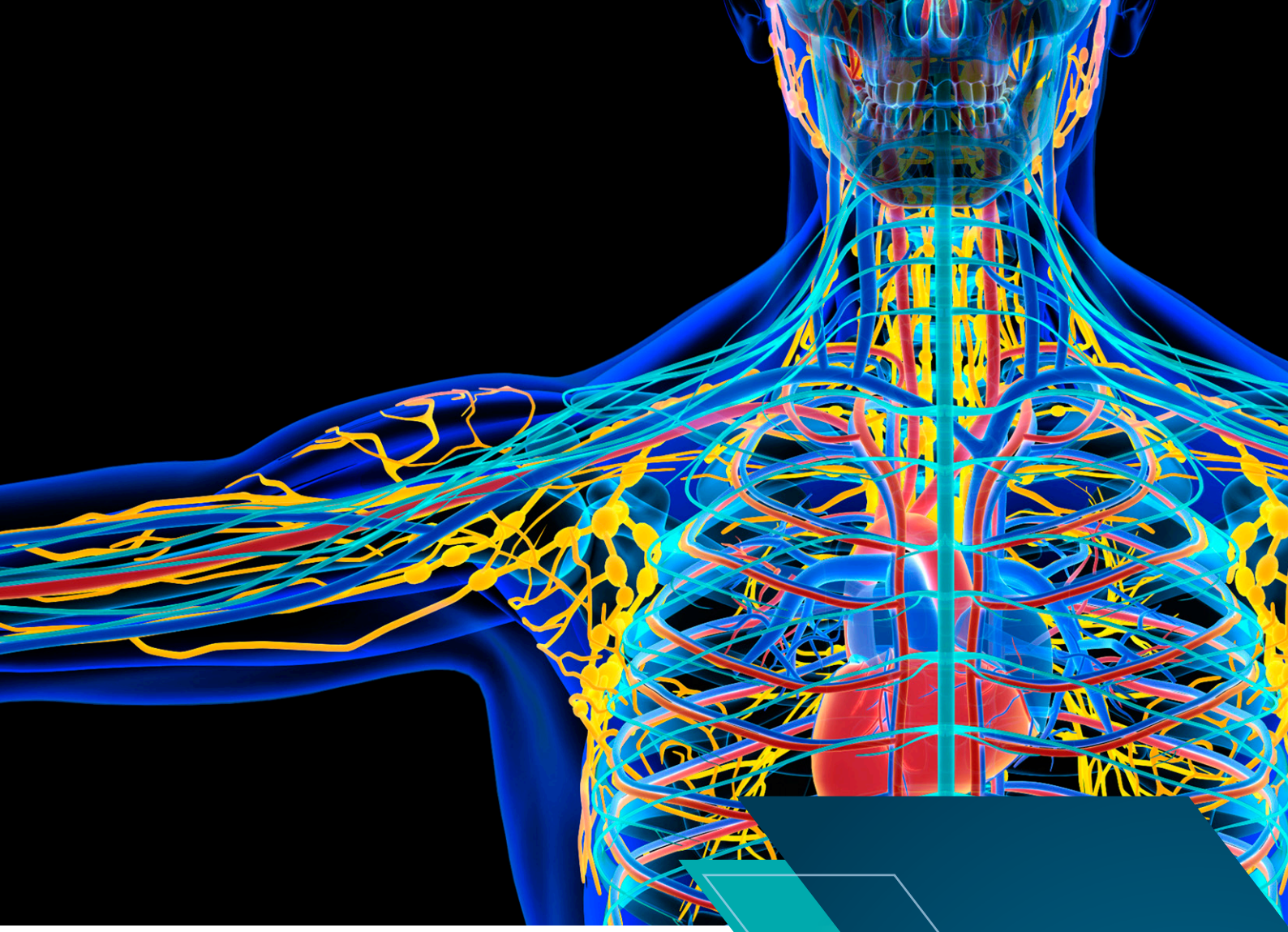

MTP Connect
MedTech and Pharma Growth Centre

BMTH BioMedTech Horizons PROGRAM

SUPPORTING TRANSLATION OF AUSTRALIAN MEDICAL TECHNOLOGY INNOVATION

A summary of the progress and impact of new Australian medical technologies supported by Round One of the BMTH Program

November 2021

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Australian Government
Department of Industry, Science, Energy and Resources

Industry Growth Centres

A MESSAGE FROM MTPCONNECT'S MANAGING DIRECTOR AND CEO

I am delighted to report that MTPConnect has completed the first round of the BioMedTech Horizons (BMTH) program for the Medical Research Future Fund (MRFF). Nine of the 11 projects identified in 2018 have successfully completed the program and all performance indicators have been met or exceeded.

MTPConnect developed the framework of the BMTH program to support the development and commercialisation of cutting edge new medical technologies, with a focus on precision medicine and 3D anatomical printing.

We brought together a Steering Committee of highly-regarded local and international medical technology sector leaders to guide the development of program guidelines, application process, selection of projects and program governance and roll-out.

Our team worked closely with the projects selected for funding, closely monitoring the objectives, management of funds and progress against milestones, particularly around managing the impact of COVID-19 pandemic lockdown restrictions.

It's pleasing to outline in this Impact report the many successes our first round cohort of projects has had – they're all developing exciting new medical products into commercial opportunities to drive better health outcomes and contribute to economic and jobs growth.

Congratulations to these successful projects for their innovation and entrepreneurial spirit; for seizing the MRFF opportunity and leveraging the funding to develop their innovations. To conquer the second 'valley of death' and move to an idea to proof-of-concept is one of the most challenging parts of the commercialisation journey.

The Medical Technology Association of Australia (MTAA) has been critical in delivering the BMTH program and I'd like to thank CEO Ian Burgess and his team for their partnership. Indeed, my thanks to all members of the Steering Committee and our MTPConnect team of Dr Gerard Gibbs, Dr Vishal Srivastava, Dr Erin McAllum, Elizabeth Stares – and our inaugural program manager Divya Kalla.

Australia is at the leading edge for research, diagnosis, management, prevention and treatment of diseases. Our MTP sector is rich with potential and reading about these innovations will surely convince you of the value of the BMTH program.

Dr Dan Grant
Managing Director and
Chief Executive Officer

Dr Dan Grant
Managing Director and Chief Executive Officer

A MESSAGE FROM THE CEO OF THE MEDICAL TECHNOLOGIES ASSOCIATION OF AUSTRALIA

MTAA is the national association representing companies in the medical technology industry. It aims to ensure the benefits of modern, innovative and reliable medical technology are delivered effectively to provide better health outcomes to the Australian community.

With this as its foundation and recognising the transformative opportunity that new technologies can offer patients, MTAA was a strong advocate for the usage of MRFF commercialisation initiative funding to support the translation of promising, transformative medical technologies. MTAA is proud to have initiated discussions that led to the development of the BMTH program.

With my role as an advocate for the medical technologies sector in Australia, I was pleased to be a founding member of the Steering Committee that provided direction for BMTH and provide advice and governance support through the first round of funding, and each of the subsequent rounds.

Through its advocacy for innovation, the reform it achieved through the Prostheses List in 2017 that included a commitment from government to provide funding to support Australian medical technology innovation and its contribution to identifying the major megatrends published in MTPConnect's first Sector Competitiveness Plan, MTAA supported the priority areas for this first round of funding in the BMTH program to focus on 3D printed medical devices and precision/personalised medicine.

I offer my congratulations to each of the teams awarded funding in this round and I am pleased to see the significant advancements they have achieved in developing their projects.

Finally, I offer my congratulations to Dr Dan Grant and the team at MTPConnect for delivering a highly effective program that engaged closely with applicants and the awardees and selected the projects to be funded through a rigorous application and selection process.

This is the first program delivered by the Medical Research Commercialisation Initiative from the MRFF and it has paved the way for more to come.

Ian Burgess
Chief Executive Officer

Ian Burgess
Chief Executive Officer

EXECUTIVE SUMMARY

MTPConnect
MedTech and Pharma Growth Centre

MTPConnect, the Growth Centre for the medical technology, biotechnology and pharmaceutical sector, has been engaged by the Department of Health (DoH) since October 2017 to operate the $45 million BioMedTech Horizons (BMTH) program for the Medical Research Future Fund (MRFF).

The BMTH initiative supports the development of innovative collaborative health technologies, drives discoveries towards proof-of-concept and commercialisation that address key health challenges and maximises entrepreneurship and idea potential.

The objectives of the BMTH1 program are to:

1. increase the number of viable biotechnology and medical technology ideas reaching the proof-of-concept stage and beyond that are attractive for private capital or third-party investment
2. expedite identification and investment into new technologies that have potential to benefit the health and wellbeing of Australians
3. foster multi-disciplinary and multi-sectoral collaboration on biotechnology and medical technology ideas offering solutions for real world health challenges
4. complement the $500 million Department of Health-led Biomedical Translation Fund, which provides co-investment to progress ideas past the second 'valley of death' to a commercialised output
5. promote Australia's international ranking as a leader in biotechnology and medical technology.

The BMTH program comprises four funding rounds, the first of which – BMTH1 – concluded activities on 29 October 2021 and is the subject of this Impact report.

Originally established as a $5 million program, MTPConnect launched the BMTH1 program with a call for Expressions of Interest (EOI) on 1 November 2017 with a focus on precision medicine and 3D anatomical printing. We received 219 EOIs. Thirty applicants were chosen to proceed to Stage 2 full applications from which six were recommended for funding.

Due to the overwhelming number and high-quality of EOIs, BMTH1 was expanded with an additional $5 million of MRFF funding provided to support five extra projects.

Overview of applications against program focus areas:

	EOI Applications	Full Application	Approved for Funding
3D Anatomical Printing	66	12	4
Precision Medicine	153	18	7
Total Projects in Stage	**219**	**30**	**11**

Of the 11 projects identified and funded as part of BMTH1, nine successfully completed their program of works resulting in clear advancement of their devices toward achieving their commercialisation objectives. These outcomes were achieved against a backdrop of COVID-19 lockdowns which at times restricted grantee access to research facilities and limited their ability to conduct clinical trials.

Two projects were terminated early when they did not meet progress milestones. Unused funds were re-invested in the program and made available to support projects and drive improved commercialisation knowledge and outcomes.

A total of $8,794,292 in funding from the MRFF has gone directly to support these BMTH1 projects, with $4,848,122 million allocated to precision medicine and $3,934,170 million to 3D printed medical device projects.

And while not a program requirement, an additional $14,722,692 in matching industry contributions was secured, comprising $6,556,375 cash and $8,166,317 in-kind, taking the total value of the BMTH1 program to $23.5 million.

In addition to project funding, carefully targeted value-add opportunities were offered to grantees, providing an extra $198,473 of direct support to project teams to address specific challenges related to market intelligence and commercialisation. These opportunities included access to and usage of the Guidance and Impact Tracking System (GAITS) project management platform and the Health Horizon Competitive Intelligence Channels.

A key objective of BMTH1 program was to "Increase the number of viable biotechnology and medical technology ideas reaching the proof-of-concept stage and beyond that are attractive for private capital or third-party investment".

By this measure, the program has been an outstanding success with **72** commercial outcomes realised and **58** new jobs created.

	New technologies invented or progressed	**New patent, trademark applications** and **licenses**	**New products** launched	**New jobs** created in **project companies** (years – direct and indirect)	Total sector **investment** into new companies (cash and in-kind)
BMTH1 PROJECTS	**27**	**42**	**3**	**58**	**$23.5M**

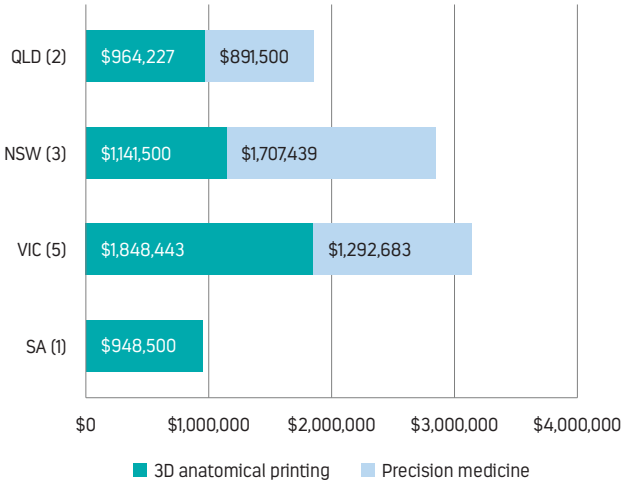
Notable achievements include:

- **WearOptimo** securing $30 million to manufacture its smart sensor technology at an advanced technology facility in Brisbane – for worldwide distribution
- **Carina Biotech** selling IP licences to the international biopharmaceutical company, Biosceptre
- **Anatomics** initiating a United States commercial launch of their 3D printed facial implants
- **The Garvan Institute** selling the fully validated Oncomine Cancer Genomics platform to SydPath
- **The Bionics Institute** establishing a commercial relationship with a world leading audiology medical device company for their EarGenie product
- **Indee Labs** generating over $1 million in revenue from top tier pharmaceutical companies.

The successful deployment of BMTH1 has formed the basis for BMTH Rounds 2-4 which are deploying an additional $35 million into Australia's medical technology sector; funding that will help translate and commercialise additional medical technologies.

Further details about the BMTH1 projects and the impact of the program are outlined in the following pages.

BMTH awardees funds expenditure as reported at the end of the program per state (number of projects in parenthesis)



3D ANATOMICAL PRINTING

World-first load-bearing interbody fusion cage set to revolutionise spinal surgery

PROJECT:
Allegra Orthopaedics

THERAPEUTIC AREA:
3D Anatomical Printing

Allegra ORTHOPAEDICS
Human Movement Technology

3D-Printed Ceramic Cervical Spinal Cage

START DATE: 1 May 2018	TOTAL BMTH GRANT: $1,141,500
END DATE: 31 July 2021	TOTAL BMTH EXPENDITURE: $1,141,500
STATUS: Completed	TOTAL CASH CO-CONTRIBUTION: $2,948,545
DELIVERABLES COMPLETED: 22 of 25	TOTAL IN-KIND: $2,004,620
	TOTAL PROGRAM: $6,094,665

Jobs within project budget	8
Number of individuals trained/ training in specific knowledge	15
Number of collaboration events	30
Collaboration events – number of attendees	150
Number of training events	5
Training events – number of attendees	10
Number of information seminars	30
Information seminars – number of attendees	60
Number of patent applications	5
Number of new technology(ies) invented/progressed	5

Eighty per cent of US residents will suffer from backpain at some point in their lives. About four million Australians (16 per cent of the total population) have back problems. In 2015, back pain was the second leading cause of disease burden in the country, costing the health system an estimated A$2.8 billion and representing 2.4 per cent of total health expenditure.

Cervical spinal fusion, a surgery that connects bones in the cervical vertebral column (neck region of the human spine), is becoming more prevalent globally due to an increase in sports injuries, degenerative or herniated discs, osteoarthritis and rheumatoid arthritis, and an ageing population. There are different methods for performing a cervical spinal fusion surgery, such as implanting a bone graft for natural regrowth of the bone, or the use of metal or polymer implants. Surgeons typically use an interbody fusion cage to maintain the height of the spine; it is inserted when the space between discs is distracted. Surgeries that include these devices allow decompression of nerves and reconstruction of the spine and can offer immediate and lasting relief. In 2016, the global interbody fusion cage market was valued at US$1.8 billion and is expected to reach US$2.3 billion by 2023 at a compound annual growth rate of 3.4 per cent.

To support body weight and the structural loading conditions in the spinal column, spinal cages are manufactured from materials such as titanium or polyether ether ketone (PEEK); however, these lack bioactivity, offer minimal bone integration, contribute to infection and inflammation, and require bone grafting, which carries additional surgical risk, with more than 10 per cent of cervical interbody fusion cage procedures requiring revisional interventions.

This can lead to surplus time spent in hospital, as well as ongoing health complications. Currently available bioactive/bioresorbable materials lack strength and toughness, so are restricted to use as fillers and non-load-bearing applications.

Seeking to overcome these limitations, Allegra Orthopaedics has developed a device that has the potential to be the world's first 3D printed ceramic cervical spinal cage that can regenerate bone under spinal load conditions. The B3D Cervical Interbody Fusion Device – made from 3D-printed Strontium-Hardystonite-Gahnite (Sr-HT-Gahnite), a synthetic bone bioceramic invented at The University of Sydney – meets this defined clinical need. Development of novel 3D-printing technology allows Allegra to produce the device with fine control over implant size, shape and internal structure.

Allegra's project, with support from the BMTH program, aimed to complete final-phase biocompatibility testing and final-phase large animal studies, and establish the required data to prepare for the first-in-human clinical trial. Throughout the course of the project, Allegra was able to develop an animal model for testing ceramic spinal cages; develop the understanding of a human spinal surgeon to perform animal implantations on the varied anatomy; maintain ongoing collaboration with researchers at The University of Sydney to advance their Sr-HT-Gahnite material; meet with the US Food and Drug Administration (FDA) to achieve clarity in regulatory approval pathway requirements; and engage experts in clinical, regulatory and technical fields.

Preclinical testing includes ISO 10993 biocompatibility testing, animal performance testing and simulated device mechanical testing. Testing can only be performed on the completed, developed device for thorough assessment, with packaging, labelling and sterilisation methods identified, developed and validated. Biocompatibility was demonstrated, including studies showing the material facilitating bone regeneration while maintaining mechanical properties. Additionally, material, design and manufacturing improvements were realised, resulting in an overall improvement in strength.

Due to the recognised advantages of additive manufacturing, reliable ceramic 3D printing equipment suitable for an ISO 13485-certified facility was required. In the first instance, and to complete the project within the timeframe, Allegra engaged with a 3D printer manufacturer in France, with the longer term goal of establishing the manufacturing facilities in-house in Australia.

Following initial large animal trials in France, delays associated with COVID-19 allowed time for further material and design development. After which the team engaged a Good Laboratory Practice (GLP) facility at the South Australian Health and Medical Research Institute, using two models – a sheep lumbar model and a sheep cervical model – to replicate the intended clinical situation as closely as possible. This final large animal pilot study was successful, with all implanted cages demonstrating complete fusion at the implanted sites. Initial images appear to confirm the formation of new bone at the fusion site, providing Allegra with the confidence to proceed to the final 26-week GLP large animal study that is required for FDA submission. Allegra plans to submit to the FDA for 510(k) approval at the start of Q4 2022.

Allegra has achieved ISO 13485 certification for design, development and manufacturing of medical devices and can be the legal manufacturer of the spinal cages in its Australian facility. The team has determined the packaging and sterilisation method for the product and confirmed optimal storage conditions and a five-year shelf life. The final activities of the project relate to biocompatibility testing and the installation of a 3D ceramic printer in Australia. These will be completed after the project term and will be fully funded by Allegra.

Once commercialised, Allegra's bioceramic product will provide rapid bone fusion with reduced risk of subsidence and without any artefacts appearing on CT scans post-op. In July 2020, having acquired the intellectual property (IP) held by The University of Sydney in relation to the Sr-HT-Gahnite material – which will allow commercialisation of this breakthrough technology – Allegra's Chief Executive Officer, Jenny Swain, said: "We are very excited by the acquisition of these patents, as we believe this material will enable us to create and commercialise highly desirable implants with unique properties that we can bring to the market.

"The acquisition of these patents is recognition of our ability to identify and work collaboratively with academic organisations such as The University of Sydney to bring innovative products to market and strengthen our company's innovative capacity."

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3D printing drives unique innovation in craniomaxillofacial implant surgery

Skull BioModel & multiple StarPore implants

PROJECT:
Anatomics Pty Ltd

THERAPEUTIC AREA:
3D Anatomical Printing

Anatomics®

START DATE: 1 July 2018	TOTAL BMTH GRANT: $891,500
END DATE: 30 June 2020	TOTAL BMTH EXPENDITURE: $891,500
STATUS: Completed	TOTAL CASH CO-CONTRIBUTION: $0
DELIVERABLES COMPLETED: 83 of 83	TOTAL IN-KIND: $1,047,446
	TOTAL PROGRAM: $1,938,946

Jobs within project budget	3
Number of collaboration events	1
Collaboration events – number of attendees	100
Number of trademark applications	3
New products launched	2
Number of new technology(ies) invented/progressed	4

When treating genetic craniofacial deformities, or head injuries that have resulted from trauma, cancer or brain swelling, bone is removed from the patient's skull and a craniomaxillofacial (CMF) implant is inserted to rebuild the skull shape and protect the brain. According to a 2018 report by the Centers for Disease Control and Prevention (CDC), an estimated 1.7 to 3.8 million traumatic brain injuries are reported each year in the US; little wonder, then, that in 2020, the global CMF devices market was valued at US$1.6 billion and is expected to increase at a compound annual growth rate of nine per cent to 2028, due to the rising number of traumatic head injuries and technology improvements making surgeries easier.

CMF implants have historically been available in standard shapes and manufactured with traditional technologies that use titanium or plastic biomaterials, such as porous high-density polyethylene (pHDPE). More recently, clinical imaging technologies, like CT scanning, and manufacturing technologies, such as 3D printing, have facilitated a shift from standard shapes to patient-specific implants (PSIs) that can be made in consultation with a patient's surgeon.

Melbourne-based biotechnology and medical device company Anatomics was the first to market with state-of-the-art CMF implant manufacturing, leveraging 3D printing to enable a reduction in turnaround time and cost of goods. The process uses patients' medical scans to develop CMF implants specific to the patient, which are then 3D printed to achieve the tailored reconstruction outcome needed by surgeon and patient alike. While the printing of the devices in this process can be done relatively quickly, the consultation, design, manufacture, validation, sterilisation and shipping components can take an extended period of several weeks.

For the past 20 years, pHDPE has been the gold standard material used in CMF implants. In 2014, Anatomics, in conjunction with CSIRO and several Australian universities, developed a breakthrough pHDPE implant material called StarPore®, which offers numerous advantages that make it superior to alternate implant materials. Not only does its tensile and flexural strength avoid cracks when bent, but it can also be screw-fixated very close to the implant edges without material breakage and features a unique scaffold that facilitates tissue ingrowth.

Supported by BMTH funding, Anatomics aimed to create a library of standard implant designs using the StarPore material, which could be selected by surgeons and modelled onto patients following a CT scan. As StarPore can be easily contoured during surgery with a scalpel or power equipment without causing fragmentation, surgeons would still be able to ensure a good fit for the patient. Crucially, the standard designs could be fabricated, sterilised, shipped and stored in hospitals, to be used on demand, without the need to wait for consultation, design, manufacture and shipping of the PSI. This process does not replace the PSI but complements it.

The goals of Anatomics' BMTH-funded project were to develop and verify a suite of implant and mould designs; develop and verify manufactured implants and moulds; conduct a clinical trial of selected implant designs; and create a software that could be used by surgeons for preoperative planning and estimation of the cosmetic outcome.

Anatomics successfully completed all activities for this project and fully realised its original aim of developing high-end 3D printing and software to support the efficient and scalable production of StarPore CMF implants. This included opening a new production facility; commissioning an SLS 3D printer; and introducing an in-house ISO 13485-certified sterilisation process. Manufactured implants were used in 20 patients throughout the trial period and the successful outcomes of the project enabled Anatomics to obtain approval from the US Food and Drug Administration (FDA) for its range of anatomically shaped StarPore implants.

A significant part of the BMTH program was the development of software and service for the surgeon to support the preoperative planning for the patient and the estimation of the cosmetic outcome. This allows the surgeon to view the different StarPore implants in a 3D-rendered environment, which includes the patient's CT scan. This visualisation supports the surgeon's planning process, with the goal of reducing complications and reoperation rates for CMF surgeries.

Anatomics has ushered in a new way of designing, manufacturing, and supplying complex CMF reconstructive implants, which were commercially launched in the US in 2020. That Anatomics can efficiently produce implants of almost arbitrary complexity in short timeframes using the new manufacturing technologies highlights the successful outcome of the project.

Highlighting the impact of the program, Anatomics' founder and Executive Chairman, Paul D'Urso, said: "The BMTH funding via MTPConnect has allowed Anatomics to develop an advanced polymer tissue scaffold manufacturing capability in Melbourne. We have achieved FDA approvals and have begun exporting Anatomics' StarPore reconstructive implants internationally. We should all be very proud of the way that the BMTH funding and MTPConnect are supporting world-leading medical device manufacturing in Australia."

The next step for Anatomics is to seek CE mark certification for the sale of StarPore implants in Europe, Asia and the Middle East. Following this, the team plans to cultivate a range of StarPore implants for chest wall reconstruction and other orthopaedic applications.

In 2020, Anatomics was awarded new funding through the third round of the BMTH program, which it is using to advance new applications for its technology. Alongside industry partner CSIRO, it is pioneering a 'smart helmet' – SkullPro® – to monitor brain activity in patients who have undergone a decompressive craniectomy for stroke or trauma. The wearable device features sensors that can relay data via 4G and wi-fi, which will enable machine learning and artificial intelligence (AI) to assist neurosurgeons to remotely determine the right time for reconstructive brain surgery.

As Robert Thompson, Anatomics' Vice President Product Innovation, explained: "Thanks to the BMTH program, StarPore is now a platform implant technology that is being leveraged to build improved solutions for a range of healthcare problems."

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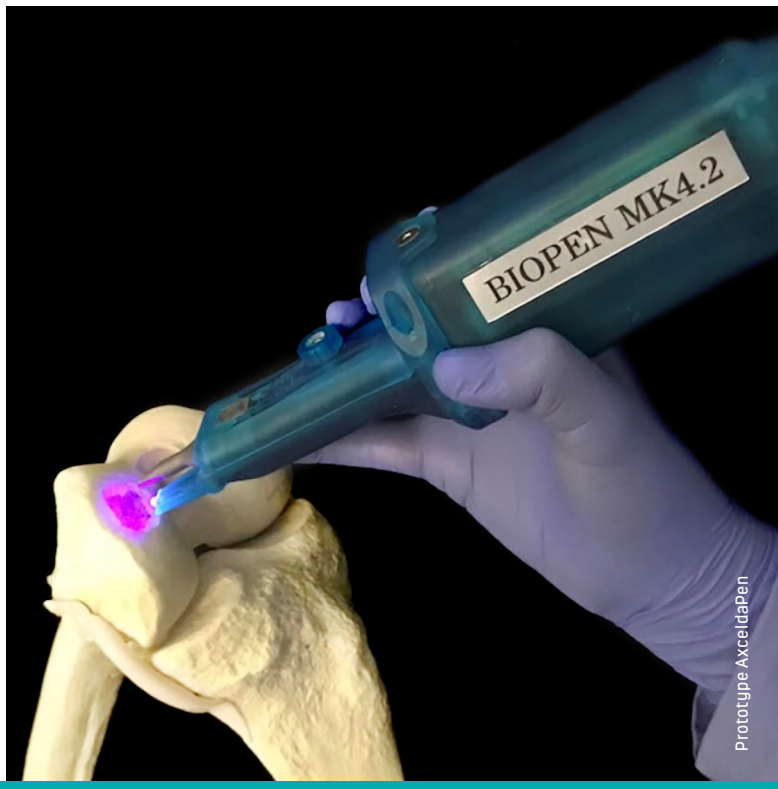
World-first in situ bioprinting treatment for cartilage injuries



Prototype AxceldaPen

PROJECT:
University of Melbourne – AxceldaPen

THERAPEUTIC AREA:
3D Anatomical Printing

THE UNIVERSITY OF MELBOURNE

Axcelda

START DATE: 1 July 2018	**TOTAL BMTH GRANT:** $966,500
END DATE: 31 December 2020	**TOTAL BMTH EXPENDITURE:** $956,943
STATUS: Completed	**TOTAL CASH CO-CONTRIBUTION:** $0
DELIVERABLES COMPLETED: 40 of 41	**TOTAL IN-KIND:** $748,529
	TOTAL PROGRAM: $1,705,472

Jobs within project budget	3
Number of individuals trained/ training in specific knowledge	10
Number of trademark applications	1
Number of patent applications	1
Number of new technology(ies) invented/progressed	3
Number of preclinical trials commenced	1

According to research from Arthritis Australia, the number of people with osteoarthritis (OA) in Australia is expected to increase from 2.2 million in 2015 to 3.1 million by 2030. It is the most common form of arthritis and the predominant condition leading to knee and hip replacement surgery in Australia, with at least a quarter of OA cases estimated to relate to the knee.

An important cause of OA is joint injury. In 2017–18, there were 532,562 injury hospitalisation cases in Australia, with 42 per cent caused by falls, a further 14 per cent by contact with objects (such as sharp or blunt objects) and 12 per cent by transport crashes. Many of these injuries involved joint trauma. In Australia, OA costs the healthcare system an estimated A$3.5 billion each year, though the total economic cost – including indirect costs, such as lost work productivity and loss of wellbeing – is estimated to be over A$23 billion.

Driven by an increase in OA and the emergence of new technologies, the global cartilage repair and regeneration market was valued at US$787 million in 2020 and is expected to reach US$1.6 billion by 2025. The escalating incidence of OA and its significant economic burden have led to major innovations in cartilage repair – among them, the BMTH-supported AxceldaPen. The project team – led by Professor Peter Choong at St Vincent's Hospital Melbourne, in partnership with The University of Melbourne, University of Wollongong and Swinburne University of Technology – set out to develop a world-leading approach to address the limitations of current treatment options for cartilage injuries with an initial focus on the knee.

The overall purpose of this project was to develop the first in situ bioprinting treatment for cartilage injuries. The approach involves rapidly isolating and amplifying stem cells, loading these into a gel scaffold, then printing directly into the cartilage defect. Important steps in this project were to develop and validate optimal isolation procedures of human-derived adipose stem cells; develop AxceldaInk formulations for cartilage repair; and develop a set of instructions for the use of the BioSphere cell proliferation technology for the required large-scale stem cell production and storage.

Each of these three technical developments was successfully completed, leading to the final phase of the overall project: preclinical animal studies to assess the effectiveness of the technology. The pivotal large animal study in a sheep model of cartilage injury was completed in 2020 and showed that the bioprinting of stem cells resulted in an improved outcome. There was no inflammation associated with in situ bioprinting and the injured area was significantly reduced or absent, demonstrating that the approach represents a superior cartilage repair strategy compared with the current microfracture treatment standard.

This project brought together surgeons, mechatronic engineers, material scientists, bioengineers, biologists and other experts in design, manufacture, quality control, regulatory, patent, and intellectual property protection and product commercialisation.

Orthopaedic Surgeon and Project Leader at St Vincent's Hospital Melbourne, Professor Choong, said the AxceldaPen device will improve the quality of life for patients living with knee problems. "The AxceldaPen brings innovation, technology and science to the point of delivery where cells are harvested, isolated and then 3D printed back into the patient in a single surgical setting," he explained. "This is very different to the typical medical device procurement and joint implantation process. The device will bring the laboratory into the operating room and deliver science to the point of care for patients."

The AxceldaPen combines the advantages of 3D printing with the versatility of using a handheld device, with the technique using stem cells that can be prepared prior to surgery, allowing for on-demand and patient-specific solutions.

The project team achieved its goal of taking significant steps toward commercialisation of this transformative tissue engineering treatment. The next phase of this project will see the first-in-human pilot studies taking place, with a target for commencement in 2022.

The AxceldaPen team's research partner, University of Wollongong, has established a world-first facility – the Translational Research Initiative for Cellular Engineering and Printing (TRICEP) – that enabled the development of BioInks and customised bioprinting systems for targeted clinical applications. The Director of TRICEP, Professor Gordon Wallace, highlighted the importance of the facility, to enhance Australia's 3D bioprinting capabilities. "We have been involved in fundamental research into the discovery and development of new materials for more than 20 years in Wollongong, but we have also had an eye on how we can translate those fundamental discoveries into new applications in the areas of energy and health," Professor Wallace said.

"Importantly, Australia has an extensive and integrated clinical network, which enables us, with our partners, to identify real clinical challenges and develop the complete solution, to ensure that it's translatable into the clinical environment."

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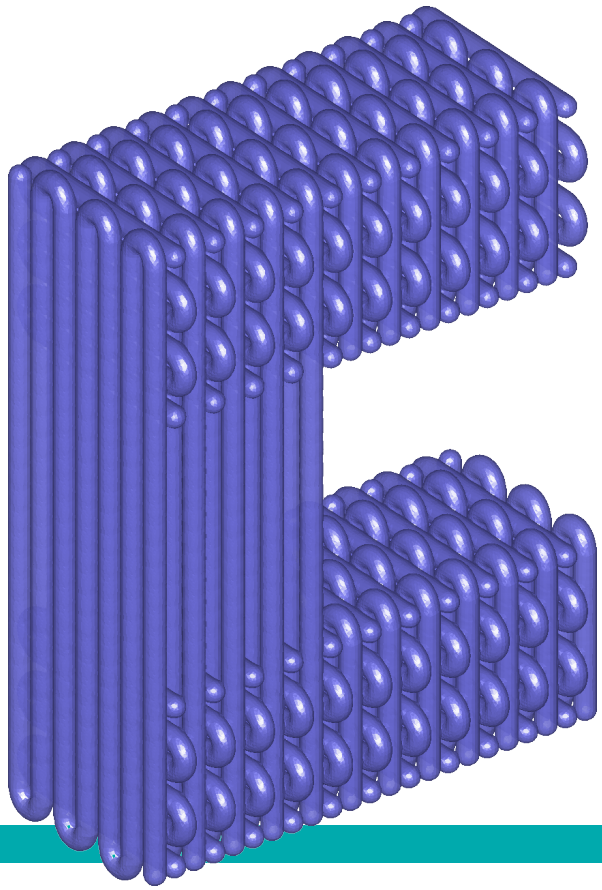
3D-printed implants creating better outcomes for a common wrist injury



CAD image of the 3D-Printed graft ligament

PROJECT:
Griffith University

THERAPEUTIC AREA:
3D Anatomical Printing

Griffith UNIVERSITY
Queensland, Australia

START DATE: 1 May 2018	TOTAL BMTH GRANT: $964,227
END DATE: 30 July 2021	TOTAL BMTH EXPENDITURE: $964,227
STATUS: Completed	TOTAL CASH CO-CONTRIBUTION: $72,247
DELIVERABLES COMPLETED: 75 of 77	TOTAL IN-KIND: $200,000
	TOTAL PROGRAM: $1,236,474

Jobs within project budget	3
Number of individuals trained/ training in specific knowledge	5
Number of collaboration events	20
Collaboration events – number of attendees	10
Number of information seminars	4
Information seminars – number of attendees	16
Number of patent applications	1
Number of new technology(ies) invented/progressed	3

A pioneering technique that designs personalised bone-ligament-bone grafts using 3D-printed biocompatible scaffolds is set to create positive results for people afflicted with a scapholunate interosseous ligament (SLIL) injury – the most common of wrist ligament injuries.

The SLIL joins the scaphoid and lunate bones, which are the major bones involved in the movement of the wrist. The overall incidence of wrist trauma is reported to be approximately 70 out of 10,000 individuals and many of these cases can be attributed to rupture of the SLIL, which is particularly prevalent in athletic populations, with an overall higher incidence in men with an average age of 40.

Typically, SLIL injuries are surgically treated, but have poor prognosis, with patients developing functional limitations and severe hand/wrist osteoarthritis, which impairs long-term health and imposes a substantial economic burden. SLIL injuries cause dislocation of scaphoid and lunate bones and can be career-ending for an athlete, as they severely impair wrist function and can result in disability. Currently, there is no commercially available product that provides reliable and effective treatment for SLIL rupture.

In 2020, the global orthopaedic soft tissue repair market was valued at US$5.9 billion and is forecast to escalate at a compound annual growth rate of 6.3 per cent up to 2028. Meanwhile, in 2016, the tissue scaffold market segment was worth US$2.3 billion, addressing common injuries to tendons and ligaments, such as the anterior cruciate ligament (ACL) of the knee and SLIL. The small joint sub-segment accounted for ~10 per cent of the market, or US$230 million. While there have been synthetic grafts developed for ACL surgeries, there is no market product for SLIL repair.

The Griffith Centre of Biomedical and Rehabilitation Engineering (GCORE), in close collaboration with clinical orthopaedics and regenerative medicine partners, sought to develop the first robust technology to address this unmet clinical need. The focus of its BMTH-funded project was to support preclinical research and development (R&D) to enable the team's research and commercialisation partner – Orthocell – to start human clinical trials, seek regulatory approval and commercialise.

The Griffith team leveraged three cutting-edge technologies for their BMTH project, which it had developed alongside its partners: the 3D-printed synthetic bone-ligament-bone template graft and biomechanical scaffold, which had been demonstrated to be effective in animal models; the maturation of the 3D-printed graft ligament using the patient's own ligament stem cells; and the creation of 3D computer musculoskeletal simulations from medical images of the patient's wrist for simulations and tailoring of the surgical procedure for each patient.

Two interconnected and concurrent streams of research were conducted. Stream one refined the 3D-printed graft, by formalising a computer design process to optimise graft mechanical performance, which was then verified experimentally by performing biomechanical testing. Stream two used 'digital twins' of intact cadaveric wrists to simulate SLIL strains produced during common daily tasks.

Digital twins are a digital representation of the graft, tissue and human organ (e.g. the wrist) that inform surgical interventions, and are an application of digital engineering used to design the graft and surgery, improve clinical outcomes, reduce material waste and save money.

The team achieved all the goals of the project, which included surgically installing the implant into three human cadaveric wrists. Getting to this point saw a range of project milestones achieved: 3D imaging of the wrist to create a personalised physical anatomical model, as well as a digital twin; using the digital twin to custom design a scaffold for safe installation and mechanical performance; design of custom surgical instruments for installation of the implant; fabrication of the implant and surgical instruments using 3D printing; successful installation of the stem-cell seeded and mechanically improved artificial ligament into three cadaveric wrists; control of the robot using the digital twin to successfully manipulate the wrist during the installation process; and finally, robotic testing and mechanical performance reports on the cadaver wrist-forearm complex.

The 3D modelling of the geometric and mechanical properties of the 3D-printed graft permitted detailed analysis and planning of the design and implantation of the synthetic ligament. Using digital twins, the Griffith team made extensive iterative computational assessments and improvements to the device and surgical procedures, including the specific anchor points in the cashew-sized-and-shaped scaphoid bone and the smaller crescent-shaped lunate bone to maximise mechanical performance, resulting in an ability to tailor surgical implants for each patient. These models were proven in test surgical procedures using cadaveric wrists.

An additional benefit was the realisation of a significant simplification of the otherwise complex and difficult surgery resulting from the custom surgical instruments. This is expected to reduce theatre time by more than half, offering major cost savings for hospitals and other surgery providers.

An advanced understanding was gained of the required regulatory pathways for key markets in the US, Europe and Australia. This advice has helped the Griffith team shape the direction of further development and sharpened its ability to communicate with current and future industry partners.

The outcomes of this project have paved the way to address the challenges linked to SLIL injuries – namely, long-term chronic difficulties and the considerable health and economic burden for impacted individuals. The Griffith team will continue to expand its cutting-edge technology through the next stage of clinical trial and validation: a world-first clinical trial to demonstrate the viability of a 3D-printed and reconstructed SLIL for human applications.

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PRECISION MEDICINE

Brain-imaging device improves diagnosis and early treatment of hearing loss in children

A representation of the headgear on a 3D-printed baby's head

PROJECT:
The Bionics Institute

THERAPEUTIC AREA:
Precision Medicine

START DATE: 1 May 2018	TOTAL BMTH GRANT: $966,500
END DATE: 30 June 2021	TOTAL BMTH EXPENDITURE: $966,500
STATUS: Completed	TOTAL CASH CO-CONTRIBUTION: $0
DELIVERABLES COMPLETED: 17 of 27	TOTAL IN-KIND: $2,935,387
	TOTAL PROGRAM: $3,901,887

Jobs within project budget	7
Number of individuals trained/ training in specific knowledge	5
Number of collaboration events	3
Collaboration events – number of attendees	10
Number of training events	5
Training events – number of attendees	2
Number of information seminars	8
Information seminars – number of attendees	45
Number of trademark applications	1
Number of patent applications	2
Number of licenses	1
Number of new technology(ies) invented/progressed	1

In the US, 1.6 per cent of screened babies fail newborn hearing tests and are referred to paediatric audiology centres for detailed assessment. Applying this ratio to the Australian population means that, with an average of 307,993 babies born annually over the period 2012 to 2019, approximately 5,000 babies required detailed diagnostic audiology assessments each year, or close to 40,000 over the whole period. One in 500 of these babies will have a permanent congenital hearing loss, a prevalence that rises to one in 300 by three years of age.

When an infant is identified as having a permanent hearing loss, it is crucial for speech and language development that intervention occurs at the earliest possible time; that is, an individually programmed hearing aid or cochlear implant (bionic ear) is provided so the infant can hear speech and appropriate hearing therapies can begin. In 2017, the National Acoustics Laboratories' *Longitudinal Outcomes of Children with Hearing Impairment* (LOCHI) study showed for the first time that early fitting of hearing devices is key to achieving better speech, language and psychosocial outcomes for children with hearing loss.

Unless treated, deaf infants face delayed and inadequate language development, which affects education, social participation and even employment later in life. Aside from the personal impact, loss of productivity alone costs the Australian economy A$12.8 billion each year, or $3,566 per person with hearing loss. In total, the direct financial cost of hearing loss is A$15.9 billion, with lost wellbeing amounting to an additional A$17.4 billion.

The Bionics Institute continued

Major barriers to language development among deaf babies and infants include delays between diagnosis and the selection and accurate adjustment of hearing devices; delayed optimisation of device features for the infant; and difficulty choosing a specific therapy to optimise language development. These diagnosis problems must be addressed earlier. This clinical need, relevant to all hearing-impaired babies, is critical for the 10 per cent diagnosed with auditory neuropathy (AN), whose parents can wait up to two years before knowing how well their child can hear or develop oral language.

To address the challenges with existing clinical methods and to transform diagnostic audiology in hearing-impaired babies and infants, the Bionics Institute has developed a novel device known as EarGenie™, which will objectively and automatically perform detailed hearing and language development assessments. EarGenie aims to give children born with hearing loss the opportunity to start their language development earlier and help audiology clinicians get faster and enhanced information about their patients' hearing needs.

Conceived by the Melbourne-based Bionics Institute team, the device uses functional near-infrared spectroscopy (fNIRS), whereby near-infrared light measures brain activity to perform a diagnostic hearing evaluation. This means hearing and speech sound discrimination can be tested in infants even before they are old enough to indicate whether they can hear a sound or tell the difference between sounds.

At diagnosis, EarGenie can enable a more accurate and complete hearing assessment, so that an appropriate hearing instrument can be confidently selected, evaluated and fine-tuned to optimise each child's hearing. In the future, it will enable clinicians to evaluate a child's language development, guiding device choice and adjustments and personalising language therapies. EarGenie will allow clinicians to see if the infant's brain is distinguishing between speech sounds, a function very difficult to achieve with other clinical testing methods.

The Bionics Institute aims to conduct clinical trials in the future to demonstrate the enhanced benefits for language development of earlier and more accurate hearing assessments and optimised hearing instrument programming.

Closeup of a newborn ear (image credit: istock)

The BMTH project supported the Bionics Institute to develop three elements of the EarGenie device: the design and manufacture of a functional prototype appropriate for very young and sleeping babies; the development and validation of the speech module; and the development and validation of the hearing module.

The speech module objectively assesses whether an infant can hear speech and also whether an infant can discriminate between speech sounds. Assessing speech detection and speech discrimination is crucial for identifying the correct intervention to treat different cases of hearing loss. The Bionics Institute completed the speech module of the EarGenie, which included development and testing of the sensors; development of algorithms and software interfaces for clinical assessment of the signal. Usage of the system on babies in controlled clinical environments was delayed due to COVID-19 lockdown rules.

Meanwhile, the hearing module identifies the child's hearing threshold (i.e. the quietest sounds that can be heard at different frequencies). Hearing thresholds are important, because the full profile of thresholds for each hearing frequency and each ear forms a basic but complete picture of a person's hearing acuity.

The hearing module will allow the classification of the degree of hearing loss and assessment of the effectiveness of a hearing device and is an ongoing part of the program. Algorithms, software interfaces and laboratory testing were significantly matured through the program; however, elements of this work could not be completed because of the restricted access to patients following COVID-19 restrictions in Melbourne. The Bionics Institute is committed to completing the hearing module within the next two years and will continue funding the project.

Aside from the incomplete hearing module, the functioning device was manufactured and performed according to the expected requirements. This manufactured device will allow the project team to take the next important steps toward clinical validation.

Having received an Emerging Needs Voucher as part of the value-add program, the Bionics Institute will use this additional funding to support the engagement of specialist audiology consultants to perform market research and analysis within Australia and internationally; to scope potential partners for commercial production and sales; and advise and assist on additional commercialisation pathways for the M3BA sensor used in EarGenie.
The team were finalists in the National Bionics Challenge competition run by Bionics Queensland and are now working through a detailed business plan with a view to forming a spin-off company.

Validating the project's success, the Bionics Institute's Principal Scientist, Professor Colette McKay, has said the device is a personalised clinical management system that will be used for optimising language development in children born with hearing loss.

"EarGenie will help us to understand language development of deaf children and to learn how to optimise the cochlear implant or hearing aid or even the therapies that children get to help them reach their full potential for language development," Professor McKay explained. "What we're aiming for is improved language development, which will lead to increased education, social and employment opportunity throughout life for infants born with a hearing loss."

EarGenie has the potential to go global, as the first commercial system that uses fNIRS to be developed worldwide specifically for pediatric hearing clinics. With up to 140 million babies born around the world each year, the clinical significance for babies with hearing loss is significant, as is the commercial opportunity.

Crucially, for children born with hearing impairments, the introduction of EarGenie in audiology clinics will significantly reduce the delay between diagnosis and optimal access to sound, leading to improved language outcomes and lifelong benefits.

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Fighting cancer through next-generation CAR-T technologies

Dr Veronika Bandara – CAR-T cell manufacturing

PROJECT:
Carina Biotech Pty. Ltd.

THERAPEUTIC AREA:
Precision Medicine

carina biotech

START DATE: 1 May 2018	TOTAL BMTH GRANT: $951,500
END DATE: 11 December 2020	TOTAL BMTH EXPENDITURE: $948,500
STATUS: Completed	TOTAL CASH CO-CONTRIBUTION: $1,392,148
DELIVERABLES COMPLETED: 37 of 40	TOTAL IN-KIND: $245,583
	TOTAL PROGRAM: $2,586,231

Jobs supported within project budget	12
Number of individuals trained/ training in specific knowledge	11
Number of collaboration events	11
Collaboration events – number of attendees	25
Number of training events	4
Training events – number of attendees	7
Number of information seminars	10
Information seminars – number of attendees	15
Number of licenses	2
Number of new technology(ies) invented/progressed	5
Number of preclinical trials commenced	12

Each year, more than 18 million cases of cancer are diagnosed globally – a figure set to increase over time as the population expands and ages. By 2040, it's expected that more than 29.5 million cancer diagnoses will be made annually, resulting in 16 million deaths. In Australia, where cancer is the leading cause of death, it was estimated that there were just under 150,000 new cases of cancer diagnosed in 2020 and just under 50,000 deaths.

To curb this trend, significant research has been undertaken into a new precision immunotherapy: Chimeric Antigen Receptor T-cell (CAR-T) therapy. This revolutionary process involves genetically engineering a patient's own immune cells to attack their cancer and induce remission, often after a single treatment.

While the approach has shown remarkable efficacy against some blood cancers, solid cancers – which represent approximatively 90 per cent of all adult human cases – have so far been less responsive. Key barriers to creating an effective CAR-T cell therapy for solid tumours include the lack of suitable target antigens; difficulty accessing tumours; and the immunosuppressive nature of the tumour microenvironment.

Hoping to overcome these obstacles, Carina Biotech was established in 2016, and for the past five years its team has worked to develop patient-specific broad-spectrum CAR-T therapies that can be used to treat multiple solid cancers. Using its proprietary platforms, the South Australian company is developing technologies to improve access to, and infiltration of, solid cancers, and to enhance CAR-T cell manufacturing.

Prior to receiving BMTH funding, Carina Biotech had identified a target antigen (a molecular marker called nfP2X7) that has been reported in literature to be present on a diverse range of solid cancers, but largely absent from healthy cells. The company's lead CAR-T cell CNA1003, had demonstrated cancer-killing activity against four cancer cell lines in laboratory experiments. With support from the BMTH program, the company hoped to optimise and achieve proof of concept for these CAR-T cells across multiple cancers and cancer cell lines and in animal models of human solid cancer.

The team likewise aimed to determine differences between chemokines produced by a variety of tumour types, to allow them to engineer and tailor the chemokine receptor(s) on CAR-T cells, so treatment could be personalised to target the chemokine expression profile of a patient's particular cancer.

Bringing together the commercial expertise of Carina Biotech with researchers from The University of Adelaide, University of South Australia, the Women's and Children's Hospital in Adelaide, Seattle Children's Research Institute and the CRC for Cell Therapy Manufacturing (CTM@CRC Ltd), the BMTH project group constructed and developed the world's first nfP2X7-targeted CAR-T cells.

Not only did their work reveal *in vitro* efficacy against more than 15 cancer cell lines including breast, ovarian, prostate, pancreatic, lung and colorectal cancers and melanoma; it also achieved *in vivo* proof of principle that CAR-T cells expressing a specified chemokine receptor are safe and inhibit the growth of human breast cancer in mouse models. Fortifying their efforts, the team optimised manufacturing protocols to ensure consistent production of CAR-T cells with effective phenotype, viability and yield.

Off the back of these results, Carina Biotech entered a commercial agreement in 2020 with UK-based biopharmaceutical company, Biosceptre – granting exclusive rights to CNA1003 and associated intellectual property.

Marking the occasion, Carina Biotech's Chief Executive Officer, Dr Deborah Rathjen, said: "The BMTH grant enabled us to progress and validate CNA1003's cancer-killing capacity *in vitro* and *in vivo* and led to Carina completing its first commercial agreement when we sold the rights to CNA1003. CNA1003 was our first 'cab off the rank', and the vital discovery and optimisation work our scientists did in getting CNA1003 to the proof-of-concept stage really underpins Carina's CAR-T building platform going forward."

Having developed the requisite skills to build, test, optimise and achieve preclinical proof of concept, Carina Biotech has established itself as a novel CAR-T cell specialist, setting the stage for further commercial deals and partnerships. Biosceptre continues to develop the nfP2X7 CAR-T program, with the aim of advancing towards first-in-human studies and further progressing the cells for patient use.

Meanwhile, having received an Emerging Needs Voucher as part of the value-add program, the company used this additional funding to progress its work with chemokine receptors – engaging consultants to perform a patent search and strategic review of the commercial landscape. These outcomes will be used to inform the development of the research program on CAR-T cells co-expressing cancer-specific chemokine receptors, which was initiated during the BMTH-funded project.

Now, the team is working to produce CAR-T cells that can be delivered intravenously, but with the addition of chemokine receptor(s) to increase migration of CAR-T cells to tumours, thereby enabling a lower cost of delivery, increased efficacy, reduced dosage rate and a corresponding reduction in manufacturing cost.

With the global CAR-T cell therapy expected to be worth US$6.13 billion by 2026 – growing at a compound annual growth rate of 33.11 per cent due to the increasing prevalence of cancer and growing pool of patients showing response failure towards alternative treatments – Carina Biotech's platform offers *significant market potential*; it also stands to reduce the economic burden of cancer, which in 2016 totalled A$10.1 billion in Australia.

Crucially, as the company continues to develop its innovative therapeutic approach, it hopes to revolutionise cancer treatment – maximising patient outcomes for a broader range of cancers than is possible today.

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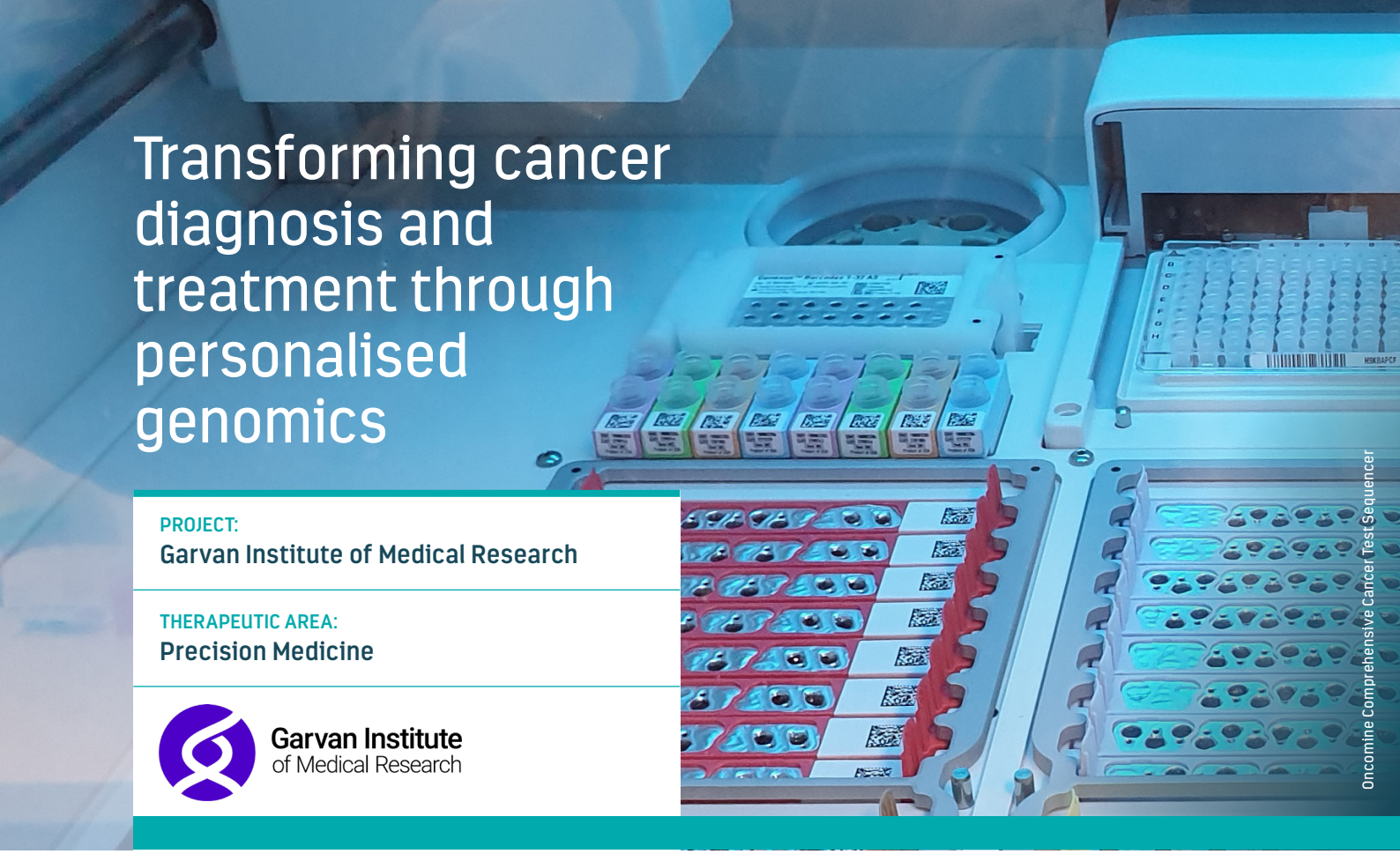
Transforming cancer diagnosis and treatment through personalised genomics



Oncomine Comprehensive Cancer Test Sequencer

PROJECT:
Garvan Institute of Medical Research

THERAPEUTIC AREA:
Precision Medicine

Garvan Institute of Medical Research

START DATE: 1 May 2018	**TOTAL BMTH GRANT:** $841,841
END DATE: 30 March 2021	**TOTAL BMTH EXPENDITURE:** $815,939
STATUS: Completed	**TOTAL CASH CO-CONTRIBUTION:** $848,063
DELIVERABLES COMPLETED: 14 of 15	**TOTAL IN-KIND:** $0
	TOTAL PROGRAM: $1,664,002

Jobs within project budget	6
Number of individuals trained/ training in specific knowledge	22
Number of collaboration events	6
Number of training events	5
Training events – number of attendees	25
Number of information seminars	10
Information seminars – number of attendees	500
Number of new technology(ies) invented/progressed	1

Cancer is a leading cause of death globally. In 2019, almost 50,000 deaths in Australia were attributed to the disease. Cancer has a significant social and economic impact on individuals, families and the community.

Cancer is a complex disease, with multiple factors contributing to its onset, including environmental and genetic factors, often a combination of both. At its foundation, cancer results from changed cell function in the body, driven by proteins or ribonucleic acid (RNA), with sequences that are determined by genes. Irrespective of the cause of cancer, all forms of the disease can be traced to a gene, or combination of gene changes in a cell.

The complexity of cancer makes early detection, diagnosis and selection of the best therapy for treatment a significant challenge for oncologists. Various genetic screening technologies available today offer a way through the puzzle.

Personalised and precision medicine is a move away from the one-size-fits-all approach. It was born from the understanding that emerged following sequencing of the human genome and development of Next-Generation Sequencing (NGS) technologies: that the genetic signature of any disease or disease variant is diverse and therefore the appropriate treatment may be different depending upon the underlying genetics. To be most effective, the right treatment for a disease should be chosen according to an individual's genetic signature.

The emergence of personalised medicine has resulted in an ability to develop drugs tailored to very specific diseases (or disease variants); it enables oncologists to identify the correct patients for use in clinical studies and to select a patient's ideal therapy based upon the genetic signature of their disease. Selecting the right patient for inclusion in a clinical trial based on genetics is a transformative shift that has the potential to result in more targeted treatments becoming available to patients.

Cancer gene panels and genomic profiling are quickly changing the diagnosis and treatment of cancers. The market is moving out of a specialised niche and going mainstream, as oncologists begin to routinely use information on hundreds of genes related to cancer. In 2020, the global cancer/tumour profiling market was valued at US$8.3 billion and is forecast to rise at a compound annual growth rate of 10.9 per cent to US$13.9 billion by 2025. Drivers of market growth include the increasing incidence of cancer across the globe, the advancement of genetic profiling technologies and heightened demand for personalised medicine, both for treatment and to support the selection of patients for clinical trials. Internationally, such trials are attracting heavy investment, with researchers seeking to develop tests that will enable fast, comprehensive and cost-effective genomic profiling of patient tumours.

The US Food and Drug Administration (FDA) recently approved two US cancer genomic tests; however, their cost (A$5,500) is prohibitive for routine use in Australia and their matching to US-approved drugs and trials are of limited utility to Australians. Offshore testing also fails to develop the necessary domestic infrastructure for precision cancer clinical trials.

Using BMTH funding, the Garvan Institute of Medical Research set out to develop a comprehensive cancer genomics platform capable of supporting clinical trials in Australia, while also providing a service to oncologists for patient management. The overarching goal was to tailor a solution for the Australian healthcare system – making comprehensive tumour sequencing accessible to all oncologists at a pricepoint that would encourage the use of this technology at diagnosis.

The Garvan team sought to establish the entire workflow, starting from an oncologist consultation, through to a validated test and cancer genomics data platform for efficient assessment and interpretation of genomic data, as well as patient-matching capabilities to identify relevant therapeutics and support recruitment to Australian clinical trials. These solutions would ensure that, in the face of increasing global capabilities and investment in precision cancer clinical trials, Australia remains an attractive trial site and leader in precision medicine.

The main challenges of the project initially related to scalability, cost and turnaround time; acquiring sufficient reference material to be able to validate the test; and having the required pathology expertise to assess tumour tissue prior to sequencing. The latter two were essential to achieving National Association of Testing Authorities (NATA) ISO 15189 accreditation – a key target in the overall project.

Through a rigorous technology screening process and by leveraging its various research, clinical and commercial networks, the Garvan team was able to overcome each of these challenges. Over 1,000 patient tumour samples were analysed to develop and validate the test and procedures. Continuous clinician feedback and the Garvan team's own experience analysing large volumes of samples helped shape a service that would deliver an informative report with clinical utility in an expedient, efficient manner and at a relatively low cost.

As the tests were validated by the Garvan team and NATA accreditation was achieved, a technology transfer opportunity was explored. A deal was finalised in early 2021 for the transfer of materials to SydPath: a commercial pathology provider involved in the project from the earliest stages. SydPath has now established the required facilities, received training from the Garvan team, undertaken validation screening and made a submission to NATA to receive its own accreditation prior to launch, which is anticipated in late 2021.

With the transition of the Oncomine Comprehensive Cancer Test service to SydPath, the Garvan team fully realised the goals of its BMTH project.

SydPath will maximise the commercial success of the test – using it to advance their existing oncology screening services and maximise its clinical impact by leveraging their existing expertise and clinician networks.

Once clinically accredited, this test will be one of the most comprehensive cancer tests available within Australia. The test has a large diagnostic range applicable to all major adult cancer types, with genes relevant to 43 FDA-approved therapies and 23 National Comprehensive Cancer Network (NCCN) guidelines. This is important for identifying sensitivity or resistance to potential therapies, but also informative for clinical trials options for which molecular biomarkers constitute part of the eligibility criteria.

The Garvan team has created an attractive cancer genomics service unlike any other in Australia. It is the first NATA-accredited platform to offer DNA sequencing, gene fusion detection and therapy/clinical trials matching in a single comprehensive assay and at a cost-effective price.

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Bringing life-saving gene-modified cell therapies to the masses

Hydropore™ µVS Delivery System™ (photo credit: Design+Industry)

PROJECT:
Indee Labs

THERAPEUTIC AREA:
Precision Medicine

indee labs

START DATE: 1 May 2018	TOTAL BMTH GRANT: $891,500
END DATE: 30 June 2020	TOTAL BMTH EXPENDITURE: $891,500
STATUS: Completed	TOTAL CASH CO-CONTRIBUTION: $60,080
DELIVERABLES COMPLETED: 18 of 18	TOTAL IN-KIND: $0
	TOTAL PROGRAM: $951,580

Jobs within project budget	4
Number of individuals trained/ training in specific knowledge	5
Number of patent applications	10
Number of licenses	5
New products launched	1
Number of new technology(ies) invented/progressed	2

Terminally ill patients are increasingly gaining access to curative therapies for a range of conditions, including many forms of cancer and autoimmune disorders, thanks to a new generation of treatments called gene-modified cell therapies (GMCTs). This is proving to be a very promising treatment platform for patients with advanced disease for whom traditional forms of medicine have failed; in fact, approximately half of all cancer deaths and all new cases are viewed as treatable with GMCTs. In 2017, Kymriah® and Yescarta® were the first GMCTs approved by the FDA, but hundreds more are in development, with many clinical trials underway and Investigational New Drug (IND) applications pending.

Despite their growing prevalence, GMCTs aren't yet readily available to the general public. Chimeric Antigen Receptor T-cell (CAR-T) therapy is a type of GMCT. CAR-T currently relies on a patient's immune T cells being extracted, genetically modified, and then returned to the patient to target cancer cells. The manufacturing of GMCTs like CAR-T requires gene delivery to cells, which is typically achieved through viral transduction or electroporation – both of which present a number of limitations, including long lead times, high costs and significant damage to the cells. Using existing methods, a one-time dose can cost up to US$475,000 and late-stage cancer patients need to wait as long as 16 weeks for treatment.

Over time, as more GMCTs are approved for use, demand for patient-specific batches of cells will create a significant bottleneck and patients will be adversely impacted due to lack of time and/or funds to access treatment. Research into alternate, scalable, non-viral gene-delivery techniques is therefore imperative.

In 2015, Indee Labs was established to find a viable solution. Led by Managing Director and Chief Executive Officer Ryan Pawell, the Berkeley- and Sydney-based biotech aimed to develop a product that would make GMCTs like CAR-T more affordable and accessible, while also reducing the lead time for treatment from months to weeks or even days.

Indee Labs has developed a platform called Hydropore™ that uses microfluidic vortex shedding (μVS) to allow the transfer of modified genetic material into donor and patient T cells. Unlike traditional methods, this ground-breaking technology provides the industrial-scale cell processing required for GMCTs, but in micro scale. Additionally, μVS is a gentle process that allows for modified T cells to function better potentially resulting in improved patient outcomes.

During μVS, the patient's original cells and modified genes flow through 'post arrays', creating vortices. These vortices disrupt cell membrane, allowing the modified genes to enter the cell; the modified cells then repair themselves with the genes inside them. The cells are then allowed to multiply until sufficient new cells are created to be reintroduced back into the human patient. Once returned, the newly modified cells attack the patient's disease, such as cancer or the modified cells can be used to suppress an autoimmune response.

Using BMTH funding, Indee Labs sought to complete industrial design of its device, including an alpha prototype and a manufacturable beta R&D instrument; develop the microfluidic device, optimising it for different cell-type and genetic constructs; and optimise application-specific kits for common cell/construct combinations. All of these goals were achieved, and the team realised its original aim of developing Hydropore™ for CRISPR Cas9 RNP delivery to T cells.

Indee Labs leveraged this success and has received follow-on funds from the United States National Institutes of Health to apply μVS or Hydropore™ to both cancer and autoimmune disorders with support from the National Cancer Institute and National Institute of Allergy and Infection Diseases, respectively. Success with the BMTH1 project has also led to significant venture capital financing from Main Sequence Ventures, Y Combinator, Social Capital and Founders Fund among others.

Indee Labs' approach surpasses existing gene-delivery methods in cost, quality and throughput. The team's claim that μVS-processed cells result in higher cell viability and faster doubling times and will decrease the manufacturing life cycle prior to harvest and cryopreservation and thus increase the number of patient treatments that can be produced. Furthermore, advanced therapies like Kymriah and Yescarta can fail manufacturing specifications due to low cell viability resulting from the existing manufacturing process.

According to Ryan Pawell, the Hydropore™ technology overcomes the challenges associated with viral delivery and electroporation: the gentle nature of the platform improved upon the yield of electroporation and avoids the associated negative effects, while allowing researchers to scale up as they would with viral manufacturing without worrying about the associated costs, lengthy timelines and safety issues.

Now that proof of principle is established, the team hopes to develop more devices to expand applications to cellular immunotherapies, as the ultimate goal is to get these devices into the manufacturing workflows.

As Pawell explained: "We can make thousands [of microfluidic devices] per day with existing manufacturing workflow. Current 5x10 mm devices process up to one hundred million cells in less than thirty seconds and we are developing one that can process over a billion cells in a similar timeframe and with a similar footprint. So, from a comprehensive perspective, we have the ideal technology for developing these T-cell immunotherapies at scale."

Indee Labs commercial revenue has already exceeded the total amount of the BMTH1 project with support from 3 of the top 10 pharmaceutical companies among others. The team has advanced its first patent family, with patents now granted in Australia, Japan, Canada and the US, and others pending in Europe and China. A second patent family has been granted patent in the United States with other jurisdictions pending.

The BMTH project enabled Indee Labs to produce a mature gene-delivery platform technology that is being distributed internationally for Research Use Only and in the process of being out-licensed to biotechnology and pharmaceutical companies. The Hydropore™ platform offers significantly more value than industry standards by resulting in equivalent or greater modified cell numbers with improved cell quality and on shorter development timeframes.

Hydropore™ is a game changer not only for the rapidly expanding R&D gene-delivery market, but also the tens of millions of patients who will one day benefit from life-saving gene-modified cell therapies like CAR-T.

Microwearable sensor technology saving lives and preventing disease

Applied Microwearable sticker-like prototype with real-time read outs on app

PROJECT:
WearOptimo

THERAPEUTIC AREA:
Precision Medicine

WearOptimo

START DATE: 1 July 2018	**TOTAL BMTH GRANT:** $891,500
END DATE: 31 October 2019	**TOTAL BMTH EXPENDITURE:** $891,500
STATUS: Completed	**TOTAL CASH CO-CONTRIBUTION:** $891,500
DELIVERABLES COMPLETED: 18 of 18	**TOTAL IN-KIND:** $700,000
	TOTAL PROGRAM: $2,483,000

Jobs within project budget	12
Number of individuals trained/ training in specific knowledge	14
Number of collaboration events	1
Collaboration events – number of attendees	40
Number of training events	4
Training events – number of attendees	45
Number of information seminars	15
Information seminars – number of attendees	150
Number of trademark applications	2
Number of patent applications	8
Number of new technology(ies) invented/progressed	2
Number of preclinical trials commenced	2

Early detection is one of the most critical factors in determining success of a treatment and the benefits of early detection for the patient and the healthcare system are immeasurable. Consider a world with wearable sensors that alert the user of potential illness before symptoms even present, so that corrective action can be taken rapidly. In this scenario healthcare changes from reactionary where we only treat illness or disease when symptoms manifest, to becoming preventative.

There is a rapid global shift transpiring in health monitoring and detection technologies, which is shifting solutions out of the hospital or clinic, to the person and increasingly to homes. Sensors that can be used by patients in real time and connected to the cloud with active notifications and alerts built in. Some early examples of this trend include wearable glucose monitors used by diabetic patients and smart watches featuring electrocardiogram (ECG) to detect signs of heart arrhythmia.

Despite the rapid advancements made in wearable health sensors and electronics to date, the application of wearable health sensors is currently very limited. For improved clinical utility, it is preferable to measure biomarker levels in the body in a non-invasive manner, giving a real-time reading for the patient.

A biomarker is a biological signal that is a sign of a normal or abnormal process, or of a condition or disease. Monitoring biomarkers can be transformative for patients and clinicians in providing an early warning signal, offering the opportunity to act before acute clinical signs emerge, such as a heart attack. In a heart attack, or myocardial infarction, a biomarker protein called 'troponin' is released by the heart and this is traditionally tested by taking blood from the patient.

Cardiac Microwearable prototype

WearOptimo's "Microwearable" sensor technology reads vital body signals and biomarkers by accessing just a hair's width into the top layer of the skin, the viable epidermis. It is a user-friendly technology that accesses signals painlessly, accurately, affordably and in real-time. By reading these signals, the Microwearable continuous monitoring sensors can detect early biomarkers of an evolving heart attack; the immune system's status and; your body's water content and hydration state and much more. Once fully validated and in use, quickly monitoring troponin in real time may allow clinicians to make treatment decisions more quickly, thereby transforming patient outcomes.

With the support of the BMTH program, Brisbane-based WearOptimo team sought to further validate its smart patch 'Microwearable' device toward a product ready for commercialisation, entailing two key objectives: establishing proof of concept of the Microwearable platform and advancing key product and commercial milestones.

The global markets for the 'internet of things' in medicine, Personalized medicine and Wearable devices are projected to reach $534 Billion, $194 Billion and, $70 Billion, respectively, by 2025. WearOptimo's Microwearable™ sensors are uniquely nestled in the intersection of these three rapidly growing markets[1].

WearOptimo has developed a robust go-to market strategy for its initial product streams: a hydration-sensing Microwearable and a troponin-sensing Microwearable. The former has applications in heat-stressed environments and in paediatric and geriatric medicine, where it can be used to detect dehydration and alert users of clinical staff that a patient is trending towards dehydration. Meanwhile, the troponin-sensing (heart attack biomarker) Microwearable can be used on patients suspected of having a heart attack and quickly and continuously measure cardiac biomarkers. Additionally, WearOptimo has in-house capabilities for Data analytics to augment an AI platform to generate insightful data for patients within each of the market segment streams.

As part of the BMTH project, the focus for testing and development of the functional prototypes was to establish the platform technology and demonstrate the application of the Microwearable sensors for hydration monitoring, and troponin-sensing functionalised sensors that could measure troponin in clinically relevant concentrations. With the platform proven, the next key milestones include a human clinical trial to validate the diagnostic performance.

With success achieved in functional prototype testing, design options were explored to suit large-scale manufacturing. Importantly, this critical stage of development showed that the devices could be manufactured for low-cost and at scale for translation to commercial products. Understanding this led to WearOptimo securing A$30 million in additional support to establish a new manufacturing facility for its devices in Brisbane.

These outcomes have highlighted WearOptimo's capacity to make a significant contribution to Australia's innovation ecosystem.

The company's founder and Chief Executive Officer, Professor Mark Kendall, explained: "We are very grateful to MTPConnect for supporting WearOptimo Enterprise with this BioMedTech Horizons project. This project accelerates the core foundation of our R&D and commercialisation of Microwearables. In doing so, the foundation is laid in the building of WearOptimo Enterprise into an Australian national asset – competing on the world stage in wearable devices and precision medicine."

Over the course of the project, WearOptimo expanded to employ 20 staff. This is projected to be ramped up to 110 employees by 2024. WearOptimo is set to take on the world of real-time molecular biomarker diagnostics.

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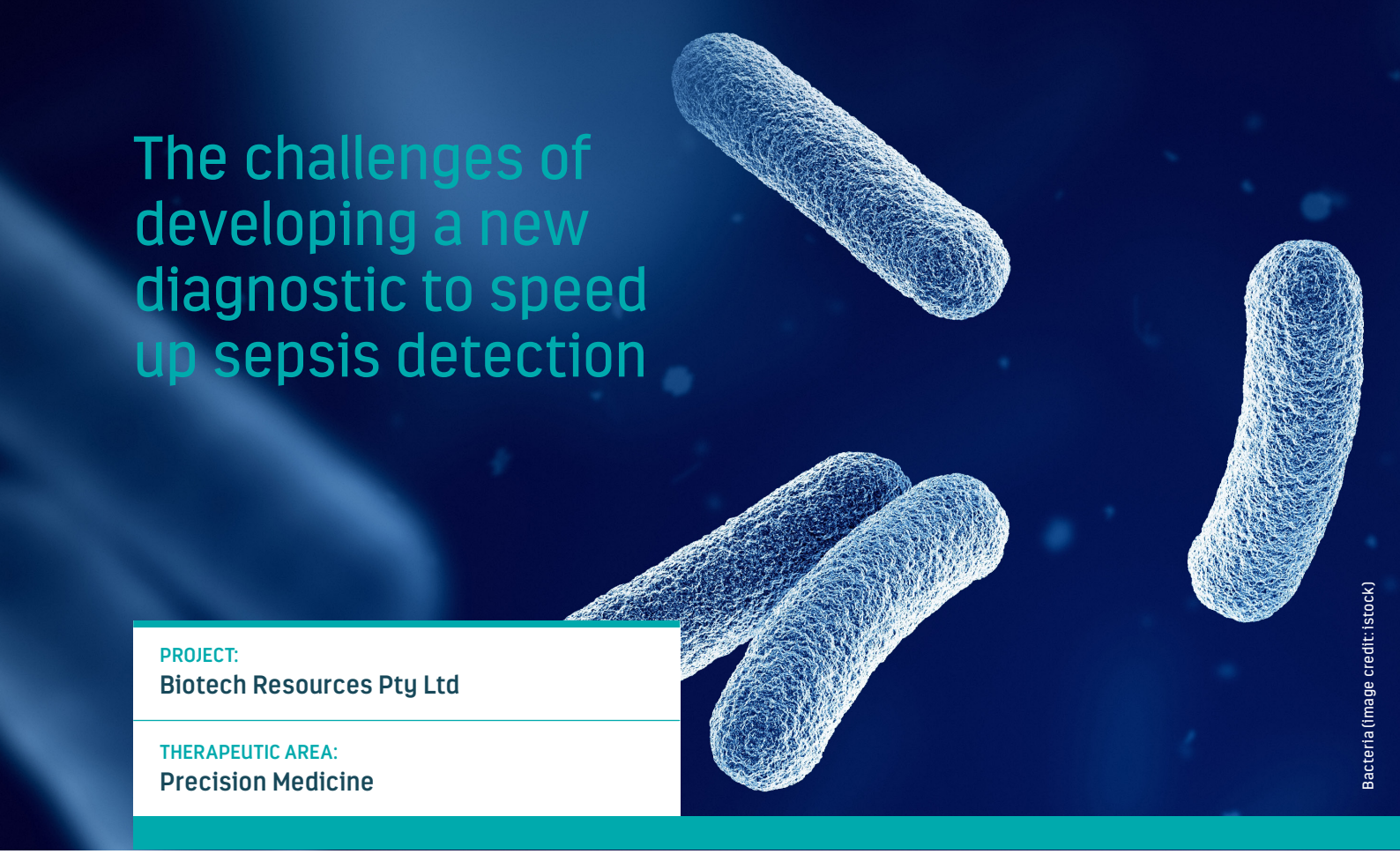
The challenges of developing a new diagnostic to speed up sepsis detection



Bacteria (image credit: istock)

PROJECT:
Biotech Resources Pty Ltd

THERAPEUTIC AREA:
Precision Medicine

START DATE:
1 May 2018

END DATE:
3 July 2019

STATUS:
Terminated

DELIVERABLES COMPLETED:
1 of 25

TOTAL BMTH GRANT:
$292,500

TOTAL BMTH EXPENDITURE:
$33,382

TOTAL CASH CO-CONTRIBUTION:
$53,396

TOTAL IN-KIND:
$0

TOTAL PROGRAM:
$86,778

Sepsis is a life-threatening condition that occurs when the body's response to infection injures its own tissue. It's a major global health problem that contributes to as many as one in five deaths worldwide. In 2017, it's estimated there were 48.9 million cases and 11 million sepsis-related deaths globally; that same year, the World Health Organization (WHO) declared sepsis a global health priority.

In addition to its high mortality rate, sepsis places a monumental burden on healthcare systems. In the US, it accounts for nearly US$24 billion in annual costs, making it the nation's most expensive condition to treat. According to a September 2021 report from The George Institute for Global Health, in Australia – where more than 6,000 adults succumb to sepsis-related death each year – the direct hospital cost to the healthcare system is approximately A$700 million per annum, with indirect costs due to premature deaths associated with the disease exceeding A$4 billion.

Sepsis is a time-critical medical emergency, whereby every hour without treatment increases a patient's chance of dying by 7.6 per cent. Yet there is currently no rapid test available to detect sepsis, and more than 30 per cent of cases are misdiagnosed. The current gold standard method for identifying the pathogens that cause sepsis is blood culturing, which takes two to six days to produce a result and is hampered by a sensitivity of 50 to 60 per cent. Other drawbacks of blood culturing include a high return of false positives, the frequency and amount of blood required, and the need to perform an additional test to identify the species of bacteria if the result is positive.

In cases where the symptoms of sepsis are missed and treatment is not administered, patient death is the likely outcome. Conversely, misdiagnoses see many patients treated with antibiotics as a precaution, which has its own detrimental consequences, as well as adding to the rise of superbug resistance.

Hoping to overcome these challenges, Biotech Resources (BTR) set out to create the world's first rapid diagnostic test, 'Aimalux', for the pathogens that cause sepsis. The technology and platform, developed by the Monash Centre for Biospectroscopy in Melbourne, were designed to detect the bacteria and fungi that cause sepsis within just 35 minutes – an achievement that would not only revolutionise the way sepsis is diagnosed, but also reduce healthcare costs and potentially save lives.

The technology combines an Attenuated Total Reflection (ATR) Fourier Transform Infrared (FTIR) mode of vibrational spectroscopy with a cloud-based artificial intelligence (AI) diagnostic platform, to unequivocally detect pathogens in whole blood samples.

Prior to receiving BMTH funding, BTR's research team worked with clinical partners at The Alfred Hospital and Monash Health for 12 months to ensure the test aligned with hospital workflows and a working proof of concept had been developed. Efficacy had already been proven with spiked blood samples, with successful verification studies performed by The Alfred Hospital.

The first activity of the BMTH-funded project was an observational study to test the sample preparation technique on actual patient samples at point of care and to test the limit of detection of the ATR-FTIR mode of vibrational spectroscopy. From the outset, the project faced three critical problems that impeded its progress: low sample numbers available for the study; nylon filter contamination; and a higher sample preparation time.

These problems were not resolved and the project fell behind schedule, with researchers unable to progress beyond the first stage. As it became evident that this would impact on all future milestones, the decision was made to terminate the project.

Though BTR's work has not yet come to fruition, it's imperative that research into rapid diagnostic tests for sepsis continues. In 2020, when WHO released its first global report on sepsis, it called on the global community to develop rapid, affordable and appropriate diagnostic tools to improve sepsis identification, surveillance, prevention and treatment. Such advances will reduce sepsis mortality and morbidity, while lowering associated healthcare costs worldwide.

As The George Institute for Global Health reported earlier this year, even a small reduction in sepsis cases would 'generate millions of dollars in savings – savings that could subsequently be used to reduce the rate of occurrence of sepsis in future'.

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Novel implantable solution set to restore vision continues development

PROJECT:
Monash Vision Group

THERAPEUTIC AREA:
Precision Medicine

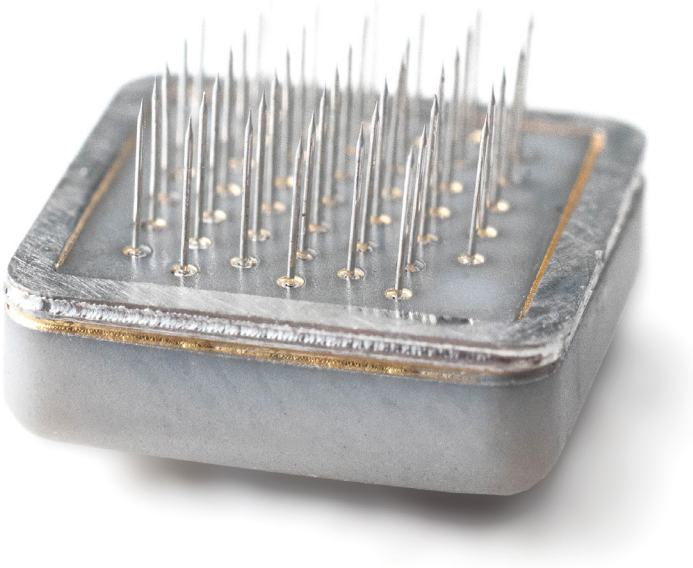
MONASH University

The attractive, comfortable and discreet headset was designed with input from the blind community.

START DATE: 1 May 2018	TOTAL BMTH GRANT: $500,000
END DATE: 28 January 2020	TOTAL BMTH EXPENDITURE: $292,801
STATUS: Terminated	TOTAL CASH CO-CONTRIBUTION: $290,396
DELIVERABLES COMPLETED: 8 of 29	TOTAL IN-KIND: $284,752
	TOTAL PROGRAM: $867,949

The total economic cost of vision impairment in Australia exceeded A$16 billion in 2009; that same year, the Clear Focus report prepared for Vision 2020 Australia revealed that 66,500 Australians were blind. For these people, treatments options are very limited, leading to a significant loss in quality of life. Using inflation adjusted estimates from the Vision2020 report in 2009, the total economic cost for a blind person per annum in today's terms is $84,250. Social and mental health challenges, as well as reduced employment opportunities, all contribute to the significant socio-economic impact on those suffering from blindness or other degenerative vision conditions.

The main causes of vision loss are uncorrected refractive errors, cataracts, age-related macular degeneration, glaucoma and diabetic retinopathy. Bilateral blindness (blindness in both eyes) can be caused by several conditions, most commonly cataracts or macular degeneration. In these cases, the optic nerve still functions; however, problems with the eye or retina prevent the signal from reaching the optic nerve. Several bionic vision restoration initiatives around the globe seek to solve this, by inserting implants into the eye to directly stimulate the retina.



The Gennaris implant is manufactured using precision laser welding processes to ensure a fully-hermetic seal protects the electronics once inside the body.

This is where Monash Vision Group (MVG) and its Gennaris system is different – and world leading. MVG's Brain-Machine Interface (BMI) was developed as a cortical vision implant that bypasses damage to the eye or optic nerve and restores basic vision. MVG's cortical vision prosthesis has been designed to treat a range of conditions that cause blindness, such as glaucoma and optic nerve damage, which are not suitable for the retinal implants used in other approaches. Under the Gennaris system, the patient wears glasses with a built-in camera, which sends a signal directly to one or more implanted chips in the visual cortex of the brain.

MVG received support from the BMTH1 program to develop its prototype BMI into a clinically viable commercial product that could provide a treatment for complete bilateral blindness. The primary aim of the project was to manufacture the first set of BMIs, allowing the first-in-human trial to begin, and to initiate processes for setting up regulatory approval and clinical trial administration. The goals addressed the technical, clinical and commercial development necessary to mature the technology.

Technical goals included in-house manufacturing to deliver a completely sealed implant for use in the NHMRC-funded first-in-human study, anticipated for 2019. Clinical measures included obtaining ethics approval from both The Alfred Hospital and Monash University Human Research Ethics Committees (HRECs), and subsequently establishing the trial site and recruiting patients to undertake the trial; it also included the creation of a spin-out company, Gennaris Neural Systems (GNS), for commercialisation.

When the first-in-human studies are initiated, a key activity will be for the device to be 'tuned' to suit the patient's physiology and disease condition, creating a uniquely calibrated device to treat blindness.

As part of its BMTH project, MVG successfully established key parts of the manufacturing pathway; made the prototype implants; and demonstrated that hermetic implant packages with electrical feedthroughs and penetrating microelectrodes could be manufactured in-house. However, the preclinical implants required laser ablation technology, which necessitated the use of a collaborating partner's custom-designed-and-made 248 nm excimer UV laser system. Changes in access to this key instrumentation caused significant delays, requiring MVG to establish new hardware, which could not be completed within the timeframe of the project. Unfortunately, this delay had downstream impacts and the vital remaining parts of the BMTH1 project could not be completed. The project was terminated in late 2019.

Since that time, MVG has continued its groundbreaking work and remains focused on its goal to restore vision to blind people. In preclinical studies published mid-2020, MVG demonstrated that its device is well tolerated in an animal model and produced no adverse effects, after successfully delivering thousands of hours of stimulating over many months. The team remains committed to achieving the first-in-human trial of its world-first cortical vision BMI.

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