandon Capital

FELLOW:
Dr Christina Kulis

EMPLOYER:
The University of Queensland

KEY FOCUS:
Biotechnology, investor priorities, commercialisation journey, venture capital investment strategies

REDI Fellow Dr Christina Kulis.

A year with leading venture capital company, Brandon Capital, gave Queensland researcher Dr Christina Kulis insights into what investors are looking for, whilst helping her develop the skills needed to deliver a winning proposal and pitch. As part of the program, Dr Kulis supported Brandon Capital by assessing pitches from research organisations, performing due diligence and reviewing many early-stage opportunities.

Brandon Capital is Australasia's leading life science venture capital firm. Through collaboration, capability uplifts and investment, it helps companies transform promising medical research breakthroughs into therapies that improve patients' lives.

The company manages Brandon BioCatalyst, which was established to make capital available to commercialise the world-class research occurring in Australia and New Zealand, catalyse the next generation of biotech companies and create new treatments for patients. Brandon BioCatalyst has invested in 50 early-stage life science companies to date.[1]

Establishing key relationships with expert teams

Prior to her REDI Fellowship, Dr Kulis completed an internship with Brandon Capital in Melbourne, working to select targets for one of its portfolio companies. She also completed the Bridge Program (supported by MTPConnect), which is designed to provide training in the scientific, legal, financial, clinical and regulatory disciplines to boost commercialisation in Australia.

Dr Kulis has extensive drug discovery and development experience and was working at The University of Queensland in Associate Professor Mark Smythe's laboratory when she commenced her Fellowship. A/Professor Smythe is the Founder of Protagonist and Infensa BioScience, which together have seven drug candidates in human clinical trials.

During the year, Dr Kulis built internal direct relationships with Brandon Capital's Australian, New Zealand, UK and US investment managers and technical advisors, as well as with professional services teams such as legal and public relations. She also established relationships with pharmaceutical executives, clinical and regulatory experts and intellectual property (IP) attorneys.

Universities, research institutes and biotech companies in Australasia submit pitches that are assessed using online research, proprietary databases, consultancies with global experts and direct engagement with key opinion leaders. Her main objective was to review early-stage opportunities by undertaking technical evaluation and due diligence.

1. https://brandonbiocatalyst.com/investments/

Developing commercial know-how

During the Fellowship, Dr Kulis performed market assessments, IP assessments, commercial positioning and assisted in creating development plans and budgets for new start-ups.

It is estimated that Dr Kulis was involved in evaluating around 70 opportunities, and as she became more independent in her work as the year progressed, she tapped into the expertise available and used the skills she learned to make recommendations to the Investment Committee.

Dr Kulis said it was fascinating to see firsthand the investor perspective of the path – from finding an opportunity through to investment and beyond to the early years of commercialisation.

"The deep training and supportive mentorship at Brandon gave me confidence in identifying and assessing a wide range of opportunities, as well as understanding commercial appetite for a technology and when to license or acquire assets with potential."

Learning key characteristics of excellent life science investments

Since completing the Fellowship, Dr Kulis has joined Brandon as an analyst at CUREator, Brandon BioCatalyst's biotech incubator, following her passion for translating medical science and using her expertise to deliver commercially driven research outcomes that improve patient lives.

There is also a chance that the research Dr Kulis contributed to at The University of Queensland could be spun out as a biotech company, with her past research group exploring the commercialisation of their research program.

Dr Goslik Schepers, Senior Investment Manager at Brandon Capital, said Dr Kulis became an integral part of its Queensland office, which led to an appointment at the company.

"Dr Kulis has shown she is passionate about translating medical research into commercial outcomes, driving her own and others' high-quality research. During the REDI Fellowship, she had exposure to the Brandon Capital Partners' portfolio and quickly learned the key characteristics that identify an excellent quality life science investment."

> "Dr Kulis was involved in evaluating around 70 opportunities."

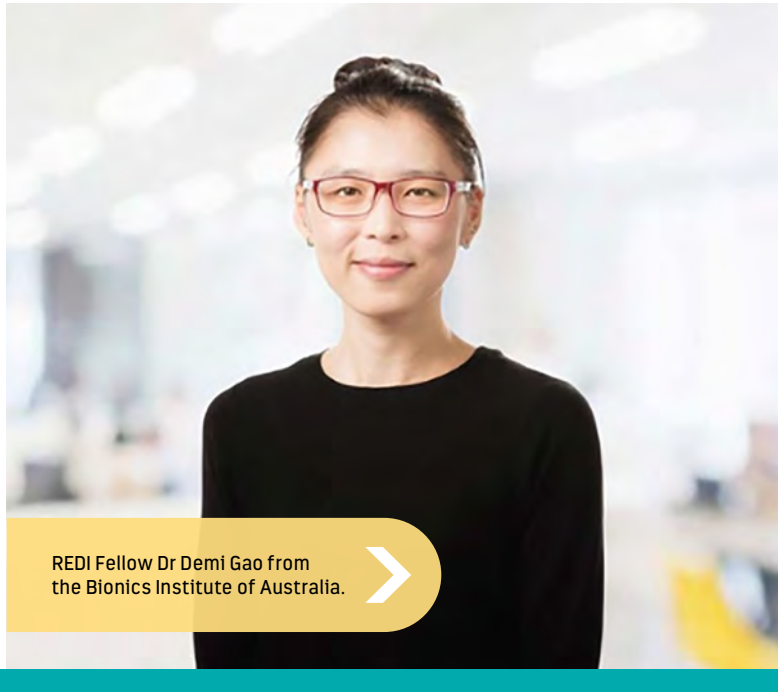
Advancing the design of an implanted microphone for next-gen cochlear implants

SPONSOR:
Cochlear

FELLOW:
Dr Demi Gao

EMPLOYER:
The University of Melbourne

KEY FOCUS:
Medical devices, clinical trial, quality assurance, commercialisation pathway, regulatory framework



REDI Fellow Dr Demi Gao from the Bionics Institute of Australia.

Cochlear has been working for many years to develop and bring a totally implantable cochlear implant (TICI) to market. A REDI Fellow, Dr Demi Gao – who has expertise in computational methods and machine learning – has helped maximise the performance of implantable microphones for future generations of implantable hearing devices.

Cochlear is a global leader in implantable hearing solutions and is considered an Australian success story. Formed in 1981, Cochlear has provided more than 750,000 hearing implants to people worldwide.

Current commercially available cochlear implants use microphones outside of the body to enable a person to hear. However, requiring an external unit restricts hearing in many situations, for example, during sleep or showering. These limitations have driven the development of totally implantable cochlear implants, which use microphones implanted inside the body. In the early 2000s, Cochlear demonstrated feasibility and safety for such a device, but the internal microphone hearing results were not adequate.

In 2018, an updated TICI device was implanted in 11 patients as part of a clinical trial. Recordings and technical characterisations of the microphones from the clinical trial provided data for Dr Gao to work with during her REDI Fellowship.

Research in the field of human hearing to better understand the human auditory system

Dr Gao is a Senior Research Scientist at the Bionics Institute of Australia, working in the field of human hearing to better understand the human auditory system, the development of analysis techniques for hearing loss diagnosis and optimising the performance of next-generation cochlear implants.

Dr Gao's REDI Fellowship at Cochlear was to support the design of future implanted microphones that provide users with sound quality equivalent to external microphones.

Director of Algorithms and Applications at Cochlear, Dr Zachary Smith, said that by breaking down the complicated research challenges into several research questions, the REDI project was able to address these research questions one at a time.

"Dr Gao brought her excellent skills resolving research questions, computational modelling and neural engineering into the project, and successfully identified potential solutions for improving the performance of totally implanted cochlear implants," Dr Smith said.

Working with the Algorithms team to improve sound quality from the implanted microphone

Dr Gao drew on her expertise in using computational methods and machine learning techniques to understand hearing performance in cochlear implants and the way that regions of the brain interact with each other.

She worked with the Algorithms team to analyse data from the 2018 trial to propose a deep learning algorithm to improve sound quality from the implanted microphone. The success of this approach has now led to a project investigating the next steps for development of these next-generation implanted devices.

"Dr Gao has established a machine-learning framework using synthetic data to tackle a challenging problem for the future of fully implanted hearing implants. We anticipate it to greatly improve with different network configurations and training with larger datasets," Dr Smith said.

Exposure to industry skills will help accelerate Fellow's own research

During her time at Cochlear, Dr Gao was exposed to industry skills that will help accelerate her own research. She received training developed for in-house staff covering regulatory jurisdictions and requirements, fundamentals of quality management, design, risk management, verification and validation and management of intellectual property.

"Thanks to the REDI Fellowship, I have a better understanding of how to work in an industrial environment and have established a clear picture of how to bridge the gap between basic research and industry needs.

"The training and development I received at Cochlear, as well as time spent working with colleagues there, was extremely beneficial and I look forward to incorporating my new skills into future translational research," Dr Gao said.

> **Dr Gao ... successfully identified potential solutions for improving the performance of totally implanted cochlear implants.**

She gained significant experience in conducting clinical translational research with a view to commercialisation of research products. She is now undertaking a three-year mid-career Fellowship to continue this translational research in human hearing.

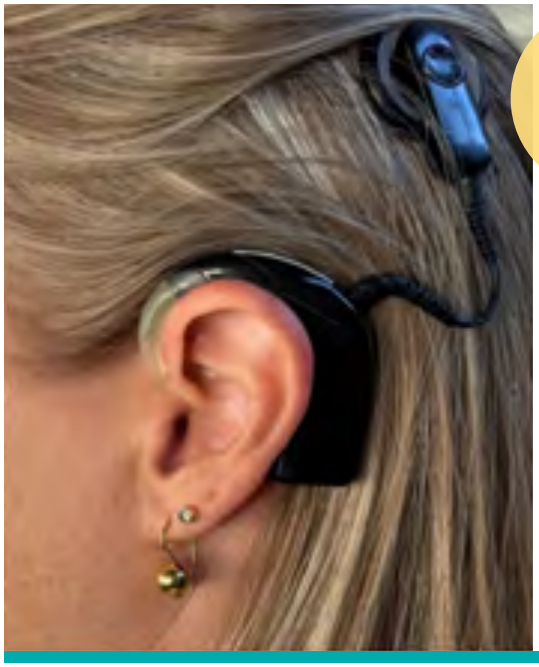
Dr Gao has also taken up a Senior Research Scientist role at the Bionics Institute of Australia and an honorary Research Fellow role at The University of Melbourne, to continue her collaboration with the university and Cochlear.

The Fellowship strengthened collaboration between Cochlear and The University of Melbourne, in particular the development and growth of relationships between Cochlear's Advanced Innovation group and the university's bionics researchers. Since inventing the bionic ear in the 1970s, The University of Melbourne has had a strategic focus on bionics research, which brings hearing to profoundly deaf children and adults.

A win-win for people living with moderate to profound hearing loss

The two organisations bring together cutting-edge technologies such as artificial intelligence with industrial application which, for example, lead to improved performance of an implanted microphone.

Through collaborative effort, expertise in different domains and sharing of insights, it is hoped the applied research will lead to the improved design and performance of smart implanted microphones and totally implantable cochlear implants. And that would be a real win-win for people living with moderate to profound hearing loss.



Left photo: Current cochlear implants use external sound processors to capture sound and send signals to an internal implant to help people hear. Right photo: Dr Demi Gao has been supporting research to develop cochlear implants that can be used without an external sound processor, using microphones implanted inside the body.

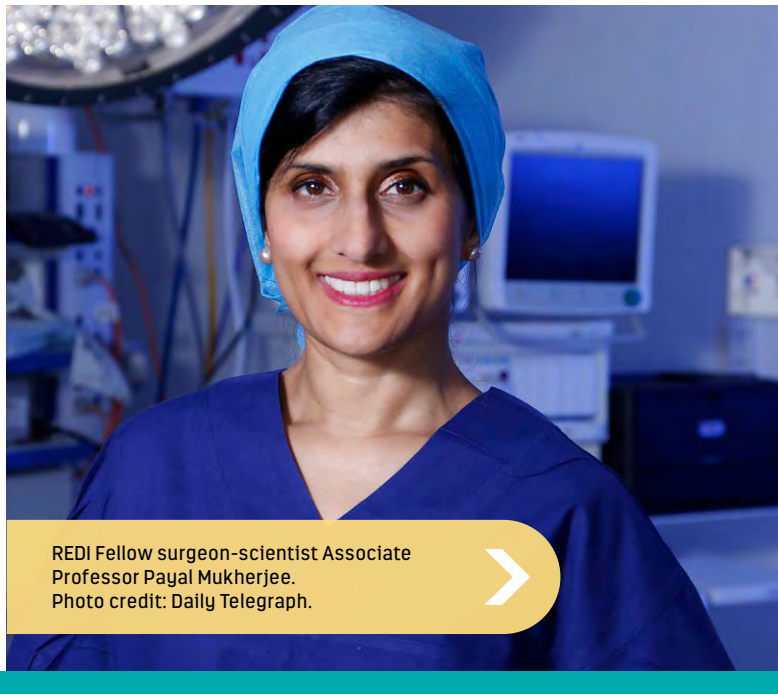
Evaluating robotics surgical technologies in cochlear implantation

SPONSOR:
Cochlear

FELLOW:
Associate Professor Payal Mukherjee

EMPLOYER:
Royal Prince Alfred Hospital,
Sydney Local Health District

KEY FOCUS:
Biomedical innovation, robotics, surgeon-scientist product life cycle management



REDI Fellow surgeon-scientist Associate Professor Payal Mukherjee.
Photo credit: Daily Telegraph.

Cochlear is the global leader in implantable hearing solutions. In 2022, the Australian-headquartered organisation was awarded a REDI Fellowship for Associate Professor Payal Mukherjee – an Ear, Nose and Throat (ENT) surgeon-scientist and Innovation Lead at the Institute of Academic Surgery at Royal Prince Alfred Hospital (RPA) – to work on the first Australian study evaluating robotics in cochlear implantation surgery.

Hearing loss is a highly prevalent condition that affects more than 1.5 billion people worldwide and costs the global economy an estimated US$980 billion annually.[1]

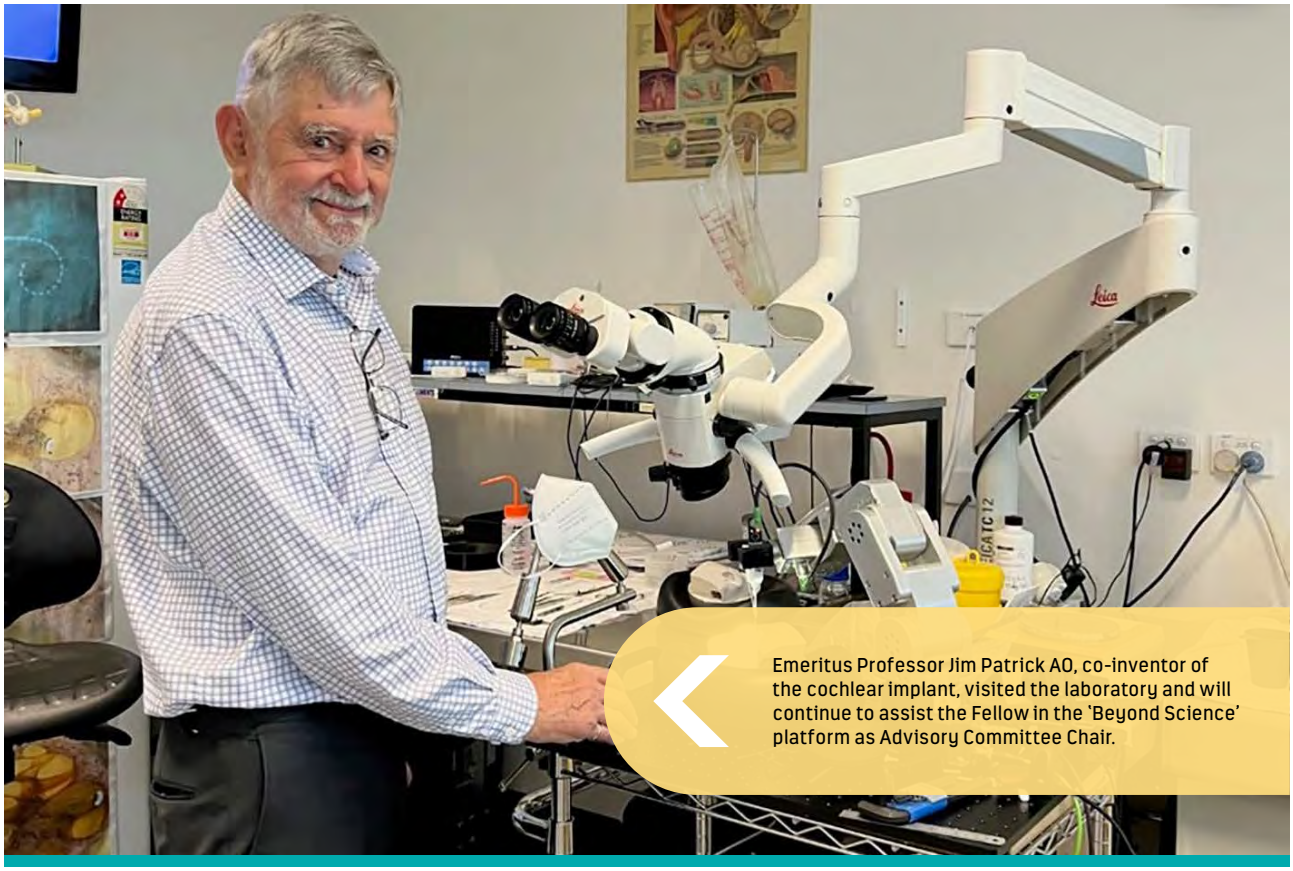
Cochlear implantation is a treatment option for severe to profound hearing loss when a patient can no longer be helped by using hearing aids. In the US and Europe, robotic systems designed specifically for cochlear implantation have been trialled in recent years, in the hope that they will increase equity and improve patient outcomes. However, research and investment in this technology is currently lagging in Australia.

Before investing substantial funding in developing robotics technology, Cochlear set out to conduct a study to evaluate the strengths and weaknesses of the system and identify strategic areas of focus for future R&D.

The REDI Fellowship provided the opportunity for A/Professor Mukherjee to evaluate new robotic technologies and provide her expert feedback to Cochlear. This unique arrangement overcame the conflict of interest in patient care that typically arises for surgeons if the industry has funded them directly for their time. She was also able to develop training 'by surgeons, for surgeons' for cochlear implantation, resulting in better outcomes for patients.

Cochlear provided A/Professor Mukherjee with valuable training and industry skills to accelerate the translation of her own research. This included training related to regulatory jurisdictions and requirements (in Australia and overseas), applicable international standards (ISO 13485), the fundamentals of a Quality Management System, the design control process, development of design inputs, risk management, verification and validation and intellectual property management. In addition, she benefitted from face-to-face sessions with Cochlear's global executives and the completion of a Foundation of Directorship course with the Australian Institute of Company Directors.

1. World Health Organization: Health topics: Deafness and hearing loss https://www.who.int/health-topics/hearing-loss
2. Work-related physical, psychosocial and individual factors associated with musculoskeletal symptoms among surgeons: Implications for ergonomic interventions – ScienceDirect https://www.sciencedirect.com/science/article/abs/pii/S0003687017302077?via%3Dihub



Emeritus Professor Jim Patrick AO, co-inventor of the cochlear implant, visited the laboratory and will continue to assist the Fellow in the 'Beyond Science' platform as Advisory Committee Chair.

Cochlear has leveraged A/Professor Mukherjee's expertise to optimise the value of robotics technology and is currently working in partnership with LifeHealthcare to integrate its electrode-testing software into robotic microscopes. These microscopes have the potential to improve surgical ergonomics to reduce musculoskeletal disorders (MSS) – such as back injuries – in surgeons. This initiative is particularly crucial given up to 90 per cent of surgeons suffer from MSS. MSS can have detrimental impacts, including poor patient outcomes, diminished surgical performance, heightened sick leave, increased healthcare-seeking behaviour and premature retirement.[2]

A/Professor Mukherjee has already trialled the robotic microscope in surgeries – a first in Australia – and is planning a study on surgical ergonomics at the time of writing. She is also supervising a student to undertake a study with NSW Health to better plan surgical services for cochlear implantation.

Off the back of the Fellowship, A/Professor Mukherjee has attained a further $8.6 million in funding support for her research. She has also acquired several exciting appointments: as a member of the Advisory Committee on Medical Devices at the Therapeutic Goods Administration (TGA); an expert panel member of NSW Health's Medical Devices Fund; and Chair of the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S).

"This has been one of the most interesting years of my career. I have acquired a very different perspective of research and collaborated with Cochlear in a way I never could have without the REDI Fellowship," A/Professor Mukherjee said.

Meanwhile, using the Fellowship as a catalyst, the RPA Institute of Academic Surgery has launched a training program in collaboration with The Royal Australasian College of Surgeons. The program – 'Beyond Science' – was co-funded by RPA Hospital and the Passe & Williams Foundation to run a statewide collaborative platform for surgeon-scientists and surgeon-innovators to learn skills, access mentorship and networks that incubate and accelerate their projects towards translation and commercialisation.

> **The REDI Fellowship provided the opportunity for A/Professor Mukherjee to evaluate new robotic technologies and provide her expert feedback to Cochlear.**

Transforming the management of significant hearing loss through informed choice

SPONSOR:
Cochlear

FELLOW:
Dr Cathy Sucher

EMPLOYER:
Ear Science Institute Australia

KEY FOCUS:
Biomedical innovation, robotics, patient engagement, clinical trial management

REDI Fellow Dr Cathy Sucher at Cochlear office.

A REDI Fellowship awarded to Cochlear, a leader in implantable hearing devices, enabled the company to bring Dr Cathy Sucher, a Senior Implant Audiologist and Cochlear Implant Research Lead at the Ear Science Institute Australia, into its team. Dr Sucher investigated how a digital tool could improve awareness and uptake of cochlear implants and the benefits they can bring.

The World Health Organization 2021 World Hearing Report found that hearing loss affects 20 per cent of the world's population – more than 1.5 billion people.[1] Of those, over 2.1 per cent suffer from moderately severe, or worse, hearing. That is around 163.5 million people. This number is expected to rise with an ageing global population. In the same report, it was estimated that the financial cost of unaddressed hearing loss globally is more than $980 billion (International dollars) annually.[1]

The benefits for many adults of addressing hearing loss are improved hearing and quality of life, as well as the potential societal, economic and health-related improvements that access to optimised hearing could achieve. Hearing loss can be devastating. It can affect a child's ability to listen, learn and talk; result in lower school attendance; affect a person's ability to advance education and find work; affect social and emotional wellbeing, including a higher risk of low self-esteem, low confidence, memory loss and depression; and lead to social isolation.[2]

Cochlear implantation is a treatment option for severe to profound hearing loss when a patient can no longer obtain benefit from hearing aids. Yet, while cochlear implants are considered the gold standard treatment for individuals with severe-profound hearing loss who wish to hear, less than 10 per cent of Australian adults that could benefit from a cochlear implant receive one – and even fewer globally.[3]

Recognising the need to raise awareness of the benefits of – and increase engagement with – cochlear implants, Cochlear developed the 'Hearing Stages Tool': a visual representation of the typical stages a person passes through when afflicted by hearing loss and the different assistive listening devices available to support them.

With the development of this tool, potential cochlear implant candidates could be empowered to discuss hearing management options with their clinicians and GPs in an informed manner, helping to shift the focus from hearing devices to hearing outcomes and needs and facilitating a more patient-centred approach.

1. World report on hearing. Geneva: World Health Organization. Licence: CC BY-NC-SA 3.0 IGO https://www.who.int/publications/i/item/9789240020481
2. Australian Department of Health and Aged Care: About ear health https://www.health.gov.au/topics/ear-health/about
3. Why don't we talk about cochlear implants? Ear Science Institute Australia website: https://www.earscience.org.au/2022/12/19/why-dont-we-talk-cochlear-implants/

The main objective of the Fellowship was to conduct a pilot study to understand the usefulness of the Hearing Stages Tool.

Based on preliminary evidence, the tool and other support mechanisms (including a website) were proven to increase patient outcomes and engagement. Off the back of these results, Cochlear has extended the study to gather further evidence.

During the nine-month Fellowship, Dr Sucher was immersed in the best practice of product development and commercialisation processes within Cochlear. In addition to enhancing her skills in a range of areas, including quantitative research and market research, she gained greater awareness of the need to move beyond immediate clinical outcomes and research to develop and translate tools that are meaningful and useable for all stakeholders.

"The experience has also provided me with some of the tools and networks to help this happen," she said. "This opportunity has increased my confidence and professional exposure, both clinically and as a clinical researcher, allowing for the development of many new future collaborations and translational research opportunities."

Assessing stigma of hearing loss

Through contacts and discussion with members of the clinical trials team at Cochlear, Dr Sucher has now joined a new project to develop an outcome measure to assess the stigma of hearing loss. Additionally, there is an opportunity to proceed to the next stage of development of the prototype tools created and studied as part of the Fellowship project.

"Should these tools become available to clinicians and potential candidates, the impact would be great, improving access to cochlear implants, and thus improved hearing and quality of life for many adults with hearing loss – as well as the potential societal, economic and health-related improvements access to optimised hearing could achieve," she said.

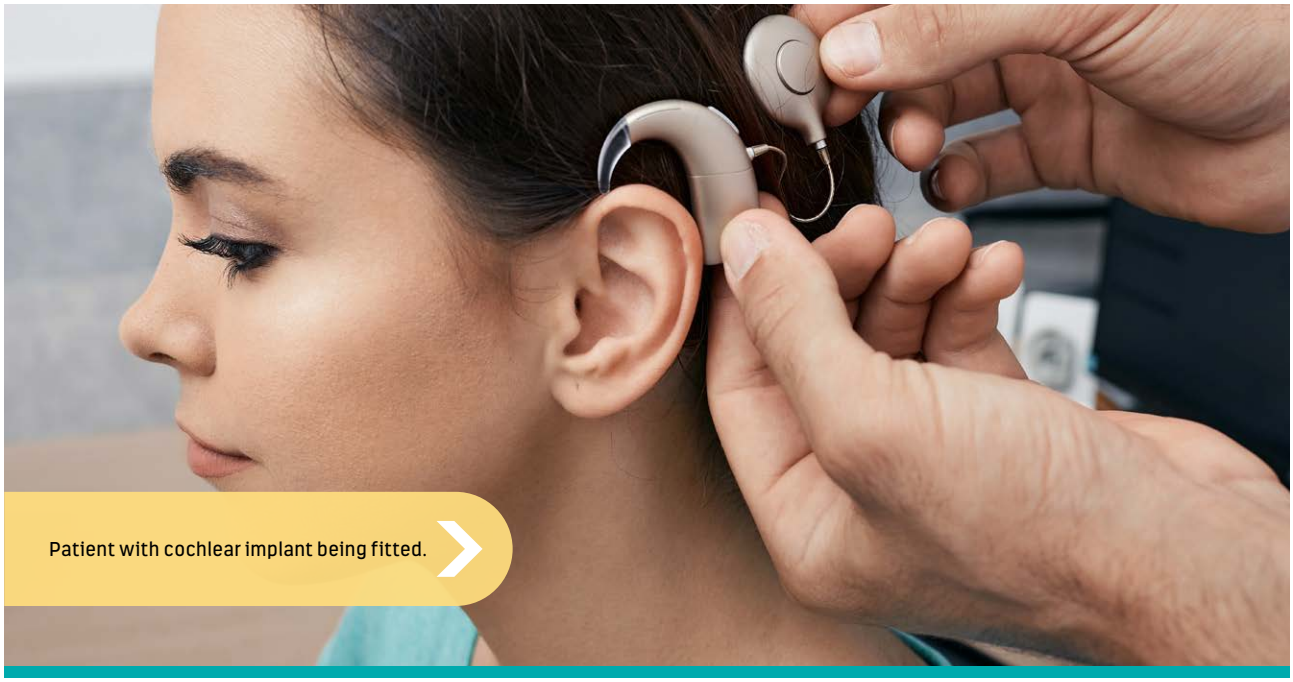
Since the Fellowship, Dr Sucher has met with Audiology Australia and been invited to join the ANZ Hearing Community Task Force, which included a presentation at its July 2023 workshop on the Hearing Stages Tool and its suitability as a utility tool.

Being involved in the ANZ Hearing Community Task Force also provides the potential to make use of the research from this study to inform hearing health guidelines and, possibly, influence national health policy.

Throughout the project, Dr Sucher's knowledge and experience as a clinician and researcher proved highly valuable to the Cochlear team.

By bridging this gap between clinical practice and product innovation, the hope is that more adults with significant hearing loss will be able to experience benefits such as improved quality of life, psychosocial and mental wellbeing, and greater access to educational and workplace opportunities that can be afforded to them, through improved hearing with a cochlear implant.

> **Dr Sucher was immersed in the best practice of product development and commercialisation processes within Cochlear.**



Patient with cochlear implant being fitted.

Improving the pathways for stem cell transplants

SPONSOR:
CSL Limited

FELLOW:
Associate Professor Kate Gartlan

EMPLOYER:
QIMR Berghofer Medical Research Institute

KEY FOCUS:
Therapeutic, clinical, commercial, intellectual property, business development and research

REDI Fellow Associate Professor Kate Gartlan leads QIMR Berghofer's Immunopathology laboratory.

New therapeutic strategies are urgently needed to combat the side effects of stem cell transplantation in patients with blood and immune system cancers. A REDI Fellowship brought the team at global biotech leader CSL together with Associate Professor Kate Gartlan, who leads the Immunopathology laboratory at QIMR Berghofer, to identify solutions.

Leukaemia, lymphoma, myeloma and other haematological cancers affect around 11,000 people a year in Australia, with up to 15 per cent of patients requiring stem cell transplantation. Most of those, however, will suffer from a major complication called Graft versus Host Disease that impacts patients' quality of life and survival.

Australia's global biotech leader CSL has been working on the problem and so was delighted to welcome A/Professor Gartlan, a specialist in the cellular and molecular mechanisms that drive immune-mediated diseases, on a REDI Fellowship.

> The experience gave A/Professor Gartlan a deep understanding of commercialisation and the process of therapeutic design at CSL.

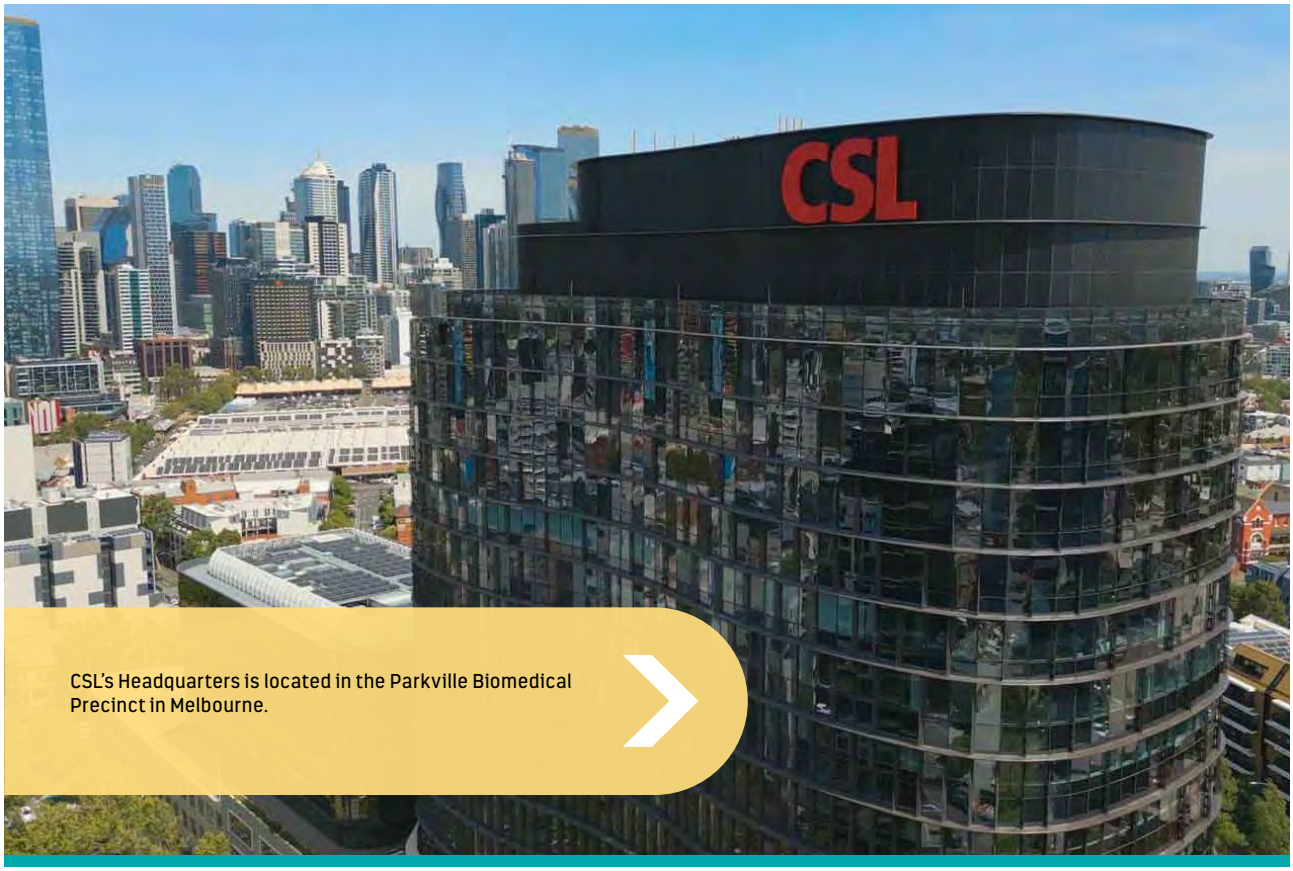
A deeper understanding of commercialisation and therapeutic design

She was recruited to investigate natural tissue repair mechanisms to limit disease and develop therapies to promote a more tolerant recipient environment, however, as CSL is a global and highly matrixed organisation, the opportunity saw her immersed in numerous linked projects and teams. The experience gave A/Professor Gartlan a deep understanding of commercialisation and the process of therapeutic design at CSL, which she is now applying to her research as Leader of the Immunopathology laboratory at Queensland's QIMR Berghofer.

A/Professor Gartlan said that one unexpected benefit of her Fellowship at CSL was the opportunity to be involved in such a broad range of teams outside of her project at the company.

"It was an incredible learning experience. I believe this would not have been possible had I not been able to be relocated to Melbourne to be embedded at CSL," A/Professor Gartlan said.

The cancer-curing benefits of donor stem cell transplantation are currently severely limited by treatment failure and complications, such that the overall survival two years post-transplant is approximately 50 per cent. Graft versus Host Disease is a major factor contributing to mortality and morbidity and is driven by immune-mediated damage to the recipients' tissues. New therapeutic strategies are urgently needed to prevent and treat this inflammatory disease and improve outcomes for transplant recipients.



CSL's Headquarters is located in the Parkville Biomedical Precinct in Melbourne.

Significant project progress and expanded focus at CSL

A/Professor Gartlan's lab has identified specific molecules that play a critical role in modulating early inflammation and affecting tissue repair, and her initial project at CSL was the design and development of novel therapeutic approaches to target these pathways and examine their efficacy both *in vitro* and *in vivo* using preclinical models of Graft versus Host Disease.

She and the CSL team made significant progress on the project, and this allowed the Fellow to expand her focus and contribute to other strategic planning teams at CSL, giving her valuable understanding of its operational nuances and strategic decision-making processes.

A/Professor Gartlan said that witnessing firsthand how CSL navigates challenges, seizes opportunities and adapts to dynamic market landscapes provided her with a unique perspective and strategic foresight.

A wonderful opportunity and exposure to global teams

"In addition to my involvement with a variety of organisational groups within CSL Research, I had regular scheduled meetings with Dr Adriana Baz Morelli, who is a Senior Director and Therapeutic Area Lead for Transplant & Nephrology at CSL, in which we discussed a broad range of industry focused topics.

"This has been a wonderful opportunity to develop my understanding of the mechanisms at CSL for therapeutic target prioritisation, strategy development, resource allocation, pipeline management and an unexpected and valuable one-on-one mentoring and learning opportunity," she said.

Dr Baz Morelli said: "Associate Professor Gartlan has had the opportunity to learn how CSL conducts medical research to enable drug development for patients. In this context, Kate was exposed to global teams including clinical, commercial, intellectual property, business development and research."

A valuable resource for other academics at QIMR Berghofer

A QIMR Berghofer spokesperson said the REDI Fellowship program offered a unique chance for A/Professor Gartlan to gain valuable expertise.

"Importantly, as one of the Research Leaders at QIMR Berghofer, Associate Professor Gartlan will have a clear opportunity to apply and disseminate this knowledge not only to her own academic research program, but also serve as a valuable resource for other academics within the institute," the spokesperson said.

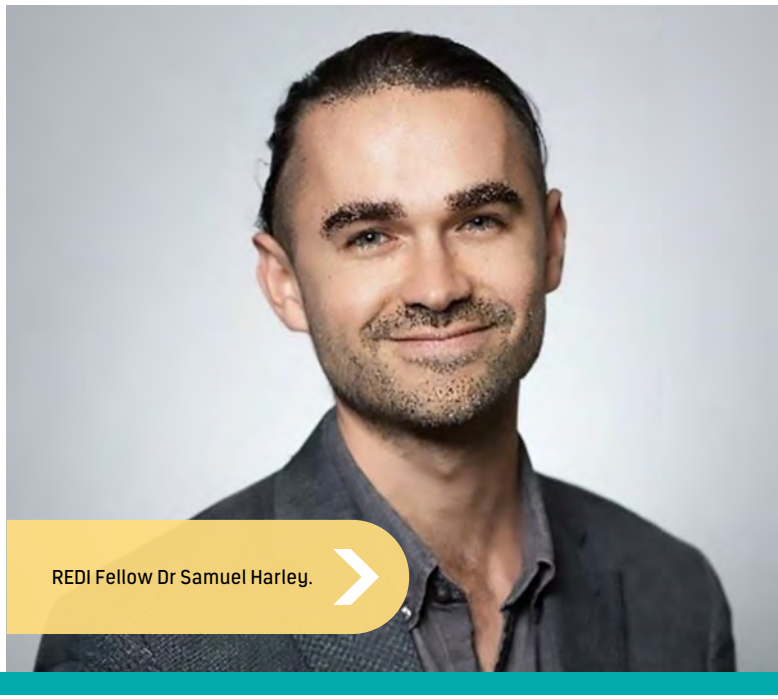
Experiencing different sides of the 'drug development pipeline' with CSL in Switzerland

SPONSOR:
CSL Limited

FELLOW:
Dr Samuel Harley

EMPLOYER:
QIMR Berghofer Medical Research Institute

KEY FOCUS:
Global collaboration, biopharmaceutical business development, portfolio development, market research and analysis



REDI Fellow Dr Samuel Harley.

CSL was awarded a REDI Fellowship to embed Dr Samuel Harley – a research translation and commercialisation professional from QIMR Berghofer Medical Research Institute – within CSL's Global Research Innovation team. Dr Harley spent the first six months of his Fellowship located within CSL's Global Research headquarters in Parkville, Australia, and relocated to Switzerland, where CSL has an R&D hub, for the second half of his project. During his Fellowship at CSL, Dr Harley contributed to the growth of CSL's early-stage immunology therapeutic pipeline. Post-Fellowship, Dr Harley has established his own consulting firm, FlameTree Biotech Consulting, to support biotechs and academic institutes in their research translation and drug development journey.

CSL is a leading global biotechnology company with a wide-ranging portfolio of lifesaving medicines and R&D projects including therapeutics for autoimmune diseases. CSL and its three businesses – CSL Behring, CSL Seqirus and CSL Vifor – provides lifesaving products to patients in more than 100 countries and employs more than 32,000 people worldwide.

A REDI Fellowship enabled CSL to embed Dr Harley within CSL's Global Research Innovation function that is led by Dr Marthe D'Ombrain. During his Fellowship, Dr Harley spent time with both the Australian and Swiss-based Research Innovation teams and worked closely with CSL's Immunology Research Therapeutic Area Lead. Dr Harley's placement in CSL's Swiss R&D site enabled him to develop a greater understanding of European academic research institutes and biotechs developing early-stage therapeutics; how European incubators and seed investors support the creation and growth of start-ups; and the different approaches being applied by large pharmaceutical companies in Europe in partnering with academia and biotechs to accelerate the delivery of drugs to patients.

Gaining a deeper understanding of the drug development process

Dr Harley's project with CSL provided opportunities for him to connect with CSL experts in drug development across research functions including target validation, antibody discovery and engineering, translational research, assay development and pharmacology. This enabled him to build a network within CSL, while gaining a deeper understanding of the drug development process and the key data needed to translate therapeutic programs towards clinical trials.

The REDI Fellowship offered Dr Harley the opportunity to better understand what research questions need to be answered to give researchers the best chance to partner with CSL and other leading biotechs. He gained experience in the various pathways and operational structures concerning research translation and commercialisation in Europe, which highlighted the subtle differences between European practices and those typically observed in Australian academic technology transfer offices.

Fellow uses new-found skills to deliver reviews of more than 100 novel therapeutics

Dr Harley used his new-found skills in drug evaluation to deliver reviews of more than 100 novel therapeutics for the Immunology Therapeutic area, as well as developing capabilities in influencing investment decision-making.

Dr Harley also leveraged new skills in data analysis and business development to establish multiple new relationships with top-tier European academic institutes for CSL to explore. It is envisaged these relationships will enable CSL to grow its access to high-quality early-stage therapeutic collaborations to build out its preclinical pipeline.

CSL's Director, Research Innovation Europe, Dr Nathan Lawless, said during his tenure with the Research Innovation – Europe team in Switzerland, Dr Harley significantly contributed to the development and execution of CSL's Research Innovation strategy in Europe.

CSL expands access to new collaboration opportunities in Europe with top-tier institutes

"As a direct result of his work, we have expanded CSL's access to new collaboration opportunities in new European geographies and are establishing relationships with top-tier academic institutes undertaking cutting-edge research aligned with CSL's therapeutic areas of interest," Dr Lawless said.

The REDI Fellowship experience paved the way for and gave Dr Harley the confidence to create a new business, FlameTree Biotech Consulting, designed to support Australian academic research institutes and biotechs.

Dr Harley said a key barrier to translation of government-funded medical research into new drugs through commercialisation has been a lack of professionals skilled in early-stage drug development and commercialisation in Australia.

REDI Fellowship provided unprecedented opportunities for Dr Harley

"The REDI Fellowship provided me with unprecedented opportunities to connect with a network of CSL's most experienced drug development experts from whom I have gained a deep understanding of how to develop new drugs, what makes a drug an attractive in-licensing and acquisition opportunity, and how to pitch drug development partnership opportunities to large pharmaceutical companies.

"The skills and knowledge acquired during my REDI Fellowship have enabled me to establish a unique consulting firm that specialises in supporting Australian biotechs and academic institutions to accelerate their drug development programs and establish partnerships with large pharmaceutical companies, and will ultimately contribute to strengthening the Australian MTP sector's capabilities in research translation and commercialisation," Dr Harley said.

> **The REDI Fellowship offered Dr Harley the opportunity to better understand what research questions need to be answered to give researchers the best chance to partner with CSL and other leading biotechs.**

Dr Samuel Harley, at the back second from left, with CSL's Research External Innovation team in Melbourne.

Global biotech CSL is fast-tracking new genomics technologies

SPONSOR:
CSL Limited

FELLOW:
Professor Matthew Ritchie

EMPLOYER:
WEHI

KEY FOCUS:
Genomics, personalised medicine, biotech and pharma

Professor Matthew Ritchie, back left with his WEHI research team at CSL Melbourne.

Australian biotech giant CSL is a global player in a fast-moving business. The company's REDI Fellowship helped take an established research relationship with WEHI (the Walter and Eliza Hall Institute of Medical Research) in a new and innovative direction.

CSL is a global leader in the research, development, manufacture and marketing of a wide portfolio of lifesaving medicines.

Its products include blood plasma derivatives, vaccines, antivenom and cell culture reagents used in various medical and genetic research and manufacturing applications. CSL has identified the need for a stratified medicine approach in its drug development and has been using a wide range of genomic technologies to derive mechanistic insights for its drugs and targets.

Genomics offers the potential to develop personalised medicine, specifically targeting individuals. However, integrating new genomic methods and analysis in its R&D pipeline is a time-consuming process. Thanks to a REDI Fellowship, WEHI's Professor Matthew Ritchie was able to join the CSL team to fast-track uptake of new high-resolution genomic approaches.

His work with the company has raised the interest in new genomics technologies at CSL, which are now available for advance preclinical biomarker research across the portfolio of therapeutic areas.

As a bioinformatician and Laboratory Head at WEHI, Professor Ritchie is used to developing statistical models and software to better understand gene regulation in health and disease. The methods he has developed at WEHI have transformed the way researchers analyse genomics data and increased understanding of the gene expression programs that go awry in diseases.

His work at CSL successfully generated a large custom-designed benchmarking dataset for spatial transcriptomics – the groundbreaking molecular profiling method that allows scientists to measure all the gene activity in a tissue sample and map where the activity takes place.

Professor Ritchie also successfully evaluated currently available single-cell fixation methods on blood samples.

CSL's position as a commercial giant gave him a real and practical understanding of the business side of drug development.

> **My experience at CSL has transformed my thinking to be more open to opportunities to commercialise the research.**

Increasing understanding of the drug development pipeline

"This Fellowship has given me a better understanding of the drug development pipeline, including the 'stage gate' system, through which projects pass on their journey to the clinic. Thinking strategically about projects in this way can definitely be applied in academia to better prioritise and allocate the scarce resources available to do research," Professor Ritchie said.

"Commercialisation is a long and expensive process in which research plays a critical role. At various times throughout the year at CSL, 'meeting-free weeks' are scheduled to give scientists back time to focus on research and think creatively about problems. Use of Electronic Laboratory Notebooks to ensure compliance with record keeping standards, which are similar between CSL and WEHI, is also something I plan to explore further upon returning to WEHI.

"My experience at CSL has transformed my thinking to be more open to opportunities to commercialise the research," he said.

Extending existing relationships

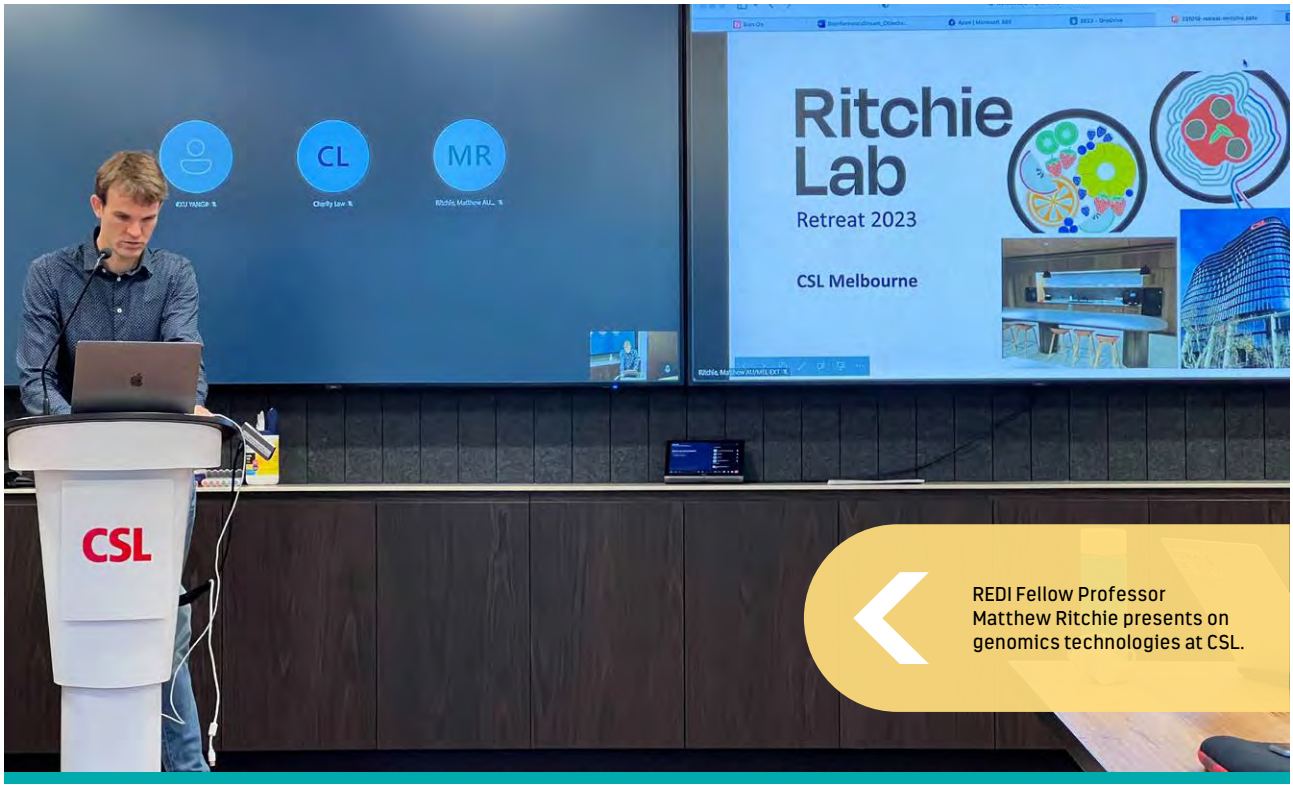
CSL welcomed the focus that came with the REDI Fellowship and the extension of existing relationships between the two organisations. CSL and WEHI have collaborated on many research projects over the past 100 years and, since 2017, there has been a substantial collaboration around data analysis for RNA research.

The company says the Fellowship has enabled collaboration in new directions by allowing the exploration of cutting-edge technologies in single-cell and spatial profiling methods that will become increasingly important in both organisations.

Director of Data Science and AI at CSL Research, Dr Monther Alhamdoosh, said Professor Ritchie attended some of CSL's key scientific meetings.

"He contributed to data analysis and discussions on technology selection and experimental design, to guide generating the right data at CSL and at external collaborators' laboratories. This was used to inform decisions on target validation and help with positioning CSL assets in the right diseases," Dr Alhamdoosh said.

From an academic perspective, several co-authored publications are expected to arise from this Fellowship and the research has been submitted to an international conference – Joint Statistical Meetings (JSM), one of the largest statistical events in the world – for presentation in August 2024.



REDI Fellow Professor Matthew Ritchie presents on genomics technologies at CSL.

CSL connects industry and academia in technology transfer

SPONSOR:
CSL Limited

FELLOW:
Dr Darcelle Thompson

EMPLOYER:
La Trobe University

KEY FOCUS:
Biopharmaceutical business development, portfolio development, market research and analysis

A REDI Fellowship gave Dr Darcelle Thompson, Manager of Business Development and Commercialisation within the Industry Engagement department, La Trobe University, the unique opportunity to be embedded within CSL Limited – providing valuable experiential learning about the business development and licensing operations of a world-leading biopharmaceutical company.

ASX-listed CSL has a dynamic portfolio of lifesaving medicines, including those that treat haemophilia and immune deficiencies, vaccines to prevent influenza and therapies in iron deficiency and nephrology.

These conditions significantly impact the quality of life of people who experience them, as well as placing a serious burden on Australia's healthcare system. For example, there are currently more than 3,200 people diagnosed with various forms of haemophilia nationwide, and there were 252,296 notifications of laboratory-confirmed influenza in 2023.[1,2]

Working on investment and partnering decisions and contributing to global team efforts

Through the REDI Fellowship, Dr Thompson undertook a 12-month project with CSL. Embedded in CSL's Research Innovation team for the first half of the project, Dr Thompson worked on investment and partnering decisions relating to new product opportunities aligned to the CSL Research strategy. In the second half of the Fellowship, Dr Thompson contributed to CSL's Global Licensing team efforts in negotiating partnering agreements for new product opportunities and technologies.

In undertaking these roles, Dr Thompson developed key skills across licence negotiation, competitive landscape analysis, new product identification and evaluation, and pharmaceutical investment and partnering.

Importantly, while working alongside the CSL team, Dr Thompson gained hands-on experience and was able to view key decisions relating to operations, expectations, priorities and positions through an industry lens. She expects these insights will contribute to more streamlined engagement and contract negotiation with industry partners in her ongoing work at La Trobe University. After completing the REDI Fellowship, Dr Thompson hosted an event during which her La Trobe University colleagues presented their research to CSL, specifically targeting the organisation's key areas of interest.

> "I've developed an 'industry lens' to understand industry priorities and provide key insights that can be translated to an academic setting ..."

1. Haemophilia Foundation Australia, Fast Facts – Haemophilia https://www.haemophilia.org.au/bleeding-disorders/faqs/fast-facts/
2. Australian Influenza Surveillance Report – 2023 End of Season Summary https://www.health.gov.au/sites/default/files/2023-12/aisr-2023-national-influenza-season-summary.pdf

Pictured, from left, at the CSL and La Trobe University Engagement Day – Pro Vice-Chancellor (Industry Engagement), La Trobe University, Dr Megan Fisher; REDI Fellow, Dr Darcelle Thompson; and Executive Director and Head of Global Research Innovation, CSL, Dr Marthe D'Ombrain.

Gaining relevant industry knowledge and networks

The REDI Fellowship enabled Dr Thompson to foster networks with a leading group of biotechnology industry professionals. The extremely relevant industry knowledge and networks she gained will be disseminated to her business development and research colleagues at La Trobe University – training the next generation of highly skilled 'tech transfer and business development' professionals.

Dr Thompson said the REDI Fellowship at CSL had been a uniquely rewarding opportunity.

"It has strengthened La Trobe's relationship with the global biotech leader CSL and contributed to driving commercialisation-focused culture change at the university. The experience provided hands-on industry exposure, deepened my skill set, enabled me to build networks with biotechnology industry professionals, and broadened my understanding of CSL's functions.

"I've developed an 'industry lens' to understand industry priorities and provide key insights that can be translated to an academic setting, fostering streamlined industry engagement," Dr Thompson said.

During her time at CSL, Dr Thompson was involved in its Research Acceleration Initiative, which aims to fast-track the discovery of innovative biotherapies and establish partnerships between CSL and global research institutions. Dr Thompson also helped to drive the progress of novel projects along the commercialisation pathway, explained CSL's Director of Global R&D Licensing, Dr Michael Jorgensen.

"Darcelle was an enthusiastic and valuable member of the CSL Global R&D Licensing team," Dr Jorgensen said.

"Over a busy six-month period, she was given broad exposure to several key activities regularly undertaken by the team, including the identification and review of new product opportunities, conducting competitor and new opportunity landscape reviews and the negotiation of several agreements with third parties."

REDI Fellowship brings diversity in thinking and refreshing energy to CSL team

CSL's Executive Director and Head of Global Research Innovation, Dr Marthe D'Ombrain, said the REDI Fellowship was a fantastic opportunity to work with a highly skilled business development professional to undertake important projects that may otherwise be limited by internal bandwidth.

"The program also brings diversity in thinking and provides a refreshing energy to the team. CSL is proud to be part of this important initiative toward upskilling the next generation of leaders in Australia," Dr D'Ombrain said.

CSL immersion provides real-world experience at industry-academia interface of drug research

SPONSOR:
CSL Limited

FELLOW:
Dr Sarah Turpin-Nolan

EMPLOYER:
Monash University

KEY FOCUS:
Pharmaceutical, commercialisation pathway and research portfolio

REDI Fellow Dr Sarah Turpin-Nolan from the Monash Institute of Pharmaceutical Sciences (MIPS), Monash University.

Streamlining the way academics and industry understand each other's priorities is good for business and for patients. Together, global biotech leader CSL and Monash University metabolic expert Dr Sarah Turpin-Nolan showed how an effective partnership can work.

As a global leader in the research, development and manufacture of a wide range of lifesaving medicines, CSL is keen to foster better understanding between industry and academic researchers. It believes by doing so, it can accelerate medical research translation to deliver health benefits.

The focus of Dr Turpin-Nolan's REDI Fellowship at CSL was to immerse herself in the commercial world to experience how new medical therapies are developed through the pharmaceutical industry from laboratory bench to bedside.

Dr Turpin-Nolan, a Research Fellow in the Cellular and Molecular Metabolism team at the Monash Institute of Pharmaceutical Sciences (MIPS), Monash University, was embedded in the company as a member of the Cardiovascular and Metabolic (CV&M) team.

Working with experts in research, product development, clinical and commercial

There, she learned how rare diseases are evaluated to become top priorities for CSL's next drug development program. She worked with experts across Research, Product Development, Clinical Development and Commercial Development at CSL, to gain insights and an overall understanding of the different pieces of the puzzle required to deliver effective clinical drug development.

CSL's Research Portfolio Strategy Lead, Professor Bronwyn Kingwell, said Dr Turpin-Nolan has been actively involved in the assessment of external new product opportunities for potential inclusion in CSL's early Research Portfolio.

"Her deep knowledge of lipid metabolism has been extremely valuable in assessing scientific plausibility and her newly acquired industry training has enabled a strong contribution to assessing multiple aspects of developability.

"Dr Turpin-Nolan's time at CSL broadened her experience and gave her a deep understanding of the type of academic project that makes a strong candidate for industry collaboration and potential product development," Professor Kingwell said.

Embedded in a team at CSL involved participating in ongoing development work

By design, Dr Turpin-Nolan's REDI Fellowship program did not involve focus on a specific commercialisation project. Instead, embedded in a team, she participated in ongoing development work and was exposed to many real-life situations throughout the Fellowship.

Dr Turpin-Nolan worked with the Cardiovascular and Metabolic Therapeutic Area team to contribute to current evaluations and decision-making processes at CSL. This allowed for discussions with multiple team members and CSL subject-matter experts regarding ongoing projects.

As a global leader in the research, development and manufacture of lifesaving medicines, CSL is keen to foster better understanding between industry and academic researchers to accelerate medical research translation to deliver health benefits.

"It has been surprising how much I have learned through performing hands-on tasks as if I were an employee of CSL's CV&M team," Dr Turpin-Nolan said. "This onsite experience at CSL is far more valuable than any course trying to educate academic researchers on how to conduct research programs to align with industry and clinical needs."

CSL leadership team extremely supportive of REDI Fellowship program

Professor Kingwell and the CSL leadership team were extremely supportive of the REDI Fellowship program, Dr Turpin-Nolan said.

"My time embedded with CSL has been an explorative experience, focused on learning by researching, critically evaluating and questioning the clinical pathway to success in a highly supportive atmosphere – the perfect learning environment."

The Fellowship's benefits are now flowing to Monash University and delivering the commercial awareness CSL had hoped for.

On returning to MIPS, Dr Turpin-Nolan is helping her fellow researchers identify the unmet clinical need and restructure research programs to be better positioned for entry into industry agreements. This includes incorporating strategies to reduce risk and account for clinical development considerations to generate more promising cardiovascular and metabolic disease therapies and smoother translation of those research results.

Enhancing commercial opportunities and the industry-academia interface

MIPS Director Professor Chris Porter praised the "excellent program" of REDI Fellowships.

"We are highly supportive of Dr Turpin-Nolan's REDI Fellowship with CSL," he said.

"The experience will not only enhance the commercial opportunities for her own research, but also that of other researchers here at MIPS as she disseminates the Fellowship learnings to help guide MIPS research, education, and commercialisation programs.

"We look forward to strengthening our ongoing relationship with CSL and see this as an extremely valuable opportunity to provide real-world experience at the industry-academia interface."

> "This onsite experience at CSL is far more valuable than any course trying to educate academic researchers on how to conduct research programs to align with industry and clinical needs."

Advancing glycotherapeutic manufacturing capabilities between South Korea and Australia

SPONSOR:
Cytiva

FELLOW:
Dr Alex Smith

EMPLOYER:
The University of Queensland

KEY FOCUS:
Bioprocessing, GMP compliance, manufacturing process optimisation, global collaboration

Dr Alex Smith working on glycotherapeutics manufacturing at Cytiva

Cytiva is a global leader in biotechnology and bioprocessing solutions, enabling the discovery and commercialisation of next-generation therapeutics. Cytiva was awarded a REDI Fellowship for The University of Queensland's (UQ) Glycotherapeutics Research Fellow Dr Alex Smith to work with its Fast Trak™ team and travel to Cytiva's Fast Trak™ Center in Songdo, South Korea.

Glycotherapeutics are reshaping the landscape of medicine, providing novel solutions for a multitude of health conditions and injuries. Glycans, which are a type of carbohydrate, are crucial for many important processes in the body like protein binding, cell communication and inflammation control. Because of this, they're seen as promising new treatments for improved blood supply, bone repair and cell therapies. Clinicians and medical technology companies are looking into using them in real-world medical treatments.

The REDI Fellowship project aimed to use Cytiva's chromatography product portfolio to establish GMP-compliant methodologies for manufacturing glycotherapeutics. This included optimising chromatographic processes and developing GMP-compliant standard operating procedures.

Dr Smith's scientific expertise in glycotherapeutic development, combined with Cytiva's proficiency in GMP methodology development, provided an ideal framework for creating GMP-compliant manufacturing of glycotherapeutics for adoption by the life sciences industry for clinical evaluation and translation.

Additionally, the experience equipped Dr Smith with the industrial and regulatory knowledge to further advance industry-aligned glycotherapeutic manufacturing capabilities in Australia. Leveraging Dr Smith's expertise in glycan structure and analysis, the project successfully adapted Cytiva's process to produce a glycotherapeutic.

As part of the Fellowship, Dr Smith developed a GMP-ready glycotherapeutic downstream bioprocess at Cytiva's APAC Fast Trak™ Center in Songdo, South Korea. The experience has enhanced his skills in process design, scaling up, regulatory compliance and technology transfer. This knowledge will be used to assess and redesign glycotherapeutic manufacturing and characterisation methodologies in Dr Smith's ongoing work at UQ.

Dr Smith will enact the recently devised GMP-compliant procedures and conduct training for laboratory members. These competencies, focused on meeting industry standards, are vital for propelling scientific research forward. They will be especially valuable in upcoming collaborations within UQ's Advanced Cell Therapy Manufacturing Initiative, driving the advancement of GMP-compliant glycotherapeutic products.

Significantly, the project has fortified the relationship between UQ and Cytiva, setting the stage for ongoing collaboration.

Cytiva's Manya Sabherwal, Business Development Manager for Fast Trak™ AU/NZ, explained the emphasis on hands-on process development, validation and analytical insights are all crucial for the successful GMP scale-up of this innovative glycotherapeutic.

Dr Alex Smith (second from right) with Cytiva's APAC Fast Trak™ Center staff in Songdo, South Korea.

"To reinforce and expand on these lessons, we arranged virtual sessions both before and after Dr Smith's time in Korea. This blended approach was designed to ensure an effective transfer of knowledge back to his team at The University of Queensland," said Ms Sabherwal.

"As a result, the knowledge and techniques learned can be practically applied in Dr Smith's Australian laboratory, accelerating the progress of UQ's vital glycotherapeutic research."

Upon completing the project, Dr Smith remarked that the REDI Fellowship provided a significant opportunity to gain crucial comprehension into developing his laboratory's manufacturing processes for the commercialisation of glycotherapeutics.

"I have used Cytiva's product portfolio for the past 15 years, so having firsthand access to this knowledge and expertise has been invaluable. I'm actively incorporating the understandings gained from the Fellowship into my research and sharing the experience with my UQ colleagues," said Dr Smith.

> **Significantly, the project has fortified the relationship between UQ and Cytiva, setting the stage for ongoing collaboration.**

DDM Health launches digital health solution in Australia thanks to REDI Fellowship

SPONSOR:
DDM Health

FELLOW:
Professor Grant Brinkworth

EMPLOYER:
CSIRO

KEY FOCUS:
Digital health platform, chronic disease management, personalised self-management, business expansion, product launch strategy

REDI Fellow Professor Grant Brinkworth from CSIRO Health and Biosecurity.

UK-based DDM Health is an award-winning provider of evidence-based digital health interventions. In 2023, the company was awarded a REDI Fellowship that saw Professor Grant Brinkworth, Senior Principal Research Scientist at CSIRO Health and Biosecurity, embedded within DDM Health to launch a digital health platform in Australia.

Globally, chronic diseases including obesity, type 2 diabetes, cardiovascular disease and arthritis have reached epidemic levels and are an enormous socioeconomic burden.

In 2017–18, 67 per cent (two-thirds) of the adult Australian population was overweight or obese.[1] Meanwhile, an estimated two million people have pre-diabetes and are at high risk of developing type 2 diabetes.[2] In 2021, almost 1.2 million Australians were living with type 2 diabetes, costing the economy approximately $2.3 billion.[3,4]

To combat this challenging health crisis, there is an urgent need for cost-effective, scalable, personalised and remotely delivered programs to support patient self-management of these and other chronic conditions. Such solutions, if available, would have the potential to improve community health and target priority and vulnerable populations, thus reducing inequalities in health outcomes.

Holistic, AI-driven, accessible behaviour-change digital health solution

One solution that could fill this gap is Gro Health – a holistic, artificial intelligence (AI) driven, accessible behaviour-change digital health platform developed by DDM Health. The platform has already been localised and demonstrated in six countries as feasible and cost-effective to manage a range of chronic diseases.

During the Fellowship, Professor Brinkworth shared and used his skills in clinical nutrition, research and commercialisation to adapt the Gro Health program for the Australian market. With his support, the localised platform launched in December 2023 and is now widely available for use by the Australian population.

Although already experienced in the translation of R&D outcomes into practical, real-world solutions, Professor Brinkworth said the REDI Fellowship broadened his understanding of the technical, business and regulatory requirements needed to successfully translate a digital health service across international territories, including Australia.

"The MTPConnect REDI Fellowship has provided me with the opportunity to undertake additional tertiary education and professional workshops in digital health, which I've then been able to apply within an action-based industry environment to translate clinical research outcomes into a practical real-world solution," Professor Brinkworth said.

1. Australian Institute of Health and Welfare: Web Report – Overweight and Obesity https://www.aihw.gov.au/reports/overweight-obesity/overweight-and-obesity/contents/about
2. Diabetes Australia: Pre-diabetes https://www.diabetesaustralia.com.au/about-diabetes/pre-diabetes/#:~:text=Two%20million%20Australians%20have%20pre,of%20developing%20type%202%20diabetes.
3. Australian Institute of Health and Welfare: Diabetes – Australian facts: Type 2 diabetes https://www.aihw.gov.au/reports/diabetes/diabetes/contents/how-common-is-diabetes/type-2-diabetes
4. Australian Institute of Health and Welfare: Diabetes – Australian facts: Health system expenditure https://www.aihw.gov.au/reports/diabetes/diabetes/contents/impact-of-diabetes/health-system-expenditure

A shift in thinking leads to more effective collaborations

"I now have a greater understanding and appreciation of the operational dynamics, performance drivers and priorities of a digital health SME business. Prior to the Fellowship, most of my work experiences have been within large-scale government and academic organisations. By gaining a greater working understanding of how a digital health SME operates, I've now shifted my thinking about business operations, and this will enable me to foster more effective future collaborations with SMEs to assist their needs and requirements."

Importantly, the valuable skills Professor Brinkworth gained during the Fellowship will benefit his broader research network at CSIRO and beyond, as he shares his learnings with colleagues and work teams across the Australian research ecosystem moving forward.

For DDM Health, the successful introduction of Gro Health into the Australian healthcare system is a big win – one that will not only empower individuals and healthcare providers to improve management of chronic disease, but also support the digital transformation of the healthcare system.

In 2024, DDM Health will build out health professional coaching and business teams to support commercialisation of Gro Health in Australia, and to secure service contacts across the healthcare ecosystem. This is expected to increase jobs growth and capacity in the digital health sector, improve uptake of the platform and, ultimately, benefit the health and wellbeing of Australians.

Supporting the translation and commercialisation of health and medical research

DDM Health's Founding CEO and Head of AI and Ethics, Arjun Panesar, believes the success of research funding applications with external researchers will enable the company to build clinical evidence for the Gro Health platform in Australia.

> By gaining a greater working understanding of how a digital health SME operates, I've now shifted my thinking about business operations.

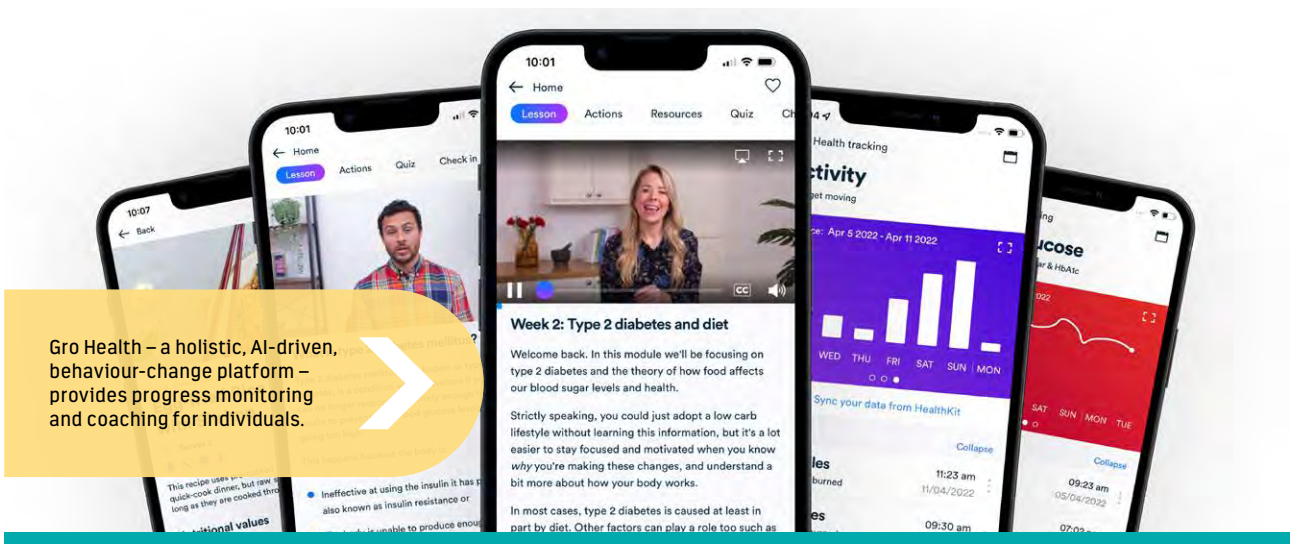
"Building relationships with several stakeholders and private health insurance industry leaders to explore integration of Gro Health into the Australian health system, will support the translation and commercialisation of health and medical research and its capabilities," Mr Panesar said.

For CSIRO and the broader research sector, the project has created a pipeline of new research grant funding opportunities with clinicians and academic researchers, including RMIT University, The University of Queensland, Monash University, Western Sydney Diabetes and the Western Sydney Local Health District.

For Professor Brinkworth, the REDI Fellowship has accelerated meaningful relationships between DDM and the broader Australian research network, to develop and embed effective evidenced-based digital health solutions into Australia's healthcare system to improve community health outcomes.

Specifically, Australian researchers have been awarded a Heart Foundation Vanguard Grant of $140,000 over two years, and a National Competitive Research Grant of $500,000 over three years, to evaluate the effectiveness of Gro Health within the Australian healthcare system.

For DDM Health, the successful introduction of Gro Health into the Australian healthcare system is a big win



Gro Health – a holistic, AI-driven, behaviour-change platform – provides progress monitoring and coaching for individuals.

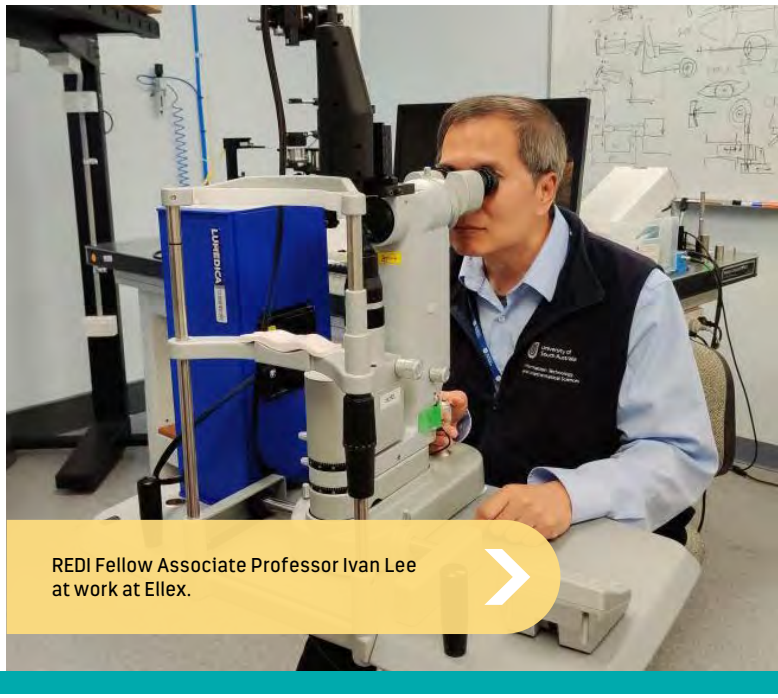
Developing a new optical-guided laser device for glaucoma treatment

SPONSOR:
Ellex Medical

FELLOW:
Associate Professor Ivan Lee

EMPLOYER:
University of South Australia

KEY FOCUS:
Medical technology, machine learning, product life cycle management



REDI Fellow Associate Professor Ivan Lee at work at Ellex.

Ellex is a leading ophthalmic equipment manufacturer that develops ophthalmic lasers for treating eye diseases. In 2022, Ellex was awarded a REDI Fellowship for Associate Professor Ivan Lee from the University of South Australia (UniSA) STEM to address challenges in image processing in the development of a new device for glaucoma treatment.

Glaucoma causes increased pressure in the eye due to failure to self-drain and can cause irreversible vision loss due to damage to the optic nerve. In 2020, the number of people aged 40-80 years with glaucoma worldwide was estimated to be about 80 million – a figure that is expected to rise to more than 111 million by 2040.[1]

For patients who are not responding to eye drops medication for glaucoma, selective laser trabeculoplasty (SLT) is recommended. SLT is a laser procedure used to reduce eye (intraocular) pressure by improving fluid outflow through the eye's natural drainage systems. However, SLT requires highly skilled surgeons to perform the procedure, which limits its uptake.

To overcome this barrier, Ellex is developing an optical coherence tomography (OCT) guided SLT device for automatically treating glaucoma without requiring a specialised surgeon. The new procedure is expected to reduce the treatment time and eliminate discomfort and complications. Plus, it could be performed by a wide range of health professionals, making it vastly more accessible. The OCT detects the progress of the treatment, facilitating laser energy adjustment for optimal results.

A major challenge in developing the device is the need for real-time imaging. A/Professor Lee and the Ellex imaging team – based in France, New Zealand and Australia – created a software solution employing both engineering and machine learning that can analyse 100 images per second. This solution held improved accuracy and computational speed, which was needed to be considered as a potential solution for the final product.

Ellex Engineering Manager David Haarhoff said A/Professor Lee's machine-learning study raised great interest.

"The machine-learning study showed good performance on our dataset; we didn't look in that direction in the past and we should investigate further. We should start testing its performance over the extended dataset and, potentially, make it an alternative to our current approach," Mr Haarhoff said.

1. National Library of Medicine, National Center for Biotechnology Information: Global prevalence of glaucoma and projections of glaucoma burden through 2040: a systematic review and meta-analysis https://pubmed.ncbi.nlm.nih.gov/24974815/#:~:text=In%202013%2C%20the%20number%20of,and%20111.8%20million%20in%202040.

From left, Ellex Engineering Manager, David Haarhoff; Ellex R&D Engineer, Morris Bahrami; and REDI Fellow Associate Professor Ivan Lee at the Ellex manufacturing centre in Adelaide.

During the placement, A/Professor Lee worked as a member of the Ellex project team participating in development activities including discussion sessions, meetings and the module-testing process. He said it was an extremely valuable experience, giving him extensive interactions with industry partners, which he had never experienced through his previous university-industry projects. The Fellowship has also paved the way for further collaboration between Ellex and UniSA.

According to A/Professor Lee, the Fellowship offered a unique opportunity to be directly involved in the development of a new medical product, narrowing the gap between industry and academia.

"I've found great insight in ophthalmology and explored how image processing techniques are used in devices for glaucoma diagnosis and treatment," he said.

While embedded at Ellex, A/Professor Lee said he and his team discussed ideas to collaborate beyond the Fellowship.

"I have learned different interests and priorities from the industrial perspective. In my regular meetings with Ellex's engineering manager, I've also learned from his strategic vision on project planning that supports and extends the existing product line. This is highly inspirational, and the practice may be applied to plan my academic projects," A/Professor Lee said.

Looking ahead, the unique skills developed during the REDI Fellowship will help A/Professor Lee fine-tune the teaching programs at UniSA, including embedded systems design in electrical engineering, laser optics in physics and image processing and software engineering in IT. The learnings he shares with future students are not limited to the clinical context, but also the development process – helping students cultivate practical skills and enriching the industry-teaching-research nexus.

More broadly, the impact of the project could be significant on Australian health outcomes. With the development of guided SLT technology for glaucoma treatment, the REDI Fellowship could be the catalyst for increasing uptake and providing better outcomes for patients.

> **The Fellowship offered a unique opportunity to be directly involved in the development of a new medical product, narrowing the gap between industry and academia.**

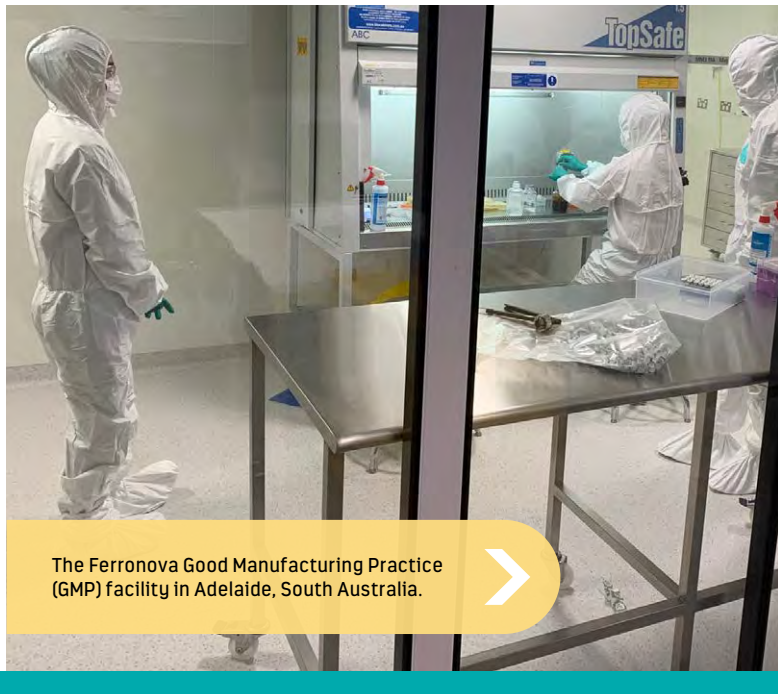
Fast-tracked: First-in-human trials for improved imaging of aggressive brain tumours

SPONSOR:
Ferronova

FELLOW:
Dr Nicole Dmochowska

EMPLOYER:
University of South Australia

KEY FOCUS:
Biotechnology, medical technology, clinical trial management, manufacturing process optimisation, regulatory affairs strategy



The Ferronova Good Manufacturing Practice (GMP) facility in Adelaide, South Australia.

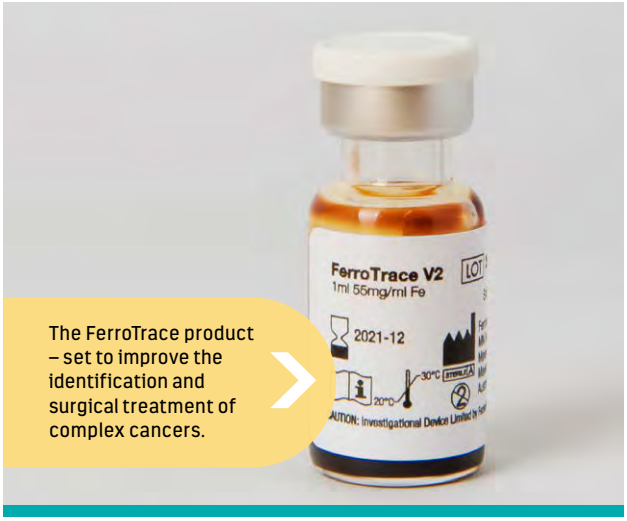
Adelaide-based Ferronova is a cancer diagnostics company developing magnetic nanoparticles to improve the identification and surgery of complex cancers. In 2022, Dr Nicole Dmochowska, a Research Associate from the Future Industries Institute at the University of South Australia (UniSA), was embedded within the organisation through a REDI Fellowship to support the development of cancer imaging technologies.

In Australia, approximately 1,900 patients are diagnosed with brain tumours each year – the most common being glioblastoma, which has an abysmal five per cent five-year survival rate.[1] To improve outcomes, there is a critical need for innovative technologies that can enable more precise targeting of tumours, resulting in more effective treatments with no additional neurotoxicity.

Working with Ferronova's R&D team, Dr Dmochowska drove the development of FerroTrace-FAPi: the first tumour-targeting iron oxide nanoformulation for the improved identification of tumours in MRI. Alongside Ferronova chemists, she learned how the team test and optimise nanoparticle formulations, including scale-up of production and quality control in preparation for in-human testing in 2024.

An introduction to all facets of business operations

While embedded with Ferronova, Dr Dmochowska was introduced to all facets of business operations and industry R&D. This included training in regulatory affairs, Good Manufacturing Practice (GMP) and quality control, as well as participation in weekly manufacturing and relevant strategy meetings. To fast-track clinical translation, she was involved in the development of a Good Laboratory Practice (GLP) safety and toxicity program for FerroTrace-FAPi, in collaboration with various regulatory consultants and contractors.



The FerroTrace product – set to improve the identification and surgical treatment of complex cancers.

1. WEHI: Brain Cancer https://www.wehi.edu.au/research/diseases/brain-cancer/#:~:text=Glioblastoma%20multiforme%20(GBM)%2C%20the,for%20five%20years%20or%20longer.

The Ferronova team with REDI Fellow Dr Nicole Dmochowska, front row, fourth from left.

Ferronova CEO, Stewart Bartlett, explained the *in vitro* and preclinical validation and promising results obtained through the Fellowship have supported the ongoing development of FerroTrace-FAPi – which will enable the company to proceed to first-in-human trials in 2025.

"The REDI Fellowship Dr Dmochowska began in May 2022 working on a program in brain cancer and MRI, has been an important factor in Ferronova securing additional equity and grant funding to further fund the program through to the completion of a Phase Ib clinical trial in glioblastoma.

"Ferronova looks forward to continuing the collaboration with Dr Dmochowska and the University of South Australia," Mr Bartlett said.

UniSA and Dr Dmochowska benefit from REDI Fellowship

UniSA has likewise benefitted from the Fellowship. Dr Dmochowska now has a stronger understanding of the path and preclinical requirements for commencing clinical trials of injectable pharmaceutical products, as well as hands-on knowledge of GMP-compliant manufacturing.

Critically, Dr Dmochowska is now equipped to design preclinical validation experiments that satisfy Therapeutic Goods Administration (TGA) and US Food and Drug Administration (FDA) requirements, which will ensure streamlined translation into clinical trials of successful candidates.

According to UniSA Professor of Bioengineering, Benjamin Thierry, Dr Dmochowska is in a strong position to lead future translational research projects into the clinical trial phase.

Fellow's understanding of Australia's medtech and pharma landscape dramatically increased

"Thanks to the REDI Fellowship, Dr Dmochowska gained important skills and knowledge that accelerated the development of a novel theranostic agent. Importantly, she will be able to apply these new skills in the future and contribute to several translational research programs at the University of South Australia," Professor Thierry said.

In completing the Fellowship, Dr Dmochowska believes her knowledge and understanding of Australia's medtech and pharma landscape has dramatically increased, giving her the tools to fast-track the development of medical devices and drugs from bench to bedside.

"Additionally, this knowledge has empowered me to approach industry with confidence, a skill often difficult for academic researchers to acquire. In fact, in collaboration with other researchers at the University of South Australia, we have already started experiments which use this knowledge and experience to develop novel medicines," said Dr Dmochowska.

> "The REDI Fellowship Dr Dmochowska began in May 2022 working on a program in brain cancer and MRI, has been an important factor in Ferronova securing additional equity and grant funding."

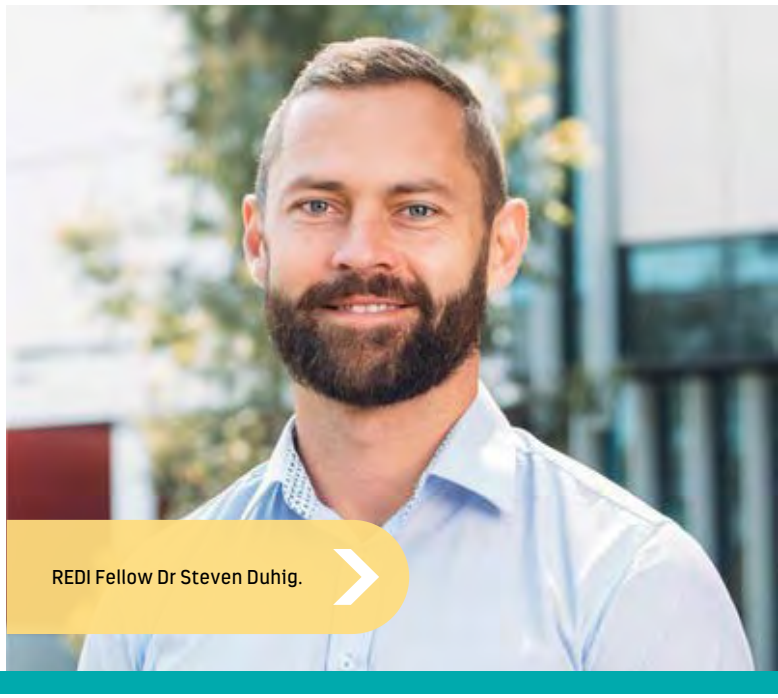
REDI Fellow's sports science expertise enhances shoulder imaging system

SPONSOR:
GE Healthcare (GEHC)

FELLOW:
Dr Steven Duhig

EMPLOYER:
Griffith University

KEY FOCUS:
Medical technology, musculoskeletal imaging, global collaboration, product production pipeline



REDI Fellow Dr Steven Duhig.

Global medical technology and diagnostics leader GE Healthcare (GEHC) is developing an ultrasound application for shoulder imaging that is a simpler and cheaper alternative to an MRI scan. A REDI Fellowship recruited Dr Steven Duhig, a specialist in musculoskeletal injuries from Griffith University, to contribute his sports science expertise to the project.

MRI is currently the gold standard for musculoskeletal imaging, but it is expensive and limited to specialised facilities. Providing a quick, cost-effective and accessible ultrasound alternative would substantially reduce costs and improve diagnosis times for many individuals.

GEHC, a global leader in medical technology and diagnostics, has developed the Shoulder Toolkit ultrasound application to provide a solution. The goal of Dr Duhig's REDI Fellowship was to evaluate musculoskeletal imaging by assessing confidence and satisfaction of healthcare practitioners across novice and expert ultrasonography skill levels.

The Shoulder Toolkit – a simpler technique to make advanced imaging accessible

The REDI Fellowship enabled the company to bring in Dr Duhig, a specialist in musculoskeletal injuries, aiming to democratise musculoskeletal imaging by assessing its potential in allowing improved confidence and satisfaction in healthcare practitioners with basic ultrasonography skills while examining how it can value-add to experts' workflow.

The Shoulder Toolkit is a simpler, user-friendly application that can make advanced imaging accessible for shoulders injured during sports and other activities. It is designed to be intuitive and effective for users with varying levels of ultrasound experience. This addresses the limitations of MRI in terms of cost and accessibility and may lessen the demand for specialised radiology clinics.

By making advanced musculoskeletal imaging accessible to exercise physiologists, sports trainers, physiotherapists and soft-tissue therapists, the project stands to revolutionise the way musculoskeletal injuries and conditions are diagnosed and managed. This also translates to better clinical outcomes and reduced waiting times for patients.

Gaining skills and a deeper understanding of product validation

GEHC specialises in a wide range of healthcare solutions including medical imaging, diagnostics, patient monitoring and pharmaceuticals. Focusing on leveraging advanced technology to enhance patient outcomes and healthcare efficiency, GEHC's extensive product portfolio serves healthcare professionals and patients across the world.

Dr Duhig's PhD included a research focus on hamstring strain injuries. His current research explores the connections between muscle architecture and injury risk, as well as performance enhancement and injury prevention in various sports including Australian Rules football, soccer, rugby league, swimming, track and field and surfing. His research goal is to provide practical applications in sport and exercise that directly improve clinical practice and athlete outcomes.

Dr Duhig benefitted from the Fellowship at GEHC by gaining skills in commercialisation and a deeper understanding of product validation studies, data analysis and user experience assessments.

Presenting research in the US and broadening professional capabilities

The Fellowship allowed Dr Duhig to travel, attending the National Strength and Conditioning Association conference in Las Vegas, where he presented his ultrasound research. He also made connections in Adelaide with sonographer academics, further broadening his professional network.

Dr Duhig said the REDI Fellowship has been transformative, expanding his professional capabilities and aligning his skills with industry needs.

"It has created tangible opportunities for further research collaborations, industry engagements and potential commercialisation ventures. I was introduced to other GEHC team members, and we will continue to collaborate in medical imaging research.

"My enhanced understanding of research translation and commercialisation is directly applicable to my future work in sports performance and injury prevention," Dr Duhig said.

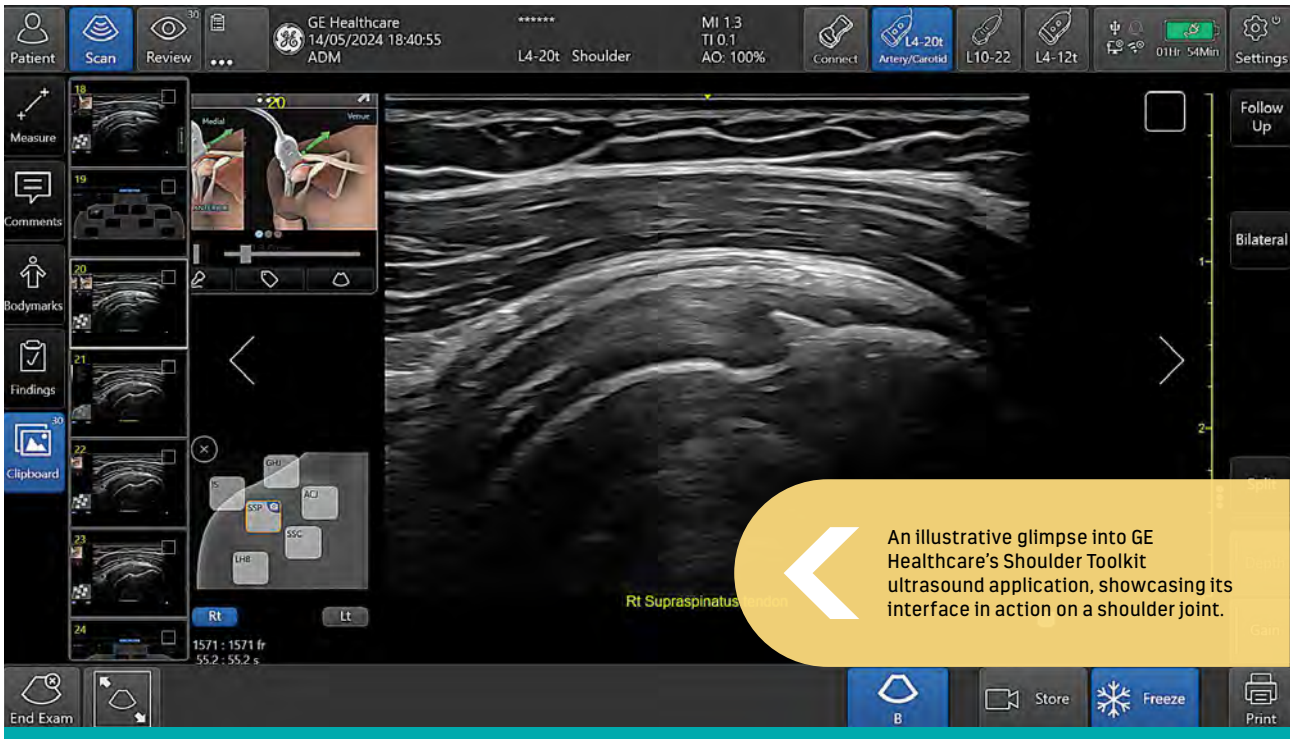
> **By making advanced musculoskeletal imaging accessible to exercise physiologists, sports trainers, physiotherapists and soft-tissue therapists, the project stands to revolutionise the way musculoskeletal injuries and conditions are diagnosed and managed.**

Benefits for Griffith University and accelerated research translation

Griffith University's Sport and Exercise team is recognised for its excellence in blending academic research with practical application in sports science. Dr Duhig expects his experiences during the Fellowship to benefit Griffith through insights into the benefits of an interdisciplinary approach in R&D, and the understanding of how effective partnerships between academia and industry can lead to innovative solutions and accelerated research translation.

"I can provide guidance on overcoming the unique challenges that arise in collaborative projects, especially those involving cutting-edge technology and new research methodologies. I want to contribute to policy development and best-practice guidelines in sports medicine and diagnostic imaging, leveraging the insights and expertise gained from the REDI Fellowship," Dr Duhig said.

GEHC's ANZ Regional Research Manager, Dr Daneh Turner, added, "The REDI Fellowship has provided a great opportunity to connect and work alongside a clinical academic with specialised knowledge and expertise that can assist in better understanding our customers, so that we can bring the most advanced technical solutions to them. At the same time our REDI Fellow has gained an insider's perspective of the importance of research to development and uptake of the latest medical technology."



An illustrative glimpse into GE Healthcare's Shoulder Toolkit ultrasound application, showcasing its interface in action on a shoulder joint.

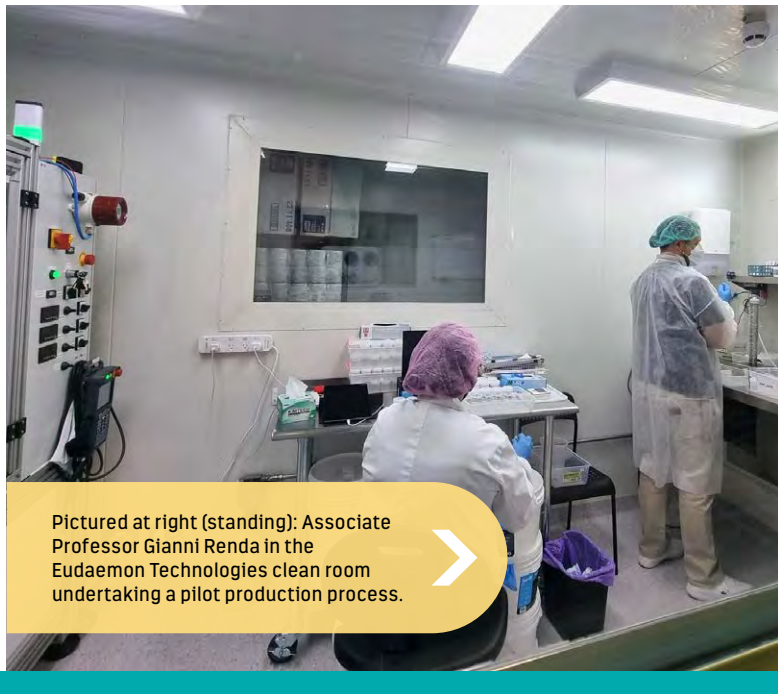
Designer brings the human touch to new medtech at IDE Group

SPONSOR:
IDE Group

FELLOW:
Associate Professor Gianni Renda

EMPLOYER:
Swinburne University of Technology

KEY FOCUS:
Medical technology, Quality Management System, product design, manufacturing process, project development



Pictured at right (standing): Associate Professor Gianni Renda in the Eudaemon Technologies clean room undertaking a pilot production process.

A unique REDI Fellowship for a designer rather than a scientist helped IDE Group and its partner Eudaemon Technologies to incorporate user-centred approaches into the company's Quality Management System.

IDE Group partners with medtech ventures to develop and commercialise new medical technologies, which can form the cornerstone of new businesses.

One such partner, Eudaemon Technologies, is working to revolutionise the safe sex industry by creating innovative, skin-like condoms from tough hydrogels. The partnership has driven the successful translation of design requirements through to an efficient manufacturing process.

Refining pilot processes to meet the demands of clinical trials and compliance

Eudaemon had created pilot processes, which needed further refinement to meet the demands of the clinical trial and ISO compliance, when industrial designer Associate Professor Gianni Renda from Swinburne University of Technology joined IDE through a REDI Fellowship.

A/Professor Renda is Chair of the Department of Architectural and Industrial Design at Swinburne. His primary research focus is investigating ways that design can empower the user in the field of health, disability and ageing. Having a Fellow with a product design background and not science is unique within the REDI program, but ideal for the project to identify areas where user-centred approaches could be integrated within the Quality Management System (QMS).

The Fellowship has helped Eudaemon and IDE further refine the product and its manufacturing process, while giving A/Professor Renda the practical experience to return to the university and begin training the next generation of product designers to engage more meaningfully with the medical technologies industry. The Fellowship provided opportunities for specialist ISO training through SeerPharma, internal ISO training through IDE Group and site visits to Enersol, a leading testing laboratory specialising in condom verification. He has also forged a strong relationship with Aikenhead Centre for Medical Discovery (ACMD), Australia's premier biomedical engineering research translation centre.

Eudaemon aims to reduce incidences of infection and unintended pregnancy

A report from Organon suggested that 40 per cent of pregnancies in Australia in 2020 were unintended, with a cumulative direct and indirect cost of $7.2 billion dollars.[1] The use of a condom during intercourse can help prevent sexually transmitted infections such as HIV, chlamydia, gonorrhoea and syphilis, as well as prevent unintended pregnancies. The Kirby Institute estimates that 28,870 HIV-infected people are living in Australia (2022), with its data also suggesting that 49 per cent of infections are attributed to male-to-male intercourse.[2] By engaging with consumer needs at the initial design stage and throughout the process, to provide a natural-feel condom product, Eudaemon hopes to reduce incidences of infection and unintended pregnancy, through increased condom use.

1. https://www.organon.com/australia/wp-content/uploads/sites/16/2022/09/ORG01_Report_FINAL_28June2022.pdf
2. HIV | Data @ Kirby Institute (unsw.edu.au)

A/Professor Renda provided IDE and Eudaemon with a context of how its internal ISO processes compared to what was being taught in academic settings, and identified areas where more user-centred development can occur within the regulatory framework.

This helped IDE and Eudaemon to better understand user needs within consumer-facing medical devices, as well as a way to record this within the QMS. This will be more cost-effective when conducting expert interviews and initial project development.

A "transformative" experience for the REDI Fellow

By the end of the Fellowship, a successful preclinical trial had been established, manufacturing and storage processes within Eudaemon were more closely aligned with ISO 13485, and a QMS was being set up within the company, taking human factors more into account. Through the REDI Fellowship, further product testing, design refinement and preclinical trials were undertaken. The results of these remain commercial-in-confidence, however, Eudaemon reports that responses have been overwhelmingly positive.

A/Professor Renda described his experience with IDE and Eudaemon as "transformative".

"I was able to not only learn new processes and skills, but also bring a unique way of looking at problems to identify novel solutions that fit within a heavily regulated environment. Understanding this has allowed me to better advise and engage with academia and industry," he said.

Showing IDE and Eudaemon a new way to identify specific user needs

IDE Group's Connected Care Group Director, Dr Andrea Ranzoni, said A/Professor Renda showed IDE and Eudaemon a new way of identifying specific user needs.

"This has allowed us to be more critical within the discovery stage of product development, ensuring that we continue to develop effective outcomes for both our clients and the end users of the products we design."

Eudaemon Technologies' Executive Director of Operations, Dr Simon Cook, said A/Professor Renda had helped the company look at problems from an unfamiliar perspective.

"Having Associate Professor Renda work with Eudaemon during this time really helped us better understand where we could improve our processes. He was eager to learn lab processes and be part of the production, running experiments and formalising a lot of our pilot processes as we move towards clinical trials," Dr Cook said.

Engaging more fully with staff and students at Swinburne and industry beyond

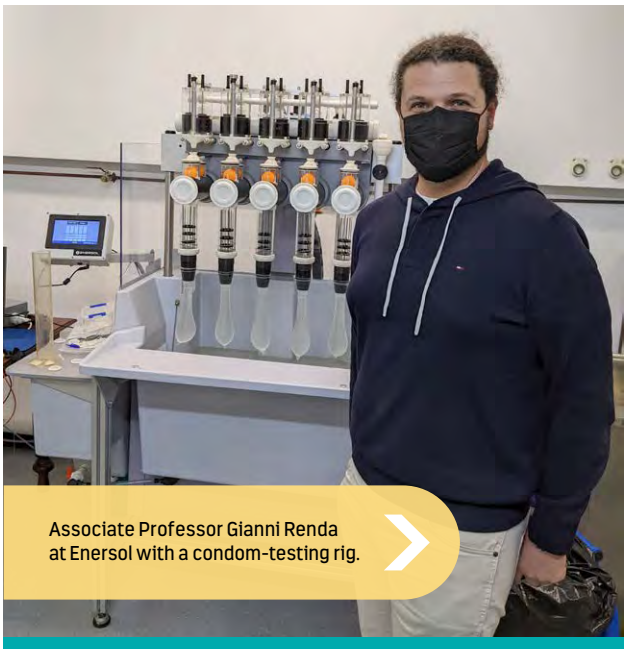
Dean of Swinburne University's School of Design and Architecture, Professor Blair Kuys, said A/Professor Renda has returned from his Fellowship.

"He is taking a leading role in mentoring staff and students, bolstering the medical and health capability within the School of Design and Architecture, which is terrific to see," Professor Kuys said.

Since the Fellowship, A/Professor Renda has used this experience to engage more fully within the medical technology space through engagements with ACMD, the MedTechVic hub at Swinburne and through an additional PhD supervision in the field of assistive technology. In addition, a representative from IDE Group is now a panel member for the Course Advisory Committee for the Bachelor of Industrial Design at Swinburne, ensuring the educational and training links between the companies are formalised and continue to add value for everyone involved.

> **A/Professor Renda showed IDE and Eudaemon a new way of identifying specific user needs.**

Pictured from left: The project team onsite – Associate Professor Gianni Renda, Swinburne; Dr Andrea Ranzoni, IDE Group; Ben Dawson, IDE Group; Dr David Shepherd, Eudaemon; and Dr Simon Cook, Eudaemon.



Associate Professor Gianni Renda at Enersol with a condom-testing rig.

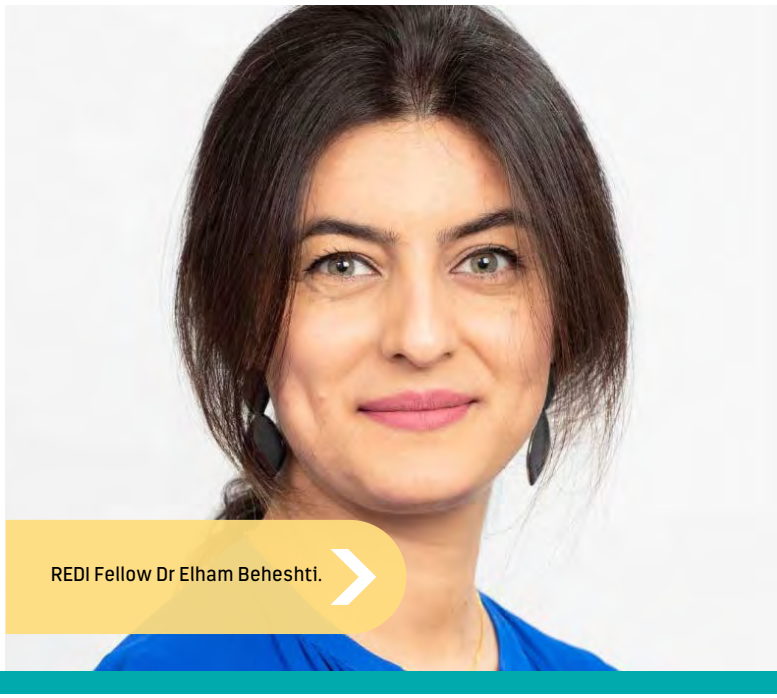
Bridge-building between investors and medical researchers

SPONSOR:
IP Group Australia

FELLOW:
Dr Elham Beheshti

EMPLOYER:
Asbestos and Dust Diseases Research Institute

KEY FOCUS:
Global collaborations, investor mindset, life science investments



REDI Fellow Dr Elham Beheshti.

Global venture capital leader IP Group has created lasting bonds with a range of research scientists and university technology offices, thanks to a unique new partnership made possible by a REDI Fellowship. The Fellowship saw Dr Elham Beheshti, from the Asbestos and Dust Diseases Research Institute (ADDRI), embedded in the company as a hands-on investment analyst for 12 months.

IP Group was established in the UK with a mission to evolve great ideas into world-changing businesses – to bridge the gap between cutting-edge scientific innovation and commercialisation. Dr Beheshti was an inspired choice for a REDI Fellowship that embedded her with a team of seasoned investment managers and partners, helping them assess opportunities from Australian research institutions.

Now a global leader with offices around the world, IP Group pioneered the concept of long-term partnerships with universities. It has created more than 300 university spin-off companies and invested more than $2 billion in companies that are collectively valued at more than $10 billion.

IP Group receives hundreds of enquiries each year from researchers wanting to commercialise their research, but it often reports significant gaps between the information presented by researchers and that required by potential venture capital backers.

IP Group recognised the strong commercial potential of Dr Beheshti's research

Dr Beheshti joined ADDRI as Principal Scientist with a decade of experience in medical sciences and a pioneering role in extracellular vesicles research. Her primary research has been focused on extracellular vesicles, nano-sized vesicles released by cell, which serve as a crucial tool for intercellular communication, presenting remarkable opportunities in liquid biopsy, novel therapeutics and targeted drug delivery system. Dr Beheshti is determined to introduce a fresh perspective into the research on asbestos- and dust-related diseases, particularly mesothelioma and silicosis. So, when IP Group recognised the strong commercial potential of Dr Beheshti's research, it offered to host her Fellowship to educate her in the 'investor mindset'.

Head of Life Sciences at IP Group Australia, Dr Siro Perez, said Dr Beheshti is a model example of how the IP Group hopes REDI Fellows will contribute to the research commercialisation ecosystem, serving as 'ambassadors' or 'liaisons' with the broader research community and helping demystify what investors do.

"We've already seen her sharing her learnings with other researchers during our university outreach activities, and we're certain she will continue adding value to the research commercialisation ecosystem for many years to come," Dr Perez said.

Gaining deep experience of the many steps involved in creating spin-off companies

At IP Group, Dr Beheshti gained a deep experience of the many steps involved in creating spin-off companies, navigating regulatory and licensing hurdles and the multiple other challenges in the life of a medical start-up.

She was immersed in the multifaceted challenges and opportunities of life science investments – meeting IP Group clients in Australia and the UK, attending biotech conferences and visiting world-leading laboratories including the MRC Epidemiology Unit at the University of Cambridge in the UK.

Dr Beheshti said the networks she built up over the year of her Fellowship will be fundamental in navigating the complexities of medical research commercialisation.

"I believe this Fellowship could be an Australian first, perhaps even a global first, in terms of enabling me to be immersed in the inner workings of a global venture capital firm," she said.

Fellowship provides a full-time immersion in day-to-day work of IP Group

Unlike conventional alliances between researchers and VC firms, which typically involve the technology transfer office (TTO) at a university or research institute, Dr Beheshti's REDI Fellowship offered a full-time immersion in the day-to-day work of the IP Group, which has been finding and commercialising medical innovations out of the world's leading universities for more than 20 years.

As well as building a new network within the biotech investment community, Dr Beheshti's Fellowship provided a direct boost in dialogue between The University of Sydney and the IP Group, which she hopes will elevate its chances of investing in the university's research.

"After gaining a better understanding of the requirements from the IP Group, I started attending TTO meetings between the IP Group and The University of Sydney, highlighting key points that could be improved in terms of communication and the timeline for presenting a project to the company," she said.

"I've conveyed this feedback to The University of Sydney's TTO team, Director of Partnerships and the Associate Dean of Research at the Faculty of Medicine and Health. I also organised a meeting for the university team to be introduced directly to the health science partner at IP Group – and I'm hopeful to continue working with both entities to overcome this challenge."

Elevated assessment and more dynamic thinking driving research to exciting new level

ADDRI's CEO Kim Brislane is heartened by what she has seen.

"Since her Fellowship, Dr Beheshti is considering the whole project picture and examining all influences including commercial prospects and real patient outcomes. Her assessment is elevated, and her risk and opportunity antennae are becoming more finely tuned.

"Dr Beheshti now brings more dynamic thinking to the institute. I expect she will take the best of what she has learned – but she'll make it her own – to significantly drive the research at ADDRI to an exciting new level," concluded Ms Brislane.

> **This Fellowship could be an Australian first, perhaps even a global first, in terms of enabling me to be immersed in the inner workings of a global venture capital firm.**

Dr Elham Behesti with the Hon Mark Butler, Minister for Health and Aged Care touring the Biaggio Signelli Laboratory at ADDRI which is dedicated to research to combat asbestos and dust-related diseases.

New investment skills boost chances to commercialise an Australian cancer therapy

SPONSOR:
IP Group Australia

FELLOW:
Associate Professor Jason Lee

EMPLOYER:
QIMR Berghofer Medical Research Institute

KEY FOCUS:
Biotechnology, investor priorities, commercialisation journey, venture capital investment strategies

REDI Fellow and breast cancer researcher Associate Professor Jason Lee.

Visionary breast cancer researcher, Associate Professor Jason Lee, had recently progressed a novel enzyme-blocking target to the stage where he was ready to take the first steps towards commercialisation. But he had no idea just how far a REDI Fellowship at the IP Group would take him on his commercialisation journey.

As the head of the Epigenetics and Disease Group at QIMR Berghofer Medical Research Institute, A/Professor Lee has established a reputation as one of Australia's most progressive breast cancer researchers. He has been developing new substances that block certain enzymes and may help prevent cancer cells from growing. The strong promise of this work to produce an effective cancer therapy encouraged A/Professor Lee to explore its commercial potential.

The chance to experience medical investment embedded in IP Group

A REDI Fellowship gave him the chance to experience medical investment as an analyst embedded in IP Group's Life Sciences team. There he evaluated applications from researchers like himself to learn precisely what biotech investors are looking for.

Established in the UK, IP Group is an intellectual property commercialisation company with more than 20 years of experience in translating breakthrough discoveries from academic institutions. In Australia, IP Group has a partnership with the Group of Eight universities and receives more than 600 opportunities from its partner universities annually. IP Group has invested in 14 companies to date, seven of them in the life sciences sector.

As one of the very few investors operating in the early-stage space, spinning off and managing companies directly out of research institutions, the investment team has a unique understanding of how to interface with technology transfer offices (TTOs) and researchers to create successful companies.

Results of Fellowship were both remarkable and instantaneous

The results of the Fellowship were both remarkable and instantaneous. Even before the Fellowship was completed, A/Professor Lee had secured several new grants for his QIMR drug development work, together with non-dilutive funding from the 2022 NHMRC Development Grant scheme. These funds will not only help progress his research but will increase the chance of attracting local venture capital (VC) funding to support his dream of launching a spin-off company from his laboratory.

During his 12 months at the IP Group, A/Professor Lee was involved in virtually every aspect of the evaluation of research opportunities and the selection of partnership models – including developing investment cases, performing due diligence and market analyses, evaluating a product's value and 'competitive differentiation' and collaborating in the creation and support of a portfolio of spin-off companies.

Head of Life Sciences at IP Group Australia, Dr Siro Perez, said through the REDI Fellowship, A/Professor Lee gained a more nuanced understanding of how investors assess projects.

"He recently mentioned that he had a much better understanding now for what constitutes 'differentiation' when comparing projects to other drugs in development or in the market. This is a concept that we find a lot of researchers struggle with – but it is fundamental to our investment decision-making," Dr Perez said.

IP Group's work attracts interest across Asia Pacific

For both the IP Group and QIMR Berghofer, the Fellowship was equally rewarding.

Having A/Professor Lee embedded in its team helped attract interest in the company's work from several scientists and business development teams across the Asia-Pacific region. Start-ups in Singapore and South Korea have expressed interest in collaborating with the IP Group and A/Professor Lee is currently supporting the Business Development Unit at QIMR to broaden its investment coverage in the region.

During the REDI Fellowship, A/Professor Lee also undertook a 10-week online Venture Capital University course, jointly set up by Berkeley Law and NVCA, which provided fundamental concepts in VC investment strategies and introduced him to a network of investors across the US.

"I feel I am much more comfortable now recognising new investment-ready opportunities by analysing their investment criteria – including IP, addressable markets and competitive differentiation – and how far advanced the opportunity needs to be in various aspects of these criteria to progress discussions further.

"By meeting researchers who have pitched to the IP Group for investment, I've also developed a greater understanding of how they're approaching commercial development of their research findings. This knowledge will have a positive impact on the progress of my own drug development program at QIMR Berghofer and developing a solid business plan for industry-ready technologies," A/Professor Lee said.

Increasing commercial success across QIMR Berghofer

Since the Fellowship, A/Professor Lee has been able to share his expertise in investor pitching and priorities with other researchers who are progressing early-stage technologies at QIMR, as well as the contacts of several proactive contract research organisations (CROs) that can potentially support its commercial aspirations.

"I will be working closely with our Business Development Unit to undertake pre-due diligence and gain firsthand experience of how internal decisions are made at QIMR to progress investment discussions.

"Once a decision to progress discussions has been made, I will be part of a team identifying key risks and then addressing them through business and investment workplans for industry-ready technologies, which I hope will ultimately increase commercial success across QIMR Berghofer," A/Professor Lee said.

> **Through the REDI Fellowship, Associate Professor Lee gained a more nuanced understanding of how investors assess projects.**

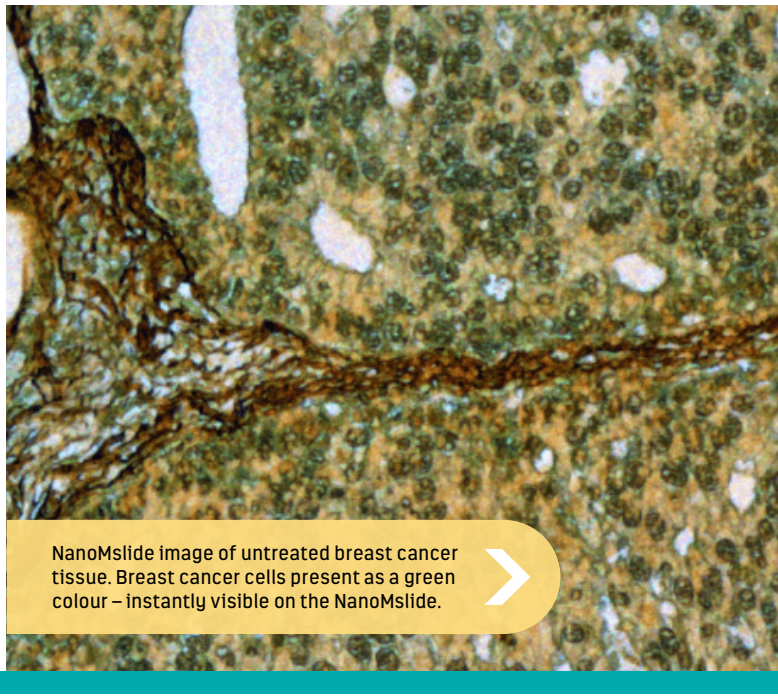
New Australian medtech spin-out aims to improve detection of early-stage cancers

SPONSOR:
Leica Biosystems Melbourne Pty Ltd

FELLOW:
Professor Brian Abbey

EMPLOYER:
La Trobe University

KEY FOCUS:
Medical technology, diagnostic, manufacturing/market validation and spin-out



NanoMslide image of untreated breast cancer tissue. Breast cancer cells present as a green colour – instantly visible on the NanoMslide.

NanoMslide is a patented nanotechnology coating for glass which enables the accurate identification of cancer cells. Co-inventor Professor Brian Abbey at La Trobe University has been developing the new technology that turns a conventional microscope slide into a powerful new tool for cancer diagnosis. A REDI Fellowship at Leica Biosystems (LBS) helped provide Professor Abbey with understanding of cancer pathology and advanced staining techniques, validated the market potential of his invention and gave the company the first opportunity to assess the technology.

As a biosensors program leader within La Trobe Institute for Molecular Science (LIMS) and Professor of Physics at La Trobe University, Professor Abbey has been using his skills in nanotechnology and optical physics to lead development of new technologies for biological imaging and sensing for the past 16 years.

NanoMslide delivers massive optical contrast enhancement, providing instant detection of cancer cells via a nanotechnology-induced colour contrast. The teams patented surface-coating technology effectively transforms a conventional microscope slide into a powerful new tool for cancer diagnosis, allowing pathologists to visually distinguish abnormal from healthy cells.

Diagnostic errors represent a significant cost to the economy

Misdiagnosis, particularly of early-stage cancers, leads to either over treatment or false negatives and significantly impacts the lives of many Australians. These diagnostic errors represent a significant cost to the economy. For example, over- and under-treatment costs for breast cancer are approximately $40,000 per patient per error.[1]

The NanoMslide technology has now been applied to the analysis of early-stage breast cancer and the patented technology will be further commercialised, validated and marketed by a La Trobe University spin-out company, AlleSense.

The collaboration between Professor Abbey and LBS helped to inform the establishment of a clear quality management system and a pathway to scale-up manufacture and distribution, as well as providing additional market validation. The preliminary assessment by LBS suggests a significant opportunity for NanoMslide within the field of pathology and new avenues for product development.

Hosting REDI Fellow at LBS was key to understanding how NanoMslide could be compatible

LBS is a global leader in tissue-based cancer diagnostics and workflow solutions with a portfolio of products from biopsy to diagnosis. Approximately 30 per cent of the world's cancer patients from more than 160 countries currently rely on LBS systems to determine their diagnosis. Hosting the REDI Fellow

1. Elmore, J.G., G.M. Longton, P.A. Carney, B.M. Geller, T. Onega, A.N.A. Tosteson, H.D. Nelson, M.S. Pepe, K.H. Allison, S.J. Schnitt, F.P. O'Malley, and D.L. Weaver, *Diagnostic Concordance Among Pathologists Interpreting Breast Biopsy Specimens*. JAMA, 2015. **313**(11): p. 1122-1132.

at LBS was key to understanding how the NanoMslide could be compatible with the current automated workflows at the company, and to get the opportunity to assess and provide feedback on the technology from a commercial perspective.

During the fellowship, and thanks to LBS support, Professor Abbey's team progressed five of its patents to national phase, with several patents now fully granted in key territories such as the US and Australia. By the end of the fellowship the team has been able to progress its NanoMslide technology from Technology Readiness Level (TRL) 4 to TRL 5 (bordering on TRL 6), with a clearly defined path to market.

The product, which is being commercialised by AlleSense, has now undergone first assessment by LBS, helping to grow investor confidence in the technology and providing a roadmap for LBS to work with other spinouts and significantly advance new research and innovations.

Viewing technology through a commercial lens and gaining insights in the US

The fellowship allowed Professor Abbey to view his technology through a commercial lens. During the fellowship, he travelled to the US where he delivered a public lecture on his NanoMslide technology and engaged with several senior US pathologists and business leaders. He gained insights into the differences between reimbursement for diagnostics in the US versus Australia and how pathology practices differ between the two countries. Pathologists in the US also highlighted the significant potential they saw for this technology in terms of digital pathology.

The visit to the US and Professor Abbey's engagement with overseas pathologists, led him to adjust NanoMslide's commercialisation pathway and provided valuable knowledge into regulatory approval from the US Food and Drug Administration for the specific breast cancer diagnostic.

Through the new skills obtained during this program, Professor Abbey's team has now helped to establish a commercialisation community at La Trobe University. Over the year, he led four workshops focused on commercialisation and knowledge sharing with more than 100 attendees at the university – ranging from early-career to established and productive researchers.

LBS is highly selective with partners – need to have potential to fulfil company vision

Former Senior Innovation Program Manager at LBS, Zbigniew Midouszewski, said the company is highly selective with partners.

"Partners are chosen with a focus on supporting new technologies – such as NanoMslide – that have the potential of fulfilling our company vision of enabling clinicians to efficiently provide patients with a highly confident diagnosis within 24-hours of biopsy. More broadly than just technical content, we also highly regard AlleSense as being backed by a strong professional team.

"We feel this REDI project addresses important questions around the real-world application of the technology within pathology," Mr Midouszewski said.

Professor Abbey, who said he will focus on achieving the commercial milestones for AlleSense while managing his academic career, recently secured a $2.9 million senior leadership fellowship from the NHMRC to research additional cancer applications for NanoMslide.

Summing up, Professor Abbey said, "The REDI Fellowship program has been instrumental in progressing the TRL of our cancer diagnostic. It has contributed to increasing investor confidence, providing me with new comprehension into scale-up manufacturing and regulatory strategy, and has supported my formation of AlleSense, a new company founded with the goal of eliminating misdiagnosis of early-stage cancers."

AlleSense Co-Founder Dr Eugeniu Balaur, (far left), NanoMslide co-inventor Professor Belinda Parker (fourth from left), Professor Brian Abbey (fifth from left) and former Vice-Chancellor of La Trobe University, Professor John Dewar (far right).

A malaria product development partnership in Geneva boosts clinical capabilities in Melbourne

SPONSOR:
Medicines for Malaria Venture (MMV)

FELLOW:
Dr Paola Favuzza

EMPLOYER:
WEHI

KEY FOCUS:
Development pipeline, malaria, global collaboration, clinical trial

REDI Fellow Dr Paola Favuzza checking on malaria-carrying mosquitos.

Recent advances in the prevention and treatment of malaria underscore the critical importance of global research partnerships to tackle this deadly disease. Medicines for Malaria Venture was awarded a REDI Fellowship to take on leading malaria researcher Dr Paola Favuzza for hands-on experience of a product development partnership based in Switzerland.

Since its foundation in 1999, as a not-for-profit public-private partnership, Geneva-based Medicines for Malaria Venture (MMV) has introduced 11 new antimalarial drugs, which have saved an estimated 2.7 million lives. A REDI Fellowship matched the organisation with Dr Favuzza from the Walter and Eliza Hall Institute (WEHI) to bring her expertise in malaria biology to help drive new drug candidates forward.

MMV follows a 'product development partnership' model which combines its cutting-edge research and clinical practice with globally sourced expertise. MMV partners with academic institutions, pharmaceutical industry partners, governments and NGOs to progress a pipeline of 65 antimalarial medicines – many of which target children, pregnant women and other vulnerable populations.

Fellow engaged in a diverse array of activities and projects at MMV

Instead of being restricted to a single project, Dr Favuzza was engaged in a diverse array of activities and projects during her year-long Fellowship. This approach provided her with a comprehensive and holistic understanding of the intricacies involved in the different stages of research, development and innovation.

Dr Favuzza said it was an incredible journey of growth and opportunity.

"This experience has not only shaped my career but has also provided a unique insight into the industrial environment. I strongly believe that more fellowships of this nature should be awarded to early-career scientists, fostering their development and exposing them to the dynamic world that awaits," Dr Favuzza said.

For MMV, Dr Favuzza's skills proved an asset to the development of treatment candidates. At WEHI, she is the Project Manager of the WEHI-MSD-Wellcome Trust research program, which identified an antimalarial drug candidate that is currently progressing to first-in-human trials and volunteer infection studies.

Fellow's profound knowledge of malaria biology was instrumental in evaluating new therapies

MMV Vice-President and Head Translational and Modelling, Professor Jörg Möhrle, said the organisation welcomed this expertise.

"We were very happy to have Dr Favuzza as a colleague. Her profound knowledge of malaria biology was instrumental in the *in vitro* evaluation of new antimalarial combination therapies," Professor Möhrle said.

The Fellowship placed Dr Favuzza at the cutting-edge of several global clinical trials, as well as partnerships with pharmaceutical companies, work on regulatory approvals and preparations for first-in-human trials and volunteer infection studies.

MMV Associate Director Program Leadership and Strategy, Dr Benoît Bestgen, described the breadth of her experience at the organisation.

"Dr Favuzza has been part of the project and study team of one compound, which is currently in Phase I in collaboration with a pharmaceutical company," said Dr Bestgen.

Learning from all parts of the studies from the sponsor perspective

"She immersed herself in a first-in-human study in the UK and an induced blood-stage malaria challenge study in Brisbane, quickly capturing the key aspects. She learned from all parts of the studies from the sponsor perspective, and I think the knowledge gained will be helpful for her future career," Dr Bestgen said.

Her experiences at MMV have proven invaluable since her return to Australia in September 2023.

She was seconded from WEHI on a part-time basis to one of the country's leading infectious diseases experts, Professor James McCarthy, as Clinical Research Project Manager at the newly opened Doherty Clinical Trials Unit at The University of Melbourne.

At Professor McCarthy's laboratory, Dr Favuzza is now undertaking preparations for an imminent Phase Ib volunteer infection study of a potent enzyme inhibitor that has shown compelling potential to control the malaria parasite.

Fellowship experience seminal for Dr Favuzza's involvement in human trials in Melbourne

She said her role in such critical human studies would simply not have been possible without the practical experience she gained during her REDI Fellowship in Geneva.

"My extensive involvement in toxicology and preclinical studies at MMV has enabled me to support the preparation of our current clinical studies, while my training in first-in-human trials planned jointly with Professor Möhrle at MMV and Professor McCarthy, has been seminal for my involvement in human trials here in Melbourne," Dr Favuzza said.

MMV Senior Director of Pharmacology and Toxicology, Dr Belen Tornesi, said Dr Favuzza was a key member of the preclinical team, immediately integrating personally and scientifically.

"Dr Favuzza helped us review many preclinical studies from rodents and rabbits to dog studies. She was key in the review and translation of a cardiovascular study in dogs that had big implications for first-in-human studies," Dr Tornesi said.

Applying the knowledge and experience gained at MMV to help the most vulnerable populations

At MMV, Dr Favuzza was also involved in several important drug development projects, including a novel *in vitro* assay for evaluating the benefits of combining different malarial drugs and a screening platform for prioritising drugs to treat pregnant women. Dr Favuzza was key in translating the *in vitro* finding to the human exposure, that helped the assays be more meaningful. She also coordinated a global research collaboration to harmonise protocols for a key 'rate of killing' malaria test.

Summing up, Professor Möhrle said, "I am confident Dr Favuzza will apply the knowledge and experience she gained during her time at MMV in her proof-of-concept studies at The University of Melbourne, to assess embryofoetal risk and thus ensure that new anti-infective drugs are safe and efficacious even in the most vulnerable populations."

> **The Fellowship placed Dr Favuzza at the cutting-edge of several global clinical trials, as well as partnerships with pharmaceutical companies.**

Dr Paola Favuzza with a cube of malaria-carrying mosquitos.

Microba advances therapies and Fellow launches cancer diagnostics start-up

SPONSOR:
Microba Life Sciences Ltd

FELLOW:
Associate Professor Michelle Hill

EMPLOYER:
QIMR Berghofer Medical Research Institute

KEY FOCUS:
Therapeutics, preclinical development, commercialisation pathway and quality management

REDI Fellow Associate Professor Michelle Hill.

Microba Life Sciences Ltd (Microba), a precision microbiome company driving the discovery and development of novel therapeutics, offers gut microbiome testing services globally. Powering the discovery of new relationships between the microbiome, health and disease, Microba was awarded a REDI Fellowship for Associate Professor Michelle Hill from QIMR Berghofer Medical Research Institute to be embedded in its therapeutics team – leveraging the microbiome for the development of therapeutics targeting inflammatory bowel disease, autoimmunity and cancer.

In the world of scientific breakthroughs, the journey from discovery to real-world application often faces hurdles, particularly for academics navigating the realm of commercialisation.

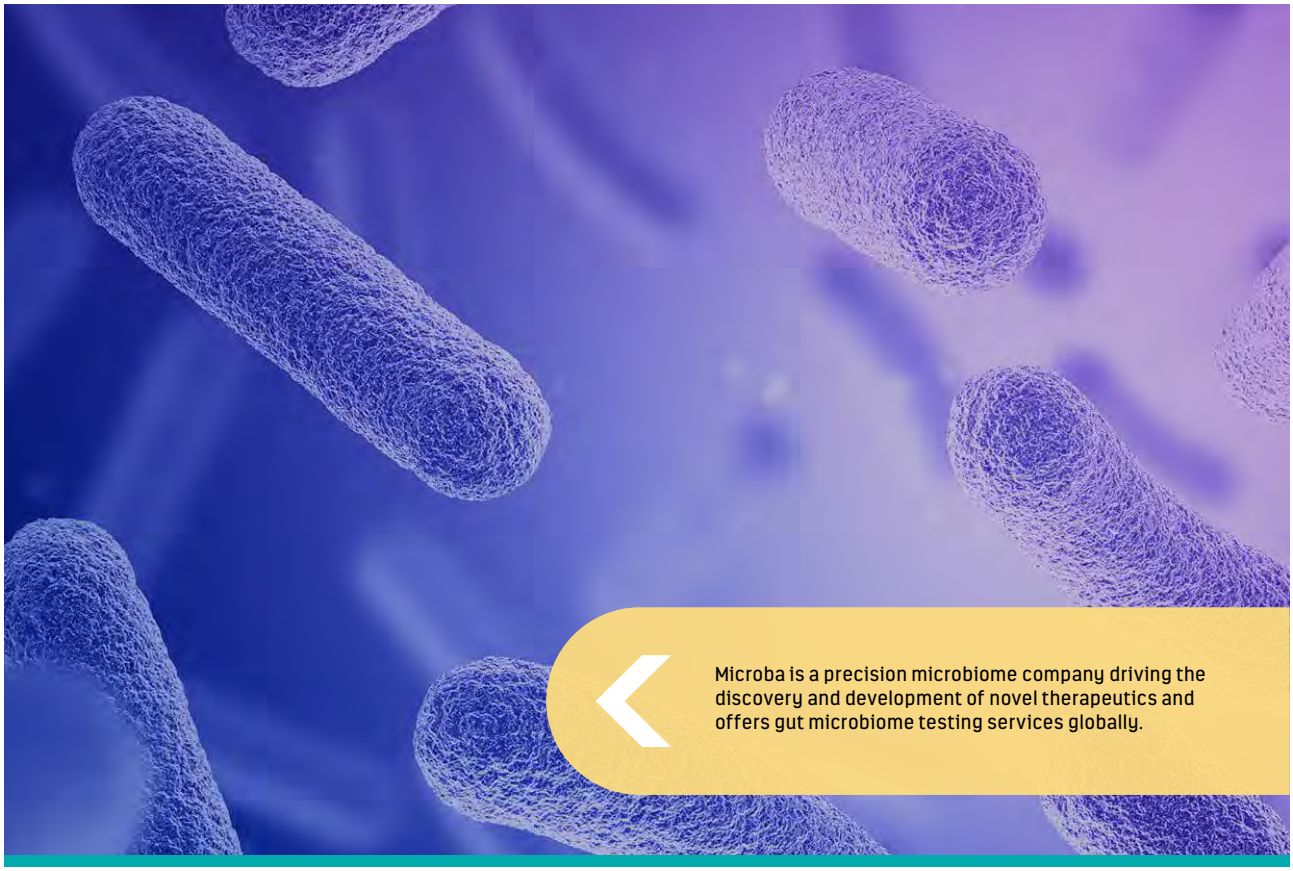
For A/Professor Hill – a translational scientist developing new clinical diagnostics for unmet needs – a 12-month REDI Fellowship at Microba provided the ideal opportunity to step out of academia and gain knowledge in commercial product development and operations to plug this gap. For Microba, the upside was being able to tap into A/Professor Hill's deep expertise in biomarker development and advanced omics technologies.

Experienced group leader in translational research and developing cancer diagnostic markers

An experienced group leader in translational research, A/Professor Hill has played a key role in establishing Australia's first mass spectrometry-based amyloidosis typing service. A/Professor Hill's oesophageal cancer diagnostic biomarkers were recently licensed by QIMR Berghofer Medical Research Institute to Perth company Proteomics International, after developing the intellectual property over 10 years at The University of Queensland and QIMR Berghofer Medical Research Institute.

Working with the Microba team, A/Professor Hill contributed to progressing a therapeutic candidate into a human clinical trial and the development of a novel prebiotic formulation.

During her Fellowship, she engaged in preclinical development of candidate therapeutics, including study design, data interpretation and biomarker strategy. In addition, she supported a human study of a novel prebiotic formulation and participated in the Quality Management program as an internal auditor. Through these activities, she gained experience in product development, regulatory requirements, and Quality Management Systems.



Microba is a precision microbiome company driving the discovery and development of novel therapeutics and offers gut microbiome testing services globally.

Fellow's expertise accelerates progress of Microba's therapeutics program

As Microba's Chief Scientific Officer, Associate Professor Lutz Krause noted that A/Professor Hill's contributions have been catalytic for Microba's therapeutics and prebiotic programs.

"Michelle's expertise has accelerated the progress of Microba's therapeutics program and enhanced our capabilities in biomarker discovery," A/Professor Krause said.

But for A/Professor Hill, the Fellowship ignited her own entrepreneurial aspirations, providing new-found knowledge and inspiration to fulfil her personal mission to translate innovations to impactful solutions.

Reflecting on her journey, A/Professor Hill credited the REDI Fellowship at Microba for providing the guidance and motivation needed to embark on this exciting new chapter.

> **For Microba, the upside was being able to tap into Associate Professor Hill's deep expertise in biomarker development and advanced omics technologies.**

REDI Fellowship opens Fellow's eyes to entrepreneurship and provides commercialisation skills

"The intended outcome of my research has always been new innovations for health. Although my team successfully identified cancer biomarkers, I had hit the 'Valley of Death' of translational research, where the lack of funding and commercialisation expertise hampers impactful product development.

"The REDI Fellowship helped me through the 'Valley of Death' by opening my eyes to entrepreneurship. Importantly, the Fellowship enabled a pause from the tasks of running an academic research laboratory to acquire experience and skills in commercialisation," she said.

Shortly after completing the REDI Fellowship, A/Professor Hill launched ProSeek Bio to develop new cancer diagnostic blood tests.

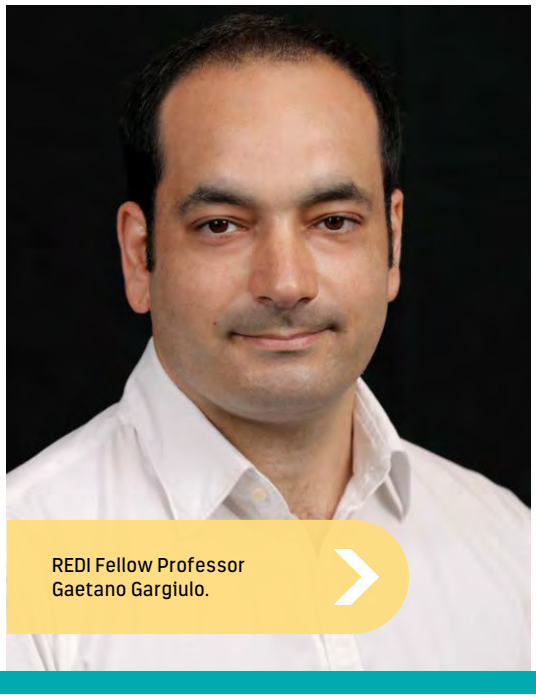
Researcher brings expertise to cardiac medtech clinical trial design

SPONSOR:
Mobius Medical

FELLOW:
Professor Gaetano Gargiulo

EMPLOYER:
Western Sydney University

KEY FOCUS:
Medical devices, clinical trials, heart disease, diagnostic, Quality Management Systems



REDI Fellow Professor Gaetano Gargiulo.

Mobius Medical, like all clinical research organisations, operates in a demanding environment of regulation and compliance, which is not always understood by academic researchers. A REDI Fellowship opened Professor Gaetano Gargiulo's eyes to these commercial realities while delivering fresh perspectives to the company's in-house team.

Mobius Medical was already managing a clinical trial of a new sensor technology for the early detection of heart disease at St Vincent's Hospital in Sydney and The Alfred in Melbourne when, thanks to a REDI Fellowship, Professor Gargiulo of Western Sydney University (WSU) joined the project team.

Heart failure was designated as an emerging global epidemic in 1997, with a prevalence of over 5.8 million in the US, and over 23 million worldwide.[1] This has recently been exacerbated by the COVID-19 pandemic. COVID-19 has been correlated to increased risk of cardiovascular conditions at the root of heart failure and early detection is paramount to a positive outcome.[2,3]

1. National Library of Medicine, National Center for Biotechnology Information: Epidemiology of Heart Failure https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3806290/#:~:text=Heart%20failure%20(HF)%20is%20a,prevalence%20or%20both%20factors%20combined
2. Oxford Academic, Cardiovascular Research: Association of COVID-19 with short- and long-term risk of cardiovascular disease and mortality: a prospective cohort in UK Biobank https://academic.oup.com/cardiovascres/article-abstract/119/8/1718/6987834
3. British Heart Foundation, Heart Matters: How does COVID-19 affect your heart? https://www.bhf.org.uk/informationsupport/heart-matters-magazine/news/coronavirus-and-your-health/what-does-coronavirus-do-to-your-body

The clinical trial is a collaboration between Mobius Medical, Medical Monitoring Solutions and a large global medical technology company. The blending of Professor Gargiulo's academic research approach with their practical and clinical trial management experience highlighted the value of integrating these perspectives. This fusion led to more robust trial designs and a deeper understanding of the practical challenges in clinical research.

Mobius Medical Co-Founder Suzanne Williams said Professor Gargiulo's involvement with the day-to-day work brought valuable, fresh perspectives to the company's team, leading to innovative approaches in clinical research.

"Bridging the gap between performing clinical trials to good clinical practice and ensuring the trial devices and trial design are structured to satisfy the required endpoints are critical to success. Professor Gargiulo fulfilled this role well and the Fellowship also provided excellent experience for him in the commercial world, that can then be shared with his university colleagues in years to come," Ms Williams said.

Mobius Medical was founded in 2008 by Ms Williams and Stefan Czyniewski. Since then, it has grown into a full-service clinical research organisation headquartered in Sydney, with offices throughout Australia and in New Zealand and the US.

The collaboration with Professor Gargiulo and WSU has broadened the company's professional network and paved the way for future joint ventures and collaborations.

He worked closely with various stakeholders including sponsors, regulatory bodies and participants and gained an understanding of the dynamics and communication strategies necessary for successful collaboration. His contribution to the project also included managing electrical safety testing, providing input into the investigators' brochure, liaison with biomedical engineers at the trial sites, ensuring all test and gold standard equipment were set up and compliant, troubleshooting any technical issues during the trial and managing the data upload.

Professor Gargiulo teaches biomedical engineering at WSU and, although he has spent time working in the medical device industry, he was keen to experience end-to-end medical device development. Working with a leading clinical research organisation such as Mobius Medical provided a much wider perspective on the practical realities of multi-site clinical trials. It also developed his skills in the clinical investigation of medical devices for human subjects (ISO 14155) and the Quality Management Systems for medical devices (ISO 13485), which Professor Gargiulo will now incorporate into his teaching at WSU.

"Despite holding the job title of Research Professor, I believe that there is still a wide gap between pure academic research and the commercial application of that research," Professor Gargiulo said.

He said this was particularly true in the case of medical technology, where the lengthy validation trials, the mandatory regulatory requirements and the lengthy intellectual propriety protection process contributed to barriers to the translation of research that is seldom understood by academics.

"The REDI Fellowship is the perfect medium to bridge this gap. It brings together commercially oriented academics willing to 'walk the extra mile' and attempt completion of their research, with visionary and open-minded industry sponsors willing to open their doors to academics – often with little to no industry experience – building a relationship that can easily extend well beyond the period of the Fellowship," he said.

Professor Gargiulo said the detailed knowledge gained during the Fellowship would deliver a two-fold advantage to his university: new and improved teaching material and direct industry connections resulting in student industrial placements.

Medical Monitoring Solutions CEO Neil Anderson said the REDI Fellowship initiative has added significant value to the company.

"Professor Gargiulo brought important skills and knowledge regarding sensor and electrical engineering of medical devices, which has played a key role in not only our current clinical trials, but our plans for future product development as well.

"This work has reduced the development timeline of the device by at least three years. We are looking forward to continuing the development of this device and working with Professor Gargiulo and WSU in the future," Mr Anderson said.

Meanwhile, the clinical trial is now complete with 50 patients recruited across the two sites. It has generated promising data that has already resulted in several novel research hypotheses which will be explored in future clinical trials. The work to date has led to the early sale of 20 devices for clinical research only.

Despite reaching the end of the Fellowship, Professor Gargiulo is working with the team to obtain ethical clearance for two additional clinical trials in Australia and one in Italy, planning to enrol more than 200 new participants, preparing the device for regulatory submission and successful commercialisation.

> **"This work has reduced the development timeline of the device by at least three years."**

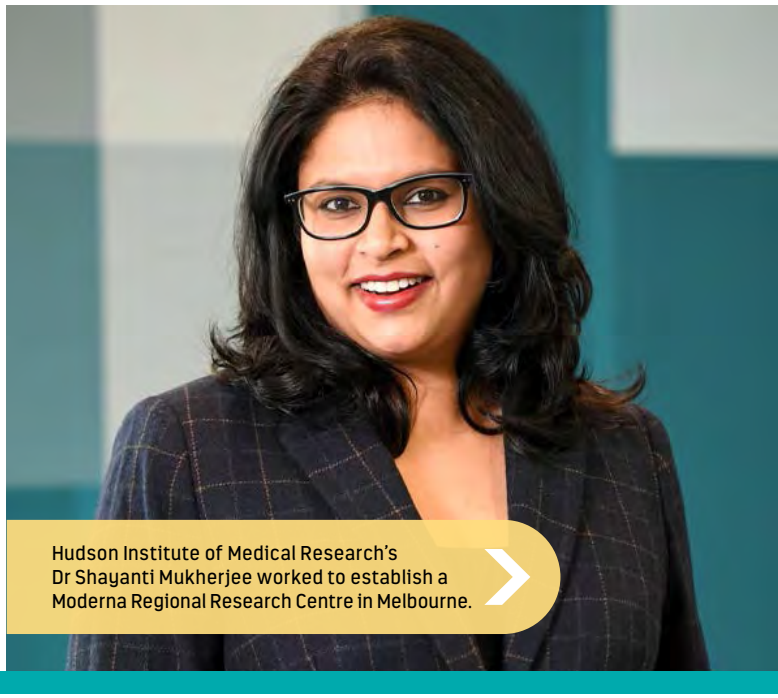
Local knowledge meets global might to build regional R&D capabilities

SPONSOR:
Moderna Australia

FELLOW:
Dr Shayanti Mukherjee

EMPLOYER:
Hudson Institute of Medical Research

KEY FOCUS:
mRNA translation and commercialisation, industry: academia partnerships, project management, leadership



Hudson Institute of Medical Research's Dr Shayanti Mukherjee worked to establish a Moderna Regional Research Centre in Melbourne.

When global pharmaceutical and biotechnology company Moderna decided to build a robust R&D presence in Australia and beyond, a REDI Fellowship put Dr Shayanti Mukherjee, a Research Group Head, Translational Tissue Engineering at the Hudson Institute of Medical Research, at the centre of a project to establish a Regional Research Centre in Melbourne.

A REDI Fellowship allowed leading researcher Dr Mukherjee to take a central role in the strategy, tactics and logistics of establishing a Regional Research Centre in Melbourne, as global pharmaceutical and biotech leader Moderna established an R&D presence in Australia and beyond.

Empowered to play a critical role in Moderna's development plans

While Dr Mukherjee is a seasoned researcher with industry experience, the Fellowship empowered her to play a critical role in the development of Moderna's plans and to work closely with the Centre Director to map the different activities and develop operating frameworks.

"This included the establishment of digital platforms and strategic collaborations, laying the foundation for continued success. Additionally, my efforts have helped to develop momentum for ongoing programs, ensuring continued progress and innovation in key areas," Dr Mukherjee said.

Dr Mukherjee also helped Moderna better engage with academia and to build robust industry-academia networks.

R&D is a global priority for Moderna as it evolves from a one-product organisation to an industry leader with a sizeable mRNA pipeline. Australia is seen as an important global centre in that, given the country's top research institutions, well-regarded regulatory systems and clinical trials infrastructure.

Contributing to the Regional Research Centre's launch

The Melbourne Regional Research Centre operations provide the physical and digital channel to support collaborations to build regional capability and deliver research and translational projects and data partnerships.

Dr Mukherjee worked closely with the Director of Moderna Australia, Dr Craig Rayner, supporting the Moderna team as the company's global R&D staff began to engage with the Australian ecosystem.

She contributed to the launch of the Regional Research Centre for Respiratory Medicines and Tropical Diseases in Melbourne and supported the strategic collaboration between Moderna and Monash Institute of Pharmaceutical Sciences, which resulted in the creation of a $3 million Quantitative Pharmacology Accelerator.

Dr Mukherjee also led the establishment of the digital platform for the mRNA platform incubator network, ensuring steady progress and successful implementation of key infrastructure and systems. This initiative – publicly launched in early November 2023 at AusBiotech – enhances functionality and accessibility for future R&D activities within the Regional Research Centre.

Navigating the intricate dynamics of complex partnerships

Dr Mukherjee developed a life cycle-in-action course for Moderna's Australia Fellowship program and attended many external meetings with academic, government and industry partners.

"These meetings were a rich source of knowledge, where I learned to navigate the intricate dynamics of academic, government and industry partnerships, while also honing my communication and negotiation skills in diverse regional contexts," Dr Mukherjee said.

The REDI Fellowship also benefitted the Hudson Institute of Medical Research with Dr Mukherjee sharing the knowledge gained at Moderna with her colleagues and introducing fresh perspectives on projects such as the development of a malaria mRNA vaccine.

Driving positive change and contributing to collective success

"The Fellowship project has sharpened my communication abilities, allowing me to effectively teach my team about industry working styles and leadership principles. This experience has equipped me to navigate institutional leadership roles, such as my executive position at the Ritchie Centre, where I can lead initiatives to enhance research excellence and interdisciplinary collaboration.

"Through the REDI Fellowship, I've gained valuable insights into project management, strategic decision-making and fostering a culture of innovation. Overall, these skills empower me to drive positive change within my team and institution, ultimately contributing to our collective success in advancing health research," Dr Mukherjee concluded.

> "I've gained valuable insights into project management, strategic decision-making and fostering a culture of innovation."

From left, Jerome Werkmeister, Hudson Institute of Medical Research; REDI Fellow Dr Shayanti Mukherjee; and Indira Losada, Moderna, at the REDI networking event in Melbourne.

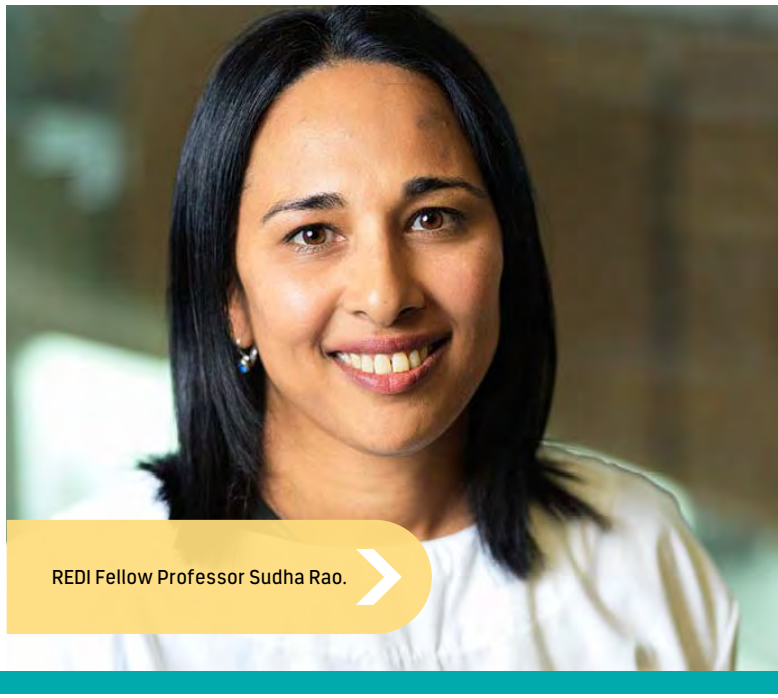
New AI tools prepare NanoString for future pandemics

SPONSOR:
NanoString

FELLOW:
Professor Sudha Rao

EMPLOYER:
QIMR Berghofer Medical Research Institute

KEY FOCUS:
Digital therapeutic, AI diagnostic, target deliverables experiment planning



REDI Fellow Professor Sudha Rao.

A REDI Fellowship helped deepen an existing relationship between Professor Sudha Rao and translational research company NanoString, and helped the company better understand immune responses in Long COVID while developing better diagnostics and targets for treatment of patients.

Despite vaccination, some people will still develop COVID-19 and require hospitalisation or will be left with the debilitating Long COVID illness. A test capable of predicting individual risk of developing severe disease or Long COVID would allow personalised protection for people at risk, as well as helping hospitals better manage patient resources.

A REDI Fellowship enabled Professor Rao, a Research Group Leader at Queensland's QIMR Berghofer, to develop an existing relationship with biotech company NanoString, to accelerate development of just such a new COVID-19 blood test, which aims to address the shortcomings of existing tests.

Test will allow for faster vaccine development for emerging new strains

The test is expected to determine the level of COVID-19 protection provided within an individual more effectively, so the patient is treated accordingly. The test will also be useful in vaccine research and allow for faster vaccine development for emerging new strains, as clinical trial participants can be selected with a specific focus.

Professor Rao previously worked with NanoString developing novel genetic signatures for diagnostic or therapeutic purposes and the two have a long history of collaboration through NanoString's Technology Access Program and bioinformatics services. She refined her real-world experience in commercialising products through the Fellowship.

During the REDI Fellowship, Professor Rao and NanoString used a systems biology approach to generate data for Long COVID from the tissues of SARS-CoV-2 biopsies.

This work in both developing the antiviral drug and the Long COVID project generated massive datasets, which were handled using cutting-edge machine learning (ML) and artificial intelligence (AI) to develop predictive models to identify patients likely to contract recurrent disease, Long COVID or were susceptible to multiple infections.

Gaining interest from US and South Korean pharmaceutical companies

During her Fellowship at NanoString, Professor Rao refined the AI-derived blood biomarker analysis. This work is currently being prepared for publication and has gained interest from both US and Korean pharmaceutical companies, leading to recent visits with a view to commercialisation.

Professor Rao said the Fellowship gave her skills in product development management, as well as target deliverables experiment planning, recording and reporting, communication and teamwork in an industry setting.

She is dedicated to a career in drug and assay development in medicine. Understanding and applying machine learning to the large datasets naturally generated during laboratory studies is a fundamental aspect of this work.

"The Fellowship gave me experience in stakeholder management and an understanding of the steps and processes involved in integrating datasets for machine learning. I also gained expertise in discussing clinical problems with machine learning experts and using their expertise in diagnostics," Professor Rao said.

Fellowship provides multiple and long-term benefits for sponsor

NanoString says it is looking forward to hosting Professor Rao at its headquarters in the US and sponsoring her travel to speak at international conferences to present her work in the future.

NanoString's Manager Technical Sales, Dr Marshall Feterl, said participating in the REDI Fellowship as a sponsor provided the company with multiple and long-term benefits.

"We connected with an experienced research group who have a deep understanding of the healthcare domain we are interested in. It helped us formulate solutions in that space from the product point while knowing that important clinical and scientific aspects were also addressed to the highest scientific standards," Dr Feterl said.

Increased reputation commercially and long-term relationship with Fellow

"It increased our reputation as a commercial entity that takes scientific rigour and medical safety seriously. Importantly, sponsoring a REDI Fellow created a long-term relationship with the Fellow herself, as well as her scientific network," Dr Feterl said.

He added that the REDI Fellowship between Professor Rao and NanoString has highlighted the importance of using the company's spatial biology tools.

"This will allow us to understand individual patient cancer progression and uncover potential treatments to better patient outcomes in the future. NanoString looks forward to continuing our partnership with Professor Rao in 2024," Dr Feterl concluded.

> **During her Fellowship at NanoString, Professor Rao refined the AI-derived blood biomarker analysis. This work is currently being prepared for publication.**

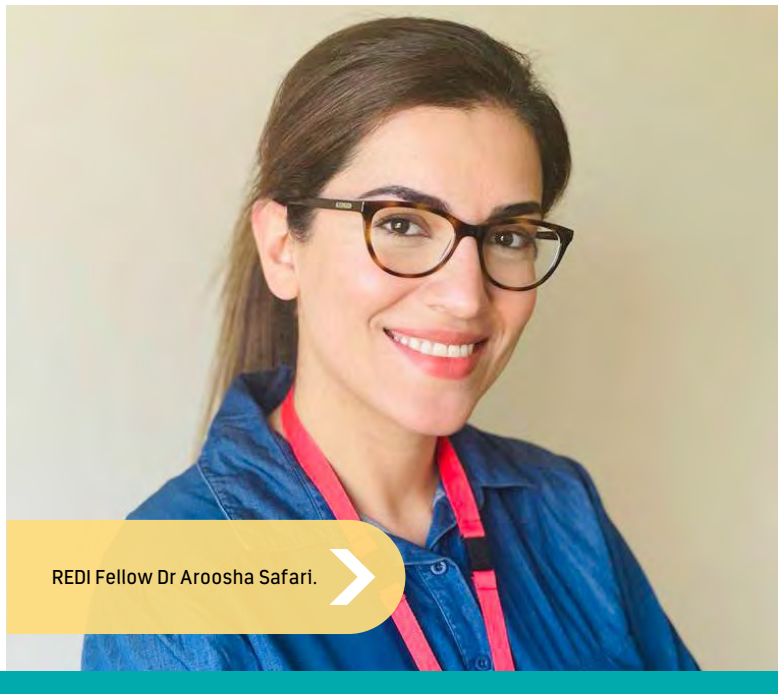
Surgeon's insights and expertise help to take a groundbreaking cancer probe into clinical trials

SPONSOR:
OncoRes Medical

FELLOW:
Dr Aroosha Safari

EMPLOYER:
South Metropolitan Health Service

KEY FOCUS:
Clinician-researcher, medical technology, clinical trial design, regulatory landscape and cancer treatment



REDI Fellow Dr Aroosha Safari.

A REDI Fellowship enabled Perth surgeon Dr Aroosha Safari to spend 12 months in the laboratories of cancer-imaging pioneer OncoRes Medical. It educated her in the life cycle of medtech commercialisation, while the company gained deeper insights into the needs of frontline breast cancer surgeons ahead of its next clinical trial.

When Dr Safari joined forces with OncoRes Medical, a Perth-based medical device company, her brief was to use her clinical expertise to inject the surgeon's perspective into the development of a revolutionary probe providing real-time imaging during breast-conserving surgery.

The cornerstone of successful cancer treatment lies in achieving complete surgical clearance. However, there are no approved technologies available for surgeons that are useful to detect any remaining cancer within the patient during breast cancer surgery, leading to cancer being left behind. This situation elevates the risks of local or distant recurrence, potential repeat surgeries, increased complication rates and heightened healthcare expenditure.

Championing a culture of research, innovation, industry collaboration and entrepreneurship

Fast forward 12 months, and Dr Safari's skills and expertise have traversed the entire gamut of the medtech R&D spectrum – from preparing scientific manuscripts and grant applications, to addressing medical conferences, designing clinical trials, supporting risk assessments and regulatory submissions and clearing the multitude of hurdles along the road to commercialisation. Moving forward, she will use these assets to champion a culture of research, innovation, industry collaboration and entrepreneurship in medicine and surgery.

In return, Dr Safari has provided OncoRes Medical with a wealth of clinical expertise and insights from the community of cancer surgeons who will ultimately use the company's device. Through the Fellowship, Dr Safari facilitated critical user testing of a prototype interface, developed training materials, and helped the clinical team train 20 surgeons and 40 nurses, ahead of the company's first multi-site clinical trial.

OncoRes Medical CEO and Managing Director, Dr Katherine Giles, said having Dr Safari on board through the REDI Fellowship has been a driving force for the company's operations.

Fellowship builds stronger bonds within the team at OncoRes Medical for better research

"Aroosha's real-world surgical know-how and experience, and her ability to bring together the OncoRes team and the clinicians at South Metro Health Service to work in focused partnership, brought a user-focused edge to day-to-day operations, advancing our clinical trial pipelines through the eyes of a surgeon.

"This collaboration has built stronger bonds within our team and with the broader healthcare system – opening doors for better research and, ultimately, improved patient outcomes," Dr Giles said.

As a surgeon with Perth's South Metropolitan Health Service, Dr Safari's immersion in the complex world of medtech R&D will be invaluable in fostering greater research ties and industry collaborations within Perth's surgical community.

During the Fellowship, she not only worked with clinical researchers and engineers at OncoRes laboratories, but with a group of specialists that included regulatory experts, clinical auditors, quality assurance (QA) managers and even media trainers. She also presented research data from OncoRes' work at three medical conferences and delivered a keynote address on innovation at the WA Health Service Providers Innovation Showcase event.

A myriad of opportunities, networks and people to collaborate with

"In terms of what I was able to learn, this Fellowship completely surpassed my expectations. The funding support gave me the chance to learn and collaborate with fellow surgeons and see things from a business perspective. I was able to dive into cutting-edge clinical research and work alongside some fantastic professionals.

"I have become aware of a myriad of opportunities, networks and people who I can collaborate with as a clinician, to help solve clinical dilemmas – from patient flow to caring for rural patients. The values practised at OncoRes Medical have shown me the importance of inclusivity, kindness and compassion to create an environment for teams to thrive and maximise creative thinking, productive planning and timely success," said Dr Safari.

OncoRes Medical's Chief Operating Officer, Dr Simon Graindorge, said: "Dr Safari's involvement in the REDI Fellowship has been a game-changer, blending her surgical insight into our team every day. It's not just about pushing technology forward – it's about making a real impact on patient care."

During her Fellowship, Dr Safari conducted in-depth interviews with five breast cancer surgeons, including detailed end-user testing of a new user interface for the OncoRes probe to determine its user experience. She also led the development of a foundational curriculum for training surgeons in its use.

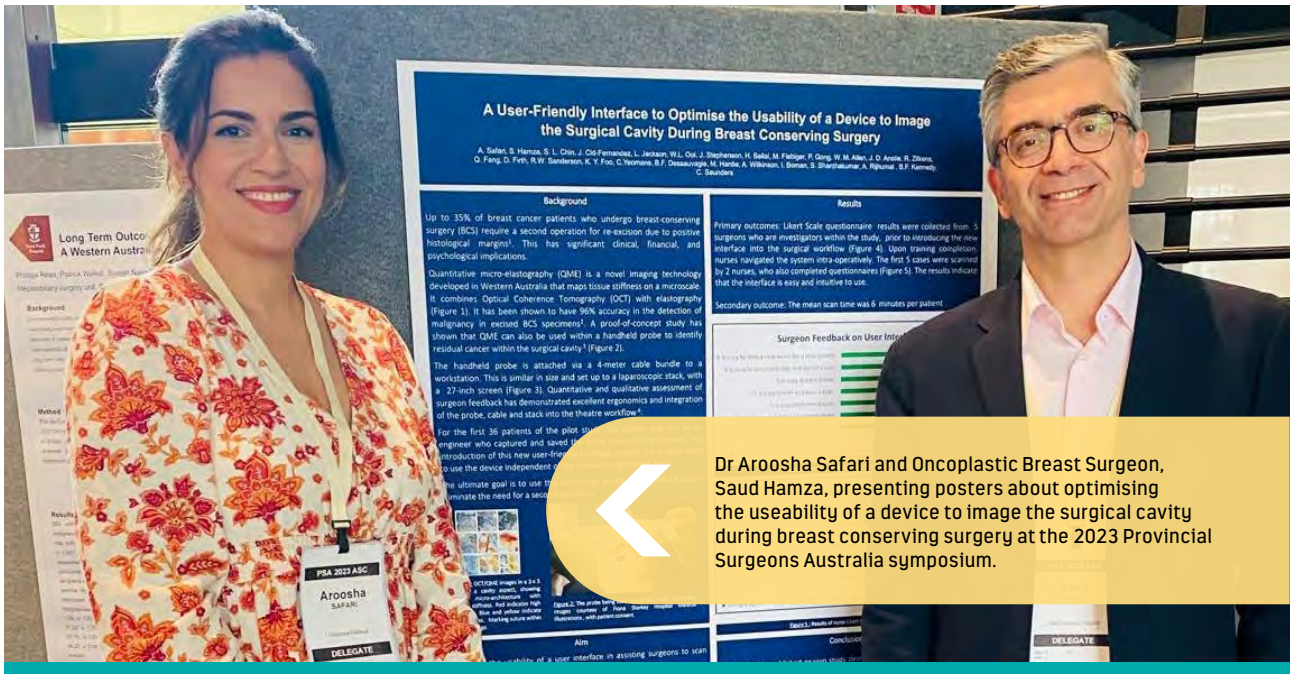
Fellow's hands-on impact resulted in stronger relationships and practical collaboration

Following the REDI Fellowship, OncoRes has commenced a clinical trial at four sites and designed a further trial to collect critical clinical data to support its regulatory submissions. The company has also redesigned the user interface to be more intuitive – using insights collected from Dr Safari's study – and locally manufactured a complete system including a workstation, probe, caps and software for its clinical trials.

Dr Giles added: "Dr Safari has been involved in the entire pipeline of progress during the Fellowship. Her hands-on impact is a testament to the vital role of stronger relationships and practical collaboration in driving progress in healthcare and medical innovation."

Indeed, the outcomes of this Fellowship have been so productive and the relationships so positive, Dr Giles and Dr Safari look forward to continuing their collaboration to advance OncoRes Medical's cancer-imaging work, while supporting the South Metropolitan Health Service in its industry engagement and relationship-building. Truly a win at either end of the life sciences spectrum.

> "Having Dr Safari on board through the REDI Fellowship has been a driving force for the company's operations."



Dr Aroosha Safari and Oncoplastic Breast Surgeon, Saud Hamza, presenting posters about optimising the useability of a device to image the surgical cavity during breast conserving surgery at the 2023 Provincial Surgeons Australia symposium.

Paige benefits from REDI Fellowship launching five new pathology products

SPONSOR:
Paige (Pathology-AI-Guidance-Engine)

FELLOW:
Dr Ewan Millar

EMPLOYER:
NSW Health Pathology (NSWHP)

KEY FOCUS:
Clinician-researcher, AI, machine learning, cancer diagnosis, digital workflow, biomarker discovery products, new products

Artificial intelligence (AI) and machine learning are transforming pathology, enabling laboratories to bring efficiency and confidence to cancer diagnosis. Dr Ewan Millar from NSW Health Pathology (NSWHP) was awarded a REDI Fellowship to work with Paige (Pathology-AI-Guidance-Engine) – a pioneer in digital pathology transformation, founded in 2017 and based in the US. Dr Millar was embedded in Paige's product development team virtually, working on AI products for clinical use.

AI is poised to revolutionise anatomical pathology practice – and particularly for cancer patients, with more efficient testing and the use of precision diagnostics on tumours. Every diagnosis requires a tissue biopsy and review by a specialist anatomical pathologist. The increase in the ageing population, coupled with an increased cancer incidence and drive towards personalised targeted cancer therapies, has resulted in a consistent year-upon-year increase in pathologist workloads. This scenario has created a 'perfect storm', coinciding with a global shortage of pathologists.

'Decision-assisting' AI will improve patient care and assist workflow

Workload-related issues for pathologists can be ameliorated through digital workflow-enabled AI to diagnostic pathology. Game-changing 'decision-assisting' AI will improve patient care and assist pathologist workflow by providing decision support in diagnosis, improved quality assurance, and reduced administrative load.

Joining Paige's US-based Global Development team virtually from Australia – due to COVID-19 pandemic restrictions – Dr Millar focused on screening novel biomarkers across several tumour streams to identify new AI algorithms for the market. This resulted in five new AI pathology diagnostic and biomarker discovery products for breast cancer and prostate cancer: HER2Complete, Prostate Biomarkers, Breast sentinel node, Breast neoplasm detection and subtype and Breast mitotic detection tool – all of which have regulatory approval for clinical use in the EU (CE-IVD) and the UK (UKCA).

REDI Fellow brought a unique perspective to the Paige team

Paige's Chief Medical Officer Dr David Klimstra said Paige significantly benefitted from having Dr Millar be part of the team, as he brought a unique perspective, focusing the team on clinically practical solutions.

"Ewan's expertise in breast anatomic and molecular pathology has been critical to the success of the development of five diagnostic AI products. The feedback he provided ensured the products met the needs of pathologists to maximise benefits to patients, thereby ensuring the products' commercial success," Dr Klimstra said.

US-based Paige benefitted significantly from REDI Fellow Dr Ewan Millar being embedded in its Global Development team, even though he joined them virtually from Australia, due to the COVID-19 pandemic restrictions.

Through the Fellowship experience, Dr Millar acquired industry-relevant skills in software development, product design and delivery, regulatory assessment, clinical trial design market evaluation and strategic design.

"My REDI Fellowship with Paige has given me unrivalled exposure to a world's best pathology AI product development pipeline – from use-case idea to data curation, iterative model performance improvement, regulatory approvals, product release and planning for real-world studies. It has also enhanced my capability to identify opportunities for new product development within my current research space and empowered me to be much more focused with my PhD students," Dr Millar said.

Dr Millar's REDI Fellowship has been equally rewarding for NSWHP – the largest provider of public pathology services in Australia, with his newly acquired industry skills giving the organisation a unique resource to bring AI into the cancer detection workflow in pathology.

> My REDI Fellowship with Paige has given me unrivalled exposure to a world's best pathology AI product development pipeline.

His work with Paige has also fostered an ongoing global research collaboration, building interest in conducting early local evaluations of current and emerging Paige products at NSWHP. Through Paige, NSWHP has gained access to a network of US, UK and European collaborators – providing potential partnership opportunities for future AI research. The Fellowship really has been a win-win for everyone involved.

New AI pathology products that will hopefully benefit many patients

NSWHP Chief Medical Information Officer Dr Stephen Braye said through the REDI Fellowship, Dr Millar has learned the complexity of product use, testing, performance and costs involved – knowledge that is critical for use in the planning of the new operating environment for NSWHP, as digital pathology AI evolves.

"The accelerated learning and experience that Paige and the REDI Fellowship provided Dr Millar has already led to new AI pathology products that, hopefully, will benefit many patients," Dr Braye said.

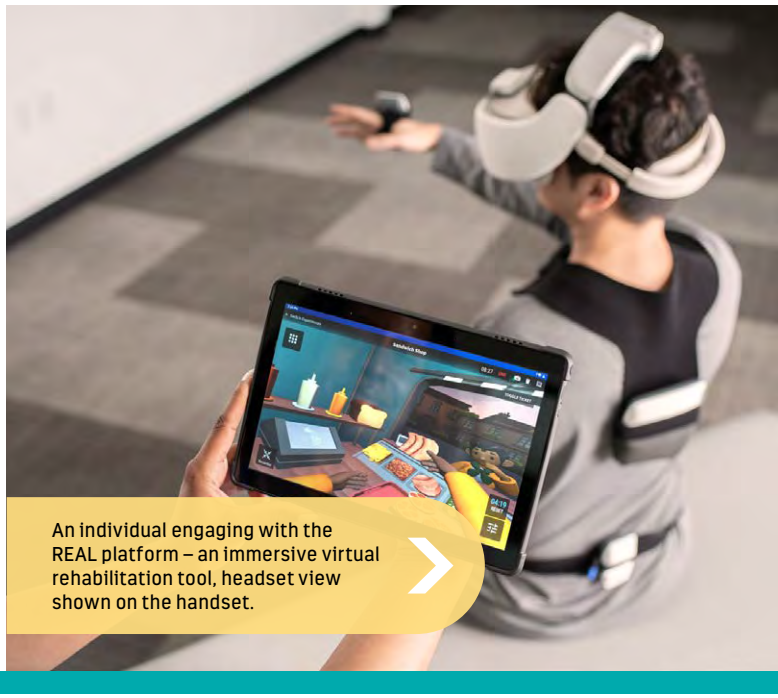
Virtual reality delivers real-world therapies for rehabilitation

SPONSOR:
Penumbra

FELLOW:
Associate Professor Belinda Lange

EMPLOYER:
Flinders University

KEY FOCUS:
Digital health, global collaboration, product development, virtual reality, rehabilitation



An individual engaging with the REAL platform – an immersive virtual rehabilitation tool, headset view shown on the handset.

Penumbra's REAL y-Series platform is one of the first virtual reality rehabilitation technologies to be used in hospitals and clinics. Through a REDI Fellowship, the US-based company worked with Associate Professor Belinda Lange, who has undertaken 20 years of international research in the clinical use of virtual reality for physical, mental and cognitive rehabilitation. For A/Professor Lange, it was a chance to gain valuable experience in product development in an industry-leading organisation.

Global healthcare company Penumbra has developed the REAL platform, an immersive virtual reality system that delivers physical and mental health therapies, a field A/Professor Lange of Flinders University has extensive and recognised research experience in.

Based in Alameda, California, Penumbra was awarded a REDI Fellowship to tap into A/Professor Lange's expertise to enhance the translation of science into the REAL system's y-Series product.

Increased knowledge and understanding of commercialisation transforms approach to research

For A/Professor Lange, the Research Lead for Technology in the Caring Futures Institute at the College of Nursing and Health Sciences and a registered physiotherapist, the appointment significantly increased her knowledge and understanding of the commercialisation process, which is transforming the way she approaches her research.

Virtual reality can be applied across the healthcare setting for wellbeing, education, training, rehabilitation, monitoring and assessment.

More than 700,000 people in Australia live with the physical, psychological and cognitive deficits associated with brain injury, including stroke.[1] Many of these Australians experience physical, psychological and cognitive deficits, leaving them unable to work, participate in social activities or care for themselves. Existing rehabilitation treatments can be challenging, and it can be difficult for people to engage meaningfully, but technology such as virtual reality can help track progress, while motivating and engaging people in their therapy activities to deliver better outcomes.

> "The Fellowship experience also contributed to the company's decision to develop a new role at Penumbra to formally provide clinical input into future product development."

1. Brain Injury Australia website https://www.braininjuryaustralia.org.au/

The REAL system – supporting rehabilitation and improving quality of life

This is exactly the sort of scenario for which the REAL system was designed. It incorporates clinically designed products that address a variety of therapeutic and wellness areas to support rehabilitation and improve quality of life.

Specifically, the REAL y-Series works to achieve full body rehabilitation with a focus on strengthening, range of motion, and postural control for use with all rehab patients.

A/Professor Lange said when she joined Penumbra's Health and Market Outcomes Research team, the REAL y-Series was already in use in hospitals and clinics across the US.

"I reviewed and evaluated the current activities and those under development, developed product specifications for new activities, provided feedback on clinical documentation, and contributed to discussions about proposed changes to the user interface," A/Professor Lange said.

Fellow brought an exceptional depth of subject matter expertise

President of Immersive Healthcare at Penumbra, Gita Barry, said A/Professor Lange brought an exceptional depth of subject matter expertise to the project.

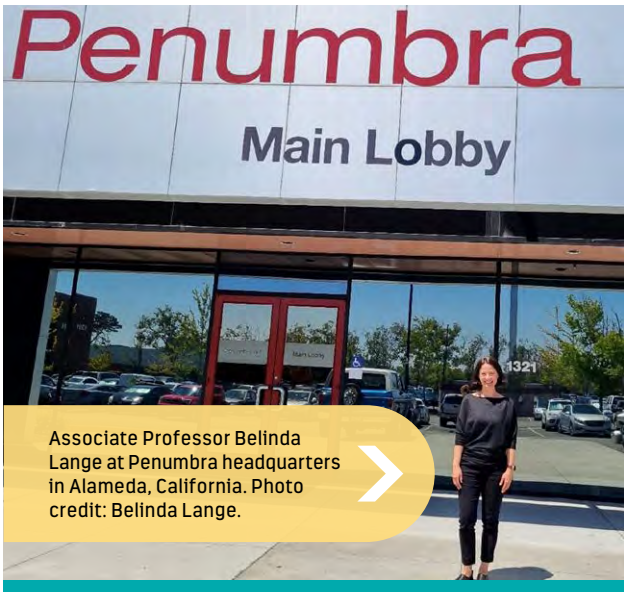
"Especially using technology within a rehabilitation setting – her insights and feedback were particularly valuable to help our team focus on what would be most impactful for clinicians during the development of our latest offering," Ms Barry said.

Associate Professor Lange's work at Penumbra has influenced the current version of the REAL y-Series offering. The Fellowship experience also contributed to the company's decision to develop a new role at Penumbra to formally provide clinical input into future product development.

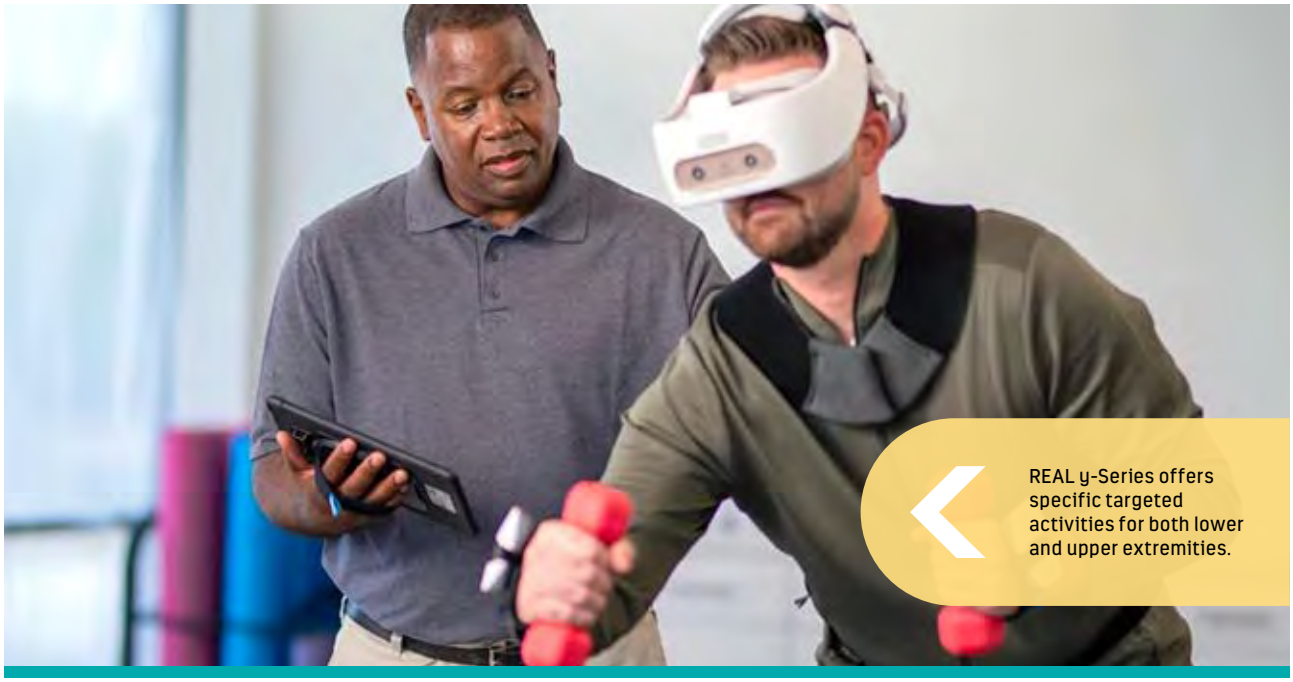
Fellowship results in firsthand experience and enhanced industry-relevant skill set

This project provided an opportunity for A/Professor Lange to experience firsthand the product development life cycle to bring a digital health product to market, including regulatory processes, documentation requirements and strategic planning and implementation. The mentorship received and the direct contribution to three teams within Penumbra's product pipeline provided significant value to enhance A/Professor Lange's industry-relevant skill set.

She said the skills learned during the Fellowship will have an ongoing impact on her approach to research planning and development activities, as well as enhancing capacity for industry engagement and providing opportunities for knowledge sharing with other Flinders University researchers.



Associate Professor Belinda Lange at Penumbra headquarters in Alameda, California. Photo credit: Belinda Lange.



REAL y-Series offers specific targeted activities for both lower and upper extremities.

Breathing easier thanks to a digital rehab program to manage lung disease

SPONSOR:
Perx Health

FELLOW:
Associate Professor Zoe McKeough

EMPLOYER:
The University of Sydney

KEY FOCUS:
Digital therapeutic, rehabilitation program, coding expertise, strategic planning

REDI Fellow Associate Professor Zoe McKeough.

People with complex health conditions need positive, persistent motivation to follow and keep to their treatment plans. Pioneering digital health company Perx Health recognised this and built a digital care management program to address the problem. The company was awarded a REDI Fellowship for Associate Professor Zoe McKeough to extend its program to support patients with chronic lung diseases – which affect more than 500 million people around the world including 7.5 million Australians.

Perx Health is making it easier for patients with chronic diseases, particularly older patients, to follow their treatment plans. Now, thanks to a REDI Fellowship, A/Professor McKeough from The University of Sydney has been embedded at the company to help extend this care to support patients with long-term lung conditions.

An academic physiotherapist, A/Professor McKeough has been researching and treating people with chronic lung diseases for more than 20 years.

The REDI Fellowship saw A/Professor McKeough working on Perx's pulmonary rehabilitation platform to guide patients through the management of their illnesses.

Managing health conditions and forming healthy habits via a mobile phone app

The resulting Perx-R platform is a digital therapeutic designed to engage and motivate patients in better managing their health conditions and to form healthy habits via an app on their mobile phone.

The Fellowship gave Perx the opportunity to integrate A/Professor McKeough's research software, called mobile pulmonary rehabilitation (m-PR), into the Perx-R platform.

By expanding its digital care management program platform and deploying the associated app within clinical settings across Australia, the Perx Health project gave A/Professor McKeough the opportunity to upskill her capabilities to effectively translate research.

Learning how to use the Perx infrastructure to help patients manage chronic health conditions

No other digital health product in Australia contains the ability to support treatment plans that actively motivate patients to stick to their daily treatment tasks. The app could assist all 7.5 million Australians living with chronic lung diseases to improve the self-management of their conditions.

A/Professor McKeough said through her experience of being embedded with Perx she was able to learn how to use the Perx infrastructure.

"This allowed me, without coding expertise, to integrate an exercise and education program into Perx's systems architecture.

> **The Perx Health project gave Associate Professor McKeough the opportunity to upskill her capabilities to effectively translate research.**

"I have also had the opportunity to evaluate this program in real-world settings with patients with chronic lung disease to gain further insights from these consumers about what works well for them," she said.

Gaining key knowledge to drive customers and the stakeholder experience

Working as part of Perx Health's marketing and sales teams gave A/Professor McKeough key knowledge on how to drive customers and the stakeholder experience, as well as an understanding of the stages of the sales process and capability with customer software such as Salesforce.

As a leading provider of digital software solutions, Perx had the resources and expertise to involve A/Professor McKeough in how to commercialise a digital therapeutic.

The project resulted in the development of a guided app – designed for individuals suffering from a range of lung conditions including chronic obstructive pulmonary disease (COPD), asthma, pulmonary hypertension and cystic fibrosis. The user-friendly app overcomes the problem of adherence to a prescribed treatment regimen.

Making products that motivate people to look after their own health

Perx Health Co-Founder Hugo Rourke said the company takes great pride in making products that motivate people to look after their own health.

"Patients quickly embraced our Perx-R with more than 90 per cent saying they would be happy to use it as part of their pulmonary rehabilitation program," Mr Rourke said.

To quote a 66-year-old female patient: "I would rather do this than sit on a waitlist for 12 months. It is good to be prompted to do the exercise program when you are not an exercise enthusiast. The most helpful part was being able to look at my steps. [Then] I would do more gardening if I had not reached the goal."

The Perx-R platform now includes the m-PR resources – which has commercialised research of the consortium of The University of Sydney, Northern Sydney Local Health District, CSIRO, Lung Foundation of Australia and Better Breathing Foundation.

There are still challenges in its implementation, with the Australian public health system needing persuasion to increase spending on digital health. But A/Professor McKeough will remain engaged with Perx Health as an advisor to help with advocacy in this area.

Excited to share the commercial experience and the great value of a REDI Fellow experience

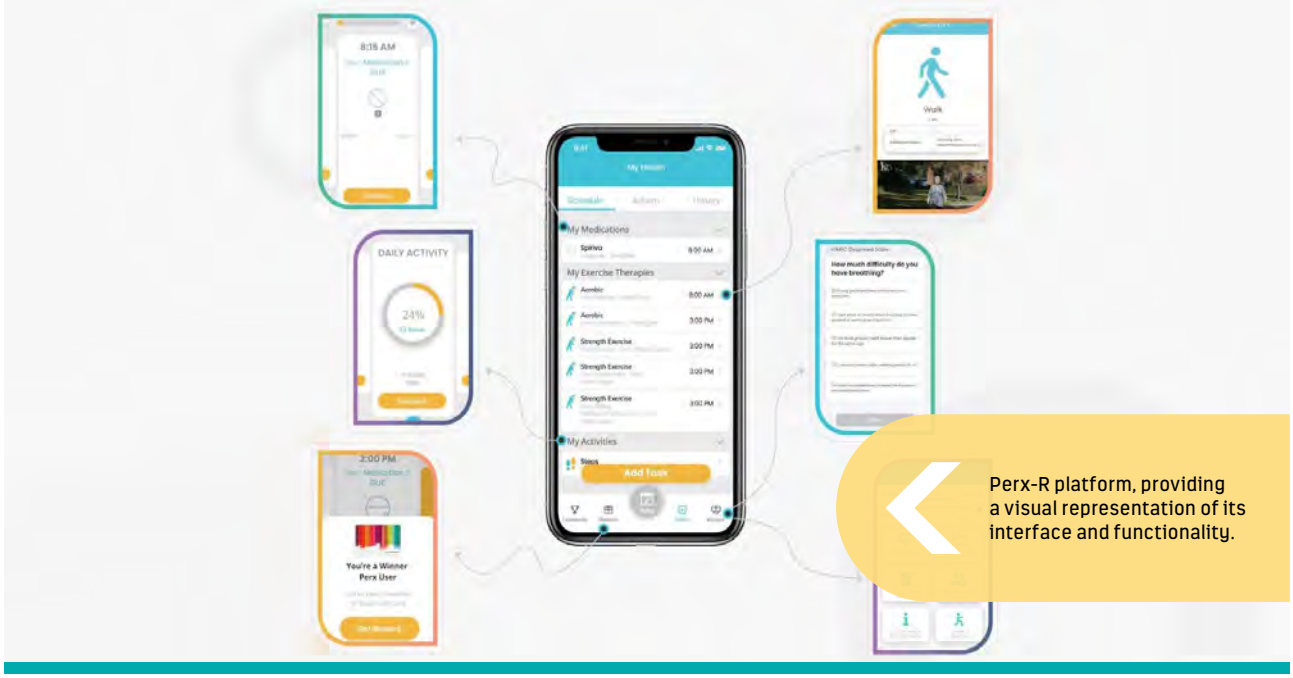
"The REDI Fellowship gave me the opportunity to interact with key stakeholders in the Australian public and private health environment to advocate for wider implementation of the Perx-R product.

"Now back at The University of Sydney, I am excited to be sharing the experience with researchers working to create digital health products, so teams understand the importance of early engagement of external industry partners and developing strategic plans for how their products might be commercialised," A/Professor McKeough said.

Talking about the Fellowship, Mr Rourke said Perx greatly valued the experience of a REDI Fellow bringing expertise to its digital health platform.

"The REDI Fellowship allowed us to accelerate and expand our vision for building digital rehabilitation programs built on the best guidelines and medical expertise.

"We also gained by having an expert such as Zoe embedded in our team, she brought unique skills and different and expanded perspectives to our development," Mr Rourke said.



Perx-R platform, providing a visual representation of its interface and functionality.

World-first hepatitis C digital therapeutic in development at Planet Innovation via REDI Fellow

SPONSOR:
Planet Innovation

FELLOW:
Associate Professor Suong Le

EMPLOYER:
Monash Health

KEY FOCUS:
Digital therapeutic, pricing and reimbursements strategies, market research and analysis, clinician-researcher

REDI Fellow Associate Professor Suong Le.

In May 2022, Planet Innovation – one of Australia's leading healthtech innovation and manufacturing companies – was awarded a REDI Fellowship for A/Professor Suong Le, a consultant gastroenterologist and hepatologist at Monash Health. Associate Professor Le was embedded in the company to work on EMPATH-C – the first digital therapeutic to support the elimination of blood-borne virus hepatitis C.

Hepatitis C presents a significant public health challenge, as it can cause serious liver disease in an infected person. In Australia more than 115,000 people are still living with chronic hepatitis C and many don't know they have the condition.[1]

Undertaking a seven-month full-time Fellowship at Planet Innovation, A/Professor Le's project, 'Engage Marginalised Populations in Accessible community-based Testing and Treatment of Hepatitis C Virus (EMPATH-C)', culminated in the design, build and pilot of a novel digital therapeutic called HepC&Me, in collaboration with the South East Public Health Unit of Victoria. A/Professor Le also contributed to a range of interdisciplinary projects, including the market validation of a new point-of-care test and the performance evaluation of a new whole slide imaging scanner.

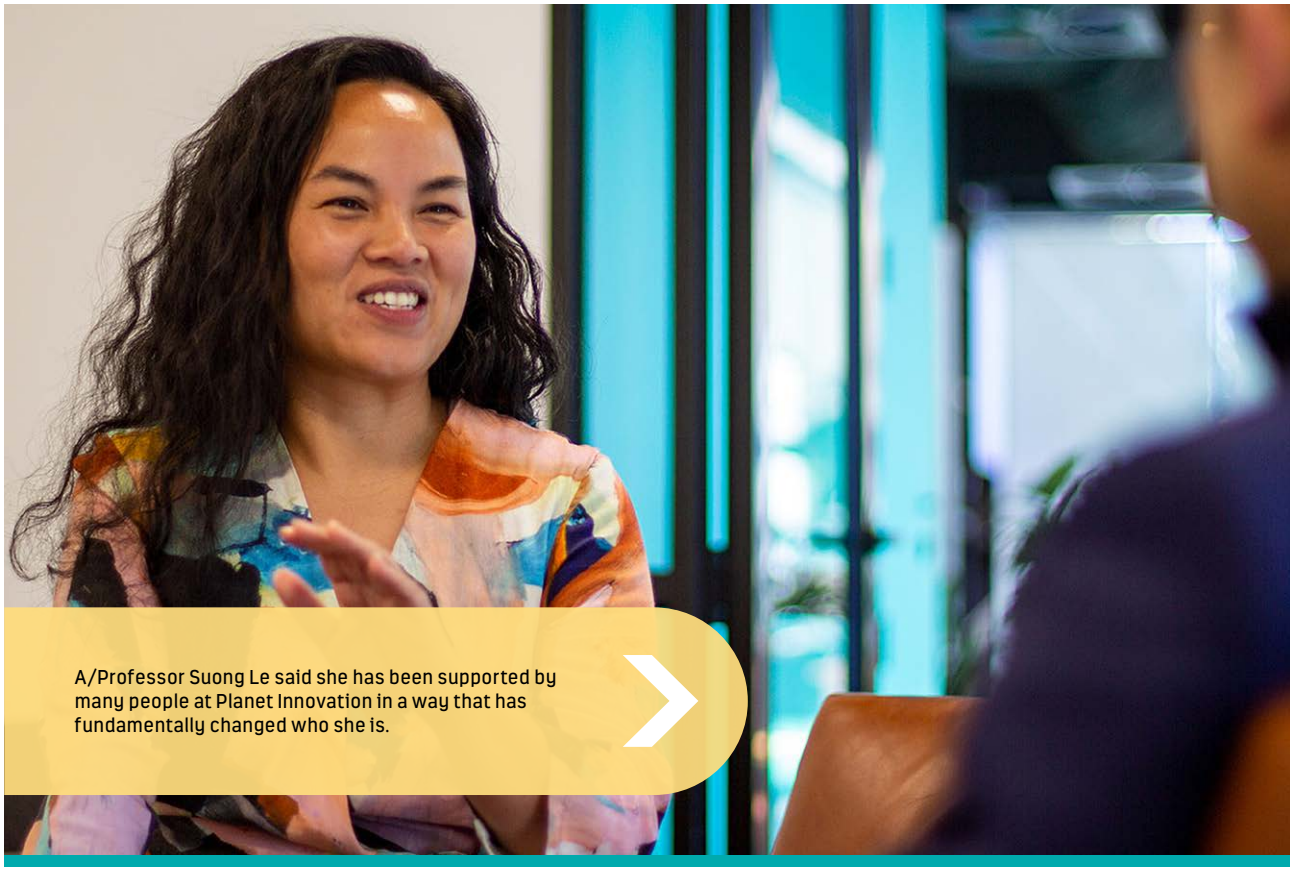
Helping Australians living with hepatitis C to access help from home

As two-thirds of Australians living with hepatitis C are not engaged with healthcare services, the project will allow patients to access help from home – to find their nearest healthcare provider, source referrals and medication scripts, generate pathology forms and receive support through to the completion of treatment.

A/Professor Le worked with experts at Planet Innovation to grow and scale this new mode of care, aiming to build sustainable reimbursement pathways for digital therapeutics in Australia. Through co-design and stakeholder engagement, she designed and implemented the clinical workflow to support implementation of EMPATH-C within complex healthcare systems. While EMPATH-C currently focuses on hepatitis C, it has the potential to scale across other blood-borne viruses, such as hepatitis B and HIV.

Planet Innovation sees great market potential in virtual diagnosis and care in this field, and the Fellowship project allowed the company to apply its experience and use its network to create a new product in an area of huge unmet clinical need.

1. Hepatitis Australia: Hepatitis C
https://www.hepatitisaustralia.com/Pages/Category/hepatitis-c



REDI Fellowship was a privilege and a life-changing experience

A/Professor Le said the Fellowship also enabled her to develop skill sets in areas such as product development and commercialisation, business operations and regulatory affairs, as well as build valuable industry relationships and share insights at national and international workshops and conferences.

"The REDI Fellowship has been both a privilege and a life-changing experience. I have been re-educated, mentored and supported by many people at Planet Innovation in a way which has fundamentally changed who I am, how I operate and what I value."

Monash Health Chief Medical Officer, Associate Professor Anjali Dhulia, also welcomed the partnership.

"Associate Professor Le's REDI Fellowship has provided valuable skills development, experiences and collaboration within the rapidly emerging field of digital health," A/Professor Dhulia said.

Continued collaboration and spinning off a new healthcare start-up

A/Professor Le continues to collaborate with Planet Innovation and share her newly gained knowledge within Monash Health and Monash University.

The REDI Fellowship has inspired A/Professor Le to spin off her own healthcare start-up – Juno Healthcare – to reimagine the delivery of specialist care for tertiary hospitals. The company now has 15 employees.

> **"The REDI Fellowship has been both a privilege and a lifechanging experience."**

Qpex Biopharma and Australian researcher develop new antibiotic ready for clinical trials

SPONSOR:
Qpex Biopharma

FELLOW:
Associate Professor Tony Velkov

EMPLOYER:
Monash University

KEY FOCUS:
Medical technology, clinical trial management, manufacturing process optimisation, regulatory affairs strategy, global collaboration

REDI Fellow Associate Professor Tony Velkov.

Qpex Biopharma is a US-based biopharmaceutical company discovering and developing innovative anti-infective therapies to meet the urgent clinical need created by antibiotic resistance. Antimicrobials under development in its portfolio include QPX9003, which was cultivated in the lab of Associate Professor Tony Velkov from Monash University's Department of Pharmaceutics. In 2023, Qpex was awarded a REDI Fellowship for A/Professor Velkov to progress QPX9003 towards manufacture and clinical trials.

Antimicrobial resistance (AMR) occurs when microbes such as bacteria, viruses, fungi or parasites become unresponsive to medicines that once killed them.[1] It is estimated that more than 5,200 Australians die from AMR-associated causes each year and more than 1.27 million people die each year from drug-resistant infections.[2]

Antibiotics are a cornerstone of modern medicine. They have made life-threatening infections treatable; chemotherapy and organ transplant possible; surgical procedures safer; and significantly reduced the burden of infectious diseases. There is an urgent unmet medical need for new antibiotics for infections caused by bacterial superbugs. The development of QPX9003 is a major step towards addressing this need.

A/Professor Velkov is a world-leading expert in several aspects of antibiotic pharmacology including their mode of action, chemistry and structure-activity relationships. The REDI Fellowship project saw him involved in the scaled-up Good Manufacturing Practice (GMP) manufacture and clinical trials of QPX9003.

Throughout his time at Qpex, A/Professor Velkov had the opportunity to develop his commercialisation skills, particularly in the areas of regulation, manufacture, clinical trial preparation and market structure. The placement also provided networking opportunities and improved awareness of his own and Qpex's resources and capabilities. The Fellowship enhanced his understanding of the development of narrow spectrum antibiotics with focused clinical trials, as well as the US government incentives programs for new antibiotics and the financial drivers for a program's success.

> **The REDI Fellowship program has proven to be a valuable opportunity that has allowed us to host Associate Professor Velkov, which has greatly strengthened our Australian–US industry collaborations.**

1 https://www.mtpconnect.org.au/programs/AAMRNet
2 https://www.csiro.au/en/about/challenges-missions/antimicrobial-resistance

It is estimated that more than 5,200 Australians die of AMR-associated causes each year – QPEX Biopharma is a US-based biopharmaceutical company discovering and developing innovative anti-infective therapies to meet this urgent clinical need.

These were all important learnings that have reset the priorities for his Australian-based antibiotic development programs. The experience delivered other personal – and far-reaching – benefits, too.

"The opportunity to receive upskilling in a US pharmaceutical company specialising in antibiotic development has provided me with professional development opportunities I could not obtain in Australia.

"The industry training opportunities I have received will be passed onto the Australian research community through my Monash University workshop programs and lectures," A/Professor Velkov said.

For Qpex, the Fellowship led to new collaborations and strengthened its ties with Monash University, laying the foundation for future joint opportunities. Already, the company is continuing to engage A/Professor Velkov's expertise on other projects.

Qpex Vice-President Dr Scott Hecker said: "The REDI Fellowship program has proven to be a valuable opportunity that has allowed us to host Associate Professor Velkov, which has greatly strengthened our Australian–US industry collaborations."

Clinical trials and drug approval expertise is extremely valuable for Australian university biotech commercialisation. To this end, having returned to Monash University, A/Professor Velkov plans to share this new-found expertise by hosting annual workshops and career development seminars to encourage the next generation of R&D scientists.

> **The opportunity to receive upskilling in a US pharmaceutical company specialising in antibiotic development has provided me with professional development opportunities I could not obtain in Australia.**

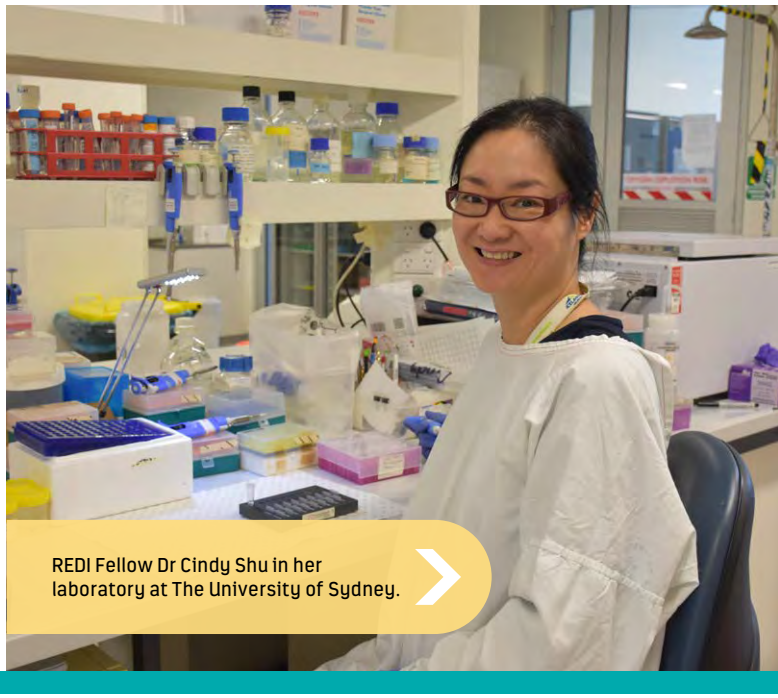
Moving a novel stem cell osteoarthritis treatment from bench to bedside

SPONSOR:
Regeneus Ltd

FELLOW:
Dr Cindy Shu

EMPLOYER:
The University of Sydney

KEY FOCUS:
Regenerative medicine, therapeutic, regulatory landscape, licensing



REDI Fellow Dr Cindy Shu in her laboratory at The University of Sydney.

A REDI Fellowship helped drive forward trials for new therapy from regenerative medicine leader Regeneus.

Regeneus is an Australian-listed regenerative medicine company that has been developing cellular therapies for osteoarthritis since 2007. A REDI Fellowship allowed the company to bring in Dr Cindy Shu from The University of Sydney to work on development of a new stem cell treatment for knee osteoarthritis, while giving her a firsthand appreciation of the processes involved in bridging basic research outcomes and clinical applications.

Regeneus previously commercialised the stem cell therapy HiQCell, which involves harvesting a small amount of a patient's own stem cells from fat tissue and re-injecting them in osteoarthritic-affected joints such as knees, hips and ankles.

Progenza™, the company's current commercialisation focus, is an allogeneic mesenchymal (anti-ageing) stem cell product for knee osteoarthritis. The therapy is at a pivotal stage of development and Dr Shu was involved in developing *in vitro* assays and conducting assessments of Regeneus' treatment Progenza™ in preclinical studies.

An in-depth understanding of osteoarthritis pathophysiology and substantial experience

Dr Shu, a University of Sydney researcher with the Raymond Purves Bon and Joint Research Laboratory team at the Kolling Institute since 2008, is exploring the pathophysiology of bone and joint diseases, with a particular focus in disease mechanism, disease progression and therapeutic intervention. She has an in-depth understanding of osteoarthritis pathophysiology and substantial experience in immune cell analysis, which is of significant interest to Regeneus.

Using the methodologies developed at her laboratory, Dr Shu critically validated the potency and efficacy of Progenza™ to demonstrate the batch-to-batch consistency. She also validated the platform's mechanism of action, providing valuable empirical data to regulatory authorities and potential licensing partners.

Dr Shu also assessed Progenza™ in an osteoarthritis model for beneficial effects on structural damage, pain and immune cell modulation as well as investigating the ability of Progenza™ to prevent the development of cardiovascular disease, which is a common occurrence in osteoarthritis treatments.

Fellow gained key insights into the operational aspects of the biotechnology industry

The REDI Fellowship allowed Dr Shu to gain insights to the operational aspects of the biotechnology industry including the tissue procurement process, donor eligibility, clinical trials application and requirements, manufacturing, Good Laboratory Practice, preclinical trial coordination and optimisation and intellectual property (IP) development.

She designed and executed a formal preclinical efficacy and safety study, working closely with Regeneus' Director of Clinical Development and Medical Affairs, Dr Sinéad Blaber, regulatory consultants and clinical research organisations, to design and manage a non-clinical study to regulatory standards.

Dr Blaber said academic research is vital in many respects and it is critical to have a scientific understanding of the pathophysiology of diseases and potential pathways that could be targeted with therapeutics.

A holistic view of the development of a novel therapeutic from an industry perspective

"However, with traditional academic research there is generally a lack of understanding on how to translate such discoveries into therapeutics. This project provided Dr Shu with a holistic view of the development of a novel therapeutic from an industry perspective.

"These new skill sets will assist Dr Shu in identifying the patentable aspects of her research, attractiveness to industry and optimal IP filing timing to maximise patent life," Dr Blaber said.

Dr Shu said it was a great learning curve of all aspects of the biotech industry from R&D to clinical trials requirements, to building international business partnerships.

> **A REDI Fellowship allowed the company to bring in Dr Cindy Shu from The University of Sydney to work on development of a new stem cell treatment for knee osteoarthritis.**

New knowledge from Fellowship will help streamline research project and increase output

"Perhaps more immediately relevant is the better understanding of product development that I can relate back to the potential of my research in the clinical space.

"A sponsor's R&D work has a more practical outcome focus – a sponsor will abandon or change tack when a project has limited future potential. This knowledge will help to streamline our research project and increase our research output. It has also meant we design our university projects differently, as we consider alternative angles and potential outcomes," Dr Shu concluded.

A better connection for epilepsy diagnosis

SPONSOR:
Seer Medical

FELLOW:
Dr Cathal O'Connell

EMPLOYER:
RMIT University

KEY FOCUS:
Medical technology, bioengineering, Quality Management System, manufacturing

The Seer Medical WaterTabs electrode product will allow long duration ECG epilepsy diagnosis monitoring at home.

Seer Medical has made huge strides towards at-home monitoring to diagnose epilepsy. A REDI Fellowship allowed the company to bring in bioengineering expert Dr Cathal O'Connell to help upgrade the product.

Monitoring the electrical activity of the brain using electroencephelogram (EEG) measurements is a crucial component in the diagnosis of epilepsy. This monitoring requires adhering electrodes to the patient's scalp, which, in the case of Seer Medical's at-home system, must be worn for seven days. This novel approach dramatically changes the requirements for electrode attachment on the skin and demands a new solution. Conventional electrode adhesives used for this longer time period can lead to skin irritation, are labour intensive to fit and do not last the duration of monitoring.

Ten years of experience in developing and optimising biomaterial

To tackle this problem, Seer Medical, Australia's largest at-home epilepsy diagnostics service, has developed a product called WaterTabs, an advanced, conductive material for adhering electrodes to the patient's head.

A REDI Fellowship allowed the company to access the expertise of Dr O'Connell, at the time a Vice-Chancellor's Postdoctoral Fellow from RMIT University, to develop WaterTabs further.

Dr O'Connell has a long-standing interest in biomaterial-electrode interfaces, beginning with his PhD at the ARC Centre of Excellence for Electromaterials Science, where he focused on developing conductive formulations for high-resolution electrode fabrication. He has 10 years of experience in developing, characterising and optimising biomaterial (hydrogel) formulations for biomedical applications.

During the Fellowship, Dr O'Connell helped the Seer team identify a new electrode adhesive formulation, which performed better in lab tests than the existing product. The project produced four new characterisation protocols for electrode materials, covering impedance testing, drying rates and adhesion.

Navigating the pipeline of medical device development

Dr O'Connell also helped Seer gain a new understanding of factors influencing long-term electrode performance and helped highlight gaps in knowledge at Seer and in the wider industry around the electrolyte-skin interaction, helping to define new research questions which will be pursued in future projects.

For Dr O'Connell, the Fellowship provided an understanding of a regulated environment and international standard compliance, showing him how the data he generates as a researcher is used for regulatory submissions.

The experience gave him the skills to engage in research under a Quality Management System, as well as experience in writing protocols, project management and the design of validation and verification tests.

REDI Fellow Dr Cathal O'Connell

Dr O'Connell said through his contributions to the new WaterTabs hydration protocol, he now has experience in navigating the pipeline of medical device development.

Research should not constrain itself to solving tech challenges

"This work necessitated regular liaison with key stakeholders across the business, including quality control, regulatory affairs, supply management and manufacturing, and I learned firsthand the various requirements for integrating a new technology into a clinical environment.

"Exposure to these real-world considerations – entirely outside the test-lab environment – has been a new experience for me and an eye-opener as to the reality of industrial research and development. On the research side, I have begun to appreciate the design aspects inherent in any biomedical engineering research project.

"This Fellowship has convinced me that research should not constrain itself to solving the technical challenges around developing a new therapy – in fact the implementation of a new solution within the clinical ecosystem is at least as challenging," Dr O'Connell said.

> "Dr O'Connell helped the Seer team identify a new electrode adhesive formulation, which performed better in lab-tests than the existing product."

Enhancing the experience for clinicians and patients

Seer Medical's Technical Product Manager, Jonathan Posniak, said Dr O'Connell played a crucial role in supporting Seer with various high-impact projects.

"By improving the understanding of the WaterTabs product, Dr O'Connell's efforts have enabled Seer to introduce new clinical procedures that enhance the experience for both clinicians and patients. The learnings are being used to develop a next-generation adhesive product that will also be used in our sleep and cardiac diagnostic devices.

"Dr O'Connell has provided support to the team in performing tests and analyses to meet regulatory requirements. This assistance has been instrumental in enabling Seer to expand its operations into new markets overseas," Mr Posniak said.

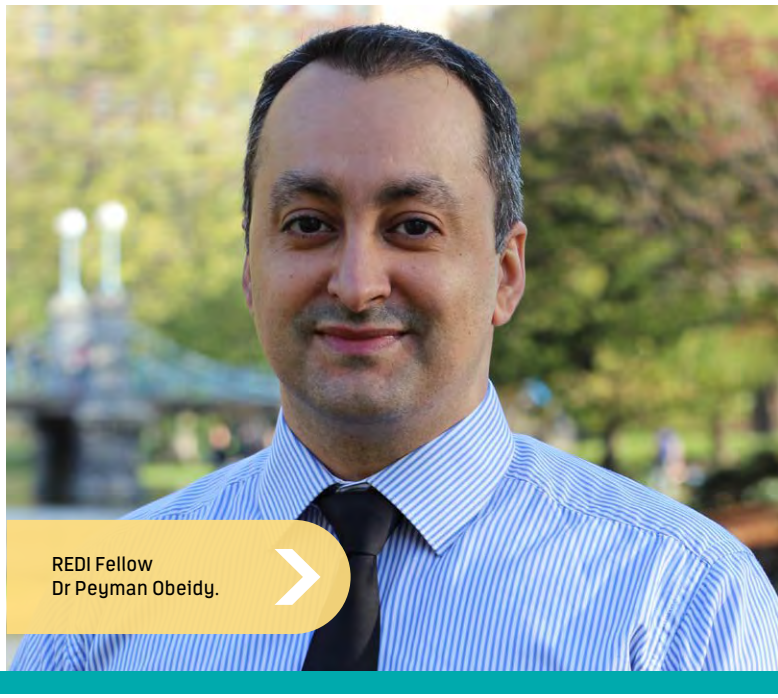
A three-way collaboration enabling coronary artery disease risk identification and stratification

SPONSOR:
Siemens Healthineers

FELLOW:
Dr Peyman Obeidy

EMPLOYER:
University of Sydney

KEY FOCUS:
Medical Technology, AI, digital diagnostics, regulatory requirements and market analysis



REDI Fellow
Dr Peyman Obeidy.

A partnership between Siemens Healthineers and medical data firm iCoreLab was facing delays common to complex collaborations, until a REDI Fellowship secondment to Siemens Healthineers for Dr Peyman Obeidy brought the University of Sydney into a three-way collaboration that progressed several projects and paved the way for future development.

Siemens Healthineers, a leader in medical imaging, laboratory diagnostics and medical information technology, was awarded a REDI Fellow to work within its local ANZ development team on a heart disease project. Imaging Core Lab Pty Ltd (iCoreLab) is a small Sydney-based company that specialises in medical data handling, annotation and processing to facilitate translational research. Dr Obeidy, from the University of Sydney, joined the Siemens Healthineers team as the project liaison between iCoreLab and Siemens Healthineers.

The Fellowship positioned Dr Obeidy as the project contact person for each party. For Dr Obeidy the project provided an opportunity to learn and participate in Siemens Healthineers commercial product development, including understanding specifications, validation and regulatory requirements, as well as learning how digital products can be positioned in the market, which paid dividends when he returned to his role at the University of Sydney.

REDI Fellowship provides opportunity to accelerate the project's development

The REDI Fellowship provided Siemens Healthineers with the opportunity to allocate the dedicated personnel to the project, accelerating the development of the project. The long duration of the Fellowship also presented unforeseen opportunities that have proven highly beneficial to the Fellow. Throughout the Fellowship, Siemens Healthineers was able to facilitate exposure to additional research projects being undertaken with other clinical partners. These projects provided Dr Obeidy insights into the different challenges and perspectives that needed to be considered when establishing industry-academic engagements. Dr Obeidy was also introduced to developing industry-focused risk assessments when assessing potential research activities. These experiences proved pivotal, as it taught Dr Obeidy to address challenges and develop contingency plans to mitigate potential risks.

Head of Collaborations and Research for ANZ at Siemens Healthineers, Dr Kieran O'Brien, said the Fellow was able to fulfil his role and help the project to get closer to defined aims.

Project management skills and commercialisation expertise help establish crucial industrial partnerships

"The Fellow's contributions have been indispensable, significantly enhancing its trajectory and outcomes. The REDI Fellowship program enabled Siemens Healthineers to gain better oversight and drive the progress of the joint collaboration project. The project's demand for additional project management support presented a valuable learning experience for Dr Obeidy, which he navigated effectively," Dr O'Brien said.

Dr Obeidy is now using his experience with industry engagement and collaboration at the University of Sydney, helping his academic colleagues develop their own understanding of industry's viewpoints. After returning to the university, Dr Obeidy has used his project management skills and commercialisation expertise from Siemens Healthineers to establish crucial industrial partnerships with Nectir, Patient Zero and Snowflake Inc, bridging the gap between industry and academia. Most recently, Dr Obeidy was appointed as the Commercialisation Coordinator by the leadership group of the Sydney Clinical Imaging Network (SCIN), during his tenure in Sydney.

Being proactive and helping to build strategic collaborations in the future

"These opportunities arose from me being proactive in June 2023, when I attended the Digital Transformation LIVE conference, one of Australia's largest ICT trade shows, during my annual leave.

"This volunteer position allows me to bring my industrial experience to the committee. The aim of this working group is to enhance SCIN members' chances of getting involved in industry opportunities, promote current projects and best practices, and help to build strategic collaborations in the future," Dr Obeidy said.

> **This project also gave Dr Obeidy an opportunity to learn and participate in SHS's commercial product development and to gain an understanding about how digital products can be positioned.**

RNA expert works with SpeeDx to develop new diagnostic test for STIs that could help fight antibiotic resistance

SPONSOR:
SpeeDx

FELLOW:
Associate Professor Nham Tran

EMPLOYER:
University of Technology Sydney (UTS)

KEY FOCUS:
Antimicrobial resistance, diagnostic medication, regulatory requirements, point-of-care device

Associate Professor Nham Tran with SpeeDx founder and Chief Scientific Officer, Alison Todd AM.

Current molecular diagnostics tests are great at identifying microbes but not so good at working out which ones are actively causing an infection, or whether they are still active. SpeeDx is working on a program that could solve this dilemma and received a REDI Fellowship to bring Associate Professor Nham Tran on board to help in the quest.

Pioneering diagnostics company SpeeDx is developing new techniques that are better able to detect infections. A REDI Fellowship allowed it to tap into A/Professor Tran's expertise in identifying pathogens through their RNA.

During the Fellowship, A/Professor Tran from University of Technology Sydney (UTS) worked on the InSignia project – a newly developed diagnostic test for sexually transmitted infections for types of chlamydia and gonorrhoea. A/Professor Tran specialises in investigation of small RNA biomarkers within clinical contexts and the exploration of the role of small RNAs in various diseases.

The SpeeDx InSignia work is important not just to provide a better diagnostic tool, but to combat increasing microbial resistance to antibiotics. The problem is that current molecular diagnostic tests for infectious diseases identify pathogens by detecting their nucleic acids, regardless of whether the pathogens are actively causing infection or not. A false positive increases the risk of over-diagnosis and over-prescription of antimicrobials.

A simple, scalable test to determine if antimicrobials are required

InSignia aims to provide a simple, scalable test to quickly determine whether a pathogen is alive and if antimicrobials are necessary.

By accurately identifying infections, it reduces the incidence of unnecessary antibiotic treatments, thereby decreasing healthcare expenditures by at least three-fold.[1] Early and precise infection detection also enables more efficient use of antibiotic resources, which is particularly crucial in high-prevalence and high-risk areas.

The InSignia product is unique, and SpeeDx launched its research-use only version into the market in May-June 2024, with the aim of developing a point-of-care device in the future.

1. National Library of Medicine, National Center for Biotechnology Information – PubMed: The Estimated Direct Lifetime Medical Costs of Sexually Transmitted Infections Acquired in the United States in 2018 https://pubmed.ncbi.nlm.nih.gov/33492093/

The company hopes that InSignia will help guide clinicians in making informed decisions about antibiotic use, while data from the program can help shape treatment protocols and public health strategies, fostering a more systemic approach to antimicrobial stewardship.

A/Professor Tran used his diagnostic experience and understanding of the market to provide a detailed analysis of the competitive environment. This input assisted in shaping the strategic direction of the project, helping SpeeDx to identify areas for development and potential market opportunities. He also used his expertise to perform bioinformatic analysis on RNA sequencing data for the InSignia project to identify potential future diagnostic targets. This would enable SpeeDx to expand its portfolio of diagnostic targets into the future.

Experienced, qualified mentors at SpeeDx for the InSignia project

At the company, A/Professor Tran was mentored by Chief Scientific Officer and Director, Dr Alison Todd, and Dr Nicole Lima, Research Manager for the InSignia project.

They helped him understand the complex labyrinth of regulatory requirements, covering Therapeutic Goods Administration (TGA) and Food and Drug Administration (FDA) approvals, compliance standards and ethical considerations in clinical applications in Australia and the US, respectively.

The experience gave A/Professor Tran a clear understanding and practical know-how to translate his research discoveries into viable diagnostic solutions with real-world impact.

"The REDI Fellowships are a career-defining program which allows for personal growth and the possibilities for future collaborations," he said.

"I hope the program will continue to be funded and allow Australian companies such as SpeeDx to invest in talent and grow our medical device industry."

Linking SpeeDx with the UTS internship program – benefits for everyone

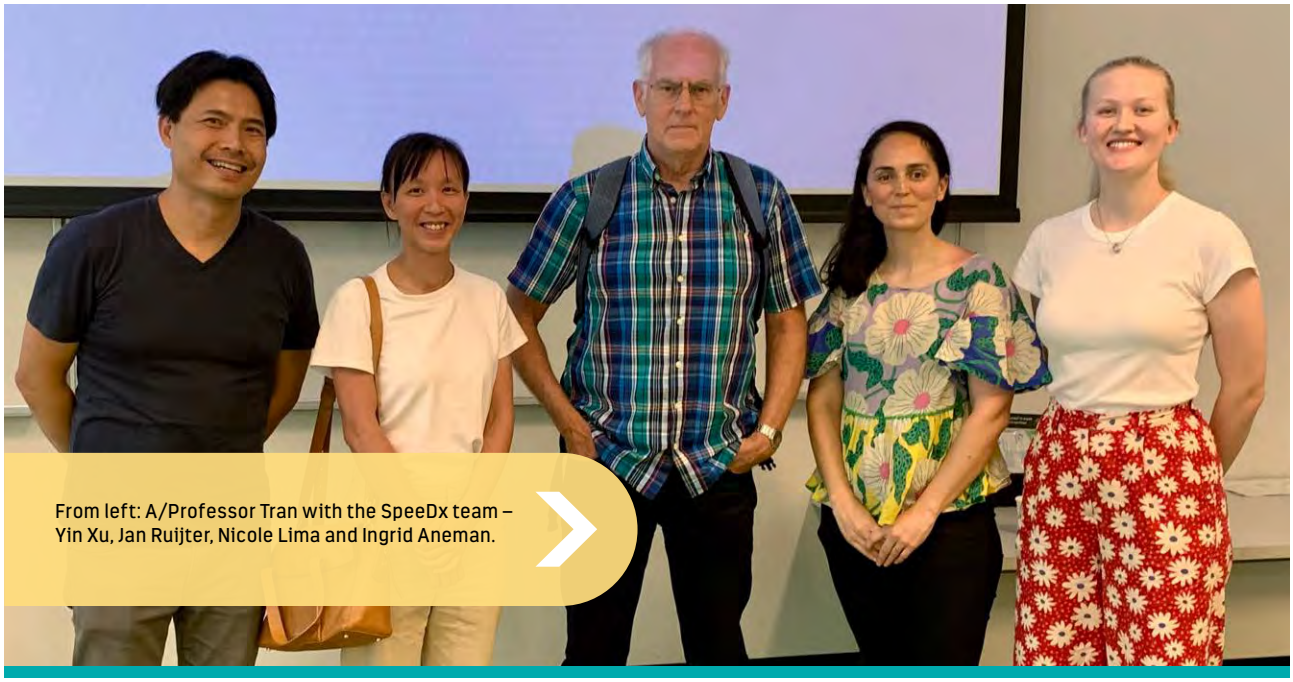
A/Professor Tran's work at SpeeDx also benefitted his home institution UTS. He linked SpeeDx with the UTS internship program, which led to SpeeDx hosting a group of biomedical engineering undergraduates for an internship project. The interns worked on the design and development of a point-of-care device to be commercialised.

A/Professor Tran also contributed expertise to the company in various other ways, including training SpeeDx staff in workshops focusing on RNA sequencing and providing network opportunities to connect with world experts in qPCR. Additionally, A/Professor Tran increased awareness of SpeeDx's products within the scientific community via connecting SpeeDx with UTS academics. This led to a collaborative project between the company and a 3D bioprinting and stem cell technology expert at UTS, focused on developing new growth mediums.

SpeeDx highly valued the input provided by A/Professor Tran and recognises the collaboration's significance and worth.

Summing up the REDI Fellowship experience, SpeeDx Director Dr Todd said: "Having Nham here as a REDI Fellow has been a true win-win for our company. We will continue working with him and others at UTS and keep exploring new opportunities."

> **The SpeeDx InSignia work is important not just to provide a better diagnostic tool, but to combat increasing microbial resistance to antibiotics.**



From left: A/Professor Tran with the SpeeDx team – Yin Xu, Jan Ruijter, Nicole Lima and Ingrid Aneman.

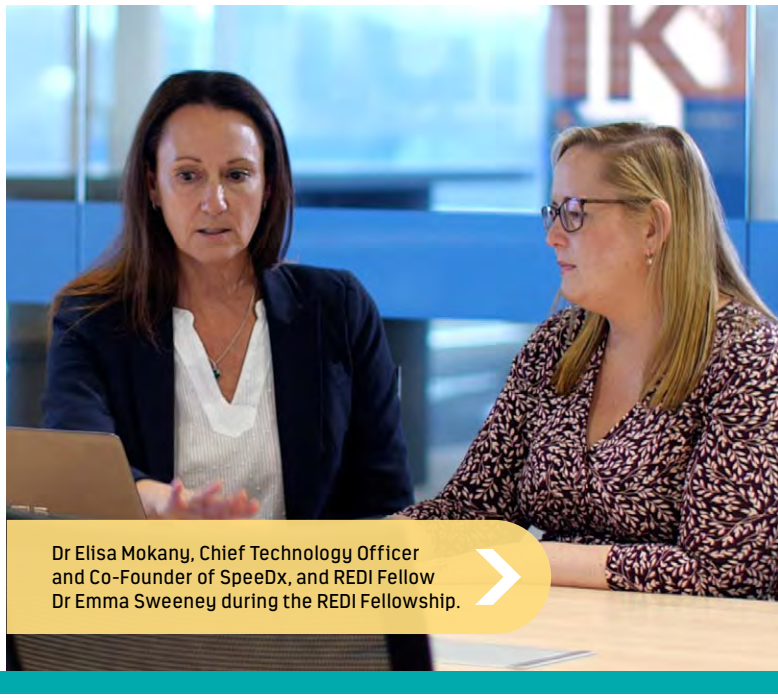
A vital test leads to better outcomes for STI patients

SPONSOR:
SpeeDx

FELLOW:
Dr Emma Sweeney

EMPLOYER:
The University of Queensland

KEY FOCUS:
Diagnostics, public health, antibiotic resistance, commercialisation pathway



Dr Elisa Mokany, Chief Technology Officer and Co-Founder of SpeeDx, and REDI Fellow Dr Emma Sweeney during the REDI Fellowship.

A REDI Fellowship brought specialist researcher Dr Emma Sweeney together with molecular diagnostic company SpeeDx, to combine forces to develop new precision medicine treatment strategies for the concerning sexually transmitted superbug *Mycoplasma genitalium*.

Four million Australians experience a sexually transmitted infection (STI) at some point in their lives, a statistic that becomes more concerning with the rise of antimicrobial resistance (AMR). The World Health Organization has identified AMR as one of the top 10 global public health threats, with the true number of deaths being hard to calculate, as detailed in the MTPConnect AAMRNet and CSIRO report, 'Antimicrobial Resistance (AMR) Impact Report: How big is Australia's AMR threat', launched in November 2022.

Superbug challenge brings REDI Fellow to SpeeDx

One pathogen of particular concern to health authorities is *Mycoplasma genitalium*, an STI pathogen with high levels of resistance to current antibiotic treatments and very limited alternative treatments available.

Under a REDI Fellowship, this superbug challenge brought together molecular diagnostic company SpeeDx and Dr Sweeney, a Senior Research Fellow at The University of Queensland Centre for Clinical Research, whose work focuses on developing molecular diagnostic tools to detect pathogens of public health importance and detection and characterisation of AMR.

Given *M. genitalium's* antibiotic resistance, accurate testing is crucial to launch individualised treatment approaches as soon as possible. A test for antibiotic resistance conducted prior to treatment is the only way to deliver treatment success.

Transforming the diagnostic landscape for individualised treatment of *M. genitalium*

The partnership between SpeeDx and Dr Sweeney under the Fellowship has transformed the diagnostic landscape for individualised treatment of *M. genitalium* by developing a prototype test for the simultaneous detection of the *M. genitalium* pathogen, and key markers of resistance to the macrolide and fluoroquinolone antibiotic drug families, the two mainstay treatments for the pathogen.

This test could be readily adopted by pathology departments globally, empowering clinicians to use precision medicine for the timely, tailored treatment of *M. genitalium* infections.

The collaboration between SpeeDx and Dr Sweeney under the Fellowship was so successful, it was subsequently bestowed both the '2023 University of Queensland Research Partnerships and Translational Excellence' award, as well as the '2023 University of Queensland Early and Mid-Career Industry Engagement' award.

Prior to the REDI Fellowship, Dr Sweeney had designed, validated and published several prototype assays to detect and characterise AMR in *M. genitalium*, including an assay to characterise fluoroquinolone antibiotic resistance, which was translated for routine use by pathology providers in Queensland and Victoria.

Critical insights into R&D stages and timelines

The opportunity to integrate within SpeeDx as part of the REDI Fellowship gave her critical insights into industry R&D stages and timelines, and an appreciation for the time taken to commercialise molecular diagnostic assays.

She also gained an understanding of the data and assay design considerations required for commercialisation of molecular assays, receiving specific training regarding intellectual property (IP) and patent searches, to ensure freedom to operate on molecular targets of interest; as well as specific training on SpeeDx's market leading ***Plex****PCR*® and ***Plex****Plus*® technologies, which were used in the design and development of this prototype assay.

Dr Sweeney said without the REDI Fellowship, she would not have had the opportunity to have such an immersive experience with industry.

Opportunities and potential for future collaborative work

"This has opened many opportunities and potential for future collaborative work with SpeeDx. Within The University of Queensland, I have been able to share some of the information gained as part of this Fellowship, which has transformed the way I and others develop molecular assays for research purposes.

"Our research is now viewed through the lens of 'if this assay is effective, where and how could this be commercialised?'," Dr Sweeney said.

Since completing the Fellowship, Dr Sweeney has continued to work closely with SpeeDx and has started developing several other important diagnostic assays with the company.

"My own specific skill set, as an emerging expert on the topic of *M. genitalium*, was also crucial to the Fellowship, as this enabled SpeeDx to get unrestricted access to my knowledge and my cutting-edge research – which I was able to share with them prior to publication to ensure that the test we developed would be market leading.

Ensuring targets selected are appropriate and globally accepted

"I also enabled access to other key opinion leaders in the field, so that we could discuss the utility of specific biomarkers for inclusion in the test, ensuring the targets we selected were appropriate and globally accepted," Dr Sweeney said.

Chief Technology Officer and Co-Founder of SpeeDx, Dr Elisa Mokany, said that often there is groundbreaking research occurring at universities, but they have no way to translate this into a commercial product.

"Partnering with industry enables the commercialisation of their ideas, their research and the ways they want to see an improvement in humankind. We can do this together, whereas alone, it would be much harder," Dr Mokany said.

Patient infections can be cured much faster

Summing up, Dr Sweeney said: "This Fellowship has been extremely beneficial for me and for my career. I have gained so much industry and commercialisation knowledge that I otherwise would not have been exposed to, and this has really set me up for the rest of my career.

"The diagnostic tools we are developing essentially ensure that clinicians can select the right antimicrobial to treat that infection in real time, which means patient infections can be cured much faster."

> **"Dr Sweeney has continued to work closely with SpeeDx and has started developing several other important diagnostic assays with the company."**

REDI Fellow Dr Emma Sweeney worked with SpeeDx on simultaneous detection of STI *M. genitalium* and its resistance to two main antibiotic drug families.

A partnership to develop greater efficiency in the additive manufacturing of orthopaedic implants

SPONSOR:
Stryker Australia Pty Ltd

FELLOW:
Dr Ali Dehghan-Manshadi

EMPLOYER:
The University of Queensland (UQ)

KEY FOCUS:
Medical devices, additive manufacturing, commercialisation pathway, project management

REDI Fellow Dr Ali Dehghan-Manshadi.

A REDI Fellowship facilitated engagement with MedTech leader, Stryker, in a promising research partnership. REDI Fellow Dr Ali Dehghan-Manshadi provided metallurgical expertise to Stryker's Irish manufacturing HQ, to optimise the manufacturing of titanium-based implants.

Stryker is one of the world's leading medical technology companies and, together with its customers, is driven to make healthcare better. The company offers innovative products and services in Medical and Surgical, Neurotechnology, Orthopaedics and Spine that help improve patient and healthcare outcomes. Alongside its customers around the world, Stryker impacts more than 100 million patients annually.

Stryker is committed to enhancing its products' manufacturing efficiency and cost-effectiveness and is exploring new additive manufacturing methods. As such, it was a perfect fit for a REDI Fellowship with Dr Dehghan-Manshadi, whose field of study focuses on titanium-based implants made using selective laser melting (SLM) – the most common method for 3D printing of metal objects using a laser that melts the powdered metal.

By conducting studies into the chemical composition of titanium alloys, Dr Dehghan-Manshadi's research has shown the effects of varying the chemistry can have on the mechanical properties, which may reduce the requirement for further processing.

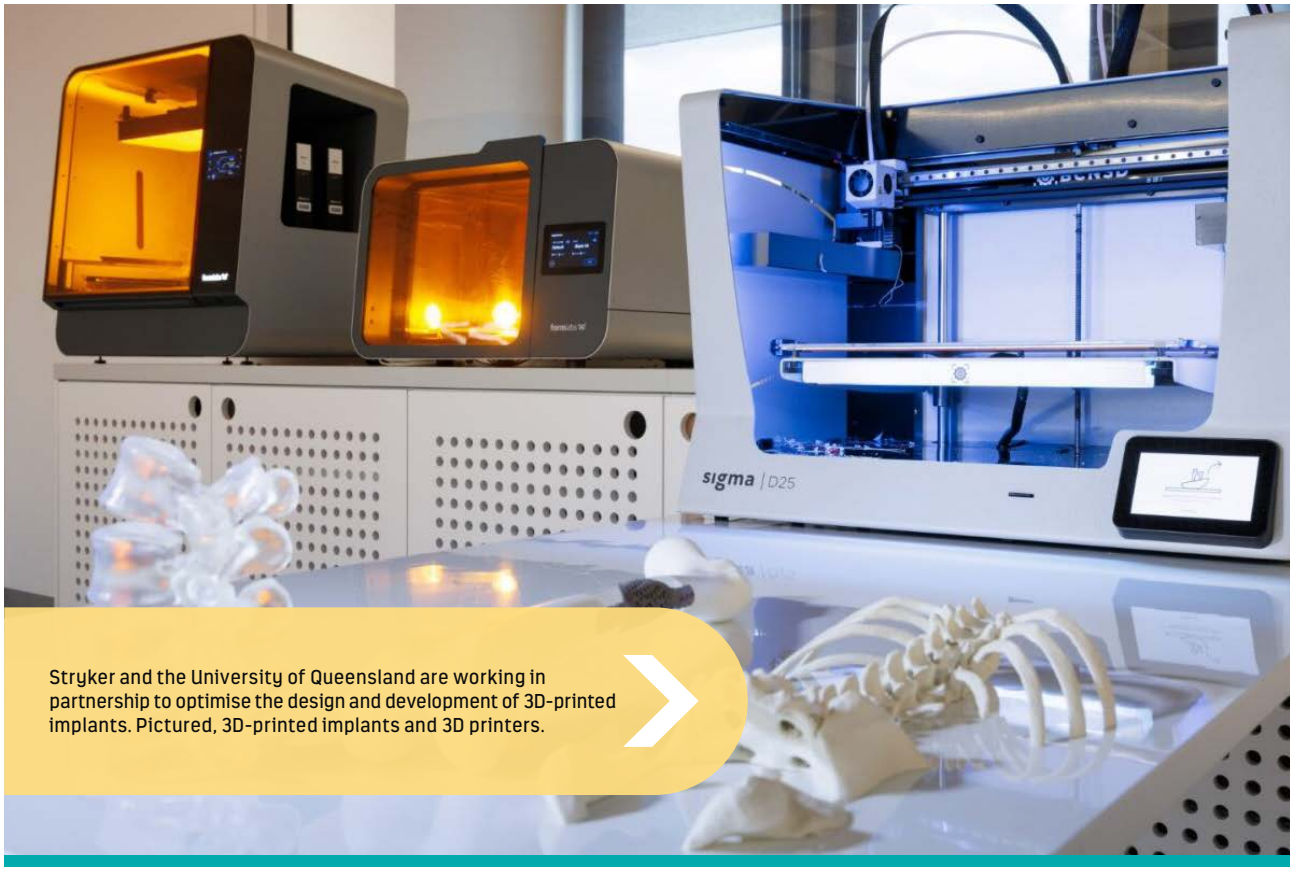
Partnership aims to make it easier to manufacture high-performance medical implants and devices

During the REDI Fellowship, Stryker opened a new R&D Lab at the Royal Brisbane and Women's Hospital – where Dr Dehghan-Manshadi was part of a research partnership involving the US company and The University of Queensland – to optimise the manufacturing of 3D-printed implants.

By using SLM printers, the partnership aims to make it easier to manufacture high-performance medical implants and devices – reducing costs, speeding up timeframes and creating devices more closely aligned with patients' specific bone geometry and density.

As well as improving his skills to lead research in the development of new implant manufacturing techniques, Dr Dehghan-Manshadi's visit to Ireland provided firsthand experience of Stryker's world-leading manufacturing facilities and enriched his skills in microstructure evaluation and alloy composition modification.

> "The outcomes of this project hold great promise for Stryker as they pave the way for the development of novel materials."



Stryker and the University of Queensland are working in partnership to optimise the design and development of 3D-printed implants. Pictured, 3D-printed implants and 3D printers.

Gaining invaluable expertise and crucial skills through the Fellowship

Dr Dehghan-Manshadi said the Fellowship gave him invaluable expertise in the advanced evaluation of the microstructure and properties of titanium-based implants, as well as how modifying the chemical composition of alloys can change their mechanical properties.

"These newly acquired skills have proven crucial in allowing me to analyse and optimise titanium-based implants, further contributing to the advancement of biomedical applications and research in this domain.

"My experiences gained through the REDI Fellowship, along with the insightful discussions I had with many experienced engineers, have equipped me with the potential to steer academic research and find innovative solutions in the additive manufacturing of biomedical implants and devices," Dr Dehghan-Manshadi said.

Conor Kelleher, Advanced Manufacturing Manager at Stryker said the Fellowship could benefit all the partners at the company's R&D Lab, as well as the patients and health providers who will ultimately use their manufacturing technologies.

Developing novel materials to offer cost-effective solutions tailored to patients needs

"The outcomes of this project hold great promise for Stryker as they pave the way for the development of novel materials. These materials offer cost-effective solutions for producing biomedical implants and devices with excellent mechanical and biomedical properties, tailored specifically for bone tissue engineering," Mr Kelleher said.

Through its R&D Lab, Stryker aims to investigate greater efficiencies for the additive manufacturing process, which may ultimately eliminate the need for heat treatment and other costly post-processing activities, that are often necessary with 3D-printed metal implants.

Dr Dehghan-Manshadi explained, "The ultimate commercial goal is to produce implants that can be used 'as built', without any additional post-processing stages. Leveraging critical research expertise in the development of titanium implants, powder metallurgy and metal injection moulding will eventually help us to eliminate these post-processing steps."

Computer scientist helps model abnormal hip shapes for Stryker to improve surgical management decisions

SPONSOR:
Stryker Australia Pty Ltd

FELLOW:
Dr Nataliya Perevoshchikova

EMPLOYER:
Griffith University

KEY FOCUS:
Medical Technology, personalised, medicine, commercial pathway

REDI Fellow Dr Nataliya Perevoshchikova.

A REDI Fellowship brought together global medtech leader Stryker and computer scientist Dr Nataliya Perevoshchikova to develop a 3D model that will help clinicians make critical surgical and patient management decisions to deal with the problem of femoroacetabular impingement.

For decades, Stryker has led the development of computer models to help clinicians plan complex orthopaedic and cranial procedures. Thanks to a REDI Fellowship, Griffith University's Dr Perevoshchikova worked in Brisbane, Switzerland and Germany, to bring her computational modelling experience to better understand the motion of abnormally shaped hips.

Femoroacetabular impingement (FAI) – a condition in which one or both bones of the hip joint are irregularly shaped, causing them to rub against each other – is surprisingly common, affecting many people around the world. Over time, it can damage the cartilage in the hip, leading to chronic problems like osteoarthritis.

Leveraging technical expertise and applying it to advance the hip range of modelling

The goal of this Fellowship was to develop range of motion simulations for abnormally shaped hips to help better understand the movement of hips with hip impingement.

Reflecting on this goal, Principal Engineer at Stryker R&D Sports Medicine, Dr Floor Lambers, said: "Dr Perevoshchikova has leveraged her technical expertise and applied it to advance the hip range of modelling beyond the common state of the art."

As well as providing Dr Perevoshchikova with a unique immersion in the world of medical imaging – and a chance to meet some of the surgeons and clinicians using Stryker's technology – the Fellowship served to bolster the already strong ties between the company and Griffith University's Centre of Biomedical and Rehabilitation Engineering (GCORE).

> **Dr Perevoshchikova worked in Brisbane, Switzerland and Germany, to bring her computational modelling experience to better understand the motion of abnormally shaped hips.**

Stryker is one of the world's leading medical technology companies, driven to make healthcare better – pictured are part of the company's Brisbane facilities.

Stryker technology impacts more than 100 million patients annually

Stryker is one of the world's leading medical technology companies and, together with its customers, is driven to make healthcare better. The company offers innovative products and services in medical and surgical, neurotechnology, orthopaedics and spine that help improve patient and healthcare outcomes. Alongside its customers around the world, Stryker impacts more than 100 million patients annually. In 2022, the company opened an R&D lab at the Royal Brisbane and Women's Hospital, where Dr Perevoshchikova was based for much of her REDI Fellowship.

During her Fellowship, Dr Perevoshchikova collaborated extensively with other computer modellers within Stryker, undertook several training programs and developed a robust professional network – as well as spending time with Stryker's sports medicine teams in Basel, Switzerland and Freiburg, Germany.

Dr Perevoshchikova said that the Fellowship delivered a deep and enduring fascination with the computer modelling and treatment of hip impingement, as well as global medical regulations, design controls and – her favourite – the Scrum project management methodology.

Improving efficiency, fostering collaboration and accelerating research translation

"Through my experience with the Stryker team, I have seen firsthand how the Scrum framework can improve efficiency, foster collaboration and accelerate the translation of research into real-world products.

"By adopting some core Scrum practices, such as daily stand-up meetings, sprint planning and retrospective reviews, I am confident that our research group at GCORE will be better positioned to deliver high-quality results and ultimately make a greater impact in the life sciences sector.

"I look forward to sharing my experiences and knowledge with my colleagues and contributing to the continued success of research endeavours," Dr Perevoshchikova said.

Dr Perevoshchikova has since taken up a role in industry after her postdoctoral role at Griffith University ended.

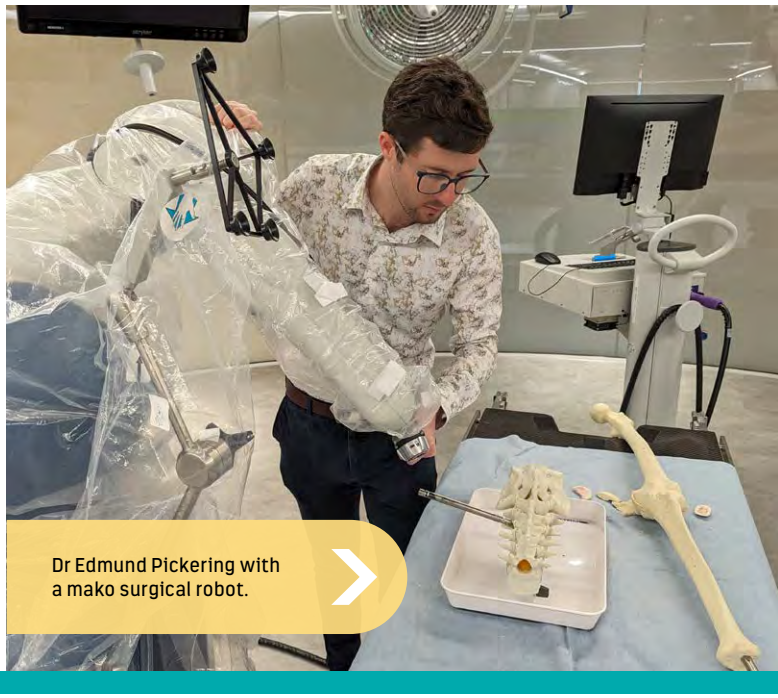
Stryker research explores new ways for medical robots to 'see'

SPONSOR:
Stryker Australia

FELLOW:
Dr Edmund Pickering

EMPLOYER:
Queensland University of Technology

KEY FOCUS:
Medical technology, global collaboration, robotics, engineering



Dr Edmund Pickering with a mako surgical robot.

Stryker is one of the world's leading medical technology companies and a global leader in robotic surgery for joint replacement. The company's robotic arm assisted surgery aims to enable a more predictable experience when performing joint replacement surgery. A REDI Fellowship allowed the company to tap into the skills of Queensland University of Technology (QUT) biomechanics researcher, Dr Edmund Pickering, to further develop how Stryker's Mako SmartRobotics system senses the material it operates on.

Stryker is one of the world's leading medical technology companies and, together with its customers, is driven to make healthcare better. The company offers innovative products and services in Medical and Surgical, Neurotechnology, Orthopaedics and Spine that help improve patient and healthcare outcomes. Alongside its customers around the world, Stryker impacts more than 100 million patients annually. Stryker opened an R&D Lab in Brisbane in 2022, to advance research focused on the development of innovative medical technology products.

The REDI Fellowship allowed the organisation to tap into the expertise of Dr Pickering, whose research is focused on the interface between biomechanics and numerical modelling, including bone healing, 3D printed tissue scaffolds and material characterisation.

The Fellowship provided a unique opportunity for Dr Pickering to work with Stryker's engineers and orthopaedic surgeons in the development of the next generation of Mako SmartRobotics – Stryker's robotic arm-assisted surgery system.

Specifically, Stryker's Mako robot is currently used for knee and hip replacements surgeries.

(In Australia, 65,570 knee and 53,663 hip replacement procedures were performed in 2022. Of those, 30.6 per cent of total knee replacements and 40.7 per cent of partial knee replacements were robotically assisted.[1,2,3]

Exploring new ways to make surgical robots sense their environment

As the use of robotic assisted surgery increases, there is motivation to incorporate new procedures, like those associated with the spine. Further developing techniques for robots to sense their environment is a priority, as spines are less stable and contain more nerves than knees and hips.

The project, led by Dr Pickering from QUT's Centre for Biomedical Technologies and the Faculty of Engineering, was designed to explore new ways to assist surgical robots sense their environment. Dr Pickering expanded his machine learning expertise and built an AI algorithm trained upon experimental data collected from cadaveric studies, enabling the robot to sense its environment based on sensor input in conjunction with the machine learning system. This embodied valuable lessons regarding the application of machine learning techniques to industry problems.

1. https://aoanjrr.sahmri.com/knees
2. https://aoanjrr.sahmri.com/hips
3. https://aoanjrr.sahmri.com/annual-reports-2022

For Dr Pickering, working with Stryker provided a new perspective into the decision making that drives product development in the next generation of commercial surgical robotics. He worked in close collaboration with Dr Tom Williamson, Robotics Manager at Stryker's R&D Lab, and one of Australia's leading medical roboticists. The engagement in the REDI program gave Stryker's team access to world-class facilities at QUT. At the end of the Fellowship, Dr Pickering was invited to visit four international Stryker sites to share the learnings and outcomes of the project with key leaders, concept developers and engineers.

Invaluable insights and understanding and meeting global leaders in medtech

Dr Pickering said working with Stryker had given him an excellent understanding in how world-leading medical technology companies pursue research and development.

"I have learnt about emerging needs and how my research can address these. Engaging in the REDI program has enabled me to meet global leaders in the medical technology industry. The insights and understanding I have gained will be invaluable in designing future research projects that are aligned to industry needs," Dr Pickering said.

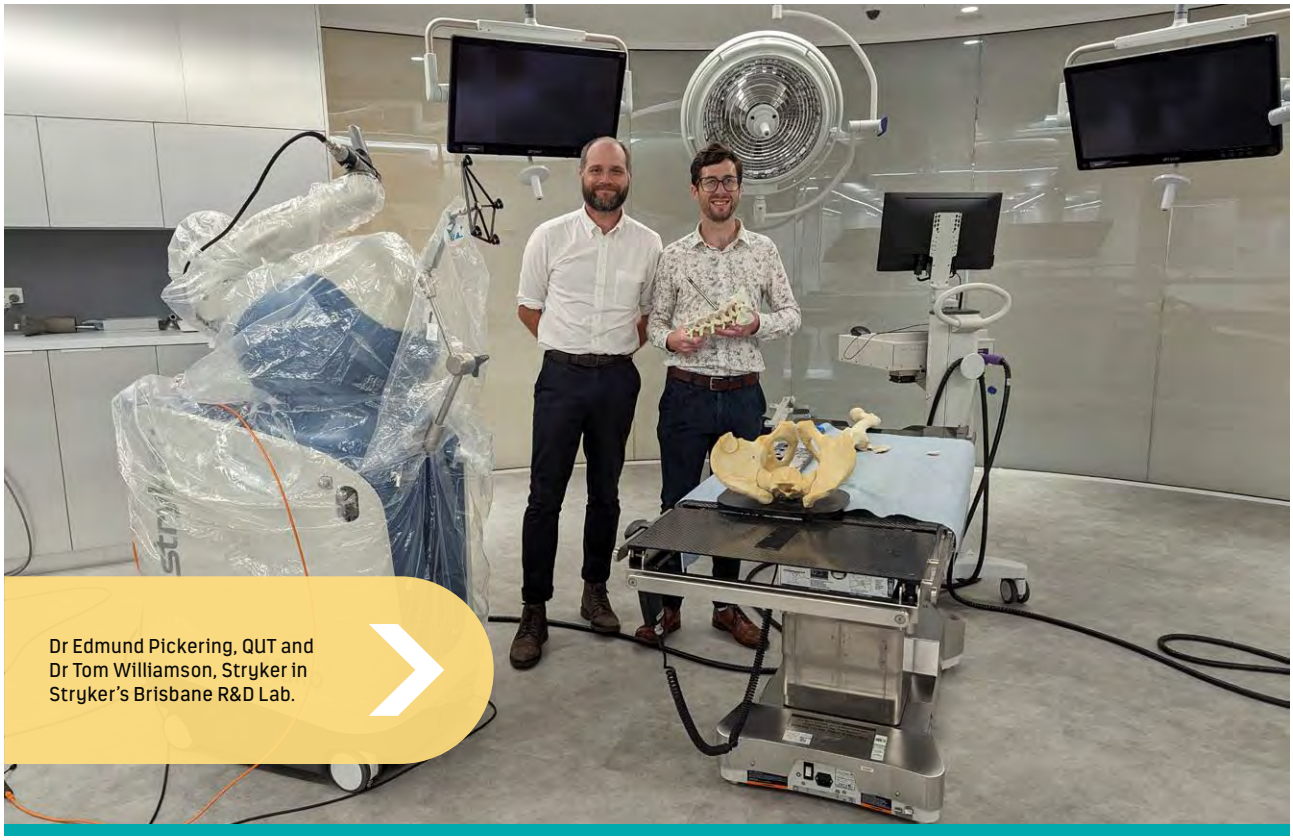
> **Engaging in the REDI program has enabled me to meet global leaders in the medical technology industry.**

Over the coming years, Dr Pickering will continue to drive this process, including inviting Stryker members to QUT and vice-versa, for lab tours, seminars and conferences. This will provide broad benefits to both Stryker and QUT and will assist in delivering research which is more aligned with industry needs.

Bringing a unique perspective and a world class set of skills to Stryker

Dr Tom Williamson said: "Working with Dr Pickering on the 'Towards smarter surgical robots' project has been a pleasure throughout. He brings a unique perspective and a world class set of skills that has enabled us to investigate new concepts and develop innovative approaches to solving important clinical problems.

"The technology developed during his fellowship could contribute to the future generations of surgical robots, making them smarter and more capable. Dr Pickering has fitted in well with the team, contributing beyond just his fellowship work and providing new ideas and a fresh set of eyes," Dr Williamson said.



Dr Edmund Pickering, QUT and Dr Tom Williamson, Stryker in Stryker's Brisbane R&D Lab.

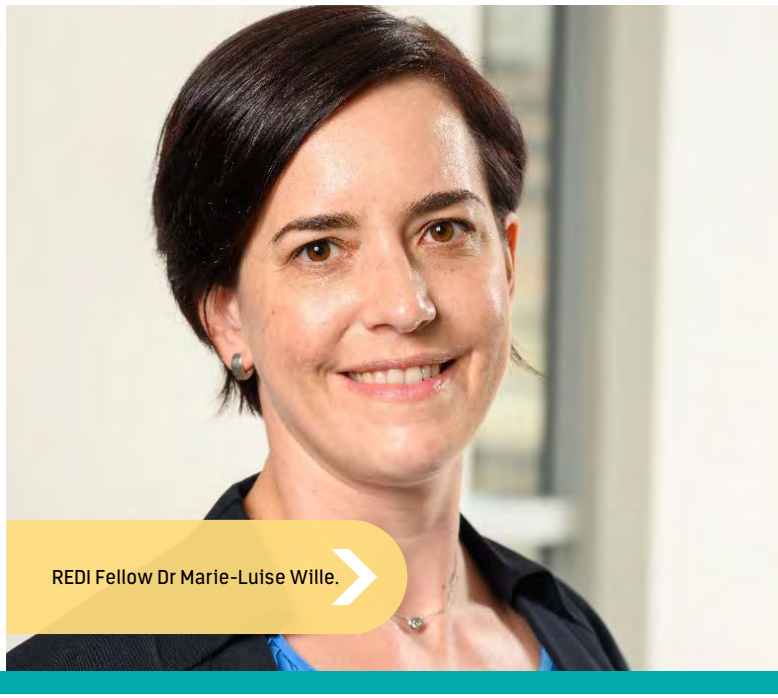
From images to implants – providing patient specific solutions at point of care

SPONSOR:
Stryker Australia

FELLOW:
Dr Marie-Luise Wille

EMPLOYER:
Queensland University of Technology

KEY FOCUS:
Personalised medicine, interdisciplinary collaboration, workflow optimisation, global collaboration



REDI Fellow Dr Marie-Luise Wille.

Driven to make healthcare better, Stryker is committed to developing low-cost, high-value patient specific biomedical implants. In 2022, Stryker was awarded a REDI Fellowship for Dr Marie-Luise Wille, a Senior Research Fellow at the Centre for Biomedical Technologies and the Max Planck Queensland Centre at Queensland University of Technology (QUT), to help the company achieve its goal of expanding its patient specific solutions portfolio.

The healthcare industry is experiencing a transformative shift towards personalised medicine and patient-centric care. The integration of patient specific solutions involves tailoring medical treatments to individual characteristics, to ensure more effective outcomes and minimise adverse effects.

To reach this goal, Stryker wishes to ensure that the current workflow that exists for the patient journey, from CT/MRI imaging to implant, is further optimised. This workflow – from initial presentation of the patient with a bone condition through to clinical assessment, design, manufacture and surgical insertion of the implant – contains multiple, time-consuming iterations.

Solving workflow issue expected to deliver value for patients by reducing time to treatment

The aim of this REDI Fellowship project was to outline the future state of patient specific solutions as a comprehensive workflow map that has applications across multiple Stryker divisions and, ultimately, develop a unified framework that is consumer- and cross-divisional centric. Optimising this workflow is expected to deliver value for patients by significantly reducing time to treatment.

Bolstered by Dr Wille's experience in biomedical 3D imaging and modelling, and her understanding of the bench to bedside pathway, Stryker made significant progress towards its goal and is now a lot closer to roadmap its patient specific technology.

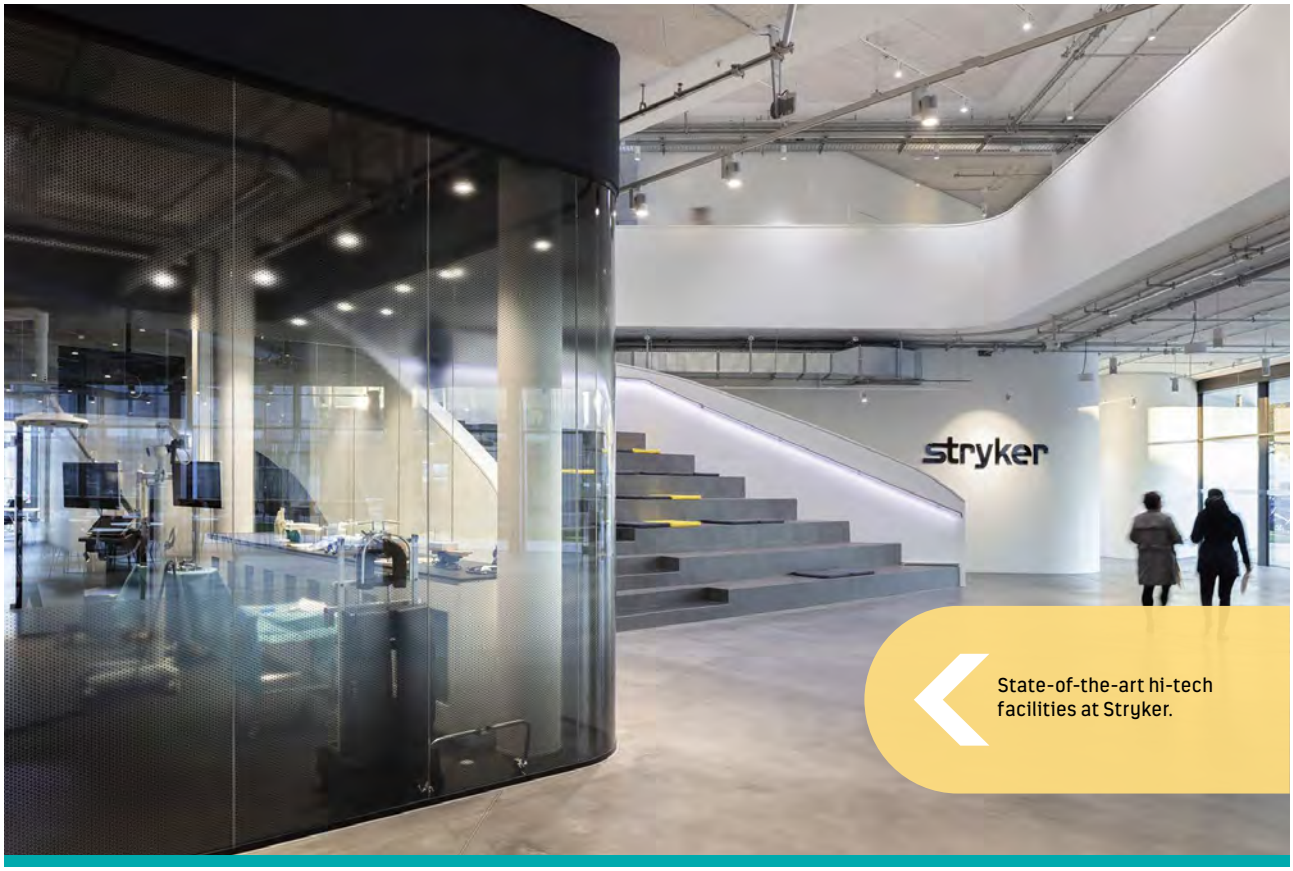
The REDI Fellowship served as a stepping stone to identify a new patient specific product – leading to the submission of a Digital Health (DH) CRC proposal, which was awarded in August 2023. This has enabled a larger team to work on a patient specific solution and establish a new collaboration with the University of Technology Sydney. The DHCRC project is now well underway.

Embedding REDI Fellow within the Stryker team proved highly valuable

Director R&D Concept Technologies at Stryker Innovation Center Freiburg, Germany, Ulrich Buehner, said having Dr Wille embedded within the team proved highly valuable.

"With her deep knowledge in the field and years of experience in direct collaboration with surgeons on patient specific solutions, she could immediately contribute to the project and bring in new perspectives and fresh ideas," Mr Buehner said.

The experience was equally beneficial for Dr Wille, giving her real industry experience and developing her skills in an assortment of areas. These included corporate decision-making, industry project management, workflow mapping, mapping of stakeholders and communication planning, application of a SWOT (strengths, weaknesses, opportunities and threats) analysis to projects and learning industry terminology, as well as upstream and downstream marketing terminology. These are elements that are often not considered



State-of-the-art hi-tech facilities at Stryker.

in academic research but are of critical importance for successful commercialisation of medical products.

Although Dr Wille's REDI Fellowship was based at the Stryker R&D Lab in Brisbane, she also visited Stryker in Sydney and Germany – spending more than three months at the Stryker Innovation Center in Freiburg and visiting Stryker Trauma in Kiel. During her placement in Germany, she worked alongside the German Craniomaxillofacial Patient Specific Team to develop and map out a new software product together with the Australian R&D Lab.

Fostering strong collaborations and partnerships in Germany, Ireland and beyond

In Freiburg, Dr Wille fostered strong collaborations and partnerships, who she continued to work with on a weekly basis for the rest of her Fellowship on her return to Australia. She also attended Stryker's internal Patient Specific Technology Summit and met with all patient specific divisions and the advanced manufacturing team to learn about their capabilities and capacities.

Time spent at Stryker taught Dr Wille how to plan a project from the industry perspective and how to align it with the voice of customer – giving her insights into the customer- and time-driven focus evident in industry R&D.

Though Dr Wille had already collaborated with industry partners for the past few years, she said being embedded and working within industry, and learning Stryker's perspective and how R&D really works, has been priceless.

"I felt very supported and valued for the knowledge that I was able to contribute within Stryker. The REDI Fellowship has provided me with the additional skillset of industry project management and knowledge of product marketing," Dr Wille.

Incorporating surgeon's feedback into Stryker's software development and more

The success of this collaboration led to Stryker supporting Dr Wille in an application for a three-year Australian Research Council Industry Fellowship. Dr Wille now holds a part-time secondment position with Stryker, so she can continue working with Stryker's Australian R&D Lab and the Freiburg team to incorporate surgeons' feedback into their software development.

Dr Wille's newly acquired knowledge in product development processes and industry project management are also being put to effective use through her ongoing role at QUT, where she will continue working with different industry partners to develop her own MedTech product for market readiness.

> **During her placement in Germany, she worked alongside the German Craniomaxillofacial Patient Specific Team to develop and map out a new software product together with the Australian R&D lab.**

Australian expertise delivers a breakthrough in computer modelling as an alternative to clinical trials

SPONSOR:
Synopsys Inc

FELLOW:
Professor Mark Taylor

EMPLOYER:
Flinders University

KEY FOCUS:
Medical technology, modelling and simulation, clinical trials market evaluation

REDI Fellow Professor Mark Taylor.

A REDI Fellowship put a leading orthopaedic modeler on the frontline of 3D simulation with software leader Synopsys, resulting in a rapid breakthrough in adapting one of its most popular programs for clinical trials.

With the rapidly growing capabilities of 3D computer models, the potential for virtual simulations to improve hip and knee replacement products is almost as unlimited as the software itself.

Helping Synopsys expand its Simpleware platform

A REDI Fellowship brought Professor Mark Taylor, who has more than 30 years' experience applying computer models in orthopaedic biomechanics, to Synopsys and helped the company expand its Simpleware platform towards *in silico* Clinical Trials (ISCT). The Simpleware software enables the generation of computational models from medical images and the development of workflows that can be used in the assessment of medical devices, surgical planning and the design and development of patient-customised implants and instrumentation.

ISCTs, named for the silicon in computer chips, are a way that computers can support clinical studies by generating data from computer models. Instead, ISCTs use virtual simulations and algorithms to study biological systems – in this case, prostheses or implants used to replace damaged joints.

ISCTs are gaining interest for use in both medical device R&D and as part of regulatory submission, as evidence of safety and efficacy for a new design or design modification. There is a current drive from the FDA and the EU to encourage more use of Computational Modelling and Simulation (CM&S) as part of the regulatory pathway. The advantages of CM&S over *in vivo* (animal/human) and *in vitro* (bench) testing includes cost saving, acceleration in development cycle and reduced time to manufacture and reduced (*in vivo*) risk and suffering. ISCT is particularly relevant to SMEs to reduce innovation costs. A key barrier to widespread ISCT use is the multiple complex software that is needed to complete a study.

Compelling results lead to Fellow discussing product with customers

The aim of the project was to explore the capabilities of Synopsys' Simpleware to perform all the necessary steps within a single software platform. The Fellowship brought together Professor Taylor's expertise of developing ISCT workflows with the image-based modelling software capabilities of Synopsys. The project successfully developed the workflows to enable the Simpleware platform to perform ISCTs.

Professor Taylor designed and embedded several ISCT workflows in the Simpleware software and demonstrated their efficacy in evaluating the performance of orthopaedic devices. His results were so compelling that, before the end of his Fellowship, Professor Taylor was participating in discussions with Synopsys customers to gauge market interest in the potential use and applications.

Synopsys' In Silico Medical Solutions Lead, Dr Rebecca Bryan, said the ISCT workflows were successfully developed and have been demonstrated to existing Synopsys customers, with a view to generating new business.

An innovative route to access world-leading academic knowledge

"As part of the development, we successfully developed and tested a statistical shape modelling module, which can be used to help understand variations in anatomy, as well as synthetically generate new anatomies when actual data is limited. This has led to the submission of a patent application which is currently under review.

"The REDI Fellowship program has offered an innovative route to accessing world-leading academic knowledge, enabling us to explore new application areas which would otherwise be out of reach. Translating academic ideas into commercially viable products is hard, but this initiative bridges the gap between these two worlds and will help to realise the potential of research for industry and patients," Dr Bryan said.

Professor Taylor said the project's 14-month duration meant he was embedded at Synopsys for a whole software development cycle.

> **His results were so compelling that, before the end of his fellowship, Professor Taylor was participating in discussions with Synopsys customers to gauge market interest in the potential use and applications.**

Valuable experience, development of IP and a patent application

"Due to COVID-19, I worked remotely most of the time but spent two periods of two weeks at Synopsys in the UK – at the beginning and end of the development cycle. As an academic, I've always been involved in the development of new assessment methods and techniques that may have commercial applications – but through this project I have become much more aware of the need to understand the associated business case," Professor Taylor said.

During his time with Synopsys, Professor Taylor also gained valuable experience in protecting software-related intellectual property. One aspect of the project led to the development of intellectual property. A patent application related to the process was duly drafted and submitted with Professor Taylor's input.

A deep immersion in the world of drug development yields a practical tool for screening lifesaving kidney drugs

SPONSOR:
Syntara

FELLOW:
Dr Long Nguyen

EMPLOYER:
Kolling Institute, The University of Sydney

KEY FOCUS:
Drug development, drug screening, chronic kidney disease (CKD)

Syntara research team performing the anti-fibrotic assay on 3D kidney model.

The devastating internal scarring known as kidney fibrosis is notoriously hard to treat. Sydney-based drug developer Syntara, previously known as Pharmaxis, was awarded a REDI Fellowship to draw on the renal disease expertise of Dr Long Nguyen in its efforts to develop a laboratory model for anti-fibrotic drug screening.

Chronic kidney disease (CKD) refers to all conditions of the kidney affecting the filtration and removal of waste from the blood for three months or more. It is identified by reduced filtration by the kidney and/or by the leakage of protein or albumin from the blood into the urine.[1] An estimated 11 per cent of people (1.7 million Australians) aged 18 and over had biomedical signs of CKD in 2011–12.[2] This will increase with an ageing population. Current treatments are only partially effective. Therefore, it is important to identify novel therapeutic targets of CKD and develop additional treatments to further improve patient outcomes.

Syntara has set its sights on developing the first specific therapy for kidney fibrosis, the internal scarring that is often the final manifestation of CKD. The company spent more than seven years developing new 3D kidney-cell fibrosis modelling tools for fibrosis and had some success, however, previous platforms were either too complex, expensive and/or unreliable. Syntara was working on a reliable 3D kidney-cell fibrosis model for screening novel drugs when it was awarded a REDI Fellowship to bring in renal disease researcher Dr Nguyen from The University of Sydney's Kolling Institute.

Developing a robust, reproducible and highly relevant 3D tissue engineering model

By the end of the 12-month Fellowship, Dr Nguyen had helped Syntara develop a robust, reproducible and highly relevant 3D tissue engineering model that incorporates the company's current instruments and reagents into the testing process, giving its laboratory greater confidence in its results.

Syntara's Head of Drug Discovery, Dr Wolfgang Jarolimek, said Dr Nguyen's contribution had significantly advanced the company's mission to develop a novel 3D assay that responds reliably to profibrotic factors, and will help the company test and progress potential therapies for fibrosis.

"During his Fellowship, Dr Nguyen was fully immersed in our drug discovery efforts and became a highly contributing and achieving member of our team," Dr Jarolimek said.

Applying deep theoretical knowledge to practical drug testing

Dr Nguyen said the Fellowship provided a deep, across-the-board immersion in Syntara's clinical work, which had an immediate and tangible impact in helping him apply his deep theoretical knowledge to practical drug testing.

1. https://www.aihw.gov.au/reports/chronic-kidney-disease/chronic-kidney-disease/contents/summary. Last updated 14 Dec 2023, accessed 14 March 2024
2. AIHW analysis of the Australian Bureau of Statistics latest National Health Measures Survey (NHMS) (ABS 2013) – the most recently available data on the total number of people affected by CKD in Australia. (To be updated in 2024)

"I worked with senior researchers across Syntara's drug discovery, quality control, medical affairs and statistical teams, experiencing a comprehensive drug development program from bench to market – including all kinds of biochemical, biological and toxicity assays, as well as Phase I and II clinical trials," Dr Nguyen said.

"This broad exposure across the drug development continuum supported my work in developing a 3D *in vitro* model of fibrosis for drug screening at Syntara. The company has invested heavily in the past to develop such a model but faced many challenges due to clinical complexity and cost."

Fellowship results in milestone development for Syntara project

"The Fellowship led to the milestone development of a novel 3D model from kidney cells that responds to kidney injury and profibrotic factors. This is going to be applied for drug testing at Syntara and will have an impact on drug discovery throughput and commercialisation," Dr Nguyen said.

The Fellowship placed Dr Nguyen at the centre of a variety of hands-on research activities that he found significantly more "fast-paced and demanding" than his traditional research in academic settings.

"Unlike academia, in which research outcomes can be suggestive rather than decisive, each research activity in industry needs to be associated with a 'go' or a 'no-go' business decision, which requires much higher reliability and certainty," said Dr Nguyen.

"Embedding at Syntara for a year was a challenging but highly rewarding experience for me, which has reignited my passion in drug discovery and made me a better researcher."

A much greater understanding of drug profile requirements for clinical studies and trials

Dr Nguyen's work in developing a high-throughput *in vitro* fibrosis assay at Syntara has led to several new research grant applications and a pending manuscript for publication.

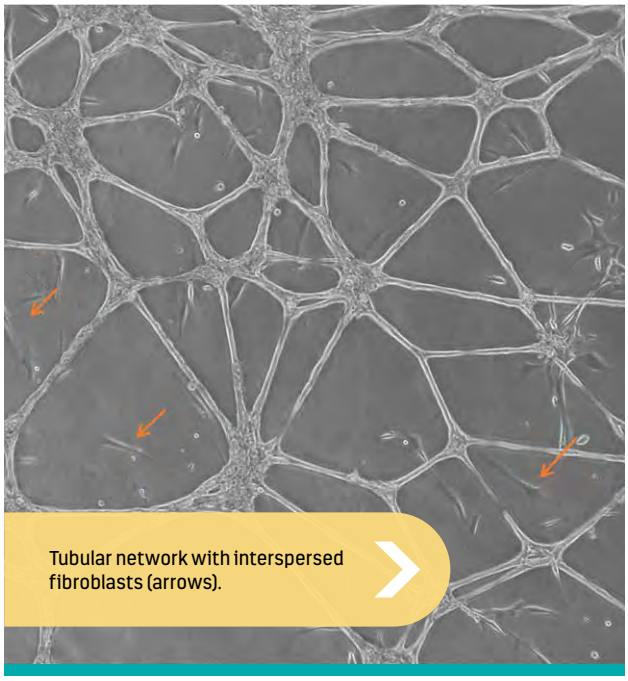
As well as furthering his knowledge of tissue preparation and compound selection for assay testing, Dr Nguyen said he'd developed a much greater understanding of drug profile requirements for clinical studies, patent applications and clinical trials.

For Dr Jarolimek, Dr Nguyen's Fellowship also paved the way for future collaborations with university-based researchers that could hold the key to new clinical breakthroughs.

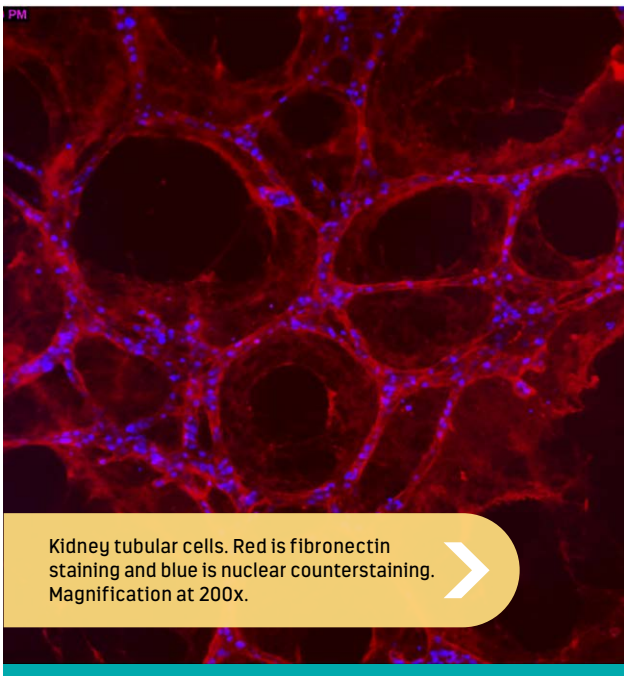
"This Fellowship has been an excellent opportunity to strengthen our collaborations with top-tier academics and provide training for the Fellow in biotech needs and thinking, which will make it easier in future collaborations to explain our needs," Dr Jarolimek said.

"With Dr Nguyen's model of fibrosis for *in vitro* studies… the synergy between academic creativity and the biotech needs for robustness yielded an assay that is highly relevant to drug discovery."

> **"Dr Nguyen's contribution had significantly advanced the company's mission."**



Tubular network with interspersed fibroblasts (arrows).



Kidney tubular cells. Red is fibronectin staining and blue is nuclear counterstaining. Magnification at 200x.

REDI Fellowship boosts Telix radiopharmaceutical development with a new way to measure success of cancer treatment

SPONSOR:
Telix Pharmaceuticals

FELLOW:
Dr Alexander Staudacher

EMPLOYER:
Central Adelaide Local Health Network Incorporated (CALHN)

KEY FOCUS:
Radiopharmaceutical development, good manufacturing practice (GMP), production pipeline, clinical trials

REDI Fellow
Dr Alex Staudacher.

Telix Pharmaceuticals is working on a commercially viable format of an antibody that could streamline the way we treat cancer. A REDI Fellowship has brought the clinical trials closer.

Australian radiopharmaceutical company Telix Pharmaceuticals is working towards commercialising APOMAB, an antibody that detects dead cancer cells resulting from cancer therapy. Dr Alexander Staudacher has significant experience working on the APOMAB therapeutic and the REDI Fellowship allowed the company to access his expertise as it progressed the product through small-scale Good Manufacturing Practice (GMP) production and into clinical trials.

APOMAB – unique ability to detect dead cancer cells

APOMAB's unique ability to detect dead cancer cells can be used to identify which patients are benefitting from ongoing therapy and allow direct therapeutic intervention. Without this, it can take months to determine whether cancer patients are responding to treatment. This will help oncologists determine the best treatment pathway for individual patients, including those which might benefit from targeted radiopharmaceuticals developed by the sponsor, Telix Pharmaceuticals.

Dr Staudacher's knowledge of the protein and its expression and purification process proved valuable for the company. The project gave Dr Staudacher commercialisation experience that will help with other potential therapeutics he is researching.

For nearly 10 years, Dr Staudacher has been a postdoctoral cancer researcher in the Translational Oncology Laboratory, University of South Australia and Central Adelaide Local Health Network Incorporated (CALHN).

He has focused on the preclinical development of the APOMAB antibody – as both a theranostic marker and a therapeutic combination to treat cancer. His work was critically important for approval of a 20-patient Phase I clinical trial of APOMAB that began at the Royal Adelaide Hospital (RAH) in 2020. The trial was completed in 2021, and the results are being prepared for publication.

Telix – HQ in Melbourne, offices in the US, Europe and Japan

ASX-listed Telix Pharmaceuticals focuses on the development, clinical evaluation and commercialisation of radiopharmaceuticals for cancer diagnosis and treatment. The company is headquartered in Melbourne with offices in the US, Europe and Japan. Telix Pharmaceuticals currently has nine radiopharmaceuticals in its clinical development pipeline spanning from Phase I trials to commercialisation and has a growing interest in manipulating the tumour microenvironment for therapeutic benefit.

Telix has an option agreement to license the radiopharmaceutical applications of APOMAB.

Although Dr Staudacher is an experienced cancer researcher, he lacked in-depth experience of the clinical translation path for a radiopharmaceutical, which includes the quality and regulatory aspects of realising a patient-ready GMP-grade product. The Fellowship with Telix enhanced his skill set with

the industry-based skills required for generating GMP-grade products of the quality required for clinical trials, together with an appreciation of the design principles of clinical trials that are used to test validated products.

During the REDI Fellowship, Dr Staudacher coordinated a project to select, produce and validate a humanised APOMAB (hAPOMAB) candidate. The work resulted in small-scale production and validation of hAPOMAB, a production pipeline for GMP-grade product, and the development of a Phase I clinical trial package.

Gaining commercialisation experience helps with other therapeutics

Dr Staudacher said the REDI Fellowship provided him with a fantastic opportunity to gain real-world, hands-on industry experience – something he would not normally be exposed to in his research career.

"Through this Fellowship, I've had the opportunity to discuss my research work and develop the project plan with experts in antibody development, biologics, preclinical development, production, clinical trials, chemistry and commercialisation at Telix.

> **Dr Staudacher's contribution under this fellowship project has allowed Telix to diligently advance the APOMAB program.**

"I have gained new skills in networking, project management and a better understanding of the requirements for the final, biological product to make it easier for it to be transitioned into clinical trials. These are all important concepts that I will bring back to CALHN and it will change some of our decision-making in preclinical studies to better align with what a final, clinical product needs to be," Dr Staudacher said.

Developing plans more rapidly towards a commercial endpoint

Telix Chief Scientific Officer Dr Michael Wheatcroft said Dr Staudacher's contribution under this Fellowship project has allowed Telix to diligently advance the APOMAB program.

"By having an expert on hand to meet the immediate preclinical needs and an in-house subject matter expert acting as a 'product champion', liaising with external vendors as well as colleagues across the business, we have been able to develop plans more rapidly towards a commercial endpoint.

"Dr Staudacher's close integration into the Telix research team has enabled him to share his detailed learnings of the APOMAB technology with colleagues, to bring highly useful insights into the mechanistic details which will optimise its positioning in the clinic and commercial landscape," Dr Wheatcroft said.

The REDI Fellowship also fostered closer ties between Telix and CALHN. Following the REDI Fellow's engagement and continued close involvement with the team, Telix learned more about the capabilities of CALHN and is currently contracting further work on a new, unrelated research project with Dr Staudacher's lab at the University of South Australia.

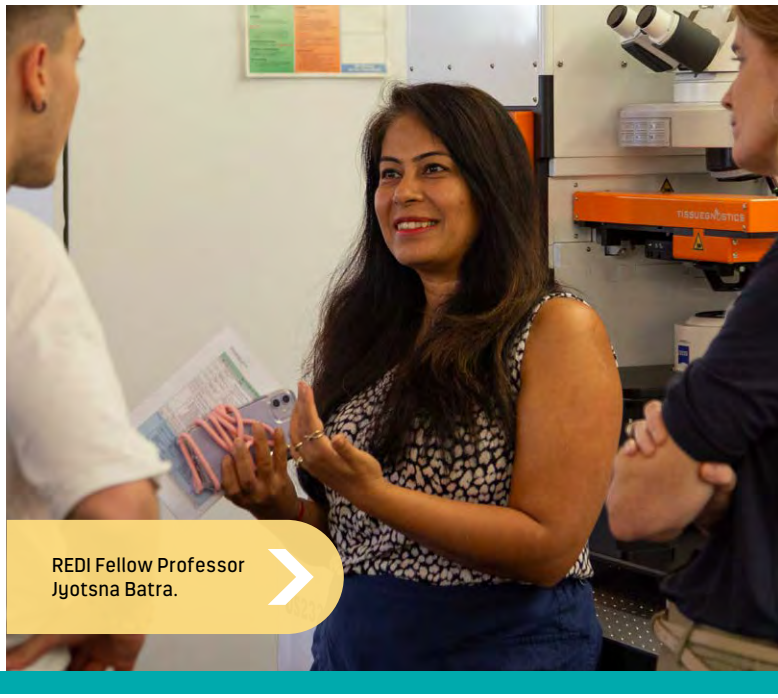
REDI Fellow's cancer detection work prompts Austrian medtech to set up Australian subsidiary to extend collaborations

SPONSOR:
TissueGnostics

FELLOW:
Professor Jyotsna Batra

EMPLOYER:
Queensland University of Technology

KEY FOCUS:
Medical technology, cancer diagnostic, global collaboration, quality control



REDI Fellow Professor Jyotsna Batra.

Leading medtech TissueGnostics is based in Vienna, Austria, with satellite offices in the US, Europe and South Africa. The company was so impressed with the work of its REDI Fellow, Professor Jyotsna Batra, that it set up an Australian subsidiary to maintain and grow connections with Australian biotech researchers.

Established in 2003, TissueGnostics has substantial expertise in the design and development of microscope-based scanning hardware for imaging and artificial intelligence (AI) solutions for tissue analysis in situ. Until recently, it lacked experience in molecular biology and the workflows used in 'wet labs', where testing and analyses are performed using samples, chemicals and liquids.

Award-winning group leader with deep knowledge

The REDI Fellowship with Professor Batra brought in expertise in cell staining and clinical workflows that helped the company to develop knowledge of working with reagents – substances used in laboratory and diagnostic tests – and ultimately to define and develop a new staining kit for detection of multiple cancer markers on a single tissue section. TissueGnostics had previously encountered challenges in working with antibody staining kits for multiplexing and during the Fellowship new protocols were established that overcame obstacles and led to successful kit development.

Professor Batra is an award-winning group leader in the Centre for Genomics and Personalised Health at Queensland University of Technology (QUT). She has deep knowledge of the complex genetic factors involved in hereditary disorders and uses bioinformatics tools and computational analysis as well as experimental approaches in her research. Her current research goal is to pioneer the development of improved biomarkers for early cancer detection.

During her Fellowship with TissueGnostics, she spent two six-month immersions at the company's Austrian headquarters, with six months back at QUT in between these periods. As well as sharing her proficiency in genetics and wet lab workflows, she provided user feedback on new hardware under development and on software displaying data for biomarker analysis in cancer research.

TissueGnostics' Senior Product Manager, Dr Felicitas Mungenast, said Professor Batra provided invaluable feedback on TissueGnostics' brand-new software, TissueFAXS Suite 8.0 and its latest cytometer COLUBRIS.

Exposure to industry standards and career development

"Both of these are now ready for market and will be launched at the upcoming annual meeting of the European Association of Cancer Research (EACR) in June, Europe's leading cancer research conference," Dr Mungenast said.

TissueGnostics' CEO Dr Rupert Ecker said, "Jyotsna also helped with the definition of our new multiplexing staining kit, which is progressing well. She remains involved in this beyond the end of her Fellowship and we expect the product to launch in 2025."

At TissueGnostics, Professor Batra worked within an ISO 13485 environment – an international quality control standard covering the entire life cycle of a medical device from development to production, installation and servicing – much different to her academic research environment.

This exposure to industry standards strengthened her industry-specific abilities and has helped in her career development.

Professor Batra says before the REDI Fellowship program, her skill sets were primarily centred around her academic expertise in molecular biology and cancer research.

Significant personal growth and tangible project outcomes

"I possessed a strong foundation in experimental design, laboratory techniques and data analysis, but my exposure to industry-specific practices and technologies was limited.

"While working with TissueGnostics, I experienced significant professional growth which led to tangible project outcomes and valuable skill enhancements, particularly in artificial intelligence and quality management, as well as enhancing my proficiency in TissueGnostics' cutting-edge technologies," Professor Batra said.

The company had previously collaborated with academics and research institutes on scientific analysis solutions and algorithms, and research groups around the world have published data using products and data-analysis solutions provided by TissueGnostics. However, this was the first time that a collaboration project focused on the development of a multiplexing reagent kit, which not only opens a whole new business field for the company, but also allows laboratories to access more streamlined and intertwined applications – from sample staining to publication-ready data.

> "This ultimately led to us making the decision to establish an Australian subsidiary of TissueGnostics in Brisbane, Queensland, and we also started a collaboration with the Queensland University of Technology (QUT) and academics there."

TissueGnostics opens an Australian subsidiary in Brisbane

This knowledge sharing produced results beyond the company's original expectations and TissueGnostics decided to open a permanent Australian subsidiary in Brisbane, creating new job positions in Australia.

Dr Ecker said the company was extremely impressed with Professor Batra's Australian research.

"This ultimately led to us making the decision to establish an Australian subsidiary of TissueGnostics in Brisbane, Queensland, and we also started a collaboration with the Queensland University of Technology and academics there," Dr Ecker said.

The Fellowship ended up surprising Professor Batra, too. She was promoted to full professor during her period working at TissueGnostics, which she said is a testament to the recognition of her contributions within both the academic and professional spheres.

A myriad of benefits and a long-term collaboration

"In summary, the embedded REDI Fellowship brought forth a myriad of benefits for me – from technological advancements and collaborative research initiatives to enhanced marketing and academic recognition. The knowledge and skills gained during this Fellowship contribute to TissueGnostics' continued success as an industry leader in tissue cytometry and histopathological diagnostics," Professor Batra concluded.

A long-term collaboration between TissueGnostics and Professor Batra extending beyond the timeframe and scope of this initial REDI project has already been initiated, three joint publications have been achieved and she has been invited to join a European Consortium in an EU-funded Marie-Curie Doctoral Network, exploring methods for eradication of cancer relapse by targeting cancer stem cells. The REDI Fellowship experience has also contributed to advancing Professor Batra's plans to commercialise her prostate cancer biomarker identified in her QUT laboratory.

Pictured: front row far right, Professor Jyotsna Batra with the TissueGnostics team and the Stop Spread Bad Bugs (SSBB) consortium members at TissueGnostics global HQ in Vienna, Austria.

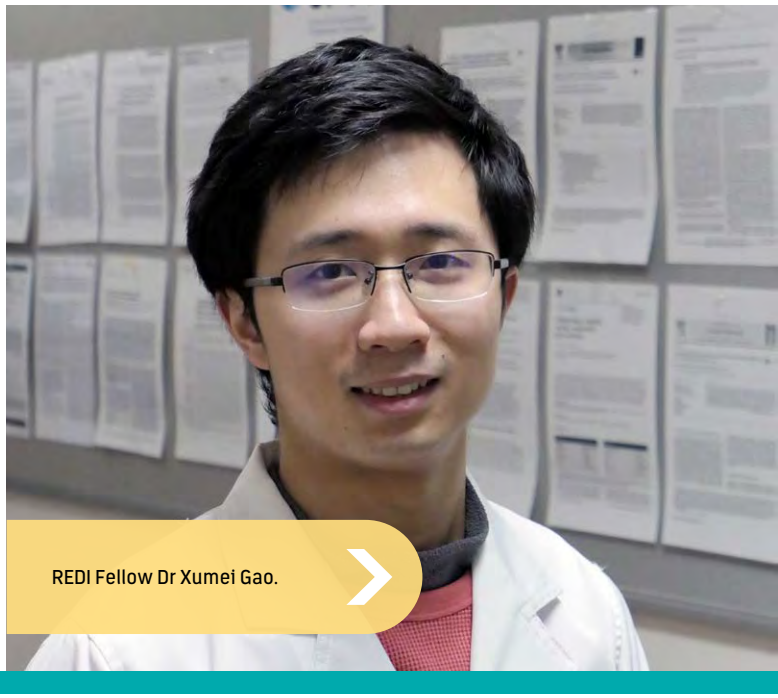
Pushing the 'missing link' in non-animal preclinical drug development closer to market

SPONSOR:
Trajan Scientific and Medical

FELLOW:
Dr Xumei Gao

EMPLOYER:
The University of Melbourne

KEY FOCUS:
Drug development, usability and market validation



REDI Fellow Dr Xumei Gao.

Supported by MTPConnect's REDI Fellowship program, Trajan Scientific and Medical and The University of Melbourne's Dr Xumei Gao are progressing biomedical research technology for non-animal methods for drug development.

Animals are extensively used in almost all preclinical drug development. However, animal welfare concerns, costs and doubts about the predictive value in humans create a large demand for alternatives.

Current non-animal methods for culturing and studying *in vitro* biological samples in a non-physiological static environment (i.e. culture dish/plate/flask) engender high rates of false-positive and false-negative results, which pose unnecessary and costly risks and uncertainties across the entire research field. This suboptimal practice is ultimately due to a lack of any practical multiplexed perfusion flow system that is economical, robust and compatible with the existing culturing workflow.

An enhanced solution compatible with conventional practices and protocols

To address this unmet need, Dr Gao, a postdoctoral researcher from the ARC Centre for Personalised Therapeutics Technologies at The University of Melbourne, has developed a continuous flow microphysiological system (MPS). This solution is compatible with conventional practices and protocols, including greatly enhanced throughput to achieve physiological emulation in cell culture.

Better known as organ-on-chip technologies, MPSs are increasingly appreciated for their unique capacity in human physiology representation. Dr Gao's technology targets the substantial industrial demand gap in MPS throughput, compatibility and automation by offering a compact and affordable fluidic management system to biomedical researchers and biopharma R&D pipelines, so that they can overcome the throughput and efficiency limitation for scaled MPS adoption.

> **Collectively, Dr Gao, Trajan and The University of Melbourne are thrilled to be contributing their efforts towards offering unique biomedical research technology for fast-tracked drug development.**

Melbourne-based Trajan Scientific and Medical, a global leader in analytical technology commercialisation, is interested in this technology, which expands its life science offerings. Trajan successfully applied for a REDI Fellowship for Dr Gao to develop his system while embedded at the company. The aim of this 12-month partnership was to validate the usability of Dr Gao's product in commercial environments; explore the target market, focusing on different customer segmentation; conduct feature bundling for application-specific products; produce a minimal viable product (MVP); and obtain contract and licence agreements for commercialisation.

Trajan – benefits and an excellent outcome from the REDI Fellowship

Trajan has benefitted from the REDI Fellowship in a number of ways. Having identified the pump technology as an excellent complementary product line to its growing analytical consumables business, the company has worked with the inventor to develop this first-in-class new product. This has increased the speed of development and focused the team on the intended use of the product in preparation of the pathway to commercialisation.

Trajan's Chief Scientific Officer, Dr Andrew Gooley, said the REDI Fellowship was a tremendous program to facilitate the translation of Dr Gao's technology.

"Dr Gao embraced the program and the opportunity to 'deep dive' into the user requirements of the platform and consider how we can position the technology within our Analytical Consumables business.

"He has been exemplary in his responsiveness and capacity to take feedback and iterate the design. An excellent outcome has been the development of the overall 'system' from the user's perspective which includes the various consumables with a focus on delivering the best user experience," Dr Gooley said.

Gaining valuable insights, increasing skills and knowledge

During the Fellowship, with the support and guidance of the Trajan team, Dr Gao gained valuable insights into the development pathway. He also increased his skills and knowledge in the commercialisation of laboratory diagnostic equipment, as well as customer engagement, manufacture design, product design and project management. Having broadened his outlook regarding the technology, how it is developed and who will use it, Dr Gao is now on track to deliver a more agile, productive, user/customer-centric end product.

"Being part of the project from conceptualisation in the university lab to MVP production with our industrial partner through the REDI Fellowship, I am thrilled to see our technology moving closer and closer to the end users," Dr Gao said.

"I can never overstate the joy of showcasing our unique technology at conferences and seeing the sparks in the audience while they earnestly ask when the technology is going to be available for them to use."

Meanwhile, The University of Melbourne has embraced the opportunity to partner with this Australian company to develop its intellectual property and get it to a commercially viable level following the protocols of a leading life sciences company.

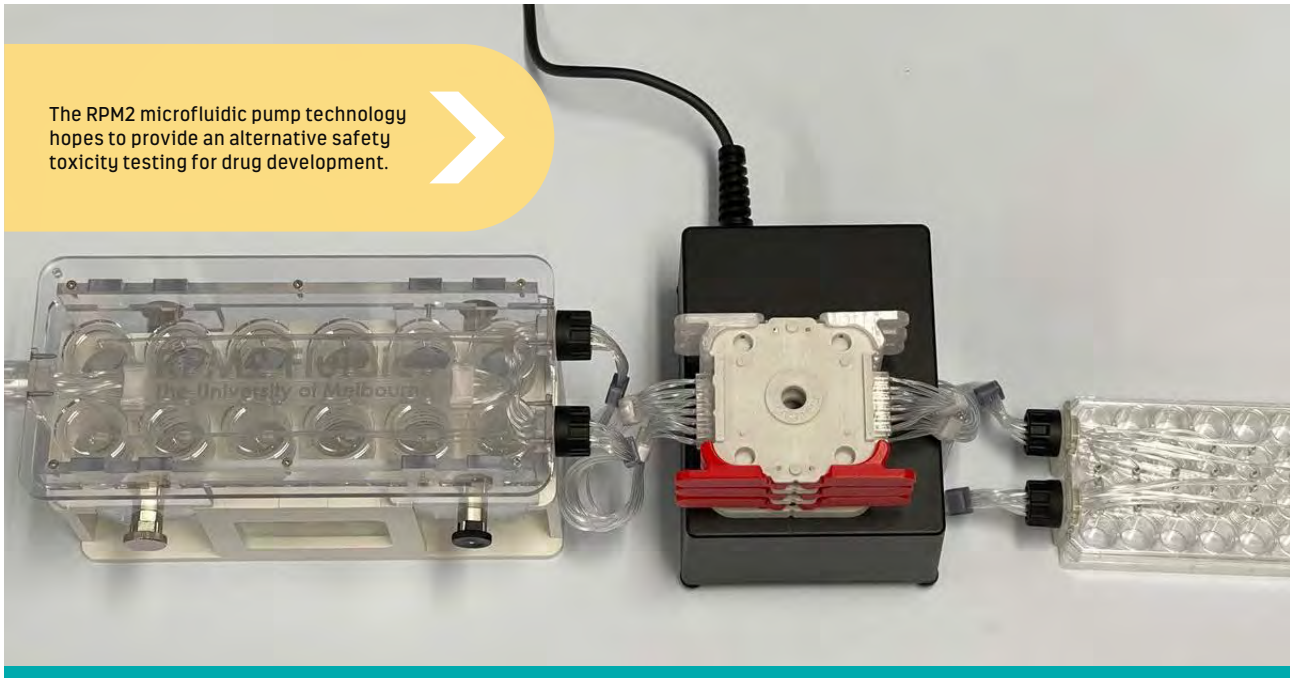
Thrilled to contribute to unique biomedical research tech

Collectively, Dr Gao, Trajan and The University of Melbourne are thrilled to be contributing their efforts towards offering unique biomedical research technology for fast-tracked drug development and facilitating Australia's commercial maturation in non-animal model capabilities.

Director of the ARC Centre for Personalised Therapeutics Technologies, Professor Alastair Stewart, said the REDI Fellowship has provided Dr Gao with an outstanding range of opportunities within Trajan.

"As a REDI Fellow with Trajan, Dr Gao has had the chance to really get to understand and apply quality by design principles into a minimum viable version of the RPM2 pump.

"The RPM2 microfluidic pump technology is a timely addition to capabilities that support long-term use of human microphysiological systems, which assume huge importance now that the FDA modernisation Act 2.0 enables drugs to be registered without necessarily using animals for safety toxicology testing," Professor Stewart said.



The RPM2 microfluidic pump technology hopes to provide an alternative safety toxicity testing for drug development.

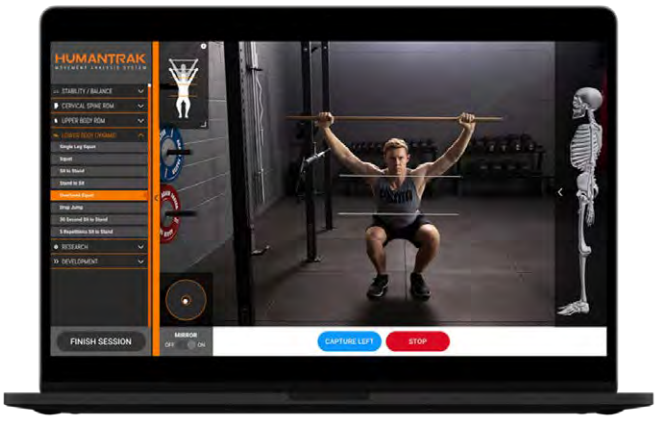
A world-first solution to the growing knee injury epidemic facing Australian sportswomen

SPONSOR:
VALD Performance

FELLOW:
Associate Professor Matthew Bourne

EMPLOYER:
Griffith University

KEY FOCUS:
Medical technology, global collaboration, product development, business development



Interface of the prototype HumanTrak Movement Analysis System, which Associate Professor Matthew Bourne employed to investigate anterior cruciate ligament injury risk factors in elite Australian female footballers.

Sports scientist Associate Professor Matthew Bourne and his injury research team at Griffith University have a longstanding relationship with VALD Performance, a company at the forefront of technology for musculoskeletal applications, but when the two were awarded a REDI Fellowship, the commercial potential of their partnership really escalated.

A/Professor Bourne is widely recognised as one of Australia's leading experts in the rapidly growing field of hamstring and knee injuries – particularly those received in the different codes of football. As head of the sports injury research team at Griffith University's Centre of Biomedical and Rehabilitation Engineering (GCORE), A/Professor Bourne develops and applies technologies to identify athletes at risk of injury and inform evidence-based prevention strategies.

Pioneering research work attracts fellowships and earns rankings

In recent years, his pioneering work has attracted fellowships from MTPConnect and Advance Queensland and earned him a ranking in the top 0.3 per cent of global leg injury experts and, in 2022, recognition as the number-one global expert in hamstring muscles.

A/Professor Bourne is based at the Menzies Health Institute at Griffith University, where he established a research partnership with acclaimed sports technology company, VALD, to develop a field-based (not laboratory-based) analysis platform to help sports teams identify and manage their players' injury risks.

During the REDI Fellowship, A/Professor Bourne and his team performed a world-first study using the HumanTrak Movement Analysis System to investigate anterior cruciate ligament (ACL) injury risk factors in elite Australian female footballers.[1]

The international success of Australian sportswomen has propagated extraordinary growth in the professionalism of female sports. However, female athletes still face considerable barriers to participation and high performance including high rates of injury. Understanding the factors that increase an athlete's risk of injury represents the first step towards developing targeted injury prevention interventions.

REDI Fellowship addresses the alarming epidemic of ACL ruptures

As one of the most catastrophic sports injuries, ACL ruptures occur up to six times more frequently in women than men. Even after surgery and rehabilitation, however, two in three female athletes will not return to their sport within 12 months, and at least half will develop knee osteoarthritis over the next 10-15 years.

To address this alarming epidemic, the REDI Fellowship project aimed to accelerate the commercialisation of VALD's HumanTrak system, which aims to replace the need for expensive laboratory analyses with a rapid, accurate, affordable tool for measuring athletes' movements to assess for risk factors in real time, on the field.

1. National Library of Medicine: Pub Med – Strength and Biomechanical Risk Factors for Noncontact ACL Injury in Elite Female Footballers: A Prospective Study https://pubmed.ncbi.nlm.nih.gov/35320148/

VALD and GCORE had already collaborated on two projects to prototype HumanTrak. Through the Fellowship, they were able to validate its capabilities through a world-first study investigating the ACL risks of 322 female AFL and soccer players, which identified several modifiable strength and biomechanical risk factors and the potential to predict up to 80 per cent of future ACL injuries.

Findings significantly improve commercial viability of VALD's measurement devices

VALD's Head of Measurement, Dr Gavin Lenton, said the results were already informing targeted training programs to prevent ACL injury in female athletes across a range of ages and performance levels.

"Importantly, the findings have significantly improved the commercial viability and practical application of VALD's suite of measurement devices in new markets, which is critical for the company's continued success as a global leader in sports technology.

"At the beginning of this project, female athletes represented less than five per cent of VALD's existing client base – but this has now increased to 25 per cent," Dr Lenton said.

VALD CEO Laurie Malone said throughout the company's ongoing partnership with A/Professor Bourne and Griffith University, VALD has expanded its client base.

> **Through the REDI Fellowship, A/Professor Bourne developed an appreciation of the drivers for business and how product development fits into the overall strategic direction of a business and product pipeline.**

Travel to the UK – Liverpool, Manchester United, Manchester City and more

"We've expanded from fewer than 500 organisations in 2020 to more than 3,500 organisations across 60 countries in 2023. This growth has solidified our position as global leaders in the provision of human measurement technology," Mr Malone said.

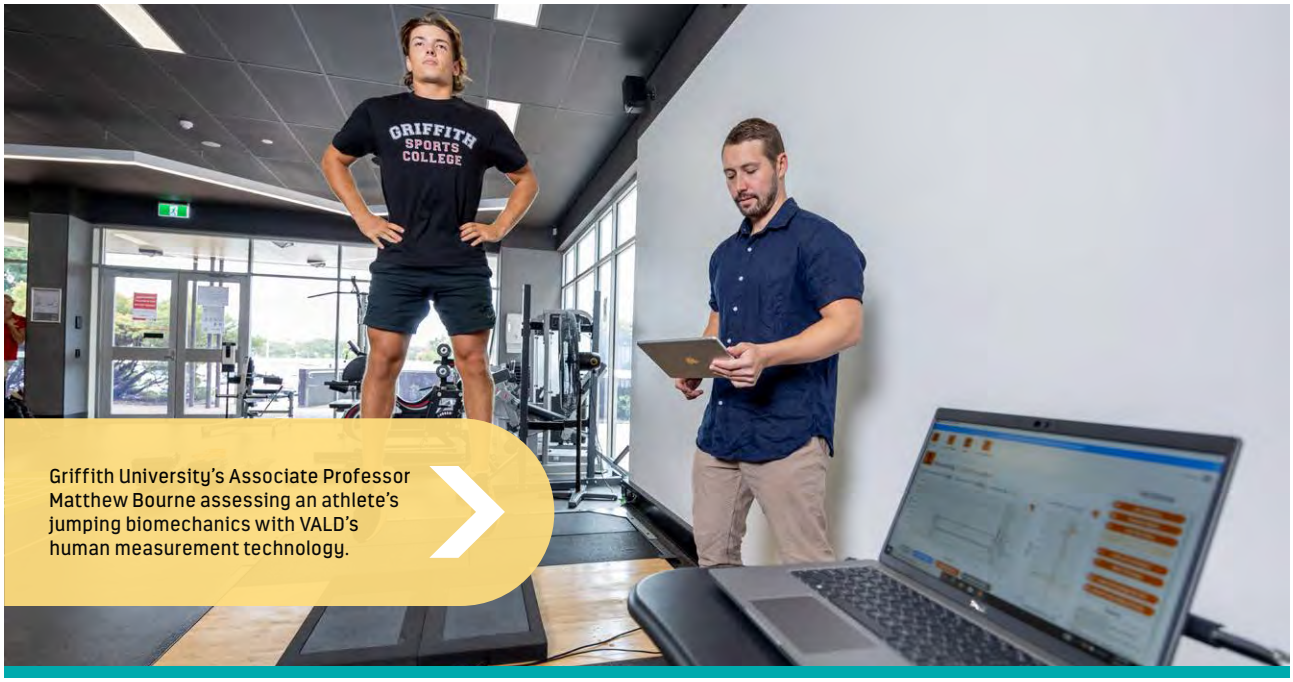
Towards the end of the Fellowship, A/Professor Bourne had the opportunity to travel to the UK and Ireland to present the HumanTrak technology to some of the most famous football clubs in the world, including Liverpool, Manchester United and Manchester City, as well as Scottish Rugby, the Irish Rugby Football Union, England Netball and the UK Sports Institute.

Through the REDI Fellowship, A/Professor Bourne developed an appreciation of the drivers for business and how product development fits into the overall strategic direction of a business and product pipeline. The most significant impact of the skills gained from the REDI Fellowship is an understanding of how to design and conduct research for successful commercialisation, including market engagement, which he can apply to his team's work at CGORE.

Significant and immediate impacts on Fellow's career and 2032 Brisbane Olympics

The impacts on A/Professor Bourne's career have been both significant and immediate. As well as being promoted to Associate Professor at Griffith University and being awarded an Advance Queensland Mid-Career Industry Research Fellowship in partnership with VALD, he has been invited to develop a 2024 National Position Statement on *Anterior Cruciate Ligament Injury Prevention* for Exercise and Sports Science Australia.

Back home in Queensland, his research is now attracting growing attention as the state gears up to host the 2032 Olympics. Queensland's Minister for Tourism, Innovation and Sport, Stirling Hinchcliffe, said: "Associate Professor Bourne's research is important as it will help ensure our Queensland athletes are on medal podiums at the Brisbane Olympics."



Griffith University's Associate Professor Matthew Bourne assessing an athlete's jumping biomechanics with VALD's human measurement technology.

Educating clinicians on the benefits of Australia's new vaccine technology

SPONSOR:
Vaxxas

FELLOW:
Dr Elke Hacker

EMPLOYER:
Griffith University

KEY FOCUS:
Medical devices, usability and user experience, regulatory compliance and market pathway, preventive medicine

Vaxxas is developing an alternative delivery mode for vaccines – a less invasive, needle-free high-density microarray patch (HD-MAP), pictured left is Dr Elke Hacker.

Founded in 2011, Vaxxas is a Queensland-based biotech company focused on revolutionising vaccine delivery. Vaxxas was awarded a REDI Fellowship for Dr Elke Hacker, an Adjunct Associate Professor from Griffith University with expertise in improving health outcomes for patients.

Vaccination is one of the most effective ways to prevent the spread of infectious pathogens and avoid severe illness. In Australia, vaccines decreased the burden of disease by nearly one-third between 2005 and 2015.[1] In recent years, the COVID-19 pandemic has highlighted the importance of effective vaccination programs.

Less invasive, needle-free vaccine delivery

For 170 years, syringes and needles have been the most common mode of delivering vaccines. However, after years of research and development, Vaxxas is developing an alternative delivery mode – a less invasive, needle-free high-density microarray patch (HD-MAP).

Yet, as with any new technology in medicine, the HD-MAP requires medical professionals to be educated and trained on how to use the product. Training and education of healthcare workers is essential to ensure clinical uptake, especially of new technologies like the HD-MAP, and, ultimately, commercial success once the device enters the market.

Working in Vaxxas' engineering and clinical teams, Dr Hacker's Fellowship focused on developing and clinically testing a suite of training resources to educate healthcare workers on the benefits of, and how to correctly use, the new device. Dr Hacker also refined and improved the product and labelling information for use in the information sheet, as well as in the product labelling information critical to advancing the product's pathway to market.

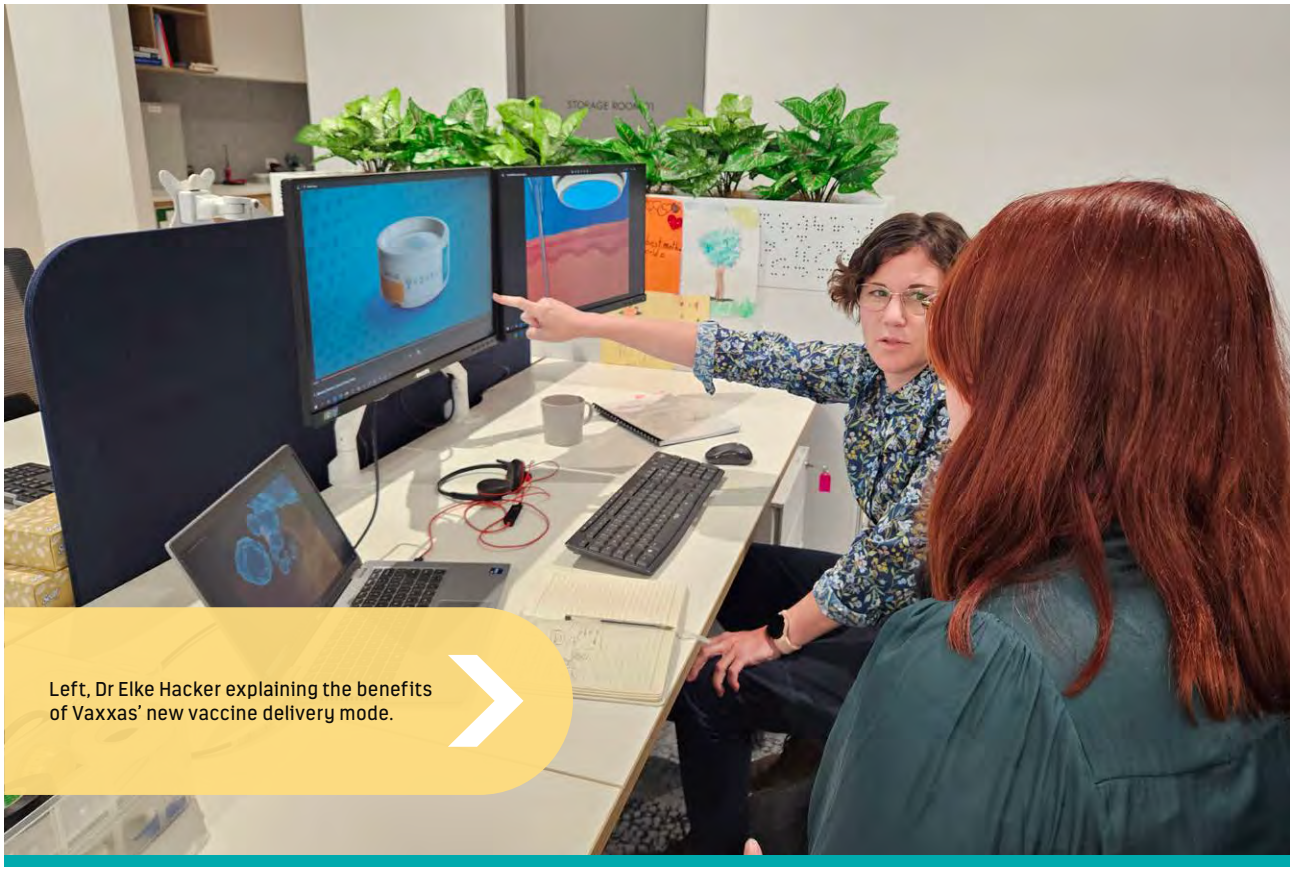
Bringing a unique set of skills and expertise to the project

Vaxxas Head of Manufacturing and Operational Excellence, Charles Ross, said Dr Hacker has brought a unique set of skills to the engineering and clinical teams with her expertise in studying the introduction of healthcare interventions.

"Dr Hacker's expertise in creating educational resources for new healthcare initiatives has been invaluable. Her work during the Fellowship helped to increase awareness and understanding among key user groups of the potential benefits our technology can bring to community healthcare programs," Mr Ross said.

> **"By working with the Vaxxas team, I've gained amazing experience that has transformed my understanding of project management, research endpoints, the importance of regulatory strategies and building data packages."**

1. Australian Institute of Health and Welfare: Report – The burden of vaccine preventable diseases in Australia https://www.aihw.gov.au/reports/immunisation/the-burden-of-vaccine-preventable-diseases/summary



Left, Dr Elke Hacker explaining the benefits of Vaxxas' new vaccine delivery mode.

Likewise, through the Fellowship, Dr Hacker gained highly in-demand skills in Quality Management Systems, medtech device manufacturing, clinical trial design and firsthand knowledge of the commercialisation pipeline for medical devices. She has also secured industry-relevant qualifications with formal training.

In-demand skills lead to broadened understanding and extended abilities

Dr Hacker believes these skills have broadened her understanding and extended her ability to undertake usability studies in the future.

"By working with the Vaxxas team, I've gained amazing experience that has transformed my understanding of project management, research endpoints, the importance of regulatory strategies and building data packages to support the safe use of new and emerging healthcare products," she said.

Strengthened collaboration results in more opportunities and exchange of ideas

This REDI Fellowship has strengthened the collaboration between Vaxxas and Griffith University with student placement opportunities and exchange of research ideas and results. Additionally, the Fellowship extended Dr Hacker's experience and increased her ability to secure industry-based contract research for her department at Griffith University – establishing a professional network that will potentially deliver substantial impact and benefit in the future.

Knowledge generated through the Fellowship will build capacity and enhance access to innovative vaccination resources that have the potential to make a significant contribution to future community health initiatives.

First cross-continent collaboration drives drug discovery in oncology

SPONSOR:
Yuhan Corporation

FELLOW:
Dr Destiny Dalseno

EMPLOYER:
WEHI

KEY FOCUS:
Global collaboration, drug discovery, biotechnology, oncology, Austrade

REDI Fellow Dr Destiny Dalseno.

A REDI Fellowship helped Yuhan Corporation develop in-house gene editing capabilities and paved the way for future partnerships between the Australian and South Korean biotech industries.

Yuhan Corporation is South Korea's oldest and largest pharmaceutical company, researching and developing new prescription medicines. It is home to a 300-strong scientist research group and has state-of-the-art facilities. But, until a REDI Fellowship paved the way for Dr Destiny Dalseno to join the team, it had not opened its day-to-day operations to external collaborators.

A Yuhan Corporation spokesperson said: "This was the first time the Yuhan Research Institute has hosted an external, trained researcher and there was a great deal of value in the exchange.

"The insights gained into experimental methods and the understanding of mechanistic biology benefitted all parties … and we look forward to future opportunities for knowledge and skill exchange between our organisation and Australian research institutions."

Fellow brought expertise in CRISPR gene editing to Yuhan Research Institute

Dr Dalseno, a researcher at Walter and Eliza Hall Institute of Medical Research (WEHI) in Melbourne – who is developing new genetic models to investigate the molecular basis of inflammatory disease – brought her expertise in CRISPR gene editing to Yuhan, helping to establish its use in the drug discovery laboratories there.

CRISPR – Clustered Regularly Interspaced Palindromic Repeat (CRISPR-Cas9) – is an emerging technology that enables geneticists and medical researchers to edit parts of the genome by removing, adding or altering sections of the DNA sequence. CRISPR-Cas9 has potential as a tool for treating a range of medical conditions that have a genetic component including cancer, hepatitis B or even high cholesterol. Research is focusing on its use in animal models or isolated human cells, with the aim to eventually use the technology to routinely treat diseases in humans.[1]

Gene editing with CRISPR allows laboratories to generate in-house cell lines for their work, resulting in cost and time savings.

Dr Dalseno said cell lines of specific genotypes are not always commercially available.

"So, companies offering CRISPR services must then be engaged to generate the cell lines needed. Much of my time at the Yuhan Research Institute was spent working with the Drug Discovery I In Vitro team to establish its use of CRISPR/Cas9," Dr Dalseno said.

1. Your Genome: What is CRISPR-CAS9? https://www.yourgenome.org/theme/what-is-crispr-cas9/

Learning the rigour, control and quality of a regulated pharma environment firsthand

During the Fellowship, Dr Dalseno worked with various teams at the Yuhan Research Institute, learning firsthand the rigour, control and quality of a regulated pharmaceutical environment.

"I presented to many researchers at the company, focusing on my research at WEHI. In addition to generating interest and discussion with several Yuhan researchers and team leaders, tailoring a presentation to a pharmaceutical industry audience was excellent for furthering my communication skills – given that previously I presented to academic audiences only," she said.

She participated in several investigative procedures with the Preclinical Oncology In Vitro team, in which new compounds were screened against known reference compounds. In this way, the company can identify promising candidates for drug development before taking the most promising ones further towards preclinical and then clinical trials.

With colleagues in the Drug Discovery I Oncoimmunology In Vitro team, Dr Dalseno conducted experiments to test different cell lines to see how they react to novel compounds and monitored how cell replication is affected, to see whether these compounds affect the growth and replication of tumour cells.

Fellowship provided essential insight into what is needed for successful drug discovery

The overall experience led Dr Dalseno to develop the skills needed to work in drug discovery in an industry environment.

> **This was the first time the Yuhan Research Institute has hosted an external, trained researcher and there was a great deal of value in the exchange.**

"While collaborations are common in academia, collaborative work in industry is essential for accomplishing goals and meeting targets. My REDI Fellowship experience provided essential insight into the highly structured collaborations required for successful drug discovery and provided hands-on experience in efficient, goal-oriented teamwork and strategic networking," she said.

During her time in South Korea, Dr Dalseno also met with Minister Counsellor and Senior Trade and Investment Commissioner for Korea and Mongolia, Julie Quinn, and Austrade Director of Trade and Investment for Korea, Juliet Woo. She was able to act as a bridge for Austrade to meet – for the first time – with the Chief Science Officer at the Yuhan Research and Development Centre, and future collaborations between Austrade and the centre are now planned as a result.

A paradigm shift in her career and a new well-rounded view of research

Summing up, Dr Dalseno said she would describe her Fellowship at Yuhan as experiencing a paradigm shift in her career.

"Coming into the Fellowship from an academic background, I had an appreciation of the importance of fundamental and translational scientific research. But now I recognise how the drug discovery and commercialisation process is instrumental in bringing new therapies to market – allowing me to approach my research with a well-rounded view of improving human health," she said.

ABOUT MTPCONNECT

MTPConnect is Australia's Life Sciences Innovation Accelerator – an independent, not-for-profit organisation established by the Australian Government to champion the continuing growth of Australia's vibrant medical products sector.

MTPConnect forges stronger connections between research and industry to help maximise opportunities for Australians to not only make scientific and technological breakthroughs, but to see them developed through the proof-of-concept stage and successfully translated and commercialised.

We achieve these outcomes with a focus on improving collaboration and commercialisation, funding cutting-edge innovations, improving management and workforce skills, optimising the regulatory and policy environment and improving access to global supply chains and strategic international markets.

MTPConnect also operates accelerator programs to support the development of cutting-edge medical technology, biotechnology and pharmaceutical innovations, with more than A$180 million invested so far in 200 projects.

MTPConnect has established key hubs at the University of Adelaide in Adelaide, within Adelaide BioMed City, the Harry Perkins Institute of Medical Research in Perth and the Translational Research Institute in Brisbane. The MTPConnect Board is led by Hon Jaala Pulford and includes other respected industry leaders.

MTPConnect

Australia's Life Sciences
Innovation Accelerator

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