



MEDIA RELEASE
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BioMedTech Horizon program funds first in human trials to restore sight

The Government announced today the first 11 recipients from the \$35 million BioMedTech Horizons program.

The program aims to support the development of new and innovative technologies by Australian medical technology (MedTech) companies.

The first round of funding focused on precision medicine and 3D anatomical printing.

Successful projects in this first round include a fully synthetic 3D printed spinal cage, a genome profiling platform to enable precision cancer medicine, a wireless Brain-Machine Interface suitable for treating neurological disorders, and microwearables for precision medicine.

Ian Burgess, Chief Executive Officer of the Medical Technology Association of Australia said:

“MTAA is proud to be part of the BioMedTech Horizons program and supporting Australian innovation.

“Our Agreement with the Government to reform the Prostheses List has provided an additional \$30 million towards the BioMedTech Horizons program and has doubled the funding available for these first recipients.

“Global advances in medical technology have resulted in a 56% reduction in hospital stays and a 16% drop in annual mortality over the past 20 years.

“This shows the significant value that medical technology can provide – saving lives, improving patients’ lives and saving costs to our health system.

“These exciting technologies that are being supported by the BioMedTech Horizons program can similarly lead to saving and improving lives, and contributing enormous value to the Australian health system.

“With an aging population comes major challenges for our health sector. MedTech will play a vital role in tackling these challenges and these 11 recipients, with a focus on precision medicine and 3D anatomical printing, will contribute towards improved health outcomes.”

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Media contact:

Polo Guilbert-Wright | 0409 631 828 | polo@mtaa.org.au

Did you know?

1. The medical technology industry currently employs more than 17,700 people and adds \$1.9 billion to the Australian economy.
2. The industry is highly skilled with over 52% of employees having a tertiary qualification, and 25% having a postgraduate qualification.
3. More than half of Australian medical device companies have grown from start-ups. 40% of all medical device businesses have been established since 2000.
4. The medical technology and pharmaceutical industry combined is the 10th largest by export value at \$5.2 billion.
5. Medical technology (7.76%) is second only to Civil Engineering (8.5%) and pharmaceuticals in third (6.3%) when it comes to filing patents for innovative technology.

About MTAA

The Medical Technology Association of Australia (MTAA) is the national association representing companies in the medical technology industry. MTAA aims to ensure the benefits of modern, innovative and reliable medical technology are delivered effectively to provide better health outcomes to the Australian community.

MTAA represents manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and management of disease and disability. The range of medical technology is diverse with products ranging from familiar items such as syringes and wound dressings, through to high-technology implanted devices such as pacemakers, defibrillators, hip and other orthopaedic implants. Products also include hospital and diagnostic imaging equipment such as ultrasounds and magnetic resonance imaging machines.

MTAA members distribute the majority of the non-pharmaceutical products used in the diagnosis and treatment of disease and disability in Australia. Our member companies also play a vital role in providing healthcare professionals with essential education and training to ensure safe and effective use of medical technology.

About the Projects

3D printed graft for surgical repair of the wrist ligament

Griffith University, Orthocell, University of Western Australia, Queensland University of Technology

Development of a 3D printed, personalised graft for surgical repair of the Scapholunate interosseous wrist ligament (SLIL) is set to produce the first SLIL repair product on the market. SLIL injuries are common and can severely impair wrist function for the 69 cases of wrist trauma per 10,000 individuals. SLIL injuries are most common in young individuals, causing long-term chronic difficulties. Therefore, a product that offers better health outcomes is likely to significantly reduce economic burden on healthcare systems over the life time of such patients. This project will support pre-clinical research and development to enable Orthocell to start human clinical trials, seek regulatory approval and commercialise.

B3D Cervical Interbody Fusion Device

Allegra Orthopaedics, University of Sydney, University of Wollongong, Boron Molecular, Sabre Medical

The Allegra Orthopaedics fully synthetic spinal cage works to regenerate bone under spinal load conditions and be completely resorbed by the body, leaving it and the intervertebral space free of foreign materials – making it a one-of-a-kind innovation. The device is 3D-printed from a synthetic bone bioceramic (Sr-HT-Gahnite) invented at The University of Sydney. The synthetic bone possesses the mechanical strength required for load-bearing conditions, bioactivity needed for outstanding bone regeneration, and resorbability that reduces the risk of rejection and infection – all in a customisable structure. No bone graft is required as the device material induces bone graft. This project will provide the necessary funding for device production for preclinical testing.

BioPen

The University of Melbourne, St Vincent's Hospital Melbourne, University of Wollongong, Swinburne University of Technology

The BioPen is set to provide the first in-situ bioprinting treatment for cartilage injuries, developed at the St Vincent's Hospital Melbourne biofabrication facility, BioFab3D@ACMD. Cartilage injuries occur in two thirds of all joint trauma, with many leading to osteoarthritis that cannot be adequately prevented or treated using current complex surgery interventions. The BioPen project is working to accurately repair the joint injury, by rapidly isolating stem cells from a patient, loading these into a gel scaffold then printing new cartilage using a hand-held device directly into the defect. The combination of stem cell technology, engineering and surgical innovation promises to simplify surgery through a one-off surgical procedure with the capacity to bank cells for future use if repeat surgery is required. The BioMedTech Horizons funding will enable this project to advance a prototype device, methodologies and bio-ink formulations towards a commercialisable therapy.

CAR-T immunotherapies for solid cancers

Carina Biotech, Seattle Children's Research Institute, The University of Adelaide, Women's and Children's Hospital Adelaide, CTM@CRC

Chimeric Antigen Receptor T-cell (CAR-T) therapy is an individually customised approach to cancer treatment that genetically engineers a patient's own immune cells to react to a specific molecular marker on their cancer. CAR-T therapy has shown extraordinary efficacy against blood cancers, however solid cancers have been less responsive to CAR-T therapy to date. Carina Biotech has produced CAR-T cells targeted to a solid cancer molecular marker, which has been published as present in many solid cancers, while having no expression on healthy cells. BioMedTech Horizons investment will allow Carina to work to achieve in-vivo proof of concept for its CAR-T cells across multiple animal models of human solid cancer.

A clinically-accredited and commercial-ready genome profiling platform to enable precision cancer medicine

Garvan Institute of Medical Research, Genome.One, Illumina

Precision cancer medicine is set to transform the clinical trial industry, with international trials attracting heavy investment. This next generation of clinical trials requires fast, comprehensive and cost-effective genomic profiling of patient tumours. The FDA recently approved two US cancer genomic tests, however, their cost (AU\$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 necessary domestic infrastructure for precision cancer clinical trials. The genome-profiling platform for precision cancer medicine is set to include a clinically-accredited tumour profiling test and a cancer genomics data platform that incorporates a national patient matching system for precision cancer clinical trial access. It aims to provide competitively priced and rapid local testing. These solutions work to ensure that, in the face of increasing global capabilities and investment in precision cancer clinical trials, Australia will remain an attractive trial site and leader in precision medicine.

EarGenie: Personalised management of hearing impairment for infants

Bionics Institute, Hydrix, Taralye Early intervention Centre, Plunkett Consulting Group, Australian Hearing

EarGenie is an innovative system for personalised management of hearing impairment, aiming to enable life-long benefits using a novel combination of electrophysiology and functional near-infrared spectroscopy (fNIRS) to perform a diagnostic hearing evaluation. Deaf infants face delayed and inadequate language development, affecting education, social participation, and even employment later in life. Major contributing factors are the delay between diagnosis and the selection and accurate adjustment of hearing devices, delayed individualised optimisation of device features, and difficulty choosing a specific therapy to optimise language development. EarGenie is set to transform the precision of diagnosis and optimisation of hearing instrument function, to

deliver major benefit to language development in deaf children. This project will allow for the development of a clinical prototype as well as plans for regulatory approval and clinical trials.

Gennaris Neural Systems (GNS)

Monash University, Alfred Health, MiniFAB

Monash Vision Group (MVG) has developed a wireless Brain-Machine Interface (BMI), offering the potential to bypass damage to nerves and neural pathways, restoring function to affected areas of the brain. MVG's Brain-Machine Interface has been implemented in a cortical vision prosthesis that is designed to bypass damage to the visual pathway and restore basic vision. This funding will assist the transition between preclinical and clinical programs, allowing the utility of the visual prosthesis to be demonstrated. A company will be established to manufacture MVG's Brain-Machine Interface and commercialise the visual prosthesis. The aim of this company is to bring the product to market by 2021 to address the unmet need of a treatment for complete blindness. MVG's cortical vision prosthesis has been designed to treat a range of blindness causes, such as glaucoma and optic nerve damage, which are not suitable for retinal implants. The successful commercialisation of this technology will establish Australia as an exporter of implantable medical devices, and global market leader in BMI manufacturing.

Leaping towards precision medicine: Microwearables

WearOptimo, The Australian National University, Queensland Government, Johnson & Johnson Innovation, Australia National Fabrication Facility

Microwearables (simple, wearable devices) have the opportunity to be a cornerstone of precision medicine by offering personalised diagnostics across a range of diseases. These devices are minimally-invasive, pain-free sensors applied to the skin to access biomarkers and biosignals. Microwearables transduce electrical, optical or biochemical biomarkers from a hair's width depth within the skin for both episodic and continuous monitoring. In doing so, it aims to leapfrog traditional diagnostics: based on lab-based assays of blood samples and histopathology – with the costs, risks and time-delays. WearOptimo will be developed as a fit-for-purpose enterprise to rapidly compete at scale – meeting the unique opportunity at the nexus of three growing markets: IoT for medicine; personalised medicine; and wearable electronics for healthcare. This project will take the next critical step in working to advance Microwearables into an enterprise – to commercial, proof-of-concept, and investor ready.

'PoreStar' – Porous Polyethylene Implant Material

Anatomics

In 2014, Anatomics, in conjunction with CSIRO and Australian universities, developed a breakthrough pHDPE implant material, PoreStar. PoreStar's material advantages include its superior tensile and flexural strength avoiding cracks when bent, the ability to adhere with screws very close to the implant margins without material breakage, and a unique scaffold architecture that facilitates tissue ingrowth. This project aims to advance the state-of-the-art in craniomaxillofacial (CMF) implant manufacturing, leveraging 3D printing to reduce process complexity, product turnaround time and cost of goods. Moreover, the project seeks to improve surgical practice by extending the use of temporary implants to patient-specific CMF surgeries, and develop improved software solutions for surgical planning and preoperative estimation of cosmesis, aiming to reduce complications and reoperation rates for CMF surgeries.

Rapid diagnostic for the pathogens that cause sepsis

Biotech Resources, Monash University Centre for Biospectroscopy, The Alfred Hospital, Monash Health, Hydrix

Biotech Resources (BTR) is working to develop the world's first rapid diagnostic test 'Aimalux' for the direct detection of the bacteria and fungi that cause sepsis from whole blood. The technology and platform has been developed by the Monash University Centre for Biospectroscopy in Melbourne Australia. Sepsis is a life-threatening disease that results in the deaths of over 6 million people every year around the world, and more

than 5,000 Australians. It is time critical medical emergency. Every hour without treatment increases a patient's chance of dying by 7.6%. And yet there is no definitive test for sepsis with more than 30% of cases going misdiagnosed. If the symptoms of Sepsis are missed and treatment is not administered, then this can result in patient death. This also means that many patients are treated unnecessarily as a precaution, which has its own detrimental consequences as well as adding to the rise of antibiotic resistance super bugs. Aimalux aims to provide a diagnostic result within 35 minutes, to revolutionise the way sepsis is currently diagnosed, reduce healthcare costs, and save lives.

Towards bedside gene therapies: Development of a microfluidic gene delivery device for immune cell modification and optimisation for clinical use

Indee, University of South Australia Future Industries Institute, Main Sequence Ventures, Defence Science Technologies Group, University of Sydney, Becton Dickinson

Pioneering cures for terminally ill patients, with conditions including many forms of cancer, are now available thanks to a new generation of treatments called gene-modified cell therapies (GMCTs). Indee Labs plans to make GMCTs accessible to the masses by solving manufacturing issues responsible for their high price tags. It also aims to reduce the lead times for a treatment from months to weeks, saving the lives of patients with aggressive conditions. Gene delivery to cells is the most critical and problematic step in manufacturing GMCTs. This project aims to will develop the only practical gene delivery technology, microfluidic vortex shedding (μ VS), into a product that will be trailed by pharmaceutical companies. μ VS will offer revolutionary improvements over existing gene delivery methods including high yield, negligible immune cell perturbation along with rapid processing of research-, clinical- and commercial-scale samples with a simple workflow and a small footprint.