



NSW Medical Device Commercialisation Training Program

2015



ATP Innovations
Success multiplied



Health

Contents

A Message from the Minister	4
A Message from ATP Innovations	5
About the NSW Medical Devices Commercialisation Training Program (MDCTP)	6
About ATP Innovations	7
Where are they now? A snapshot of the alumni from MDCTP 2014	8
Sheridan Gho and Michael Weaver	8
Paul Keall	8
Ilana Feain	8
Evelyn Linardi	8
Ryan Pawell	8
Meet our graduands of the MDCTP 2015	9
Aiden O’Loughlin	9
Annabelle Chan	10
David Yeo	11
Dharmica Mistry	12
James Otton	13
Josef Goding	14
Robert Gorkin	15
Sandra Ast	16
Sean Pollock	17
Stephen Bradford	18
Stephanie Watson	19
Yang Chen	20
Notes	21

A Message from the Minister



Hon Jillian Skinner MP
Minister for Health

The NSW Government is committed to building world class health and medical research capability in NSW. More than half of Australia's medical devices companies are headquartered in NSW including two of the nation's most successful: Cochlear Ltd and ResMed Ltd. Our Medical Device Commercialisation Training Program and Medical Device Fund assist the medical technology sector to encourage and enable the translation of innovations for the benefit of patients and our economy.

Quality medical research leads to greater knowledge and understanding of specific diseases, new treatments and medicines, new skills, better practices and, above all, better health outcomes.

Medical devices have an extraordinary capacity to transform lives - but this can only happen if they are taken from the laboratory to market, where their impact can best be felt. The Medical Device Commercialisation Training Program helps innovators who are in the proof of concept phase of development. This early engagement is vitally important as it helps researchers identify need and maximise opportunities.

The NSW Government's commercialisation initiatives are designed to open up pathways to clinicians, scientists and engineers to advance technologies in NSW. The Medical Device Commercialisation Training Program is instrumental in building even stronger foundations for our medical technology sector.

The participants in the program have gained valuable skills that will help them turn their ideas into the health improvements of the future. Importantly, the skills the graduates have gained during the program will have a lasting influence on their own research and practice, while helping to grow the medical device sector in NSW.

A Message from ATP Innovations



Ben Wright

Director,
Commercial Development,
ATP Innovations

Director, Medical Device
Commercialisation Training
Program

The NSW Medical Device Commercialisation Training Program (MDCTP) is a strategic asset critical to the development of commercialisation capability within NSW. The MDCTP capitalises on medical technology research excellence in the state by developing entrepreneurial skills in clinicians and medical device researchers.

Clinicians and researchers are exposed to commercialisation skills and practices that are often neglected in an academic environment. Over 12 weeks students self-identify whether they are an entrepreneurial academic or an entrepreneur, explore the value proposition for their own unique technologies and engage face-to-face with stakeholders across the commercialisation continuum from patients and clinical specialists to payers and regulators, often leading to profound insights that change their business model. Upon completion, graduates of the MDCTP have a clear understanding of the market dynamics, market opportunity, capital requirements, regulatory and commercialisation pathways required to build a business and launch new products and services.

We are developing a pool of extremely talented researchers, technologists and clinicians who are able to translate complicated science and engineering into clear value propositions that solve real world health problems. The ability to communicate effectively with customers, funders and industry partners is critical to the success of technology commercialisation.

Minister Skinner has demonstrated exemplary leadership and vision in her commitment to innovation and capability development through the launch and continued patronage of the Medical Device Commercialisation Training Program and the NSW Medical Device Fund. MDCTP has now graduated 32 post-doctoral medical device researchers and clinical specialists, each armed with knowledge and skill required to change the face of healthcare.

About the NSW Medical Device Commercialisation Training Program (MDCTP)

The MDCTP is an intensive 3-month medical commercialisation training program for clinicians and medical device postdoctoral researchers.

The Program delivered by world leading technology incubator ATP Innovations on behalf of the Office for Health and Medical Research. The purpose of the program is to increase the commercialisation capability of medical device researchers in order to create health impact and develop new career opportunities in Australia.

During this intensive Program candidates are exposed to entrepreneurship and develop the necessary skills to commercialise their technologies including; customer discovery, medical device design and commercial value. The course is based on extended Lean LaunchPad® methodologies going beyond the “Search” for the right business model to include structural elements of medical device commercialisation, including IP management, regulatory affairs and strategies to raise capital.

The MDCTP was first launched in 2014 in partnership with the NSW Government, to build medical device commercialisation capabilities in NSW. Graduates of the 2014 program have started companies, raised capital from investors, engaged industry partners, received over \$1 million in development grants to-date and created new career opportunities in Australia, USA and Europe.

About ATP Innovations

ATP Innovations is Australia's leading technology business incubator. ATP Innovations partners with technology-based startups to give them the best chance of achieving commercial success in the shortest time possible. ATP Innovations works with researchers and entrepreneurs to help them raise capital, build a team, secure government grants, create new products, grow revenue and ultimately exit their business profitably.

Our experienced executive team has worked with more than 80 businesses since 2006, helping them raise over \$130 million, file 250 patents and trademarks, sell products across the globe and for eight, sell their business. ATP Innovations is home to the Accelerator HUB, a central location for Sydney's accelerator programs and hosts Sydney's largest community of technology entrepreneurs within the National Innovation Centre, where more than 70 companies employ over 350 staff. ATP Innovations accepts applications from startups 365 days a year.



Where are they now?

A snapshot of the alumni from MDCTP 2014

Sheridan Gho and Michael Weaver

Awarded NSW-QB3 Scholarships to the Rosenman Institute in San Francisco for two years to work with clinician innovators and entrepreneurs to advance their technology. Dr Gho and Dr Weaver have been working to address lymphoedema - a condition of localised fluid retention and painful tissue swelling, caused by a compromised lymphatic system, it affects one in three breast cancer survivors. Dr Gho and Dr Weaver's invention involves a wearable sleeve that treats and manages the painful condition by actively massaging the lymphatic system, allowing patients to conduct normal lives.

Paul Keall

Respiratory Innovations hired its first CEO and received an \$588,475 NHMRC development grant to develop 'BreatheWell', a biofeedback device that assists cancer patients to breathe predictably while undergoing radiotherapy.

Ilana Feain

Co-founded Nano-X with Paul Keall and hired a CEO. Nano-X is a new cost effective and compact linear accelerator for radiotherapy. The innovation is in patient (rather than gantry) rotation. By rotating the patient, Nano-X decreases the cost and infrastructure requirements at hospitals. This makes the technology accessible and affordable for developing countries and rural areas, while delivering first world health outcomes.

Evelyn Linardi

Started a new career. The program gave her a big picture understanding of the medical devices industry and a broader perspective of what it takes to bring a product to market. Since completing the program Evelyn has transitioned from being a Scientist to becoming a Marketing Coordinator at Speedx. In addition to marketing, she also contributes to Business Development and Communications. Founded in 2009, Speedx is a provider of innovative multiplex qPCR and isothermal amplification solutions for clinical diagnostics. Its portfolio of market leading detection and priming technologies enable new healthcare paradigms that lead to improved delivery and reduced costs. Speedx was a recipient of \$1.8 million from the NSW Medical Device Fund in 2014.

Ryan Pawell

Founded Indee incorporated, a multi-national company. Indee just closed a meaningful acceleration round and is partway through the IndieBio San Francisco Accelerator Program. To date, Indee have finished new device prototypes, hired a Chief Scientific Officer, hired a contractor for system fabrication, recruited five people to the advisory board and are in the process of validating the technology for therapeutic development, all while building relationships for the next financing round.

Meet our graduands of the MDCTP 2015



Aiden O'Loughlin
Stabilizer

One in three people in Australia die of cardiovascular disease. The underlying process causing the majority of these deaths is atherosclerosis. Atherosclerosis is a disease where fatty material is deposited in sections of the wall of the artery. Deaths occur when local atherosclerotic lesions rupture, stimulating clot formation, leading to occlusion of the artery. These lesions are termed 'vulnerable plaques'. Both heart attacks and strokes can be caused by vulnerable plaques rupturing. Recent research has shown that vulnerable plaques can be identified prior to their rupture. The Stabilizer device provides treatment that will prevent future heart attacks and strokes with the development of a locally applied treatment to stabilise these plaques.



Annabelle Chan
Rapid Templating System

The rise in rapid prototyping technologies has presented a unique opportunity for the creation of custom made implants. However, the logistical shift from generic high volume production systems to individually customised implants prevents its widespread usage. The Rapid Templating System aims to form patient specific implants quickly and effectively. The system involves the production of a 3D-printed guided mould, based on patient scans, to shape terminally sterilised generic materials into patient-customised implants. The generation of custom implants within packaged materials allow implants to be immediately ready for use, avoiding treatment delays due to sterilisation post production. This approach has the capacity to significantly reduce inventory costs for medical device companies, as abundant implant-size ranges are no longer required to accommodate all patient cases. Further developments in regenerative medicine may allow further customisation material properties, allowing the implant to be patient specific anatomically as well as a biomechanically.



David Yeo
Pivot Sphincterotome

Endoscopic retrograde cholangiopancreatography (ERCP) is an endoscopic procedure that allows access into the biliary system and has revolutionised the management of bile duct pathology. However, it is a notoriously difficult procedure to learn and even in experienced hands, this procedure is associated with complications including pancreatitis, bleeding, perforation and in rare cases, death. Cannulation of the bile duct remains the most challenging step of the procedure even with current sphincterotome technology. The Pivot Sphincterotome has been developed to facilitate easier, faster and ultimately safer biliary access. The ERCP sphincterotome US market alone is worth approximately \$USD150 million and with an increasingly elderly population requiring less invasive procedures, it is expected to increase. Developed by an ERCP practitioner, the Pivot Sphincterotome aims to accommodate the shortcomings of current technology making the ERCP experience more user-friendly, efficient and safe.



Dharmica Mistry *BCAL Diagnostics*

To develop and commercialise a novel universal screening test for the detection of breast cancer that is highly accurate, safe, cost effective, and available to all women regardless of age, race and geographic location.

Breast cancer is the most common cancer amongst women, therefore, the effectiveness of the screening and diagnosis technology used is a high priority. The current model relies on a woman being physically present at a clinic for breast imaging which is not always convenient. While the present technologies are currently state of the art, there is a high cost involved. There are also well known performance limitations that result in only a small subset of women who are actually eligible for screening.

BCAL Diagnostics aims to shift the paradigm in breast cancer screening and diagnosis by introducing a blood test for detection of the disease. The implication of such a technology could revolutionise the way breast cancer is managed by allowing a blood sample to be taken remote from the site of analysis. This technology will allow access to more women, anywhere in the world, who could provide a blood sample, at a time and place convenient to them. Such a test would fit into a woman's routine health regime and be incorporated into their personal lifestyle. In addition, with such high levels of accuracy, this technology would provide greater peace of mind between annual checks. The BCAL Diagnostics technology could utilise a single blood test on multiple levels for disease prevention, diagnostic mass screening and post-intervention.



James Otton
SeCure Beating Heart Repair

Mitral regurgitation is a condition caused by a leaking heart valve and affects more than four million individuals in the USA. The standard method of fixing valves is with open heart surgery, a complex operation performed on cardiopulmonary bypass. The operation is expensive, and recovery time from the operation is measured in weeks or months. The SeCure Beating mitral heart repair device enables heart valve repair while the heart is still beating, with no need for bypass or long anaesthesia time or surgical scars. Patients can recover in hours or days and the cost of surgery can be dramatically reduced. The heart repair can be repeated if necessary and conventional surgery can also be performed at a later date. With the new technology many patients who have been deemed unfit for surgery could be given life saving treatment.



Josef Goding
CardioFlex

CardioFlex is the next generation of cardiac pacemaker leads. Conventional pacemaker leads are comprised of a long, coiled metal wire running from the neurostimulator to the electrode implanted in the heart. These conventional leads are prone to infection, dislodgement and mechanical failure. They are also incompatible with MRI because they act as antenna and generate unsafe amounts of heat in the body under MRI. CardioFlex leads do not use metal wires but are instead fabricated from conductive elastomers, a novel material being developed at UNSW. Conductive elastomers allow the CardioFlex lead to be soft, flexible and totally MRI compatible. This means recipients are less likely to require a surgical lead extraction and they do not need to worry about their pacemaker interfering with ongoing or future medical treatments. Other applications of conductive elastomers being investigated include flexible electrode arrays and nerve cuffs for neural interfacing.



Robert Gorkin
Geldom

Backed by experts at the University of Wollongong and Swinburne University of Technology, Geldom is helping make condoms more wearable by replacing latex with better feeling materials called tough hydrogels. These tough hydrogels are superior to latex and can improve the experience by offering more tissue like sensation. They also have other revolutionary benefits – no bad odours or tastes, no latex allergies, inherent self lubrication, and can even be embedded with anti-sexually transmissible infections agents or stimulants. These new options have the potential to dramatically increase condom use. The impact – not only redefining what safe sex should feel like – but the added social benefits of improved family planning and disease prevention. This work is geared towards disrupting the \$6 billion condom industry desperate for innovation. This patent pending work has been supported by the Bill & Melinda Gates Foundation and has featured on ABC's Catalyst.



Sandra Ast
AusSI Systems

This product allows for simple medical testing remotely from home. The home diagnostics kit consists of a small device attachable to a smartphone and together with an app, it allows for the analysis of the same urine dipsticks that are commonly used in the GP's office. The medical results can then be shared with the GP online instead of going to the doctor, when unwell or busy. This will assist in a comprehensive assessment of the patient's health problem currently not possible via online consultations. This smartphone diagnostics device also features recording of the test results over time opening up numerous additional applications, ranging from personalised healthcare to new testing methods for diseases.

As the healthcare sector is moving towards a digital platform, these internet connected devices will be essential in the generation of digital medical records as well as the successful implementation of online medical services.



Sean Pollock
Breathe Well

Breathe Well is an interactive medical device that allows breast cancer patients to help improve their own cancer treatment, simply by breathing. In breast cancer radiation therapy, nearby healthy tissues like the heart and lungs are at risk of receiving unnecessary, and potentially fatal, radiation damage. Breathe Well shows patients how to hold their breath to put as much distance possible between the heart and radiation beam to achieve the most accurate breast radiation treatment possible.

Breathe  Well



Stephen Bradford
Methy/C&Me

Obesity is a growing global health problem with direct costs estimated at \$21 billion annually (Australian Diabetes, Obesity and Lifestyle Study). Current therapeutic and policy intervention is not working. Evidence suggests that early directed intervention for individuals with a predisposition to obesity and related co-morbidities is more effective at maintaining long term positive health outcomes. This technology measures the levels of specific modifications to a person's DNA (DNA methylation marks) that are associated with current or future health status. The core IP is in panels of such DNA methylation biomarkers that could be used to identify an individual's risk and likely trajectory for obesity and Type 2 diabetes mellitus. This would help direct clinicians, such as endocrinologists and dietitians, in the clinical management of patients and identify at risk people early – reducing the health burden of chronic disease.



Stephanie Watson

Kleer-i

One in twenty cataract surgery wounds leak, causing infection and blindness to occur. Sutures cause scarring, are time-consuming to apply, require great skill, and distort vision. In addition to this, patients have poor compliance with postoperative eye drops. Cataract surgery is the most common operation and has the longest waiting list in NSW. Eye surgery costs are rising as the population ages.



Kleer-i is a next-generation “patch”, bonded over an eye wound by a low-powered laser. It falls off once the wound heals. Surgeons will use Kleer-i to rapidly seal eye wounds without sutures, while simultaneously delivering drugs. Kleer-i will save 25% to 40% of operating time and promote faster wound healing, reducing vision loss from scarring, distortion and infection.

Kleer-i is unique in combining drug delivery with sutureless wound closure. It avoids the toxic side-effects and high failure rates associated with existing therapies: sutures, histoacryl glue and fibrin sealant.



Yang Chen
Scintilla Electrostatic Inhaler

Metered dose inhalers (MDI) are a commonly used device to deliver aerosolise medications for the treatment of pulmonary diseases. The emitted aerosols from MDI contain millions of fine particles that carry intrinsic charge that is imparted on them during the atomisation phase. These static charges can cause variations in particle aerosolisation and dosage. Moreover, the MDI requires manual actuation force to operate and its efficacy relies on patient's co-ordination between actuation and inhalation, which can be difficult for elderly patients with chronic obstructive pulmonary diseases (COPD). The Electrostatic Metered dose inhalers (EMDI) is a novel electrostatic metered dose inhaler, which utilises electronic force and electrostatic charges to generate inhalable aerosol. It will reduce the need of excipients in the drug formulation to help with the aerosolisation process, and also minimise the difficulties that can occur when using conventional MDIs. EMDI can provide more efficient treatment to people with respiratory diseases, especially for the 65 million patients who currently suffer from COPD around the world.





Notes



