2020

HEALTH+MEDICAL RESEARCH

Medical Device Commercialisation Training Program

NSW GOVERNMENT

Office for Health and Medical Research

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A message from the Minister

The NSW Government has been an early adopter in support of the medical device and health technology sector, recognising that investment in research, including the development of medical devices and technologies, is critical to improving patient outcomes.

The NSW Medical Device Commercialisation Training Program fulfils a commitment to embed research into the health system, build medical device commercialisation capacity in NSW, and contribute to the discovery and application of new treatments and diagnostic techniques to improve patient outcomes. It allows research to deliver lifesaving benefits to individuals and the community.

The success of the Program is seen in its contribution to developing the innovation ecosystem in NSW. The Program equips candidates with the knowledge and skills needed to successfully commercialise medical device technologies. It improves research translation in NSW, improves the timeframes and success rates of the commercialisation of NSW medical devices and ensures that these devices enter the NSW health system to improve patients' lives.

One of the unique elements of the Program is that candidates conduct user interviews to help understand the real-life problem that their technology has the potential to solve. In recognition of the quality of the Program, the Medical Device Commercialisation Training Program has been awarded 12 credit points towards MBA Programs at the University of New South Wales and the University of Wollongong.

Since its inauguration in 2014 there have been 80 graduates who have launched over 16 companies and raised over $53 million in grants and private investments to commercialise their innovations.

To all of the 2020 graduates, there is no doubt that you are working in a challenging, complex and dynamic environment. The resilience and determination you have shown in completing the Program in such challenging times will no doubt prepare you well for the future. I congratulate you all and look forward to seeing you build on the knowledge and experience you have accumulated as part of this fantastic Program

Hon Brad Hazzard MP
Minister for Health and Medical Research

A message from Cicada Innovations

This year, health has come to the forefront of conversation and thinking, in a way that no one could have predicted. The world ground to a halt in an unprecedented and collective effort to contain the coronavirus pandemic, and health systems, policies and innovations around the globe were placed under urgent scrutiny and enormous pressure. COVID-19 has been a worldwide wakeup call to the challenges we face in a multitude of areas, including preventing and treating major diseases, accessibility to health services and more.

Australia has a history of punching above its weight when it comes to medical innovation. Ground-breaking technologies like CPAP, cochlear implants, gene silencing, zinc cream, spray on skin, and multi focal contact lenses have enabled transformational change and improved patient outcomes globally, all while reducing costs on the healthcare system and allowing the reallocation of resources to other areas of need. It is the ecosystem inspired by these pioneers in deeptech that Cicada Innovations has been committed to growing over the course of its 20 years in existence.

Deep technology companies with their strong STEM foundations, have the capability to adapt rapidly to combat new and evolving global challenges. Companies with products already in market are ideally positioned to do this, building additional capabilities to existing tech or even pivoting to address emerging needs.

This has never been more apparent than in the past few months, where some of Cicada Innovations' resident businesses were able to contribute to the COVID-19 response with impressive speed and agility.

Calumino adapted thermal imaging technology originally meant for the aged-care sector into a low-cost, one-second temperature sensor for mass use in crowded environments like schools and airports. SpeeDx diversified their core business to include a COVID-19 test alongside their other diagnostic platforms for bacterial infections. Both examples make a strong case for the need to unearth and nurture promising Australian medical technologies as well as the creative, dynamic teams behind them.

Digital health technologies have also increasingly changed the way we manage health and health-related data. Software, artificial intelligence and virtual augmentation are increasingly being deployed across the patient journey, improving speed and accuracy across the board. Patients are now able to make proactive decisions about their health informed by countless data points.

This year we have included a Software As a Medical Device component into the wider Medical Device Commercialisation Training Program in recognition of this important facet of modern healthcare.

For Cicada Innovations, it has been an incredible honour to deliver the Medical Device Commercialisation Training Program for the past six years through our partnership with NSW Health. It has given us the opportunity to have a hand in developing and nurturing the next generation of Australian medtech entrepreneurs and we are so excited to see where their continued journeys will take them.

We know it takes many years and a strong deep tech ecosystem to bring novel medtech ideas to fruition to make a global impact. Now more than ever it is critical that we - government, venture capitalists, universities, industry and deep tech organisations like Cicada Innovations - continue to come together and collaborate, with renewed vigour and urgency, to ensure the success of the next generation of medical innovation in Australia.

Dharmica Mistry, Head of Medtech, Cicada Innovations

About the Medical Device Commercialisation Training Program

The Medical Device Commercialisation Training Program is an initiative by NSW Health and delivered by Cicada Innovations. It drives change by accelerating the commercialisation of medical technologies in NSW to bring lifesaving healthcare innovations to market.

The program integrates 1-day workshops on clinical trials, regulatory strategy and intellectual property with 3-month business building courses designed to challenge bias, enlighten and upskill participants. NSW-based researchers, clinicians and entrepreneurs participate in the Program at no cost to themselves. Training has been provided to 426 researchers, clinicians and entrepreneurs over the past 12 months. The Medical Device Training Program is designed for healthcare entrepreneurs from diverse backgrounds of medicine, engineering, science and business, and provides a tailored curriculum that explores how to transform their visionary concepts into viable businesses.

Following the 6th cohort of MDCTP CORE, we proudly graduate 12 innovators this year. CORE participants learn to search for the right business model for their technologies and gain insights from over 22 mentors and domain experts on every facet of running a medical technology business from IP, Regulatory and Reimbursement to Corporate Governance, Finance and Capital Raising.

The first 80 graduates of CORE have launched 16 companies and raised over $53M to commercialise their ideas. A further 17 have access alternate career pathways following their PhDs and entered industry in commercialisation roles. Standing on the shoulders of these giants we are extremely excited for the future of medtech in NSW.

Program presenters and mentors

Teaching team / mentors

Ben Wright – Business

Phil Smith – Business

Peter Spencer – Business

Guest speakers

Anne O'Neill – Office for Health and Medical Research, NSW Health

Guy Ford – University of Sydney Business School

Gavin Recchia – Davies Collison Cave

Will Hird – Davies Collison Cave

Arthur Brandwood – Brandwood CKC

Lisa Emerson – Saluda Medical

Eugene Salole – Value-Based Access Pty Ltd

Peter Fisher – Act One

Richard Sokolov – IDE Group

John Paul McKeown – Ingenuity Design

Kath Hamilton – loop+

Anita Van Der Meer – Office for Health and Medical Research

Chris Smith – Brandon Capital

Jess Gledhill – Brandon Capital

Gabriel Douville – One Ventures

Jane Cockburn – Kairos Now

Phil Smith – Luminos Labs

Richard Horton – Squire Patton Boggs

Award partners

Industrial design
IDE Group

Intellectual property
Davies Collison Cave

Corporate and commercial law
Addisons

Market access strategy
Value-Based Access Pty Ltd

Customer strategy
Kairos Now

Sponsored Incubation
Medical Device Commercialisation Training Program

Medical Device Commercialisation Training Program Graduates 2020


MEDICAL ANALYSIS
02-08-38 | MALE
DOCTOR
HS
OH
HN

Alessandro Simeoli

NSW Toll Ambulance Rescue Helicopter Service

ETOM

ETOM is a portable, compact and durable medical device which monitors the oxygenation level of critically ill patients prior to Rapid Sequence Intubation (RSI). RSI is a medical procedure that involves administration of a general anaesthetic and tracheal intubation to secure the patient's airway. Prior to RSI, Critical Care Paramedics and Doctors routinely pre-oxygenate their patient with a bag valve mask (BVM) which delivers 100% Oxygen. ETOM is designed to connect to the respiratory circuit of the BVM to measure the expired Oxygen level of the patient, which helps to determine when it is safe to commence the RSI procedure.

"The path to commercialisation of a medical device is a minefield, with dangers and pitfall for the unaware! The Medical Device Commercialisation Training Program gave me a map to navigate through this minefield whilst maximising my chances of becoming a successful entrepreneur. Partnering and networking with the right experts and organisations is key to learning what knowledge is important to bring your idea to life."

Early pilot studies have identified that at times clinicians don't pre-oxygenate their patients to the recommended level. This can lead to undesirable consequences such as dysrhythmia, hypotension and cardiac arrest. Anaesthetists in operating theatres have been using the technology behind ETOM for decades, in the form of a gas analyser integrated into their large anaesthetic machines.

ETOM aims to bring this technology to clinicians in emergency departments and pre-hospital settings in a portable and compact format. ETOM is moving through the concept phase with further evidence being sought to determine its clinical applicability.

Beena Ahmed and Kirrie Ballard

Say66

Automated Speech Therapy Tool

3.5 million children in Australia and the US have speech sound disorders, making them difficult to understand. Fewer than 50% of children in need receive therapy. Children whose speech problems are unresolved before entering school risk failing to learn to read, difficulties in developing friendships, bullying, and later on reduced job opportunities and mental health problems. While therapy is most effective when done multiple times a week, speech pathologists typically see children only once a week due to geographical, time and cost constraints.

“The Medical Device Commercialisation Training Program has taught us how critical it is to speak with a range of people in the community to critically evaluate all components of your business model, especially the value proposition and feasible channels. The introduction to financial modelling was invaluable in understanding how to maximise chances of viability over the first couple of years.”

Say66 has produced a technological solution backed by academic research that can provide children who are slipping through the cracks with access to remote therapy. It stands apart from the 100+ speech therapy apps on the market as it not only engages children but also guides their learning. By building our evidence-backed therapy protocols into platformer-type games, we have shown superior child engagement over months of therapy in initial clinical trials. Our proprietary AI algorithms analyse children’s in-game speech productions to provide real-time feedback and inform remote monitoring and adjustment by the speech pathologist.

In the next year, Say66 will release the first therapy game to gauge market uptake and conduct a large-scale clinical trial to test effectiveness in the field.

Jason Fairclough

Kangaroo Medtek

Butterfly Skin Traction

BTS

Butterfly Traction System

We are a sporting nation, but it comes at a cost. Over five thousand people in Australia sustain finger fractures and dislocation each year that require hospital admission and surgery. Some will develop infections, loss of function and ongoing pain which are not outcomes people expect.

My solution was to develop the Butterfly Traction System, a portable traction device that could gently pull finger fractures back into position and provide early gentle protected movement.

It can be combined with gentle foam buffering blocks to further assist translation and reduction of fracture fragments.

“The program was a wonderful experience. It was based on the Lean StartUp methodology of Steve Blank. My greatest learning was how to engage in customer discovery, and I conducted over 100 interviews to understand people’s experiences. The presenters were amazing, and I also learnt a great deal about market analysis, design control, regulation, pitching, and business modelling.”

The technology is unique. Over the next 12 months my goal is to conduct further clinical trials and have the device available for patients, paramedics and medical staff both in Australian and Internationally.

Jonathan Hribar

Blindness Assistive Technologies

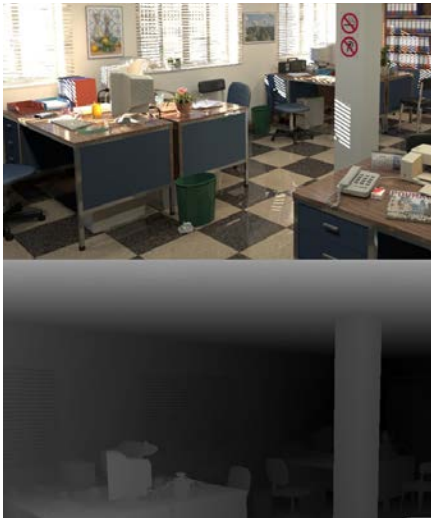
Sound Sense

People with blindness and severe vision loss find themselves with substantially limited navigation options that often forgo independence and utility. Current mobility aids do not allow users to easily navigate new locations, and traditional solutions such as the guide dog are in extremely short supply while costing up to $50,000 to train and $150 per month to maintain.

The ultimate goal of SoundSense is to create the perfect complement to the cane and guide dog, in a hands free visual aid wearable prosthetic that enables high fidelity spatial perception, object and person detection, and navigational and orientational awareness for the blind and visually impaired, allowing the user to feel more at ease while navigating the world.

“The Medical Device Commercialisation Training Program was an eye-opening experience that showed me the value of real-world feedback. It taught me the importance of holding the needs of the patient above the technology. This means that the design should start with the patients’ needs and fit the problem that it is trying to solve, rather than trying to fit the problem to the solution.”

The Sound Sense solution uses discreet wearable sensors, fitted in a pair of glasses, to map objects in 3D space and indicates where these are through intuitive spatial sound. The novel spatial to audio translation techniques require little to no training time, painting the world to the blind, in real time, through the conduit of sound. Over the next 12 months Sound Sense will work with blind societies and gather customer feedback to drive product development and ensure it is built around the user’s needs.



Luke Gordon

University of Sydney

Neurospec

Parkinson's disease is an insidious neurodegenerative disorder with symptoms varying from person-to-person. The disease progressively corrupts a person's ability to complete motor tasks and can eventuate in debilitating symptoms, including difficulties in speech, sleep and cognition.

Over 6 million people with Parkinson's lack an effective disease-modifying treatment. The gold-standard treatment of over six decades, Levodopa, only offers symptomatic relief which diminishes as the disease progresses.

Photobiomodulation technology, the use of red to near-infrared light exposure to protect tissues, shows promise to arrest the degenerative processes that affect the brain.

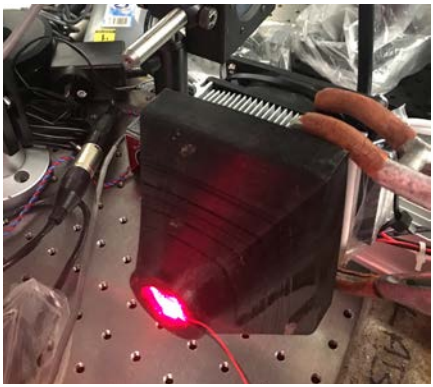
“Academic research is only half of what is required. This course has taught me how to design medical technologies via consulting with the people who need it; a skill that I will now employ in everything I design.”

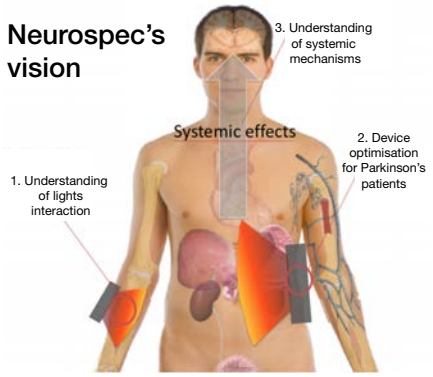
As investigated in mice models of Parkinson’s disease, directing light to the head or body has been shown to preserve brain cells which would ordinarily die due to the disease. For humans, however, our skulls permit only 4% of light to penetrate to outer limits of the brain.

Neurospec’s technology utilises body-directed light to initiate systemic responses which can have protective effects in the brain, altering the progression of Parkinsonian injury.

The Neurospec goal for the next 12 months is to generate a light-emitting device, that is optimised to offer people with Parkinson’s a treatment capable of slowing this sinister disease through the delivery of simple at-home treatment.

There needs to be more efforts to translate lab bench technologies to outputs that can directly help people.





Nafiseh Mirabdolhosseini

Western Sydney University

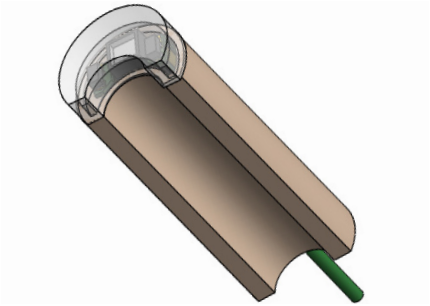
ClearView

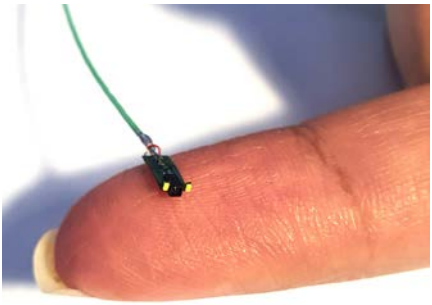
Gastro-oesophageal reflux disease (GORD) affects over one in ten Australians and increases the risk of more serious conditions such as Barrett's oesophagus and oesophageal adenocarcinoma. More frequency endoscopic surveillance of GORD patients is recommended but is held back by the high clinical and financial burdens.

ClearView is a disposable endoscope that allows for quick visual assessment of the oesophagus and monitoring of functional abnormalities. The optical technology in our device is comparable to conventional endoscopy (full HD, 60 fps) but all fits within a catheter head smaller than a grain of rice.

"The Medical Device Commercialisation Training Program has given me a much clearer understanding of medical device commercialisation. We have a novel device that is technologically comparable or superior to existing endoscopy in many aspects. But during the discovery phase, I learnt that implementation into practice required more than technical competence, other factors such as reimbursement pathways and clinical culture played an important role."

It allows for minimally invasive surveillance and monitoring of the oesophagus in a primary care setting. Over the next 12 months, the research will focus on the wearable capabilities of ClearView. The novel ability to wear an endoscopy during daily activities will help identify abnormalities previously speculated but no observed in GORD patients, such as transit sphincter relaxation, non-acidic reflux, and reflux hypersensitivity. A machine learning algorithm will automate video analysis to provide new diagnostic criteria and better classify existing reflux diseases. ClearView plans to further develop the capabilities of our device to create more value for stakeholders.





Nicole Hasick

SpeeDx Pty Ltd

ResistancePlus™ MABSC/MAC

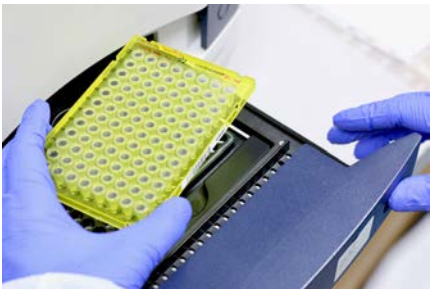
SpeeDx
Diagnostics Defining Therapy

Mycobacterium abscessus complex (MABSC) and *Mycobacterium avium* complex (MAC) are opportunistic pathogens that cause life-threatening respiratory infections, especially in immunocompromised patients such as those with lung conditions like cystic fibrosis (CF). Treating MABSC and MAC infections are particularly challenging as they are highly resistant to most antimicrobials. Current reliance on slow culture-based diagnostic methods leaves doctors with little information and unable to quickly guide treatment decisions.

SpeeDx Pty Ltd is a privately-owned, Australian molecular diagnostics company that develop world-leading in-vitro-diagnostic tests for infectious diseases and antimicrobial resistance using their proprietary PlexPCR® and PlexPrime® technologies.

“The Medical Device Commercialisation Training Program taught me the importance of listening with ‘childlike curiosity’ in order to understand the true problem. This means listening to the customer and listening to the patient, especially if they are saying something that challenges important assumptions.”

Here, SpeeDx are developing a product that will rapidly diagnose MABSC, MAC and facilitate resistance-guided therapy much faster than current methods (hours instead of weeks), ultimately improving clinical management and outcomes for high risk patients such as CF. This diagnostic test allows patients to have a plan in a day rather than waiting through weeks of uncertainty.



Ricky O'Brien

University of Sydney

Motion Scan

The human body is dynamic, and we often have knee, hip and shoulder issues as we move. Current CT and MRI imaging technologies image the patient while they are stationary and usually while they are lying flat inside the bore of the MRI or CT scanner.

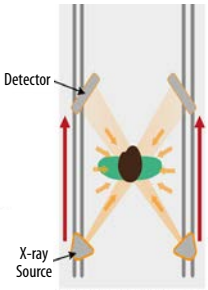
The Motion Scan technology aims to reinvent medical imaging from a modality where the patient remains stationary during the scan to a technology to image the patient as they are moving or walking.

"The Medical Device Commercialisation Training Program helped us to develop a methodology to test the technologies value proposition through extensive customer and stakeholder engagement. The emphasis on company founders getting out of the office and talking to the users, choosers and payers of the technology is a concept that will be of value in both my research and commercial endeavours going forward."

Over the next 12 months the goals for the technology are to:

1. Develop a prototype device by adapting existing scanners to follow a patient as they move.
2. Develop the image reconstruction algorithms to account for the patient motion.
3. Continue stakeholder and customer engagement so that a stronger value proposition has been established.

X-ray panels can move along and up and down on the rails.



Step 1. Patient remains still. X-ray source moves around the patient.

Step 2. Patient walks. X-ray source follows the patient as they walk.

Robert Walker

OCULENCE

Dry Eye Digital Health app

Dry Eye Syndrome (DES) is a chronic, episodic disease caused by a lack of sufficient lubrication and moisture on the surface of the eye, resulting in inflammation and irritation. Currently it affects 1 in 5 Australian adults, and new research suggests that this condition is becoming increasingly prevalent amongst younger generations as a result of increased screen time which strains the eyes. DES can be effectively managed by consistent compliance to eye drops, however data shows that approximately 50% of patients will discontinue treatment within the first 6 months.

“Through the Medical Device Commercialisation Training Program, I realised that there is an invaluable resource in actively communicating your product thoughts and ideas with peers, teachers, and (most importantly) patients, and to then take their responses on board, learn, and improve your business outcomes.”

The OCULENCE goal is to combat noncompliance to eye medication and improve clinical outcomes for Dry Eye. To achieve this, OCULENCE is developing a digital health app for DES which aims to equip patients with the necessary tools to successfully self-manage their eye condition. Partnering with the Save Sight Institute, our ‘Dry Eye Digital Health app’ aims to harness real world evidence from the *Save Sight Dry Eye Registry* and utilise this data to better inform patients on the management of DES.

The team at OCULENCE is currently designing a personalised method for communicating to patient’s their own clinical outcomes data to further enhance compliance and thus improve outcomes.

Sarah Holland

The Black Dog Institute

The InSTIL Platform – Intelligent Sensing to Inform and Learn

Mental health illness affects nearly 1 in 2 people with almost half of all Australians aged 16 to 85 years experiencing mental illness at some point in their lives. Australians spent 9.9 billion dollars on mental health services in 2018. It is a growing problem.

With the introduction of smartphone technology may be the missing ingredient to start to solve this problem and explore a new frontier to help prevent mental illness.

The technology solution is a digital phenotyping platform called InSTIL – Intelligent Sensing to Inform and Learn. Digital phenotyping or personal sensing is the moment by moment in situ analysis of the human phenotype using data from personal digital devices.

"I have learnt that commercialising new technology in the health sector requires an understanding of reimbursement pathways, therapeutic regulations and knowledge of stakeholders that are specialised across different fields. Understanding how to ask the right questions to get the right information is a skill that I thought I had until I started this course. It's been a wonderful journey."

The smartphone that 91% of Australians now use allows the capture of behavioural signals, sensor data and self-reported information that we can use as an alert system.

The first iteration of this planform is currently being trialled. The goal for the next 12 months is to further engage the research ecosystem, form delivery partnerships and continue to build the evidence of effectiveness to enable the technology to deliver on the mission – to build a mentally healthier world.

Turaab Khan

Ischaemia Solutions

iiPJ

Kidney transplantation is the best available treatment for end-stage kidney failure. When a kidney re-warms during the transplantation procedure before its blood supply has been restored, its subsequent function is impaired, leading to delayed graft function, which is the need for dialysis within 7 days after transplantation. This temperature increase introduces a time pressure for surgeons to perform the surgery as quickly as possible, leading to surgical complications, the leading cause of delayed graft function and graft failure.

The ischaemic injury protective jacket, iiPJ™, is a transplant jacket that maintains the kidney at a safe and cool temperature in the body during transplantation in order to increase short- and long-term kidney function, increase patient quality-of-life, reduce the pressure for rapid

“I was fortunate enough to develop strong connections with so many talented people from our cohort and professionals within the biomed industry.”

surgery, allowing for robotic transplantation, improve surgical training, reduce surgical complications due to time pressure and reduce post-transplant treatment costs.

Currently, there is no existing medical device on the market that aims to provide intra-operative thermal protection in order to reduce the occurrence of delayed graft function.

The next 12 months shall be spent in manufacturing clinical prototypes of the iiPJ in order to perform animal testing and a phase 1 clinical trial.

The Medical Device Commercialisation Training Program brought to light the importance of the customer discovery process and identifying a problem to solve, rather than trying find a problem to fit your current product.

About the Office for Health and Medical Research

The Office for Health and Medical Research sits within NSW Health and is vital to delivering better treatments and interventions to improve health outcomes. The Office is focused on providing researchers, clinicians, managers and policy makers with the tools they need to translate research into innovative policy and practice to create healthier communities and deliver better patient care.

The Office was established to implement the NSW Government's strategic plan to build research capability in NSW following its NSW Health and Medical Research Strategic Review in 2012. Key priorities include facilitating engagement of stakeholders; assisting with the development of state-wide strategic research priorities; providing a supportive policy framework; administering funding programs that support research infrastructure and innovation; supporting clinical trials and working with pillar organisations, local health districts, primary care providers and the non-government sector in the translation of research into clinical practice, healthy lifestyles and illness prevention.

Health and medical research is an integral part of the NSW health system. It is vital for the delivery of better treatments and interventions for patients, improving health services delivery, and health outcomes at both the clinical and population level.

The integration of health and medical research within the health system supports innovation within the system, builds a strong culture of continuous improvement to ensure we deliver the best evidence-based health care for Australians, and is crucial for ensuring the health system's efficiency and sustainability.

Investment in health and medical research also benefits the State's economy, stimulating the biotechnology industry, building commercialisation capacity and helping to reduce the costs of health care delivery.

The Office for Health and Medical Research works with health and medical research communities, the higher education sector and business to promote growth and innovation in research to achieve better health, environmental and economic outcomes

NSW GOVERNMENT Health

Office for Health and Medical Research

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About Cicada Innovations

Cicada Innovations is Australia's pioneer deep tech incubator, supporting startups and scaleups solving the world's most pressing problems. A unique melting pot of business, industry and science, we supercharge innovators of disruptive, life-changing technologies with the know-how and networks they need to commercialise their products and get them into the hands of people in faster and smarter ways.

Established in 2000 by Australia's top Universities — ANU, UNSW, USYD and UTS — Cicada Innovations operates on the belief that deep tech is the resource that will fuel the future of humanity, and that the most precious resource is the visionary research that emerges from our brightest minds. Cicada's resident companies benefit from our rich research partnerships, networks of multi-disciplinary domain experts, in-house specialist infrastructure and access to theshareholder Universities.

To date, Cicada have helped more than 300 companies raise $350m+ in venture capital and government grants, file 500+ patents and trademarks and launch 700+ deep technology innovations globally.