It is my pleasure to introduce the 2020 Annual Report of the Bionics Institute. We have seen a year filled with innovation, as our scientists, engineers and clinical researchers progress their research. Their work would not have been possible without the dedicated staff in finance, governance, IT and administration.

We are a cohesive team at the Bionics Institute, and it is a pleasure to work with such talented and devoted individuals.

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To end the year on a positive note, we were pleased to announce that our Head of Development and Research Translation, Dr Erol Harvey, was appointed as CEO of ACMD, Australia’s first hospital-based biomedical engineering research, development and education centre. Erol will continue to divide his time between his roles at the Bionics Institute and the ACMD. The Bionics Institute is proud to be one of the nine partners of ACMD, which include internationally recognised universities, medical research institutes, and hospitals.

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In October we also celebrated the Bionics Institute becoming the first and only Australian medical research institute to receive a comprehensive ISO 9001 certification covering all operations, research and development processes. This certification reinforces our commitment to research excellence and generating real clinical impact from our work.

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I hope you enjoy reading about all our research projects in this Annual Report.
I have been proud to serve as Chairman of the Bionics Institute over the past year, and witness the progress that has been made in our research. We have seen the first patients in a clinical trial implanted with the seizure monitoring device Minder™, developed from our epilepsy research programme and I look forward to following the progress of this study. Our researchers have made significant progress in developing improvements to Deep Brain Stimulation to treat Parkinson’s disease, and our studies around control of inflammation in Crohn’s disease are moving closer to clinical trials.

The COVID-19 pandemic has shifted much of the world’s focus onto health, and the fact that individuals with a chronic disease are at a higher risk of complications from this novel coronavirus. This has cemented the Institute’s focus on continuing our research into bionic solutions to improve the diagnosis and treatment of many conditions.

I am always impressed that our researchers have the vision to consider new areas of disease where they may be able to have an impact. Our people have the core skills, and through collaboration with other industry leaders, they work to create products that will impact and improve the lives of people with chronic diseases. For example, this year we have seen some promising results from a study into the treatment of diabetes.

It has been a pleasure to work with our CEO Mr Robert Klupacs and the management team as they continue to lead the Institute in the translation of innovative bionic health solutions. I am grateful to my fellow Board members, who provide their extensive expertise and valuable time to support me in my role as Chairman.

The work of the Bionics Institute would not be possible without our donors, and I would like to acknowledge their generosity, particularly in the uncertain environment we have faced in the first half of 2020. I encourage you to learn more about the exciting work underway at the Institute outlined in this Annual Report.
The Bionic Ear Institute was founded in 1986 by one of Australia’s greatest scientists – Professor Graeme Clark AC. During the 1970s, Professor Clark and his team conducted pioneering research and in 1978 the prototype multiple-electrode cochlear implant (‘bionic ear’) was implanted in the first adult at The Royal Victorian Eye and Ear Hospital. Professor Clark was determined for cochlear implant and hearing research to continue in an independent and multi-disciplinary environment, and with this in mind, he founded the Bionic Ear Institute.

Professor Clark continued to lead the Bionic Ear Institute until 2005, when Professor Rob Shepherd AM took over as Director. Professor Shepherd was one of the original members of the University of Melbourne team that created the cochlear implant, and was responsible for the pre-clinical safety and efficacy studies that enabled FDA approval for the device in 1985. During his 12 year tenure as Director, Professor Shepherd drove the expansion of our research into different areas of clinical need including blindness, Parkinson’s disease, epilepsy, and inflammatory bowel disease. To reflect the expansion of research beyond hearing impairment, in 2011, we changed our name to the Bionics Institute of Australia; our areas of research continue to expand to this day.

In 2017, Robert Klupacs was appointed CEO, and brought over 30 years of experience in research commercialisation and bio-technology transfer to the Institute. Robert has driven an increased focus on opportunities and diversification of our funding streams enabling more rapid translation of our research into devices and products that will make a tangible difference to the quality of life of patients around the world.

“Building upon our past expertise, the Bionics Institute has a unique set of skills that combine advanced neurological research with leading engineering designs. I am proud to be leading such a talented and committed team and strongly believe that we are on the cusp of groundbreaking change in addressing the unmet needs of patients.”

— MR ROBERT KLUPACS
About Us

The Bionics Institute is an independent medical research organisation and registered charity, which undertakes innovative research into areas of clinical need to develop medical devices and diagnostic tools which can transform people’s lives. Our staff pioneer new technologies that address the unmet needs of patients living with hearing impairment, neurological conditions, inflammatory diseases, movement disorders and other conditions.

Medical bionics is an exciting area where biology, medicine and engineering intersect. Our scientists understand the physiology of how nerves respond to electrical stimulation, which forms the basis of bionic technologies. They work together with our mechanical engineers, electrical engineers and biomedical engineers to develop safe and effective designs for bionic devices. Clinicians advise and collaborate with them at every step of the process.

In addition to strong partnerships with clinicians, we have forged vital relationships with patient care and advocacy groups as well as individual patients. These strong links between research, clinicians, patients and community groups are critical for the successful development of new devices and treatments.

Our research is underpinned by the Institute’s business model that aims to deliver our technologies into clinical applications, which in turn generates revenue that contributes to funding further research and development. This is enhanced by our strong industry collaborations, increasing capacity for contract research, and ensuring research is clinically-relevant and sustainable.

Our CEO Robert Klupacs leads market strategies for all our research and has directed the establishment of two start-up companies in the past two years. Epi-Minder Pty Ltd was established in 2018 to commercialise a long term seizure-monitoring device to improve the diagnosis and clinical management of those living with epilepsy. Deep Brain Stimulation Technologies Pty Ltd was established in 2019 to commercialise an adaptive deep brain stimulation system for Parkinson’s disease which automatically adjusts therapy according to the changing needs of patients.

“I enjoy working at the Bionics Institute because of the atmosphere; smart people doing amazing things, highly respectful of their co-workers and passionate about improving the health of patients with chronic health conditions.”

— DR EROL HARVEY, HEAD OF DEVELOPMENT AND RESEARCH TRANSLATION

Our Research

The fundamental research that underpins the work we do at the Bionics Institute is aimed at understanding the nervous system’s response to electrical stimulation or using technology to measure symptoms of disease. Our research facilities are housed at two locations – close to the Royal Victorian Eye and Ear hospital in East Melbourne and within St Vincent’s Hospital Melbourne. We make extensive use of our proximity to leading clinician-researchers at these and other major hospitals to ensure that all of our research programs are driven by expert opinion and clinical need.

Hearing Impairment
We aim to improve clinical outcomes for cochlear implant recipients, and those with hearing loss. We use diverse tools – from brain imaging and smart engineering to nanotechnology and gene therapy techniques. See pages 10–15 for more details.

Neurological Conditions
We are developing an implantable medical device that can measure brain activity over long periods of time and has the ability to monitor epileptic seizures outside the clinic. We are also developing a sub-scalp implant to enhance functional recovery after stroke. See pages 16–17 for more details.

Movement Disorders
We have discovered a unique brain signal in patients receiving deep brain stimulation for the treatment of Parkinson’s disease. Using this signal, we aim to improve the outcomes of deep brain stimulation treatment. See pages 18–21 for details.

Inflammatory Diseases
We are researching devices that modulate the activity of peripheral nerves to restore healthy organ function to manage conditions such as Crohn’s disease and diabetes. See pages 22–23 for details.

Electric medicine
Electric medicine involves using electrical impulses to provide therapeutic benefit and this is usually achieved through an implanted device with electrical contacts (electrodes) placed on or near a nerve. Our research involves modulating sensory and motor pathways to the bladder, developing an implant to protect the retina from degeneration, and improving the next generation bionic eye. See pages 24–25 for details.
Hearing Impairment

Optogenetics

Improving the precision of bionic devices

Cochlear implants electrically stimulate nerves in the cochlea enabling people with a profound hearing loss to hear. However, contemporary cochlear implants have limited precision due to the spread of neural activation within the inner ear. This reduces speech understanding in everyday background noise and results in poor perception of complex sounds such as music.

The use of light to activate auditory neurons has the potential to improve the spatial precision of stimulation and therefore improve patient outcomes. The emergence of a new technique called optogenetics now enables scientists to alter the auditory neurons themselves by introducing light sensitive ‘switches’ so that they can now be activated by optical stimulation.

Our optogenetics research program, led by A/Prof Rachael Richardson, along with A/Prof Andrew Wise, A/Prof James Fallon and Dr Alex Thompson, is examining how combining both optical and electrical stimulation can improve the precision of sound information sent to the brain from a cochlea, and the application of that technology to other systems such as the retina where high precision neural stimulation is required.

The future aims of this research program are to validate this new way of activating the auditory pathway using state-of-the-art optogenetic technologies, develop new bionic device technology for delivery of light and electrical current to the cochlea, and the application of that technology to other systems such as the retina where high precision neural stimulation is required.

“I enjoy the applied nature of research at the Bionics Institute. I enjoy having a problem to solve and I love that there is a real chance of a discovery that is game-changing for science and for people with sensory deficits.”

-- A/PROF RACHAEL RICHARDSON

Restoring hearing

A unique drug delivery system to repair hearing loss

Untreated hearing loss not only impacts our ability to communicate, but also leads to social isolation, depression, loneliness, and cognitive decline. Research suggests that people with hearing loss are more likely to develop dementia.

Hearing loss from noise exposure is currently untreatable, and affects people in the military, construction, transport, manufacturing, live music and entertainment industries. Hearing loss usually arises from changes in the inner ear as we age, and exposure to severe noise can result in a permanent loss of hearing.

The current treatment options for people with hearing loss, either hearing aids or cochlear implants, do not repair or treat the underlying cause of hearing loss, which is the damage to the delicate sensory hair cells, nerve fibres and their synaptic connections.

Our hearing therapeutics research team is led by A/Prof Andrew Wise, along with A/Prof James Fallon, A/Prof Rachael Richardson, Dr Niliksha Gunewardene, and Dr Alex Thompson in collaboration with Dr Sherryl Wagstaff, an ENT specialist from Epworth Healthcare. The team is working on the development of a novel technology that may stop the progression of hearing loss, and even improve the hearing loss that has already occurred. The technology uses nano-engineering to create tiny particles that can slowly deliver therapeutic agents into the inner ear in a safe and effective way.

Dr Wagstaff is filled with a sense of confidence that one day soon she will have a hearing loss treatment to offer her patients that will provide life-changing benefits. She has a sense of satisfaction that the collaboration with the Institute has been instrumental in an incredible advancement in hearing impairment research.

In the past year, the team tested the effect of drug therapy on hearing impairment caused by noise exposure, and established how the technology delivered drugs throughout the inner ear. In the coming year, their goals are to continue to determine the safety and efficacy of this unique drug delivery system; develop the processes required for clinical grade manufacturing of the technology, and work towards a first-in-human clinical trial.

“There is great potential for the Bionics Institute to develop technologies to transform lives but the real challenge is for this potential to be realised.”

-- A/PROF ANDREW WISE
**Hearing Impairment**

**Tinnitus and understanding listening effort**

**What is fNIRS?**

Functional near-infrared spectroscopy (fNIRS) is a non-invasive brain imaging technique we are using in our translational hearing research program. Patients wear a cap that shines lights into their head and records the amount of light that is reflected. The amount of light provides a measure of brain activity.

Help millions escape the daily torment of tinnitus

Tinnitus is a persistent ringing, buzzing, or whirring sound in your ears, and affects 10-20 percent of the population. The personal description of what a tinnitus sufferer is experiencing is often the only factor on which a doctor can base their diagnosis and treatment. The lack of an objective method for measuring tinnitus remains a significant hurdle to patient care and the development of new treatments.

A pilot study led by Dr Mehrnaz Shoushtarian, offers hope of establishing a baseline for tracking the complex changes that tinnitus triggers in our brains, and for measuring the severity of individual cases.

Dr Shoushtarian has analysed the brain activity of volunteers, using fNIRS, to measure how different parts of the brain respond to sight, sound, and the absence of both. Results showed that fNIRS is a viable technique for measuring tinnitus-related brain activity and certain features associated with subjective ratings of tinnitus severity were identified.

Over the next 12 months our researchers aim to file a patent, and validate their objective measure of tinnitus in a subgroup of patients with cochlear implants who also have tinnitus. This will provide valuable data from the same individuals with their tinnitus turned ‘on’ and ‘off’.

**Measuring the effort required to understand what you hear**

Increased listening effort means more brain power, is needed to recognize and understand speech, and many believe it is this use of additional cognitive resources that leads to the feeling of being mentally tired or drained when trying to understand speech. Many people fitted with a hearing device still struggle with ‘listening effort’, especially in a noisy environment.

To understand listening effort, PhD student Ms Alicia Carabali is using fNIRS to determine which parts of the brain are activated during easy and difficult listening tasks. Participants listen to recordings of someone talking with background noise whilst wearing the fNIRS cap. The results identify which parts of the brain are activated during the listening task. The goal is to develop a standardised method to measure listening effort, which could be used in clinical practice to help clinicians customize patient-specific treatments. This will also provide beneficial information for hearing aid manufacturers to help improve their technology.

**Infant hearing**

**Giving speech and language skills to babies with hearing loss**

Twenty years ago, newborn hearing tests were introduced in Australia since it was recognised that early access to hearing is crucial for the development of brain networks involved in language development and speech perception.

Unfortunately, for those parents whose babies fail the test, there remains an agonising wait – often of nine months or more – before comprehensive behavioural tests can provide a thorough understanding of their baby’s hearing ability.

At our Behavioural and Brain Imaging Laboratory (BabiLab) our research offers some hope to those parents and their audiologists in that critical first year of life. The EarGenie™ project led by Prof Colette McKay, along with Dr Mikhail Korneev, Dr Michael Eager, Dr Julia Wunderlich, Dr Darren Mao, Dr Boris Savkovic, Ms Emily Jeffreys and Ms Namita Bhojani, are working on a solution for the personalised management of hearing impairment in infants that aims to optimise their language development.

*After 40 years of measuring just the loudness of sound getting through, we now have the capacity to minutely capture a baby’s response to very specific speech sounds,* explains Dr Julia Wunderlich, a Senior Audiologist at Monash Health and part of the EarGenie™ team. *The information this gives us to choose and finesse the right hearing device and therapies for each baby holds enormous implications for their education, their interaction with other children… basically, all the life chances that come from clear communication.*

During the past year, the team finalised an EarGenie™ prototype that measures speech detection and discrimination in babies. The goals for the coming year are to commence the use of this prototype in a clinical trial and further develop the technology based on clinicians’ feedback.
Improving cochlear implants

The cochlear implant has revolutionised the lives of many people with hearing impairment worldwide. However, there is great variation in the degree of benefit gained by individuals and limitations to how the implant is programmed. Two of our projects seek to address these issues.

Understanding why some adults with a cochlear implant do not understand speech well

There are three main factors that have been associated with poor benefit from a cochlear implant: damage within the inner ear may be irregular; the ability of a person to perceive the differences in intensity at different frequencies in a sound may be limited; or the speech perception networks in the auditory cortex may be compromised by changes due to periods of deafness.

Dr Maureen Shader and Prof Collette McKay are investigating these factors in adult cochlear implant recipients. Soon after implantation, each person undertakes three distinct tests to detect each of these factors. These initial findings will then be related to their speech understanding after 12 months of implant use. Different strategies will then be designed to overcome each individual’s underlying cause of poor speech understanding.

This year, the team have validated the experimental protocols, and completed pilot testing on normal hearing individuals and two cochlear implant users. Plans for the coming year are to recruit implant participants to commence this comprehensive study.

Automatic programming for cochlear implants

During cochlear implant programming, the recipient provides feedback to clinicians on the loudness of sounds they hear, in a process that can be imprecise and time consuming. Babies are unable to provide this feedback at all, yet we know that accurate device programming and early access to hearing is vital to language development.

Dr Darren Mao along with Prof Colette McKay and Dr Matt Petoe are developing a quicker, objective method to program cochlear implants without needing a recipient’s verbal feedback. They have measured electrical signals from the brains of cochlear implant users, and developed a novel method to process this information to inform adjustments to the implant’s settings. It is Dr Mao’s hope that this work will be incorporated into a clinical device that sets a person’s cochlear implant program ‘at the push of a button’, and enable better hearing outcomes, especially for babies.

“I am passionate about how different fields of knowledge come together. My work is a great example – how do we combine engineering and biological concepts to solve a clinical problem? The solution, of course, requires many of us to put our minds together.”

— DR DARREN MAO

Understanding the hearing brain

Hearing Impairment

Establishing safe stimulation limits

Contemporary cochlear implants deliver safe electrical stimulation of the cochlea under very strict guidelines to minimise the release of toxic electrochemical by-products and damage associated with metabolic stress of the stimulated neurons.

Current guidelines as to the safe levels of stimulation are based on short-term experiments using electrodes in contact with brain tissue rather than inner ear tissue. These guidelines are regarded as extremely conservative, but must be adhered to until there is rigorous evidence that stimulation levels can be safely changed.

Research led by Prof Rob Shepherd along with A/Prof James Fallon and A/Prof Andrew Wise, aims to define the safe limits for cochlear stimulation and to establish the safety for the next generation of cochlear implant electrodes. Expectations are that the safe stimulation levels for cochlear implants will be significantly greater than those defined by the present guidelines. The research will also provide additional insight into the understanding of the mechanisms associated with stimulation induced neural damage.

This year, we confirmed that long term stimulation above the established limits does not damage auditory nerve function, although a tissue reaction around the electrodes was observed. However, these higher stimulation levels caused undesirable changes to the electrodes’ surface. Future plans are to determine stimulation limits in different models of hearing loss, and to see if the electrode changes can be reduced.

Understanding how the brain combines electric and acoustic stimulation

Cochlear implants were originally used only in people with profound deafness, but are now being used in patients who have substantial residual hearing at low frequencies. These patients have access to information from both acoustic hearing (via their remaining low-frequency hearing, usually in both ears) and electric hearing (via their cochlear implant, usually located in the ear with the worst hearing). Such people are said to have electro-acoustic hearing.

Although stimulation via a cochlear implant and a hearing aid in the same ear has been shown to improve speech understanding, our researchers want to understand the physiological mechanisms underlying these benefits.

Research led by A/Prof James Fallon along with Prof Dexter Irvine, A/Prof Andrew Wise and Dr Alex Thompson is aiming to understand the way in which acoustic, electric, and electro-acoustic stimulation is processed in the central auditory system. The researchers have established models, techniques and protocols to quantify how the brain combines acoustic and electric stimulation. Future plans are to conduct research on how to optimise the integration of acoustic and electric information to provide a unified perception of the auditory environment.

“Understanding how the brain integrates information from electrical stimulation and natural stimulation will become increasingly important as bionic devices, including brain machine interfaces, become more widespread.”

— A/PROF JAMES FALLON
Neurological Conditions

Stroke

Restoring function after stroke with a bionic implant

A stroke occurs when blood flow to any part of the brain is disrupted, and after suffering a stroke, people often have problems with moving, thinking, and talking. Rehabilitation can improve function and reduce disability; however, recovery is frequently incomplete.

Outcomes from physiotherapy can be ‘boosted’ using electrical or magnetic stimulation of affected brain regions, as evidenced by the positive effects of transcranial magnetic stimulation; however, this equipment is bulky and requires administration in a clinic.

Our research team, led by A/Prof Chris Williams along with Dr Matt Petoe and Mr Owen Burns in collaboration with The Florey Institute and St Vincent’s Hospital Melbourne, are investigating a stroke therapy using targeted low-level electrical stimulation. The team have developed a stimulator that can enhance functional recovery and guide management after stroke. This small implant is positioned under the scalp, and uses a novel design of embedded electrodes to therapeutically stimulate the motor cortex. The system requires a minimal surgical approach and has an excellent safety profile.

Importantly, the implant is designed to record EEG brain activity after stroke and during treatment which will provide powerful diagnostic information. This information will enable goal-directed therapy, monitoring of efficacy, detection of adverse events, and assistance with patient care.

The researchers have shown a relationship between motor function, stroke severity, and measured brainwave activity. The next steps are to develop and test a closed-loop stimulator to restore hand and arm function after stroke. The results from this project will enable clinical therapeutic trials to be initiated for patients with middle cerebral artery stroke. Enhancing outcome and optimising management of stroke has great personal and societal benefits.

Epilepsy

Clinical trial provides hope for epilepsy patients

Epilepsy is one of the most common serious neurological diseases after stroke, and affects people of all ages. In the first half of 2020, as part of a world-first trial, six patients were implanted with a new medical device Minder™, with further patients expected to be using the device over the next year.

Minder™ is the culmination of years of research and development led by leading neurologist Prof Mark Cook, Chair of Medicine at St. Vincent’s Hospital Melbourne, and A/Prof Chris Williams from the Bionics Institute, along with colleagues from the University of Melbourne and Cochlear Ltd.

Minder™ is made up of a small, thin and flexible electrode that is implanted under the scalp to allow continuous and long-term recording of brain activity. The brain signals are captured from the implant via a body worn micro-processor and can be stored and then analysed in real time by expert technicians. The approach requires minimal surgery and risk, in much the same way as implantable monitors are currently used to diagnose heart abnormalities.

The data recorded by this device will provide clinicians with an accurate and long-term record of seizures, and an opportunity to tailor drug treatments to individuals in an effective and efficient way. Future trials of new anti-epileptic medications will be greatly enhanced by the use of this system that can objectively monitor seizures outside of the clinic.

Over the past year, our team which also includes Prof Peter Seligman, Dr Yuri Benovitski, Mr Owen Burns and Mr Rodney Millard finalised the implant design for surgery; successfully implanted the device in trial participants; and confirmed that the device can generate clinically relevant data for analysis. In the coming year, the team’s goal is to improve the design and develop the next generation implant following analysis of patient results and clinician feedback.

Our researchers are confident that Minder™ will have a profound impact on the lives of individuals, their carers and families as well as the clinicians who manage their treatment.

“Our stroke therapeutic exemplifies precision medicine. By monitoring the brains response we can personalise treatment and support the patient in their recovery. We hope to see these bionic devices become part of standard clinical care.”

— DR MATT PETOE

They are already working towards extending the capabilities of Minder™ to include features such as remote notification to carers that a seizure has occurred (‘call-home’ function) and prediction of likely times for seizure risk (early warning system).

“We working with the research team at the Bionics Institute has been a life changing experience for me. Having the opportunity to collaborate with specialists in their respective fields, outside of biological science with expertise in medical technologies and materials, has been pivotal in the development of electric medicine.”

— PROFESSOR MARK COOK
Movement Disorders

A biomarker of Parkinson’s disease

Evoked Resonant Neural Activity biomarker

Parkinson’s disease is a common movement disorder that causes debilitating slowness, stiffness, tremor, and imbalance. An established treatment when medication becomes ineffective is deep brain stimulation (DBS), which uses a surgically implanted medical device to deliver electrical stimulation via electrodes to specific areas in the brain that control movement.

Whilst DBS has been a very successful development in the treatment of Parkinson’s disease, there are limitations to the existing therapy; patients must remain awake during surgery to provide feedback to their surgeons; errors in the placement of electrodes in the brain can result in unwanted side-effects or ineffective therapy; and the electrical stimulation delivered is fixed at a constant level determined during surgery and ongoing clinician visits. Unfortunately, current DBS treatments cannot adapt to the ever-changing symptoms of a person with Parkinson’s disease.

The DBS team at the Bionics Institute, led by Prof Hugh McDermott, along with A/Prof Wes Thevathasan, A/Prof James Fallon, Mr Nick Sinclair, Dr Thushara Perera, Dr Joel Villalobos, Dr Tomoko Hyakumara, Dr Wendy Adams, Dr Jonathon Miegel and Dr Kiaran Lawson, are developing improved DBS systems, and to do this, a robust feedback signal, or biomarker, that correlates with Parkinson’s disease symptoms is required.

Senior research engineer Nick Sinclair, in collaboration with neurologist A/Prof Wes Thevathasan, recorded brain signals from over 100 people receiving DBS for Parkinson’s disease and identified a novel biomarker signal that occurs within the target brain region. This signal is known as ERNA – Evoked Resonant Neural Activity. There is potential for ERNA to be used as a tool for providing insight into brain network function and it has the key attributes of a dynamic feedback signal for optimizing therapy and surgery.

It provides a means to improve the targeting of the small brain region to be stimulated, enable surgery while a patient is under general anaesthesia, and allow ‘adaptive’ stimulation that responds to a patient’s immediate needs.

A/Prof James Fallon is leading the pre-clinical research into validating ERNA’s use as a biomarker since ERNA must be measurable and stable over extended periods of implantation and recording. Our neurosurgical collaborators are already observing the biomarker during surgeries, demonstrating its potential for improving treatment for those living with Parkinson’s disease. Over the coming year, our aim is to establish the stability of ERNA over long periods of implantation.

Improving deep brain stimulation

Deep brain stimulation (DBS) for the treatment of Parkinson’s disease targets a very small brain region (millimetres) and the stimulating electrodes are sometimes positioned inaccurately during surgery, leading to inadequate therapy and/or excessive side effects.

Patients are usually awake on the operating table while the electrodes are inserted so that clinicians can interact with them to assess if the electrodes are in the right position. This can be a confronting prospect and dissuades some patients who could benefit from the treatment when drug therapies lose their effectiveness.

Research led by Prof Hugh McDermott is developing a device called ADEPT (Assisted Determination of Electrode Positioning and Therapy), which uses the biomarker ERNA, discovered by Bionics Institute researchers with clinical colleagues and described on page 18. ADEPT will be used during DBS surgery to guide electrode implantation and to identify settings to use for ongoing therapy.

Using ERNA the patient can be either awake or under general anaesthesia. As electrodes are inserted into the brain, ADEPT will scan for ERNA and provide information to the neurosurgeon to enable them to position the electrodes in the most clinically beneficial location. Once the electrodes have been implanted, the ADEPT device will then use ERNA measurements to determine the initial stimulation settings to use for ongoing therapy.
Developing adaptive stimulation technology

A personalised treatment for Parkinson’s disease

A major limitation of existing deep brain stimulation (DBS) technology is that, while each patient’s clinical state changes greatly over short and long time spans, stimulation is constant. Consequently stimulation may at different times be insufficient, resulting in poor symptom alleviation, or excessive, resulting in side-effects. In current practice, DBS settings are adjusted only infrequently, as changes require a trial-and-error process involving neurologists relying on expert observations and patients providing feedback.

Our researchers, led by Prof Hugh McDermott, in collaboration with neurologist A/Prof Wes Thevathasan, are developing a so-called ‘closed-loop’ DBS system that adapts stimulation automatically in response to changes in the patient’s symptom state. The biomarker called ERNA, as described on page 18, is ideal to control closed-loop stimulation. Our clinical studies have demonstrated that ERNA is robust and reliable, varies with changes in stimulation settings, and is affected by each patient’s movement state. The ERNA signal is easily monitored using the same electrodes that deliver DBS for Parkinson’s disease treatment.

An effective closed-loop device will not only optimise symptom control and minimise side-effects, but also facilitate personalised programming of DBS systems. This will reduce the burden and cost for people living with Parkinson’s disease, their carers, and clinicians.

Our new system has been named Adaptive Stimulation Technique Upgrading Therapeutic Efficacy (ASTUTE). Our team have developed algorithms for controlling stimulation based on ERNA and we are now poised to proceed to trials of an implantable device containing embedded technology to control DBS automatically.

“I have experience of clinical neurology and research in many areas in the world, and the model that the Bionics Institute has adopted is unique – and demonstrates that incredible things can happen when medical and technical experts from different areas collaborate with a shared mission.”

— A/PROF WES THEVATHASAN

Improving diagnosis of Parkinson’s disease

A novel device to diagnose and monitor the symptoms of Parkinson’s disease

Parkinson’s disease has four main symptoms: hand tremor, slowness, muscle rigidity (stiffness), and poor balance. Currently, the accuracy of diagnosis is limited by differences in referral habits of general practitioners, restricted availability of specialist neurologists, and inadequate access to health services in remote regions.

Our researchers, led by Dr Thushara Perera, have developed a prototype wearable device called the Bionics Institute Rigidity Device, or BiRD. The BiRD device has sensors to accurately measure stiffness, tremor and slowness of movement. It is worn on the patient’s hand and each assessment takes less than two minutes to complete, giving precise information on rigidity, tremor, and movement speed to support clinical decisions.

An early-stage clinical study has been completed, the results of which showed that the device could distinguish between people with and without disease as well as track effects of therapy. Initial results show promise, however a larger clinical trial across a greater number of patients is required to determine the utility of the device, with the aim of increasing diagnostic accuracy and reducing the uncertainty and apprehension felt by patients. The next stage is to build a demonstrator prototype BiRD device with improved sensors for use in a clinical study.

“No other place 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. The Bionics Institute’s access to clinicians, on-site experts, and rapid prototyping facilities are absolutely unique.”

— DR THUSHARA PERERA
Crohn’s disease

Relief on the horizon for people living with Crohn’s disease

Inflammatory bowel disease (IBD), including Crohn’s disease and ulcerative colitis, is a debilitating, relapsing condition that usually emerges in young adulthood and affects patients throughout their life. There are a number of drugs that are used to treat inflammatory diseases, however these can have variable symptom relief and often have serious side effects.

Our IBD researchers, led by A/Prof James Fallon and Prof Rob Shepherd AM, along with Dr Sophie Payne, Dr Tomoko Hyakumura, Mr Owen Burns, and Mr Ross Thomas, have created a novel device that will therapeutically stimulate the vagus nerve (the major nerve that connects the brain to the gut) to reduce gut inflammation. Our researchers work in collaboration with gastroenterologist A/Prof Peter De Cruz, who is excited at the prospect of being able to prevent the recurrence of Crohn’s disease after surgery.

This research program has also identified a biomarker for gut inflammation that may be incorporated into our device to form a ‘closed-loop’ system. Such a device would constantly monitor the degree of inflammation in the gut and, when an increase in inflammation is detected initiate stimulation. Stimulation would be delivered via an electrode array that contacts the vagus nerve. In this ‘closed-loop’ system, the timing and pattern of stimulation will automatically be adjusted depending on the degree of inflammation in the gut.

During the past year, the team have focussed on the final preparations for a first-in-human clinical trial to test vagal nerve stimulation as a means to reduce inflammation and relapse following surgery for Crohn’s disease. The team have been busy finalising the manufacture and testing of custom devices as well as regulatory approvals.

Researchers had planned to commence their first-in-human clinical trial this year, but it was delayed due to COVID-19. Our hope is to begin that trial in the near future and, based on clinical trial results, develop the next generation device.

“I feel incredibly privileged to be part of such a fantastic team that has taken a proof-of-concept from pre-clinical research, to a world first-in-human clinical trial to assist Crohn's disease patients.”

— A/PROF PETER DE CRUZ

Diabetes

Potential new treatment option for type 2 diabetes

Diabetes is one of the most prevalent chronic diseases in the country, with around 1 million Australians currently diagnosed. The majority (90 per cent) of diabetic patients suffer from the type 2 form of the disease.

With type 2 diabetes, the body becomes resistant to the normal effects of insulin and gradually loses the capacity to produce enough insulin in the pancreas. As a result, the insulin is increasingly ineffective at managing glucose levels in the blood. Sustained high blood glucose in people with diabetes may lead to complications including kidney disease, loss of sensation and pain in feet, legs or hands, and loss of vision.

Initially, type 2 diabetes can often be managed with healthy eating and regular physical activity, however over time most people will also need medication and many will require insulin injections. Despite advancements in pharmacological therapies, nearly half of type 2 diabetic patients fail to achieve adequate glucose control due to difficulties in maintaining consistent doses or the body becoming resistant to the effects of medication over time.

Our research team, led by Dr Joel Villalobos along with Dr Sophie Payne, Dr Tomoko Hyakumura, A/Prof James Fallon and clinical collaborators from St Vincent’s Hospital are working on a new therapy using vagal nerve stimulation to help patients achieve better blood glucose control. A small pre-clinical study has been completed which showed that blood glucose levels can be modified during an oral glucose challenge with stimulation to the vagus nerve, compared to unstimulated controls. The vagus nerve regulates energy metabolism, blood glucose control, and food intake, amongst other things.

In the coming year, we will extend the evaluation of our stimulation method to assess improvement of diabetic symptoms over several weeks. We will study the mechanisms that enable blood glucose control from vagal nerve stimulation, and whether there are side-effects on other abdominal organs such as the liver, kidney or intestines.

“I love the vagus nerve! This nerve contacts most of the organs in your body and we are harnessing it to treat inflammatory bowel disease and diabetes. How cool is that?”

— DR SOPHIE PAYNE
Improving the next generation bionic eye

The Bionics Institute was a key partner of Bionic Vision Australia’s first clinical trial of a prototype bionic eye, successfully completed in 2014 in three patients with retinitis pigmentosa (the most common cause of inherited blindness).

As an extension to this research now sponsored by Bionic Vision Technologies, Dr Matt Petoe leads the Institute team currently involved in a clinical trial of the second generation bionic eye along with a number of collaborating institutions.

The upgraded version of the prototype device has been effective in eliciting visual perceptions in the recipients, allowing them to identify shapes, perceive movement, and undertake unassisted navigation tasks. This next generation device is fully implantable and portable, allowing continued testing of the recipients’ perceptions within our purpose-built laboratory and enabling the recipients to use the device in everyday life.

Ongoing data collection demonstrates that the device is safe and effective at providing functional vision for end-stage retinitis pigmentosa. In the next twelve months our researchers will further refine the video processor and work with Bionic Vision Technologies on the path to commercialisation.

Implant to delay blindness

Retinal degenerative conditions, such as age-related macular degeneration and retinitis pigmentosa, cause the light sensitive cells in the retina to die and result in blindness; currently, there is no effective treatment to promote the survival of these cells.

Chronic low-level electrical stimulation is known to protect the retina from degeneration; however, until now, there has been no clinically-viable means of delivering ongoing neuroprotective stimulation to patients with retinal degeneration.

Our researchers, led by Dr David Nayagam and A/Prof Chris Williams along with Prof Peter Sellgman, Mr Mark Harrison and Mr Owen Burns, in collaboration with colleagues at the Centre for Eye Research (CERA) have pioneered a minimally-invasive therapeutic stimulator that can arrest retinal degeneration without blocking natural vision. Initial preclinical results indicate that our ‘Minimally Invasive Retinal-degeneration Arrestor’ (MIRA) protects against progressive vision loss in a genetic vision loss model.

Work over this past year has seen researchers finalise the design of the MIRA eye implant and complete the pre-clinical safety and efficacy tests; two patents have also been filed. Working with our clinical and surgical colleagues at CERA, our goal is to commence a first-in-human clinical trial in retinitis pigmentosa patients in the near future.
Collaboration is fundamental to our progress and key to the ongoing development of innovative technologies at the Institute. We are very proud of our history of partnerships with some of the world’s leading universities, research institutes, hospitals and commercial entities.

Our research collaborators
— ARC Centre of Excellence in Convergent Bio-Nano Science and Technology, Australia
— Centre for Eye Research Australia (CERA)
— Charlie Hospital, Berlin
— Data61
— Florey Institute of Neuroscience and Mental Health
— Hearing Australia
— La Trobe University
— Monash University
— Oxford University
— Swinburne University
— The University of Melbourne
— The University of New South Wales

Our clinical collaborators
— Alfred Health
— Austin Health
— Cabrini Health
— Epworth Healthcare
— Royal Melbourne Hospital
— St Vincent’s Hospital Melbourne
— The Royal Victorian Eye and Ear Hospital
— Taralye

Our networks
— ACMD
— Association of Australian Medical Research Institutes
— Convergence Science Network
— Melbourne Academic Centre for Health (MACH)
— Medical Device Partnering Programme (MDPP)
— Neurosciences Victoria
— Veski
— Victorian Platform Technologies Network (VPTN)

Our commercial collaborators
— Bionic Vision Technologies
— Cochlear Ltd
— Deep Brain Stimulation Technologies Pty Ltd
— Design + Industry
— Epiminder Pty Ltd
— Hear and Say
— Polyactiva Pty Ltd
— PT Group Coatings LLC

We aspire to create an environment in which our students can cultivate their skills with guidance from dedicated supervisors who are world-class researchers. As the students are integrated into an existing research team, they are expected to work cooperatively and to the highest scientific standards. It truly is an immersion into the day-to-day working lives of scientists, engineers and clinicians conducting research and development at the Institute.

Our current PhD students are Ms Alicia Carabali, Mr Steven Lee Onn Wah, Mr Yutian Ma, Mr Ishara Paranawithana, Mr Sam Titchener, Mr Michael Warburton, and Dr San San Xu. Their research studies range from hearing research through to neural signals in the brain and tailoring deep brain stimulation to treat Parkinson’s disease.

During the year, we were pleased to announce Darren Mao was awarded his PhD. Dr Mao is now working full time in the Translational Hearing Research team led by Prof Colette McKay. Dr Mao’s area of focus for his PhD was developing an objective measure of hearing, by recording responses from individuals’ brains using electrodes placed on their scalp. You can read about this project on page 14 of this report.

We also celebrated the announcement during the year that Joy Tan was awarded her PhD. In addition to completing her PhD studies at the Bionics Institute, Joy has been working as a physiotherapist at the Royal Melbourne Hospital specialising in movement disorders. Dr Tan’s thesis studied the effects of medication and deep brain stimulation (DBS) on postural instability in Parkinson’s disease, and she hopes that her findings will improve future therapeutic outcomes.

At the Bionics Institute, we believe it is vital to have students as part of our research teams. We provide opportunities for students with backgrounds in neurosciences, audiology, engineering, medicine, physics, mathematics, psychology, and computer science. They bring fresh ideas and enthusiasm, and have a passion for research. We value their initiative, independence and inventiveness.

“We the Bionics Institute is at the forefront of developing innovative translational medical technologies to improve the quality of life of patients with chronic conditions. The cross-disciplinary approach of the research at the Bionics Institute brings together experts from different fields and backgrounds. This makes the Institute a really exciting place for me to be a part of.”

— MRISHARA PARANAWITHANA, PHD STUDENT
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Thank you to the generosity of our donors

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Nell & Hermon Slade Trust
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The Dabbski Lang Foundation
The Eirene Lucas Foundation
The Garnett Passe and Rodney Williams Memorial Foundation
The Ian Potter Foundation
The Pearson Charitable Trust
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Estate of Ms Siew Cleeland
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Dr Alice Murkies
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Mr Clyde Parker
Mrs Vera Payne
Dr Thushara Perera
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Ms Mrs Karen Plant
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Mr Hayden Whiteside
Ms Anne Wootford
Mr Ian Young
Mrs Grace Zanotto

Our Supporters

Support us

Your donations
At every stage of our 34 year history, our donors have demonstrated their trust in us through their gifts and supported us in transforming people’s lives through research into areas of chronic disease and innovative medical device engineering. Your donations contribute to every facet of the research undertaken at the Bionics Institute. Whether you are an individual, a philanthropic foundation or a company, your gift will bring us closer to making discoveries and breakthroughs. As the world continues to grapple with the economic and social impact of COVID-19, the importance of medical research has become very apparent. For those who are able to offer support, no matter how large or small, all of us at the Bionics Institute would like to thank you.

To register your donation, please refer to our website www.bionicsinstitute.org. You can either click on the “donate” button or donate to a specific appeal listed under “Support us”.

“I have included a gift in my will to the Bionics Institute with the hope of bringing joy to many more deaf children in years to come.”

— BETTY

Planned giving
Remembering the Bionics Institute in your will is a wonderful and practical way of helping to make a real difference. All gifts in wills contribute to our important biomedical research and will help support research projects, laboratory equipment purchases, research fellowships and student scholarships. Having a will that is up-to-date provides you with peace of mind knowing that the security of your family and friends has been assured, and it helps loved ones manage and deliver your decisions with ease during a highly emotional and sensitive time. A will ensures that your assets are distributed the way you want and ensures you can support those causes you were passionate about throughout your life.

A gift in your will is a simple but powerful way to provide support for the causes that matter the most to you. It transforms your will into one of the most potent tools for change there is, with little or no impact on your lifestyle today. If you are considering supporting the Bionics Institute with a gift in your will, we encourage you to contact us on 03 9667 7500 or email us at enquiries@bionicsinstitute.org. Should you wish your request to remain anonymous, we will respect this and acknowledge your gift privately.
## Abridged Financial Statement for the year ended 30 June 2020

### Consolidated Income Statement

<table>
<thead>
<tr>
<th></th>
<th>2020 ($)</th>
<th>2019 ($)</th>
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</thead>
<tbody>
<tr>
<td>Federal Government grants</td>
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<td>Trusts &amp; foundations</td>
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<td>Research contracts</td>
<td>9,623,152</td>
<td>2,387,616</td>
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<tr>
<td>Investment &amp; interest income</td>
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<tr>
<td>Other income</td>
<td>1,429,319</td>
<td>651,979</td>
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<td><strong>Total Revenue From Ordinary Activities</strong></td>
<td><strong>12,111,603</strong></td>
<td><strong>10,472,469</strong></td>
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<td><strong>Less Expenditure on ordinary activities</strong></td>
<td><strong>(12,137,349)</strong></td>
<td><strong>(10,797,008)</strong></td>
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<tr>
<td><strong>Deficit On Ordinary Activities</strong></td>
<td><strong>(25,746)</strong></td>
<td><strong>(324,539)</strong></td>
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<tr>
<td>Gain on sale of available-for-sale financial assets</td>
<td>284,136</td>
<td>276,137</td>
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<td>Unrealised gain on available for sale financial assets</td>
<td>(964,859)</td>
<td>419,479</td>
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<td>Impairment write down of available-for-sale financial assets</td>
<td>–</td>
<td>(250,100)</td>
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<td><strong>Net Surplus</strong></td>
<td><strong>(706,469)</strong></td>
<td><strong>120,977</strong></td>
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### Funding of Our Research

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<tr>
<th>Source</th>
<th>2020</th>
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<tr>
<td>Government funding</td>
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<td>Private funding</td>
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<tr>
<td>Foreign funding</td>
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<tr>
<td>Research contracts</td>
<td>17%</td>
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<tr>
<td>Other income</td>
<td>6%</td>
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<tr>
<td>Institute funding</td>
<td>24%</td>
<td>26%</td>
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### Consolidated Statement Of Financial Position

<table>
<thead>
<tr>
<th></th>
<th>2020 ($)</th>
<th>2019 ($)</th>
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<tbody>
<tr>
<td>Current Assets</td>
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<tr>
<td>Non-Current Assets</td>
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<td><strong>Total Assets</strong></td>
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<tr>
<td>Current Liabilities</td>
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<tr>
<td>Non-Current Liabilities</td>
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<td><strong>Total Liabilities</strong></td>
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<tr>
<td>Net Assets</td>
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<td>13,874,128</td>
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<tr>
<td>Total Institute Funds</td>
<td>13,167,659</td>
<td>13,874,128</td>
</tr>
</tbody>
</table>

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

It is with sadness that the staff at the Bionics Institute learned of the passing of Mr Robert Bulley in September 2019.

Mr Bulley was a supporter of the Bionics Institute for over twenty years.

Mr Bulley was a great admirer of Professor Graeme Clark AC; he followed with keen interest the subsequent diversification of the research that the Institute has undertaken since his first donation. Mr Bulley’s generosity, through his Charitable Fund currently supports A/Prof Andrew Wise’s research into restoring hearing.

We also acknowledge the honour that Mr Bulley and his extended family and close work colleagues received when the late Mr Robert Charles Bulley OAM was awarded the Order of Australia Medal 2020 for service to the community.

At the Bionics Institute, the research we undertake and the breakthroughs that we have accomplished would not be possible without the generosity of donors such as Mr Bulley.

The Institute acknowledges Mr Bulley’s generosity with gratitude, and extends our deepest sympathy to his family and friends.
We believe in developing medical bionics and therapies to transform people’s lives.