2020-21

Bionics Institute Annual Report

Bionics Institute

The Bionics Institute is an internationally recognised, independent medical research institute that solves medical challenges with technology.

We lead the world in the research and development of innovative medical devices and therapies to improve human health.

Our multidisciplinary team comprises world-class scientists, engineers and researchers, and our laboratories are located in St Vincent's Hospital Melbourne, close to our clinical collaborators.

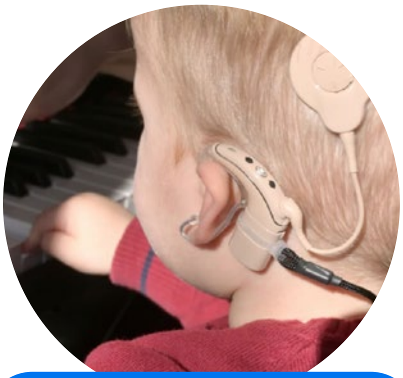
Together we transform the lives of people with a range of conditions, including hearing impairment, vision loss, Crohn's disease, Parkinson's disease, epilepsy, stroke, arthritis, incontinence and diabetes.

Contents

Medical bionics is a multidisciplinary field of research combining **bio**(logy) and (electro)**nics** to develop devices that electrically modulate or monitor neural activity to provide innovative treatments for a range of medical conditions.

Our Year at a Glance

2
IP patents granted



A step forward in improving cochlear implants

33
Number of publications

Bionics Institute CEO recognised by ATSE

1
Number of startup companies

Bionic eye breakthrough technology

7
Number of media stories

Launching Neo-Bionica - an Australian first

23
New recruits/ appointments

13
New students

Community outreach events
7

Forging ahead with new infant hearing test

Tinnitus diagnostic tool shows high accuracy

$1.33 million
Private donor funding

$5,355,343
Grant funding

Message from our Chair

I am delighted to present this Annual Report for the 2020–21 financial year. It highlights the people who have made a difference, the impact of our research and outlines our plans for investing in the future.

As Chair of the Bionics Institute, I am fortunate to lead a dynamic and talented Board who are committed to changing the lives of people living with debilitating conditions, such as Parkinson's disease, rheumatoid arthritis and hearing loss. I am very grateful for their knowledge, expertise and guidance.

Despite a challenging year caused by the COVID-19 pandemic, the Bionics Institute made great strides forward, maintaining its position at the forefront of medical bionics research. I applaud CEO Robert Klupacs, the researchers and the support staff for their resilience, passion and achievements.

Together we are focused on leading the world in the development and translation of research into clinical applications that make a lasting difference to people's lives. Our strategy of growth and renewal is taking shape, and this is very well illustrated by our achievements.

We have launched three companies over the past 4 years; a number of our unique devices are now in clinical trials throughout the world; and we have significantly increased our research staff numbers over the past 12 months to accelerate our innovation and development activity.

Medical devices developed at the Bionics Institute are being successfully commercialised through Epi-Minder Pty Ltd and Deep Brain Stimulation Technologies Pty Ltd. I was delighted to attend the launch of our third company, Neo-Bionica Pty Ltd, at an event in May 2021.

Neo-Bionica, a joint initiative between the Bionics Institute and the University of Melbourne, is a highly specialised laboratory, which will significantly increase the speed of medical device development from initial concept to clinical application for the benefit of patients throughout the world.

There are exciting times ahead for the Bionics Institute as we continue to grow.
I do hope you will join us on the journey.

Mr John Stanhope AM
Chair

"There are exciting times ahead for the Bionics Institute as we continue to grow. I do hope you will join us on the journey."

Message from our CEO

It is a privilege to lead the Bionics Institute team of scientists, engineers and support staff, who work together to innovate, create and develop medical devices that transform the lives of millions of people around the world.

Forging ahead with excellent research and achieving milestones in a normal year is a cause for celebration. To do this during the unprecedented COVID-19 pandemic, when Melbourne endured 6 months of hard lockdown, is remarkable.

I am incredibly proud of everything our team has achieved in the 2020–21 financial year, from pioneering technologies and preparation for first-in-human clinical trials, to an expansion of our commercial ventures and investing in future growth.

It has been a pleasure to work with our dedicated Board, led by Chair John Stanhope, and I look forward to working with them and the Bionics Institute team to build on this year's successes.

Pioneering new technologies

Optogenetics

Results of a world-leading study, published in the Journal of Neural Engineering by Associate Professor Rachael Richardson and her team, showed that the use of hybrid light and electrical stimulation on genetically modified auditory nerves has the potential to improve the accuracy of sound heard via cochlear implants. This lays the foundations for the next generation of improved bionic devices.

Vagus nerve stimulation

In just 4 years, Professor James Fallon's team developed a vagus nerve device that can treat the debilitating effects of Crohn's disease and Ulcerative Colitis. This year, in collaboration with our clinical collaborator Associate Professor Peter De Cruz at the Austin Hospital Melbourne, clinical grade devices were manufactured ready for a first-in-human trial to begin after COVID-19 restrictions have lifted; expected by April 2022. This is an excellent example of rapid translation of research into clinical applications at the Bionics Institute.

Objective measure of tinnitus

A study published in the journal PLOS One into an objective measure of tinnitus showed that new technology under development by Dr Mehrnaz Shoushtarian's team can differentiate between mild and severe tinnitus with high accuracy. These findings show great promise for the future use of the non-invasive brain imaging technique to monitor effectiveness of treatment in tinnitus.

Bionic eye

The second-generation bionic eye clinical trial was successfully completed in March 2021 with four patients reporting the ability to see objects for the first time using the implanted technology. Our team, led by Dr Matt Petoe, designed and fabricated the 44 electrodes used in the bionic eye and will continue to work with collaborators at CERA, Data61 and Bionic Vision Technologies in the next phase of trials.

Expanding commercial ventures

It is very pleasing to see our business model coming to fruition with the expansion of our commercial ventures, ensuring Bionics Institute technologies are translated into clinical applications to improve human health.

Epi-Minder Pty Ltd, the company we launched to commercialise a breakthrough epilepsy monitoring device developed at the Bionics Institute, continues to go from strength to strength. The Minder™ device prototype went into a pivotal clinical trial in 2020, with the trial expected to be complete in late 2022 to enable US Food & Drug Administration approval. Epi-Minder also initiated a new collaboration with Seer Medical in May 2021, which gives great hope that patients could one day be able to predict seizures before they occur. Together, Epi-Minder and Seer Medical will develop cloud technology to enable the device to predict, as well as monitor, seizures and give people with epilepsy more control over their lives.

Following the launch of Deep Brain Stimulation Technologies Pty Ltd last year, we are making great progress in the commercialisation of the technology developed by Professor Hugh McDermott's team. The technology, which combines improved electrodes with bespoke software, is set to revolutionise the treatment of Parkinson's disease. The company is currently undertaking clinical trials in Melbourne using its technology to better place electrodes into the brain, which will improve the therapeutic outcomes.

We were delighted to launch Neo-Bionica Pty Ltd this year, a joint initiative with the University of Melbourne and the first company of its kind in Australia to combine the expertise and facilities needed to develop medical device prototypes for clinical trials. The ability to manufacture prototype devices to clinical trial quality has long been a major impediment in translating Australian medical device innovation. Neo-Bionica will fast-track research translation, train the next generation of researchers and enhance Victoria's reputation as a global biomedical powerhouse.

Thank you for supporting innovation

Innovation has been the key to our success over the past 30 years, inspired by our founder Professor Graeme Clark, who led the cochlear implant development team at the Bionics Institute.

We are extremely grateful to the individual donors, philanthropic trusts and foundations for supporting today's innovators – our scientists, engineers and collaborating clinicians. I would like to thank our generous supporters for the donations that provide vital funding for the early research essential for success in our applications for competitive government grants.

We gratefully acknowledge the research funding we receive from the Victorian Government and the Federal Government. This included awards from the Victorian Medical Research Acceleration Fund to advance research to improve deep brain stimulation, and a National Health and Medical Research Council Development Grant to the Hearing Therapeutics research team to stop the progression of hearing loss.

Securing these grants would not have been possible without the dedicated work of our Head of Grants and Research Governance, Dr Janine Clarey. After an outstanding career spanning 23 years at the Bionics Institute, we said farewell to Janine in 2021 and wish her all the best for her retirement.

Message from our CEO *cont.*

Investing in the future

The Bionics Institute has bold plans for growth over the next 20 years. To realise our plans, we are currently recruiting world-class talent in all areas of the Institute to increase the scope of our work and speed up the development of transformational medical devices.

Recruiting talented scientists and engineers means we have an increasing need for laboratory space. We are grateful for the leadership and vision of our partners in the Aikenhead Centre for Medical Discovery (ACMD) who have worked tirelessly to establish Australia's first hospital-based biomedical engineering research centre at St Vincent's Hospital Melbourne. We will be moving into the new ACMD building when it is complete in 2024.

I hope you enjoy reading about our achievements and the stories from the people benefitting from our research.

Mr Robert Klupacs
CEO

"I am incredibly proud of everything our team has achieved in the 2020–2021 financial year, from pioneering technologies and preparation for first-in-human clinical trials, to an expansion of our commercial ventures and investing in future growth."

Our Board

We would like to thank the Board of Directors for their dedication and commitment to the mission of the Bionics Institute.

John Stanhope AM
Chair

John Bryson
Deputy Chair

Charles Bagot

Phill Binns

Stella Clark AM

Roger Gillespie OAM

Christina Hardy

Brian Jamieson

Ken Jefferd

John Simpson

Sherryl Wagstaff

Our Achievements

1978

First Australian cochlear implant developed at the University of Melbourne Department of Otolaryngology implanted by Professor Graeme Clark into the first patient.

1981

A company, later to become Cochlear, established to commercialise the cochlear implant, which is implanted into over 600,000 people worldwide by 2021.

1986

The Bionic Ear Institute

Professor Graeme Clark founds the Bionic Ear Institute to undertake independent research into improvement of the cochlear implant.

Bionic eye research commences.

Hearing research expands.

Epilepsy research commences.

2011

Bionics institute

To mark a new era in bionic research and expansion from hearing into brain and vision research, the institute is rebranded as The Bionics Institute of Australia.

Diagnostic & Therapeutic Technologies

2011-

Hearing research expands to incorporate infant hearing test EarGenie™, a tinnitus diagnostic tool, nano-particle drug delivery for hearing loss, optogenetics, and continuing research into improving cochlear implants.

2011

Deep Brain Stimulation (DBS) for Parkinson's disease research commences.

2010

Polyactiva Pty Ltd established

2013

First generation epilepsy seizure monitoring Minder™ device created at the Bionics Institute.

2015

Vagus nerve and peripheral nerve research commences.

2018

Second generation bionic eye clinical trial.

2017

EarGenie™ trademarked

2019-

Vagus nerve device adapted for type 2 diabetes and rheumatoid arthritis.

2019

Deep Brain Stimulation Technologies Pty Ltd established

2018

Epi-Minder Pty Ltd established

2019

First Australian MRI to achieve ISO 9001 accreditation.

2022

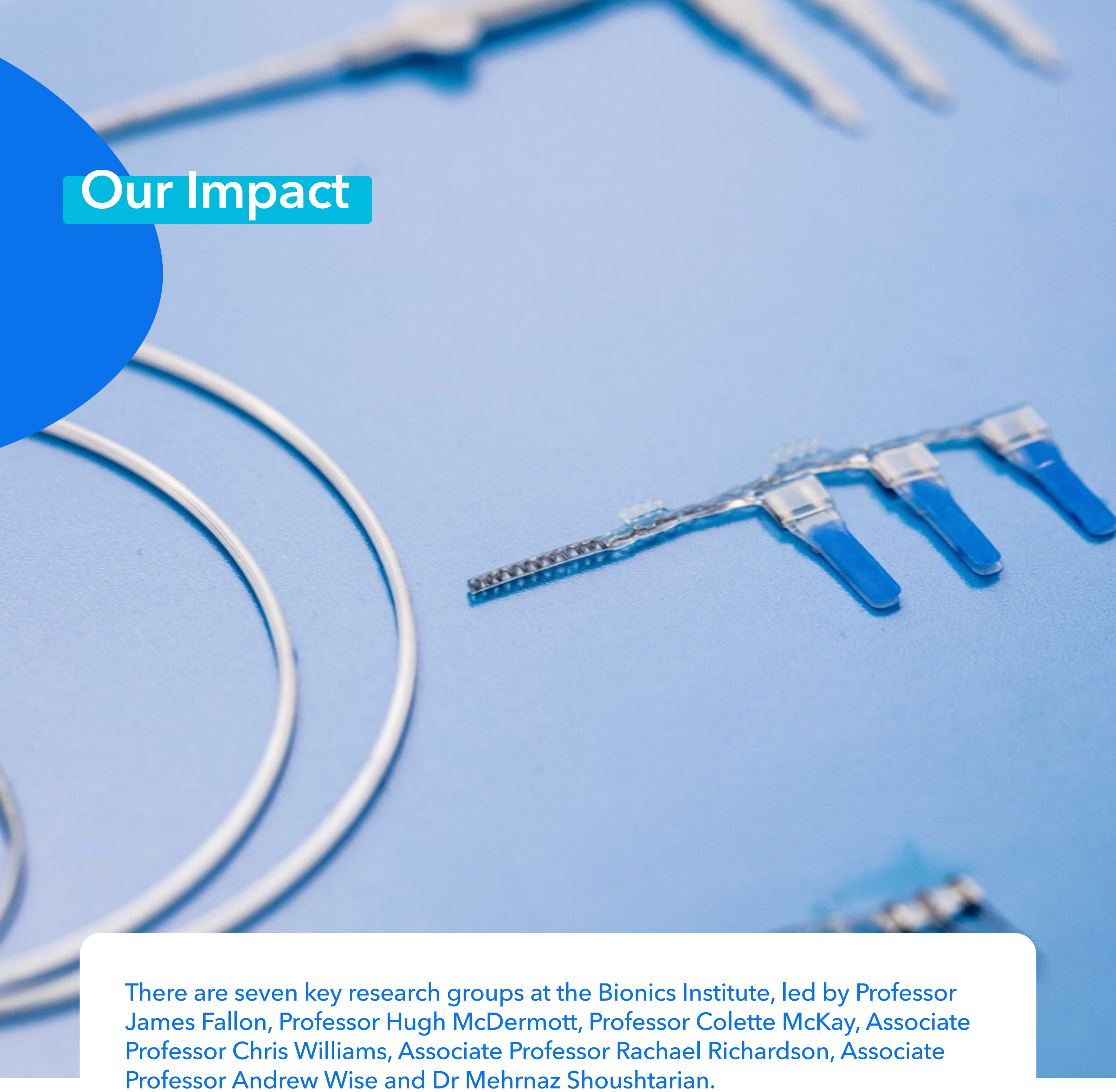
IBD vagus nerve device clinical trial for Crohn's disease.

2021

Neo-Bionica Pty Ltd established

2019

First-in-human clinical trials of Minder™ device for epilepsy.



Our Impact

There are seven key research groups at the Bionics Institute, led by Professor James Fallon, Professor Hugh McDermott, Professor Colette McKay, Associate Professor Chris Williams, Associate Professor Rachael Richardson, Associate Professor Andrew Wise and Dr Mehrnaz Shoushtarian.

These teams are supported by our excellent capability providers: the pre-clinical research team led by Dr Peta Grigsby; the histology team led by Ella Trang; and data analytics provided by Dr Gautam Balasubramanian.

Report from our Research Director

Excellent progress, improved collaboration and strengthened capabilities are achievements most organisations wouldn't associate with the COVID-19 pandemic. However, when I reflect on the second half of 2020 and the first half of 2021, that's what stands out. As an essential service, medical research continued to operate during Melbourne's long lockdowns, and our amazing research teams didn't take their foot off the pedal!

Excellent progress

Our hearing research encompasses potential treatments and diagnostic tools at all stages of life, from an infant hearing test to restoring age-related hearing loss. The Optogenetics team continue to build core knowledge and systems that can be applied to the next generation of cochlear implants. Our Hearing Therapeutics team continues to progress well towards a clinical trial next year. And, while clinical studies for EarGenie™ and tinnitus were curtailed due to lockdown, researchers refined the equipment and developed the software ready for the next round of testing and assessment.

It was great to see the epilepsy monitoring device, developed at the Bionics Institute and commercialised by Epi-Minder, go into a clinical trial in 2020. Our Neuro team also continued early-stage development of a new device, based on our own novel electrode designs, that shows promise of improving rehabilitation after stroke.

The Deep Brain Stimulation team made great strides in improving the technology they have developed ready to take the next step from research into commercialisation. Their work will ensure accurate positioning and programming of devices to help people with Parkinson's disease.

Our vagus nerve stimulation research into a new device to lower blood glucose levels in type 2 diabetes and dampen the inflammatory response in rheumatoid arthritis both progressed incredibly well. As did research into a peripheral nerve device to control bladder function in incontinence. Unfortunately, clinical trials to test the vagus nerve device to prevent recurrence of Crohn's disease following surgery were put on hold due to COVID-19, but we are ready to move ahead as soon as restrictions ease. We expect these world-first trials to commence at the Austin Hospital Melbourne soon.

Improved collaboration

One silver lining of COVID-19 was the normalising of online meetings, which in turn improved our collaboration with clinicians and researchers. Finding the best time to meet a busy doctor or surgeon can be very difficult. For example, even a 1-hour meeting at the Austin Hospital used to take several hours once we'd travelled there and back, let alone the travel required to meet our international collaborators. In contrast, moving to shorter, more frequent online meetings required no travel and improved effectiveness and efficiency. While online meetings will never replace the power of in-person networking to establish new connections, it is definitely a good way to progress established collaborations.

Strengthened capabilities

Our Pre-clinical Research and Histology teams form the bedrock of our research at the Bionics Institute. During the height of lockdown, we were concerned that their work would come to a halt if all staff needed to quarantine. Cross-training and upskilling of staff to learn specialised techniques from the internal experts allowed us to effectively run two parallel pre-clinical research teams, meaning if one team was sent into quarantine, the other could take over. The increased resilience and surge capacity this provided flowed through to our Histology team, and also led to a strengthening of our structure to provide capabilities as needed for each research project.

Our ambitious plans for growth took flight early in 2021 when we recruited new talent into our research team. We were delighted to welcome a number of new post-doctoral researchers, early career researchers, specialised engineers and students.

And finally, it was exciting to launch our medical device prototype manufacturing facility Neo-Bionica in May 2021. A joint initiative of the Bionics Institute and the University of Melbourne, Neo-Bionica promises to be an excellent asset for our researchers and the global medtech industry.

All in all, we had a very successful year and built an excellent base for growth and development of innovative, life-changing medical devices to help people with challenging medical conditions.

Professor James Fallon
Research Director

James Fallon

Brain Research

We made great strides with our research and development of medical devices to improve outcomes for people with conditions affecting the brain. This research encompasses new technology to enhance deep brain stimulation treatment for Parkinson's disease; development of an objective measure of rigidity in Parkinson's disease; continuing improvements to the Minder™ device that monitors seizures in people with epilepsy; and early-stage research into a device to aid rehabilitation after stroke.

Triathlon triumph over Parkinson's disease

A triathlon is not something you'd expect to be able to take on with Parkinson's disease. Yet physical triumphs like this are now possible for people like Andrew Lindsay, thanks to improving treatments. Diagnosed with Parkinson's disease in 2016, Andrew says his symptoms had become very difficult to manage by 2021.

Andrew said: 'I was taking medication every 3 hours to get relief from the symptoms of stiffness and muscle pain, but it wasn't helping with the foot drag and loss of arm function. 'I had always intended to have deep brain stimulation treatment when the drugs stopped helping. My specialist, Dr Wesley Thevathasan, suggested I join a clinical trial using new technology.' The new technology, developed at the Bionics Institute to improve deep brain stimulation, is used to ensure the electrodes are placed accurately.

Previously patients had to be awake during surgery to report on their symptoms and guide placement of the medical device, but patients can now have the 4-hour procedure under anaesthetic. 'I would have been happy to be awake during the operation if that would have contributed to the success of the procedure. But the doctors were very confident in the new system and said it's easier if I'm asleep,' he said. 'How do I feel now? Wow. Amazing!'

Andrew is grateful for the new lease on life he's been given. In fact, he's feeling so good he signed up for a triathlon just 4 months after having the operation.

'With a progressive disease you forget how well you can feel, not just physically but mentally. My wife Mandy says "I have my husband back". It's been such a positive outcome for me.'

Signaling success

Parkinson's disease is often treated with deep brain stimulation (DBS) therapy – where a battery-operated medical device is surgically implanted to deliver electrical stimulation to specific areas of the brain. The electrical stimulation blocks abnormal nerve signals causing Parkinson's disease patients to experience symptoms such as slow, reduced or involuntary movements.

Current DBS therapy is hindered by two factors. Firstly, inserting the electrode into the correct part of the brain is incredibly difficult and patients need to be awake to report on symptoms to guide placement of the electrode.

Secondly, the electrode is programmed via a pacemaker-like device to deliver stimulation to the brain at a constant level post-surgery. This means there is no flexibility for the treatment to be tailored in response to symptom severity over time, resulting in too much or too little stimulation being generated.

Our DBS team have developed groundbreaking technology to overcome these constraints. Our researchers discovered that certain neural clusters in the brain associated with Parkinson's disease respond to electrical stimulation with a large signal, or Evoked Resonant Neural Activity (ERNA). They've developed a software system that captures the ERNA signal, meaning surgeons can implant DBS devices in anaesthetised patients with greater accuracy using the signal as a guide.

The software will also be incorporated into the DBS device, eventually enabling it to deliver levels of stimulation that adapt to each individual patient's varying needs in real time.

Research report

Monitoring and predicting seizures in epilepsy

Associate Professor Chris William's research team has worked closely with leading neurologist Professor Mark Cook from St Vincent's Hospital Melbourne over the past decade to develop a seizure monitoring device that can record brain activity (EEG) long term. Implanted under the scalp, Minder™ was designed to monitor seizures outside the clinic and allow patients to go about their daily lives, rather than attend multiple hospital stays for conventional EEG recordings.

An estimated 50 million people worldwide live with epilepsy and as many as one-third are unable to control seizures with medication. Epileptic seizures can affect movement, cause temporary loss of awareness, sensation and mood. Seizures are mostly unpredictable, which means people with epilepsy may not be able to work or drive. A way to reliably predict seizures would make it easier for people with epilepsy to carry out everyday activities. It would also benefit their safety, mental health and employability.

Data recorded by a wearable processor connected to the device is stored in the cloud and analysed in real time by expert technicians. This provides clinicians with an accurate, long-term record of seizures, which can be used to tailor drug treatments, reduce the likelihood of seizures and improve life for people with epilepsy.

In 2018, Professor Mark Cook and the Bionics Institute set up a commercial venture, Epi-Minder Pty Ltd, to manufacture, get regulatory approval and market this technology to ensure it benefits patients around the world. In 2019 first-in-human clinical trials were conducted and the results are being used to further develop the device for a larger clinical trial to commence in 2022.

Research highlights

The first-in-human clinical trial of Epi-Minder's device started with two patients implanted at the end of 2019. Additional patients have been implanted and tested at St Vincent's Hospital Melbourne. The goal is a 6-month clinical study with an additional 30-month follow up aimed at evaluating the long-term safety and stability of the sub-scalp EEG monitoring system in patients with focal or generalised epilepsy. This study is registered with the Australian New Zealand Clinical Trials Registry, and we are currently recruiting more patients.

Data from the current patients are being used to assess signal quality by means of measuring stability and repeatability. This will be used by the team to develop the next generation implant while moving towards a larger, multi-centre clinical trial.

In 2021, Epi-Minder formed a collaboration with Seer Medical to extend the capability of the Minder to predict seizures using cloud technology. The new technology will use an app-based platform to warn patients of impending seizures via their phone, allowing them to move to a safe place and regain more control over their lives.

Funding and research communication highlights

In 2020, Epi-Minder raised $18m to develop the Minder epilepsy monitoring device. Professor Mark Cook was featured in the Herald Sun in May 2021 and on Channel Nine's A Current Affair in June 2021.

Meet the team

Led by Associate Professor Chris Williams and Professor Mark Cook, the Epilepsy team comprises Dr Yuri Benovitski, Alexia Saunders, Owen Burns, Rodney Millard, Mark Harrison and Associate Professor Graeme Rathbone. Valuable assistance is provided by Dr Rohan Hoare, Dr John Heasman and the team at Epi-Minder, Dr Alan Lai, Associate Professor Wendyl D'Souza and neurosurgeons Mr Kristian Bulluss and Associate Professor Michael Murphy.

Research report

Aiding rehabilitation after stroke

Associate Professor Chris William's research team is in the early stages of developing a device to enhance recovery and guide management after stroke. The small implant is designed to be positioned under the scalp and uses embedded electrodes to stimulate the part of the brain responsible for controlling body movement.

Physiotherapy, an important way to improve function and reduce disability following a stroke, can be boosted using electrical stimulation of affected brain regions. However, the equipment currently used in research is bulky and needs to be used in a clinic.

The aim of this research is to provide an implantable device that stimulates the affected regions to boost the treatment provided during physiotherapy appointments and while the patient is carrying out exercises at home. This will increase both the speed and effectiveness of rehabilitation.

In addition, our researchers have shown that the relationship between muscle function, stroke severity and brainwave activity can be used to assist with the overall management of patients following a stroke. The next steps will be to develop and test a closed-loop stimulator that can record EEG brain activity to detect adverse events and provide clinicians with the information needed to determine ongoing treatment.

Meet the team

Led by Associate Professor Chris Williams, the Stroke team comprises Dr Matt Petoe, Alexia Saunders, Dr Yuri Benovitski, Owen Burns and Associate Professor Graeme Rathbone with the valuable assistance of Professor Clive May and Associate Professor Michael Murphy.

Research report

Enhancing deep brain stimulation treatment for Parkinson's disease

Professor Hugh McDermott's research team is focused on the improvement of deep brain stimulation (DBS) for the treatment of Parkinson's disease and other movement disorders. DBS involves the implantation of electrodes into the brain to deliver electrical impulses that block the abnormal brain signals causing symptoms in conditions such as Parkinson's disease.

There are currently two challenges with deep brain stimulation. Firstly, inserting the electrode into the correct part of the brain is very difficult, and surgeons depend on the person being awake to give feedback on symptoms to ensure it has been placed correctly. Secondly, stimulation is applied at a constant level based on the individual programming session following surgery. However, symptoms and the need for specific levels of stimulation continually fluctuate and the lack of flexibility can result in too much or too little stimulation, leading to unwanted side effects or poor symptom control.

The research group previously discovered that certain neural clusters in the brain respond to electrical stimulation with a large signal, known as Evoked Resonant Neural Activity (ERNA). Since this discovery, the group has been undertaking research to establish how the ERNA signal can be used to improve accuracy of positioning and effectiveness of the therapy for Parkinson's disease treatment.

The practical outcomes of the group's research will include a new software system that enables clinicians to implant DBS electrodes in anaesthetised people with greater precision using the ERNA signal. This will also include an implantable DBS device that automatically adapts stimulation therapy to suit each person's unique needs as they vary over time. In 2019, the Bionics Institute set up a company, Deep Brain Stimulation Technologies Pty Ltd, to further develop and commercialise this technology and ensure it benefits people around the world.

Research highlights

The year has been very successful for the DBS team despite the adverse effects of the global pandemic. Our work has accelerated towards practical outcomes from the research based on the ERNA brain signal. Working closely with the Bionics Institute's commercial partners is expected to lead to highly successful products that will benefit clinicians as well as people living with Parkinson's disease and other challenging disorders.

This year's highlights include:

- Making ERNA recordings in over 60 clinical study participants, bringing the total number of participants in our studies to well over 200.
- Developing a new intra-operative system to assist clinicians in DBS surgery.
- Completing the design of a new implantable DBS research system that will be capable of recording ERNA chronically.
- Investigating the presence of ERNA-like signals in other regions of the brain and in study participants living with other neurological disorders.
- Securing ethical approval for a new multi-centre study that will increase our understanding of how treatment of Parkinson's disease is benefited using ERNA during surgery.

- Obtaining support from two prestigious neurosurgical research centres overseas to participate in our new clinical study and beginning the process of obtaining regulatory approvals in the UK.
- Expansion of the DBS team in Melbourne to include additional research clinicians and specialised medical device engineers to undertake activities on an accelerated timeline towards commercially significant outcomes.
- Ongoing collaboration with the Bionics Institute's commercial venture, Deep Brain Stimulation Technologies, which is driving the rapid translation of the research into practical outcomes.

Funding and research communication highlights

Professor Hugh McDermott's team was supported by funding from the National Health and Medical Research Council; the Victorian Medical Research Acceleration Fund; and the Biomedical Translation Bridge Program, an initiative of the Medical Research Future Fund.

Meet the team

Led by Professor Hugh McDermott, the Deep Brain Stimulation team comprises Nicola Acevedo, Angus Begg, Mica Haneman, Dr Kiaran Lawson, Dr Wee-Lih Lee, Dr Jonathan Miegel, Dr Thushara Perera, Dr Matt Petoe, Nicholas Sinclair, Dr Paul Minty, Dr San San Xu, Mr Kristian Bulluss and Associate Professor Wesley Thevathasan.

Research report

Improving rigidity assessments in Parkinson's disease

Led by Dr Thushara Perera, our researchers are developing a device that enables objective measurement of muscle rigidity, a common symptom of Parkinson's disease.

Medical practitioners need accurate ways to measure the symptoms of Parkinson's disease so they can tailor and improve treatment to maximise quality of life. However, the symptoms of Parkinson's disease can change over time and doctors need to continuously adjust treatment to ensure therapy is just right. Currently, health professionals rely on seeing or feeling changes to symptoms as treatment is tweaked and fine-tuned. Accurate assessment can be challenging for clinicians, especially when small changes occur in response to treatment, or there are long periods of time between assessments. In addition, the pandemic has challenged health professionals to manage patient therapy via telehealth, highlighting another need to develop innovative solutions to measure symptoms remotely.

Our research is focused on the development of a wearable device called the Bionics Institute Rigidity Device (BiRD) that is placed on the hand for 2 minutes to give precise information on the level of rigidity. Early-stage clinical trials have shown that the device can distinguish between people with and without the disease as well as track efforts of therapy. The next step is to test the device in a larger clinical trial, with the aim of characterising device performance across a variety of people with Parkinson's disease.

Research highlights

This year we received ethical approval for a clinical study to confirm the effectiveness of the device, registered our clinical trial on the Australian and New Zealand Clinical Trial Registry, established formal agreements with our collaborating hospitals and configured an electronic database for efficient data entry. Manufacturing of a third-generation prototype of the BiRD device for use in the study commenced and we received TGA approval for its use in trials. We recruited a postdoctoral research fellow to oversee the study and two specialised nurses to perform the clinical assessments.

Funding and research communication highlights

Dr Thushara Perera's team was supported by a grant from the AMP Tomorrow Fund.

Meet the team

Led by Dr Thushara Perera, the BiRD team comprises Dr Melissa Louey, Angus Begg and Asif Mohammed in collaboration with Associate Professor Wesley Thevathasan.

Research report

Pre-clinical research into deep brain stimulation for Parkinson's disease

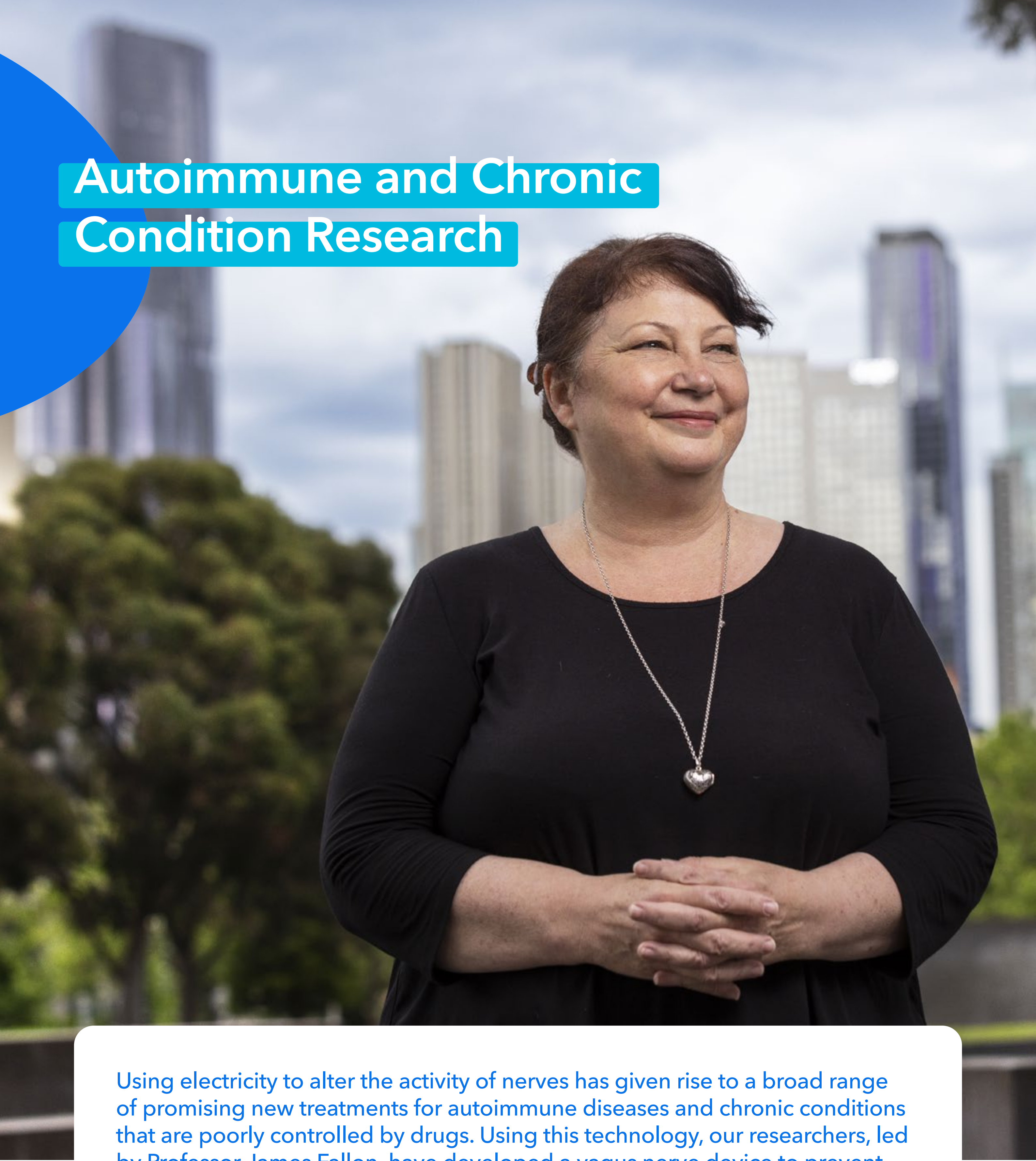
Deep brain stimulation (DBS) uses electrodes inserted into specific regions of the brain to deliver therapeutic electrical stimulation for the treatment of Parkinson's disease. Pre-clinical research was completed this year into the characteristics of the ERNA brain signal and how it can be used to guide electrode insertion into the correct location during surgery.

Additional studies investigated the performance and stability of new electrode coatings and found that conductive hydrogel coatings significantly improved long-term recording of neural activity in the brain. Our researchers were invited to publish this data in Frontiers in Neuroscience.

Meet the team

Led by Professor James Fallon, the pre-clinical DBS team comprises Dr Tomoko Hyakumura, Dr Joel Villalobos, Dr Wendy Adams, Michael Warburton and Professor Rob Shepherd. Key collaborators include Dr Ulises Aregueta-Robles and Professor Laura Poole–Warren from UNSW.

Autoimmune and Chronic Condition Research



Using electricity to alter the activity of nerves has given rise to a broad range of promising new treatments for autoimmune diseases and chronic conditions that are poorly controlled by drugs. Using this technology, our researchers, led by Professor James Fallon, have developed a vagus nerve device to prevent the recurrence of Crohn's disease; and are developing similar devices to reduce inflammation in rheumatoid arthritis, and lower blood sugar levels in type 2 diabetes, in addition to a peripheral nerve device to improve bladder control.

Breaking free of drug treatments for rheumatoid arthritis

For nearly half a million Australians, the debilitating pain and swollen joints caused by rheumatoid arthritis makes basic tasks like holding a coffee cup or turning on a tap almost impossible. A new groundbreaking treatment being developed by our researchers is now giving hope to those suffering from the chronic condition.

Hope that a normal life free from pain and medication may be on the horizon.

Having suffered from rheumatoid arthritis for over 22 years, Karen Down has tried every treatment available to her. 'The medication makes the pain bearable most of the time, but when I have a flare-up it's a struggle to do anything. Some days my joints are burning hot, stiff and swollen. I find it very hard to walk. I can't put my car key into the ignition,' Karen said.

The cocktail of drugs Karen needs to take has severely restricted her life and caused concerning side effects, more so in the last few years. 'The medication has pretty much destroyed my immune system. During COVID I've had to avoid people most of the time. It's been awful.'

Karen says she will be first in line to test a new medical device under development at the Bionics Institute to provide a drug-free treatment for rheumatoid arthritis.

Karen's niece Dr Sophie Payne is leading the research at the Bionics Institute, which could help her aunt in the future. Dr Sophie Payne and her team have developed a device that uses electricity to stimulate a nerve in the body that triggers the body's natural healing response to the damaging inflammation caused by rheumatoid arthritis.

The new treatment, which would remove the side effects caused by drug treatments for rheumatoid arthritis, will move into clinical trials soon.

Combating inflammation with electricity

In rheumatoid arthritis, the body attacks its own tissues, causing damage to the lining of the joints and painful swelling. Although a range of drug therapies are available, they can cause very unpleasant side effects and around 40% of patients don't respond to treatment.

The vagus nerve, which runs from the brain to the gut with branches to almost every organ, including the heart, lungs, liver and pancreas, controls many processes in the body. One of those processes is the body's immune response. If the vagus nerve detects inflammation in the body, it transmits a signal to start an anti-inflammatory response.

Bionics Institute researchers are developing a medical device that stimulates the vagus nerve to activate the body's natural healing processes and suppress the damaging inflammation caused by rheumatoid arthritis. The tiny piece of technology – the size of a thumbnail – is inserted onto the vagus nerve at abdomen level via keyhole surgery and is powered by a battery that sits under the skin at hip level.

When this technology is available to patients, it will provide a set-and-forget treatment for the debilitating disease without the side effects of drug treatment.

Research report

Preventing recurrence of Crohn's disease

In 2015, the Bionics Institute received significant funding from the US Government's Defense Advanced Research Projects Agency to develop a bionic therapy for the treatment of inflammatory bowel disease. The funding facilitated the development of new technology that provides long-term electrical activation of the abdominal vagus nerve, a key nerve involved in the body's natural anti-inflammatory reflex.

Within just 4 years, the research team, then led by Professor Rob Shepherd and Professor John Furness designed, tested and validated a prototype device ready for a first-in-human clinical trial. Around 80% of people with Crohn's disease, characterised by inflammation of the gut, eventually need surgery to remove sections of the bowel if drug treatments stop working. This new medical device uses electricity to stimulate the vagus nerve that runs from the brain to the gut and controls the body's natural anti-inflammatory response. Powered by a small battery, the device will stop damaging gut inflammation, prevent the need for further surgery and transform the lives of people living with Crohn's disease.

Research highlights

This year, an active clinical trial team was established, and the project was granted human ethics approval at the Austin Hospital Melbourne to start a pilot study in Crohn's disease patients. The manufacture of clinical grade devices was completed and they are ready to be implanted into patients following bowel resection surgery as soon as COVID-19 restrictions on elective surgery are lifted.

Meet the team

Led by Professor James Fallon, the Crohn's disease team comprises Dr Sophie Payne, Owen Burns, Ross Thomas and Professor Rob Shepherd. Key collaborators include Professor John Furness, Professor David Grayden, Dr Martin Stebbing, Professor Bob Jones, Mr Graham Starkey, Mr David Proud and Associate Professor Peter De Cruz.

Research report

Reducing inflammation in rheumatoid arthritis

Dr Sophie Payne's team is working on a revolutionary new treatment for rheumatoid arthritis. Based on the technology developed for Crohn's disease, the new device will stimulate the vagus nerve to kick-start the body's natural anti-inflammatory response in a similar way. This in turn dampens the inflammation causing joint pain and stiffness, allowing people with rheumatoid arthritis to move freely without constant pain.

In contrast to vagus nerve treatments for rheumatoid arthritis trialled by other research institutes, this device is positioned on the vagus nerve in the abdominal cavity, rather than at neck level. This means that unwanted side effects to the heart and lungs are avoided. In addition, the device is powered by a battery that sits under the skin at hip level and only needs to be changed every 10 years, which means it is a set-and-forget treatment.

Although a range of drug treatments is available for rheumatoid arthritis, they can cause unpleasant side effects and nearly half of patients with rheumatoid arthritis don't respond to treatment. This new device will provide a drug-free treatment that will give people with rheumatoid arthritis a new lease on life.

Research highlights

This year we completed a study funded by the Bionics Incubator Fund that showed in a pre-clinical model of rheumatoid arthritis, abdominal vagus nerve stimulation significantly improved limping, inflammation and ankle swelling. This data is being prepared for publication and has formed the basis of a divisional patent.

Meet the team

Led by Dr Sophie Payne, the Rheumatoid Arthritis team comprises Professor James Fallon, Dr Erol Harvey and Robert Klupacs. Key collaborators include Associate Professor Evange Romas.

Research report

Lowering blood sugar levels in type 2 diabetes

Stimulation of the vagus nerve is also under investigation by our researchers to develop a drug-free treatment that activates the body's natural processes to treat type 2 diabetes. The aim of the research is to develop a medical device that activates the pancreas to release hormones and lower blood sugar levels. The device will be implanted using keyhole surgery and connected to a remote control that can be used to switch on stimulation after eating to control blood sugar levels and improve the health of people living with type 2 diabetes.

Despite advancements in drug therapies, type 2 diabetes is poorly controlled in many people, who are unable to keep their blood sugar levels within a healthy range. In addition, common treatments are often inconvenient to administer and can cause unpleasant side effects. A new drug-free treatment for type 2 diabetes will not only benefit patients but also reduce the economic burden of the disease.

Research highlights

Using efferent vagus nerve stimulation or 'eVNS', we have shown that it is possible to reduce blood glucose levels in pre-clinical models during a glucose challenge test. This also remained equally as effective after 5 weeks of implantation of the eVNS device. This data is under review for publication and has contributed towards the filing of a PCT patent, which will protect the invention in a large number of countries. Further work is currently underway to modify the eVNS protocol so it can be delivered by existing clinical grade commercially available stimulators.

Meet the team

Led by Professor James Fallon, the Diabetes team comprises Dr Sophie Payne, Dr Tomoko Hyakumura and Dr Joel Villalobos. Key collaborators include Dr Glenn Ward, Professor Johannes Prins, Associate Professor Sofianos Andrikopoulos and Professor Richard MacIsaac.

Research report

Improving bladder control to prevent incontinence

The focus of this research is to develop a new way to both monitor and control bladder function for people with incontinence. We are investigating ways to use electricity to alter the activity of the pelvic nerve to stimulate voiding of the bladder when it reaches a certain degree of fullness. To achieve this, we have patented new ‘sensing’ technology that detects bladder pressure.

Together, these stimulating and sensing devices will allow adaptive control over bladder function and, if successful, patients will never have to worry about incontinence again. This technology will be welcomed by people with incontinence due to conditions such as diabetes, spinal cord injury and multiple sclerosis.

Research highlights

New technology for neuromodulation and recording is being developed for the pelvic nerve with the overarching aim of developing closed-loop control over bladder function for the treatment of urinary incontinence. This large-scale project is funded by the US Government (under the National Institutes of Health’s Stimulating Peripheral Activity to Relieve Conditions (SPARC) program) and this year has seen the successful completion of several milestones.

Firstly, our researchers established that our patented ‘sensing’ technology can detect bladder nerve activity with a high specificity and selectivity of fibre type (sensory vs. motor) and class (fast vs. slow). We also showed that the sensing technology was also able to detect neural activity over 2 weeks, even in the presence of infections such as cystitis.

A second body of work is investigating stimulation strategies to delay or inhibit urination. Early observations indicate that blocking stimulation strategies show promise of delaying urination, and this work will continue into 2022. A new histological method has been developed and optimised for this system and allows the visualisation of the electrode-tissue interface in situ.

Meet the team

Led by Professor James Fallon, the Bladder Control team comprises Dr Tomoko Hyakumura, Jerico Matarazzo and Dr Sophie Payne. Key collaborators include Dr Peregrine Osborne, Dr Calvin Eiber and Professor Janet Keast.

Hearing and Vision Research

The Bionics Institute has a long, proud history in the development of medical devices to diagnose and treat hearing and vision impairment. We continue to seek new ways to improve the cochlear implant, originally developed by the Bionics Institute's founders and, despite lockdown hampering clinical studies, our diagnostic tools for infant hearing and tinnitus have moved onto the next stage of development. Restoring hearing to people with age-related impairment and vision to people with retinitis pigmentosa continues to be a strong focus for the Institute.

The race against time for children with hearing loss

For new parents Ashleigh and Dave, the joy felt after the birth of their son, Charlie, was quickly followed by anxiety when they were given the heartbreaking news that Charlie was partially deaf.

'When we found out Charlie couldn't hear us call his name we were devastated,' said Ashleigh.
'We knew it was a race against time. He needed hearing aids as early as possible to make sure he wasn't left behind at school.'

Charlie was fitted with hearing aids and is now a happy and healthy baby. But his life could have been very different.

Hearing a parent's voice in the first few months of life is crucial for children to develop language. If children with hearing impairment miss out on those early sounds their speech development can be delayed, sometimes permanently.

Researchers at the Bionics Institute are developing a groundbreaking new test called EarGenie™ that indicates if children with hearing issues need a cochlear implant or a hearing aid. Without the early intervention made possible by EarGenie, many children miss out on the treatment they need to hear and learn to speak.

Ashleigh and Dave are passionate advocates for the new technology. 'We will do everything we can to support research that gives deaf children like Charlie the chance to learn to speak and live life to the fullest.'

Shining a light on early intervention

While the current newborn hearing test indicates whether a child has a hearing impairment, it doesn't provide key data about whether a baby can discriminate between sounds. This information is vital for clinicians to decide whether a hearing aid or cochlear implant is necessary.

Some children currently need to wait until they are 9 months old before they can be properly assessed for a hearing device.

EarGenie, a new diagnostic tool developed by researchers at the Bionics Institute, gathers key data by using near-infrared light to measure a baby's response to sound.

A soft band containing small light sources and light detectors is wrapped around the baby's head while they're asleep. When a sound is played, specialised software records the brain's response through changes in the reflected light. Audiologists can then confidently select an appropriate hearing device based on the assessment produced by EarGenie.

Our researchers are continuing to develop the technology for use in audiology clinics so that all children with hearing impairments are given the support they need as early as possible.

Research report

Ensuring hearing impaired infants get the best start in life

Professor Colette McKay's team has developed new technology using near-infrared light (functional near-infrared spectroscopy or fNIRS) to measure the brain's response to sound in infants, called EarGenie™.

Babies born with hearing impairment can miss out on the vital sounds they need to hear at a young age to learn to talk. If the right treatment isn't found in the first months of life, they never catch up with their peers and suffer permanent communication deficit delay. The earlier hearing loss is identified, and the baby provided with either a hearing aid or cochlear implant, the sooner the baby can start learning to speak, and the better language development will be.

For many babies, the current newborn hearing test can indicate how severe the hearing loss is but does not give key information about discrimination between sounds. These babies have to wait until they are 9 months old before audiologists can determine if their treatment is helping them develop language.

The EarGenie test will ensure babies born with hearing impairment are diagnosed correctly and provided with the correct treatment as early as possible. This in turn will give them the ability to hear and distinguish between the sounds that teach them to speak and give them the best chance to succeed in life.

Research highlights

Our clinical study into the EarGenie prototype was halted due to lockdown in the second half of 2020. However, during this time we developed new signal processing strategies that have lifted the accuracy of infant speech detection and discrimination assessment to around 80%. This is great news for the clinical feasibility of EarGenie, and we predict that the ongoing work will lift this accuracy rate even higher.

In the first half of 2021, when lockdown lifted, we were finally able to test a new EarGenie prototype, specifically for infants. This demonstrated that its function is comparable to the fNIRS device we initially used to establish feasibility of the technique in research trials for both adults and children. We are now looking forward to further work on the prototype to prepare it for formal clinical studies.

PhD student Steven Lee is working to improve methods of testing speech discrimination in infants for the EarGenie. He has shown that the cardiac component of the fNIRS signal has useful information that can contribute to the accuracy of EarGenie's tests in infants.

Funding and research communication highlights

Professor Colette McKay's EarGenie work was supported by a Development Grant from the National Health and Medical Research Council. EarGenie was featured on ABC Radio in August 2020 and on Channel 7 News in June 2021.

Meet the team

Led by Professor Colette McKay, the EarGenie team comprises Dr Mikhail Korneev, Dr Julia Wunderlich, Dr Darren Mao, Dr Gautam Balasubramanian, Associate Professor Gérard Loquet, Mica Haneman, Steven Lee and Ishara Paranawithana.

Research report

Individual optimisation for cochlear implant users

Led by Dr Maureen Shader, as part of Professor Colette McKay's hearing research group, our researchers are investigating why some cochlear implant recipients don't understand speech as well as others.

Research highlights

In a longitudinal study, our researchers are assessing three factors that can affect speech understanding with the cochlear implant: uneven or poor survival of auditory neurons in the cochlea; difficulty processing information in the auditory brain pathways; and detrimental brain changes because of deafness. We have recruited 15 study participants so far and published two papers that showed the brain regions that respond strongly when people are listening to a story, and how those differ for very new cochlear implant users.

Our preliminary data comparing two different ways to estimate the pattern of neural survival in the cochlea (electrophysiology and behavioural measurements) show that for many cochlear implant users, there are regions of very poor nerve survival, and that both methods can locate these regions. This work was ably assisted by audiology student Helena Bujalka. Next steps are to use this information to re-programme the implant to avoid these areas in the cochlea to improve speech perception.

Funding and research communication highlights

Dr Maureen Shader's research was funded by a Project Grant awarded to Professor Colette McKay from the National Health and Medical Research Council.

Meet the team

Led by Dr Maureen Shader as part of Professor Colette McKay's hearing research group, the Individual Optimisation for Cochlear Implant Users team comprises Mica Haneman in collaboration with Dr Robert Luke.

Research report

Improving clarity of sound for cochlear implant recipients

Our Optogenetics team, led by Associate Professor Rachael Richardson, is investigating how a combination of electrical and light stimulation could improve clarity of sound for people with a cochlear implant. While electrical stimulation – currently used in cochlear implants – is efficient, current spread from the electrodes distorts the sound. Using light as an alternative to electrical stimulation has the potential to increase precision, as light can be easily directed, and improve specificity, as only nerves that are genetically modified respond to light.

Research highlights

In a world-leading study published in the Journal of Neural Engineering our team showed that by combining light and electricity, genetically modified nerves in the ear could be stimulated with high precision, while retaining the efficiency of electrical stimulation. This shows great promise, not just for cochlear implants, but for a range of medical devices where the key shortcoming is the excessive spread of electrical current away from the target nerves.

Our hybrid neural modulation device consists of individually implanted light emitters and electrodes in an alternating configuration on a flexible base. Clinically, this platform requires a once-off co-application of a genetic construct to modify the neural tissue with a light-sensitive ion channel. The technology has the potential to be applied to hearing and vision restoration, as well as deep brain stimulation and modulation of the peripheral nervous system.

Funding and research communication highlights

Associate Professor Rachael Richardson's research was supported by an Ideas Grant from the National Health and Medical Research Council.

In February 2021, our work was presented as a research poster at the Association for Research in Otolaryngology, USA (virtual meeting) and in March 2021, our research featured in a cover story in The Hearing Journal on the potential advantages and challenges of optical cochlear implants. The article showcased our findings alongside the work of other leading international researchers working in the area of optogenetics.

Meet the team

Led by Associate Professor Rachael Richardson, the Optogenetics team comprises Professor James Fallon, Associate Professor Andrew Wise, Dr Jason Marroquin, Dr Alex Thompson, Dr Niliksha Gunewardene, Elise Ajay and Ajmal Azees. They work in collaboration with Professor Paul Stoddart, Professor Michael Ibbotson, Professor Stephen O'Leary, Professor David Grayden, Professor David Garrett, Dr Patrick Ruther, Dr Anita Quigley, Dr Wei Tong, Dr Emma Brunton and James Begeng.

Research report

Investigating combination treatments for hearing loss

Initially, cochlear implants were provided only to people who were profoundly deaf, but they are now routinely provided to people with partial hearing loss. A combination of stimulation via a cochlear implant and a hearing aid in the same ear has been shown to improve speech understanding, particularly in noisy environments, and to increase the aesthetic quality of sound. However, nothing is known about the physiological mechanisms underlying these benefits.

The aim of our research is to address this knowledge gap by measuring the patterns of neural activity in the auditory centre of the brain evoked by speech sounds. We will then assess how the pattern of neural activity relates to discrimination between the different speech sounds, which is a vital aspect of hearing.

Our goal is to understand how the electrical stimulation from the cochlear implant and the acoustic information amplified by a hearing aid is combined in the brain to produce a unified perception of sound. This will inform clinical decisions on providing this combination to patients to treat hearing loss.

Funding and research communication highlights

Professor James Fallon's team was supported by a Discovery Projects Grant from the Australian Research Council.

Meet the team

Led by Professor James Fallon, the Cochlear Hearing Investigation team comprises Professor Dexter Irvine, Associate Professor Andrew Wise and Dr Alex Thompson. They work in collaboration with Professor David Grayden.

Research report

Restoring hearing loss with therapeutics

Hearing impairment usually arises from damage to the delicate sensory cells within the inner ear that can occur as we age and because of exposure to noise in our environment.

Unfortunately, there is no available treatment to halt the progression of hearing loss or to restore any lost hearing function that has already occurred. The only available options are hearing aids and cochlear implants. While these devices can provide significant benefits to people, they do not treat the underlying cause of hearing loss.

Research is underway at the Bionics Institute to change this reality. We are developing a world-first treatment for hearing impairment using nanotechnology to deliver drugs to the inner ear. Tiny particles that can be loaded with growth factors and delivered into the inner ear will restore the delicate connections between the nerve fibres and sensory hair cells that have been lost.

Research highlights

Current research is underway to validate the technology in pre-clinical models and develop a manufacturing process to enable a future clinical trial of the drug delivery particle system. Our research has shown that our particle-based delivery system can maintain the bioactivity of the growth factors over extended durations and deliver them to the inner ear where they are needed to treat the damaged sensory cells.

Funding and research communication highlights

Associate Professor Andrew Wise's research is supported by grants from the US Department of Defense and the National Health and Medical Research Council.

Meet the team

Led by Associate Professor Andrew Wise, the Hearing Therapeutics team comprises Dr Niliksha Gunewardene, Dr Alex Thompson, Professor James Fallon, Dr Erol Harvey, Robert Klupacs, Associate Professor Rachael Richardson, Dr Yingjie Hu, Dr Victoria McLeod, Dr Jason Marroquin, Dr Mikhail Korneev, Ella Trang and Patrick Lam. They work in collaboration with Professor Frank Caruso, and Dr Sherryl Wagstaff.

Research report

Associating cognitive decline with hearing loss

Although several research groups have reported a possible association between age-related hearing loss and cognitive decline, to date no one knows why it exists and how it manifests itself neurologically. Considering the current growth of the elderly population across the globe and the significant health, social and economic burden cognitive decline is representing, the Bionics Institute has taken the challenge to prepare a feasibility study for investigating the link between hearing loss and dementia. In collaboration with the neurology department of St Vincent's Hospital, we have gathered a team with all the necessary skills, equipment, networks, and access to patients to conduct this research. The main outcome of this project will be to characterise a strong marker for the onset of cognitive impairment so that early diagnosis can be made, and treatments can be started quickly. The choice of bringing both behavioural and neurophysiological evidence to understand the nature of the link between hearing loss and cognitive decline has the potential to change clinical practice by integrating neuroimaging tools in routine checks. The output of this research will directly serve the lives of ageing individuals who are at risk of developing dementia and the clinicians who are trying to help them.

Funding and research communication highlights

In 2021, this new research line at the Institute has focused on funding consolidation and resource gathering, and we are hoping that favourable surroundings will be in place by the first quarter of 2022 to launch a pilot study.

Meet the team

A new team is currently being formed under the leadership of Associate Professor Gérard Loquet.

Research report

Establishing an objective measure of tinnitus

Tinnitus is described differently by everyone who experiences it, and reliance on self-reported symptoms makes diagnosis and monitoring of this condition difficult. Led by Dr Mehrnaz Shoushtarian, our Tinnitus team at the Bionics Institute has developed an objective measure of tinnitus using a non-invasive optical imaging device. The optical imaging device uses a cap to shine near-infrared light (functional nearinfrared spectroscopy or fNIRS) over the head and measure changes in blood oxygen levels in the brain.

The light reflected into the cap provides detailed information on brain activity. This information is recorded on a computer and analysed by researchers, with the aim of setting a baseline for tracking changes in the brain triggered by tinnitus. The aim of this research is to develop a definitive test of the presence and severity of tinnitus to aid diagnosis and develop potential treatments.

Research highlights

In November 2020, we published our findings from an initial study showing fNIRS is a viable technique for measuring tinnitus-related brain activity. Using machine learning to combine different fNIRS signal features, we showed high accuracy in classifying individuals with tinnitus from controls and individuals with mild vs. severe tinnitus. Our paper received worldwide interest from media and scientific news websites and since then we have been approached by over 250 patients with tinnitus from around the world expressing interest in taking part in our study.

In 2021, we collected further fNIRS data from individuals with tinnitus and healthy participants, lockdowns permitting. An important application of our objective measure is the evaluation of tinnitus treatments. We have therefore initiated discussions with a broad range of collaborators undertaking development of a range of potential tinnitus therapeutic approaches.

The next steps are to refine our objective measure by combining physiological measures including heart rate and skin conductance with fNIRS signals recorded from the brain. We are now continuing our data collection to further refine our algorithms.

Funding and research communication highlights

Funding was received from the 2020 Medical Device Partnering Program for an objective tinnitus measurement system. Presentations were made to the Victorian Lions Club in February 2021, the University of Melbourne Audiology Department Seminar Series in March 2021 and the Swinburne University Industry 4.0 Seminar Series in April 2021.

The research garnered a lot of media coverage, including Digital Planet (BBC World Service), Tinnitus Talk Podcast, Verywell Health, Channel Nine News, Channel Seven News, Inverse, ANT, New Scientist and Swedish Public Radio.

Meet the team

Led by Dr Mehrnaz Shoushtarian, the Tinnitus team comprises Michelle Bravo, Shreyasi Datta and Professor James Fallon.

Research report

Second generation Australian bionic eye clinical trial

In 2021 the bionic eye program completed its 2-year feasibility study of a second-generation bionic eye. In collaboration with the Centre for Eye Research Australia and CSIRO, we successfully demonstrated that this device is safe and provides significant improvement to quality of life and functional vision for four recipients. The results have been published in the clinical ophthalmology journal, Translational Vision Science and Technology, and shows that the system encourages more independence, social interactions, and awareness of the environment.

This bionic eye device is most suitable for people suffering from the later stages of inherited retinal diseases such as retinitis pigmentosa. In partnership with the Australian medical technology company, Bionic Vision Technologies Pty Ltd, the next step is to initiate worldwide clinical trials ahead of seeking regulatory approval in key markets, subject to additional capital funding.

Funding and research communication highlights

Clinical trial activities and interviews with bionic eye recipients were showcased throughout the year on Channel Seven News, ABC Evenings and in the Herald Sun.

Meet the team

Led by Dr Matt Petoe, the Bionic Eye team comprises Dr Sam Titchener, Dr Jessica Kvansakul and Dr David Nayagam, in collaboration with the Centre for Eye Research Australia research team: Associate Professor Penny Allen, Maria Kolic, Elizabeth Baglin and Dr Carla Abbott.

Staff spotlight

Farewell to Dr Janine Clarey

It is with mixed feelings that we say farewell to Dr Janine Clarey, who retired from the Bionics Institute in 2021. Janine is the epitome of the quiet achiever, and she will be missed very much by her friends and colleagues.

Janine's service to the Institute spans a breathtaking 23 years. In 1987 she was awarded her PhD at Monash University. She joined what was then the Bionic Ear Institute in 1999 as a Research Fellow, specialising in encoding complex sounds and speech within the auditory brainstem.

During this period, she not only pursued her own research work, but also contributed to the development of a number of post-doctorate students – James Fallon, Rachael Richardson and Andrew Wise – who now form the core of the Institute's research team.

After a family break, Janine returned to the Institute in 2010 as a crucial member of the research leadership team, using her extensive research knowledge and acumen to support the Institute as Head of Grants and Research Governance.

Her tireless efforts and commitment have contributed to the successful awarding of multiple NHMRC and other government grants helping to secure the Institute's researchers and mission over the years.

Janine was instrumental in setting up the Institute's clinical research framework and has volunteered her time as one of the Institute's Research Integrity Advisors, playing a key role in helping the Institute be the first medical research institute in Australia to gain ISO 9001 certification.

A respected researcher and colleague, and a passionate and dedicated staff member, she worked hard to make the world a better place for others.

Dr Janine Clarey

Investing in the Future

The Bionics Institute has bold plans for growth and the development of innovative medical device. To realise this plan, we're investing in training the next generation of researchers and ensuring they have access to world-class research facilities.

PhD student spotlight

Following an undergraduate degree in electrical engineering and biomedical science, Elise Ajay's passion for music and keen interest in prosthetics led her to undertaking her PhD working with the Bionics Institute's hearing team in optogenetics. Their project investigates how a combination of electricity and light stimulation can improve sound and enjoyment of music for people with a cochlear implant.

Elise said: 'I thought, wow, that would be amazing to really help people with limited or no hearing enjoy music.' Elise's talent and passion for the future of bionic hearing was quickly recognised as she won the national 2021 'Pitch It Clever' competition, which challenges young researchers to create a short video explaining why their research matters. She attributes this impressive start to her hearing research career in part to her time spent at the Bionics Institute. 'The Bionics Institute is a really conducive environment to research collaboration and learning. The tools, the resources, the training, the support, the environment – all makes this project possible, and helps make me successful.'

Elise Ajay
PhD student

Looking to the future, Elise still has a couple of years before completing her PhD but sees herself continuing in the field of research as there are many different paths that enable her to continue her prosthetics and biomedical engineering interests. 'There's a lot of different things that I want to pursue. Technology is advancing rapidly, so we'll see where it ends up, so that we're hopefully making a positive impact on people's lives.'

> *"The Bionics Institute is a really conducive environment to research collaboration and learning."*

Short placement student spotlight

While completing her Master of Laboratory Medicine degree at RMIT, Maheeka Samayadasa selected one of the Bionics Institute's many short placement opportunities to gain practical laboratory experience in a research setting. Maheeka said: 'I had an exciting opportunity to be involved with something new and was drawn to the Bionics Institute to learn about how their medical device innovation can support and improve people's daily quality of life.'

Maheeka joined the histology team under the supervision of team lead Ella Trang, to support the Institute's research into the function of the inner ear. The project focuses on creating three-dimensional images of the inner ear structure called the cochlea, which can be used as a more accurate way to analyse how it responds to various forms of damage. Since finishing her placement with the Institute, Maheeka has successfully graduated with distinction and is using her new skills as a medical laboratory scientist in a histopathology laboratory.

Maheeka Samayadasa
Short placement student

'As I move on to the next chapter of my professional life, I thank the entire team at the Bionics Institute for helping me excel in my professional career. They are a remarkable set of people with whom I've greatly enjoyed working and who helped me towards my goal of working in cancer diagnostics research,' Maheeka concluded.

> *"They are a remarkable set of people with whom I've greatly enjoyed working."*

Girls in STEM Mentoring Program

The Bionics Institute Girls in STEM Mentoring Program was a huge success this year. Six students from Ivanhoe Girls' Grammar School were mentored by the Institute's leading female research scientists over a 6-month period. The program culminated in a Junior Science Awards of Excellence Ceremony in October.

Dr Fiona Alderson from Ivanhoe Girls' Grammar School said the students have relished the opportunity to work in research with acclaimed female mentors. She said: 'Not only have they had experience in laboratories and other research settings, the mentors gave them a firsthand account of a career for women in science research fields.

'They provided insights from undergraduate entry and experiences to the process of applying for grants and other funding, as well as presenting research finding at conferences. These insights have been invaluable for our students.'

From 2022 the Institute plans to expand this program across more schools, to inspire more young women to work across all STEM-qualified industries and achieve gender equity in STEM in Australia by 2030.

Bridging the gap between research and the clinic

The Bionics Institute is renowned for being at the forefront of medical device innovation. In May 2021, this trend continued with the official launch of a new company, Neo-Bionica Pty Ltd.

Neo-Bionica combines the engineering expertise and state-of-the-art facilities needed to develop medical devices from initial concept to first-in-human prototypes for clinical trials.

Fast-tracking new treatments for people with diseases such as epilepsy, Parkinson's disease and diabetes, Neo-Bionica will create employment and unique training opportunities for the next generation of scientists, engineers, data analysts and mathematicians.

Creating a unique platform that enables scientists, engineers and clinicians to partner with industry partners worldwide, Neo-Bionica will help to grow Melbourne's reputation as a global biomedical powerhouse and expand Australia's global leadership in medical technologies to improve health outcomes for people everywhere.

Investing in world-class facilities

The Bionics Institute laboratories are located in the heart of a busy state hospital, close to our clinical collaborators. The Bionics Institute is a partner in the Aikenhead Centre for Medical Discovery (ACMD) – Australia's first hospital-based biomedical engineering research centre located at St Vincent's Hospital Melbourne. We will be moving into the new ACMD building when it is complete in 2024.

Philanthropy

“We are pleased that our philanthropic support is helping the Bionics Institute move more quickly into clinical trials in different areas.”

/ Neville and Diana Bertalli

Donor spotlight

Creating a lasting impact

The Bionics Institute has received generous research funding from Neville and Diana Bertalli over many years.

Neville said: ‘As a former member of the Board, I have seen at first-hand the real innovation that the Bionics Institute is driving with its medical research. The Institute has always stretched the boundaries of technology.’

Neville spent many years contributing his extensive business knowledge to support the Institute’s mission. We are delighted that Neville’s commitment to being a Board member has also led to the Bertalli family giving long-term philanthropic support.

Diana and Neville have helped make a big difference through the Bertalli Family Foundation by establishing and continuing support for the Bertalli Research Fellowship. This was initiated in 2018 to support the work of Professor James Fallon, a world-class researcher and the Bionics Institute’s Research Director.

‘Di and I have been delighted to support Professor James Fallon. His research in neuro-stimulation is leading the Bionics Institute into new areas, such as rheumatoid arthritis, diabetes and inflammatory bowel disease.’

Professor Fallon said: ‘The support from the Bertallis has given me the freedom to spend more time with a younger group of researchers, helping and encouraging them. It has allowed us to take greater risks and move our technology into new disease areas. I am proud to be the holder of the Bertalli Research Fellowship.’

Neville said: ‘We are pleased that our philanthropic support is helping the Bionics Institute move more quickly into clinical trials in different areas. My involvement in business over many years has shown me the importance of innovation and getting new products to market that can transform people’s lives.’

Diana and Neville Bertalli’s inspiring commitment to helping others through supporting medical research has had a major impact on the Bionics Institute that will last for years to come. We thank them for their generosity.

> *“The support from the Bertallis has given me the freedom to spend more time with a younger group of researchers, helping and encouraging them. It has allowed us to take greater risks and move our technology into new disease areas.”*
>
> */ Professor James Fallon*

Trust and Foundation spotlight
The Victorian Lions Foundation

Thanks to the generous and ongoing support received from trusts and foundations, such as the Victorian Lions Foundation, our researchers continue to progress their life-changing work.

The Victorian Lions Foundation's longstanding commitment to the funding of Bionics Institute researchers helps provide the long-term security they need to advance their research and further the Bionics Institute's mission: to address the unmet needs of patients living with challenging conditions.

Victorian Lions Foundation secretary John Mitchell said: 'We have enjoyed a longstanding relationship with the Bionics Institute since the Lions supported Professor Graeme Clark's early work to invent a multiple channel cochlear implant.

Since that time, we have been continuous supporters of the Bionics Institute. We are more than proud to be able to stand up and say that Lions Clubs of Victoria and Southern New South Wales play a vital role in contributing to the Bionics Institute's projects.'

Associate Professor Wesley Thevathasan joined the Bionics Institute in 2015 as the first Lions International Neurobionics Fellow, working as a clinical collaborator to develop and evaluate improved deep brain stimulation systems.

In 2018, the team discovered a unique brain signal (ERNA) that could be used to guide and improve the accuracy of how electrodes are implanted. Use of this brain signal also enables surgery to be performed under full anaesthetic, avoiding the need for patients to be awake, which can be a daunting prospect for those who could benefit from this treatment.

This brain signal discovery will transform the way neurosurgeons perform the deep brain stimulation procedure, and also underpins an advanced and adaptive system that can respond to patients' changing symptoms.

In 2021, funding from the Victorian Lions Foundation supported Associate Professor Gérard Loquet, who joined the Institute as a leading member of the translational hearing research group, and Professor Colette McKay, group lead and long standing recipient of Victorian Lions Foundation support.

This cross-disciplinary team, comprising audiologists, engineers and scientists, focuses on the translation of hearing instrument innovation and clinical management into commercial or clinical use. The aim of the team is to make a tangible and positive impact on the quality of lives of people of all ages who are living with hearing loss.

The Bionics Institute would like to thank the Victorian Lions Foundation for their generosity. We are extremely grateful for their ongoing support.

“We are more than proud to be able to stand up and say that Lions Clubs of Victoria and Southern New South Wales play a vital role in contributing to the Bionics Institute's projects.”

Community fundraising spotlight

Running for a cause

In September 2020, Cynthia McLarty commemorated her 50th birthday by running 50km and raising over $7500 towards the Bionics Institute's infant hearing research.

Cynthia is a long-time supporter of the Bionics Institute and has often volunteered her time. Cynthia's son Sam was born profoundly deaf and, at 9 months old, became one of the youngest children in Victoria to receive a cochlear implant.

'Sam caught up with other kids and was speaking normally by the age of 4 with the help of his cochlear implant,' said Cynthia.

'We tell other parents that we don't regret it – it was the best thing for Sam. We are so grateful to the Bionics Institute for enabling Sam to talk and live a full, normal life.'

The funds raised by Cynthia have supported the development of EarGenie™, a new hearing test for babies with hearing loss. EarGenie will enable clinicians to select the right treatment as early as possible, giving these children the best chance to hear different sounds and learn to talk.

Cynthia's original goal was to run from her home all the way to Mornington. However, due to strict COVID-19 lockdown restrictions, Cynthia ran the whole distance over 2 days in a circuit that kept her within just 5km of her home.

The Bionics Institute greatly appreciates the incredible support from Cynthia and all those who give their time and energy to support our life-changing research.

We would like to thank Museums Victoria for generously providing the Bionics Institute with free family entry passes for Melbourne Museum, Immigration Museum or Scienceworks. The passes have been shared with our EarGenie trial participants for their support in helping us create a new hearing test that uses light to measure hearing in babies.

Our Supporters

We would like to acknowledge all the individuals and organisations who have supported us this year – your support really does make a difference.

Mr Nick Acquarola
Dr Wendy Adams
Ms Valentina Aksonova
Mr Robert O Albert
Dr Michael Allam
Mr Grant Allison
Mr Duncan Andrews
Mr David Arden
Ms Debra Ashbolt
Mr & Mrs S & L Athan
Mr Emir Badic
Ms Melissa Bartelt-Siladi
Ms M Bartlett
Mr Geoffrey Becher
Dr Yuri Benovitski
Mrs Meg Bentley
Mr Neville and Diana Bertalli
Mrs Noela M Billington
Ms Suzanne Blanco
Mr Trevor Blum
Mr Michael Boone
Ms Jenny Botheras
Mrs Dorothy Bourke
Mr & Mrs Andrew & R Bradey
Mr Denis Brick
Mr Bernard Brickhill
Mrs Corinne Broom
Mrs Marion Brown
Mr James Buck
Miss Joy Buckland
Estate of Mr Robert Bulley
Mr Fin Cai
Mrs Karen Campitelli
Ms Michelle Cappuccio
Ms Natalie Carmody
Mrs Judith M Cassell
Ms Francine Catley
Ms Amelia Cavanagh
Mrs Dulcie Chard
Dr Charles Chen
Dr Janine Clarey
Associate Professor Stella Clark AM
Mr Paul Clarke
Mr Adam Clarke
Mrs Margaret Cleary
Estate of Ms Siew Cleeland
Mr John Cochran
Mrs Mary-Ann Cohn
Ms Jane Cole
Mrs Robyn Compton
Mr & Mrs W H & J T Cook
Mrs Joan Cooper
Ms Madge Correll
Ms Jo Crowston
Mr Ian Cruickshank
Mr Norman Dalton
Mr Geoff Davis
Mrs Joan de Carvalho
Professor David M de Kretser
Ms Suzanne de Pelsenaire
Mr Pamal Dias
Mr Patrick Didenko
Ms Fiona Dinale
Ms Lucy Dinale
Ms Melissa Dineen
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Mr & Mrs Tom & Colleen Donaldson
Ms Helen Donnerborg
Ms Frances Drew
Mr & Mrs Wes & Jane Dunn
Mr Barry Dunn
Ms Samantha Dunne
Mr & Mrs Ian and Lesley Dyson
Mrs Isabella Edgoose OAM
Dr & Mrs Frank Elsworth
Mr & Mrs Leone & Harry Engel
Estate of Dr Brian Roger Entwisle
Mr Tom Evans
Ms Cindy Fairweather
Mr Joshua Farrugia
Mr Michael Faulkner
Mrs M Ann Fazakerley
Belinda, David & Ari Fisher
Mrs Carol Gabbott
Mrs & Mr Julie & Ray Gabelich
Mr & Mrs A & R Gardner
Mr Malcolm Gardner
Mr Alex Gaythorpe
Mr Donald Geddes
Ms Emma Gelsumini
Ms Angela Giannoukos
Mrs Margaret Gibson
Ms Julie Gillespie
Ms Debra Gilligan
Ms Sharon Giovannini
Mr Donald R Girdham
Mrs Inez Glanger
Ms Jenny Gleeson
Dr Ergad Gold
Mr Peter Gover
Mr Michael Green
Ms Lynne Grimes
Mr Scott Hailes
Mr Martin Halacek
Ms Robyn Hall
Ms Helen Hammond
Ms Lainey Haratsis
Ms Christina Hardy
Mrs Jane Hargreaves
Mr Kenneth Harrison
Ms Louise Harrison
Mr James Hassell
Mr Graeme A Haussmann
Mr Luke Headland
Mr Bill Henderson
Ms Clio V Hertzberg
Mrs Rosalie Heymanson
Mr Matthew Hilton
Mr Ross Hocking
K Hogg
Miss Gwen Hotton
Ms Donna Howell
Mr M D Howes
Mr Austin A Hukins
Ms Niela Isherwood
Mr Arpan Jain
Mrs Joan Jobling
Mr Ivor Johnson
Ms Joanne Johnson
Ms Jennifer Johnstone
Ms Yolante Jones
Mrs Lisa Jones
Ms Gail Jones
Mr James Joughin
Mr & Mrs Jim & Enia Kakaflikas
Mrs Bev Kennedy
Mr Thomas Klee
Mr Robert Klupacs
Ms Linda Knowles
Mr Cande Kokalevski
Mr Christopher Koren
Ms Lindy Kulpa
Ms Donna Kutey
Ms Dianne Lacaze
Ms Lindee Lam
Mr Greg Leetham
Ms Sarah Leitch
Ms Elizabeth R Lithgow
Ms Lidia Lowery
Ms Lisa MacLennan
Ms Sue Madden
Mrs M March
Ms Julie Martyn
Mr Sanjay Mattoo
Mrs Lynette Anne McAlister
Ms Elizabeth McCauley
Professor Hugh McDermott
Professor Colette McKay
Mr & Mrs Cynthia, Deane & Sam McLarty
Ms Ann McLarty
Ms Wendy McManamny
Ms Heidi Meehan
Ms Monica Merey
Ms Kate Moore
Mr Terry Moore
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Mr Con Mouratidis
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Mrs Ethel Murchland
Dr Alice Murkies
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Ms Laurie Murphy
Ms Kay Newman
Mr & Mrs J & D Newman
Mr Jie Ng
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Mrs Karen Plant
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Mr Anthony Pyman
Mr & Mrs Steve & Helen Rachcoff
Ms Linda Rallakis
Mr Roger G Randle
Mr Alastair Robinson
Mr Peter Rush
Mr Joe Russo
Mr Colin Safinofsky
Ms Kathleen Sanderson
Mr Donald Sanderson
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Mr Leon Serry
Mr & Mrs Kenneth and Frances Severs
Ms Catherine Sharp
Mr Kevin Sheehan
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Ms Robyn Stokes
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Ms Sharyn Taylor
Ms Katherine Temme
Mr Ewen Templeton
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Mr Paul Walter
Ms Beverley Webb
Ms Jane Westbrook
Ms Kaye Weston
Ms Shirley White
Mr Hayden Whiteside
Ms Nicole Wicks
Mr Angus Wither
Ms Sharon Woodcock
Mrs Ann Wurster
Mr David Wyers
Mrs Grace Zanotto

Bruce Hyams Foundation
Hilton White Estate
Nell and Hermon Slade Trust
Pleasant Charity Pty Ltd
Rallou Pty Ltd (Massey Charitable Foundation)
S.T.A.F - Margaret Robertson Wilson Memorial
The Eirene Lucas Foundation
The Garnett Passe and Rodney Williams Memorial Foundation
The William Angliss (Victoria) Charitable Fund
Victorian Lions Foundation Inc.
Perpetual Foundation – Kevin Darrell Clarke Endowment

We also extend our grateful thanks to those supporters who wish to remain anonymous.

Thank you

External Engagement Committee

We welcomed our inaugural External Engagement Committee in 2021 to drive engagement with our supporters.

John Simpson
Chair

Caroline Chernov

Jim Hayman

Kunal Rastogi

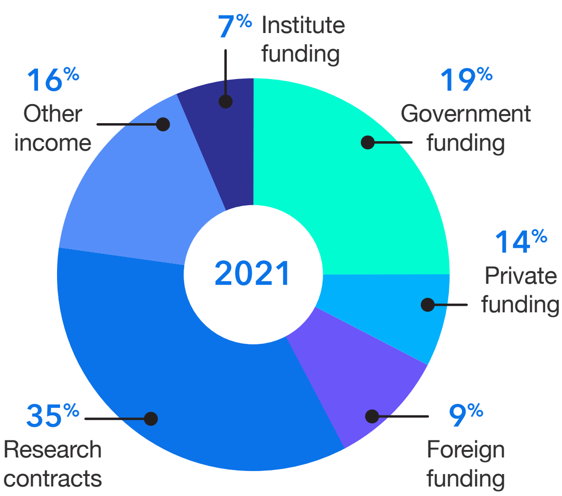
Michael Stillwell

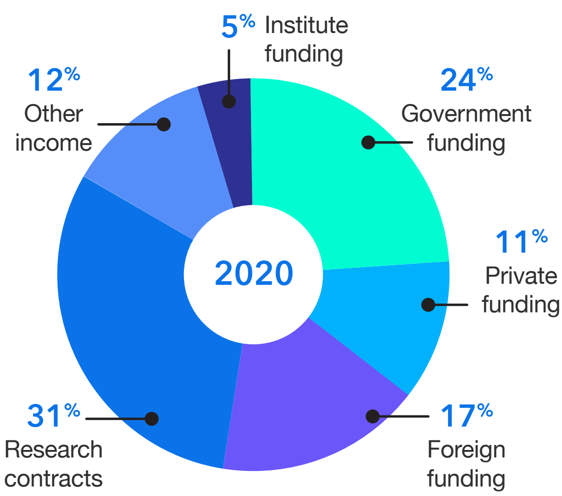
Financial Statement

ABRIDGED FINANCIAL STATEMENT
for the year ended 30 June 2021

CONSOLIDATED INCOME STATEMENT	2021 $	2020 $
REVENUES FROM ORDINARY ACTIVITIES		
Federal Government grants	1,748,382	2,267,862
Victorian Government grants	693,519	657,914
Foreign grants	1,220,327	2,022,562
Trusts & foundations	490,859	837,351
Public fundraising	1,386,774	551,262
Research contracts	4,575,328	3,823,152
Investment & interest income	590,641	522,181
Other income	2,107,238	1,429,319
TOTAL REVENUE FROM ORDINARY ACTIVITIES	12,813,068	12,111,603
less Expenditure on ordinary activities	(11,337,905)	(12,137,349)
DEFICIT ON ORDINARY ACTIVITIES	1,475,163	(25,746)
Gain on sale of property	9,511,007	-
Gain/(Loss) on sale of available-for-sale financial assets	213,295	284,136
Unrealised (loss)/gain on available-for-sale financial assets	2,090,547	(964,859)
Impairment write down of available-for-sale financial assets	(750,000)	-
NET SURPLUS	12,540,012	(706,469)

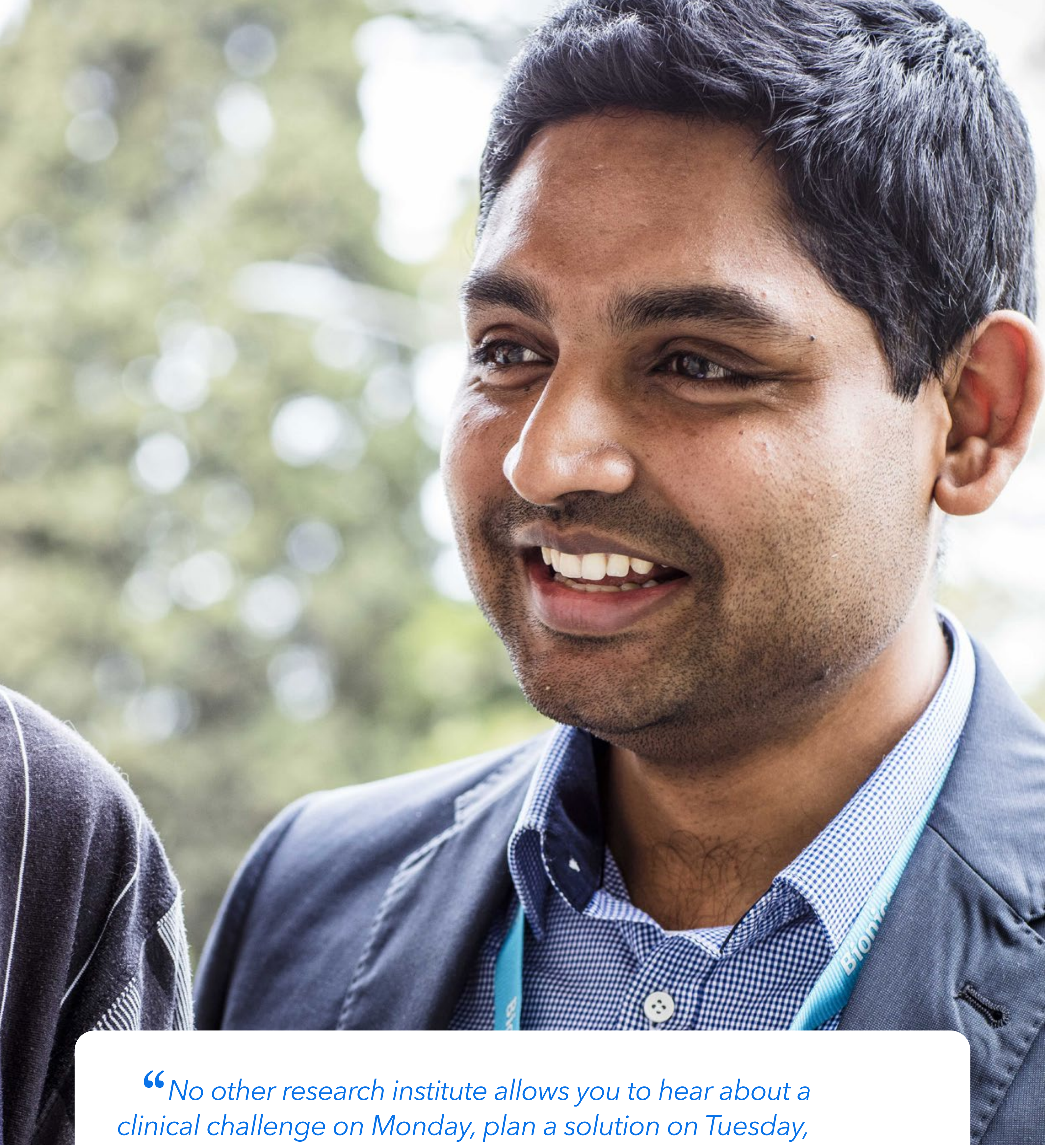
FUNDING OF OUR RESEARCH





CONSOLIDATED STATEMENT OF FINANCIAL POSITION	2021 $	2020 $
Current Assets	7,988,129	6,701,383
Non-Current Assets	26,409,384	12,601,079
TOTAL ASSETS	34,397,513	19,302,462
Current Liabilities	6,935,855	5,177,927
Non-Current Liabilities	1,753,987	956,876
TOTAL LIABILITIES	8,689,842	6,134,803
NET ASSETS	25,707,671	13,167,659
TOTAL INSTITUTE FUNDS	25,707,671	13,167,659

Full audited financial statements are available from the Institute's registered office by request.



“No other research institute allows you to hear about a clinical challenge on Monday, plan a solution on Tuesday, design a prototype on Wednesday, manufacture it on Thursday and get it into the clinician’s hand by Friday. Our access to clinicians, on-site experts, and rapid prototyping facilities is absolutely unique.”

/ Dr Thushara Perera

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