MTPConnect

MedTech and Pharma Growth Centre

Annual Report FY2022

31 October 2022

Australian Government
Department of Industry, Science and Resources

Industry Growth Centres


WESTERN AUSTRALIA
IT'S LIKE NO OTHER.

Contents

Foreword from the Chair and CEO

Since establishment in 2015, MTPConnect has played an invaluable role in supporting Australia's medical technology, biotechnology and pharmaceuticals (MTP) sector.

As the COVID-19 pandemic continues to evolve, MTPConnect has continued to deploy funding to foster research and development and cement collaborations and connections between industry and research to bring life-saving medical products from bench to bedside.

Across MTPConnect's operations, we have so far injected $141.2 million into the sector, supporting 184 projects. We're also leveraging industry support, with our investments yielding $827 million in additional industry contributions and flow-on external investment.

Across all our programs and initiatives, MTPConnect has contributed to $1.3 billion flowing into Australia's MTP sector. The overall economic impact of MTPConnect's activities, calculated by applying a benefit-cost ratio of $3.90[1] to reflect the wider economic benefits of medical research, shows a total attributable return of ~$5.1 billion. And we still have more funds to deploy.

Examples of our support for FY2022 include the rollout of the first round of the $19.75 million Clinical Translation and Commercialisation – Medtech (CTCM) initiative, which is supporting the translation of innovative medical devices. The $47 million Targeted Translation Research Accelerator (TTRA) initiative, which is focused on diabetes and cardiovascular disease, has launched two $20 million collaborative research centres – ACADI and ASHRA – and awarded two funding rounds for research projects. And there's more funding to come.

Back in 2017, we provided funding to CSIRO to develop a National Vaccine and Therapeutics Lab in Melbourne, and it was great to see it opened this year by the Minister for Industry and Science, the Hon. Ed Husic MP. The facility now fills a gap in biomedical capabilities for sovereign advanced manufacturing.

MTPConnect was also appointed by the Government of South Australia to deliver the Adelaide Intermediary Program to grow SA's health and medical industry sector by fostering collaboration, strategically building innovation capacity and attracting new talent and opportunity to the state. And our hub in Perth, delivered in partnership with the Government of Western Australia and the University of Western Australia, continues to support stakeholders across the breadth of WA's health and medical life sciences sector.

The pandemic has highlighted the need for health security initiatives, sovereign manufacturing capabilities and supply chain resilience. MTPConnect has secured funding from the Australian Government to develop a national action plan for building end-to-end sovereign manufacturing capability for diagnostic tests. We're rolling out this project in partnership with Pathology Technology Australia.

We've been active on the policy front too, engaging with the sector and the TGA on Australia's regulatory framework for gene, cell and tissue therapies, developed a position statement on stimulating R&D for new antimicrobials and launched a new report on the Australian medicinal cannabis industry.

After two years of pandemic restrictions, we reignited our resolve to re-introduce Australia's MTP capabilities to the world. With a strong message that Australia is 'open for business', we supported the Australian pavilion at the BIO conference in San Diego as co-exhibitor and took 18 Australian companies to the MedTech Conference in Boston, helping our medtech innovators tap into the US market and secure new business opportunities.

Skills gaps and workforce shortages remain a pressing issue for the sector. Through our Researcher Exchange and Development within Industry (REDI) initiative, we are investing in training and skills programs to address key skills gaps in medical product development and commercialisation. This year we launched 11 new industry training courses with seven new industry partners – delivering training, mentoring and industry opportunities to more than 4,000 individuals across Australia. And our highly successful REDI Fellowship Program went from strength to strength with an additional round and 16 new fellows selected for priority industry placements.

With an extended operating runway, expanded teams and more funding to deploy in the coming years, MTPConnect is set to build further on our $1.3 billion contribution to Australia's MTP sector.

Sue MacLeman
Chair

Stuart Dignam
Chief Executive Officer

1 KPMG, *Economic Impact of Medical Research in Australia*, October 2018.

Scope of Report

This Annual Report from MTP-IIGC Ltd, trading as MTPConnect, is provided to the Department of Industry, Science and Resources (DISR) as a contracted deliverable, as detailed in the Funding Agreement signed by MTPConnect and DISR on 18 December 2015 and in variations to the Funding Agreement signed on 16 February 2016, 3 May 2016, 15 January 2019, 22 April 2021, 24 December 2021 and 3 May 2022.

The report relates to the 2021 financial year: 1 July 2021 to 30 June 2022.

During this period, MTPConnect has met or exceeded all milestones and reporting obligations within the Funding Agreement and Variations to the Funding Agreement.

Overview

MTPConnect, the Medical Technologies and Pharmaceuticals (MTP) Industry Growth Centre (IGC), was established in 2015 to champion a sector-led approach to accelerating the growth of Australia's MTP sector. As an independent, not-for-profit organisation, MTPConnect is attuned to the needs of all participants in the sector, allowing it to act as a trusted voice to inform and shape government regulation, public policy and funding. MTPConnect is guided by an experienced Board of Directors and managed by a professional executive team.

The Board of Directors and Senior Management

Sue MacLeman
Chair

Dr Nicholas Cerneaz
Director

Alex Fowkes
Director

Julie Phillips
Director

Dr Douglas Robertson
Director

Stuart Dignam
Chief Executive Officer

Lisa Dubé
Chief Operating Officer

MTPConnect Organisational Structure

*Date: Effective 30 June 2022
Headcount: 33

Notes:

- Stuart Dignam also Co-Chair AAMRNet
- Elizabeth Stares, Director Corporate Reporting and Risk Management, and Director BMTH
- Andrew Bowskill is Director SE QLD and Co-Chair AAMRNet
- Denotes funded by Department of Industry, Science and Resources (DISR)
- Denotes funded by Department of Health's Medical Research Future Fund (MRFF)

BOARD

Sue MacLeman (Chair), Dr Nick Cerneaz, Alex Fowkes, Julie Phillips, Dr Douglas Robertson

EXECUTIVE MANAGEMENT

Chief Executive Officer
Stuart Dignam

EA to CEO and Office Manager
Jenny Devlin

Chief Operating Officer
Lisa Dubé

COMMUNICATIONS

Director Media & Communications
Caroline Duell

- **Senior Manager Communications**
  Deborah Sippitts
- **Communications & Digital Projects Manager**
  Libby Pearce
- **Social Media Specialist**
  Natalie Vella

SPECIAL PROJECTS

AAMRNET

Co-chair AAMRNet
Andrew Bowskill

- **AAMRNet Project Manager**
  Dr Meghana Kulkarni

DIAGNOSTICS INDUSTRY ENGAGEMENT

Director Diagnostics Industry Engagement
Dr Dharmica Mistry

- **Project Officer**
  Jo Glew

CORPORATE REPORTING & RISK MANAGEMENT

Director Corporate Reporting & Risk Management
Elizabeth Stares

STAKEHOLDER ENGAGEMENT

Senior Director Stakeholder Engagement
Vacancy

- **Director SE NSW & ACT**
  Dr Duncan Macinnis
- **Director SE QLD**
  Andrew Bowskill

ADELAIDE INTERMEDIARY PROGRAM

Director Adelaide Intermediary Program
Jo Close

- **Director Innovation and Translation**
  Stephanie Morris
- **Innovation and Translation Intermediary**
  Dana Bell
- **Engagement and Communications Manager**
  Pia Vogrin

WA LIFE SCIENCES INNOVATION HUB

Director SE WA
Dr Tracey Wilkinson

- **Coordinator SE WA**
  Rebekah Craggs

MRFF PROGRAMS

BMTH

Senior Director BMTH Program
Dr Gerard Gibbs

- **Director BMTH**
  Dr Vishal Srivastava
- **Director BMTH**
  Elizabeth Stares

BTB

Senior Program Manager BTB Program
Dr Amelia Vom

- **Associate Project Manager**
  Dr Andionne Parlade

CTCM

Director CTCM Program
Danielle Shand

- **Senior Program Manager**
  Dr Michelle Lam
- **Associate Project Manager**
  Kevin Rajasekaran

REDI

Director REDI Initiative
Jarrod Belcher

- **Project Manager**
  Dr Michelle Low

TTRA

Senior Director TTRA Program
Lauren Kelly

- **Director TTRA**
  Dr Mana Liao
- **Project Manager**
  Dr Erin McAllum

Additional roles recruited in 2022 'after FY22 reporting period':

Director Health and Biosecurity Strategy (Dr Amelia Vom, October 2022)

Associate Project Manager, TTRA (Dr Andionne Parlade, October 2022)

International Markets and Engagement Manager (Tamlyn O'Connor, September 2022)

Associate Project Manager, REDI Initiative (Tori Mynard, July 2022)

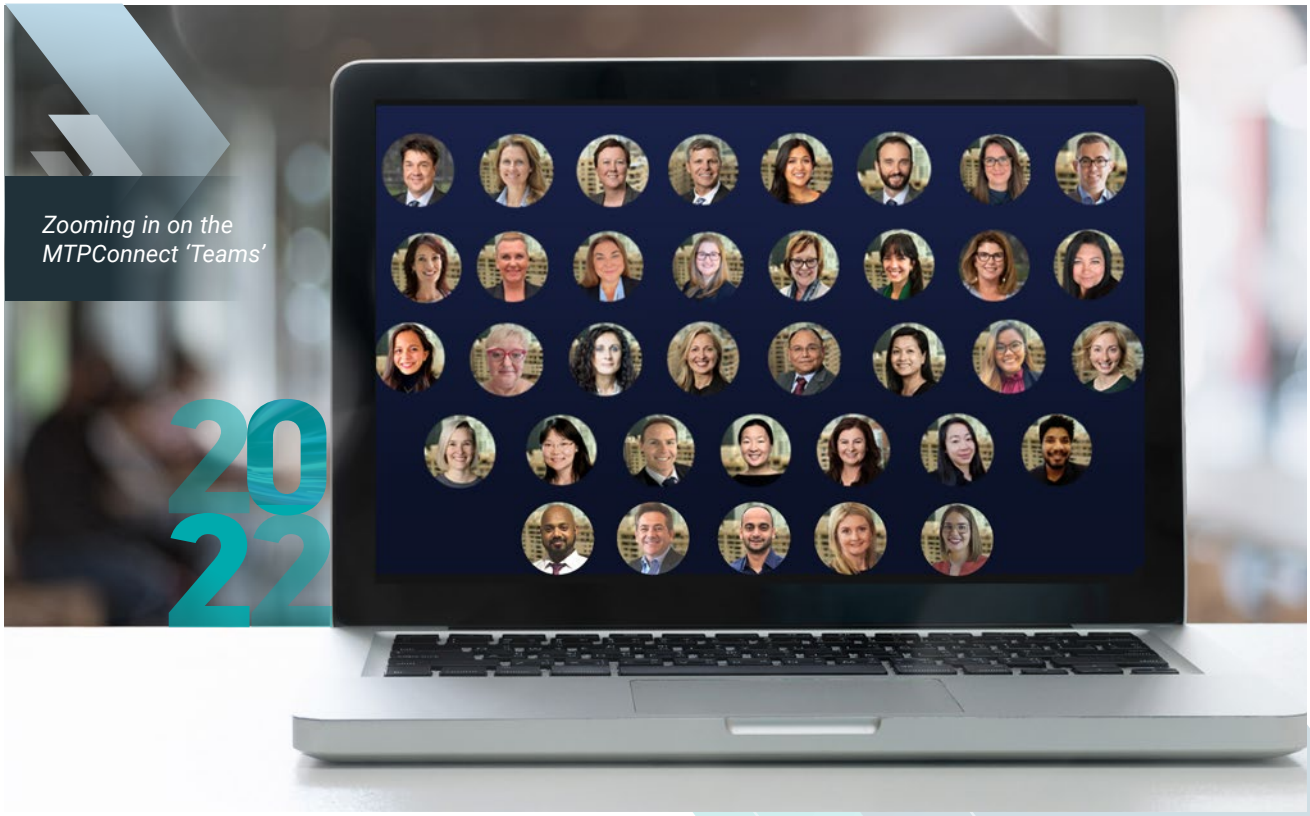
Project Manager, REDI Initiative (Dr Ashwin Dhanasekaran, September 2022)

Intern, Adelaide Intermediary Program (Taochakkreytap Lee, August 2022)

Manager, Stakeholder Engagement WA (Dean Nedelkos, August 2022)

Project Manager, Diagnostics Industry Engagement (Dr Jafar Hasan, August 2022)

Our People



Top row (L–R) *Stuart Dignam, Lisa Dubé, Elizabeth Stares, Andrew Bowskill, Dr Dharmica Mistry, Dr Duncan Macinnis, Jo Close, Dr Gerard Gibbs.*

Second row (L–R) *Stephanie Morris, Dana Bell, Pia Vogrin, Jo Glew, Dr Tracey Wilkinson, Rebekah Craggs, Caroline Duell, Jenny Devlin.*

Third row (L–R) *Dr Meghana Kulkarni, Deborah Sippitts, Natalie Vella, Libby Pearce, Dr Vishal Srivastava, Dr Amelia Vom, Dr Andionne Parlade, Lauren Kelly.*

Fourth row (L–R) *Dr Erin McAllum, Dr Mana Liao, Jarrod Belcher, Dr Michelle Low, Danielle Shand, Dr Michelle Lam, Kevin Rajasekaran.*

Fifth row (L–R) *Dr Ashwin Dhanasekaran, Dean Nedelkos, Dr Jafar Hasan, Tamlyn O'Connor, Tori Mynard.*

To continue to support delivery of an expanded suite of programs, FY2022 saw a change in CEO, an office move and the recruitment of 10 additional staff.

On 31 January 2022, Stuart Dignam commenced as MTPConnect's interim CEO, replacing Dr Dan Grant who left the organisation after three years in charge and contributed signficantly to the organisation's growth. Mr Dignam was formally appointed as CEO on 22 April 2022. In May, Lisa Dubé was appointed as Chief Operating Officer, based in Melbourne.

The MTPConnect head office was moved from Cremorne to Melbourne's bayside on 24 March 2022, located at Level 1, Suite 1.01, 250 Bay Street, Brighton.

MTPConnect recruited three interns this year from the Monash University Biomedicine Discovery Institute Internship Program, who have all been subsequently employed within MTPConnect. A team has been recruited to manage the External Innovation and Translation Intermediary services for the Adelaide BioMed City (ABMC) health and life sciences Innovation District, led by Jo Close. A team has been recruited to undertake the Australian Diagnostics Action Plan project, led by Dr Dharmica Mistry. In addition, two new members of the communications team were recruited and two new team members were appointed to work with Danielle Shand in delivering the Clinical Translational Commercialisation – Medtech (CTCM) program.

Dr Amanda Ruth served as the 2022 Guest of the Chair, the third appointment under this initiative, which provides emerging sector leaders with board-level experiences.

Executive Summary

Executive Summary

As Australia's Growth Centre for the MTP sector, MTPConnect forges stronger connections between research and industry and maximises opportunities for Australians to make scientific and technological breakthroughs that are successfully translated and commercialised.

Focusing on the four objectives of the IGC initiative – increasing collaboration and commercialisation, improving management and workforce skills, optimising the regulatory and policy environment and improving access to global supply chains and markets – MTPConnect works to enhance outcomes from the pre-production, production and post-production phases of the medical products development and manufacturing cycle.

In this way, MTPConnect is building a more resilient and competitive medical products manufacturing sector.

MTPConnect has secured **$182 million** in sector support funds across multiple funding initiatives.

Growth Centre Project Fund (Department of Industry, Science and Resources)

Through the GC Project Fund, MTPConnect has committed $15.6 million across 40 projects, which have achieved demonstrable results (more information on page 46), including:

488 **technologies** being **invented or progressed**

549 **patents, trademark applications** and **licences**

274 **new products** launched

150 **new start-up** companies

1,525 years of direct and indirect **jobs** being created

$257.7 million **investment** flowing into companies developed during the GC projects

Medical Research Future Fund Projects (Department of Health and Aged Care)

MTPConnect has leveraged its successes in operating the GC Project Fund to secure five additional and complementary funding programs through the Medical Research Future Fund (MRFF), worth **$166 million** and supporting 139 projects to date:

- **BioMedTech Horizons (BMTH): $45 million** program/49 projects
- **Biomedical Translation Bridge (BTB): $22.3 million** program/21 projects
- **Researcher Exchange and Development within Industry (REDI): $32 million** program/46 training programs and 47 industry fellowships
- **Targeted Translation Research Accelerator (TTRA): $47 million**/16 research projects/two research centres
- **Clinical Translation and Commercialisation – Medtech (CTCM): $19.75 million**/five projects.

Industry-Focused Grant Reviews

MTPConnect also assists research institutes and small and medium-sized enterprises (SMEs) with pre-submission review of their translational and industry-focused product development competitive grant applications. Since 2015 this has included:

- 227 consortia advised/mentored prior to their application submission
- reviews of 435 MMI, ARC, CRC, CRC-P and GIL grant applications.

This value-add activity has seen grants worth **$330.7 million** awarded to 71 MTPConnect-supported projects (not including matching industry funding).

Western Australia Manufacturing Voucher Program

The MTPConnect Western Australian Life Sciences Innovation Hub's medical products manufacturing program was rolled out in FY2022, delivering:

- **$450,000** in grants to five Western Australian SMEs, leveraging a further **$600,000** in matching industry contributions, injecting more than $1 million into the state's medical manufacturing sector.

Return on Investment – Grant Investments Parlayed into $827 million

Across MTPConnect's funding programs, a total of **$141.2 million** has so far been committed to support 184 projects, with more funding to be deployed in the coming years.

With its focus on increasing collaboration and commercialisation, MTPConnect has been able to draw on multiple industry partners to secure matching industry contributions and substantial flow-on industry investment to amplify the grant funding and help drive projects through the early stages of clinical development and maximise the chances for commercialisation success.

- **40 GC projects** – **$15.6 million** investment has leveraged **$38.8 million** in matching industry and other contributions and generated a further **$257.7 million** in third-party, external investment.
- **139 MRFF projects** – **$125.6 million** investment (so far) has leveraged **$157.6 million** in matching industry contributions and generated a further **$372.9** million in flow-on external investment, including capital raises and other funding support.
- **Five Western Australia manufacturing vouchers** – **$450,000** in grants leveraged a further **$600,000 i**n matching industry contributions.

Across all programs, MTPConnect's **$141.2 million** in strategic funding investments to date has yielded **$827 million** in additional industry contributions and flow-on external investment.

MTPConnect's $1.3 Billion Impact

Combining the **$141.2 million** deployed to date through MTPConnect's Growth Centre, MRFF and Western Australian granting programs, the additional contributions to those projects of **$196.4 million**, the flow-on external investment secured by those projects of **$630.7 million** and the **$330.7 million** from successful grant reviews, MTPConnect has so far contributed **$1.3 billion** flowing into Australia's medical products sector – with more funds still to be deployed.

The overall economic impact of MTPConnect's activities, calculated by applying a benefit-cost ratio of **$3.90**[1] to reflect the wider economic benefits of medical research, shows a total attributable return of **~$5.1 billion**.

These outcomes clearly demonstrate not only MTPConnect's impact but also the effectiveness of the Industry Growth Centres Initiative in supporting the growth of Australia's medical products sector.

The GC and MRFF strategic funding programs enable MTPConnect to foster commercialisation and collaboration and address the skills gaps and key constraints identified across the sector. With significant funding still to be deployed, MTPConnect remains an important funding body supporting the development and translation of Australia's health and medical research into valuable and clinically important medical products.

In September 2022, DISR approved an extension of MTPConnect's operating timeframe to 30 June 2024, with discussions ongoing around additional sustainability options.

1 KPMG, *Economic Impact of Medical Research in Australia,* October 2018.

Highlights FY2022

Highlights FY2022

MTPConnect's vision is for Australia's MTP sector to create more products that reach proof-of-concept stage, achieve greater commercialisation success, increase the number of companies with late-stage product successes and maximise the value of Intellectual Property monetisation events along the way. This vision was developed through a series of wide-reaching sector consultations in 2016 and 2019 with over 600 participants and stakeholders.

To deliver on this vision, MTPConnect brings a value proposition based around a unique ability to take a national, independent and informed approach to:

1. delivering strategic funding that enables key initiatives and programs
2. undertaking direct action to support the MTP ecosystem
3. acting as a trusted and independent voice to inform government on the key issues, challenges and opportunities for the sector.

The 2022 financial year has been another year of substantial achievement for MTPConnect.

MTPConnect-backed National Biologics Manufacturing Facility Opened by Industry Minister

Pictured: From left, the Hon. Ed Husic, Minister for Industry and Science, MTPConnect Chair Sue MacLeman and CSIRO CEO Dr Larry Marshall.

With funding support from MTPConnect, CSIRO's new biomanufacturing facility in Melbourne was opened in 2022.

The development was supported with funding of $1.1 million from MTPConnect's Growth Centre Project Fund and leveraged a further $3.4 million in industry co-contributions and state government funding, bringing the total value of MTPConnect's contribution to the project to $4.5 million.

The facility, which was opened by the Minister for Industry and Science, the Hon. Ed Husic MP, will enable SMEs and researchers to manufacture biologics to the standard required for in-human studies – thereby boosting Australia's capability to manufacture vaccine and drug candidates.

MTPConnect Awarded New MRFF Funding Program

FY2022 saw the launch of MTPConnect's CTCM program, an MRFF initiative aimed at increasing the number of innovative medical devices that progress through the early stages of research and development (R&D) and into early clinical trials. The $19.75 million program, MTPConnect's fifth MRFF program, has already seen Round 1 funding deployed to five projects, with Round 2 well advanced.

MTPConnect Secures New Program in Adelaide

In February 2022 it was announced by the South Australian Government that MTPConnect had been appointed to deliver the External Innovation and Translation Intermediary services for the Adelaide BioMed City (ABMC) Innovation District. Under the $3 million initiative, MTPConnect is working with ABMC and its research, clinical and business partners to build collaborations and realise the innovation potential of South Australia's health and biomedical industry sectors.

Deploying Funds into the Medical Products Sector

During FY2022, MTPConnect announced funding of **$44 million to support 31 projects with an additional $71.6 million in industry contributions** – a total injection into the sector of $115.6 million. These included:

- **BMTH Round 4:** $4.9 million for eight medtech projects, leveraging $6.6 million in contributions from industry for a total of $11.5 million injected into the sector.
- **TTRA Projects Round 1:** $5.2 million for seven diabetes and cardiovascular disease research projects, with an additional $9.1 million in matching industry funds – a $14.3 million contribution to growing the sector.
- **TTRA Research Centres:** $20 million for two new research centres to be established in Australia, attracting substantial co-contributions totalling $34.4 million – a $54.4 million contribution to growing the sector.
- **TTRA Projects Round 2:** $6.7 million awarded to nine diabetes and cardiovascular disease research projects, which attracted an additional $8.6 million in co-contributions – a $15.3 million contribution to growing the sector.
- **CTCM Round 1:** $7.2 million awarded to five projects, which attracted a further $12.9 million in co-contributions – a $20.1 million contribution into the medtech sector.

Medical Products Manufacturing Boost for Western Australia

A new voucher scheme from the MTPConnect Western Australian Life Sciences Innovation Hub, announced in November 2021, has boosted medical products manufacturing in Western Australia. Under the scheme, five Western Australia-based companies were awarded a total of $450,000 to accelerate innovation projects requiring advanced manufacturing capabilities. The companies awarded have committed an additional $600,000 to their projects, contributing more than $1 million into the Western Australian sector.

Boosting Clinician-Led Entrepreneurism

A new REDI program initiative – the Australian Clinical Entrepreneur Program (AUSCEP) – was launched, aiming to develop the innovation and commercialisation skills of Australia's clinicians. Through a competitive process, The University of Melbourne and The University of Western Australia partnership was selected to deliver the program. Based on the successful UK NHS Clinical Entrepreneur Programme, the AUSCEP pilot will be delivered across three states: Victoria, Western Australia and New South Wales.

The REDI Fellowship Program Re-opened

The highly successful REDI Fellowship Program, which supports researchers and other sector professionals to work in industry, opened a fourth round in May 2022. Through three rounds, the initiative has already placed 32 fellows with research-intensive companies including CSL, Cochlear, Telix Pharmaceuticals, Leica Biosystems, Stryker, SpeeDx, Paige.AI, Pharmaxis and Synopsys. With new funding secured from DISR of $1.25 million, as well as $1 million from CSIRO, the latest round saw an overwhelming number of applications and 16 new fellows selected for placement in industry.

Indigenous Advisory Group Formed to Inform Unmet Needs Assessment

MTPConnect's TTRA program established an Indigenous Advisory Group (IAG) to help identify and prioritise diabetes and cardiovascular disease-related unmet health and medical needs of Aboriginal and Torres Strait Islander peoples in rural, remote, regional and urban Australia. The IAG held its first meeting in March 2022.

New Sector Competitiveness Plan Launched

MTPConnect launched an updated Sector Competitiveness Plan (SCP) in Q4, tracking the growth of innovation, productivity and competitiveness of the MTP sector. As well as examining the sector's performance in 2020 and 2021, this SCP provided a progress report at the halfway point of the 10-year plan outlined in our first SCP in 2016. It shows growth across all key economic, commercial and R&D metrics.

Diagnostic Testing Project Announced

In April 2022, we announced a project to develop a national action plan for sovereign manufacturing capability for diagnostic tests. The project is well underway, with staff recruited and a five-person External Advisory Group confirmed. The project is being led by MTPConnect, in partnership with Pathology Technology Australia.

Health Security Project Announced

Additionally in April we announced a new project with DMTC Limited to map the capability and capacity of Australia's health biosecurity ecosystem, including end-to-end supply chains and workforce.

BTB Program Project Activities Conclude

All project activities in the BTB program were concluded on 30 June 2022 and an end-of-program networking and engagement event was held in Sydney in August. The BTB program successfully achieved its key objective to 'nurture, de-risk and develop competitive ventures that are attractive for further funding opportunities' and delivered real outcomes, with 29 new technologies invented or progressed, seven new products launched and 56 new jobs created. Through the $22.3 million BTB program, and with industry contributions and substantial amounts of external development capital raised, a total of $160 million has been injected into Australia's MTP sector. A comprehensive BTB Impact Report has captured a series of powerful case studies highlighting the journey of the 21 innovations supported by the program, as they strived to commercialise their medical products.

MTPConnect Supports the Australian Pavilion at BIO 2022 San Diego

The MTPConnect team of Chair Sue MacLeman, CEO Stuart Dignam and Director of Stakeholder Engagement for Western Australia Dr Tracey Wilkinson travelled to San Diego for the 2022 Biotechnology Innovation Organization (BIO) International Convention, which returned to an in-person event after two years of pandemic travel restrictions. Our Western Australian team worked closely with the Western Australian Government to support WA's life sciences' mission to the US to coincide with BIO. The Hon. Stephen Dawson MLC – Minister for Emergency Services, Innovation and ICT, Medical Research and Volunteering – led WA's mission. In addition, MTPConnect joined AusBiotech as co-exhibitor of the Australian pavilion.

Pictured: MTPConnect's Stuart Dignam and Sue MacLeman at the Australian Pavilion at BIO 22.

Sector Reports

MTPConnect's policy papers and reports are much valued by the sector and this year saw the publication of seven new reports. All reports are available on the MTPConnect website.

MTPConnect REDI Initiative Skills Gap Analysis – October 2021. The third report delivered through the REDI program highlights skills gaps in areas that have become more pronounced due to the COVID-19 pandemic.

Australian Medicinal Cannabis Industry Report – October 2021. Provides an evidence base for the current size of Australia's medicinal cannabis industry, as well as future estimates for the sector.

BioMedTech Horizons Impact Report – November 2021. A case study-based impact report highlighting the progress of the first cohort of medtech projects to complete MTPConnect's BMTH program.

Cell, Gene and Tissue Regulatory Framework in Australia: Stakeholder Perspectives – November 2021. A stakeholder review conducted by MTPConnect for the Therapeutic Goods Administration (TGA).

Medical Technology, Biotechnology and Pharmaceutical Sector Competitiveness Plan – April 2022. A refreshed Sector Competitiveness Plan with extensive input from key MTP sector participants.

AAMRNet Position Statement – May 2022. A report on pricing and reimbursement of novel antimicrobials in Australia, highlighting innovative strategies for bringing new antibiotic treatments to market.

Biomedical Translation Bridge Impact Report – August 2022. Summarising the progress and impact of these projects that have now completed the BTB program.

Guest of the Chair

The Guest of the Chair is a unique workforce initiative aimed at giving emerging sector leaders exposure to a range of board-level activities.

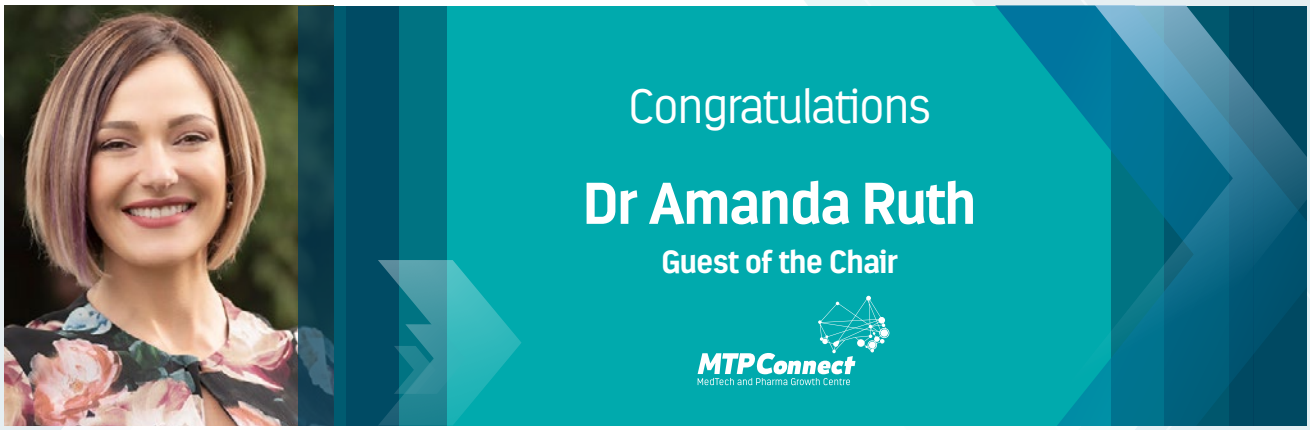
Dr Amanda Ruth, then Head of Policy and Public Affairs at Rare Cancers Australia, was appointed as MTPConnect's 2022 Guest of the Chair. It is the third appointment under this initiative.

MTPConnect held a networking event in July 2021 to connect past and present Guests of the Chair with senior leaders from across the sector. A keynote presentation was made by Catherine Livingstone, then Chairman of Commonwealth Bank of Australia and current Chancellor, University of Technology Sydney, and Director at Saluda Medical. Ms Livingstone was able to reflect on her leadership journey, which included six years as CEO of Cochlear.

Joining the MTPConnect Board and senior leadership team and previous Guests of the Chair, Dr Parisa Glass and Dr Emma Ball, for the virtual event was a range of senior sector leaders, including:

- **Christi Kelsey** (GSK Australia Managing Director)
- **Dr Chris Behrenbruch** (Telix Pharmaceuticals CEO and Managing Director)
- **Susan Martin** (Johnson & Johnson Medical Devices Managing Director)
- **Dr Chris Roberts** (OncoSil Medical Chair and Cochlear Foundation Board member)
- **Dr Anna Lavelle** (Medicines Australia Chair)
- **John Grill** (Chair and former CEO of engineering company Worley)
- **Dr Katharine Giles** (OncoRes Medical Managing Director and CEO)
- **Maria Halasz** (then Cellmid CEO)
- **Dr Megan Baldwin** (Opthea CEO and Managing Director)
- **Dr Peter Devine** (Uniseed CEO)
- **Professor Peter Klinken** (Chief Scientist of Western Australia)
- **Chris Lee** (traditional custodian of the Gulumerridjin People and member of TTRA Research Centre Assessment Panel).

The Guest of the Chair program is all about giving our emerging leaders the opportunity to experience a range of board-level activities, including attending MTPConnect Board meetings over a 12-month period.



Modern Manufacturing Strategy Activities

Modern Manufacturing Strategy Activities

Australian Diagnostics Action Plan Team (ADAPT) Project

MTPConnect has established a Diagnostics Industry Engagement team to deliver a national action plan for sovereign manufacturing capability and supply chain resilience for diagnostic tests. MTPConnect, working with Pathology Technology Australia, is developing a plan for building end-to-end sovereign manufacturing capability for diagnostic tests, establishing Australia as a regional centre of excellence for diagnostic technology manufacturing. The plan will be developed over 12 months through extensive consultation and a rigorous examination of the diagnostic testing landscape to identify gaps, opportunities and strategies to nurture world-class research and development. An interim report has been developed that focuses on the preliminary findings from the stakeholder engagement process at the six-month mark. The plan will be outlined in a final report to be published in April 2023, and will highlight the domestic capabilities that will build resilience for critical products and examine supply chain and other barriers to Australia producing in vitro diagnostic (IVD) devices reliably and sustainably. For more information see page 43.

Boosting Health Biosecurity Capability

This year, with a focus on health biosecurity capability, MTPConnect announced it is funding a new project with DMTC Limited to provide a picture of the capability and capacity of Australia's health biosecurity ecosystem. The project will use artificial intelligence (AI) and machine learning to create a comprehensive digital database of sovereign capability and capacity in the health biosecurity sector – focusing initially on antimicrobial resistance.

Biomanufacturing Growth Centre Project – CSIRO Protein Production

As a Growth Centre Project Fund project, MTPConnect has worked with CSIRO, Monash University, SMEs Telix Pharmaceuticals, CEPI and Sementis, the Victorian Government and a Science and Industry Endowment Fund (SIEF) grant to develop and fit out a biomanufacturing facility at CSIRO's Clayton site in Melbourne.

The CSIRO National Vaccine and Therapeutics Lab, completed in June 2022, is the only facility in Australia available to SMEs and academics for Good Manufacturing Practice (GMP) manufacture of biologics from mammalian cell culture for evaluation in human clinical studies. It is a state-of the-art facility supported by a robust Quality Management System. It means Australian SMEs can manufacture their biologics in Australia. This is faster and more cost effective than manufacturing overseas, allowing more Australian discoveries to make it to clinical trials and into the clinic. More detail is provided in the case study on page 48.

GMP Small Batch Pharmaceutical Products – Ab Initio Pharma

As a Growth Centre Project Fund project, MTPConnect has worked with Ab Initio Pharma, The University of Sydney and ARCS to provide manufacturing capability and local R&D for small batch quantities of pharmaceutical products in a purpose-built GMP environment facility. Ab Initio Pharma is co-located within the Professor Marie Bashir Centre in Camperdown, Sydney. The facility will be fully registered by the TGA and will initially focus on solid-dosage forms, inhalation products and non-sterile product manufacture. The products can then be used in early-phase clinical trials by the medtech and academic sector.

Since the project commenced and Ab Initio Pharma was formed, the company has recruited 10 staff and secured R&D contract formulation work totalling more than $1.5 million.

Western Australia Manufacturing Voucher Program

Under our Western Australia Manufacturing Voucher Program, five companies have been selected to receive vouchers for a total value of $450,000 to accelerate innovation projects requiring advanced manufacturing capabilities. Recipients include:

- **OncoRes Medical:** clinical feasibility of a diagnostic imaging device for cancer surgery
- **Proteomics International:** manufacturing next generation in vitro device to predict diabetic kidney disease
- **SynGenis:** establishing certified oligonucleotide (DNA and RNA) manufacturing capabilities in Western Australia
- **VeinTech:** improving first pass cannulation success with VeinWave
- **VitalTrace:** developing Perth into a precision biosensor development and manufacturing hub.

How MTPConnect is Addressing the Growth Centre Program Objectives

How MTPConnect is Addressing the Growth Centre Program Objectives

The objective of the Industry Growth Centres Initiative is to improve the productivity and competitiveness of six sectors of competitive strength and strategic priority in the Australian economy. To drive connectivity, innovation, productivity and competitiveness in Australia's MTP sector, MTPConnect systematically addresses the four GC objectives: improving collaboration and commercialisation, improving management and workforce skills, optimising the regulatory and policy environment and improving access to global supply chains and markets.

MTPConnect Growth Centre Objectives

1
Improving coordination and collaboration between research and industry, and within industry, to achieve stronger commercialisation outcomes

2
Improving management and workforce skills necessary for sector growth

3
Identifying and acting on opportunities to address regulations and policies that are unnecessary or overly burdensome and impede growth

4
Improving the capability of the sector to engage with international markets and access global supply chains

In addition to benefiting the sector, the projects we support through DISR and MRFF support clinical trials and have direct impact on patients.

Clinical trials

Preclinical and clinical **trials commenced** 796

New patients recruited to clinical trials 2,517

Increase in **patients treated** 240,754

Objective 1: Improving Collaboration and Commercialisation

Team Activities

In addition to delivering strategic funding directly into the sector, MTPConnect assists research institutes and SMEs with pre-submission review of their translational and industry-focused product development competitive grant applications. From 2015 to 2022, MTPConnect has advised 227 consortia, resulting in 71 successful applications and an additional $330.7 million flowing into the MTP sector.

Following introductions facilitated by MTPConnect, a new partnership between Perth-based oligonucleotides manufacturer SynGenis and Sydney-based diagnostic company SpeeDx has led to an investment and ongoing collaboration between the two companies. SpeeDx has a portfolio of kits for detection of infectious disease pathogens and antimicrobial resistance markers, including COVID-19, but faced constrained supply of oligonucleotides, which are critical components. SynGenis operates a facility in Perth's Technology Park Bentley to manufacture oligonucleotides for the Australian and New Zealand market, and international customers. Understanding their capabilities and needs, MTPConnect's Directors of Stakeholder Engagement for Western Australia and New South Wales/Australian Capital Territory, Dr Tracey Wilkinson and Dr Duncan Macinnis, connected the two companies. The partnership is detailed in the case study on page 25 and has evolved into a growing commercial relationship, which is building supply chain resilience and sovereign capabilities.

With MTPConnect's office in Western Australia open to in-person events, the MTPConnect Western Australian Life Sciences Innovation Hub delivered a range of commercialisation and collaboration activities, including Western Australia's 30th INCITE Awards, a Perth Angels MTP-focused pitch night and monthly 'spotlight events', featuring companies from the Western Australia sector, such as OncoRes Medical, Epichem and Argenica Therapeutics Limited (ASX:AGN).

Details of funding awarded under the MTPConnect Western Australian Life Sciences Innovation Hub manufacturing voucher scheme were announced in November 2021 by the state's Deputy Premier, the Hon. Roger Cook. Under the scheme, five Western Australia-based companies have been awarded a total of $450,000 to accelerate innovation projects requiring advanced manufacturing capabilities. Matched with cash co-contributions of $600,000, the initiative is injecting more than $1 million into Western Australia's medical products sector to drive job creation and economic growth. Awardees include:

- **OncoRes Medical:** clinical feasibility of a diagnostic imaging device for cancer surgery
- **Proteomics International:** manufacturing next generation in vitro device to predict diabetic kidney disease
- **SynGenis:** establishing certified oligonucleotide (DNA and RNA) manufacturing capabilities in Western Australia
- **VeinTech:** improving first pass cannulation success with VeinWave
- **VitalTrace:** developing Perth into a precision biosensor development and manufacturing hub.

MTPConnect was appointed to deliver the External Innovation and Translation Intermediary services for the Adelaide BioMed City (ABMC) health and life sciences Innovation District. Under the $3 million initiative awarded by the South Australian Government, MTPConnect will work with ABMC and its research, clinical and business partners to build collaborations and realise the innovation potential of South Australia's health and biomedical industry sectors.

The Adelaide Intermediary Program launched the SA Insights Series in June with MTPConnect's Jo Close in conversation with BiomeBank's then CEO Thomas Mitchell and Co-Founder and Chief Marketing Officer Sam Costello, discussing the journey from clinician to start-up and the company's progress. The second event featured MTPConnect's Dr Duncan Macinnis with speakers Professor Caroline McMillen, Chief Scientist of South Australia, and Professor Tim O'Meara, Government and Research Strategy Manager ANZ at Cytiva, on developing compelling projects for Cooperative Research Centres Projects (CRC-P) submissions.

The GC Project Fund-supported Australian Antimicrobial Resistance Network (AAMRNet) has teamed up with Therapeutic Innovation Australia (TIA) to support research projects targeting antimicrobial resistance (AMR). Earlier this year, an AMR-focused round of the TIA Pipeline Accelerator voucher program provided vouchers to researchers to access National Collaborative Research Infrastructure Strategy (NCRIS) facilities to progress their AMR R&D. This is detailed further on page 42.

We are connecting our website users with the sector by including the Health Horizon Projects Tracker live feeds on MTPConnect's website. The progress of BMTH-funded projects and all Western Australia-based life sciences projects can now be tracked. MTPConnect provided initial funding to Health Horizon through the Growth Centre Project Fund and the company has evolved to become a trusted provider of real-time market intelligence to the sector.

Leveraged Funding

MTPConnect is working to make Australia more effective in translating research into commercial outcomes. Achieving this requires not only effective research and start-up sub-sectors, but a healthy, full value-chain ecosystem. MTPConnect manages the BMTH, BTB, REDI, TTRA and CTCM programs for the MRFF. The BMTH, TTRA, REDI and CTCM programs opened funding rounds this year, resulting in funding of $44 million to support 31 projects, with an additional $71.6 million in industry contributions.

In September 2021, the then Minister for Health and Aged Care, the Hon. Greg Hunt MP, announced funding for seven diabetes and cardiovascular disease research projects through MTPConnect's TTRA initiative. The initiative is supporting new research approaches to improve the prevention, diagnosis, treatment and management of diabetes, cardiovascular disease and their related complications.

In January 2022, MTPConnect announced that two new research centres will be established in Australia, with $20 million committed through the TTRA initiative, delivered by MTPConnect. The new research centres are the Australian Centre for Accelerating Diabetes Innovations (ACADI) and the Australian Stroke and Heart Research Accelerator (ASHRA). Each research centre has been awarded $10 million over four years. Together, the centres have attracted substantial co-contributions from academic and industry partners. They will initially progress 31 research projects addressing diabetic kidney disease, peripheral neuropathy and diabetic foot syndrome, and short-term complications of hypoglycaemia, hyperosmolar hyperglycaemic syndrome (HHS) and ketoacidosis, coronary artery disease, cardiomyopathy and heart failure, and transient ischaemic attack (TIA) or stroke.

In October 2022, MTPConnect and the Minister for Health and Aged Care, the Hon. Mark Butler MP, announced the outcomes of Round 2 of the TTRA Research Projects funding opportunity, with $6.7 million awarded to nine diabetes and cardiovascular disease research projects, which attracted an additional $8.6 million in co-contributions. These projects included research innovations addressing atherosclerosis, cerebrovascular disease, cardiomyopathy and heart failure, as well as mental health and glucose control for those living with diabetes.

This year we also announced almost $5 million in funding for eight highly promising medical technology projects across Australia. The funding – which has attracted additional industry contributions – comes from the fourth round of the BMTH program. This round focused predominantly on the development and manufacture of pre-commercial prototypes that are entering human clinical trials.

MTPConnect has commenced rollout of the new CTCM funding program to identify and nurture high-quality medical device projects with strong commercial potential. The program is focused on Australian SMEs and aims to boost commercialisation of home-grown medical products with funding of between $250,000 and $1.5 million per project across two funding rounds. Five pre-eminent industry partners have been selected as an integral part of the CTCM program – the Medical Technology Association of Australia, the Medical Device Partnering Program, Cicada Innovations, The BridgeTech Program and Therapeutic Innovation Australia.

Case Study: The Chemistry of a Perfect Match for SpeeDx and SynGenis

A new partnership between Perth-based oligonucleotides manufacturer SynGenis and Sydney-based diagnostic company SpeeDx has led to an investment and ongoing collaboration between the two companies.

Pictured: SpeedDx and SynGenis team meet in Perth to discuss oligo supply.

SpeeDx is a privately owned company that specialises in innovative multiplex real-time quantitative polymerase chain reaction (qPCR) solutions for clinical diagnostics. The Sydney-based organisation has a portfolio of kits for detection of infectious disease pathogens and antimicrobial resistance markers, including COVID-19.

In the wake of the pandemic, demand rose for diagnostics along the supply chain, but SpeeDx faced constrained supply of oligonucleotides (oligo), which are a critical component of its diagnostic kits. Oligonucleotides are molecules, oligomers, that have a wide range of applications in genetic testing, research and forensics. When Australia's last oligo manufacturer closed its doors in late 2019, the company was forced to look to overseas manufacturing facilities for supply.

"[We were] totally reliant on overseas production suppliers, and suppliers that the rest of the world were reliant on. It seems that everyone was scaling up at the exact same time," SpeeDx CEO Colin Denver said.

"Oligo lead times from the overseas suppliers were up to a year for more complex molecules. A typical lead time before COVID was a month," SpeeDx Director of Operations Tom Lin added.

Perth start-up SynGenis was established in late 2020 by Associate Professor Rakesh Veedu, who had run the oligonucleotide synthesis service out of the Murdoch University campus in Western Australia. The company operates a large facility in Technology Park Bentley to manufacture high-quality oligonucleotides for the Australian and New Zealand market, and international customers.

In early 2021, MTPConnect Directors of Stakeholder Engagement (for Western Australia and New South Wales/Australian Capital Territory, respectively), Dr Tracey Wilkinson and Dr Duncan Macinnis organised an introduction between the two organisations, having recognised synergies in their activities.

"When I heard about SynGenis, it seemed like a great fit for SpeeDx – their values and commercial needs aligned," Dr Macinnis said. "The success of their collaboration is indicative of the many opportunities that the MTP sector has to connect stakeholders across all geographical and interest areas, building our industries' expertise and capability as 'Team Australia'."

Within five days of MTPConnect setting up the first introductory meeting, SynGenis had sent SpeeDx a shipment of oligos for a supplier assessment – a record supply time! This initial partnership allowed SpeeDx to meet an obligation to a large overseas customer and set the foundation for a longer-term collaboration.

Dr Wilkinson believes that the pandemic has reaffirmed the importance and value of MTPConnect's nation-wide team in assisting collaboration and commercialisation efforts across the sector, regardless of geographic distance.

"This successful partnership is a great illustration of how combining our on-the-ground awareness and local knowledge of the sector within MTPConnect's national team can identify opportunities for collaboration. Without strong communication and strategic connections across the country, the sector risks missing opportunities like this – opportunities that then head overseas, which is not ideal for suppliers, customers, patients, or the economy and jobs," Dr Wilkinson said.

The ability to solve domestic challenges with domestic solutions has proven to be an effective way to combat supply resilience issues and enable potential expansion in domestic and international markets in the future. SynGenis and SpeeDx are both excited to see where those future opportunities take them, after SpeeDx announced an investment in SynGenis in October.

What started as an exploratory introduction between two companies has led to a financial investment that will support the expansion of SynGenis to provide reliable, high-quality large-scale oligos and bolster the capacity of SpeeDx to support large-scale increases in manufacturing.

"Moving forward, it's exciting to be increasing local capacity at a time when we really had no local options. Having our two companies aligned means we can better respond to Australian and international commercial demands," Mr Lin said.

"It is an absolute pleasure that we have this partnership now, which is based in Australia, and manufactured in Australia, and supplied in Australia," said SynGenis Founder and Managing Director Associate Professor Veedu.

MTPConnect's matchmaking means SpeeDx and SynGenis can now develop and expand the sovereign capacity of important raw materials used in molecular diagnostics and also expand efforts in the global diagnostic market.

NB: SpeeDx is a BTB program Round 1 recipient, seeking to commercialise its ResistancePlus® MABSC/MAC test – a rapid in vitro diagnostic tool to accurately and quickly identify bacterial infections related to cystic fibrosis, while using gene markers to predict antibiotic susceptibility or resistance.

Objective 2: Improving Management and Workforce Skills

Team Activities

The Guest of the Chair program is all about giving our emerging leaders the opportunity to experience a range of board-level activities, including attending MTPConnect Board meetings over a 12-month period. Where needed, Guests of the Chair are supported to undertake the Australian Institute of Company Directors course.

Following the appointment of MTPConnect's new Guest of the Chair for FY2022, Dr Amanda Ruth, we held a major networking event on 21 July 2021 for sector leaders to meet past and present Guests of the Chair. A keynote presentation was made by Catherine Livingstone, then Chairman of Commonwealth Bank of Australia and current Chancellor, University of Technology Sydney, and Director at Saluda Medical. Information on the event and the Guest of the Chair scheme is available on page 17.

MTPConnect executed a new partnership with the Australian Centre for Health Services Innovation (AusHSI) to provide support and mentoring for standalone behavioural intervention applicants and awardees within the TTRA program. AusHSI, based at Queensland University of Technology, is one of Australia's leading health service research centres, with strengths in health economics, implementation science, statistics and data analysis. This partnership will allow applicants and awardees with standalone behavioural interventions in the TTRA program specialist advice and reviews as part of their application, improving the impact of the program in the sector.

MTPConnect, in partnership with Life Sciences WA (LSWA), has been awarded an X-TEND WA Program grant, supported by the Western Australian Government (Department of Jobs, Tourism, Science and Innovation). This funding will bolster LSWA's current efforts to increase the awareness of the opportunities available to investors in Western Australia's burgeoning life science sector through the creation of a bespoke 'Investment Series' education program. The matched funding component of this grant has been provided through MTPConnect's REDI initiative.

This year saw the final Growth Centre-funded projects finish, including the fellowship program run by Certara, which trained five fellows for two years each in Model-Informed Drug Discovery and Development (MID3) science and regulatory science. Certara is using the course material for further fellowships and a Master of Pharmaceutical Science course at Monash University.

Also finishing this year as a Growth Centre project is the IMNIS program run by the Australian Academy of Technological Sciences and Engineering (ATSE). This MTPConnect-supported program has evolved into a comprehensive suite of national and international industry engagement programs in STEM. This year, the IMNIS Engage program spanned all industry sectors, and has grown to more than 400 mentoring partnerships. IMNIS mentees in STEM, all PhD students, from 53 leading research organisations and centres of excellence around Australia have been connected with industry leaders throughout the country. IMNIS continues to be supported through the REDI program.

Further information on Certara fellowships and IMNIS is available on page 29-31.

Information sharing and workforce skills development

8,836
Individuals received workforce skills / commercialisation training

59,221
people attended **3,114** training events and information seminars

36,046
people attended **871** collaboration events

Leveraged Funding

MTPConnect's workforce skills program, the REDI initiative, continued to deliver on management and workforce training. REDI now has 20 partners offering 46 programs, with the following highlights this year:

- Twenty pharmaceutical and medtech researchers, entrepreneurs and innovators from around Australia have been awarded industry-based fellowships to boost skills and advance their research or technology towards commercialisation through the Bridge and BridgeTech Industry Fellowships Program. These opportunities are facilitated by Queensland University of Technology (QUT), and provide up to $10,000 to support the placement of participants and alumni of the Bridge Program and The BridgeTech Program within industry.

- SeerPharma is delivering four new courses to help researchers and companies implement Quality Management Systems and gain accreditations for Good Laboratory Practice and medical product manufacturing. The information session held on 17 August 2021 is now available as an on-demand webinar.
- Cicada Innovations' medtech commercialisation workshops rolled out around Australia, with New South Wales, Queensland and Western Australian workshops fully booked. The training will help innovators take their healthcare solutions from idea to business.
- Delivered by ATSE, the new IMNIS Clinical program was launched in December 2021 and connects 10 PhD student mentees at the forefront of clinical and health-tech-related research with high-calibre industry champion mentors.

There has been substantial interest in MTPConnect's REDI Fellowship Program, which provides companies in the medical products sector with up to $250,000 to bring researchers, clinicians and MTP sector professionals in-house for up to 12 months to work on priority research projects. Due to extensive interest from the sector, eligibility for the REDI Fellowship Program was expanded to allow participation by smaller companies.

In Q2, an additional 20 high-skilled Australian researchers, clinicians and professionals from the sector were announced as the next REDI fellows. The new fellows, from South Australia, New South Wales, Victoria and Queensland, are working with major companies from Australia, the US, the UK and Europe. In Q4, the Fellowship Program re-opened with another round, and 16 new fellows selected, taking the total number of fellows supported through the program to 47.

Continuing the REDI initiative's commitment to addressing workforce skills gaps, five consortia were awarded contracts through Round 3 of the Contestable Program to deliver training and education programs: ARCS Australia Consortium, PRAXIS Australia Consortium, IntelliHQ Consortium, Centre for Biopharmaceutical Excellence Consortium and Wrays Consortium.

GSK Australia announced the second year of its Graduate Researcher Program, welcoming a new cohort of six PhD graduates who are working across GSK projects. All six graduate researchers from 2021 have now been employed in industry or received industry placements after the completion of their program. The GSK Australia Graduate Researcher Program, supported by our REDI initiative, looks to bridge the skills gap between academia and the pharmaceutical industry.

Pictured: In May 2022, MTPConnect announced 18 new REDI fellows from NSW, QLD, SA, VIC and WA.

Case Study: Certara-Monash University Industry Fellowship Program

The Certara-Monash University Industry Fellowship Program was designed to increase sector-wide capabilities in Model-Informed Drug Discovery and Development (MID3) science and regulatory science through consistent, scalable, expert-led, industry-focused training of postdoctoral fellows. Five fellows were recruited, of which three have successfully completed the fellowship and are actively engaged in the MTP sector in Australia. One graduate accepted a position in the field of modelling and drug development and completed the fellowship early to take on this role in December 2020. Two graduates have achieved ongoing positions within Certara focusing on MID3. Fellows from the second and third cohorts have completed their 12-month assessment within the fellowship program and are performing well. Both remaining fellows will continue to be supported by Certara following the conclusion of the MTPConnect project.

Both Certara and Monash University are exploring other ways to incorporate the MID3 curriculum in future courses and training programs to develop the next generation of pharmaceutical scientists. This will include the following three programs:

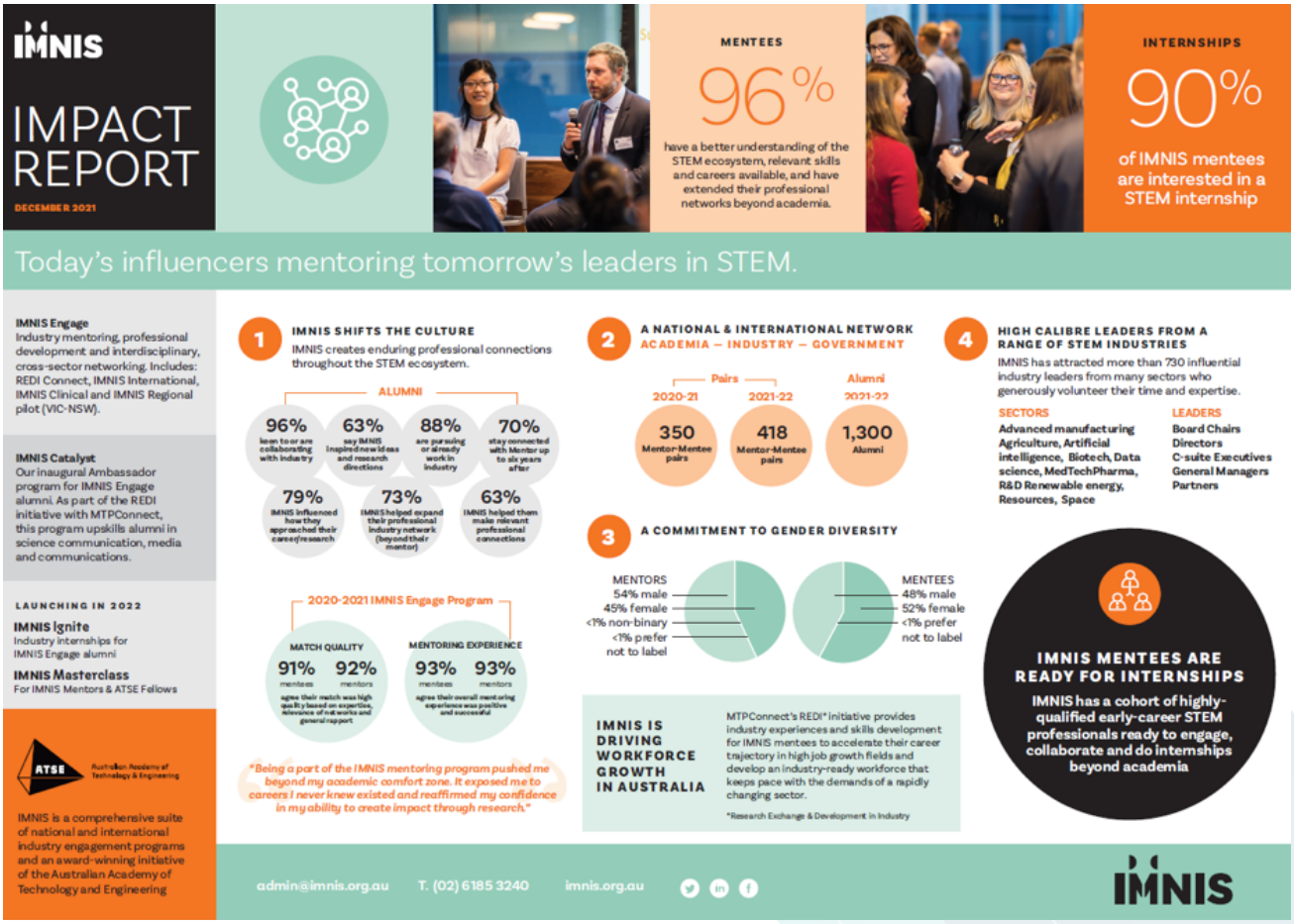
Monash University, Master of Pharmaceutical Science
The Master of Pharmaceutical Science equips students with the knowledge and skills they need for a career in the pharmaceutical sector and related industries. Students gain hands-on experience in analytical, formulation, modelling and other techniques relevant to the practice of contemporary pharmaceutical science. The guiding principles of social responsibility, sustainability and positive impact underpin all learning in this course. The course culminates in an extended placement in an industrial or research organisation. The placement is integrated with a capstone unit that gives students the chance to consolidate their learning across the entire degree, giving them a folio of evidence that demonstrates their value in a professional environment.

There has been strong interest in the course with a first cohort of 70 students commencing in 2022. For 2023 commencements, there are 289 applications and 100 offers of places to date at 30 September 2022. Monash University expects a cohort of 85 to 100 students to commence in the new year, and graduations of the first students by the end of 2023.

Certara, Applied Pharmacometrics Training Fellowship in Africa in partnership with Pharmacometrics Africa, CP+ Associates and other industry and academic partners
The Applied Pharmacometrics Training Fellowship in Africa aims to build scientific and leadership capability in the region by enhancing the skills of scientists and facilitating knowledge transfer to wider scientific communities. The first cohort of 15 began their fellowship in January 2022.

Certara Fellowships
One Australian-based fellow commenced the Certara Fellowship in January 2022 with a focus on MID3 within Certara's clinical science division. They will draw on learnings from the Certara-Monash University Industry Fellowship Program. A new Certara residency program is planned, including intensive training in pharmacometrics and clinical pharmacology with an industry focus.

Case Study: IMNIS Industry Mentoring Positions Australia's Future Workforce For Success



IMNIS is the Australian Academy of Technological Sciences and Engineering's (ATSE) award-winning industry engagement initiative that connects emerging leaders in STEM with influential, high-level industry leaders and the broader sector, and prepares them to participate effectively in real-world industry settings.

The first IMNIS program funded by MTPConnect (now called 'IMNIS Engage') is the flagship professional development program for PhD students and early-career professionals and equips future STEM leaders from diverse backgrounds across Australia to excel within the STEM ecosystem. IMNIS Engage partners motivated PhD students and early-career researchers (mentees) in STEM with influential industry leaders (mentors) in a one-year mentoring and professional development program. Regular educational events and roundtables facilitate interdisciplinary, cross-sector networking.

IMNIS Engage helps mentees increase their understanding of industry, identify the skills needed to succeed, learn about different career opportunities, and extend their professional network. Since IMNIS began, over 1,700 early-career researchers from more than 50 leading research organisations around Australia have been matched with industry leaders, including 418 mentees in the 2021–22 program.

IMNIS Engage mentors include senior-level industry professionals who have approximately 10 or more years industry experience as well as executive or management-level skills. Mentors can also be CEOs, C-suite, directors, managers, team leaders or technical specialists. Mentors can also come from research and development, business development, data analytics, innovation, consultancy and other areas from within the STEM ecosystem. IMNIS Engage mentors come from industry (75 percent), not-for-profit (15 percent) and public organisations (eight percent) – with two percent being retired industry professionals.

As part of the project, IMNIS Engage extended its reach into regional areas, hosting programs in five universities in Queensland, New South Wales and Victoria to increase industry engagement in the next generation of sector leaders and to strengthen industry research connections and collaborations. With support from MTPConnect, this initiative provided PhD students and postdoctoral fellows in regional areas the same access to industry mentoring and online activities as mentees in metropolitan areas.

A key outcome of IMNIS Engage is the transformation mentees experience in how they conceive, evaluate and communicate their research, expertise and professional activities. Two-thirds of mentees said the IMNIS Engage program extended their networking skills, increased their understanding of industry and the broader STEM ecosystem, as well as the commercialisation and innovation pipeline. Most mentees (more than 85 percent) also stated they gained the knowledge and skills to assist them in attaining an internship or job in industry and how to engage and collaborate with industry. Most mentees have also developed a greater understanding of their transferable skills (86 percent) and the diverse careers available beyond academia (88 percent).

Most IMNIS Engage alumni say IMNIS influenced them to consider a career beyond academia, with one-third actively working in industry and more than half (59 percent) pursuing a role in industry. Only 10 percent of alumni state they are pursuing an academic career after completing their IMNIS Engage program. Most IMNIS Engage alumni in research want to collaborate or are collaborating with industry (85 percent) and two-thirds indicated that IMNIS revealed novel ideas and inspired a shift in research focus or a change of research direction altogether. IMNIS has led to enduring cross-sector connections, with more than 71 percent of IMNIS alumni staying in contact with their industry mentor.

The IMNIS initiative is growing significantly, and ATSE remains committed to delivering opportunities that will help create a more inclusive, diverse and connected STEM sector in Australia.

Objective 3: Optimising Regulatory and Policy Environment

Team Activities

Leveraging its expertise and national sector networks, MTPConnect worked with the TGA to deliver sector-wide consultation and review of Australia's regulatory framework for gene, cell and tissue therapies. The review was instigated by the TGA following submissions to the House of Representatives' 'Inquiry into approval processes for new drugs and novel medical technologies in Australia' in which stakeholders mentioned concerns with the current framework.

The TGA approached MTPConnect to undertake the stakeholder engagement review, recognising the unique capabilities and networks MTPConnect could bring to delivering the project.

Commencing in August 2021, the project involved one-on-one interviews and group sessions with key stakeholders focusing on clinical trial pathways for gene therapies, GMP requirements, coordination and alignment of regulatory requirements for gene therapies, parallel processing of cell and tissue/gene therapy applications and priority and provisional pathways for biologicals. The project was completed with the final report delivered to the TGA on 29 November 2021. Details of this report are in the case study on page 34.

MTPConnect also launched a new report in Q2 on the Australian medicinal cannabis industry. Commissioned to provide an evidence base for the current size of Australia's medicinal cannabis industry, as well as future estimates for the sector, the report aims to serve as a valuable resource to inform policymakers, industry and consumers. As it is a developing industry, there are many agricultural producers, pharmaceutical manufacturers, medical practitioners, researchers and industry representative bodies seeking to understand how the industry might – and should – evolve as it matures. The report found that the global medicinal cannabis market has rapidly expanded in recent years, with medicinal cannabis now legalised in over 30 countries. It notes that the global medicinal cannabis market will be worth $80 billion (US$62.6 billion) by 2024, providing opportunities for growth for Australia's industry.

MTPConnect also supported the ACannabis conference, 'Bridging the gap: evidence, confidence, access' held in Melbourne. Our Director of Stakeholder Engagement for New South Wales and the Australian Capital Territory, Dr Duncan Macinnis, joined a panel discussion on the first day of the conference, providing an overview of the *Australian Medicinal Cannabis Industry Report.*

Australian Antimicrobial Resistance Network (AAMRNet)
Established by MTPConnect in 2020, AAMRNet is an Australian-first network bringing together industry, clinicians and researchers to address the impact of AMR on human health. The network has over 28 active partners.

To mark World Antimicrobial Awareness Week 2021, *The MTPConnect Podcast* partnered with AAMRNet to produce a special week of programming shining a light on Australia's expertise and innovations to fight superbugs. The four AMR-focused episodes featured biomedtech innovators from around Australia, covering issues from developing new treatments to finding faster methods of detection. During the same week, AAMRNet Co-Chair Andrew Bowskill joined the AMRelay – a 24-hour virtual global event offering a series of 96 consecutive contributions by pioneering stakeholders in the global AMR sector. In August 2022, AAMRNet hosted a special guest at its member meeting: the New Zealand Prime Minister's Chief Scientific Advisor, Professor Dame Juliet Gerrard.

With antimicrobial resistance widely acknowledged as one of the biggest threats to global health, a new position statement from AAMRNet was published in Q4, which canvases ways to stimulate R&D for new treatments, novel reimbursement approaches to support and ensure a continuing pipeline of novel therapies and discusses the merits of a pilot Australian fund to provide access to new antimicrobials. For more information on AAMRNet see page 44.

Regenerative Medicine Catalyst Body

The 'foundation stones' for Australia's regenerative medicine (RM) future have now been laid with the publication of eight resources offering new knowledge and benchmarking, a purpose and firm unified direction for the industry's future. Outlined at the AusBiotech 2021 conference, the Regenerative Medicines Consortium (established and funded by MTPConnect through the GC Project Fund) has now delivered the final elements of the 12-month project, which collectively demonstrate the breadth of opportunity present in the Australian RM sector.

Each report provides a new evidence base and model against which to map, build and strengthen our RM clinical trials and sovereign GMP manufacturing position over time. By leveraging Australia's reputation for delivering high-quality, complex, and safe medical products, as well as our highly skilled workforce, we can become the RM clinical trials and manufacturing hub for the region and deliver potentially life-changing treatments to patients, both in Australia, and the broader Asia-Pacific region.

- The inaugural *Australia's Regenerative Medicine Manufacturing Capacity and Capability* (manufacturing report) highlights how Australia has RM manufacturing sites from east to west, with seven TGA-licensed GMP sites and five non-TGA licensed sites.
- Delivering clarity of the development landscape, the inaugural CT Database captures the portion of clinical trials in RM and seeks to categorise them into type and phase. This benchmarking is important as it enables the ecosystem to develop in a way that capitalises on the opportunities that present now and in the future. In 2021, there were over 1,220 ongoing clinical trials investigating RM globally; of these, 130 (11 percent) were ongoing and investigating RM in Australia, and two were in progress and being conducted by Australian companies overseas.

Industry Genomics Network Alliance (InGeNA)

The final report from the Industry Genomics Network Alliance (InGeNA) was released in Q2 and featured case studies showing the ways genomics will be useful in diagnosis and treatment across Australia's future healthcare system, and the value that this can bring to individuals and the health system. InGeNA was established and funded by MTPConnect through the Growth Centre Project Fund and is managed by the Australasian Institute of Digital Health. Its report *Valuing the impact of genomics on healthcare in Australia* was undertaken by Deloitte Access Economics. The case studies profile potential applications of genomics across the screening, diagnosis and treatment stages of the care continuum. This is the last of four reports covering the four focus areas of InGeNA: access and equity, workforce, data and tech innovation and quantifying the benefits of genomics. InGeNA is now established as an ongoing, self-sustaining entity with involvement from over 35 companies in the sector, and continues to produce webinars, seminar series and strategic papers highlighting the role and needs of the genomics sector in the Australian healthcare system.

Case Study: Cell, Gene and Tissue Regulatory Framework in Australia – Stakeholder Perspectives

In November 2021, MTPConnect was commissioned by the TGA to deliver a stakeholder engagement review of Australia's regulatory framework for gene, cell and tissue therapies. The review was instigated by the TGA following submissions to the House of Representatives' 'Inquiry into approval processes for new drugs and novel medical technologies in Australia' in which stakeholders mentioned concerns with the current framework. Access to gene, cell and tissue therapies was a concern for stakeholders.

Working with Evohealth, MTPConnect conducted one-on-one interviews and group sessions with key stakeholders focusing on clinical trial pathways for gene therapies, GMP requirements, coordination and alignment of regulatory requirements for gene therapies, parallel processing of cell and tissue/gene therapy applications and priority and provisional pathways for biologicals.

The review involved individual interviews and group sessions with key stakeholders from across the sector. A total of 17 one-hour individual stakeholder interviews were carried out, with two stakeholders requesting follow-up interviews to provide additional feedback. Additionally, five two-hour workshops were undertaken with:


researchers


clinical trial experts


regulatory experts


manufacturers


clinicians

Key Themes

Following these conversations, core themes were distilled from the consultation notes associated with the questions and detailed below. Key themes to emerge from the consultations to ensure Australia is competitive and patients have access to these new medicines with fit-for-purpose and harmonised processes include:

1. The flexibility of the TGA and their willingness to engage with stakeholders and seek feedback was commended; however, it was suggested that the TGA could be more proactive.
2. Better communication by the TGA. This included feedback with regards to plain language and contemporary information being available on the website, supporting better understanding of the clinical trial and regulatory pathways as well as interactions/interdependencies with other agencies (defined timelines and greater clarity around requirements at each step of the process). Several stakeholders suggested there was a need for flowcharts and diagrams, webinars with Q&A guidance and tailored communications (e.g. via SME Assist, specific newsletters or otherwise).
3. Alignment with comparable overseas regulators (CORs) is recommended with respect to definitions and classifications, dossiers, pathways and data requirements. Industry stakeholders in particular noted there had been significant improvements with evaluating dossiers that had previously been submitted to CORs.
4. While the Clinical Trial Notification (CTN) pathway is an advantage for conducting trials in Australia in a timely manner, process improvements were noted for the Clinical Trial Approval (CTA) process. Clinical trial experts, researchers, clinicians and industry stakeholders all noted that the CTA process needed improvement and timelines needed to be equivalent to international benchmarks "at the minimum". There was a general perception that the CTA process was resource intensive and had substantially lengthier timelines when compared to key international jurisdictions and that the TGA had less experience in evaluating Advanced Therapies (ATs) in particular.
5. Process improvements for biologicals. It was noted that the biologicals pathway was less well defined relative to the prescription medicines pathway and that this was unique to Australia. Ensuring that these therapies had appropriate designations in terms of orphan drug status as well as expedited pathways based on need, rather than classifications, was a key theme across all stakeholder groups.
6. Reduced duplication of effort across key agencies. Industry stakeholders and patient advocacy group representatives in particular suggested that there should be a single point of entry for data requirements and a more streamlined and holistic approach to enabling patient access to new therapies. Industry stakeholders noted that at times they were submitting near identical information to separate agencies and that there was seemingly little communication across these agencies.

The full report has now been published, including MTPConnect's major findings and the TGA's response to the major recommendations.

Objective 4: Improving Access to Global Supply Chains and Markets

Pictured: BioNTech representatives visit Sydney in March 2022.

Team Activities

In Q1, MTPConnect concluded its collaborative work with DMTC for Austrade, which explored Australia's capabilities in the biologics sector and the value proposition for foreign direct investment (FDI). The work was driven by our stakeholder engagement team and focused on four sub-sectors of the biologics sector: cell therapies, CAR T-cell therapies, antibody therapies and gene therapies. We also analysed the landscape for FDI and, to examine the investment value proposition and competitive benchmarking, we chose the markets of Singapore, Ireland and Canada for comparison.

In September 2021, MTPConnect's then Managing Director and CEO, Dr Dan Grant, was on the jury of the Falling Walls Lab Australia event. This international forum promotes interdisciplinary connections between aspiring academics, innovators, entrepreneurs, investors and professionals, known for their excellent work.

MTPConnect supported the AusBiotech 2021 conference, themed 'Engage, your way' and held from 25 to 29 October 2021 in an online and on-demand format. As well as being a conference sponsor and supporting the panel session 'Catalysing regenerative medicine in Australia', MTPConnect Chair Sue MacLeman joined a panel session on 'National health security – unpacking supply chain resilience and agility'.

Senior representatives of German biotechnology company BioNTech, thy organisation behind Pfizer's COVID-19 vaccine, visited Australia during the year. MTPConnect Director, Julie Phillips, and Director of Stakeholder Engagement for New South Wales and te& Australian Capital Territory, Dr Duncan Macinnis, met with BioNTech's Chief Operating Officer Dr Sierk Poetting and Dr Oliver Hennig, the company's Senior Vice President Operations and Managing Director of BioNTech Manufacturing, at a roundtable in Sydney. Erica Kneipp, the Research Director for the Human Health program ae CSIRO, also attended along with Professor Pall Thordarson, Head of the University of New South Wales (UNSW) RNA Institute, and Jiamin Aw, Professor Regina Crameri and Nur Sidki Gomez from Austrade. As well as the meeting in Sydney, the BioNTech team also visited Victoria and Western Australia, where MTPConnect's Dr Tracey Wilkinson supported the delegation on site visits and government engagement meetings.

MTPConnect Chair Sue MacLeman and CEO Stuart Dignam presented at two sessions of the virtual Ignite Summit, an executive-level summit for leaders across sectors to meet and positively impact medical innovation through a series of debates. This year, the UK summit focused on how the UK's health science community can best support a national and international effort to tackle bio-emergencies.

MTPConnect had a strong involvement in the AusMedtech conference in Melbourne during Q4. Our Director of the Adelaide Intermediary Program, Jo Close, chaired the session, 'Global competitiveness of Australia's growing manufacturing hubs', which was sponsored by MTPConnect, while Senior Director of the TTRA program, Lauren Kelly, appeared as part of the session hosted by Illumina, 'Lunch & Learn – Accelerators and Incubators Reverse-Pitch'.

As part of MTPConnect's commitment to opening international markets and boosting access to international supply chains, we supported the Australian pavilion at the BIO International Convention in San Diego as co-exhibitor. With a message of 'open for business', we helped to re-introduce Australia's biotech and pharma capabilities to the world after two years of pandemic travel restrictions. BIO, held from 13 to 16 June, is the largest business partnering event for the sector in the world, with around 20,000 participants. Read more about BIO in the case study on page 36.

Leveraged Funding

ATSE has launched a dynamic new IMNIS international mentoring program designed to nurture Australia's future leaders in science, technology, engineering and maths to engage with industry globally. Ten outstanding REDI Connect PhD students in the job growth areas of regenerative medicine, gene and cell therapy and digital health technologies have been selected and will be mentored by high-calibre experts to develop their career pathways. Read more about how the group is advancing medical research in new fields of endeavour on the MTPConnect website here.

IMNIS announced ten REDI Mentees in 2021 – these PhD students are undertaking research in job-growth areas.

Case study: Showcasing Team Australia at BIO 2022

Pictured: The Australian pavilion at BIO 2022, supported by MTPConnect.

As part of MTPConnect's commitment to opening international markets and boosting access to international supply chains, we supported the Australian pavilion at the Biotechnology Innovation Organization (BIO) International Convention in San Diego as co-exhibitor with AusBiotech and the Australian Trade and Investment Commission (Austrade). Additional support for the conference was provided by DISR as part of the MTPConnect transition projects grant.

BIO, held from 13 to 16 June, is the largest business partnering event for the sector in the world, with around 20,000 participants.

With a message of 'open for business' we helped to re-introduce Australia's biotech and pharma capabilities to the world after two years of pandemic travel restrictions. MTPConnect Chair Sue MacLeman and CEO Stuart Dignam attended. Our Western Australian team, led by Dr Tracey Wilkinson, worked closely with the Western Australian Government to support the WA life sciences' mission to the US, led by the State's Minister for Innovation and Medical Research, the Hon. Stephen Dawson MLC, and Chief Scientist Professor Peter Klinken. In addition to BIO, the Western Australian mission included visits to Stryker (San Jose), Microsoft (Seattle), the University of Arizona Health Sciences' Simulation Technology and Education Center (Tucson), the SPARK program at Stanford University and the Texas Medical Center in Houston.

During the conference MTPConnect Chair Sue MacLeman and CEO Stuart Dignam caught up with Australia's Ambassador to the US, the Hon. Arthur Sinodinos AO, and some of that conversation can be heard in the special BIO 2022 MTPConnect Podcast released on 15 June. The team also met up with NSW Minister for Health, the Hon. Brad Hazzard MP, who was supporting the New South Wales showcase event.

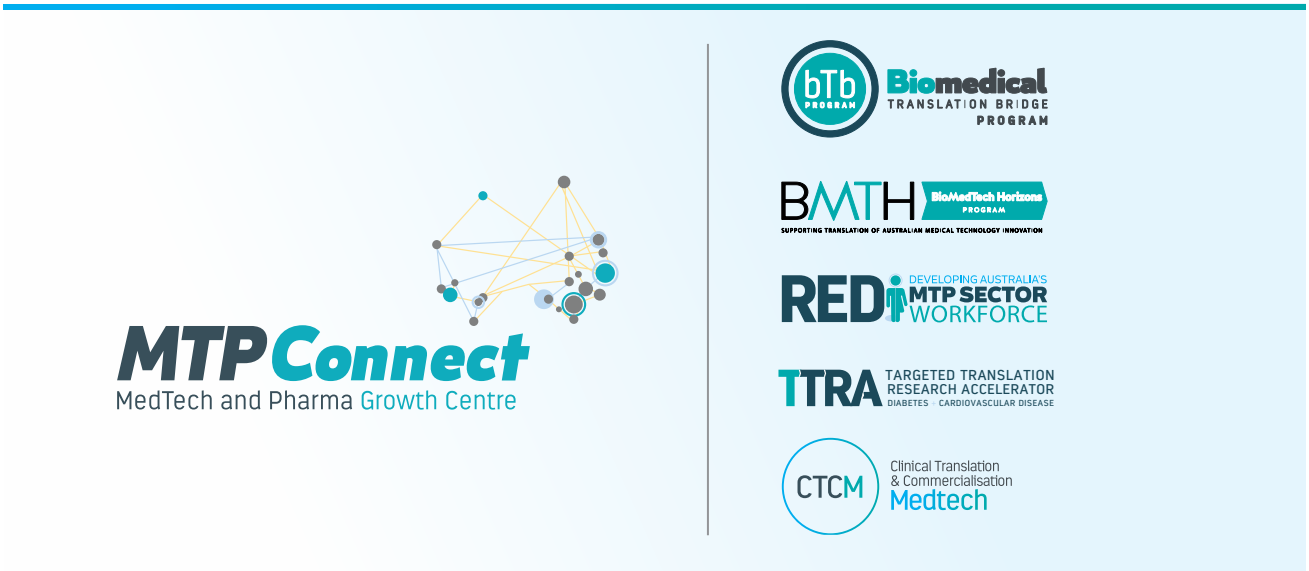
Pictured: Left – Australia's Ambassador to the US, the Hon. Arthur Sinodinos AO, with Sue MacLeman at BIO 022.

Right – UWA's Prof Kevin Pfleger, MTPConnect's Dr Tracey Wilkinson with WA Minister for Innovation and Medical Research Hon. Stephen Dawson.

MTPConnect Programs

All MTPConnect projects are detailed in the following section (pages 40- 84) with their description, outcomes, funding amounts and duration. These numbers are accurate as of 31 October 2021. Where a project is shown as finished the values shown are the finalaudited amounts. Final details may differ from the project applications due to changes in project start dates and projectdevelopments. More information can be found at www.mtpconnect.org.au.

MTPConnect Programs



MTPConnect has $182 million in sector support funds under management, across six strategic funding initiatives:

- The $15.6 million Growth Centre Project Fund
- The $45 million BioMedTech Horizons program
- The $22.3 million Biomedical Translation Bridge program
- The $32 million Researcher Exchange and Development within Industry initiative
- The $47 million Targeted Translation Research Accelerator initiative
- The $19.75 million Clinical Translation and Commercialisation – Medtech program.

In parallel with these programs, MTPConnect has a number of state-based initiatives and sector-focused projects including:

- The Adelaide Intermediary Program
- The Western Australian Life Sciences Innovation Hub
- The Australian Diagnostics Action Plan Team (ADAPT) Project
- The Australian Antimicrobial Resistance Network – AAMRNet.

Each of these programs are detailed in the following pages 41-45.

Where project descriptions, funding amounts and duration are detailed, these numbers are accurate as of 31 October 2022. Where a project is shown as finished, the values shown are the final audited amounts. Final details may differ from the project applications due to changes in project start dates and project developments. More information can be found at www.mtpconnect.org.au

Adelaide Intermediary Program

MTPConnect
Adelaide Intermediary Program
In partnership with
Adelaide BioMed City
Government of South Australia

MTPConnect was appointed by the South Australian Government as the External Innovation and Translation Intermediary for Adelaide BioMed City (ABMC) in February 2022. The government has invested $3 million over three years, as part of its EXCITE Strategy to drive excellence in research, collaboration, innovation and translation. This investment supports MTPConnect's Adelaide Intermediary Program (AIP) to drive collaboration and knowledge transfer between researchers and industry within Adelaide BioMed City Innovation District and across South Australia.

Through targeted activities and services, AIP is focused on growing South Australia's health medical innovation (HMI) sector by fostering collaboration, strategically building capacity, and attracting new talent and opportunity across the research, innovation and translation value chain. The AIP team will deliver services to increase effective and productive collaborations between researchers, clinicians, entrepreneurs and businesses working within and beyond the geographical span of the ABMC.

AIP launched into the South Australian HMI sector with a series of targeted presentations, hosted panel sessions and curated networking and skills events. A new monthly event program to bring the HMI sector together kicked off in June 2022. The SA Insights Series is a fireside chat hosted by an AIP team member and features leaders and companies in the South Australian ecosystem sharing their journey, successes, insights and future plans. Themes are connected to the sector megatrends and the networking that follows provides an opportunity to connect the diverse stakeholders in the sector.

The AIP team has also led a series of workshops to connect more than 100 researchers, clinicians, innovators, policymakers and investors to prepare compelling bids to build and enhance South Australia's infrastructure capacity to conduct health and medical research in programs such as the Australian Research Council's cooperative research centres.

Pictured: Left – AIP Director Jo Close and South Australian Deputy Premier the Hon. Susan Close at the Medical Device Partnering Program Showcase on 28 June.

Right – AIP Director Jo Close with BiomeBank's Sam Costello and Thomas Mitchell at the first SA Insights Series event in June.

Western Australian Life Sciences Innovation Hub

WA Life Sciences Innovation Hub

Western Australia has a history of innovative medical research that has been successfully translated and commercialised into novel health and medical therapies and devices. The MTPConnect Western Australian Life Sciences Innovation Hub was created in July 2018 to develop and accelerate this capability and, in doing so, stimulate economic diversification, drive jobs growth and improve patient outcomes.

The hub is a partnership between MTPConnect, The University of Western Australia and the Western Australian Government. The hub partners drive activities and policies that engage and support all stakeholders across the breadth of the Western Australian health and medical life sciences sector.

The hub works in partnership to grow the state's health and medical life sciences sector by focusing on local capability development and challenges, in alignment with national and state policy priorities.

19 events led by the WA hub

Combined hub activities supported the creation of 151 new jobs

27 invitations to contribute (conferences, panels, roundtables)

Combined hub activities contributed to $14,647,792 funding; this includes matched funding of $450,000 towards the five WA companies awarded under the WA Manufacturing Voucher Scheme, who have boosted their medical product manufacturing capabilities.

A standout hub initiative is the WA MTP Sector Spotlight, a monthly series bringing together a wide range of stakeholders to engage and network on a regular basis, while also showcasing a local MTP company that has achieved a significant milestone. The events are held in a congenial fireside-chat style with a C-suite representative and prioritise opportunities for audience Q&A. In FY2022 12 Western Australian companies have been showcased at 11 events.

In 2022, the hub worked closely with the Western Australian Government to support a life sciences mission to the US led by the Hon. Stephen Dawson MLC, Western Australia's Minister for Emergency Services, Innovation and ICT, Medical Research and Volunteering, along with Western Australia's Chief Scientist Professor Peter Klinken. The mission included a series of meetings with key US-based companies and a delegation attending the BIO International Convention in San Diego. Thirty-three

Pictured: PYC Therapeutics' Chief Scientific Officer Professor Sue Fletcher AO and CEO Dr Rohan Hockings joined MTPConnect's Dr Tracey Wilkinson in conversation at the WA MTP Sector Spotlight.

Pictured: The Western Australian BIO delegation consisted of over 30 representatives from the state's academia, government and industry.

Australian Diagnostics Action Plan Team (ADAPT) Project

ADAPT
Australian Diagnostics Action Plan Team

MTPConnect has established a Diagnostics Industry Engagement team to deliver a national action plan for sovereign manufacturing capability and supply chain resilience for diagnostic tests, establishing Australia as a regional centre of excellence for diagnostic technology manufacturing.

Vision

Create economical value, advance health outcomes and improve health security for all Australians by fostering sovereign capability and resilience. Develop a sustainable healthcare model that embeds diagnostics at the core of care delivery by ensuring the right diagnosis leads to the optimum treatment.

Mission

Working with a wide-ranging group of informed and embedded stakeholders, engaging the sector to gather insights and understand the deep problems with developing, commercialising and supplying IVDs in the Australian market.

MTPConnect, in partnership with Pathology Technology Australia (PTA), will develop the national action plan over nine months through extensive consultation and a rigorous examination of the diagnostic testing landscape to identify gaps, opportunities and strategies to nurture world-class research and development. The final report will outline the domestic capabilities that will build resilience for critical products. It will also examine the supply chain and other barriers to position Australia to successfully produce IVD devices reliably and sustainably. The national action plan has been designed to examine, highlight and address key supply chain resilience issues facing the health security of Australia and assess our ability to manufacture and produce critical diagnostic tests onshore to minimise the effects of geopolitical and logistic issues on supply.

The Diagnostics Industry Engagement team is engaging with a wide range of organisations in the diagnostics sector across Australia to gather insights and learnings. They are targeting key stakeholders to contribute to the national action plan and have their voice heard. This is an opportunity for the MTP sector to come together as a collective and present validated findings to the government to solve shared common problems.

Dr Dharmica Mistry was appointed Director of Diagnostics Industry Engagement and leads the team with Jo Glew appointed as Project Officer, and Dr Jafar Hasan appointed as Project Manager in Q1 FY2023 .

Pictured: ADAPT Team in NSW for stakeholder consultations: L-R PTA's Justin Meredith with MTPConnect's Dr Dharmica Mistry, Jo Glew and Dr Jafar Hasan

Australian Antimicrobial Resistance Network (AAMRNet)

AAMRNet is an Australian-first network bringing together key stakeholders from industry and research to address the impact of antimicrobial resistance (AMR) on human health. The network was established to deliver on a key recommendation of the report, *Fighting Superbugs*, published by MTPConnect.

AAMRNet is supported by the MTPConnect Growth Centre Project Fund as well as industry contributions from: Pfizer ANZ, CSIRO, Botanix Pharmaceuticals, Recce Pharmaceuticals, MSD Australia, GSK Australia, SpeeDx, Medicines Australia, Tenmile, Biointelect, Monash University's Centre to Impact AMR and Bugworks Australia.

Additional partners of the AAMRNet include: AusBiotech, BiomeBank, Community for Open Antimicrobial Drug Discovery (CO-ADD), DMTC, Epichem, Formulytica, Global Antibiotic Research and Development Partnership (GARDP), Incubator for Antibacterial Therapies in Europe (INCATE), LBT Innovations, Lixa, Menzies School of Health Research, Microbio, Monash Biomedicine Discovery Institute, RESULTS International (Australia) and Roche Diagnostics Australia.

Co-chaired by MTPConnect CEO Stuart Dignam and Director of Stakeholder Engagement for Queensland Andrew Bowskill, the AAMRNet Steering Committee comprises leading Australian AMR researchers, clinicians and industry representatives. To help support its extensive workplan, AAMRNet recruited Dr Meghana Kulkarni as Project Manager. Shortly after commencing, Dr Kulkarni was also selected for the Future Leaders Against AMR program. This is a prestigious international program for students and early-career professionals, designed to support their development as future leaders in the work against AMR.

In 2022, AAMRNet launched its bimonthly *Member Update*, providing information to its members on the latest developments on AMR from Australia and around the globe.

Partnering with TIA Pipeline Accelerator Scheme

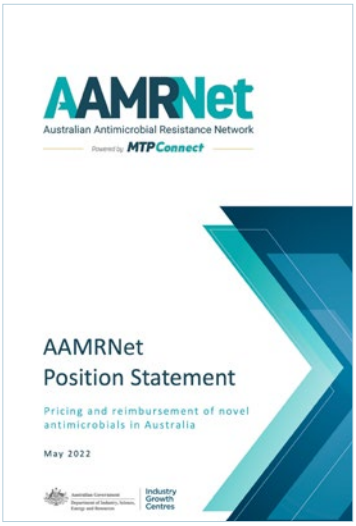
This year, AAMRNet collaborated with Therapeutic Innovation Australia (TIA) to support an AMR-focused stream of the TIA Pipeline Accelerator scheme. The initiative was well received, and three vouchers were awarded to support access to the TIA national network of leading translational research facilities.

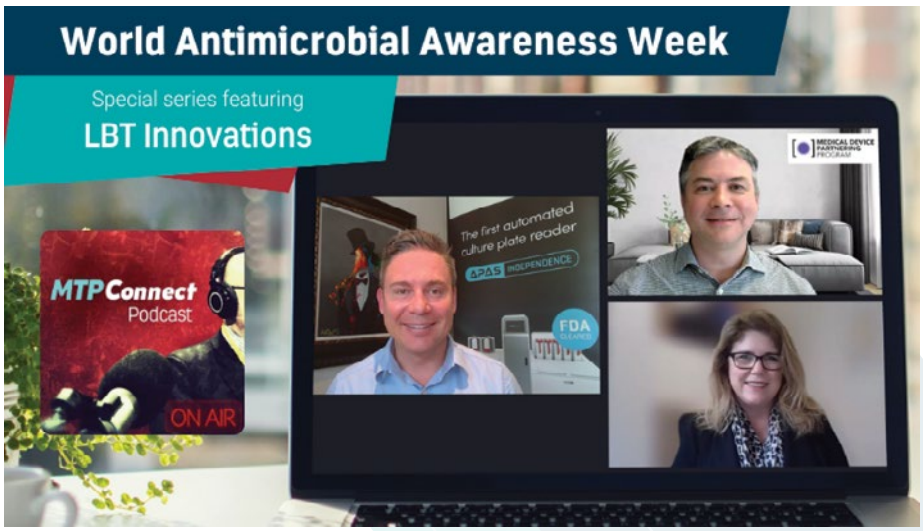
- **Dr Katherine Locock**, CSIRO, received a $20,000 voucher to access Compounds Australia and the Community for Open Antimicrobial Drug Discovery for a project entitled 'Accelerated antibiotic discovery through high-throughput screening of the CSIRO Compound Library'.
- **Dr Sohinee Sarkar**, from the Murdoch Children's Research Institute, received a $10,000 voucher to access Compounds Australia for a project entitled 'A new treatment for the cystic fibrosis superbug, Mycobacteroides abscessus'.
- **Professor Timothy Stinear**, from The University of Melbourne, has been awarded a $50,000 voucher to access the Victorian Centre for Functional Genomics for a project entitled 'A high-throughput screening

Position Statement Launched
In May 2022, through the efforts of its working group on pricing and funding, AAMRNet published the *AAMRNet Position Statement: Pricing and reimbursement of novel antimicrobials in Australia*, highlighting innovative strategies for bringing new antibiotic treatments to market.

AAMRNet received significant recognition in the Standing Committee on Health, Aged Care and Sport's report The New Frontier – Delivering better health for all Australians, which acknowledged the critical need to take action on AMR.

World Antimicrobial Awareness Week
For World Antimicrobial Awareness Week 2021, AAMRNet developed a special *MTPConnect Podcast* series, celebrating Australia's expertise and innovations tackling AMR superbugs. Featured organisations included the Community for Open Antimicrobial Drug Discovery (CO-ADD), BiomeBank, Recce Pharmaceuticals and LBT Innovations.





Visit by CARB-X Chief Scientist, Dr Richard Alm
In August 2022, AAMRNet hosted Boston University-based, Combatting Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) Chief Scientist, Dr Richard Alm, during his visit to Australia. Events were held in Brisbane and Sydney, giving Australian researchers and companies the opportunity to showcase their research and capabilities, and learn more about CARB-X and the opportunities it can provide. During the visit, MTPConnect interviewed Dr Alm for an episode of *The MTPConnect Podcast* and organised for him to meet with leading companies, universities and medical research institutes, as well as federal and state government representatives and several chief scientists to discuss antimicrobial resistance and the critical threat it poses to human health.

Pictured: CARB-X Chief Scientist Dr Richard Alm and AAMRNet Co-Chair Andrew Bowskill leading an AMR roundtable of leading Queensland researchers, including Professor Ian Frazer, at the Translational Research Institute in Brisbane in August 2022.

Growth Centre Project Fund Outcomes

Our GC projects achieved substantial results. From 2017 until the end of FY2022, these projects have resulted in 488 new technologies being invented or progressed, 549 patents/trademark applications and licences, 150 start-up companies formed, 1,525 new jobs created and more than $257 million of investment flowing into incubator companies. Over 240,000 patients have been impacted, with over 780 clinical or preclinical trials commenced.

Pictured: (L–R) Cardiovascular Technology Services' Darius Chapman, the Medical Device Partnering Program's Professor Karen Reynolds, MTPConnect's Jo Close and South Australian Deputy Premier the Hon. Susan Close MP at the MDPP Showcase and 14th birthday celebration in Adelaide in June 2022.

When selecting projects to fund through the Growth Centre Project Fund, MTPConnect focused on capacity building for the MTP sector through training, accelerators, catalyst bodies and manufacturing facilities. A number of significant successes have been achieved this year including:

- **The MedTech Actuator** has now supported over 80 start-ups, creating at least 174 new jobs. This program is now supported by REDI.
- The upgrade for the **CSIRO** (Clayton) protein production platform to human GMP capability is now complete (see case study on page 46). It was opened by the Hon. Ed Husic MP, Minister for Industry and Science on 11 August 2022. The biologics facility's design and buildings were inspected by the Office of the Gene Technology Regulator (OGTR) and the facility has been certified. The CSIRO biologics facility's capability has been presented to the Coalition for Epidemic Preparedness Innovations (CEPI), the Department of Foreign Affairs and Trade (DFAT), the Department of Defence and the Defense Advanced Research Projects Agency (DARPA). In 2021, although the CSIRO biologics facility was not yet complete, CSIRO used its trained staff to manufacture a COVID-19 vaccine for The University of Melbourne. That vaccine is now in clinical trials in Australia.
- The **BioFab3D@ACMD centre** has provided training and internships to 56 students. A total of 30 projects have been supported by the facility, with 34 publications produced. This effective collaboration model will be used by the Aikenhead Centre for Medical Discovery (ACMD), which will also consist of multiple partners co-locating in one building. Over $1.8 million has now been raised for this new centre, with building commencing in June 2022.
- The 10 companies that participated in the pilot **ANDHealth+ program** have raised over $74 million in funding, created 351 jobs, undertaken 45 clinical trials and studies and impacted over 244,000 patients in just four years. The success of the ANDHealth+ pilot funded through MTPConnect has been recognised with $19.75 million of follow-on funding from the Medical Research Future Fund Early Stage Translation and Commercialisation Support Program.

- The Adelaide-based **Medical Device Partnering Program (MDPP)** turned 14 this year. The MDPP is the longest running medtech program in the country and has seeded innovations that have found their way into start-ups, scale-ups and multinational device companies. In 2017, the program was funded through the Growth Centre Project Fund to create a national footprint and was able to expand into Victoria with additional support from the Victorian Government. Through the life of the MTPConnect project, MDPP reports investment into companies in the program of over $1.8 million and an increase of almost 100 jobs. MDPP also supports three MTPConnect MRFF-funded programs: BTB, TTRA and CTCM.
- The **Clinical Oncology Society of Australia** (COSA) developed a national guide for implementation of the Australasian Tele-Trial Model and MTPConnect provided funding for a pilot project to implement the process. At project commencement there were no tele-trials open within Australia. By the project's end, 24 sites with 150 patients had participated in tele-trials. In October 2020, the project received a $75.2 million federal government grant 'to give patients access to clinical trials where they live'.
- **The Bridge Program** was a consortium of 15 companies, universities and industry associations that aimed to transfer practical skills on pharmaceutical commercialisation through online and residential training in drug discovery and development. By 2022 (and with further support from BTB, TTRA and REDI) they had extended the project in medical devices and delivered commercialisation training to over 800 individuals across Australia over nine cohorts. Key outcomes reported over both programs include 36 patents completed or initiated by participants, 48 contracts completed or initiated by participants, 51 participants secured external funding, 38 preclinical or clinical trials initiated or assisted by participants and 43 start-ups initiated or assisted by participants.
- **Ab Initio Pharma's** GMP facility has been completed; this will establish a manufacturing and training facility to provide cost-effective pharmaceutical manufacturing solutions for early-phase clinical trials in Australia. It was audited by the TGA in August and is now waiting for feedback. Several manufacturing campaigns have been lined up for FY2022–23. The facility now employs 10 people and has contributed to two publications as a result of contract research performed in collaboration with clients.
- **Garvan Institute of Medical Research** worked to deliver a molecular profiling platform. The platform included a clinically accredited molecular test for cancer trials, a genomics data platform to support clinical trials, and patient-matching capabilities to facilitate recruitment. The technology has been successfully transitioned to SydPath. SydPath has received NATA accreditation and is now routinely offering a clinically accredited and commercial-ready genome profiling platform with a single cost-effective test to enable precision cancer medicine.
- **The Translational Research Institute (TRI)** in Brisbane worked with Vaxxas, PharmOut and Eurofins AMS to establish a medtech/pharma clinical manufacturing and training hub to enable the translation of concepts into products for clinical studies. In the last year, TRI received 10 new enquiries for their clean room facilities, while Vaxxas and The University of Queensland continue to utilise the clean rooms for technical work and training. The continued enquiries and needs of the start-up companies in TRI and externally have identified the need to expand the current capability and this has resulted in $60 million of support from the Queensland Government to develop the TM@TRI facility.

Case Study: CSIRO Opens Australia's New Biologics Manufacturing Facility for Clinical Trials

Pictured: CSIRO's new National Vaccine and Therapeutics Lab follows a successful pilot facility in the early stages of the COVID-19 pandemic.
© Copyright NICK PITSAS

With the completion of CSIRO's National Vaccine and Therapeutics Lab in Melbourne, Australian SMEs and academics will for the first time be able to manufacture their biologics in Australia to prepare for human clinical trials.

This project was supported with $1.1 million in funding from MTPConnect's Growth Centre Project Fund in 2017, starting with the development of a business plan and progressing to support for the design of the laboratory and the purchasing and installation of specialist equipment. The build of the facility was funded by CSIRO. The final stage of the project is to install and qualify the equipment and to complete the facility documentation.

The fundamental research in academic and SME laboratories is discovering biologics with the potential to address major unmet clinical needs, but the research must be translated to medical products to create impact. Australia is an attractive destination for clinical trials, with an excellent medical system and a streamlined regulatory system for Phase I trials (the TGA CTN scheme); however, in the absence of a facility in Australia to manufacture biologics to the standard required for in-human studies, Australian researchers can struggle to overcome the 'valley of death' – the gap between fundamental research and clinical trials.

For clinical trials, biologics must be produced in clean rooms, under GMP conditions, with robust Quality Control – and an overarching Quality Management System. There were no publicly available facilities in Australia that could manufacture biologics to the required quality for clinical trials beyond Phase I, hence the need for CSIRO's National Vaccine and Therapeutics Lab.

MTPConnect worked with CSIRO, Monash University, Telix Pharmaceuticals, Sementis, CEPI, the Victorian Government and a SIEF grant to develop and fit out the biomanufacturing facility at CSIRO's Clayton site.

With the advent of COVID-19, the need for a biomanufacturing facility for clinical trials became urgent; although CSIRO's National Vaccine and Therapeutics Lab had not been completed, CSIRO was operating clean rooms for the manufacture of biologics derived from mammalian cell culture, and there was a robust Quality Management System in place, enabling manufacture to a quality required for Phase I clinical trials. Using these facilities, and staff trained in process development and GMP manufacture, CSIRO manufactured two COVID-19 vaccines for clinical trial purposes: one for The University of Queensland in 2020, and one for The University of Melbourne in 2021.

CSIRO's National Vaccine and Therapeutics Lab is the only facility available to SMEs and academics for GMP manufacture of biologics from mammalian cell culture in Australia. The facility consists of a state-of the-art facility for manufacture of investigational materials for evaluation in human clinical studies and is supported by a robust Quality Management System. While building a dedicated Quality Control laboratory, the Quality Control team is operating in a temporary facility, offering qualified and validated assays to support the GMP manufacture of biologics.

With a breadth of activities – from research and development to manufacture, quality control, analytics, quality assurance, upstream and downstream processing, bioconjugation and testing – and with products ranging from antibodies, protein-based vaccines, theranostics and more produced in mammalian and insect platforms, this facility is truly able to serve the needs of the biomedical industry.

With the completion of CSIRO's National Vaccine and Therapeutics Lab, Australian SMEs and academics will be able to manufacture their biologics in Australia. They will be able to engage closely with the scientists performing the process development and manufacture, facilitating transfer of their technology and enabling their qualified person (QP) to monitor the product quality at all stages of manufacture.

Manufacture in Australia will be faster and more cost effective than manufacture overseas, meaning more Australian discoveries make it to clinical trials and eventually to the clinic, leading to better health outcomes for all patients, and more value from Australian research captured in Australia.

With more trained scientists, and closer ties between universities, CSIRO and the local biotech industry, there will be greater potential to grow Australia's valuable medical technology and pharmaceutical sector.

Pictured: Left – Industry Minister Ed Husic opens CSIRO's new National Vaccine and Therapeutics Lab in Melbourne in August 2022.

Right – At the opening in Melbourne, MTPConnect Chair Sue MacLeman, CSIRO Chair Kathryn Fagg AO, Victoria's Lead Scientist Dr Amanda Caples, MTPConnect CEO Stuart Dignam and CSIRO's Dr Susie Nilsson.

Growth Centre Project Fund Projects

Growth Centre Objective addressed by Project

- Improving collaboration and commercialisation
- Management and workforce skills
- International markets and global value chains
- Regulation reform

Accelerating Australia – Stage 1

Centre for Entrepreneurial Research and Innovation (CERI)
Scoping work for a national consortium for translational medical technology and pharmaceuticals research and training.

Outcomes: This program received additional funding to assist in a national rollout – see Accelerating Australia – Stage 2 for impact details.

Location: Western Australia
MTPConnect grant: $150,000
Industry contributions: $618,931
Status: Finished

Accelerating Australia – Stage 2

Centre for Entrepreneurial Research and Innovation (CERI)
To facilitate translation of biomedical research through experiential entrepreneurial courses, brokerage and early-stage commercialisation support services to identify and reduce hurdles in our biomedical translation ecosystem.

Outcomes: Over the course of receiving MTPConnect support, CERI trained 344 participants in their Entrepreneurial Mindset Bootcamp and 102 participants in their 14-week Concept to Creation program. CERI has since gone on to train a further 376 participants. Perth Biodesign trained 168 people in 2022 and the Biodesign course is expected to run in Adelaide, Sydney and Victoria in 2023.

Location: Western Australia
MTPConnect grant: $1,000,000
Industry contributions: $2,870,135
Other government contributions: $5,000
Status: Finished

Accelerating precision therapies through digital infrastructure for adaptive trials and trial-ready cohort studies

Queensland University of Technology (QUT)
To develop digital infrastructure to support adaptive clinical trials and 'trial-ready' natural history cohort studies. The open-source solution is specifically intended to facilitate capture of clinical evidence to inform the licensure and funding of new therapeutic products.

Outcomes: The platform continues to grow in both user-base and capabilities year on year. The Motor Neurone Disease MiNDAUS Registry has over 128 participants and the Global Angelman Syndrome Registry is now active in 80 countries. Due to the success of the launched instances of the platform, two new clients requested their own instances of the platform to support health research in rare kidney diseases and orthopaedic surgery.

Location: Queensland
MTPConnect grant: $200,000
Industry contributions: $446,072
Status: Finished

An AI digital health platform for cardiovascular clinical decision support.

Integrated Cardiovascular Clinical Network (iCCnet)
To implement a cloud-based artificial intelligence (AI) digital health platform to eliminate avoidable/preventable errors in healthcare services by automating best practice clinical guidelines.

Outcomes: Early data shows promising results that the clinically derived algorithms can allow scale up of home monitoring software and this has been taken further by one of the industry partners within the project.

Location: South Australia
MTPConnect grant: $253,420
Industry contributions: $408,341
Status: Finished

ANDHealth

ANDHealth
Creating an integrated ecosystem for the development and commercialisation of evidence-based digital health products.

Outcomes: The 10 companies who participated in the pilot ANDHealth+ program have raised over $74 million in funding, created 351 jobs, undertaken 45 clinical trials and studies and impacted over 244,000 patients in just four years.
The success of the ANDHealth+ pilot funded through MTPConnect has been recognised with $19.75M of follow-on funding from the Medical Research Future Fund Early Stage Translation and Commercialisation Support Program.

Location: Victoria
MTPConnect grant: $1,150,000
Industry contributions: $5,153,903
Status: Finished

Asialink

Asialink Business

Develop two Asia Industry guides: 'digital health in Indonesia' and 'frugal innovation ecosystem in India' as well as identification of Asia capable leaders with Australia's ASX-listed MTP companies.

Outcomes: Both guides have been launched and well received. The guides were launched at information seminars with panel events discussing the subject. Both events are available as podcast downloads on MTPConnect website.

Location: Victoria
MTPConnect grant: $193,424
Industry contributions: $193,424
Status: Finished

Australia-China Life Sciences Partnership Program

AusBiotech Ltd

To increase awareness, and thus, opportunities for communication, collaboration and commercialisation between the life sciences sectors in Australia and China.

Outcomes: A free-to-use database was generated. Uptake was lower than expected and the project was terminated.

Location: Victoria
MTPConnect grant: $111,590
Industry contributions: $111,590
Status: Terminated

Australian Anti-Microbial Resistance Network (AAMRNet)

MTP-IIGC LIMITED

The formation of an Australian-first network bringing together key stakeholders to address the impact of antimicrobial resistance (AMR) on human health.

Outcomes: AAMRNet continued to grow its supporter and partner base during FY21-22, whilst progressing action on its strategic priorities. Awareness of the Network, both in Australia and around the world has grown through extensive engagement as AAMRNet progresses work to explore establishing itself as an Australian AMR accelerator.

Location: Victoria
MTPConnect grant: $469,367
Industry contributions: $781,000
Status: Ongoing

Australian Cardiovascular Alliance (ACvA)

Australian Cardiovascular Alliance

To map the capabilities and resources specifically available to support cardiovascular MedTech development in Australia. and develop a clinical trial service to support research groups.

Outcomes: This project has resulted in a network totalling almost 50 Australian entities and individuals, all of whom feature in a globally accessible, online directory https://www.ventriclinical.org/. Ventri Clinical has been directly influential in the confirmation of a small number of device studies to be held in Australia, one put forward by a French based company. Ventri acts as sector advocates for members throughout the pitching and remain unbiased and connected to each as projects are due to progress. Consortium partners have continued funding to allow Ventri Network development to continue, and the network continues to recruit.

Location: New South Wales
MTPConnect grant: $41,743
Industry contributions: $141,500
Status: Finished

Australian Centre for Commercialization of Regenerative Medicine (CCRM) – Stage 1

Monash University

Scoping work for an Australian hub of Canada's Centre for Commercialisation of Regenerative Medicine (CCRM).

Outcomes: During the project ten regenerative medicine product companies started collaborating internationally and five collaboration events were held with over 500 attendees.

Location: Victoria
MTPConnect grant: $200,000
Industry contributions: $358,382
Other government contributions: $150,000
Status: Finished

Australian Centre for Commercialization of Regenerative Medicine (CCRM) – Stage 2

Monash University

To progress the commercialisation of Australian regenerative medicine technologies, therapies and related products.

Outcomes: CCRM Australia continues to provide specialist expertise, funding opportunities and promoting collaborations across industry stakeholders. During 2022 CCRM Australia has supported existing stakeholders with over 116 discussion meetings, including directly supporting companies from 7 different countries in accessing Australian resources; some of which include plans to conduct clinical trials in Australia. In addition, CCRM Australia has continued to grow a partner network of over 50 organisations in regenerative medicine.

Location: Victoria
MTPConnect grant: $340,000
Industry contributions: $723,282
Status: Finished

Growth Centre Project Fund (continued)

Growth Centre Objective addressed by Project

- Improving collaboration and commercialisation
- Management and workforce skills
- International markets and global value chains
- Regulation reform

BioFab3D@ACMD

St Vincent's Hospital Melbourne

A robotics and biomedical engineering centre, embedded within a hospital to build biological structures such as organs, bones, brain, muscle, nerves and glands.

Outcomes: In the FY2021-2022, BioFab3D have provided training and internship to 56 students. A total of 30 projects have been supported by the facility with 34 publications produced. This effective collaboration model will be used by the Aikenhead Centre for Medical Discovery which will also consist of multiple partners co-locating in one building – over $1.8 million has now been raised for this new centre.

Location: Victoria
MTPConnect grant: $1,100,000
Industry contributions: $1,274,864
Status: Finished

Herston Biofabrication Institute

Queensland University of Technology (QUT)

Support for a biofabrication research centre located on a hospital campus utilising 3D digital scanning, modelling and advanced manufacturing technologies. Initially scanning and modelling ears for children with microtia.

Outcomes: Specifications for a biofabrication centre, with industry partners engaged.
At least eight children recruited to a pilot project investigating biofabrication of ears. Support from the Queensland Government for four specialist teams within the centre.

Location: Queensland
MTPConnect grant: $100,000
Industry contributions: $1,614,000
Other government contributions: $100,000
Status: Finished

Certara-Monash University Industry Fellowship Program

Certara Australia

To identify and develop the next generation of pharmaceutical scientists – a combination of academic coursework, hands-on industry training and research.

Outcomes: 5 Certara-Monash Fellows are expected to have graduated in October 2022.
The unique and specialized Model Informed Drug Discovery & Development curriculum developed for the Fellowship has since been incorporated in the following three programs: Monash University, Master of Pharmaceutical Science – 68 students. Certara, Applied Pharmacometrics Training Fellowship in Africa – 16 students and the Certara Fellowship

Location: Victoria
MTPConnect grant: $750,000
Industry contributions: $1,091,941
Status: Finished

Clinical Trial : Impact and Quality (CT:IQ)

Bellberry Ltd

A vision for a whole-of-sector approach to improve the quality, efficiency and impact of clinical trials.

Outcomes: CT:IQ is now a self-sustaining collaborative activity for the Australian clinical trials sector. There are presently 40 organisations who have signed up as Executive Committee and Steering Committee members, and an additional 9 individuals who are members of the CT:IQ advisory committee.

Location: South Australia
MTPConnect grant: $370,000
Industry contributions: $850,455
Other government contributions: $3,000
Status: Finished

Clinical Trial Assist – facilitating clinical trial recruitment in general practice

VentureWise Pty Limited

To identify, develop and evaluate a model to support clinical trials in Australia through GP engagement

Outcomes: Fifty-Two GP's attended educations sessions and an additional 38 GP practices were engaged with assisted recruitment.
Three clinical trials were assisted with recruitment and 54 individuals recruited in total during the project. No progress has been made in this work since the project conclusion due to the labour intensive work needed.

Location: New South Wales
MTPConnect grant: $144,749
Industry contributions: $144,749
Status: Finished

ClinTrial Refer – Improve recruitment to all clinical trials in Australia

South Eastern Sydney Local Health District.

To create one combined ClinTrial Refer database with new search functions to build a national solution to trials recruitment.

Outcomes: The ClinTrial Refer platform continues to grow and has launched a new pricing schedule to enable it as a self-sustaining entity. The App now has 3700 registered users and lists over 1950 trials across 712 sites.

Location: New South Wales
MTPConnect grant: $313,000
Industry contributions: $583,677
Status: Finished

Comprehensive Global Investment

AusBiotech Ltd
Development of a comprehensive global investment education program for the Australian life science sector – companies, investors and researchers.

Outcomes: The Australian MTP sector's attraction for investment was impacted greatly by the COVID-19 global pandemic in terms of trends: with few opportunities to travel nationally or internationally or meet in a traditional face-to-face manner; and yet IPO activity increased markedly in the sector. The rise in IPOs saw the Roadmap to a successful IPO for life science companies gain attention during the period and as such prompted a review of outdated information and a relaunch in FY2021.

Location: Victoria
MTPConnect grant: $398,043
Industry contributions: $400,000
Status: Finished

CRITERIA – Building clinical trial capability and capacity.

ARCS Australia Ltd
To connect MTP companies with appropriately trained graduates and equip them with clinical trials job ready skills.

Outcomes: Following the success of the MTPConnect project, ARCS Australia was successful in the REDI grant entitled 'Shortage of Clinical Research Associates'. This training targets the same group but commences these students once they have secured a position in the relevant MTP companies.

Location: New South Wales
MTPConnect grant: $250,000
Industry contributions: $260,422
Status: Finished

Enabling precision cancer clinical trials for SME's.

The Garvan Institute of Medical Research
A clinically accredited molecular test for cancer trials, a genomics data platform to support clinical trials, and patient-matching capabilities to facilitate recruitment.

Outcomes: The technology has been successfully transitioned to SydPath. SydPath have received NATA accreditation and are now routinely offering a clinically accredited and commercial-ready genome profiling platform to enable precision cancer medicine.

Location: New South Wales
MTPConnect grant: $316,256
Industry contributions: $338,820
Status: Finished

Establishment of a early-stage product manufacturing facility and training hub

Translational Research Institute
A MedTech/pharma clinical manufacturing and training hub to enable the translation of concepts into products for clinical studies.

Outcomes: In the last year TRI received 10 new enquiries for their cleanroom facilities, Vaxxas and UQ continue utilising the cleanrooms for technical work and training. The continued enquiries and needs of the start-up companies in TRI and externally have identified the need to expand the current capability and this has resulted in $60 million of support from the Queensland government to develop the TM@TRI facility.

Location: Queensland
MTPConnect grant: $499,990
Industry contributions: $1,300,845
Status: Finished

Formulation and GMP product manufacturing services for clinical trials in Australia

Ab Initio Pharma and the University of Sydney
A manufacturing and training facility that provides cost-effective pharmaceutical manufacturing solutions for SME's, academics, clinicians and larger pharma for early-phase clinical trials in Australia.

Outcomes: Ab Initio's GMP manufacturing lab has recently been audited by TGA and are now waiting for feedback. Several manufacturing campaigns have been lined up for FY22-23. The facility now employs 6 people and had contributed to 2 publications as a result of contract research performed in collaboration with clients.

Location: New South Wales
MTPConnect grant: $500,000
Industry contributions: $997,696
Other government contributions: $200,000
Status: Finished

Genomics National Alliance (InGeNA)

The Australasian Institute of Digital Health
An industry group from across the genomics value chain with a focus on activities to allow Australia to be a global leader in genomics and deliver precision health at a population level.

Outcomes: InGeNA has published a total of 4 reports to FY2022 and is now a self-sufficient entity from membership funding with 12 industry partners to date. InGeNA continues to develop webinars and other events to promote genomics to the sector and address current challenges.

Location: Victoria
MTPConnect grant: $300,000
Industry contributions: $542,158
Status: Finished

Growth Centre Project Fund (continued)

Growth Centre Objective addressed by Project

- Improving collaboration and commercialisation
- Management and workforce skills
- International markets and global value chains
- Regulation reform

Hit ID platform

Cancer Therapeutics CRC Pty Ltd (CTx)
A purpose-built drug discovery library of more than 315,000 small molecules, an ultra-high throughput screening facility and a state-of-the-art software platform for in silico drug discovery.

Outcomes: Over the period 2021-22 the ALIDC Consortium have transferred the library to the new acoustic-tubes at Compounds Australia, worked as a consortium to reformat the library sub-sets, developed a new access protocol to broaden the use of the library and worked to promote the library to the research community.

Location: Victoria
MTPConnect grant: $1,100,000
Industry contributions: $2,044,302
Status: Finished

Industry Mentoring Network in STEM (IMNIS) program – Stage 1

ATSE
Aiming to narrow the cultural gap that exists in Australia between business and academia. This project will develop a national mentoring program linking PhD students with qualified industry mentors.

Outcomes: Four hundred industry knowledgeable PhD students have been trained. Over 80% of mentees were maintaining contact with their industry mentor after their one-year program has ended.

Location: Victoria
MTPConnect grant: $187,390
Industry contributions: $895,568
Status: Finished

Industry Mentoring Network in STEM (IMNIS) program – Stage 2

ATSE
To continue PhD mentoring activities, develop an alumni program and pilot rural and remote mentoring.

Outcomes: The GC IMNIS program has now concluded with 768 mentees paired with a mentor and an alumni network established of 1300 individuals. IMNIS is now supported by REDI.

Location: Victoria
MTPConnect grant: $215,000
Industry contributions: $1,493,698
Status: Finished

Installation of robotic sterile clinical trial manufacturing capability

Pharmaceutical Packaging Professionals Pty Ltd
A fully robotic, sterile vial-filling line to manufacture Phase II and III products.

Outcomes: Project was terminated due to lack of progress as a result of company relocation.

Location: Victoria
MTPConnect grant: $50,000
Industry contributions: $192,250
Status: Terminated

Medical Device Partnering Program (MDPP) – Stage 1

Flinders University
Scoping of the rollout of a national Medical Device Partnering Program (MDPP)

Outcomes: This program received additional funding to assist in a national rollout – see Medical Device Partnering Program (MDPP) – Stage 2 for impact details.

Location: South Australia
MTPConnect grant: $150,000
Industry contributions: $174,000
Status: Finished

Medical Device Partnering Program (MDPP) – Stage 2 – National Expansion

Flinders University
To establish the foundations for national operations of the MDPP program

Outcomes: MDPP's 'Ideas Incubator' is a proven program for fuelling the medical device innovation pipeline and is now operating a national program from South Australia and continues to show a good return on investment. In 2022 MDPP continued to grow the number of complementary programs offered as a venture partner within MTPConnect's BTB, REDI, TTRA and CTCM programs.

Location: South Australia
MTPConnect grant: $290,000
Industry contributions: $1,146,823
Status: Finished

Microscopy Australia – Technical Voucher Fund

University of Sydney
Vouchers to support MedTech R&D by providing easy and discounted access to microscopy services.

Outcomes: The companies who took advantage of the vouchers have all continued to progress their products since, with effects ranging from additional patents, success in manufacturing grants and growing their company by 30%.

Location: New South Wales
MTPConnect grant: $110,837
Industry contributions: $330,144
Status: Finished

Pilot implementation of the Australasian Tele-Trial Model

Clinical Oncology Society of Australia (COSA)
To implement a feasible and effective tele-health strategy to increase access to clinical trials closer to home, while at the same time ensuring the proper conduct of cancer clinical trials.

Outcomes: The project has developed National Tele trial Principles and standard operating procedures for clinical trials and tele trials. These documents have been endorsed by all states and territories, together with the Therapeutic Goods Administration (TGA) and the National Health and Medical Research Council (NHMRC).
At project commencement there were no tele-trials open within Australia. By the project end 24 sites with 150 patients had participated in tele-trials. In October 2020, the project received a $75.2 million Federal Government grant "to give patients access to clinical trials where they live".

Location: New South Wales
MTPConnect grant: $115,000
Industry contributions: $297,233
Status: Finished

Regenerative Medicine (RM) Catalyst Body

AusBiotech
To investigate and analyse the Regenerative medicine sector in all four Industry Growth Centre (IGC) pillars.

Outcomes: AusBiotech, Medicines Australia and five partners have secured additional funding for the ongoing work of the 'Cell and Gene Catalyst', which will build on the work of the Regenerative Medicine Catalyst Project. The first project of this consortium will be a manufacturing-focused project.

Location: Victoria
MTPConnect grant: $300,000
Industry contributions: $447,000
Status: Finished

The Bioprint Facility for Translational Science and Medicine in the MTP Sector

University of Wollongong
To create a facility to expedite the development of commercial opportunities in 3D bioprinting.

Outcomes: TRICEP staff has gone through intensive 3 days training on quality management system and management is committed to have TRICEP and its bioinks processing facility to have ISO 13485 accreditation. The work at TRICEP continues to advance bioprinting and bioInks and has provided expertise to a number of patent applications for partner companies.

Location: New South Wales
MTPConnect grant: $400,000
Industry contributions: $1,115,134
Status: Finished

The Bridge Program

Queensland University of Technology (QUT)
To transfer practical skills on pharmaceutical commercialisation through online and residential training in drug discovery and development.

Outcomes: Since commencement, the Bridge and the BridgeTech programs have now delivered commercialisation training to over 800 alumni across Australia in the pharmaceutical and medical technology sectors over 5 cohorts. Key outcomes reported over both programs include 36 patents completed or initiated by participants, 48 contracts completed or initiated by participants, 51 participants have secured external funding, 38 pre-clinical or clinical trials initiated or assisted by participants and 43 start-ups initiated or assisted by participants

Location: Queensland
MTPConnect grant: $576,157
Industry contributions: $1,109,748
Status: Finished

The Bridge Tech Program

Queensland University of Technology (QUT)
To transfer practical skills on medical device commercialisation through online and residential training.

Outcomes: The BridgeTech has now completed the delivery of year-long training programs in the area of medical technology, devices and diagnostics for 4 cohorts, held 15 seminars and webinars, held one domestic industry tour and two international conference tours, with an additional conference tour planned for October 2022, held 4 symposiums involving industry talks, workshops, seminars and pitching exercises and held 12 networking events. See the Bridge project for additional outcomes.

Location: Queensland
MTPConnect grant: $294,035
Industry contributions: $742,323
Status: Finished

Growth Centre Project Fund (continued)

Growth Centre Objective addressed by Project

- Improving collaboration and commercialisation
- Management and workforce skills
- International markets and global value chains
- Regulation reform

Health Horizon

Health-Innovate Pty Ltd

To catalogue and track publicly exposed medical innovations under development in Australia using a humanised machine learning system.

Outcomes: The Health Horizon has become financially sustainable and has continued to grow to almost 2,500 innovations achieving 18,627 milestones. In the last year it has grown from 21 licensed users across 7 paying companies to over 200 licensed users across 74 companies finding opportunities for partnership, sales and investment.

Location: Australian Capital Territory
MTPConnect grant: $100,000
Industry contributions: $124,791
Status: Finished

The MedTech Actuator

The Actuator Operations

To leverage existing industry and research capabilities in the acceleration of medical device technology development opportunities through 15-month actuator programs.

Outcomes: Over 80 start-ups have now been supported, creating at least 174 new jobs. This program has been supported by REDI.

Location: Victoria
MTPConnect grant: $1,100,000
Industry contributions: $3,171,755
Status: Finished

Training programs for the biologics and biomedical-based industry sector.

Australian Institute for Bioengineering and Nanotechnology, the University of Queensland

Training programs for R&D and advanced manufacturing of biologic medicines.

Outcomes: Six hundred and seventy participants received training during the project, this was a mixture of in-person training and access to an e-learning platform.

Location: Queensland
MTPConnect grant: $110,000
Industry contributions: $110,000
Status: Finished

Upgrade CSIRO protein production platform

CSIRO

To upgrade the CSIRO (Clayton) protein production platform to human Good Manufacturing Practise (GMP) capability.

Outcomes: The facility is now complete. The Biologics Facility design and buildings were inspected by the OGTR and the facility has been certified for PC2 and PC2 large scale work.
In 2021, although the CSIRO Biologics Facility was not yet complete, CSIRO used their trained staff to manufacture a Covid-19 vaccine for the University of Melbourne. That vaccine is now in clinical trials in Australia.

Location: Victoria
MTPConnect grant: $1,100,000
Industry contributions: $2,626,196
Other government contributions: $750,000
Status: Finished

Vaccine research in Australia: Landscaping capabilities and services

Vaxine

Landscaping Australia's vaccine research capabilities and Australia's first national vaccine conference.

Outcomes: A better connected Australian vaccine community, engaging through events and in person. Ten events were held with over 350 attendees. Two products have been developed. The company was also successful in winning a BioMedical Translation Bridge (BTB) grant.

Location: South Australia
MTPConnect grant: $250,000
Industry contributions: $371,697
Status: Finished

BioMedTech Horizons

The BMTH program launched in April 2018 to address gaps in early biomedical and medical technology product development and increase the number of viable, new medical technologies and devices reaching proof-of-concept stages or beyond, and that become attractive for private capital investment and commercialisation. It provides up to $1 million in funding over a maximum two-year period to help eligible organisations progress their innovations.

The program continues to deliver – in September 2021, MTPConnect and the Hon. Greg Hunt MP, then Minister for Health and Aged Care, announced the outcomes of Round 4 of the program, with five projects announced. A further three projects announced in May 2022, totalling $4.9 million of BMTH funds for Round 4. BMTH funding attracted an additional $6.6 million in industry contributions.

Over the four rounds of BMTH, a total of $39.4 million has been allocated to 49 projects, with matching contributions from industry of $53.5 million.

Commercialisation impact from awardees of the BMTH1 program

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

The first round – BMTH1 – concluded in June 2021. BMTH1 focused on precision medicine and 3D-printed medical devices. Eleven projects were identified and funded as part of BMTH1, with nine successfully completing their program of works. Impact metrics for BMTH1 are shown below.

An overview of BMTH1 was published in a program impact report in November 2021. Key achievements include:

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

This financial year saw significant progress being made across the partners in the BMTH2 and BMTH3 funding rounds despite ongoing COVID-19 restrictions, and the award to eight new projects in the BMTH4 funding round, as listed in the BMTH Projects table on page 61.

The BMTH program was granted an extension of time through a Letter of Variation of Agreement with the Department of Health, until November 2023. This extension allowed the BMTH management team to extend timelines of BMTH awardee programs to recover from the impacts of COVID-19 and still deliver on research and development objectives. Development and execution of these variations formed a substantial part of the program activities in the period March to June 2022. As indicated below, many projects will now finish activities and reporting in the 2023 financial year and the BMTH program will subsequently complete all reporting and closedown activities.

Notable achievements of program awardees include:

- US Food and Drug Administration (FDA) 510(k) and TGA Australian Register of Therapeutic Goods (ARTG) listings for Seer Medical, and CE marking registration for ZiP Diagnostics for the COVID-19 rapid test. Breakthrough device designations with the US FDA for Bionic Vision Technologies, Synchron, OncoRes and VitalTrace.
- Significant fundraising outcomes totalling more than $130 million were announced for Inventia Life Science, Synchron, Artrya (ASX listing), WearOptimo, Seer Medical, Atmo Biosciences, Hemideina, Venstra and Cyban.

Site Meetings

The BMTH team travelled to meet project partners face to face, in many cases for the first time as COVID-19 restrictions had limited that opportunity. Visits supported an important program governance activity and provided a hands-on opportunity to see the products being developed. Site visits were completed with Seer Medical, Cyban, Enlighten imaging, PolyActiva, Synchron, Anatomics, Atmo Biosciences, Optiscan, OncoRes, Cortical Dynamics, Proteomics International, Neuromersiv, Aria Research, 3DMorphic, IDE Group, Inventia Life Science, ResusRight, Bionic Vision Technologies, Zip Diagnostics, Macuject, Apollo Medical Imaging Technology, Ferronova, Anisop Holdings, Miniprobes and Hemideina.

Pictured: MTPConnect team members Dr Duncan Macinnis, Dr Gerard Gibbs and Dr Vishal Srivastava visited the Neuromersiv team in Sydney for an update on their BMTH-funded innovation. Co-Founders Anshul Dayal and Oliver Morton-Evans are revolutionising brain rehabilitation therapy using virtual reality technology.

Other program activities

Media, communications and engagement training was delivered to BMTH awardees by CPR Communications in a series of small and engaging workshops. Workshops addressed presenting to investors, practical tips and techniques for media interviews, communicating with government, managing communication for product recalls, generating media interest and leveraging social media.

The BMTH team hosted an intern, Victoria (Tori) Mynard, from the Monash University Master of Biomedical and Health Science program, through May and June.

BMTH Case Study: BMTH – Ingestible Capsule Set to Revolutionise Gut Health Diagnosis

Pictured: The Atmo Gas Capsule aims to play a critical role in diagnosing – and improving – gut health.

Sophisticated gas-sensing technology is paving the way for better understanding of gut health – in the hope of giving clinicians a world-first tool to aid diagnosis and manage debilitating gastrointestinal disorders.

Gut disorders impact tens of millions of people globally, yet many go untreated, as conclusive diagnostic tests remain elusive. A new platform developed by Atmo Biosciences is aiming to provide an accurate, cost-effective, and user-friendly diagnostic solution.

Small intestinal bacterial overgrowth (SIBO) is one such disorder that is difficult to diagnose. SIBO occurs when excess bacteria in the small intestine ferment undigested food, generating hydrogen as a by-product. SIBO is thought to be associated with a range of uncomfortable symptoms, including bloating and gas. If left untreated, SIBO can lead to serious complications like inflammation, autoimmune disease, nutrient deficiencies and malnutrition.

Currently, the prevalence of SIBO is unclear, mainly due to the lack of reliable diagnostic tools. Diagnoses are further complicated by the absence of universally accepted diagnostic parameters, and significant overlap with symptoms of other gastrointestinal (GI) disorders, such as irritable bowel syndrome (IBS) and functional dyspepsia. Without conclusive diagnoses, clinicians often trial antibiotics for symptom relief, which contributes to issues of over-prescription and the spread of antibiotic resistance.

With SIBO suspected to be significantly underdiagnosed in the general population, there is an unmet medical need for an accurate and readily repeatable diagnostic test.

Digital health company Atmo Biosciences is working to address this issue by developing the Atmo Gas Capsule System[1]: a world-first gas-sensing capsule that, when swallowed, travels through the gut and detects gases in real time from known GI locations. Clinicians hope to use these biomarkers to diagnose conditions such as SIBO, and consequently provide targeted treatment to patients.

The Atmo Gas Capsule was invented at RMIT University in Melbourne. In 2018, Atmo Biosciences signed a licensing deal with RMIT, securing the exclusive worldwide rights to commercialise the capsule. The capsule inventors are continuing to lead research and development at Atmo, together with a dedicated team of Atmo engineers.

Supported by funding from MTPConnect's BioMedTech Horizons (BMTH) program, in 2020 Atmo Biosciences set out to demonstrate proof-of-concept for its gas-sensing technology. The team benchmarked its diagnostic criterion against the two existing diagnostic methods: hydrogen breath testing and the gold-standard jejunal aspirate. The preliminary pilot results showed a good correlation to the latter, while emphasising the poor outcomes offered by breath testing. While the outcome measures were strong, additional work is required to validate the diagnostic method in a diverse population.

1 The Atmo Gas Capsule is currently an investigational device exclusively for use in clinical investigations and is not available for sale.

Future work will leverage the diagnostic criterion created during the BMTH project and focus on the development of an algorithm for SIBO diagnosis using the Atmo Gas Capsule. Additional clinical data will also be obtained to build the managed dataset that is required for the next phases of algorithm development. Further data will likewise be collected to demonstrate the clinical utility of the technology in monitoring patient outcomes, and its impact on treatment decisions.

In September 2021, Atmo Biosciences raised $9.56 million, led by two new investors – Sydney-based investment firm Alium Capital Management and Japanese multinational company Otsuka Pharmaceutical Co.

In mid-September 2022, Atmo Biosciences announced that the US Patent and Trademark Office (USPTO) had granted the patent for Atmo's ingestible gas-sensor capsule. The granted patent protects the ingestible capsule's unique gas-sensing functionality and the ability to wirelessly transmit the data it collects.

Atmo CEO and Managing Director Malcolm Hebblewhite said: "The grant of this patent is an exciting milestone for Atmo Biosciences. The patent is an important cornerstone of Atmo's IP strategy for protection of the Atmo Gas Capsule System and the Atmo future product pipeline.

"Grant of the patent in the USA is particularly satisfying, as it supports our commercial plans, which prioritise this large and important market," he said.

In October 2022, Atmo Biosciences announced the publication of a clinical study supporting the Atmo Gas Capsule's ability to determine its location in the gastrointestinal tract. The study demonstrates strong agreement between data from Atmo's Gas Capsule and a validated, FDA-cleared Wireless Motility Capsule (WMC), in determining transit metrics in healthy subjects. Based on this data, Atmo intends to conduct a clinical trial in patients with gastrointestinal motility disorders. The study was published in the journal Alimentary Pharmacology and Therapeutics.

Recent data released by the American Gastroenterological Association showed that nearly 40 percent of Americans have stopped routine activities such as doing exercise or running errands in the last year due to uncomfortable bowel symptoms[2]. Measurements of gut motility are important for evaluating and diagnosing these patients.

Professor Peter Gibson, Head of Luminal Gastroenterology Research at the Central Clinical School, Monash University, commented: "Results from this recent study are particularly pleasing in that they demonstrate such strong agreement between Atmo's gas-sensing capsule and WMC. The gas-sensing capsule is able to provide useful data to determine if a person's gut motility is too fast or slow. This personalised information is likely to be key for future clinical practice as different gastrointestinal disorders require different interventions."

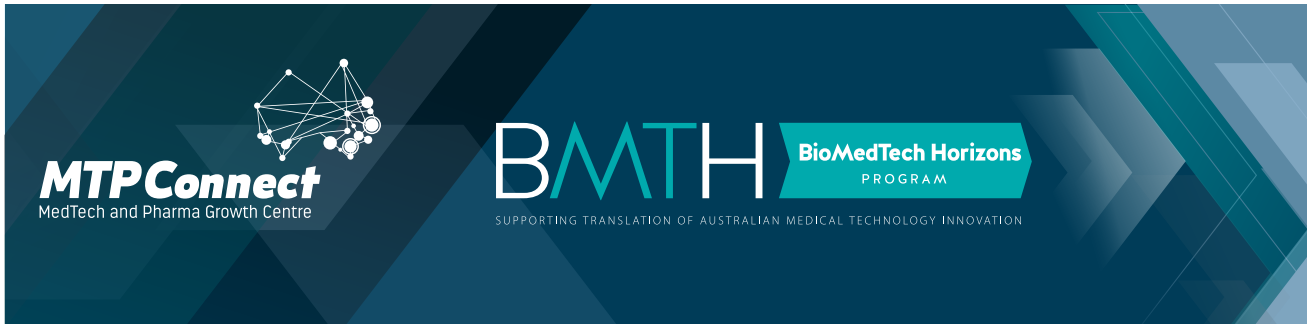
Mr Hebblewhite added: "Data from this study has provided us with the confidence to progress to a study involving patients who suffer from the motility disorders that we are aiming to diagnose. We are very excited to be working with key opinion leading gastroenterologists who specialise in functional gut disorders to support the upcoming study."

Once developed, the Atmo Gas Capsule aims to play a critical role in diagnosing – and improving – gut health. By enhancing the efficiency and accuracy of diagnoses, it may simplify the diagnostic journey for millions of individuals suffering from SIBO, mitigating the need for repeated medical appointments and offering substantial longer-term benefits for the healthcare system, both here in Australia and worldwide.

Other long-term benefits include the potential to limit the unnecessary use of antibiotics – thereby preventing indiscriminate harm to the gut microbiota of patients – while also decreasing the financial burden experienced by SIBO sufferers and enhancing their quality of life.

2 American Gastroenterological Association, 'New survey finds forty percent of Americans' daily lives are disrupted by digestive troubles', 14 September 2022.

BioMedTech Horizons Projects



Allegra Orthopaedics

Ceramic Interbody Fusion Device
Location: New South Wales
BMTH Grant: $1,141,500
Industry Contribution: $4,953,165
Duration: 1 May 2018 – 31 July 2021
Status: Finished

Anatomics

Porous Polyethylene Implant Material 'StarPore' – development and commercialisation of cranio-maxillofacial (CMF) implants
Location: Victoria
BMTH Grant: $891,500
Industry Contribution: $1,047,446
Duration: 1 May 2018 – 30 June 2020
Status: Finished

Bionics Institute

Innovative system for personalised management of hearing impairment enabling lifelong benefits
Location: Victoria
BMTH Grant: $966,500
Industry Contribution: $2,935,387
Duration: 1 May 2018 – 31 July 2021
Status: Finished

Biotech Resources

Preclinical Trials of a Rapid POC Sepsis Diagnostic
Location: Victoria
BMTH Grant: $33,382
Industry Contribution: $53,396
Duration: 1 May 2018 – 30 July 2019
Status: Terminated

Carina Biotech

CAR T -cell immunotherapies for solid cancers
Location: South Australia
BMTH Grant: $948,500
Industry Contribution: $1,637,731
Duration: 1 May 2018 – 31 December 2020
Status: Finished

Garvan Institute of Medical Research

A clinically accredited and commercial-ready genome profiling platform to enable precision cancer medicine
Location: New South Wales
BMTH Grant: $815,939
Industry Contribution: $848,063
Duration: 1 May 2018 – 31 March 2021
Status: Finished

Griffith University

Development of a 3D-printed graft for surgical repair of the Scapholunate Interosseous wrist ligament (SLIL)
Location: Queensland
BMTH Grant: $964,227
Industry Contribution: $272,247
Duration: 1 May 2018 – 31 July 2021
Status: Finished

Indee Labs

Towards bedside gene therapies: Development and optimisation of microfluidic gene delivery device optimisation and clinical development
Location: New South Wales
BMTH Grant: $891,500
Industry Contribution: $60,080
Duration: 1 May 2018 – 30 June 2020
Status: Finished

Monash Vision Group

Bionic Vision Implantation Pilot Study
Location: Victoria
BMTH Grant: $292,801
Industry Contribution: $575,148
Duration: 1 May 2018 – 31 January 2020
Status: Terminated

St Vincent's Hospital Melbourne/ BioPen

Advanced Limb Reconstruction Programme
Location: Victoria
BMTH Grant: $956,943
Industry Contribution: $748,529
Duration: 1 May 2018 – 31 December 2020
Status: Finished

WearOptimo

Leaping towards precision medicine: Microwearables
Location: Queensland
BMTH Grant: $891,500
Industry Contribution: $1,591,500
Duration: 1 May 2018 – 31 October 2019
Status: Finished

Advanced Genetic Diagnostics

Genetic Tests to Identify People at High Risk of Heart Disease
Location: Western Australia
BMTH Grant: $998,802
Industry Contribution: $601,765
Duration: 1 April 2020 – 2 March 2023
Status: Ongoing

Cyban

Development of a novel brain pulse oximeter to monitor brain oxygen levels following traumatic brain injury
Location: Victoria
BMTH Grant: $960,000
Industry Contribution: $750,000
Duration: 1 April 2020 – 30 November 2022
Status: Ongoing

BioMedTech Horizons Projects (continued)

Enlighten Imaging

A novel hyperspectral retinal imaging platform for next generation AI diagnostics
Location: Victoria
BMTH Grant: $1,000,000
Industry Contribution: $1,650,000
Duration: 1 April 2020 – 30 November 2022
Status: Ongoing

IDE Group

Control Sleeve for Intravitreal Injection System
Location: New South Wales
BMTH Grant: $1,000,000
Industry Contribution: $1,014,967
Duration: 1 April 2020 – 30 November 2022
Status: Ongoing

IntelliDesign

Portable Bedside Low Field Magnetic Resonance Imaging
Location: Queensland
BMTH Grant: $1,000,000
Industry Contribution: $481,250
Duration: 1 April 2020 – 2 March 2023
Status: Ongoing

Kunovus Technologies

An elastomeric motion-preserving implant to treat lumbar spine osteoarthritis as an alternative to fusion
Location: New South Wales
BMTH Grant: $998,600
Industry Contribution: $880,063
Duration: 1 April 2020 – 30 December 2022
Status: Ongoing

Macuject

AI-based Clinical Decision Support Software for Intravitreal Management of Age-related Macular Degeneration
Location: Victoria
BMTH Grant: $948,000
Industry Contribution: $1,060,000
Duration: 1 April 2020 – 31 May 2023
Status: Ongoing

PolyActiva

Development of sustained release ocular implants for delivery of steroids and non-steroidal anti-inflammatory drugs (NSAID) to the eye for the prevention and treatment of macular oedema
Location: Victoria
BMTH Grant: $829,147
Industry Contribution: $1,832,584
Duration: 1 April 2020 – 30 September 2022
Status: Terminated (awardee initiated)

WearOptimo

Advancing Cardiac Microwearables to the clinic: for rapid, minimally invasive personalised cardiovascular medicine
Location: Queensland
BMTH Grant: $983,127
Industry Contribution: $2,452,000
Duration: 1 April 2020 – 31 May 2023
Status: Ongoing

Anatomics

Digitally enabled skullcaps to monitor brain swelling in craniectomy patients to optimise timing of skull reconstruction surgery
Location: Victoria
BMTH Grant: $997,920
Industry Contribution: $371,693
Duration: 1 October 2020 – 31 May 2023
Status: Ongoing

Anisop Holdings

A nano-optimised surface to prevent orthopaedic implant infections
Location: New South Wales
BMTH Grant: $1,000,000
Industry Contribution: $793,750
Duration: 1 October 2020 – 2 March 2023
Status: Ongoing

Apollo Medical Imaging Technology

Artificial Intelligence-Based Clinical Decision Support Software for Guiding Acute Stroke Therapy
Location: Victoria
BMTH Grant: $346,500
Industry Contribution: $505,000
Duration: 1 October 2020 – 30 November 2022
Status: Ongoing

Artrya

Automated methods for evaluating cardiac CT angiography and high-risk imaging biomarkers
Location: Western Australia
BMTH Grant: $987,428
Industry Contribution: $540,000
Duration: 1 October 2020 – 31 May 2023
Status: Ongoing

Atmo Biosciences

Application of Atmo ingestible gas-sensing capsule to irritable bowel syndrome
Location: Victoria
BMTH Grant: $620,000
Industry Contribution: $650,000
Duration: 1 October 2020 – 31 May 2022
Status: Finished

Bionic Vision Technologies

Bionic Eye Generation 3
Location: New South Wales
BMTH Grant: $1,000,000
Industry Contribution: $1,289,862
Duration: 1 October 2020 – 2 March 2023
Status: Ongoing

Carbon Cybernetics

High Resolution Cortical Recording for the Prediction and Prevention of Epileptic Seizures
Location: Victoria
BMTH Grant: $999,676
Industry Contribution: $313,000
Duration: 1 October 2020 – 31 May 2023
Status: Ongoing

Ear Science Institute Australia

ClearDrum®: an acoustically optimised silk fibroin membrane for the treatment of chronic middle ear disease
Location: Western Australia
BMTH Grant: $993,500
Industry Contribution: $348,915
Duration: 1 October 2020 – 30 November 2022
Status: Ongoing

Ferronova

Improving Colorectal Cancer Outcomes with Hybrid Cancer Tracers
Location: South Australia
BMTH Grant: $826,000
Industry Contribution: $1,620,000
Duration: 1 October 2020 – 31 May 2023
Status: Ongoing

Hemideina

Development of miniature, low-energy wireless power and data transmission systems for implantable medical devices
Location: Victoria
BMTH Grant: $660,520
Industry Contribution: $532,003
Duration: 1 October 2020 – 30 November 2022
Status: Ongoing

Inventia Life Science

Developing a 3D bioprinting system for intraoperative skin regeneration
Location: New South Wales
BMTH Grant: $1,000,000
Industry Contribution: $1,425,729
Duration: 1 October 2020 – 31 May 2023
Status: Ongoing

Merunova

Augmented Digital Re-Construction and Re-Visualisation of Spine MRI for the Personalised Diagnosis of Back Pain
Location: New South Wales
BMTH Grant: $976,989
Industry Contribution: $137,100
Duration: 1 October 2020 – 31 May 2023
Status: Ongoing

Miniprobes

A smart brain biopsy needle for faster, safer neurosurgery
Location: South Australia
BMTH Grant: $1,000,000
Industry Contribution: $1,345,000
Duration: 1 October 2020 – 30 November 2022
Status: Ongoing

Neuromersiv

Commercialisation of hand and arm wearable for use with Neuromersiv VR rehabilitation system
Location: New South Wales
BMTH Grant: $994,000
Industry Contribution: $753,700
Duration: 1 October 2020 – 31 May 2023
Status: Ongoing

Northern Research

PulseVAD Pulsatile Rotary Blood Pump
Location: New South Wales
BMTH Grant: $170,000
Industry Contribution: $5,067,900
Duration: 1 October 2020 – 30 November 2022
Status: Terminated

OncoRes Medical

Compact Wireless Technology for Improved Accuracy During Breast Conserving Surgery
Location: Western Australia
BMTH Grant: $1,000,000
Industry Contribution: $231,582
Duration: 1 October 2020 – 30 November 2022
Status: Ongoing

Optiscan

Use of Non-Invasive Confocal Endomicroscopy System to Enhance Oral Cancer Screening and Surgical Margin Assessment
Location: Victoria
BMTH Grant: $971,000
Industry Contribution: $480,186
Duration: 1 October 2020 – 30 November 2022
Status: Ongoing

Seer Medical

Personalised epilepsy treatment via mobile and wearable monitoring
Location: Victoria
BMTH Grant: $1,000,000
Industry Contribution: $658,070
Duration: 1 October 2020 – 31 May 2023
Status: Ongoing

Synchron Australia

Stentrode: enabling people with paralysis to communicate with the power of their mind
Location: Victoria
BMTH Grant: $989,175
Industry Contribution: $980,137
Duration: October 2020 – 28 November 2022
Status: Terminated (awardee initiated)

Venstra Medical

Development of a Transcatheter Blood Pump System for Cardiogenic Shock and Hemodynamically Compromised Patients (Project SAVA)
Location: New South Wales
BMTH Grant: $850,000
Industry Contribution: $131,000
Duration: 1 October 2020 – 30 November 2022
Status: Ongoing

ZiP Diagnostics

Establishing domestic capabilities for combined R&D and manufacture of point-of-care diagnostics
Location: Victoria
BMTH Grant: $600,000
Industry Contribution: $3,580,000
Duration: 1 October 2020 – 30 August 2022
Status: Finished

3DMorphic

Personalised spinal surgery for Australians; a clinical trial of 3DMorphic's advanced manufactured patient-matched spinal fusion devices
Location: New South Wales
BMTH Grant: $800,000
Industry Contribution: $800,000
Duration: 1 October 2021 – 31 May 2023
Status: Ongoing

BioMedTech Horizons Projects (continued)

Aria Research

Non-Invasive Bionic Vision Wearable Development Prototype for Blind and Vision Impaired
Location: New South Wales
BMTH Grant: $800,000
Industry Contribution: $818,000
Duration: 1 October 2021 – 31 May 2023
Status: Ongoing

Atmo Biosciences

Acceleration of Ingestible Gas Sensor Commercialisation
Location: Victoria
BMTH Grant: $343,310
Industry Contribution: $343,310
Duration: 1 October 2021 – 31 May 2023
Status: Ongoing

Cortical Dynamics Limited

Brain Anaesthesia Response Monitor BARM™ technical upgrade
Location: Western Australia
BMTH Grant: $137,000
Industry Contribution: $137,000
Duration: 1 October 2021 – 30 September 2022
Status: Ongoing

Proteomics International

Manufacturing the next generation in vitro diagnostic device to predict diabetic kidney disease
Location: Western Australia
BMTH Grant: $413,516
Industry Contribution: $955,516
Duration: 1 October 2021 – 31 May 2023
Status: Ongoing

ResusRight

Development of a novel ventilation monitoring system for neonatal resuscitation
Location: New South Wales
BMTH Grant: $800,000
Industry Contribution: $833,995
Duration: 1 October 2021 – 31 May 2023
Status: Ongoing

Seer Medical

Cloud-enabled wearable cardiac monitor
Location: Victoria
BMTH Grant: $800,000
Industry Contribution: $1,215,000
Duration: 1 October 2021 – 28 November 2022
Status: Terminated (awardee initiated)

VitalTrace

Development of a precision real-time fetal biosensor for the prevention of stillbirth and fetal complications during childbirth
Location: Western Australia
BMTH Grant: $800,000
Industry Contribution: $1,175,962
Duration: 1 October 2021 – 31 May 2023
Status: Ongoing

Biomedical Translation Bridge

Pictured: BTB awardees, Steering Committee and Operations team at the BTB Finale showcase event. Photo credit: Edoardo Capriotti

The BTB program launched in May 2019 to nurture the translation of new therapies, technologies and medical devices through to the proof-of-concept stage, with expert industry support and mentoring. The program provided funding of between $100,000 and $1 million to projects for up to two years to accelerate the development of their innovation.

By bringing key organisations together, the BTB program formed an Australian-wide initiative with partners including BioCurate (joint venture between The University of Melbourne and Monash University), UniQuest (through the Queensland Emory Drug Discovery Initiative [QEDDI], a business unit of UniQuest, the commercialisation company of The University of Queensland) and Medical Device Partnering Program (MDPP, led by Flinders University). The BTB program's education partners, the Bridge and BridgeTech programs, coordinated by Queensland University of Technology, ensured hundreds of early-career researchers gained the critical skills needed to translate and commercialise their research outputs.

It has delivered three funding rounds, including a specific COVID-19 round set up swiftly in early 2020 as the pandemic took hold. Being able to pivot this BTB funding round so quickly to support Australia's pandemic response was testament to the effective design and governance framework of this funding program. MTPConnect mobilised resources across its organisation to support this crucial pivot for this unprecedented national health emergency. In what could not be a more challenging time to carry out health and medical research, 19 of the 21 projects successfully completed the program in the two-year timeframe.

The BTB program successfully achieved its key objective to 'nurture, de-risk and develop competitive ventures that are attractive for further funding opportunities'. Projects advanced through the BTB program, with regular mentoring, commercialisation advice and project management. Opportunities were given to project teams to participate in the Bridge and BridgeTech programs delivered by Queensland University of Technology, to enhance their commercialisation knowledge, skills, capabilities and build their network.

An in-depth commercialisation review was undertaken, facilitated by Venture Partners (BioCurate, UniQuest and MDPP) to tailor a program of value-add activities to support product development, market research/competitive intelligence analysis, intellectual property advice, business development support, regulatory support, consultancy services including technical experts, development and/or manufacturing support to de-risk, build and strengthen the commercialisation strategy and product position. A top-up of $1.7 million of direct support went to project teams to address these specific challenges.

The BTB program has delivered real outcomes, with 29 new technologies invented or progressed, seven new products launched, and 56 new jobs created.

	New technologies invented or progressed	**New patents, trademark applications** and **licences**	**New products** launched	**New jobs** created in **project companies** (years – direct and indirect)	Total sector **investment** into new companies (cash and in-kind)
BTB Program Outcomes	29	47	7	56	$36.2M

Through the $22.3 million BTB program, and with industry contributions and substantial amounts of external development capital raised, a total of $160 million has been injected into the sector.

As an outcome of the BTB program, notable achievements include:

- **AdAlta** established a partnership with Telix Pharmaceuticals to commercialise a radiolabelled AD-214 (RL-AD-214) for treatment of idiopathic pulmonary fibrosis that can effectively be monitored in preclinical and clinical imaging. In August 2020 the company raised $8.1 million to progress development of AD-214, and a further $3.75 million was secured in December 2021.
- **Cincera Therapeutics** developed a drug candidate that is safe and shows promising anti-fibrotic efficacy (for the liver, lungs and kidneys), as well as high selectivity against a large range of safety pharmacology targets. Data supporting the therapeutic benefits and safety of its drug candidate has enabled Cincera Therapeutics to secure an additional $2 million in funding from Brandon BioCatalyst under a Series A option.
- **Deep Brain Stimulation Technologies** has developed a 'smart' human-grade bionic implant that treats the symptoms of Parkinson's disease and adaptively optimises the therapy dose, based on the patient's response. The device and other system components are now ready for manufacture and first use in humans in a Melbourne-based clinical trial. During the term of the BTB project, the company established a pathway to global commercialisation with a leading manufacturer and distributor of deep brain stimulation systems.
- **Dimerix's** lead drug candidate, DMX-200 – selected for inclusion in the global REMAP-CAP trial as a possible treatment for acute respiratory distress syndrome (ARDS) associated with COVID-19 – has been administered at 14 sites across the UK and the Netherlands and dosed 742 patients in the domain as at 25 January 2022. The company raised $24 million in September 2021 to fund multiple DMX-200 Phase III clinical programs.
- **Envision Sciences** developed a tissue biopsy test, using its combinatorial set of biomarkers that achieved above 95 percent sensitivity and specificity in patient samples. This represents a huge step towards the development of a precision tissue biopsy test that outperforms the existing gold standard in accurately confirming prostate cancer diagnosis, as well as determining patient prognosis. Envision Sciences has partnered with a major global diagnostics company to facilitate the development of a Laboratory Developed Test (LDT) ready for clinical practice.

- **INOVIQ** (previously known as BARD1 Life Sciences Ltd) successfully translated its proprietary SubB2M-based detection technology into an immunoassay format for the monitoring and detection of breast cancer, and this is now being further developed into a commercially viable assay format. In July and August 2021 INOVIQ raised a total of $18.4 million to fund the advancement of its breast, ovarian and prostate cancer diagnostic programs towards key development and commercialisation milestones.
- **LBT Innovations** automated the process of determining the antibiotic resistance or susceptibility of infectious bacteria cultured from clinical samples. This new technology can markedly improve efficiencies in pathology labs, enable timely and effective treatment of infectious diseases, and help to control the indiscriminate use of antimicrobials. The assessment module will be deployed for use on LBT Innovations' APAS Independence instrument manufactured by Planet Innovation in Melbourne.
- **MycRx** developed one of the most advanced small molecule inhibitors targeting Myc oncoprotein directly to treat oncology indications such as lung cancer. This high-quality data package has already attracted commercialisation, partnering and investment interest from international venture capital firms and transnational pharmaceutical companies, culminating in a successful Series A2 venture capital financing round in late 2021.
- **Starpharma** registered its antiviral nasal spray Viraleze™ for sale in more than 30 countries, including in Europe and the UK. The product is available online in certain markets, making Starpharma the first ASX-listed biotech to bring a COVID-19 preventative product to the global retail market. Its application with the TGA for registration in Australia is ongoing and the company has also signed an exclusive sales and distribution agreement for Viraleze in the Middle East. Starpharma also raised $48.9 million to accelerate development of its dendrimer products including the nasal spray Viraleze.
- **The University of Melbourne**'s **Medihood McMonty** is listed as a medical device on the ARTG. It is currently used in more than 145 hospitals around Australia, including in regional centres, and is also enjoying early adoption overseas. The team secured a commercialisation and manufacturing partner, Evan Evans, and the patient isolation hood was the joint winner of the 'Workplace Health and Safety Solution of the Year' accolade at the WorkSafe Victoria Awards.
- **UniQuest** identified a novel preclinical development candidate for the treatment of prostate cancer with a demonstrated on-target mechanism, and the project is positioned to enter preclinical development to compile a clinic-ready package to support first-in-human studies. Strong interest has prompted initial discussions with prospective partners.
- **Vast Bioscience** demonstrated the versatility of its platform to develop 3D small molecule inhibitors, achieving high specificity and selectivity in its candidate – a critical requirement in the development of safe and effective therapies for severe acute and chronic pain. Vast Bioscience's lead candidate outperformed competitor lead molecules in efficacy and safety data, securing more than $1 million in 2021 to further advance the product.
- **Vaxine's** COVID-19 vaccine candidate became the first Australian candidate to commence human Phase I safety trials.

BTB Case Study: Solid-dose Needle-free Vaccine to Combat Zika Virus

Pictured: Dr Makutiro Masavuli, working in the lab. Photo supplied by The University of Adelaide

Zika virus is a viral disease primarily transmitted by the bite of an infected Aedes mosquito, though it can also be passed from mother to fetus during pregnancy. Sexual transmission of Zika virus has likewise been documented, with the virus able to infect, damage and persist in testes.[1]

Though the symptoms associated with Zika virus are relatively mild, the World Health Organization (WHO) has designated it a priority disease, because it can trigger catastrophic complications, such as Guillain-Barré syndrome. It can also cause severe congenital defects, like microcephaly, if infection occurs during pregnancy.

During the most recent Zika virus outbreak, which occurred between 2015 and 2016, about 174,000 cases of infection were confirmed in Central and South America, with most of them reported in Brazil. To date, a total of 89 countries and territories have documented evidence of autochthonous mosquito-borne transmission of Zika virus, distributed across five of the six WHO regions (all except the Eastern Mediterranean Region).[2]

Currently, treatment for Zika virus is directed only towards relieving symptoms, and despite intensive efforts, there are no licensed vaccines that completely prevent infection. One of the key challenges of developing a vaccine platform is ensuring its safe application during pregnancy; other considerations include its feasibility and scalability for deployment in an epidemic situation.[3]

Under the leadership of Associate Professor Branka Grubor-Bauk, Head of Viral Immunology at the Adelaide Medical School, a team from The University of Adelaide has taken on the challenge of developing a DNA vaccine for Zika virus. DNA vaccines not only induce humoral and cellular immunity against the virus but are also less expensive to manufacture than traditional vaccines. DNA-based vaccines, which are produced using standardised manufacturing, have several features that make them attractive for managing epidemics in resource-poor settings – namely, they don't require cold-chain storage, and they offer long-lasting immunity. A DNA-based Zika virus vaccine would therefore ensure long-term efficacy and enable rapid deployment during future outbreaks.

According to Associate Professor Grubor-Bauk, such a vaccine has the potential to significantly restrict maternal-fetal transmission of Zika virus.[4] "Zika virus is extremely dangerous if you're pregnant, as severe birth defects such as microcephaly cannot be corrected, and the accompanying disabilities are lifelong and catastrophic. This research aims to develop a novel needle-free vaccine to prevent infection of pregnant women and the resulting devastating congenital effects in the unborn child," said Associate Professor Grubor-Bauk.

The University of Adelaide team secured a valuable non-exclusive partnership with Enesi Pharma to provide its proprietary intradermal, needle-free vaccine delivery system. Enesi Pharma is an award-winning biotech company based in the UK, where it develops a range of next-generation, ImplaVax®-enabled, needle-free injectable unit solid-dose vaccines.

1 Griffin, B, Muthumani, K, Warner, B et al. 'DNA vaccination protects mice against Zika virus-induced damage to the testes', ***Nature Communications* 8,** 15743 (2017). https://doi.org/10.1038/ncomms15743
2 WHO, 'Countries and territories with current or previous Zika virus transmission'. Accessible at: https://www.who.int/health-topics/zika-virus-disease#tab=tab_1 accessed February 2022.
3 Wilder-Smith, A, Vannice, K, Durbin, A. et al. 'Zika vaccines and therapeutics: landscape analysis and challenges ahead', ***BMC Medicine* 16,** 84 (2018). https://doi.org/10.1186/s12916-018-1067-
4 Cao, B, Diamond, M, Mysorekar, I. 'Maternal-Fetal Transmission of Zika Virus: Routes and Signals for Infection', ***Journal of Interferon and Cytokine Research*** (2017) Jul;37(7):287-294. Doi: 10.1089/jir.2017.0011. Epub 2017 Apr 12. PMID: 28402153; PMCID: PMC5512303.

In 2020, The University of Adelaide was awarded $675,000 in matched funding through Round 2 of the BTB program, and was supported by BTB Venture Partner, UniQuest, to complete preclinical evaluation of its novel Zika virus DNA vaccine. Ultimately, the project aimed to evaluate a needle-free, solid-dose formulation for its Zika virus vaccine, in partnership with Enesi Pharma.

During the 20-month grant period, The University of Adelaide successfully completed an in vivo evaluation of the optimal dose and vaccination regime required to achieve protection with the naked Zika virus DNA vaccine. This was done by measuring Zika viral loads in mice that had been vaccinated with two or three doses of the DNA vaccine. The studies showed that the naked vaccine conferred protection after two doses at a standard dose, or three doses at a lower dose. A pregnancy study was also done in a mouse model of Zika infection, which demonstrated that the vaccine conferred protection to both the mother and fetus, and prevented fetal brain damage, microcephaly and intrauterine growth retardation. The vaccine also demonstrated efficacy in eliminating the persistence of Zika virus in the male reproductive tract, preventing testicular damage. The naked Zika DNA vaccine progressed through to evaluation in NHP and was found to be highly immunogenic.

Vaccine dose optimisation was also evaluated in mice for the Zika solid-dose implant, and its delivery method was further investigated with better outcomes achieved with transdermal delivery. Formulation of the Zika vaccine into a solid-dose implant showed efficacy and protection in mice vaccinated with the standard dose. Thermostability studies at a range of temperatures over a period of 6 months for both naked and solid-dose Zika vaccines demonstrated excellent thermostability for both formulations.

The development of the solid-dose implant formulation of the vaccine is ongoing. The University of Adelaide has continued its partnership with Enesi Pharma, and if the delivery platform is successful, it may secure a licensing arrangement. Alternatively, Enesi Pharma will license the vaccine for further development.

An additional top-up funding of $103,750 allowed The University of Adelaide to engage several consultants towards meeting their commercial goals, including a technical expert to assist them in developing a go-to-market (GTM) model, business strategy and competitor landscape benchmarking analysis. An IP consultant was also engaged to enhance their strategy and strengthen their IP position. Two regulatory consultants were also engaged to provide advice that puts the team in a good position to expand their reach to market, accelerate clinical programs, increase the value of their assets, and position their start-up for future capital raise.

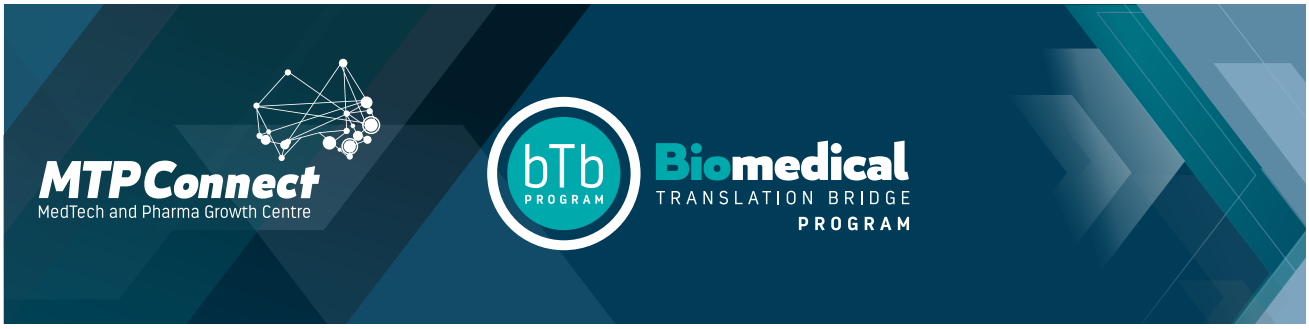
The vaccine is one of the first Zika virus T-cell-based vaccines extensively evaluated and validated. The efficacy of the vaccine in different models now opens avenues for the development of other flavivirus vaccines incorporating T-cell antigens that can provide protection and completely abrogate the risk of flavivirus antibody-dependent enhancement of disease. The team's excellent work gained recognition as a finalist for Best Invention in the 2022 Knowledge Commercialisation Australasia (KCA) Research Commercialisation Awards, highlighting 'top-tier work' in Australasian tech transfer.

Although the initial target population for the vaccine is females of childbearing age, given the favourable safety profile anticipated, and longevity of protection provided, there is also potential for it to be used in younger age groups.

While cases of Zika virus have significantly declined in recent years, it's expected that further transmission will occur, particularly in areas with a large naïve population and abundant Aedes mosquitoes.[5] In the event of Zika re-emergence or future epidemics, it's anticipated that initial uptake of The University of Adelaide's vaccine would most likely occur in endemic countries across many age groups, before moving into annual cohort-driven national immunisation programs. The next market segment would be travellers to endemic areas, and eventually – depending on disease epidemiology and mosquito movement with climate change – the vaccine could potentially be introduced routinely in national immunisation programs globally.

5 Aliota, M, Bassit, L, Bradrick, S et al. 'Zika in the Americas, year 2: What have we learned? What gaps remain? A report from the Global Virus Network', ***Antiviral Research***, Volume 144, 2017, Pages 223-246 https://doi.org/10.1016/j.antiviral.2017.06.001

Biomedical Translation Bridge Projects



In partnership with

AdAlta Limited (ASX:1AD)

Clinical imaging of CXCR4 in the development of an i-body therapeutic for idiopathic pulmonary fibrosis
Location: Victoria
BTB Grant: $1,100,167
Industry Contribution: $1,525,162
Duration: 1 February 2020 – 30 June 2022
Status: Finished

Australian National University

Rapid and objective eye and brain testing for better management of ophthalmic and neurological diseases
Location: Australian Capital Territory
BTB Grant: $680,819
Industry Contribution: $4,916,670
Duration: 1 February 2020 – 31 March 2022
Status: Finished

DBS Technologies Pty Ltd

Better quality of life for people living with Parkinson's disease using an innovative device providing adaptive DBS
Location: Victoria
BTB Grant: $1,064,063
Industry Contribution: $1,963,405
Duration: 1 April 2020 – 31 March 2022
Status: Finished

MycRx Pty Ltd

Novel, small molecule therapeutics for the treatment of lung cancer
Location: Victoria
BTB Grant: $1,021,000
Industry Contribution: $2,180,686
Duration: 1 February 2020 – 30 June 2021
Status: Finished

Noisy Guts Pty Ltd

Noisy Guts
Location: Western Australia
BTB Grant: $260,186
Industry Contribution: $659,066
Duration: 1 March 2020 – 15 March 2021
Status: Terminated

SpeeDx Pty Ltd

ResistancePlus® MABSC/MAC diagnostic test for detection of Mycobacterium abscessus complex (MABSC), Mycobacterium avium complex (MAC) and gene markers associated with susceptibility or resistance to macrolides and amikacin antibiotics
Location: New South Wales
BTB Grant: $213,299
Industry Contribution: $482,650
Duration: 1 April 2020 – 30 June 2022
Status: Finished

The University of Melbourne – Melbourne Dental School

Progressing a novel dental implant to commercial reality
Location: Victoria
BTB Grant: $63,719
Industry Contribution: $581,528
Duration: 1 February 2020 – 30 June 2022
Status: Finished

Vast Bioscience Pty Ltd

3D small molecule sodium channel inhibitors for the treatment of postsurgical pain
Location: Queensland
BTB Grant: $936,702
Industry Contribution: $1,621,368
Duration: 1 February 2020 – 31 December 2021
Status: Finished

INOVIQ (ASX:IIQ) (previously BARD1 Life Sciences Limited ASX:BD1)

Development and commercialisation of high-throughput liquid biopsy assays for the detection of breast cancer and monitoring of recurrence based on a unique, proprietary cancer-specific probe
Location: Victoria
BTB Grant: $436,201
Industry Contribution: $837,870
Duration: 7 September 2020 – 30 June 2022
Status: Finished

Cincera Therapeutics Pty Ltd

Developing a new drug treatment for metabolic and fibrotic disease
Location: Victoria / South Australia
BTB Grant: $1,225,000
Industry Contribution: $2,389,321
Duration: 20 July 2020 – 30 September 2021
Status: Finished

Envision Sciences Pty Ltd

Diagnosis and prognosis of prostate cancer using blood and tissue tests
Location: South Australia
BTB Grant: $1,071,986
Industry Contribution: $1,271,986
Duration: 3 September 2020 – 30 June 2022
Status: Finished

LBT Innovations Limited (ASX:LBT)

APAS®-AMR: Automated Plate Assessment System for Anti-Microbial Resistance (AMR) using Artificial Intelligence (AI)
Location: South Australia
BTB Grant: $859,107
Industry Contribution: $952,104
Duration: 3 September 2020 – 30 June 2022
Status: Finished

Pharmaxis Ltd (ASX:PXS)

Development of Pharmaxis' tailored dual action compound PXS-4699 to treat Duchenne Muscular Dystrophy
Location: New South Wales
BTB Grant: $505,390
Industry Contribution: $970,504
Duration: 8 September 2020 – 26 April 2022
Status: Terminated

The University of Adelaide

Development of a needle-free solid dose Zika virus vaccine
Location: South Australia
BTB Grant: $779,250
Industry Contribution: $780,000
Duration: 14 October 2020 – 30 June 2022
Status: Finished

The Florey Institute of Neuroscience and Mental Health

Device for guiding therapy in ataxia and imbalance
Location: Victoria
BTB Grant: $622,500
Industry Contribution: $980,547
Duration: 28 September 2020 – 30 June 2022
Status: Finished

UniQuest Pty Ltd

Developing a first in class oral therapy for the treatment of prostate cancer and other cancers
Location: Queensland
BTB Grant: $1,100,660
Industry Contribution: $1,623,644
Duration: 1 July 2020 – 30 June 2022
Status: Finished

Dimerix (ASX:DXB)

New treatment for respiratory complications as a result of COVID-19 in global clinical study with a potential fast track pathway to clinical practice
Location: Victoria
BTB Grant: $1,122,500
Industry Contribution: $2,845,986
Duration: 15 September 2020 – 30 November 2021
Status: Finished

Starpharma Pty Ltd (ASX:SPL)

Developing an intranasal spray, utilising an already-marketed, broadspectrum antiviral dendrimer for COVID-19 and potential use in future pandemics
Location: Victoria
BTB Grant: $1,103,750
Industry Contribution: $2,154,170
Duration: 7 September 2020 – 31 August 2021
Status: Finished

SpeeDx Pty Ltd

Development, validation and commercialisation of the VITRO assay (Virus Induced host RespOnse) – a rapid-response COVID-19 assay to enhance Australia's current and future pandemic preparedness.
Location: New South Wales
BTB Grant: $513,630
Industry Contribution: $753,630
Duration: 2 November 2020 – 31 March 2022
Status: Finished

The University of Melbourne

A novel ventilated hood for patient isolation (I-Hood) to protect hospital staff from COVID-19
Location: Victoria
BTB Grant: $690,000
Industry Contribution: $1,924,487
Duration: 14 September 2020 – 31 December 2021
Status: Finished

Vaxine Pty Ltd

Developing an Australian COVID-19 vaccine
Location: South Australia
BTB Grant: $1,000,000
Industry Contribution: $4,830,379
Duration: 1 December 2020 – 30 September 2021
Status: Finished

Researcher Exchange and Development within Industry

Improving workforce skills and driving jobs growth is the focus of the $32 million REDI initiative, awarded to MTPConnect in February 2020. The initiative is building an industry-ready workforce with the skills and capacity to keep pace with the demands of a rapidly changing sector for now and into the future. REDI has identified current and future sector skills gaps through a comprehensive 'root and branch' review.

The first interim report published in 2020 identified priority skills gaps that needed addressing across the sector in the near term to unlock significant value for the MTP sector within the following 12 to 18 months.

The second, more comprehensive 'root and branch' review, *Driving skills development and workforce training for the future MTP workforce*, was published in March 2021 and identifies 20 skills gaps that require priority action in the sector to power the next wave of innovation and growth.

The third review, *Positioning the MTP workforce for post-pandemic prosperity*, examines skills gaps that have grown in importance because of the COVID-19 pandemic.

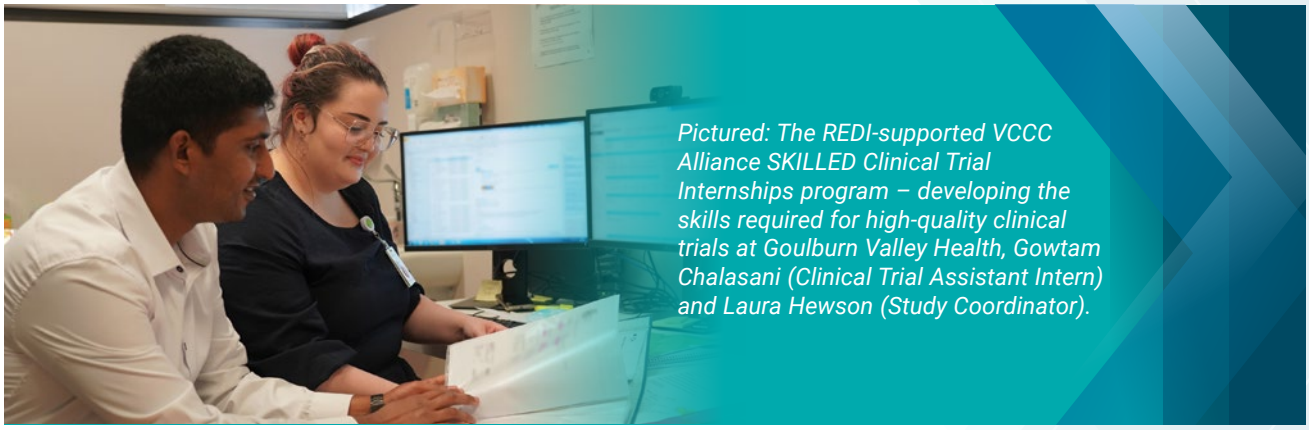
Collectively, these three reports provide a skills development blueprint to ensure Australia's MTP workforce is industry-ready, fit for post-pandemic prosperity and appropriately positioned to capitalise on current and future global opportunities.

The reports identified 81 skills gaps spanning seven key themes: advanced manufacturing and supply chain; business operations; clinical trials; health data and cybersecurity; health economics and regulatory affairs; product development and commercialisation; and specialist and technical skills, and included a deep dive into 24 of these skills gaps.

REDI is now addressing a number of skills gaps through its engagement of 20 partners to deliver a total of 46 programs consisting of training, traineeships, internships, fellowships, education, development and mentoring. As of 30 June, REDI has had 4,469 participants and delivered over 380 events, engaging with over 10,000 people throughout the sector.

The quality of the programs is rated extremely high, with an average Net Promoter Score of 71 across all partners. Participation extends to all states and mainland territories, with 52 percent female participants. Of the participants in the fellowships/internships opportunities, 52 percent are researchers, 27 percent are students, 14 percent are MTP professionals and six percent are clinicians coming from industry (pharmaceutical, biotechnology, digital and medtech), universities, hospitals, research institutes and consultancies including funding organisations.

The REDI Fellowship Program provides financial support to Australian and/or multinational medtech and pharma companies to bring the best Australian talent in-house to work on priority research projects. There are now 47 fellows being supported through our REDI program, all gaining real-world industry experiences, driving greater collaboration between industry and research and commercialisation-focused culture change.



Pictured: The REDI-supported VCCC Alliance SKILLED Clinical Trial Internships program – developing the skills required for high-quality clinical trials at Goulburn Valley Health, Gowtam Chalasani (Clinical Trial Assistant Intern) and Laura Hewson (Study Coordinator).

REDI is having a significant impact in bringing MTP stakeholders together, developing knowledge, skills and networks and also strengthening Australia's capability and capacity to translate medical research. In the six months following one REDI-supported course, 50 new jobs were created, over $20 million capital raised and 10 clinical trials commenced.

REDI partners are helping to develop the skills and knowledge of MTP companies to understand the path to market, develop robust business plans and then to execute them. Many of the participants in REDI training programs have been able to secure new funding, employ new staff and progress their innovations.

REDI has also worked to assist partnerships between academia and industry and it has received many reports of new and deepening relationships, particularly through the REDI Fellowship Program, which has facilitated connections between 31 fellows and research-intensive companies located in Australia and internationally.

In July 2022, REDI delivered a series of three investor workshops to demystify investing in the healthtech sector. The workshops were held for investors only, in Sydney, Adelaide and Melbourne. The **Investor Workshop Series** gave potential healthtech investors the chance to hear from other investors and experts in the medtech, biotech and pharmaceutical sector, to improve their knowledge about the benefits and risks of investing in MTP companies, and to learn how to assess investment opportunities. The workshops were led by Richard Dale and Rob McInnes – both of whom have experience and credentials in investing, commercialisation, innovation, new venture development and venture capital.

Pictured: Discussion panel from the Investor Workshop Series event in Adelaide – from left to right is Rob McInnes, Kirsten Bernhardt, Stephanie Morris, Richard Dale, David Saint and Jo Close.

REDI Case Study: APR.Intern & MUVi Light the Way for Collaboration

Pictured: Mahjabeen Khan from the University of New South Wales (UNSW) said she learnt how to work in a multidisciplinary team at MUVi and would highly recommend the APR.Intern program to others.

With COVID-19 spreading by aerosols and contaminated surfaces in hospitals and healthcare settings, a medtech disinfection systems start-up, Mobile UV Innovations (MUVi), developed a new device that uses ultraviolet photon light to rapidly disinfect hospitals.

Ultraviolet (UVC) photon light has long been known for its antimicrobial and disinfecting efficacy. At the forefront of this UVC photon light technology is MUVi – a Melbourne-based medtech start-up that designs and develops disinfection systems for hospitals, healthcare and medical settings.

When COVID-19 led the healthcare sector to re-evaluate systems, MUVi started developing a new device that used UVC light to rapidly disinfect hospital and medical equipment and contaminated surfaces, and to minimise the spread ofhighly infectious multi-resistance microorganisms.

To fast-track testing, the team engaged a PhD intern through APR.Intern, with financial support from MTPConnect's REDI initiative, funded by the Medical Research Future Fund (MRFF). MUVi was matched with Mahjabeen Khan from the University of New South Wales (UNSW), who specialised in microbiology.

Over a six-month internship, with the guidance of her academic mentor, UNSW's Professor Mark Willcox, Ms Khan applied her expertise to design experiments, test and analyse the efficacy of MUVi's new device.

Reported results revealed the MUVi UVC photon light device killed approximately 99.99 percent of all tested microorganisms, including bacteria, fungi and a COVID-19 surrogate.

Ms Khan said the internship was a good opportunity to collaborate with people from different backgrounds.

"I learnt how to work in a multidisciplinary team and how to develop reports per industry requirements, which differ from academic ones. I would highly recommend the APR.Intern program to others," Ms Khan said.

For MUVi Director, Murray McDonald, the APR.Intern project was an opportunity to gain local Australian microbial research data and build a strong pathway into Australia's university research sector. "APR.Intern, and the financial support we received from MTPConnect, allowed our start-up to access critical talent resources to undertake key testing data at a valued research institution (UNSW)," said Mr Murray. "The project results have the potential to create new job opportunities and bring greater benefits to sectors beyond just healthcare," he added.

Following the successful internship, MUVi and UNSW have applied for two international grants to continue their innovative industry-university research.

Through our REDI initiative, Australian Postgraduate Research Intern (APR.Intern) provides eligible companies in the medtech, biotech and pharmaceutical sector with a rebate to take on a talented PhD student in a short-term subsidised industry placement. These placements allow businesses to fast-track R&D, while students are given the opportunity to develop in a practical industry research environment – strengthening research translation within the sector.

APR.Intern is Australia's only all-sector, all-discipline PhD internship program, transforming Australian businesses through university-research collaborations.

See www.aprintern.org.au for more information.

REDI Partners

- ANDHealth
- ARCS Australia
- ARCS Australia Consortium
- Biointelect Consortium
- Centre for Biopharmaceutical Excellence
- Cicada Innovations
- Flinders University (Medical Device Partnering Program)
- GSK Australia
- IntelliHQ
- Life Sciences WA
- MedTech Actuator
- PRAXIS Australia
- Queensland University of Technology (Bridge and BridgeTech programs)
- SeerPharma
- The George Institute for Global Health
- The Industry Mentoring Network in STEM (IMNIS)
- The University of Melbourne
- The University of Melbourne (APR.Intern)
- VCCC Alliance
- Wrays

Targeted Translation Research Accelerator

TTRA TARGETED TRANSLATION RESEARCH ACCELERATOR
DIABETES + CARDIOVASCULAR DISEASE

The $47 million TTRA program was launched in June 2020 as an integrated research program to improve the prevention, diagnosis, treatment and management of diabetes and cardiovascular disease (D&CVD) and their associated complications in Australia, by establishing two new national research centres and three rounds of contestable funding opportunities to support individual D&CVD research projects. The overall goal of the TTRA program is to see Australian D&CVD research translated into patient outcomes, jobs growth, economic outcomes and savings in our health system, and to reduce the burden of D&CVD.

The TTRA program is delivered in collaboration with an independent Expert Advisory Board, as well as modality expert partners – ANDHealth, the Australian Centre for Health Services Innovation, Medical Device Partnering Program and UniQuest – who provide mentoring, commercialisation and implementation advice to those applying for and receiving TTRA Research Projects funding. Highlights of the TTRA program this year were:

- **In September 2021**, MTPConnect and the then Minister for Health and Aged Care, the Hon. Greg Hunt MP, announced the outcomes of Round 1 of the TTRA Research Projects funding opportunity, with $5.2 million awarded to seven D&CVD research projects, which attracted an additional $9.1 million in co-contributions. These projects included research innovations addressing mental health conditions, chronic kidney disease and cardiac and vascular complications in people living with D&CVD. These priority areas for Round 1 were identified through an evidence-based, national, coordinated health sector needs assessment conducted by MTPConnect in partnership with Monash University's BehaviourWorks Australia, Australian National University and Research Australia.
- **In January 2022**, MTPConnect and the then Minister for Health and Aged Care, the Hon. Greg Hunt MP, announced the establishment of two new major research centres, which are detailed in the TTRA case study below.
- **In October 2022,** MTPConnect and the Minister for Health and Aged Care, the Hon. Mark Butler MP, announced the outcomes of Round 2 of the Research Projects funding opportunity, with $6.7 million awarded to nine D&CVD research projects, which attracted an additional $8.6 million in co-contributions. These projects included research innovations addressing atherosclerosis, cerebrovascular disease, cardiomyopathy and heart failure, as well as mental health and glucose control for those living with diabetes.

Based on the outcomes from the needs assessments for Rounds 1 and 2, the third and final round of the TTRA Research Projects funding opportunity will specifically focus on supporting D&CVD projects that address the unmet health and medical needs of Aboriginal and Torres Strait Islander peoples in rural, remote, regional and urban centres. To guide the delivery and implementation of the Round 3 Research Projects funding opportunity and maximise its impact, MTPConnect has established the TTRA Indigenous Advisory Group, which involves/includes prominent Indigenous researchers, clinicians and thought leaders, as well as representatives from organisations that have deep engagement with Aboriginal and Torres Strait Islander communities through direct healthcare delivery.

Additionally, it is imperative that priority-setting for Indigenous research is Indigenous-led, so MTPConnect has commissioned Lowitja Institute, a community-controlled organisation and Australia's National Institute for Aboriginal and Torres Strait Islander Health Research, to lead a prioritisation project to determine the Indigenous-specific priority areas for this focused round. Priority-setting will take place over the remainder of 2022, with Round 3 set to open for applications in early 2023.

TTRA Case Study: A New Approach To Do More

In January 2022, then Minister for Health and Aged Care, the Hon. Greg Hunt MP, announced the establishment of two new national research centres for diabetes and cardiovascular disease, made possible through the TTRA program. The Australian Centre for Accelerating Diabetes Innovations (ACADI) and the Australian Stroke and Heart Research Accelerator (ASHRA) were each awarded $10 million from the TTRA program, attracting substantial co-contributions from academic and industry partners totalling $34.4 million.

ACADI and ASHRA are accelerating therapies towards clinical practice for the prevention, diagnosis, treatment and management of disease-related complications for diabetes or cardiovascular disease, respectively. They include carefully considered portfolios of research projects to initially address sector-identified priorities.

Both ACADI and ASHRA bring together large sector-wide collaborations of clinical, research, industry and community partners across Australia. These extensive collaborative networks will facilitate the breaking down of silos in diabetes and cardiovascular disease research in Australia, fostering innovation and the translation of medical research into tangible outcomes for Australians living with diabetes and/or cardiovascular disease, their families and carers, and the health system more broadly.

Both research centres are focused on the adoption and implementation of their therapies and subsequent delivery of health system outcomes, public health policy outcomes, consumer outcomes, commercial outcomes and reducing the burden of disease and health inequities in Australia. It is anticipated that each research centre will become self-sustainable with continued financial viability and talent management of the entity beyond the four years of TTRA funding. In addition to research and development, each research centre has a training program to support students and early-to-mid career researchers and clinicians to strengthen and grow capability and capacity in the sector and create the next generation of diabetes and cardiovascular disease research leaders.

The TTRA research centres initiative was showcased by the American Diabetes Association (ADA) as part of its 2022 'Thought Leadership' series. This involved production of a six-minute editorial film highlighting the intent of the funding and each centre's vision, as well as some key innovations. The film was played during the ADA's Scientific Sessions, a hybrid virtual and in-person conference in New Orleans, in June 2022. The ADA is one of the most prominent scientific associations, with a global audience of over half a million across industry, government and academia. The ADA's Scientific Sessions is the largest diabetes meeting in the world, bringing together nearly 20,000 participants – including more than 14,000 clinicians and researchers from over 100 countries.

The film was distributed as part of the official ADA TV 2022 broadcast during the meeting and post-meeting and shared on the ADA TV Twitter account to over 15,800 followers. The film was also integrated into the daily ADA TV program, which was distributed online via the meeting platform, on the ADA YouTube Medicine Channel with 11,000 subscribers, various other social media platforms, the ADA website, and all other ADA TV social media accounts.

The film is available on the ADA TV YouTube channel.

Pictured: ADA 'Thought Leadership' series filming underway in Melbourne.

The Australian Centre for Accelerating Diabetes Innovations (ACADI)

Led out of The University of Melbourne by Centre Director Associate Professor Elif Ekinci, ACADI includes over 65 partners across all Australian states and territories. Over its four-year term, ACADI will deliver at least 18 projects that progress a series of therapeutic, device, in vitro diagnostic, digital health products and behavioural interventions towards practical use.

To support Australian diabetes research and enable cutting-edge innovation, ACADI will establish a contract research organisation as part of its ongoing sustainability plans.

ACADI will train future leaders, providing critical skills in clinical evaluation, translation and commercialisation and will be a place of new ideas intersecting with innovation in diabetes. This will support Australia in being a global leader addressing many of the serious complications of diabetes.

Ultimately ACADI strives to address inequities in diabetes-related healthcare, particularly for Indigenous Australians, for whom the rates of diabetes are highest, and to reduce disease burden and improve quality of life for all people living with diabetes, regardless of their geographic location or cultural background.

Pictured: ACADI centre launch, from left to right is Dr Susan Alberti AC, Professor James McCluskey AO, Dr Erin McAllum, Associate Professor Elif Ekinci, Lauren Kelly, Professor John Prins, Dr Mana Liao, Lisa Dubé.

Australian Stroke and Heart Research Accelerator (ASHRA)

Bringing together a team of internationally renowned Australian researchers and institutions, ASHRA is a partnership between Monash University, The University of Sydney, Victor Chang Cardiac Research Institute, The George Institute for Global Health (Australia), Australian National University, The University of Melbourne and Menzies School of Health Research. In addition to these core academic partners, ASHRA has support from 29 additional partner organisations.

ASHRA is led by Australia's foremost heart and stroke researchers, with Professor Clara Chow and Professor Stephen Nicholls as Centre Director and Deputy Director, respectively, for its first year.

ASHRA's initial portfolio of 13 research projects has significant commercialisation and impact opportunities and span preclinical, clinical and policy pathways. ASHRA aims to rapidly accelerate discoveries to the clinic with an explicit focus on reducing health inequities for Indigenous Australians, as well as those living in rural and remote areas. Through its training program, ASHRA is bringing a new sector-wide focus on clinical impact and entrepreneurship with a specific focus on building the capacity of Indigenous researchers and the next generation of researchers to see the translation of their discoveries into practice.

Pictured: ASHRA launch, from left to right is Professor Bruce Neal, Professor Alex Brown, Professor Clara Chow, Dr Erin McAllum, Professor Jason Kovacic, Dr Mana Liao, Professor Stephen Nicholls.

Targeted Translation Research Accelerator Projects

Deakin University's Australian Centre for Behavioural Research in Diabetes

Low Intensity mental health Support via a Telehealth Enabled Network (LISTEN) for adults with diabetes and CVD – effectiveness and scalability

Aim: To improve the mental health of adults with diabetes and CVD through the LISTEN program.

Priority 1: Mental health conditions in people living with at least two of the following: Type 1 diabetes, Type 2 diabetes and/or cardiovascular disease.
Location: Victoria
TTRA Funding: $748,384
Co-contribution: $223,600 cash, $565,677 in-kind
Project Duration: December 2021 – February 2024 (Ongoing)

Heart Research Institute and The University of Sydney

Development of novel safe adjunctive antithrombotic therapies for the improved treatment of acute ischaemic stroke

Aim: To develop a novel anticoagulant with unique thrombin-inhibitory characteristics that is both safe and efficacious, and suitable for use with current standard or care thrombolysis.

Priority 3: Cardiac and vascular complications arising in people living with diabetes (Type 1 or Type 2) and cardiovascular disease; OR Cardiovascular disease in people living with Type 1 diabetes and insulin resistance (double diabetes).
Location: New South Wales
TTRA Funding: $750,000
Co-contribution: $323,978 cash, $1,652,917.12 in-kind
Project Duration: January 2022 – February 2024 (Ongoing)

Inosi Therapeutics Pty Ltd

Lead optimisation of novel inhibitors of IRAP for the treatment of fibrosis in diabetes-induced renal and cardiovascular disease

Aim: To develop an orally administered IRAP inhibitor with demonstrated efficacy in animal models of diabetic kidney and cardiac fibrosis.

Priority 2: Chronic kidney disease in people living with at least two of the following: Type 1 diabetes, Type 2 diabetes and/or cardiovascular disease.
Location: Victoria
TTRA Funding: $704,230
Co-contribution: $786,095.60 cash, $539,898.76 in-kind
Project Duration: October 2021 – November 2023 (Ongoing)

Nirtek Pty Ltd

NIRAF guidewire for detection of unstable coronary plaques to prevent heart attack and death

Aim: To advance the NIRAF guidewire to TRL5, where all of the components will have been validated in model systems, and the technology will be ready for safety and efficacy testing.

Priority 3: Cardiac and vascular complications arising in people living with diabetes (Type 1 or Type 2) and cardiovascular disease; OR Cardiovascular disease in people living with Type 1 diabetes and insulin resistance (double diabetes).
Location: Victoria
TTRA Funding: $750,000
Co-contribution: $375,000 cash
Project Duration: October 2021 – May 2023 (Ongoing)

Queensland University of Technology

Towards a diagnostic tool for atheroma assessment to better manage vulnerable patients

Aim: To develop a prototype diagnostic software tool for atheroma assessment in vulnerable patients with diabetes and cardiovascular disease.

Priority 3: Cardiac and vascular complications arising in people living with diabetes (Type 1 or Type 2) and cardiovascular disease; OR Cardiovascular disease in people living with Type 1 diabetes and insulin resistance (double diabetes).
Location: Queensland
TTRA Funding: $745,623
Co-contribution: $20,000 cash, $509,500 in-kind
Project Duration: January 2022 – February 2024 (Ongoing)

The University of Melbourne

Future Health Today and TorchRecruit – changing the course of chronic disease

Aim: To facilitate chronic disease management (with a focus on diabetic kidney disease) and clinical trial recruitment in general practice using new technology platforms (Future Health Today and TorchRecruit).

Priority 2: Chronic kidney disease in people living with at least two of the following: Type 1 diabetes, Type 2 diabetes and/or cardiovascular disease.
Location: Victoria
TTRA Funding: $749,981
Co-contribution: $997,548.68 cash, $288,189.96 in-kind
Project Duration: January 2022 – February 2024 (Ongoing)

The University of Sydney

Local regulation of inflammation for the treatment of peripheral arterial disease

Aim: To complete preclinical safety and efficacy testing of a new nanotherapy comprising i) a nanocarrier platform, ii) a therapeutic human cytokine interleukin-10 and iii) balloon delivery catheter for local treatment of peripheral artery disease.

Priority 3: Cardiac and vascular complications arising in people living with diabetes (Type 1 or Type 2) and cardiovascular disease; OR Cardiovascular disease in people living with Type 1 diabetes and insulin resistance (double diabetes).
Location: New South Wales
TTRA Funding: $739,128
Co-contribution: $60,292.20 cash, $696,600 in-kind
Project Duration: February 2022 – March 2024 (Ongoing)

BiVACOR Pty Ltd

Development of the BiVACOR total artificial heart controller for long-term use

Aim: To develop a pump controller for long-term use and to test it against regulatory safety standards to prepare it for clinical use in Australia and abroad.

Priority 2: Cardiomyopathy and heart failure.
Location: Queensland
TTRA Funding: $750,000
Co-contribution: $190,000 cash, $1,627,438 in-kind
Project Duration: September 2022 – October 2024 (Ongoing)

Cardihab Pty Ltd

Getting to the heart of It – improving heart failure outcomes with the smart-HF program

Aim: To co-design a digital solution for the management of heart failure (HF) patients by developing technologies and applying it to real-world settings to assess the feasibility, viability and safety of a community-based digital program. This will address the urgent need for a safe, cost-effective, convenient and scalable approach for improving and monitoring the management of HF in the community.

Priority 2: Cardiomyopathy and heart failure.
Location: Queensland
TTRA Funding: $740,153
Co-contribution: $250,000, $764,472 in-kind
Project Duration: September 2022 – October 2024 (Ongoing)

Cyban Pty Ltd

A hospital-based point-of-care monitor to provide earlier detection and treatment of stroke, that prevents long-term disability and death

Aim: The objective of this project is to demonstrate, via a pilot study, if Cyban's point-of-care monitor (BPOx) can be used for earlier detection and ongoing monitoring of stroke. The pilot study will assess BPOx in three patient groups with increased risk of death and disability from stroke against the gold standard of CT scan.

Priority 1: Atherosclerosis, including cerebrovascular disease.
Location: Victoria
TTRA Funding: $700,000
Co-contribution: $700,000 cash
Project Duration: August 2022 – September 2024 (Ongoing)

Deakin University's Australian Centre for Behavioural Research in Diabetes

HypoPAST – online psycho-educational training for 'Hypoglycaemia Prevention, Awareness of Symptoms, and Treatment' in adults with Type 1 diabetes

Aim: To evaluate HypoPAST, in terms of its effect on hypoglycaemia-related anxiety and related outcomes among adults with Type 1 diabetes (T1D), and its suitability for real-world implementation.

Priority 4: Mental health as it relates to diabetes.
Location: Victoria
TTRA Funding: $749,764
Co-contribution: $412,354 in-kind
Project Duration: October 2022 – November 2024 (Ongoing)

Garvan Institute of Medical Research

Restoring glucose control in T1D patients with genetically engineered GARV-AAV2-A20-islet cells – a first-in-human safety and efficacy trial

Aim: To generate preclinical safety data and to conduct first-in-human proof-of-concept trial to determine safety and efficacy of engineered islet cells.

Priority 5: Glucose control in Type 1 diabetes (T1D), Type 2 diabetes (T2D), double diabetes and/or gestational diabetes mellitus (GDM).
Location: New South Wales
TTRA Funding: $749,979
Co-contribution: $1,546,336 in-kind
Project Duration: September 2022 – October 2024 (Ongoing)

Monash University

Improved glucose control, with lower insulin doses, for the treatment of Type 1 diabetes

Aim: To develop and validate a candidate compound that can be taken in combination with insulin to improve glucose control and/or spare insulin use. After the project, we will pursue private investment for preclinical toxicology.

Priority 5: Glucose control in Type 1 diabetes (T1D), Type 2 diabetes (T2D), double diabetes and/or gestational diabetes mellitus (GDM).
Location: Victoria
TTRA Funding: $750,000
Co-contribution: $673,494 in-kind
Project Duration: August 2022 – September 2024 (Ongoing)

The University of Sydney

Bringing oral quantum dot insulin to Phase I clinical studies

Aim: To extend their highly positive data showing the effectiveness of oral insulin in animal models of diabetes and non-human primates and commence accredited manufacturing and certified preclinical toxicity testing in preparation for first-in-human (FIH) clinical trials.

Priority 5: Glucose control in Type 1 diabetes (T1D), Type 2 diabetes (T2D), double diabetes and/or gestational diabetes mellitus (GDM).
Location: New South Wales
TTRA Funding: $750,000
Co-contribution: $100,000 cash, $786,588 in-kind
Project Duration: September 2022 – October 2024 (Ongoing)

The University of Sydney

Small molecule inhibitors of the P2X7 receptor as a safe and effective way of tackling the inflammatory contribution to atherosclerosis

Aim: To develop small molecule inhibitors of the P2X7 receptor as an effective and clinically translatable approach to reduce the burden of atherosclerosis and heart attack.

Priority 1: Atherosclerosis, including cerebrovascular disease.
Location: New South Wales
TTRA Funding: $749,536
Co-contribution: $20,000 cash, $543,396 in-kind
Project Duration: September 2022 – October 2024 (Ongoing)

Western Sydney University

The APHLID-M project – Apps and Peer support for a Healthy future and Living Well with Diabetes Project

Aim: To refine and test the implementation and effectiveness of a blended, technologically empowering care model including peer support, on mental health (MH) and diabetes outcomes among young adults with Type 1 or Type 2 diabetes (i) with MH conditions (ii) without current MH conditions but at risk of acute MH events.

Priority 4: Mental health as it relates to diabetes.
Location: New South Wales
TTRA Funding: $744,873
Co-contribution: $1,046,548 in-kind
Project Duration: August 2022 – September 2024 (Ongoing)

TTRA Research Centres

The University of Melbourne

Australian Centre for Accelerating Diabetes Innovations (ACADI)

Vision: The Australian Centre for Accelerating Diabetes Innovations (ACADI) aims to benefit people with diabetes at each stage, from diagnosis to its devastating complications. Led out of The University of Melbourne, ACADI will deliver novel interventions for timely diagnosis, prevention and treatment of diabetes and its complications with access to clinical evaluation, leadership and networks, research commercialisation experience and workforce training. ACADI's design responds to key barriers slowing Australian development of innovations.

Priorities of Research Portfolio: Diabetic kidney disease, peripheral neuropathy and diabetic foot syndrome, and short-term complications of hypoglycaemia and/or hyperglycaemic hyperosmolar syndrome (HHS) and ketoacidosis.
TTRA Funding: $10,000,000
Co-contribution: $2,673,951 cash and $10,744,352 in-kind
Duration of funding: February 2022 – February 2026 (Ongoing)

Monash University, The University of Sydney, Victor Chang Cardiac Research Institute, The George Institute for Global Health (Australia), Australian National University, The University of Melbourne and Menzies School of Health Research

Australian Stroke and Heart Research Accelerator (ASHRA)

Vision: The Australian Stroke and Heart Research Accelerator (ASHRA) will transform the field of cardiovascular research in Australia by bringing a new sector-wide focus on clinical impact and entrepreneurship. ASHRA will deliver major health, social and economic benefits that will be clearly apparent within four years and sustained into the future. ASHRA will achieve this by building a culture of collaboration, commercialisation and translation.

Priorities of Research Portfolio: Coronary artery disease (including angina and major adverse cardiovascular events [MACE]), cardiomyopathy/heart failure, transient ischaemic attack (TIA)/stroke (ischaemic and haemorrhagic).
TTRA Funding: $10,000,000
Co-contribution: $8,392,000 cash and $12,597,340 in-kind
Duration of funding: January 2022 – February 2026 (Ongoing)

Clinical Translation and Commercialisation – Medtech

In August 2021 the Australian Government announced that MTPConnect would operate a new $19.75 million Clinical Translation and Commercialisation – Medtech (CTCM) program offered under the 2020 Early Stage Translation and Commercialisation Support Grant of the Medical Research Future Fund's Medical Research Commercialisation Initiative.

Since launching in late 2021, the program identifies and nurtures high-quality medical device projects that have commercial potential and supports their translation through early clinical trials. The program is focused on supporting Australian SMEs and aims to boost commercialisation of Australian medical products. Projects must focus on the development of a medical device for human use, the purpose of which is to diagnose, prevent, monitor, treat or alleviate a disease or injury, or modify or monitor anatomy or physiological functions of the body. Funding is only awarded to projects where the device's capability has already been validated with research and/or preclinical studies.

Funding valued between $250,000 and $1.5 million per project over a 24-month period is awarded across two funding rounds. In addition to funding support, the CTCM program has been specifically designed to leverage the expertise of Program Partners to help SMEs turn their early clinical innovations into medical devices that can improve the health of Australians, while also generating commercial returns and helping create high-paying jobs. These partners include the Medical Technology Association of Australia (MTAA), the Medical Device Partnering Program (MDPP), Cicada Innovations, The BridgeTech Program and Therapeutic Innovation Australia (TIA). The program also takes a national and inclusive approach to working with clinicians, researchers, health groups and consumers to ensure projects are using holistic approaches to address critical unmet needs.

The CTCM program supports innovations taking the next step from preclinical studies into human clinical trials. It complements MTPConnect's other MRFF programs such as the BioMedTech Horizons and Biomedical Translation Bridge programs, whose objectives are to nurture and prime early technology through the proof-of-concept and validation stages.

Formally launched in November 2021, CTCM has now completed calls for applications on two funding rounds. Round 1 Expressions of Interest (EoI) applications opened on 17 December 2021 and closed on 11 March 2022. Round 2 EoI applications opened on the 9 September 2022 and are now closed, with applications being assessed.

The first round of CTCM awards will inject a total of $20.1 million into the medtech sector to drive the development of Australian medical technologies. Five medtech projects were awarded funding of $7.2 million, which attracted a further $12.9 million in additional contributions from the awardees and their partners.

The CTCM team expects to announce Round 2 funding awards in 2023.

CTCM Program Partners

Pictured: The MTPConnect CTCM team and Program Partners at the Round 2 information session in Brisbane.

MTPConnect will deliver the CTCM in partnership with the following highly-esteemed medical technology commercialisation, education and infrastructure support Program Partners:

MTAA Medical Technology Association of Australia

The Medical Technology Association of Australia (MTAA) represents the diverse interests of the medical technology sector and undertakes a very broad role on behalf of the industry – from political advocacy to professional development. MTAA represents manufacturers and suppliers of medical technology used in the diagnosis, prevention and treatment and management of disease and disability.

MEDICAL DEVICE PARTNERING PROGRAM

The Medical Device Partnering Program (MDPP) is Australia's longest-running medtech innovation program, fostering collaborations between researchers, industry, end-users and government and developing novel medical devices with global market potential. Now in its fifteenth year, MDPP has assessed over 1,000 ideas for new medical and assistive technologies, facilitated nearly 200 ideation workshops, completed more than 120 Research and Development projects for medical technology companies and provided manufacturing, partnering and new long-term commercial opportunities with organisations across the country.

CICADA INNOVATIONS

Cicada Innovations (CI) supports deep-tech ventures and innovators with cutting-edge labs, access to mentors and experts, commercialisation training, and a cohort of ambitious peers. By connecting a growing community of entrepreneurs, policymakers, researchers and the public, Cicada's mission is to make Australia a leader in deep technology. The company's expertise covers the full spectrum of the start-up life cycle: from benchtop to IPO commercialisation and regularly conducting ideation workshops, as well as acceleration and long-term incubation programs.

THE BRIDGETECH PROGRAM

The BridgeTech Program is a national professional development program that trains researchers and entrepreneurs on how to effectively navigate the medtech commercialisation pathway. Convened and administered by Queensland University of Technology (QUT), the program involves a consortium of partners including medtech companies, universities, and industry associations. Leveraging off the industry expertise and global connections that the consortium offers, it equips participants with the necessary skills and networks needed to take new medtech to market.

THERAPEUTIC INNOVATION AUSTRALIA

The BridgeTech Program is a national professional development program that trains researchers and entrepreneurs on how to effectively navigate the medtech commercialisation pathway. Convened and administered by Queensland University of Technology (QUT), the program involves a consortium of partners including medtech companies, universities, and industry associations. Leveraging off the industry expertise and global connections that the consortium offers, it equips participants with the necessary skills and networks needed to take new medtech to market.

Clinical Translation and Commercialisation – Medtech Projects

In partnership with

LBT Innovations Ltd

APAS Compact – Development of a desktop device for automated microbiology culture plate reading and reporting
Location: South Australia
CTCM Grant: $1,500,000
Industry Contribution: $1,835,000
Duration: November 2022 – October 2024
Status: Ongoing

ARIA Research Pty Ltd

ARIA non-invasive bionic vision system clinical trial and pilot
Location: New South Wales
CTCM Grant: $1,500,000
Industry Contribution: $5,775,626
Duration: November 2022 – October 2024
Status: Ongoing

OncoRes Medical

Commercialisation of a diagnostic imaging system for cancer surgery
Location: Western Australia
CTCM Grant: $1,500,000
Industry Contribution: $1,064,328
Duration: October 2022 – September 2024
Status: Ongoing

Navi Medical Technologies Pty Ltd

Safer care for critically ill children: clinical translation of a new medical device to place and monitor paediatric central vascular catheters
Location: Victoria
CTCM Grant: $1,239,187
Industry Contribution: $832,044
Duration: November 2022 – October 2024
Status: Ongoing

Eudaemon Technologies Pty Ltd

Clinical trial of the next generation condom
Location: New South Wales
CTCM Grant: $1,500,000
Industry Contribution: $3,423,000
Duration: November 2022 – October 2024
Status: Ongoing

MTP Sector Performance and Vision

MTP Sector Performance and Vision

The MTP sector is a major contributor to R&D, both globally and within Australia. The MTP value chain encompasses a vibrant sector with a diverse range of participants, including consumers and patients, universities, other research organisations, small and large local and multinational companies, investors, service providers, industry organisations, infrastructure providers, governments, regulators, policymakers, funders and those involved in healthcare delivery, such as state health departments and private medical practice. Each participant has a critical role to play in the sector's growth and success.

In the 2016 Sector Competitiveness Plan (SCP), MTPConnect outlined an aspirational scenario that aimed to reverse the decline in Gross Value Added (GVA) and jobs experienced from 2010 to 2015 within five years, and to continue this growth at an equivalent rate out to 2025. The interim five-year goal of reversing the decline in GVA and jobs has been met.

MTP Sector Performance Since 2015

MTPConnect's 2022 SCP and other sector reports provide updates on the MTP sector's knowledge priorities, sector growth priorities and regulation reform agenda.

In 2016, we published our first SCP, a comprehensive sector snapshot and 10-year vision for growth developed following extensive consultation with hundreds of sector participants.

As well as examining the MTP sector's performance in 2020 and 2021, this year's 2022 SCP provides a progress report at the halfway point of our 10-year plan.

Between 2016 and 2021, GVA has grown steadily at two percent per annum, an additional 13,000 jobs have been created by the sector and the net number of MTP companies has increased by more than 100. The four percent per annum growth rate for MTP sector jobs observed from 2016 to 2021 was higher than overall jobs growth in Australia of 1.2 percent per annum.

The sector contributed $5.3 billion and $5.5 billion in GVA to the Australian economy in 2020 and 2021, respectively. These figures represent an increase of $100 million and $300 million respectively when compared to the MTP sector GVA in 2019. The sector also added an additional 5,000 jobs during this two-year period. The market capitalisation of MTP companies continued to grow strongly at 20 percent per annum and MTP companies raised nearly $3.4 billion in capital through this period, as markets realised how resilient and vital the sector was to the broader economy.

However, MTP sector manufacturing exports slipped, declining by 18 percent per annum across the two years, as MTP companies faced supply chain challenges that impacted their ability to get their products to overseas markets. Similar disruptions were experienced across a range of sectors. As demonstrated by these metrics, the positive growth trajectory indicates the valuable contribution that the MTP sector makes to the Australian economy.

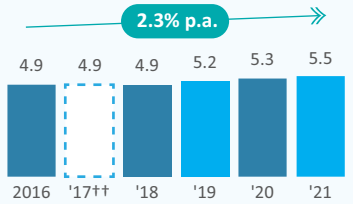
Despite the pandemic challenges, the MTP sector has made steady progress towards the 2025 sector aspiration set out in the 2016 SCP. The sector supported 73,000 jobs across industry and research in 2021. An addition of another 3,000 jobs over the next three years will see the sector achieve its 2025 sector aspiration. Similarly, the sector is more than halfway towards the target of 200 additional MTP companies compared to 2015, as an additional 116 companies were added to the sector from 2015 to 2021.

More information about MTP sector performance can be found in the 2022 SCP.

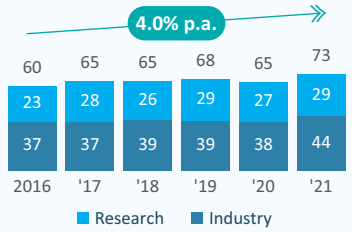
MTP Sector Progress to 31 December 2021

ECONOMIC METRICS†

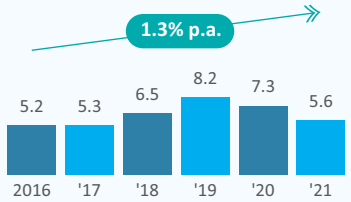
GROSS VALUE ADDED (PER ANNUM)
A$ billions



JOBS SUPPORTED – INDUSTRY* AND RESEARCH
Thousands of employees

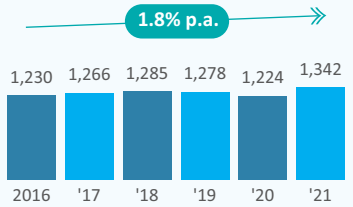


MTP MANUFACTURING EXPORTS
A$ billions

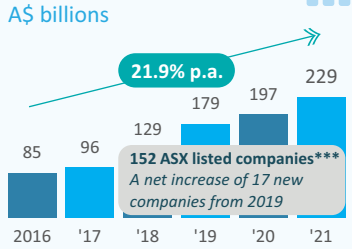


COMMERCIAL METRICS†

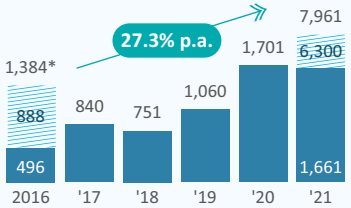
COMPANIES IN THE MTP INDUSTRY
No. of companies



MARKET CAPITALISATION OF MTP COMPANIES**
A$ billions



CAPITAL RAISED^
A$ millions

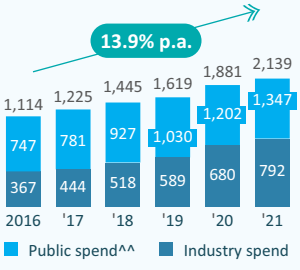


^(excludes Mayne Pharma + CSL capital raisings)

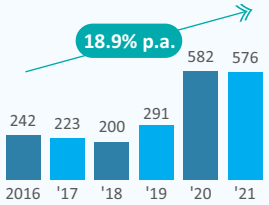
Outliers (Mayne+CSL) Capital raised

R&D METRICS†

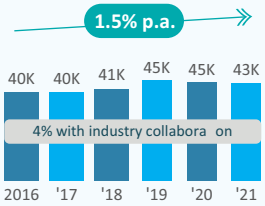
R&D INVESTMENT
A$ millions



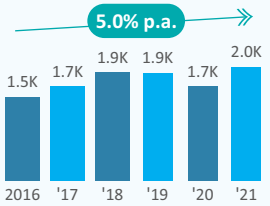
NUMBER OF COMPANIES PATENTING^^^



NUMBER OF PUBLICATIONS^^^



NUMBER OF CLINICAL TRIALS^^^^



Notes:

† All growth rates shown in the graphs below represent compound annual growth rates

†† GVA data shown here is as reported in the respective SCPs for consistency. 2017 GVA figure is interpolated using 2016 and 2018 data as GVA was only tracked as a sector metric annually from 2018 onwards

* Due to the volatile nature of quarterly employment metrics, the industry job porton of the presented figures is calculated as a rolling 2-year average of the quarterly data. In the 2019 SCP, industry jobs was calculated as an annual average.

** 2016 market cap as at 2016, 2019 market cap as at November 2019.

*** The definition of ASX-listed MTP companies was broadened in the 2018 analysis to include medical software / digital health companies whose products are not necessarily regulated by the TGA.

^ Capital raised in 2016 was artificially high due to a $888 million capital raise by Mayne Pharma.

^^ Public spend analysis comprises grants made by ARC, NHMRC, BTF and MRFF; NHMRC and ARC (announced before August 2021) grant funding per year assumes grant funding distributed equally in each year of the grant; ARC funding estimates for grants announced after August 2021 assume a) the duration of each of these grants is the average duration of a grant of equivalent type (e.g., Linkage Project, Discovery Project) over the period from January 2016 to August 2021, and b) grant funding is distributed equally across each year of the assumed grant duration; MRFF funding is based on committed funding announced by the MRFF; BTF funding is based on BTF grants awarded by year.

^^^ Data provided by Clarivate Analytics.

^^^^ Data provided by NHMRC CTC

Source: MTPConnect 2022 SCP – April 2022

MTP Sector Megatrends

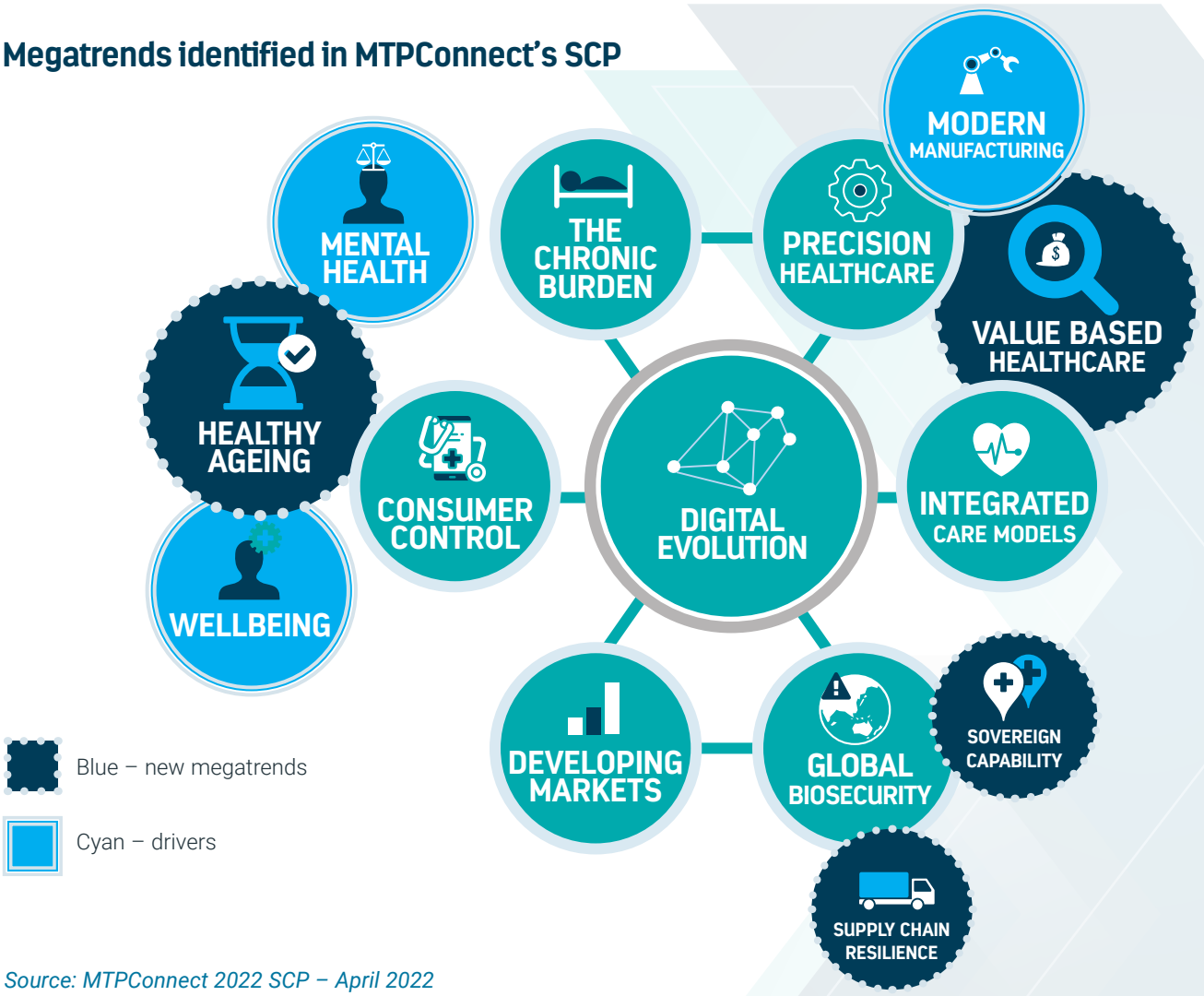
Megatrends are the overarching social, economic, environmental, technological and geopolitical forces that will shape the future of industries over the next 10 to 20 years. These megatrends are often disruptive, altering existing business models and presenting opportunities and challenges for organisations. By nature, they are forward looking and as a result do not vary significantly from year to year; rather they evolve gradually.

Technological developments and shifts in consumer behaviour are creating exciting opportunities within the MTP sector. These include genomics, gene editing, big data and analytics, while the ability to develop products and services tailored to individuals/groups of consumers with digital connectivity and integration is becoming increasingly feasible, alongside a rise in consumer awareness of overall health and wellbeing.

As a result of the dramatic global impacts of COVID-19, two additional megatrends – sovereign capability and supply chain resilience – have been added to the set of nine megatrends identified in the 2020 SCP report. The disruptions to global supply chains during the COVID-19 pandemic have led to businesses and governments around the world actively pursuing initiatives to critically review and strengthen supply chains. Governments are also building sovereign capability in key areas such as manufacturing of critical medical products and vaccines, and equipment such as masks and ventilators. It is acknowledged that the continued evolution of COVID-19 and future global pandemics will influence many of these megatrends, including global biosecurity, digital evolution and chronic burden. These impacts will need to be considered as part of strategic planning, policy development and operational activities for MTP businesses and governments alike.

These megatrends, knowledge and sector priorities, as detailed in the 2022 SCP, are shaping how Australia can build long-term, world-class positions in targeted areas of research and development, where patient outcomes can be realised, and opportunities exist for strong commercial returns.

Megatrends identified in MTPConnect's SCP



Source: MTPConnect 2022 SCP – April 2022

The Global Biosecurity Megatrend and COVID-19

The MTP sector is critical for responses to pandemics and global biosecurity threats. Many Australian researchers, start-ups and SMEs are working in vaccine design and manufacture, diagnostics and imaging, bioprocessing technologies, ventilation technology, telemedicine, infection control and protection and immune system-directed therapies.

Industry input into federal government taskforces has been integral to securing essential supplies of ventilators, testing kits and other personal protective equipment (PPE) supplies required by the healthcare system. Australia's medical device sector is uniquely placed to inform and deliver sovereign manufacturing capability and robust supply chains as part of future pandemic planning.

Following on from MTPConnect's role in supporting Australia's response to COVID-19, we have now established a Health Biosecurity Team to work with key sector stakeholders and further drive connectivity between industry and defence and national security agencies and their capability priorities.

Communication Activities

A range of communications are used to promote the activities of MTPConnect and the MTP sector, including podcast series episodes, website e-news stories, and social media – some of these are detailed here, covering the period 1 July 2021 to 30 June 2022.

The MTPConnect Podcast Series

The MTPConnect Podcast series, launched in February 2019, is now a popular bi-weekly podcast that promotes the people, projects and issues behind the Australian MTP sector. The show published 26 episodes in FY2022, delivering a total of 129 episodes as of 30 June 2022. Speaking with 51 guests during the year and reaching listeners in 80 countries, the podcast was downloaded more than 12,398 times.

12,398
Total podcast downloads for reporting period

51
Number of guests

80
Total number of countries

26
Number of episodes published

129
Total number of episodes to 30 June 2022

Top 10

Podcast episodes by downloads:

1. South Australia's Novel Response to Coronavirus
2. Improving Workforce Skills: How the GSK Australia Graduate Researcher Program is Making a Difference
3. Spotlight: Starpharma's COVID-19 Nasal Spray for UK & Europe
4. Clinical Trials in Australia: opportunities for growth
5. Australia's global search for a Strep A vaccine
6. Sementis' Quest for an Australian Second-Generation COVID-19 Vaccine
7. Recce Scouts New Synthetic Anti-Infectives to Overcome Resistance
8. Ancient and New: WA's Cliniface and Lyfe Languages Improving Indigenous Healthcare Through Technology
9. BiomeBank Develops Pioneering Microbiome Treatments
10. Synchron's Breakthrough Brain-Computer Interface Helping Treat Paralysis

Top 10

Countries listening:

1. Australia
2. US
3. UK
4. Germany
5. New Zealand
6. Singapore
7. Taiwan
8. Japan
9. France
10. South Korea

The MTPConnect Podcast Series (continued)

Pictured:

Left – 'Taking Australian science from lab bench to boardroom', Professor Mark Hutchinson and Misha Schubert, President and CEO respectively at Science & Technology Australia, chat on the podcast with MTPConnect CEO Stuart Dignam about how Australian science can create companies, jobs and products.

Right – The MTPConnect Podcast was on the ground at BIO 2022 in San Diego, checking in with companies in the Australian delegation, including ARIA Research and Argenica Therapeutics, and talking with the Hon. Arthur Sinodinos AO about trade opportunities with the US.

Episode 104: Clinical Trials in Australia: opportunities for growth (13 July 2021). Carrie Bloomfield, Co-Chair, R&D Taskforce, and Director Clinical Research, GlaxoSmithKline Australia; Dr Janelle Bowden, Managing Director, AccessCR; Dr Megan Robertson, Group Chief Research Officer, St Vincent's Health Australia, and Chair, AusBiotech Clinical Trials Advisory Group; and Professor John Zalcberg, Head, Cancer Research Program, Monash University.

Episode 105: Partnering in the age of COVID: Real World Tips from SpeeDx (28 July 2021). Colin Denver, CEO, SpeeDx (BTB project).

Episode 106: Australia's global search for a Strep A vaccine (11 August 2021). Professor Jonathan Carapetis, Executive Director, Telethon Kids Institute; and Professor Andrew Steer, Infection and Immunity Director, Tropical Diseases, Murdoch Children's Research Institute – both Co-Directors of the MRFF-funded Australian Strep A Vaccine Initiative (ASAVI).

Episode 107: Vantari VR Takes Healthcare Training Virtual to Save Lives (25 August 2021). Dr Nishanth Krishnananthan and Dr Vijay Paul, Co-CEOs of Vantari VR.

Episode 108: Synchron's Breakthrough Brain-Computer Interface Helping Treat Paralysis (10 September 2021). Associate Professor Thomas Oxley, CEO, Synchron, and Vascular and Interventional Neurologist, Mount Sinai Hospital in New York City; and Associate Professor Nicholas Opie, Chief Technology Officer, Synchron – both Co-Heads of the Vascular Bionics Laboratory at The University of Melbourne, Australia (BMTH project).

Episode 109: Improving Workforce Skills: How the GSK Australia Graduate Researcher Program is Making a Difference (22 September 2021). Abraham Daniel, Graduate Researcher, GSK (REDI partner)/ViiV Graduate Researcher Program; and Dr Lachlan Gray, Medical Manager, ViiV Healthcare Australia.

Episode 110: Sementis' Quest for an Australian Second-Generation COVID-19 Vaccine (6 October 2021). Leanne Hobbs, CEO, Sementis, and Adjunct Senior Industry Fellow, University of South Australia; and Professor John Hayball, Chief Scientific Officer, Sementis, and Head, Experimental Therapeutics Laboratory, University of South Australia.

Episode 111: Trials & Tribulations – Developing the World-First Oxford AstraZeneca COVID-19 Vaccine (14 October 2021). Dr Maheshi Ramasamy, Principal Investigator, Oxford Vaccine Group, and Consultant Physician, Oxford University Hospitals NHS Foundation Trust, and Deputy Director, Graduate Entry Medicine Course, and Florey Lecturer, Magdalen College, both of Oxford.

Episode 112: New Funding for Diabetes & Cardiovascular Disease on Offer Through the TTRA Initiative (20 October 2021). Grace Lethlean, Co-Founder and Chief Product Officer, ANDHealth; Olivia White, National Program Manager, MDPP; and Dr Leigh Ford, Project Manager, TTRA program, UniQuest (TTRA partners).

Episode 113: Visionary Telehealth Start-Up Coviu Builds a Platform for Global Growth (11 November 2021). Dr Silvia Pfeiffer, Global Director, CEO and Co-Founder, Coviu.

Episode 114: CO-ADD Sparks Up the Hunt for New Antibiotics (19 November 2021). Dr Mark Blaskovich, Director, Centre for Superbug Solutions, Institute for Molecular Bioscience (IMB), and Associate Professor and Co-Founder, Community for Open Antimicrobial Drug Discovery (CO-ADD) (AAMRNet partner), both of The University of Queensland; and Dr Alysha Elliott, Research Officer, IMB.

Episode 115: LBT Innovations' Technology Aims to Speed Up Detection of Antimicrobial Resistance (22 November 2021). Brent Barnes, CEO, LBT Innovations (BTB project); and Dr Andrew Milligan, MedTech Ventures Case Manager, MDPP (BTB partner).

Episode 116: Recce Scouts New Synthetic Anti-Infectives to Overcome Resistance (23 November 2021). James Graham, CEO, Recce Pharmaceuticals (AAMRNet partner).

Episode 117: BiomeBank Develops Pioneering Microbiome Treatments (24 November 2021). Thomas Mitchell, CEO, BiomeBank.

Episode 118: Ancient and New: WA's Cliniface and Lyfe Languages Improving Indigenous Healthcare Through Technology (17 December 2021). Dr Gareth Baynam, Head, Western Australian Register of Developmental Anomalies, and Founder of Project Y, Cliniface and Lyfe Languages; and Yarlalu Thomas, Co-Founder of Lyfe Languages, medical student, Precision Public Health Fellow in Genetic and Rare Diseases, and Young West Australian of the Year in 2020.

Episode 119: The COVID Chemistry of a Perfect Match for SpeeDx and SynGenis (7 February 2022). Associate Professor Rakesh Veedu, Founding and Managing Director, SynGenis; and Colin Denver, CEO, SpeeDx (BTB project).

Episode 120: Australia's World-First Bionic Eye System Breakthrough (24 February 2022). Dr Ash Attia, CEO, Bionic Vision Technologies; and Associate Professor Penelope Allen, Principal Investigator, Centre for Eye Research Australia.

Episode 121: New Funding On Offer: Clinical Translation & Commercialisation – Medtech program (28 February 2022). Ian Burgess, CEO, Medical Technology Association of Australia (MTAA); Dr Andrew Milligan, MedTech Ventures Case Manager, Medical Device Partnering Program (MDPP); Dr Dharmica Mistry, Head of Medtech and Biotech, Cicada Innovations.

Episode 122: Taking Australian science from lab bench to boardroom (11 March 2022). Misha Schubert, CEO, Science & Technology Australia; and Professor Mark Hutchinson, President, Science & Technology Australia, and Director, Centre for Nanoscale BioPhotonics, The University of Adelaide.

Episode 123: Health Horizon: tracking health innovations around the world (28 March 2022). Dr Mat McGann, Co-Founder and CEO, Health Horizon.

Episode 124: ARIA Research: bionic glasses giving vision via sound (12 April 2022). Robert Yearsley, Co-Founder and CEO, ARIA Research.

Episode 125: Health 10x Accelerator Boosts Nuroflux Stroke Care Innovation (27 April 2022). Dina Titkova, Program Manager, Health 10x Accelerator, UNSW Founders; and Sam van Bohemen, Co-Founder and CEO, Nuroflux.

Episode 126: Rapid Response Revival: Life-saving defibrillation in the palm of your hand (16 May 2022). Donovan Casey, Co-Founder, CEO and Executive Chairman, Rapid Response Revival.

Episode 127: BTB: Dimerix investigates new treatment for COVID-19 complications (30 May 2022). Cécile Francis, BTB Project Manager, UniQuest; and Dr Robert Shepherd, Vice President Research and Development Director, Dimerix.

Episode 128: Australian Biotech Open for Business at BIO 2022 (15 June 2022). The Hon. Stephen Dawson MLC, Western Australia's Minister for Emergency Services, Innovation and ICT, Medical Research and Volunteering; Robert Yearsley, CEO and Co-Founder, ARIA Research; Dr Liz Dallimore, Managing Director and CEO, Argenica Therapeutics; Professor Lyn Griffiths, Director, Bridge Program, Queensland University of Technology; and the Hon. Arthur Sinodinos AO, Australia's Ambassador to the US.

Episode 129: TTRA supports Nirtek's mission to prevent heart attacks and save lives (30 June 2022). Olivia White, MedTech Venture Partner, MDPP; and Matthew Hoskin, CEO, Nirtek.

Pictured: Australian-Sri Lankan Dr Maheshi Ramasamy joined The MTPConnect Podcast with former MTPConnect CEO Dr Dan Grant and current MTPConnect CEO Stuart Dignam to discuss the trials and tribulations of developing the world-first Oxford AstraZeneca vaccine.

Pictured: Co-hosts Caroline Duell and Elizabeth Stares chat to Health Horizon Founder and CEO Dr Mat McGann in Canberra about their health innovation tracking and discovery platform, funded through our Growth Centre Project Fund Program

Case Studies

27 July 2021 ClinTrial Refer – A Mobile App Transforming Clinical Trial Access and Recruitment

30 August 2021 REDI: Mastering Commercial Success for Digital Health Start Ups

22 September 2021 REDI: Driving Entrepreneurship Education of Solve Global Health Challenges

27 October 2021 East Meets West – The Chemistry of A Perfect Match For SpeeDx and SynGenis

23 November 2021 REDI: Empowering Scientists with Training in The Growing Clinical Trials Sector

15 December 2021 BTB Case Study: Shining a Light on Collaboration to Accelerate Anti-Cancer Drug Discovery

31 January 2022 The Birth of a WA Start-Up: VitalTrace Biosensors Seek to Improve Childbirth Outcomes

28 February 2022 New Drug Treatment in Development for Patients Living with Liver Disease

30 March 2022 BTB Case Study: Pioneering Australian Technology is Keeping Hospitals COVID-Safe

28 April 2022 APR.Intern Lights the Way for New Industry-University Collaboration on Disinfection Technology

30 May 2022 Epichem's Formula for Success and WA Connections

29 June 2022 Case Study: Neurode Wave – Changing the Way ADHD Is Treated

Pictured. Case Study on WA's Vital Trace: Front left: Dr Michael Challenor, (Co-Founder and CTO) Middle : Nadia Rahman (Scientist), right: Dr Shaghraf Javid (Electrochemist), rear: Robert Atkinson (Research Chemist and Patent Officer)

Social and Digital Media

5,686 Twitter followers

7,746 LinkedIn followers

3,035 Newsletter subscribers

83,612 Website total users

MTPConnect Website

Reach:
- 83,612 total users
- 76,336 new users
- 115,705 sessions
- 232,145 page views
- Average time users spent on the top pages 1.51

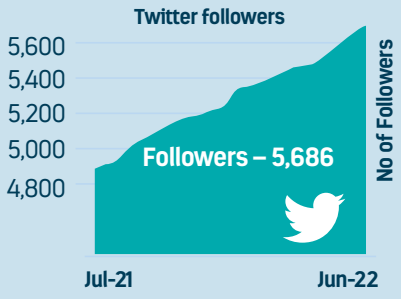
Top locations of website visitors:
1. Australia – 53,656
2. US – 12,212
3. India – 1,946
4. UK – 1,003
5. Germany – 831

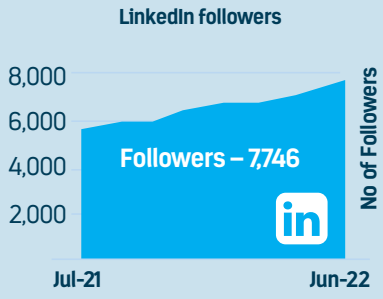
Top pages viewed:
6. Homepage – 26,856
7. REDI – 11,248
8. REDI Fellowship Program – 10,940
9. Programs/TTRA – 7,375
10. Programs/TTRA Research Projects – 7,052

MTPConnect Social Media

MTPConnect Twitter:
- 5,686 followers
- Total number of tweets – 565
- 848,253 impressions
- Average engagement rate over 12 months – 2.08%

MTPConnect LinkedIn:
- 7,746 followers
- Total number of posts – 435
- 428,207 impressions
- Average engagement rate over 12 months – 3.98%





MTPConnect Newsletter

- Recipients at June 2022 – 3,035
- Average open rate over 12 months – 32.68%
- Average click rate over 12 months – 20.81%

Financial Information and Directors' Report

A financial report on MTPConnect

MTP-IIGC LTD
ABN 53 608 571 277

For the year ended 30 June 2022

Directors' Report

The directors present their report together with the financial statements of MTP-IIGC Ltd ('the Company' or 'the entity') for the year ended 30 June 2022.

Directors

The following persons were directors of MTP-IIGC Ltd during the whole of the financial year and up to the date of this report unless otherwise stated.

Ms Sue MacLeman
Dr Nicholas Cerneaz
Dr Douglas Robertson
Ms Julie Phillips
Dr Alexander Fowkes

Principal activities

During the financial year, the principal activities of the Company were to boost competitiveness, productivity and innovative capacity of Australia's Medical Technologies and Pharmaceuticals sector by identifying opportunities to reduce regulatory burden, increasing collaboration and commercialisation, improving capabilities to engage with international markets and global supply chains and enhancing management and workforce skills.

Review of operations

The company reported a surplus before tax of $312,035 for the year ended 30 June 2022 (30 June 2021: $884,980). The decrease was substantially driven by an increase to project funding.

Short-term and Long-term Objectives

The Company's short-term objectives are to:

- Accelerate industry initiatives aimed at enhancing competitiveness and productivity, in particular those that have the strongest impact on supporting SMEs.
- Increase coordination across the sector to link industry public and private research organisations to state and Australian Government initiatives, reduce duplication and identify opportunities for alignment.
- Develop a more competitive market for investment and funding.
- Build a skills and knowledge base to embed a commercialisation culture that pulls research through to market development.
- Improve capabilities to engage with international markets and global supply chains.

The Company's long-term objectives are to:

- Create a vibrant and prosperous MTP Sector.
- Build, strengthen and expand the connections for long term sector success:
    - Facilitate collaboration.
    - Educate and disseminate knowledge.

- Identify and encourage the removal of unnecessary regulatory barriers.
- Redefine and execute next phase of programs.
- Establish a sustainable funding base for MTPConnect.

Strategies

To achieve its stated objectives, the Company will take action, be an independent voice and fund projects to achieve the following strategies:

- Align investment in Knowledge Priorities that meet current and future market needs.
- Create a highly productive commercialisation environment from research to early clinical trials and proof-of-concept.
- Transform the SME sub-sector to support the growth of smaller companies into larger, more stable and successful companies.
- Support the development of digital healthcare solutions: devices and data analytics.
- Strengthen Australia as an attractive clinical trial research destination.
- Position Australia as a preferred partner for international markets.
- Support advanced manufacturing as part of the broader Australian innovation ecosystem.

Significant changes in the state of affairs

The Company entered into a Deed of Variation with the Department of Industry, Science and Resources ('DISR') on 24 December 2021 in relation to the Growth Centre Funding Initiative. The Deed extended the program end date to 30 June 2023.

The Company entered into a Deed of Variation with the Department of Industry, Science and Resources ('DISR') on 03 May 2022 in relation to the Growth Centre Funding Initiative. The Deed provided $4.55m of additional funding to support transition plan activities.

Other than the above there were no significant changes in the state of affairs of the Company during the financial year.

Matters subsequent to the end of the financial year

Apart from matters already disclosed in this report, no other matter or circumstance has arisen since balance date that has significantly affected or may significantly affect the Company or the results of its operations in future financial years.

Environmental regulation

The Company is not subject to any significant environmental regulation under Australian Commonwealth or State law.

Directors' Report

Information on directors

Ms Sue MacLeman
Chair
Sue MacLeman has more than 30 years' experience as a pharmaceutical, biotechnology and medical technology executive having held senior roles in corporate, medical, commercial and business development. Sue has served as CEO and Board member of several ASX, AIM and NASDAQ listed companies in the healthtech sector. She is current Chair of MTPConnect a not-for-profit industry growth centre for the medtech, biotech and pharmaceutical sectors. She is also Chair TALi Digital Ltd (ASX:TDI), and a non-executive director of Anatara Lifesciences Ltd (ASX:ANR), Planet Innovation Holdings and Omico. Sue is appointed to several academic and government advisory boards . Her broad commercial and technical experience is underpinned by a Bachelor of Pharmacy from the University of Queensland, a Master of Laws from Deakin University and a Master of Marketing from Melbourne Business School. She is also a Fellow and Chair of the Health Forum at the Australian Academy of Technology and Engineering (ATSE) and Fellow/Graduate of Australian Institute of Company Directors (AICD).

Dr Nicholas Cerneaz
Non-Executive Director
Dr Cerneaz has been commercialising academic and industrial research for more than two decades. Leveraging his D. Phil (doctorate) in mammography image analysis technologies for managing breast cancer, he has driven the development of a number of medical technology startup companies, covering fields from radiology, oncology, ophthalmology, pathology and immunology. Other industrial experience includes automation and process optimisation in heavy manufacturing and process industries, astronomy instrumentation design and implementation, and advanced computer vision safety systems for the automotive industry.

Dr Cerneaz has previously been a director of NFP and AIM listed companies, advisor to both research and education sector enterprises, and is currently Head of Engineering of Australian Astronomical Optics at Macquarie University - a global leader in the design, construction and commissioning of bespoke instrumentation for the world's largest professional astronomy facilities.

Dr Douglas Robertson
Non-Executive Director
Dr Robertson has been the Director of Research Services at The Australian National University since July 2013 and has over 30 years' experience in research, economic development, technology transfer, spin-out companies and commercialisation in the UK and Australia. During that time, he has negotiated over $3.9bn of research funding, served on the boards of over 20 technology companies and assisted the establishment of over 20 other early stage technology businesses.

Dr Robertson was a founding Director of PraxisAuril (formerly Praxis), a major UK and international technology transfer and training association, from 2003-2013 and Chair in 2012 and 2013. Dr Robertson serves on the boards of four NCRIS facilities and is passionate about seeing the outcomes of research leading to economic and social benefit.

Ms Julie Phillips
Non-Executive Director
Ms Julie Phillips is Chief Executive Officer and a Director of BioDiem Ltd and Managing Director of BioDiem's subsidiary, Opal Biosciences Ltd. She has a strong background in the biotech and pharmaceutical industry, having worked as the CEO and Director of start-up Australian biotechnology

companies operating in the life sciences sector. Her technical background in clinical trials, regulatory affairs and pharmacoeconomic assessment/pricing of therapeutics was gained in multinational pharmaceutical companies. From 2014-2021 she was Chair of AusBiotech Ltd, the peak biotechnology industry association in Australia.

Julie chairs Industry Innovation and Science Australia's R&D Incentives Committee. She is a member of the University of Newcastle Council.

Alexander Fowkes
Non-Executive Director
Alex Fowkes is former life science executive having worked in industry around the world including Europe, China, Singapore and the USA. He is an experienced leader and thought partner for life science strategy, commercial operations and business development. He has extensive experience in leading strategy development and operational improvement projects within the pharmaceutical, contract research and bioinformatics industries with a core expertise in the strategy, execution and management of strategic partnerships. His specialties are life science strategy & operations, business development and strategic transactions.

Meetings of directors

The number of meetings of the board of the Company during the year ended 30 June 2022 and number of meetings attended by each director were:

	Board		Audit		Remuneration	
	Number eligible to attend	Number attended	Number eligible to attend	Number attended	Number eligible to attend	Number attended
Ms Sue MacLeman	11	11	N/A	N/A	2	2
Dr Nicholas Cerneaz	11	11	2	2	N/A	N/A
Dr Douglas Robertson	11	10	2	2	N/A	N/A
Ms Julie Phillips	11	11	N/A	N/A	2	2
Dr Alexander Fowkes	11	11	N/A	N/A	2	2

Rounding
The amounts contained in this report and in the financial report have been rounded to the nearest $1 (where rounding is applicable) and where noted ($) under the option available to the Company under ASIC Corporations (Rounding in Financial/Directors' Reports) Instrument 2016/191. The Company is an entity to which the legislative instrument applies.

Auditor's independence declaration
A copy of the Auditor's Independence Declaration as required under s.60-40 of the Australian Charities and Not-for-profits Commission Act 2012 is included in page 8 of this financial report and forms part of the Company' Report.

Directors' Report

This report is made in accordance with a resolution of Board of directors of the Company and is signed on behalf of the directors by:

Ms Sue MacLeman
24 August 2022
Melbourne

Auditor's Independence Declaration

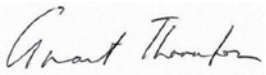
Grant Thornton Australia Limited
Level 22 Tower 5
Collins Square
727 Collins Street
Melbourne VIC 3008
GPO Box 4736
Melbourne VIC 3001

T +61 3 8320 2222

Auditor's Independence Declaration

To the Directors of MTP-IIGC Ltd

In accordance with the requirements of section 60-40 of the *Australian Charities and Not-for-profits Commission Act 2012*, as lead auditor for the audit of MTP-IIGC LTD for the year ended 30 June 2022, I declare that, to the best of my knowledge and belief, there have been no contraventions of any applicable code of professional conduct in relation to the audit.



Grant Thornton Audit Pty Ltd
Chartered Accountants

M A Cunningham
Partner - Audit & Assurance

Melbourne, 24 August 2022

ACN-130 913 594

Statement of Profit or Loss and Other Comprehensive Income

MTP-IIGC LTD

For the year ended 30 June 2022

Revenue	Notes	30 June 2022	30 June 2021
		$	$
Grants	2	40,109,403	33,547,207
Interest		6,290	5,875
Other Income		134,473	2,500
Total Revenue		**40,250,165**	**33,555,582**
Expenses			
Travel and accommodation		119,169	32,595
Accounting, legal & audit		418,799	395,703
Depreciation and amortisation		108,719	128,931
Employment costs		4,260,057	3,815,261
Consulting Fees		405,939	49,298
Corporate communications & sponsorship		831,470	377,319
Office and Administration		165,445	210,827
Sector Support Projects		874,499	1,214,715
Project Funding		32,754,034	26,445,953
Total Expenses		39,938,130	32,670,602
Surplus before taxation		**312,035**	**884,980**
Net surplus for the period		**312,035**	**884,980**
Total comprehensive surplus for the period		**312,035**	**884,980**

Statement of Financial Position

MTP-IIGC LTD

As at 30 June 2022

	Notes	30 June 2022	30 June 2021
		$	$
Assets			
Current Assets			
Cash and cash equivalents		89,679,232	71,441,077
Trade and other receivables	3	338,346	895,346
Total Current Assets		90,017,575	72,336,422
Non-Current Assets			
Right of Use Asset	4	77,479	77,342
Property, plant and equipment		69,612	63,860
Total Non-Current Assets		147,090	141,202
Total Assets		**90,164,668**	**72,477,625**
Liabilities			
Current Liabilities			
Trade and other payables	5	5,213,787	1,057,560
Contract liability	6	83,071,679	69,902,995
Provisions	7	335,295	300,097
Lease liability	4	66,660	78,914
Total Current Liabilities		88,687,422	71,339,566
Non-Current Liabilities			
Provisions	7	33,241	17,740
Lease liability	4	11,650	-
Total Non-Current Liabilities		44,891	17,740
Total Liabilities		**88,732,313**	**71,357,306**
Net Assets		**1,432,355**	**1,120,320**
Equity			
Current Year Earnings		312,035	884,980
Retained Earnings (Members Funds)		1,120,320	235,340
Total Equity		**1,432,355**	**1,120,320**

Statement of Changes in Equity

MTP-IIGC LTD

For the year ended 30 June 2022

Equity	30 June 2022	30 June 2021
	$	$
Opening Balance	1,120,320	235,340
Increases		
Net surplus for the period	312,035	884,980
Total comprehensive surplus for the period	**312,035**	**884,980**
Total Equity	**1,432,355**	**1,120,320**

Statement of Cash Flows

MTP-IIGC LTD

For the year ended 30 June 2022

	30 June 2022	30 June 2021
	$	$
Cash flows from Operating Activities		
Receipts from grants for internal funding and deployment of projects	53,084,000	60,712,000
Payments to suppliers, employees and deployment of projects	(34,882,378)	(33,543,217)
Interest received	6,290	5,875
Cash receipts from other operating activities	145,290	-
Total Cash flows from Operating Activities	**18,353,202**	**27,174,658**
Cash flows from Investing Activities		
Payment for property, plant and equipment	(41,864)	(47,763)
Total Cash flows from Investing Activities	**(41,864)**	**(47,763)**
Cash flows from Financing Activities		
Repayment of lease liability	(73,183)	(94,447)
Total Cash flows from Investing Activities	**(73,183)**	**(94,447)**
Net increase in cash held	**18,238,155**	**27,032,448**
Cash Balance		
Opening cash balance	71,441,076	44,408,629
Closing cash balance	**89,679,232**	**71,441,076**

Notes to the Financial Statements

1. Statement of Significant Accounting Policies

a. Basis of Preparation

MTP-IIGC Ltd is a company limited by guarantee, incorporated and domiciled in Australia. Its registered office and principal place of business is: Level 1, Suite 1.01 250 Bay Street Brighton VIC 3186.

These general purpose financial statements have been prepared in accordance with Australian Accounting Standards and Interpretations issued by the Australian Accounting Standards Board and the Corporations Act 2001. MTP-IIGC Ltd is a not-for-profit entity for the purpose of preparing the financial statements. The financial statements of the MTP-IIGC Ltd comply with Australian Accounting Standards – Simplified Disclosures as issued by the Australian Accounting Standards Board (AASB).

These are the group's first general purpose financial statements prepared in accordance with AASB 1060. As permitted by the amended AASB 1053 Application of Tiers of Australian Accounting Standards, the group has not provided comparative information for those disclosures that it had not previously made in the notes of its general purpose financial statements prepared in accordance with Australian Accounting Standards – Reduced Disclosure Requirements

Australian Accounting Standards set out accounting policies that the AASB has concluded would result in financial statements containing relevant and reliable information about transactions, events and conditions. Material accounting policies adopted in the preparation of these financial statements are presented below and have been consistently applied unless stated otherwise.

The financial statements, except for the cash flow information, have been prepared on an accruals basis and are based on historical costs, modified, where applicable, by the measurement at fair value of selected non-current assets, financial assets and financial liabilities. The amounts presented in the financial statements have been rounded to the nearest dollar.

The financial statements were authorised for issue on 24 August 2022 by the Directors of the Company.

b. New and Revised Accounting Standards Adopted by the Company

The company has adopted all of the new or amended Accounting Standards and Interpretations issued by the Australia Accounting Standards Board ('AASB') that are mandatory for the current reporting period.

Any new or amended Accounting Standards or Interpretations that are not yet mandatory have not been early adopted.

Other standards not yet applicable

There are no other standards that are not yet effective and that would be expected to have a material impact on the Company in the current or future reporting periods and on foreseeable future transactions.

c. Going Concern

MTP-IIGC LTD is dependent on the Department of Industry, Science and Resources ('DISR') for the majority of its grant revenue used to operate the business. The Growth Centre Initiative is scheduled to cease 30 June 2023. As of the date of this report, the Board of Directors are in discussions with DISR to extend the Initiative end date and utilise surplus funds to continue to operate the business. In the event that an extension is

not permitted and surplus funds are required to be returned to DISR, MTP-IIGC LTD will cease operations if it cannot secure other sources of revenue.

d. Accounting Policies

i. Revenue

Under AASB15 Revenue from Contracts with Customers, revenue is recognised when a performance obligation is satisfied, being when control of the goods or services underlying the performance obligation is transferred to the customer.

ii. Government grants

Grant income without sufficiently specific and enforceable performance obligations

Grant funds received by the Company that do not have sufficiently specific and enforceable performance obligations are recognised as income on receipt of the funds.

Grant revenue with sufficiently specific and enforceable performance obligations

These grants are recognised as revenue, over time, as the Company satisfies its Grant funds received by the Company that have sufficiently specific and enforceable performance obligations, in accordance with AASB 15, are recognised as a contract liability on receipt and are recognised performance obligations.

Fundraising and donation income

Fundraising and donation income are recognised when the Company gains control of the funds and are only recognised as income when the funds have been provided to further the Company's objectives for no consideration or where consideration is significantly less than the funds provided and when the funds provided do not give rise to an obligation.

iii. Interest income

Interest income from a financial asset is recognised when it is probable that the economic benefits will flow to the Company and the amount of revenue can be measured reliably.

iv. Other income

Other income consists of consulting income, collaboration income and contributions towards the WA Life Sciences Sector End of Year event and is recognised when it is probable that the economic benefits will flow to the Company and the amount of revenue can be measured reliably.

v. Income of Not-for Profit Entities

The timing of income recognition under AASB 1058 is dependent upon whether the transaction gives rise
to a liability or other performance obligation at the time of receipt.

Income under the standard is recognised where:

- an asset is received in a transaction, such as by way of grant, bequest or donation;
- there has either been no consideration transferred, or the consideration paid is significantly less than the asset's fair value; and
- where the intention is to principally enable the entity to further its objectives.

For transfers of financial assets to the entity which enable it to acquire or construct a recognisable nonfinancial asset, the entity must recognise a liability amounting to the excess of the fair value of the

Notes to the Financial Statements

transfer received over any related amounts recognised.

Related amounts recognised may relate to:

- contributions by owners;
- AASB 15 revenue or contract liability recognized;
- lease liabilities in accordance with AASB 16;
- financial instruments in accordance with AASB 9; or
- provisions in accordance with AASB 137.

Where the agreements entered into by the Company include conditions that are 'enforceable' and 'sufficiently specific', there will be a contract liability and revenue will be recognised under AASB 15 when (or as) 'performance obligations' are satisfied by the provision of goods or services.

vi. Employee Benefits

Short-term employee benefits

Provision is made for the Company's obligation for short-term employee benefits. Short-term employee benefits are benefits (other than termination benefits) that are expected to be settled wholly within 12 months after the end of the annual reporting period in which the employees render the related service, including wages, salaries and annual leave. Short-term employee benefits are measured at the (undiscounted) amounts expected to be paid when the obligation is settled.

The Company's obligations for short-term employee benefits such as wages, salaries and annual leave are recognised as a part of current trade and other payables in the statement of financial position.

Retirement benefit obligations

Defined contribution superannuation benefits - all employees of the Company receive defined contribution superannuation entitlements, for which the Company pays the fixed superannuation guarantee contribution (10% of the employee's average ordinary salary for the financial year) to the employee's superannuation fund of choice.

All contributions in respect of employees' defined contribution entitlements are recognised as an expense when they become payable. The Company's obligation with respect to employees' defined contribution entitlements is limited to its obligation for any unpaid superannuation guarantee contributions at the end of the reporting period. All obligations for unpaid superannuation guarantee contributions are measured at the (undiscounted) amounts expected to be paid when the obligation is settled and are presented as current liabilities in the Company's statement of financial position.

vii. Cash and Cash Equivalents

Cash and cash equivalents include cash on hand, deposits held at call with banks, other short-term highly liquid investments with original maturities of three months or less, and bank overdrafts. Bank overdrafts are shown within short-term borrowings in current liabilities on the statement of financial position.

viii. Good and Services Tax (GST)

Revenues, expenses and assets are recognised net of the amount of GST, except where the amount of GST incurred is not recoverable from the Australian Taxation Office (ATO).

Receivables and payables are stated inclusive of the amount of GST receivable or payable. The net amount of GST recoverable from, or payable to, the ATO is included with other receivables or payables in the statement of financial position.

Cash flows are presented on a gross basis. The GST components of cash flows arising from investing or financing activities which are recoverable from, or payable to, the ATO are presented as operating cash flows included in receipts from customers or payments to suppliers.

ix. Income Tax

No provision for income tax has been created as the entity is exempt from income tax under Div. 50 of the *Income Tax Assessment Act 1997.*

x. Provisions

Provisions are recognised when the Company has a legal or constructive obligation, as a result of past events, for which it is probable that an outflow of economic benefits will result, and that outflow can be reliably measured. Provisions recognised represent the best estimate on the amounts required to settle the obligation at the end of the reporting period.

xi. Trade and Other Receivables

Trade receivables and other receivables are recognised at the nominal transaction value without taking into account the time value of money. If required a provision for doubtful debt has been created. Trade and other receivables represent the assets for goods and services supplied by the Company during the reporting period that remain unpaid at the end of the reporting period. The balance is recognised as a current asset with the amount normally received within 30 days of recognition of the asset.

xii. Trade and Other Payables

Trade and other payables represent the liabilities for goods and services received by the Company during the reporting period that remain unpaid at the end of the reporting period. The balance is recognised as a current liability with the amount normally paid within 30 days of recognition of the liability.

xiii. Significant management judgement in applying accounting policies

When preparing the financial statements, management undertakes a number of judgements, estimates and assumptions about the recognition and measurement of assets, liabilities, income and expenses.

Notes to the Financial Statements

Estimation uncertainty

Information about estimates and assumptions that have the most significant effect on recognition and measurement of assets, liabilities, income and expenses is provided below. Actual results may be substantially different.

Useful lives of depreciable assets

Management reviews its estimate of the useful lives of depreciable assets at each reporting date, based on the expected utility of the assets. Uncertainties in these estimates relate to technical obsolescence that may change the utility of certain software and IT equipment.

xiv. Fair Value of Assets and Liabilities

The Company measures some of its assets and liabilities at fair value on either a recurring or non-recurring basis, depending on the requirements of the applicable Accounting Standard.

"Fair value" is the price the Company would receive to sell an asset or would have to pay to transfer a liability in an orderly (i.e. unforced) transaction between independent, knowledgeable and willing market participants at the measurement date.

As fair value is a market-based measure, the closest equivalent observable market pricing information is used to determine fair value. Adjustments to market values may be made having regard to the characteristics of the specific asset or liability. The fair values of assets and liabilities that are not traded in an active market are determined using one or more valuation techniques. These valuation techniques maximise, to the extent possible, the use of observable market data.

To the extent possible, market information is extracted from the principal market for the asset or liability (i.e. the market with the greatest volume and level of activity for the asset or liability). In the absence of such a market, market information is extracted from the most advantageous market available to the Company at the end of the reporting period (i.e. the market that maximises the receipts from the sale of the asset or minimises the payments made to transfer the liability, after taking into account transaction costs and transport costs).

For non-financial assets, the fair value measurement also takes into account a market participant's ability to use the asset in its highest and best use or to sell it to another market participant that would use the asset in its highest and best use.

The fair value of liabilities and the Company's own equity instruments (if any) may be valued, where there is no observable market price in relation to the transfer of such financial instrument, by reference to observable market information where such instruments are held as assets. Where this information is not available, other valuation techniques are adopted and, where significant, are detailed in the respective note to the financial statements.

xiii. Leases

At inception of a contract the Company assesses if the contract contains or is a lease. If there is a lease present, a right-of-use asset and a corresponding lease liability are recognised by the Company where the Company is a lessee. However, all contracts that are classified as short-term leases (i.e. leases with a remaining lease term of 12 months or less) and leases of low-value assets are recognised as an operating expense on a straight-line basis over the term of the lease.

Initially, the lease liability is measured at the present value of the lease payments still to be paid at the commencement date. The lease payments are discounted at the interest rate implicit in

the lease. If this rate cannot be readily determined, the Company uses incremental borrowing rate.

Lease payments included in the measurement of the lease liability are as follows;

- fixed lease payments less any lease incentives;
- variable lease payments that depend on index or rate, initially measured using the index or rate at the commencement date;
- the amount expected to be payable by the lessee under residual value guarantees;
- the exercise price of purchase options if the lessee is reasonably certain to exercise the options;
- lease payments under extension options, if the lessee is reasonably certain to exercise the options; and
- payments of penalties for terminating the lease, if the lease term reflects the exercise of options to terminate the lease.

The right-of-use assets comprise the initial measurement of the corresponding lease liability less, any lease payments made at or before the commencement date and any initial direct costs. The subsequent measurement of the right-of-use assets is at cost less accumulated depreciation and impairment losses.

Right-of-use assets are depreciated over the lease term or useful life of the underlying asset, whichever is the shortest.

Where a lease transfers ownership of the underlying asset or the costs of the right-of-use asset reflects that the Company anticipates to exercise a purchase option, the specific asset is depreciated over the useful life of the underlying asset.

xiv. Reporting period

The current period of the financial statements is from 1 July 2021 to 30 June 2022.

2. Grants

	30 June 2022	30 June 2021
	$	$
Grants from DISR	4,156,317	6,169,732
Grants from DOH (BMTH 1)	240,746	816,579
Grants from DOH (BMTH 2)	9,946,416	11,283,083
Grants from DOH (BTB)	9,010,539	7,654,856
Grants from DOH (REDI)	8,536,296	5,227,609
Grants from DOH (TTRA)	6,140,011	1,253,906
Grants Non-Government - AAMRNet	289,000	879,500
Grants from WA Government	730,339	261,942
Grants from SA Government	500,000	-
Grants from DOH (CTC-M)	540,297	-
Grants from Diagnostics Engagement (DISR)	18,443	-
Total	**40,109,403**	**33,547,207**

Notes to the Financial Statements

3. Trade and other receivables

	30 June 2022	30 June 2021
	$	$
Prepayments	239,800	66,676
Trade Receivables	98,546	115,170
GST Receivable	-	713,500
Total	**338,346**	**895,346**

4. Right of use asset and lease liability

	30 June 2022	30 June 2021
Right of use asset:	**$**	**$**
1. Cremorne Street Lease		
Current	-	-
Non-current	-	77,342
	-	**77,342**
Carrying value at the beginning of the year	77,342	-
On initial recognition	-	117,695
Depreciation for the year	(47,078)	(40,352)
Balance retired upon termination of the lease	(30,265)	-
Carrying Value at end of period	**-**	**77,342**
2. Bay Street Lease		
Current	-	-
Non-current	77,479	-
	77,479	**-**
On initial recognition	99,616	-
Depreciation for the year	(22,137)	-
Carrying Value at end of period	**77,479**	**-**
Lease liability:		
1. Cremorne Street Lease		
Current	-	78,914
Non-current	-	-
	-	**78,914**
Carrying value at the beginning of the year	78,914	-
On initial recognition	-	117,695
Interest for the year	1,527	2,386
Lease repayments for the year	(44,850)	(41,167)
Balance retired upon termination of lease	(30,265)	-
Loss/(Gain) on termination of lease	(5,326)	-
Carrying value at end of period	**-**	**78,914**
2. Bay Street Lease		
Current	66,660	-
Non-current	11,650	-
	78,310	**-**
On initial recognition	99,616	-
Interest for the year	1,361	-
Lease repayments for the year	(22,667)	-
Carrying value at end of period	**78,310**	**-**

Notes to the Financial Statements

The Cremorne Street lease was terminated on 22 February 2022. Right of use asset and lease liability balances as of this date were retired, with the resultant gain on termination of lease recognised in the statement of profit or loss and other comprehensive income.

Option to extend or terminate

The Company uses hindsight in determining the lease term where the contract contains options to extend or terminate the lease**.**

Property leases

The right-of-use asset is being depreciated over the lease term on a straight-line basis. Depreciation expense of $69,215 was charged as an expense over the period (Bay Street lease: $22,137 and Cremorne Street lease: $47,078).

At initial recognition, the Bay Street lease liability was measured as the present value of minimum lease payments using the Company's incremental borrowing rate of 4.75%. The incremental borrowing rate was based on the unsecured interest rate that would apply if finance was sought for an amount and time period equivalent to the lease requirements of the Company. Each lease payment is allocated between the liability and interest expense. An interest expense of $2,888 was charged as an expense over the period (Bay Street lease: $1,361 and Cremorne Street lease: $1,527).

At initial recognition, the Cremorne Street lease liability was measured as the present value of minimum lease payments using the Company's incremental borrowing rate of 5.03%. The incremental borrowing rate was based on the unsecured interest rate that would apply if finance was sought for an amount and time period equivalent to the lease requirements of the Company.

All amounts payable within 12 months are shown as current liabilities. All non current lease liabilities are payable within 12 months to 5 years.

5. Trade and other payables

	30 June 2022	30 June 2021
	$	$
Trade Creditors	3,685,547	265,790
Accrued Expenses	849,813	715,414
GST Payable	569,849	-
Other Payables	108,578	76,357
Total	**5,213,787**	**1,057,560**

6. Contract liability

Deferred income represents the life to date surplus of grants received as compared to expenditure (on both operating and project activities) incurred for respective funding:

	30 June 2022	30 June 2021
	$	$
Deferred income related to funding received from:		
Department of Industry, Science and Resources	10,667,898	6,542,688
Department of Jobs, Tourism, Science and Innovation (WA)	730,245	924,736
Department of Health (BioMedTech Horizons Program)	210,989	449,465
Department of Health (BioMedTech Horizons 2 Program)	11,610,303	21,556,719
Department of Health (Biomedical Translation Bridge Program)	3,420,362	11,130,901
Department of Health (Clinical Translation and Commercialisation - Medtech Program)	16,709,703	-
Department of Health (Researcher Exchange and Development within Industry Program)	15,616,095	11,552,391
Department of Health (Targeted Translation Research Accelerator Program)	24,106,083	17,746,094
Total	**83,071,679**	**69,902,995**

7. Provisions

	30 June 2022	30 June 2021
Current		
Provision for Annual Leave	319,228	287,738
Provision for Long Service Leave	16,067	12,359
Total current	335,295	300,097
Non-current		
Provision for Long Service Leave	33,241	17,740
Total non--current	33,241	17,740
Total	**368,536**	**317,837**

8. Income Tax

MTP-IIGC Ltd is exempt from Income Tax as it is a registered charity under Australian Charities and Not-for-Profits Commission.

Notes to the Financial Statements

9. Events after reporting date

The directors are not aware of any significant events since the end of the reporting period.

10. Key management personnel compensation

Any person(s) having authority and responsibility for planning, directing and controlling the activities of the Company, directly or indirectly, including any director (whether executive or otherwise) of that Company is considered key management personnel ("KMP").

The total remuneration paid to KMP of the organisation during the period are as follows:

	30 June 2022	30 June 2021
	$	$
KMP compensation for the year	1,023,506	1,131,255

11. Other related party transactions

There have been related party transactions during the period ending 30 June 2022 totaling $27,992 exclusive of GST for Graphic Design work for Conference Brochures, Business Cards and Annual Highlights document.

Other related parties include close family members of key management personnel and entities that are controlled or jointly controlled by those key management personnel individually or collectively with their close family members.

Transactions between related parties are on normal commercial terms and conditions no more favourable than those available to other persons unless otherwise stated.

12. Contingent Liabilities

There are no significant commitments and contingencies at balance date in the current or prior reporting periods.

13. Events after the reporting period

There has not been any matter or circumstance that has arisen since the end of the financial year that has significantly affected or may significantly affect the operations of the Group, the results of these operations, or the state of affairs of the Group in future financial years.

14. Remuneration of auditors

During the year the following fees were paid or payable for services provided by Grant Thornton as the auditor.

	2022	2021
	$	$
Audit of financial reports	35,750	32,500
Other Statutory assurance services	18,500	15,500
Total	54,250	48,000

Directors' Report

MTP-IIGC LTD

For the year ended 30 June 2022

The directors have determined that the Company is not a reporting entity and that this deduced disclosure financial report should be prepared in accordance with the accounting policies outlined in Note 1 to the financial statements.

The directors of the Company declare that:

1. The financial statements and notes, present fairly the Company's financial position as at 30 June 2022 and its performance for the year ended on that date in accordance with the accounting policies described in Note 1 to the financial statements; and
2. In the directors' opinion there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable.

This declaration is made in accordance with a resolution of the Board of Directors.

Director: Ms Sue MacLeman

Sign date: 24 August 2022

Auditor's Report

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Independent Auditor's Report

To the Members of MTP-IIGC Ltd

Report on the audit of the financial report

Opinion

We have audited the financial report of MTP-IIGC Ltd (the Company), which comprises the statement of financial position as at 30 June 2022, the statement of profit or loss and other comprehensive income, statement of changes in equity and statement of cash flows for the year then ended, and notes to the financial statements, including a summary of significant accounting policies, and the Directors' declaration.

In our opinion, the accompanying financial report of the Company is in accordance with the *Division 60 of the Australian Charities and Not-for-profits Commission Act 2012* and the *Corporations Act 2001,* including:

a giving a true and fair view of the Company's financial position as at 30 June 2022 and of its performance for the year ended on that date; and

b complying with Australian Accounting Standards *AASB 1060 General Purpose Financial Statements - Simplified Disclosures for For-Profit and Not-for-Profit Tier 2 Entities*, Division 60 of the *Australian Charities and Not-for-profits Commission Regulation 2013 and* the *Corporations Regulations 2001*.

Basis for opinion

We conducted our audit in accordance with Australian Auditing Standards. Our responsibilities under those standards are further described in the *Auditor's Responsibilities for the Audit of the Financial Report* section of our report. We are independent of the Company in accordance with the *Corporations Act 2001* and the ethical requirements of the Accounting Professional and Ethical Standards Board's APES 110 *Code of Ethics for Professional Accountants (including Independence Standards)* (the Code) that are relevant to our audit of the financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

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Information other than the financial report and auditor's report thereon

The Directors are responsible for the other information. The other information comprises the information included in the Company's annual report for the year ended 30 June 2022, but does not include the financial report and our auditor's report thereon.

Our opinion on the financial report does not cover the other information and accordingly we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial report, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial report or our knowledge obtained in the audit or otherwise appears to be materially misstated.

If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Responsibilities of the Directors' for the financial report

The Directors of the Company are responsible for the preparation of the financial report that gives a true and fair view in accordance with Australian Accounting Standard – *AASB 1060 General Purpose Financial Statements - Simplified Disclosures for For-Profit and Not-for-Profit Tier 2 Entities*, the *Australian Charities and Not-for-profits Commission* Act 2012 and the *Corporations Act 2001*. The Directors' responsibility also includes such internal control as the Directors determine is necessary to enable the preparation of the financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error.

In preparing the financial report, the Directors are responsible for assessing the Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the Directors either intend to liquidate the Company or to cease operations, or have no realistic alternative but to do so.

Auditor's responsibilities for the audit of the financial report

Our objectives are to obtain reasonable assurance about whether the financial report as a whole is free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with the Australian Auditing Standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of this financial report.

A further description of our responsibilities for the audit of the financial report is located at the Auditing and Assurance Standards Board website at: https://www.auasb.gov.au/auditors_responsibilities/ar4.pdf. This description forms part of our auditor's report.

Grant Thornton Audit Pty Ltd
Chartered Accountants

M A Cunningham
Partner – Audit & Assurance

Melbourne, 24 August 2022

Grant Thornton Australia Limited

MTPConnect
MedTech and Pharma Growth Centre

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