



MTPConnect

MedTech and Pharma Growth Centre

Business Plan **FY2021**

1 JULY 2020



Australian Government
Department of Industry, Science,
Energy and Resources

Industry
Growth
Centres

The background of the page is a teal-colored overlay on a photograph of two scientists in a laboratory. One scientist, a woman with dark hair, is in the foreground, looking through a microscope. Another person is partially visible in the background on the left. The overall tone is professional and scientific.

INTRODUCTION

The following report is the Business Plan from MTP-IIGC Ltd (trading name MTPConnect) to the Department of Industry, Science, Energy and Resources (DISER); a contracted deliverable as detailed in the Funding Agreement signed by MTPConnect and DISER on 18 December 2015 and in the two Variations to the Funding Agreement signed on 3 May 2016 and 15 January 2019.

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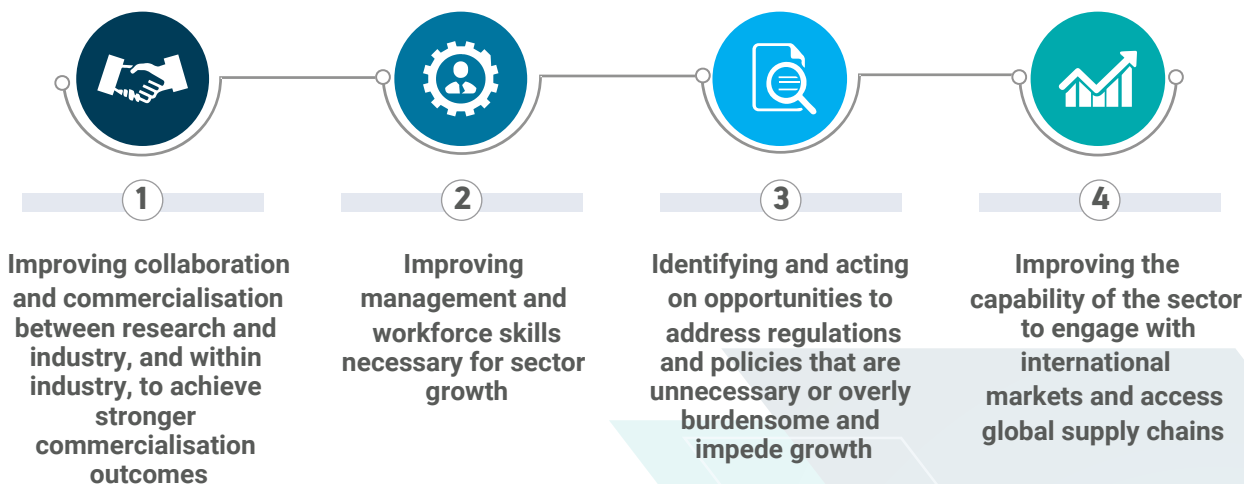
Executive Summary

MTPConnect is an independent, not-for-profit Growth Centre (GC) driving connectivity, innovation, productivity and competitiveness in Australia's medical technology, biotechnology and pharmaceuticals (MTP) sector.

Focusing on the four objectives of the Industry Growth Centre (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 forges stronger connections between research and industry and maximises opportunities for Australians to make scientific and technological breakthroughs that are successfully translated and commercialised.

MTPConnect Growth Centre Objectives



MTPConnect has delivered concrete and measurable outcomes against each of the four growth centre objectives over the past five years. MTPConnect has achieved this through three themes:

- Deploying strategic initiative funding. MTPConnect now delivers almost \$115 million in strategic initiatives through Commonwealth and State funding programs focused on translating and commercialising Australian MTP innovation and the development of workforce skills
- Providing industry thought leadership through its independent voice. MTPConnect works with sector participants across the MTP value chain to identify policy and regulatory barriers and provide independent advice and recommendations to government
- Taking direct action focused on the four GC objectives. MTPConnect has achieved this in numerous ways including delivering education events to build greater collaboration and commercialisation expertise and outcomes and facilitation of national and international connections and collaborations for Australian researchers and companies. Through the GC Project Fund MTPConnect has committed \$15.6 million across 36 collaborative projects, engaging over 160 consortium members. MTPConnect-funded projects have achieved demonstrable results, including 170 technologies being invented or progressed, 125 patents/trademark applications and licenses, 54 start-up companies, 344 direct and indirect jobs being created and more than \$31 million of investment flowing into incubator companies (as at 30 June 2019)

Note: Data as at 30/06/2018

MTPConnect's GC work is complemented by three Medical Research Future Fund (MRFF) programs worth nearly \$100 million:

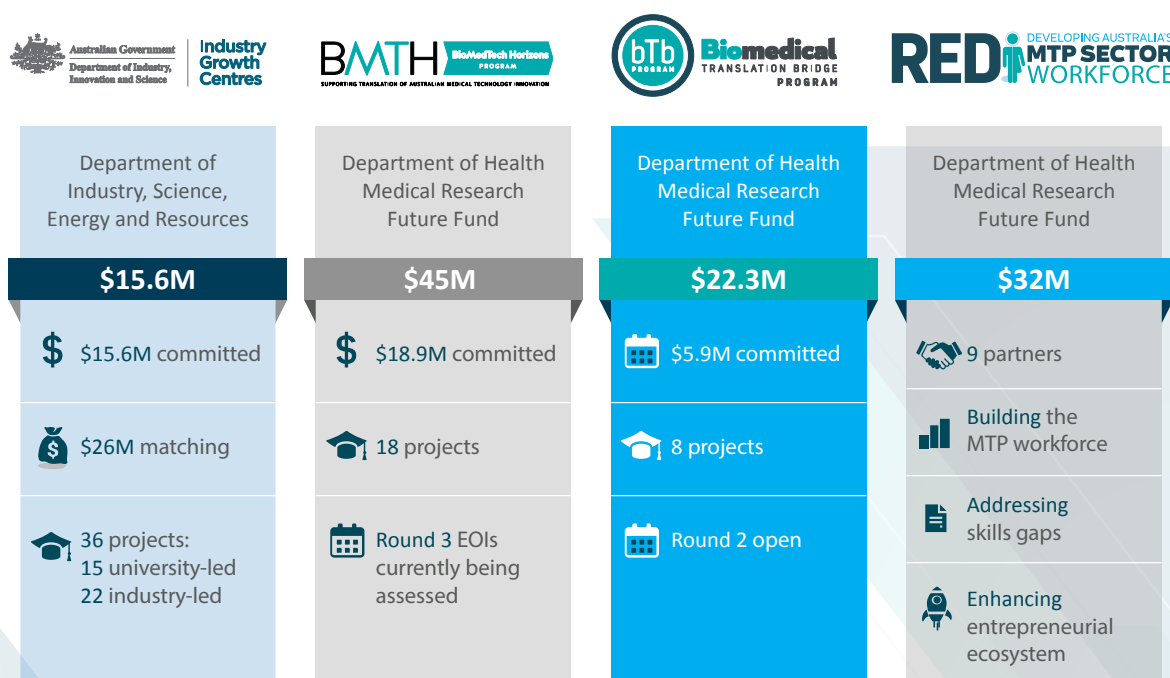
- The \$45 million BioMedTech Horizons (BMTH) program
- The \$22.3 million Biomedical Translation Bridge (BTB) program
- The \$32 million Researcher Exchange and Development within Industry (REDI) initiative

The BMTH program has committed \$18.9 million to support 18 projects across two funding rounds, with a third to be completed during 2020. The first round of the BTB program

saw eight projects share \$5.9 million in funding, with industry providing an additional \$14.6 million. The second round of BTB will be completed during 2020, while a third round - specifically designed to support COVID-19 related projects - has also been launched.

Together, these GC and MRFF programs enable MTPConnect to foster commercialisation and collaboration and address the skill gaps and key constraints identified across the sector. They will ensure that MTPConnect remains relevant as a major funding body over the next four years and can continue supporting translation of Australia's health and medical research into commercial and clinical outcomes

Strategic Funding Programs



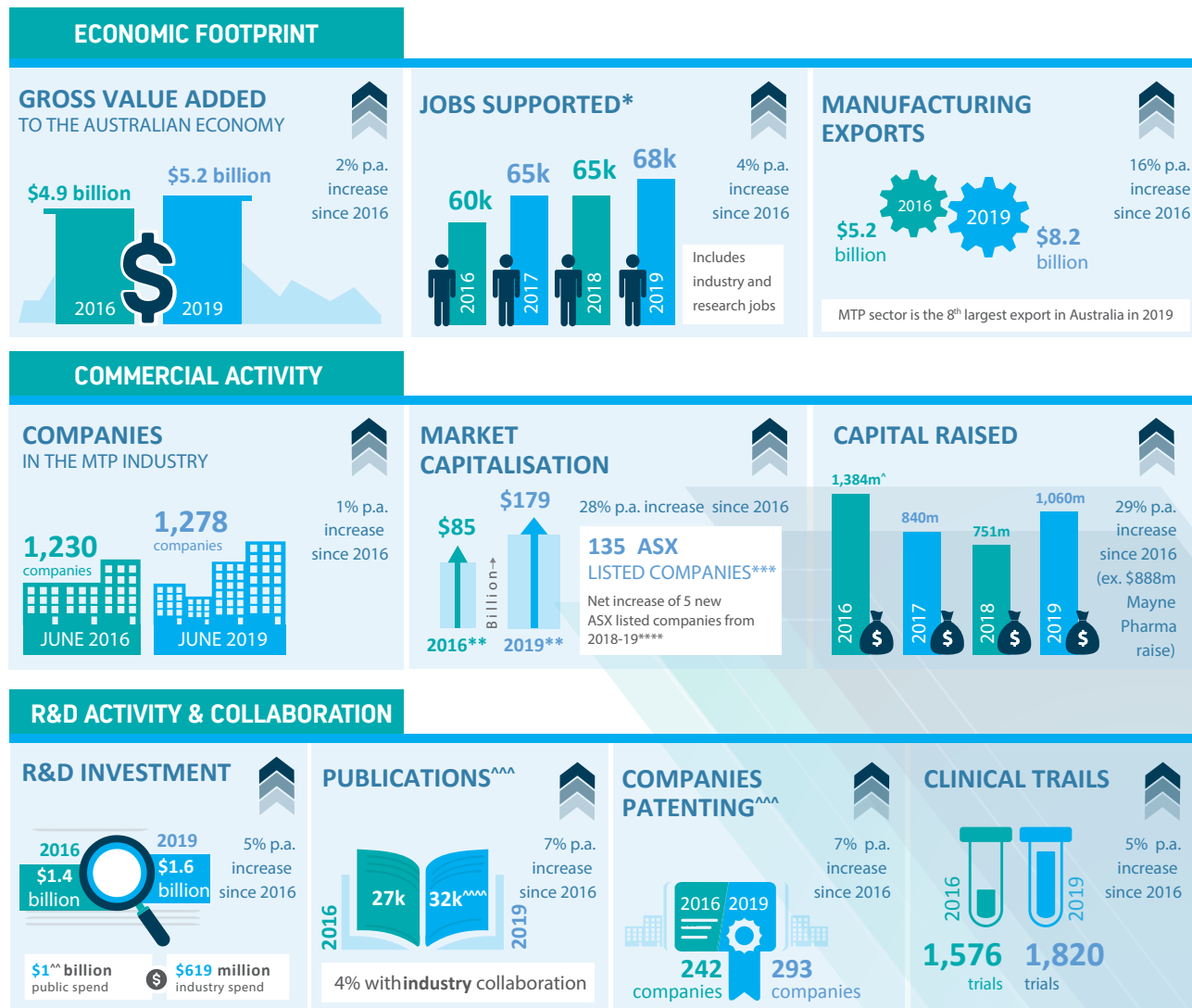
Note: * MTPConnect was selected to manage the REDI program in early 2020

MTP Sector Success Since 2015

MTPConnect recently released the 2020 Sector Competitiveness Plan (SCP) which revisits the MTP sector's Knowledge Priorities, Sector Growth Priorities and regulation reform agenda, and reviews the growth achieved by the sector over the last four years - up until 31 December 2019, the period prior to the emergence of the novel coronavirus (SARS-CoV-2). The SCP documents robust growth across many key metrics for the reporting period, including Gross Value Added which has grown steadily at 2 per cent p.a. since 2016 and manufacturing exports which have grown 16 per cent p.a. since 2016 to now be worth \$8.2 billion, making the MTP sector the 8th largest export segment in Australia.

While the impacts of the coronavirus disease (COVID-19) are developing, the SCP's pre-COVID-19 reporting period establishes a baseline of sector performance against which to assess the pandemic impact. A major focus of activities for MTPConnect in 2020/2021 will be the delivery of a leading, relevant and forward-looking report series on the impact COVID-19 has had on the MTP sector and lessons learned from Australia's response to the pandemic. The report series will provide timely, valuable and verifiable information for the community, MTP sector participants and government and provide a roadmap for the implementation of rebuilding strategies and future preparedness response.

MTP Sector Progress on Specific Data Analysis 2015 to Present, MTPConnect's 2020 SCP



Notes: * Due to the volatile nature of quarterly employment metrics, the industry job portion 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.

**** 2018 figure for ASX listed companies adjusted from 135 to 130 for the 5 companies that were de-listed during the year.

[^] 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 2018) grant funding per year assumes grant funding distributed equally in each year of the grant; ARC funding estimates for grants announced after August 2018 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 2018, and b) grant funding is distributed equally across each year of the assumed grant duration; MRFF funding is FY2019 committed funding per 2018-20 Priorities Discussion Paper; BTF funding assumes increase between previous announcement and current grant funding occurred in 2019.

^{^^^} Data provided by Clarivate Analytics.

^{^^^} There were an additional 79 reporting organisations whose publications output was included in the data from 2017 onwards.

MTPConnect's Long-term Sustainability

Originally funded in 2015 for four years, with an additional two years of funding allocated following a successful performance review in 2019, MTPConnect's DISER Growth Centre funding is due to expire on 31 October 2021.

MTPConnect has always held a focus on long-term sustainability. A detailed assessment of self-sustainability was initiated in 2017 and substantial steps have been taken to diversify the organisation's revenue, leveraging the original GC investment to amplify impact and find new ways to support health and medical research projects, translation, commercialisation and sector growth.

MTPConnect has been successful in securing three MRFF programs worth nearly \$100 million and will continue identifying opportunities to leverage other government initiatives. It has also secured funding from the Government of Western Australia (\$300,000 p.a. over three years) to support MTPConnect's activities to develop the burgeoning MTP ecosystem in WA.

However, with DISER funding finishing in October 2021, a broader sustainability plan has been developed and programs initiated to identify further alternative and diverse revenue sources to underpin the organisation's sustainability, beyond 2021. The revenue mix to achieve full financial independence may require a level of ongoing government funding until 2025 (i.e. a 10-year term) with a staggered reduction in funds, year-on-year.

Sustainability Initiative

MTPConnect's Sustainability Initiative is a two-phase project looking to identify and address a currently unmet market need in the MTP sector. MTPConnect's rare blend of capacity, capabilities and reputation will be leveraged to develop a compelling value proposition to market participants that complements and augments existing offerings.

In phase one, a business advisory firm will provide advice to MTPConnect on potential market platforms to defragment opportunities in the sector around intellectual property. The assessment includes MTPConnect's market role, business model, commercial model, platform model and cost, as well as strategy and technology analysis and market testing. Phase one is due to be completed during Q1 FY2021.

Phase two of the Sustainability Initiative is focused on trialing and implementing the new business proposition/s identified by the firm with beta launch/pilot study by December 2020. The real-world engagement will inform MTPConnect and the firm of the on-the-ground viability of the business concept, informing business case iteration and refinement.

The Sustainability Initiative will guide MTPConnect towards a degree of financial independence and viability in the absence, or scaling back, of ongoing government funding.

MTPConnect's Vision for the MTP sector

MTPConnect's vision is for Australia's MTP sector to create more products that reach proof-of-concept and achieve greater commercialisation success, increase the number of companies with late-stage product successes and to maximise the value of Intellectual Property (IP) 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.

The Australian MTP sector has the potential to be a significant contributor to improving patient outcomes and also a key driver of economic and jobs growth over the next 10-20 years. 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 their overall health and wellbeing.

The MTP sector's ability to respond to megatrends is also important, as has been highlighted in Australia's responses to the global biosecurity challenges posed by the COVID-19 pandemic, and will play a key role in establishing sovereign capabilities, resilient supply chains and in defining our economic and job creation path out of COVID-19.

These megatrends, knowledge and sector priorities, as detailed in the 2020 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.

Emerging Megatrends

Megatrends are the overarching social, economic, environmental, technological and geopolitical forces that will shape the future of industries. They are often disruptive; they change existing business models and present opportunities and challenges for organisations. By nature, they are forward-looking and as a result the list of megatrends does not vary significantly from year to year; rather they evolve gradually.

Digital evolution is central as an enabler and disrupter for all other megatrends. Mental health and wellbeing, while not megatrends, are highlighted as underlying drivers in the chronic burden and consumer control megatrends respectively, contributing to pressure on the sustainability of healthcare delivery. It is acknowledged that, over time, the manifestations of climate variability (higher temperatures, altered rainfall patterns and more frequent or intense extreme events) will influence many of these megatrends, including global biosecurity, healthy ageing and wellbeing, developing markets and chronic burden and will need to be considered as part of strategic planning and operational activities.



The Global Biosecurity Megatrend and COVID-19

As we have seen, the MTP sector is critical for responses to pandemics and global biosecurity threats. With Australia confirming its first case of the coronavirus on 25 January 2020, it wasn't long before COVID-19, the disease caused by SARS-CoV-2, emerged as an international public health emergency which was classified by the World Health Organization as a pandemic on 11 March 2020 pointing to over 118,000 cases of the illness in over 110 countries. As the number of cases and deaths continued to rise, the broad MTP sector in Australia, on the frontline for research, diagnosis, management, advanced manufacturing, prevention and treatment of infectious diseases, has mobilised to meet the challenge.

Many Australian researchers, startups and SMEs are currently 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 and Working Groups and state interagency COVID-19 committees, as well as membership of the CSIRO Health and Biosecurity Advisory Committee and the DMTC Medical Countermeasures Stakeholder Committee.

MTPConnect has leveraged its expertise and extensive industry networks to play a critical role in supporting Australia's response to COVID-19. This has included close involvement in the Federal Government Taskforces and Working Groups and state interagency COVID-19 committees, as well as membership of the CSIRO Health and Biosecurity Advisory Committee and the DMTC Medical Countermeasures Stakeholder Committee.

Knowledge Priorities

MTPConnect has identified a suite of Knowledge Priorities (KPs), or areas where there is a high level of unmet need globally and where Australia is or has the potential to be a leading contributor, to provide strategic focus to the sector's activities for FY2020 and beyond. As shown in the diagram below, six areas of science, nine therapeutic areas, five device / diagnostic areas and four other existing national priorities have been identified as Current KPs while nine areas have also been identified as Emerging KPs.

As a result of COVID-19, we will see new priorities emerging, with an emphasis on building sovereign capabilities and supply chain resilience, advanced manufacturing, vaccines and diagnostics.

The following Knowledge Priorities have been shortlisted based on our analysis

 SCIENCE AREAS	 THERAPEUTIC AREAS	 DEVICE & DIAGNOSTIC AREAS	 SKILLS & CAPABILITIES	 OTHER EXISTING NATIONAL PRIORITIES
Current				
<u>Biochemistry and cell biology (including synthetic biology)</u> <u>Psychology and cognitive sciences</u> <u>Genetics and precision medicine</u> <u>Microbiology</u> <u>Immunology</u> <u>Paediatrics and reproductive medicine</u>	<u>Oncology</u> <u>Infectious disease (including antimicrobial resistance)</u> <u>Neurosciences and neurology</u> <u>Cardiac and cardiovascular systems</u> <u>Diabetes, endocrinology and metabolism</u> <u>Respiratory disorders (e.g. asthma)</u> <u>Arthritis and musculoskeletal conditions</u> <u>Aged and palliative care</u> <u>Aboriginal and Torres Strait Islander Health</u>	<u>Diagnostic device – POC / lab</u> <u>Surgical devices and consumables</u> <u>Implantables (including 3D printed custom devices and bionics)</u> <u>Wearable devices</u> <u>Digital health and monitoring</u>	Certain skills / capabilities have been identified through prior work, including advanced manufacturing, clinical trials expertise and big data analytics. MTPConnect will complete a 'root and brand' skills audit of the MTP sector as part of the MTP REDI program sector participants to identify skills gaps within these KPs	<u>Drug repurposing</u> <u>Biosecurity</u> <u>Data science</u> <u>Rare diseases</u>
Emerging				
<u>Human movement and sports science</u> <u>Medical physiology</u> <u>Medical biotechnology</u> <u>Nanotechnology</u>	<u>Regenerative medicine</u> <u>Optometry and ophthalmology</u> <u>Pain management</u> <u>Dematologicals</u>			

Sector Priorities

Seven sector priorities underpin the achievement of the vision for enhanced healthcare and economic outcomes for Australia. As with the megatrends and knowledge priorities, these sector priorities were developed in consultation with the sector in 2016 and 2019 and remain relevant in FY2021. The table below lists the sector priorities and demonstrates their alignment with the four GC objectives.

Sector Priorities		Growth Centre Objectives:			
		Improving collaboration and commercialisation	Improving management and workforce skills	Identifying opportunities to address regulations	Improving access to global supply chains & markets
P1	Align investment in KPs identified based on current and future market trends	✓✓✓	✓✓	✓	✓
P2	Create a highly productive commercialisation environment from research to proof-of-concept and early clinical trials	✓✓✓	✓✓✓	✓	✓
P3	Transform the SME sub-sector to support the growth of smaller companies into larger, more stable and successful companies	✓✓	✓✓	✓✓	✓✓
P4	Strengthen Australia as an attractive clinical trial research destination	✓✓✓	✓	✓✓✓	✓✓
P5	Support the development of digital healthcare solutions: devices and data analytics	✓✓✓	✓✓✓	✓✓	✓
P6	Position Australia as the preferred partner for international markets	✓✓	✓	✓✓	✓✓✓
P7	Support advanced manufacturing as a part of the Australian innovation ecosystem	✓✓	✓✓✓	✓✓	✓✓✓

- ✓✓✓ Greater focus on addressing particular Growth Centre Objective
- ✓ Less focus on addressing particular Growth Centre Objective

With a continuing focus during 2020/2021 on activities which address the key knowledge and sector priorities, and which align with the four GC objectives, MTPConnect will continue to help the sector:



Create more products that reach the proof-of-concept phase and early-stage commercialisation;



Increase the number of companies that have late-stage product successes; and



Maximise the value of any IP monetisation events.

How MTPConnect is Achieving the Program Objectives

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As stated in MTPConnect's Funding Agreement with the Commonwealth, the Industry Growth Centre Initiative aims to encourage the commercialisation of new products; enhance workforce skills; reduce red tape; and forge closer links with global supply chains. MTPConnect is achieving these objectives through targeted activities and initiatives under the four GC objectives:

Objective 1 - Collaboration and Commercialisation

Objective 2 - Management and Workforce Skills

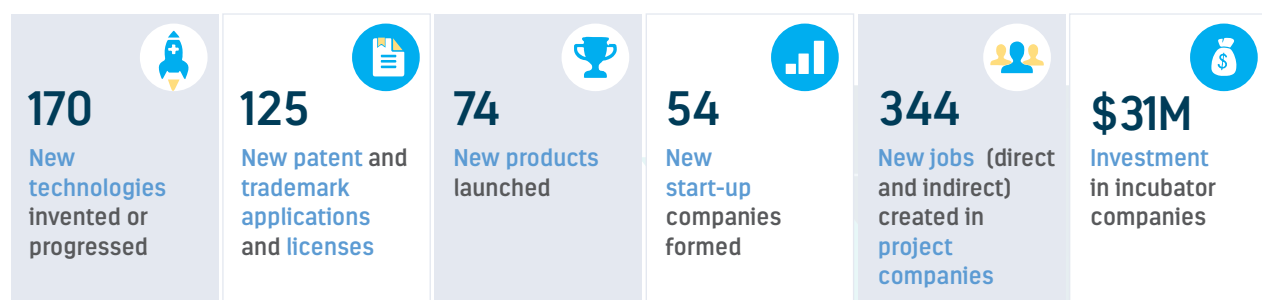
Objective 3 - Regulatory and Policy Environment

Objective 4 - Global Supply Chains and Markets

MTPConnect has worked with DISER to develop a Program Logic and Performance Framework to record, evaluate and assess the short, medium and long-term impact the initiatives and activities we support has on the overall MTP sector. MTPConnect is also working with the DISER Evaluation Unit on the 2020 Growth Centre impact assessment.

The image below provides a summary of the impact of MTPConnect supported activities against each of these objectives to June 2019 (more details can be found in the MTPConnect FY2019 Annual Report).

Growth Centre Objective 1: Improving Collaboration and Commercialisation



Growth Centre Objective 2: Improving Management and Workforce Skills



\$32M Funding secured to deliver MTP REDI program

Growth Centre Objective 3: Identifying Opportunities to Address Regulation and Policy Environment



Growth Centre Objective 4: Improving Access to Global Supply Chains & Markets



Objective 1: Collaboration and Commercialisation

Australia has a vibrant research sector supported by world-class infrastructure, yet its commercialisation productivity continues to decline. In 2018, Australia ranked 20th and in 2019, 22nd on the [Global Innovation Index](#) even though since 2014 it has ranked 10th to 15th in the world for Innovation Inputs. During the same period, Australia's Innovation Outputs fell from 22nd in 2014 to 31st in 2019. While these measures are not MTP sector-specific, they underscore the importance of the public policy objective of lifting innovation outputs that arise from research.

MTPConnect plays a leading role in addressing the challenges faced by the MTP sector in translating research through to commercial outputs. We have successfully deployed GC Project Funding as well as BMTH and BTB funding across a wide range of project areas, ranging from 3D anatomical printing and precision medicine to clinical trials, advanced manufacturing and industry mentoring. These projects have driven cross-sector collaborations, with 60 per cent of MTPConnect projects involving industry-research collaborations.

COVID-19

During 2020/2021, a key focus for MTPConnect will be the delivery of a leading, relevant and forward looking report series on the impact of COVID-19 on the MTP sector, lessons learned from Australia's response to the pandemic and activities needed to ensure the sector recovers. From our networks and direct involvement in DISER COVID-19 Taskforces and Working Groups, we know there have been differential impacts on the sector with some segments experiencing minimal impact (e.g. pharmaceutical product sales) but the large majority of sector organisations and participants significantly impacted through issues including supply chain disruption, reduced access to funding, cancellation of elective surgery, unpredictable fluctuations in demand, changes in working patterns to meet distancing requirements and reduced financial performance. MTPConnect's COVID-19 sector impact reports will explore these impacts in detail and provide timely, valuable and verifiable information for the community, MTP sector participants and government to inform actions to rebuild and sustain the sector and the jobs it supports.

MTPConnect will continue to strategically deploy capital from its three funding schemes supporting research and project translation; GC Project Fund, the BMTH and BTB programs. These funds will help Australian entities translate world-leading research into medical technologies, biological and pharmaceutical products that significantly improve patient outcomes, grow jobs and deliver economic returns.

As part of MTPConnect's contribution to supporting the sector during the COVID-19 crisis, a special round of the BTB program has been launched, specifically designed to support COVID-19 related research projects. Capital will be deployed during 2020 to support medical devices and diagnostics research, prophylactic development - such as vaccines - and therapeutic approaches that will achieve an impact on the global response to the pandemic in 12-months or less. MTPConnect designed this rapid COVID-19 round to get results as quickly as possible to help protect the health of Australians and others around the world with the earliest possible deployment of new vaccines, therapeutics and devices.

Engagement and collaboration between research and industry are improving, through programs like the Cooperative Research Centre (CRC), Cooperative Research Centre Project (CRC-P) and Australian Research Council (ARC) and the Industrial Transformation Research Program (ITRP). Applications to these programs are being encouraged to align and engage with the GC priorities and commercialisation factors are being considered when evaluating proposals to these schemes. MTPConnect will continue to work closely with applicants to help ensure they have success.

MTPConnect is engaging with an increasing number of research entities to help build connections to industry; connections which in turn improve the impact of their work. MTPConnect is working collaboratively with the sector's key participants, including industry peak bodies and associations, CRCs and federal and state governments. Memoranda of Understanding (MoUs) have been established between MTPConnect and relevant CRCs, ARCS Australia, AMGC, Life Sciences Queensland (LSQ), CSIRO, Medical Technology Association of Australia, AusBiotech, BioMelbourne Network and Medicines Australia, as well as international groups such as the Medical Alley Association (USA) and Confederation of Indian Industry (India).

MTPConnect will continue working closely with these organisations as they work through the challenges presented by the COVID-19 crisis. For example, we are actively supporting the MTAA in its work with the Federal Government Taskforces to promote industry collaboration and we supported ARCS Australia's COVID-19 Webinar series 'COVID-19: considerations and strategies for running trials during the pandemic' that commenced in mid-March. Our sponsorship allowed ARCS to open what would normally have been a paid, member-only event to the whole sector for free.

Objective 2: Management and Workforce Skills

The MTP sector faces a shortage of skills in enabling disciplines such as data analytics and bioinformatics, health economics, regulatory affairs and advanced manufacturing, including biologics and cell therapies. The sector's response to COVID-19 and the rebuilding that will follow will also require access to key skills. It is essential to address these areas of need if Australia is to achieve its full potential in the sector.

Attracting and retaining talent in a globally competitive market is difficult. In early-stage clinical development, SMEs often struggle to fund, attract or engage strong managerial talent, staff with business development skills or skilled advisors. Researchers and researcher-founded start-ups often lack the business acumen and experience needed to assess the commercial potential of their research or to translate it into commercial products.

By effectively blurring the lines between industry, research and teaching, MTPConnect is helping to ensure that Australia develops an industry-ready workforce. Through programs like IMNIS, Bridge and BridgeTech, MTPConnect's funding has grown the sector's skills base. The BTB program which began in 2019 is providing additional financial support for the Bridge and BridgeTech programs, ensuring that hundreds of early career researchers will gain the critical skills needed to translate and commercialise their research outputs.

MTPConnect, in collaboration with program partners, has played an important role in upskilling Australia's industry participants. We have maintained strong engagement across the sector and supported our partners to deliver activities such as workshops, webinars, pitching competitions, accelerator incubators, networking events and inbound and outbound trade missions, and in doing so, have connected with over 3,750 companies, universities, research organisations and industry associations.

We will expand this focus to ensure that the sector's skills keep pace with changing needs by rolling out the new \$32 million Researcher Exchange and Development within Industry (REDI) initiative. To deliver the program, MTPConnect is partnering with research, training and industry organisations to deploy an integrated, three-pillar plan driving skills development and workforce training that brings together researchers, clinicians, industry and the entrepreneurial ecosystem.

REDI partners include The George Institute for Global Health, APRIntern, Industry Mentoring Network in STEM (Australian Academy of Technology and Engineering), the Victorian Comprehensive Cancer Centre (VCCC), the Medical Device Partnering Program (MDPP), MedTech Actuator, the Bridge and BridgeTech programs (Queensland University of Technology) and ANDHealth. The program will also leverage the expertise and experience of Research Australia, CSL, Innovative Manufacturing CRC, the Medical Technology Association of Australia (MTAA), Pharmaceutical Manufacturing Industry Reference Committee, the University of NSW and the NSW Office of Health and Medical Research.

As an immediate step, MTPConnect is leading 'Project elephant,' a workforce skills survey being undertaken in collaboration with ANDHealth, AusBiotech, MTAA and Medicines Australia. This survey seeks to identify the current and anticipated future management and workforce skills gaps at various levels of seniority, across the MTP and digital health sector, that need to be addressed in order to drive greater sector growth in Australia. The survey will include both skills in specific disciplines, and general business and commercialisation expertise with the findings to be published during 2020 and incorporated into the REDI program.

Objective 3: Regulatory and Policy Environment

Precision medicine, regenerative medicine, digital health and 3D printing of personalised medical devices have created an increasingly complex regulatory and policy pathway. The advances in medicinal cannabis, anti-microbial resistance (AMR) and drug repurposing require new regulatory and reimbursement considerations. More than ever, Australian SMEs will need assistance in negotiating these pathways.

By continuing to identify regulations and policies that are unnecessary or overly burdensome, MTPConnect will remain a key independent and sector-wide voice for change to ensure Australia's regulatory, policy and tax environment keeps pace with rapidly changing sector needs, while at the same time safeguarding patients.

MTPConnect's work with the Therapeutic Goods Administration (TGA) and other agencies on adaptive regulation for new technologies is one recent example of how we are supporting the sector. MTPConnect has coordinated development of a new report, 'Adaptive Regulation for Digital Health' which examines how Australian digital health industry stakeholders are engaging with the Australian therapeutic goods regulatory framework and is due for release during 2020.

MTPConnect is also driving the development and release of a new report on AMR. After convening a multi-disciplinary workshop to bring together key stakeholders from the health and medical research sector, the biotech and pharmaceutical industry, government and regulators to discuss the serious threat of AMR, the report will outline a vision for creating an end-to-end world leading value chain (from discovery to delivery) that grants Australian patients access to world-class antimicrobial therapies, creates jobs and enables the export of Australian therapies to the world. The report is due for release during 2020.

MTPConnect is also playing a leadership role in drug repurposing of medicines, an area of focus identified in the MRFF research priorities. An MTPConnect project brought together key industry players to consider options, pathways and potential impacts of drug repurposing, including for more rapid and cost-effective new therapeutics for COVID-19. The project is ongoing, with a report to be released during 2020/2021.

Objective 4: Global Supply Chains and Markets

To be successful, Australian companies need to develop their products for global markets. By establishing strong links to global markets early in their development, Australian companies can better understand international market opportunities and the development and regulatory requirements needed to access these markets.

MTPConnect continues to play a key role in international engagement for the MTP ecosystem by promoting the strengths and capabilities of the Australian MTP sector and its participants to the world.

MTPConnect has partnered with Austrade and peak bodies such as AusBiotech and MTAA to put Australian MTP stakeholders in front of international customers and investors. Since establishment, we have led or directly supported 23 trade missions involving 850 companies. Our GC project partners have been involved in 119 inbound and outbound trade missions.

MTPConnect will continue to play a key role in international engagement. Memoranda of Understanding (MoUs) have been established with international groups such as the Medical Alley Association (USA) and Confederation of Indian Industry (India) to strengthen international relationships.

We will work with Austrade and Australia's peak industry bodies to strategically develop the sector's presence in national and international markets by fostering relationships and partnerships, leading outbound trade missions, supporting inbound delegations and bringing global best practice to Australia. For example, MTPConnect recently hosted US expert Frank Jaskulke from Medical Alley in Minnesota as part of our 2020 Seminar Series, sharing his insights on "How to Crack the U.S. Market" with the sector at events in Brisbane, Perth and Sydney.

Recently, as part of the GC Project Fund Program, an Asialink Business research project identified opportunities for Australian companies to access global markets. With the support of Austrade, the project has developed practical and timely industry guides including frugal innovation in India, digital health opportunities in Indonesia and an assessment of the Asia capability of industry senior executives and Board members.

We will continue to support Australia's presence at key conferences (subject to COVID-19 related restrictions on travel and large gatherings) to ensure Australian MTP companies continue to build key international connections and sophisticated market entry strategies and that Australia remains a preferred destination for clinical trials. In the short term, MTPConnect will support a virtual presence at key conferences such as BioKorea to ensure Australia is well positioned to respond internationally in the post-COVID-19 era.

MTPConnect's Priority Actions

MTPConnect's Priority Actions

MTPConnect's priority actions for FY2021 build on our achievements since inception and address the key challenges of the sector. These include assessing and addressing impacts related to the COVID-19 pandemic. MTPConnect's priority actions can be broadly categorised into three themes:



During 2020/2021, MTPConnect will undertake strategic initiatives that are informed by knowledge and sector priorities and align with the four GC objectives, as detailed in the following tables.

Measuring Success and Promotion

The performance and impact of MTPConnect's FY2021 strategic initiatives will be monitored using our recently developed (in collaboration with DISER) program logic and data matrix, on the back of a largely supportive performance review in 2019 (the Nous Review) and the ongoing 2020 Impact Assessment.

Additional impact assessment will be provided by measuring levels of engagement with MTPConnect's social media and digital channels and in the weekly Podcast series.

Growth Centre Objective 1: Improving Collaboration and Commercialisation

MTPConnect plays a leading role in addressing the challenges faced by the MTP sector in translating research through to commercial outputs. This work will continue through the deployment of strategic initiative funding and provision of specialist skills and services to develop greater commercialisation expertise.

Deploy strategic initiative funding	Provide industry thought leadership through an independent voice	Taking direct action	
		Provide specialist skills / services	Promote and connect Australia globally
Deploy DISER, BMTH and BTB funding, including a tailored COVID-19 round	Develop and release COVID-19 report series, assessing impacts of the pandemic on MTP sector, lessons learned from Australia's response and the pathway to recovery	Develop programs that link large research-intensive Multinational Companies to Australia's researchers / SMEs through the REDI fellowships	Continue to promote Australia as a specialist clinical trial destination and develop case studies of local trials that showcase Australia's expertise and niche experience
Secure and deliver additional non-GC sourced funding to key initiatives in the sector	Engage with funding bodies such as NHMRC, ARC, MRFF to encourage inclusion of commercialisation factors in sector rankings and grant assessment criteria, and encouraging increases to translation and commercialisation-focused grant programs	Expand activity in existing state-based Hubs (WA, NSW, VIC, QLD) and explore establishing a new Hub in (SA)	Continue working with accelerators, including ANDHealth and the MedTech Actuator
Help ensure high quality MTP projects are funded by assisting entities with CRC, CRC-P, ARC ITRP and Global Innovations Linkage program pre-submission review and mentoring and providing post-submission	Continue to refine Knowledge Priorities considering market pull or science push (eg Biosecurity)	Expand communications and engagement with the general public, including patients	
Conduct 'Collaboration and Skills Summit' to bring together recipients of MTPConnect's GC, BMTH and BTB funding, and industry leaders	Continue to monitor, assess and promote international best practice approaches to funding SMEs	Enhance effectiveness of technology transfer offices by sharing best practices	
	Review and revise "The Economic Benefits of Clinical Trials to Australia" report following sector consultation	Collate and report on a consistent set of sector metrics on behalf of the sector	
		Deploy Guidance And Impact Tracking System (GAITS) software through BMTH/BTB program participants	

Centre Objective 2: Improving Management and Workforce Skills

Developing and refining workforce commercialisation skills remains a key priority for the MTP sector if it is to realise its full potential. With the newly established MTP REDI program, MTPConnect will continue to support skills development across the sector, bringing together researchers, clinicians, industry and the entrepreneurial ecosystem to deploy the integrated workforce training plan.

Deploy strategic initiative funding	Provide industry thought leadership through an independent voice	Taking direct action – Provide specialist skills / services
<ul style="list-style-type: none"> Deploy REDI funding to expand training programs with proven partners (e.g. The MedTech Actuator, IMNIS, MDPP, ANDHealth) Deploy REDI funding to support new programs to fill emerging skills gaps across the industry value chain (selection through contestable RFP process) Review and address skills gaps identified as a result of COVID-19 Conduct national 'Collaboration and Skills Summit' to bring together recipients of MTPConnect's GC, BMTH and BTB funding, and industry leaders from VC, IP and regulation 	<ul style="list-style-type: none"> Finalise research and deliver report of Project Elephant, a cross-sectoral initiative to better understand skills gaps and workforce shortages, with findings to inform REDI program analysis Conduct an assessment of the MTP sector's digital cyber capabilities Continue to engage the sector and government to develop skills-training packages specifically applicable to the MTP sector (e.g. digital health, regenerative medicine, precision medicine) Continue to produce and publish the MTPConnect Podcast Series to share information about sector activities, events and achievements 	<ul style="list-style-type: none"> Continue ongoing REDI work to establish best practice industry placement, internship and fellowship programs that link researchers and industry Continue and report on 'Project elephant' – skills gap analysis. Promote an SME education program to maximise negotiated funding outcomes, out-licensing arrangements or divestment Explore opportunities for provision of coordinated professional development programs for TTOs Launch Growth Centre Project cohort network and Alumni Event to promote knowledge sharing and provide specific training for project leads

Growth Centre Objective 3: Regulatory and Policy Environment

MTPConnect has been involved in a number of cross-sectoral forums to identify and address areas of regulatory burden and optimise policy frameworks within the MTP sector. It will continue to drive progress against this objective by focusing on generating independent insights regarding emerging areas such as AMR, adaptive regulation for digital health, clinical trials, drug repurposing and precision medicine. In addition, MTPConnect will work with sector participants and government to develop appropriate frameworks to position Australia as an efficient and cost-effective destination for investment.

Deploy strategic initiative funding	Provide industry thought leadership through an independent voice
<ul style="list-style-type: none"> • Continue using the Project Fund Program to co-fund projects to improve regulation and clinical trials in Australia • Identify and establish a national Regenerative Medicine sector 'catalyst' collaboration body to advance the development of Australia's RM sector • Identify and establish a national Genomics 'catalyst' collaboration body to advance the development of Australia's genomics sector • Identify and establish a national Anti-Microbial Resistance 'catalyst' collaboration body to advance the sector 	<ul style="list-style-type: none"> • Hold roundtables, 'future forums' and seminars, and deliver white papers on future trends and significant growth areas as we have done in the past for digital health, precision medicine, 3D printing and clinical trials to help government develop appropriate responses and identify areas for regulatory renewal • Continue to deliver white papers on emerging sectoral issues and megatrends to inform policy development (e.g. AMR, adaptive regulation for digital health and drug repurposing) • Continue to work with relevant government bodies such as TGA on streamlining and harmonising the regulatory regime for clinical trials and provide advice, formally and informally, to government, regulators and policymakers on key sector issues • Continue to engage with CSIRO on sector specific initiatives such as the Adaptive Regulation project and roadmap projects • As part of COVID-19/pandemic activities, build on our work with the CSIRO's Health and Biosecurity Advisory Committee and the Medical Countermeasures Strategic Advisory Committee of DMTC/Department of Defence aimed at development of technologies to combat global threats and maintaining strong on-shore advanced manufacturing and research capabilities for biosecurity products to enable Australia to retain access to the products and know-how required to combat such risks

Growth Centre Objective 4: Improving Access to Global Supply Chains & Markets

To succeed in a highly competitive global marketplace, Australia needs to continue to engage with international markets. Links to global markets are necessary to understand international unmet needs, global regulatory requirements, market opportunities, international collaboration and access strategies. This is even more difficult in the face of COVID-19, we need to find new ways to be globally connected and relevant. To achieve this objective, MTPConnect will continue to promote Australia's capabilities internationally and foster connections between international companies and institutions and Australian businesses and researchers.

Provide industry thought leadership through an independent voice	Taking direct action – Promote and connect Australia globally
<ul style="list-style-type: none"> Continue to work with Asialink to deliver white papers on emerging trends and opportunities for Australian developers and producers (e.g. Frugal Innovation in Medical Devices and Technologies—The India Opportunity) Work with AusBiotech to help coordinate, fund and recruit delegates to attend the BIO2021 Conference 	<ul style="list-style-type: none"> Work with Austrade and peak industry bodies including AusBiotech to develop a cohesive, reframed approach to promoting Australia's MTP sector internationally to re-establish momentum post COVID-19 (e.g. conferences like BIO2021, Medtech conference) Subject to COVID-19 restrictions on travel and large gatherings, continue to attend and present at focused conferences and exhibitions domestically and internationally to develop MTPConnect and Australia's MTP sector's in-market presence (including virtual attendance) including 2020 MedTech Conference, BioJapan, BioEurope Continue to evaluate global best practice around international engagement strategies and translate into Australian initiatives, including CIMIT, MaRS Innovation, Catapult UK and Fraunhofer Institute Provide advice, guidance and connections to international market experts to help prepare Australian companies for international expansion

Activities and Milestones – FY2021

FY2021 Activities Milestones and Performance Criteria

The following Milestones relate to specific activities and reports as detailed in the Funding Agreement and subsequent Deeds of Variation to the Funding Agreement between DISER and MTPConnect and the Commonwealth's Growth Centre Guidelines.

Milestone number	Activity	Due Date	Deliverable
1	MTPConnect Quarterly Report Q4 (1/4/2020 to 30/6/2020)	31 July 2020	Report submitted to DISER
2	MTPConnect Quarterly Report Q1 (1/7/2020 to 30/9/2020)	31 October 2020	Report submitted to DISER
3	MTPConnect 2020-2021 Annual Report	31 October 2020	Report submitted to DISER and, once approved by the Commonwealth, published on MTPConnect website
4	MTPConnect Quarterly Report Q2 (1/10/2020 to 31/12/2020)	31 January 2021	Report submitted to DISER
5	Updated Sector Competitiveness Plan for 2020 - 2021	28 February 2021	SCP submitted to DISER and, once approved by the Commonwealth, published on MTPConnect website
7	MTPConnect 2021 - 2022 Business Plan	30 April 2021	Business plan submitted to DISER and, once approved by the Commonwealth, published on MTPConnect website
8	MTPConnect Quarterly Report Q3 (1/1/2021 to 31/3/2021)	30 April 2021	Report submitted to DISER

MTPCONNECT LTD ABN: 53 608 571 277

As of 1 April 2020, the members in Medical Technologies and Pharmaceuticals Industry Innovation Growth Centre are, or have been:

Member	Date joined	Date ceased	Comments
Ms Sue MacLeman	November 2018		MTP-IIGC Ltd chair
Dr Nicholas Cerneaz	June 2017		MTP-IIGC Ltd founding director
Ms Julie Phillips	June 2017		MTP-IIGC Ltd founding director
Dr Douglas Robertson	June 2017		MTP-IIGC Ltd founding director
Dr Bronwyn Evans	November 2015	October 2018	MTP-IIGC Ltd founding chair

Total Inactive Members for Period Ended March 2020: 1



Budget

In-Kind Contributions for FY2021

MTP-IIGC Ltd (trading as MTPConnect) has four company members.

The MTP sector individuals can join MTPConnect as network associates and MTP sector entities will join as network affiliates, through the MTPConnect website. They are not members of the company.

Member	In-kind contribution	Contribution value
Ms Sue MacLeman	Currently paid at approximately 50% of market rate – other 50% donated as in-kind.	
Dr Nicholas Cerneaz	Currently paid at approximately 50% of market rate – other 50% donated as in-kind.	
Ms Julie Phillips	Currently paid at approximately 50% of market rate – other 50% donated as in-kind.	
Dr Douglas Robertson	Currently paid at approximately 50% of market rate – other 50% donated as in-kind.	
Mr Alex Fowkes	Currently paid at approximately 50% of market rate – other 50% donated as in-kind.	
TOTAL		\$173,000

Entity	In-kind contribution	In-kind value
Monash University	One hot desk space.	\$10,000
University of Sydney	Two desk spaces in a self-contained office. Up to \$10,000 contribution to events.	\$50,000
University of Western Australia	Two desk spaces in a self-contained office.	\$40,000
Translational Research Institute, Brisbane	One hot desk space in a self-contained office.	\$20,000
TOTAL		\$120,000

Cash Contributions for FY2021

A table of Cash Contributions from Growth Centre Members' and Other Participants and Growth Centre Program funding.

Member	Contribution value
Ms Sue MacLeman	\$0
Ms Julie Phillips	\$0
Dr Douglas Robertson	\$0
Dr Nicholas Cerneaz	\$0
Mr Alex Fowkes	\$0
Other Participants	Contribution value
None	\$0

Other Participants	Contribution value for FY2021
DoH BMTH funding	\$20 million to be deployed in FY2021 as grant and operating funds.
DoH BTB funding	\$5.3 million to be deployed in FY2021 as grant and operating funds.
DoH REDI funding	\$10 million to be deployed in FY2021 as grant and operating funds.
Western Australia (WA) State support for WA Hub	\$300,000 to support sector activities in WA

Growth Centre Program funding	Date of payment if reporting milestone achieved	Contribution (excluding GST)
Payment 19	31 Aug 2020	\$1,250,000
Payment 20	30 Nov 2020	\$1,250,000
Payment 21	31 Mar 2021	\$1,250,000
Payment 22	31 May 2021	\$1,250,000
TOTAL		\$5,000,000

MTPConnect Project Funding Cash Contributions

To date, 36 projects have been contracted, with over \$27.5 million of matched funding committed and \$17.5 million of matched funding and \$12 million of in-kind evidenced by projects so far. Growth Centre projects will continue into FY 2021 with matched funding assessed by MTPConnect for each project on a quarterly basis.

As detailed in the Funding Agreement - Deed of Variation signed by MTPConnect and DISER on 3 May 2016, each Financial year the Growth Centre must obtain cash

contributions for projects using Project Funds (Item 1 of Schedule 2). Each financial year the Growth Centre must specify a total dollar amount to at least match known government sourced cash contributions they will obtain for projects undertaken using Project Funds. The estimates of cash contributions below are based on project budgets and may alter as the projects progress.

		Minimum Cash Contributions to projects received from industry				
Government Sourced Contributions (Year of invoice)	Value	FY2017	FY2018	FY2019	FY2020	FY2021+
FY 2016 – carried over to FY 2017 with DISER permission.	\$1,400,000	\$1,671,993	\$1,988,704	\$5,047,654	\$3,285,865	\$3,605,784
FY 2017	\$3,200,000					
FY2018	\$8,000,000					
FY2019	\$3,000,000					

Expenses Budget

A table of MTPConnect's FY2021 expenditure budget is included below. This budget is subject to change pending review and approval by the MTPConnect Board and future business requirements.

MTP-IIGC LTD (MTPConnect) Business Plan - DISER - FY2021

Operating Income	FY2021
Grants - operating expenses	\$5,000,000
Other Income	\$31,754
Total Income	\$5,031,754
Total Operating Income	\$4,660,769

Operating Expenses	FY2021
Travel Expenses	\$273,700
Office & Administration	\$241,781
Accounting, Audit and Legal	\$349,631
Employment, Board and Consultants	\$1,797,931
Sector Sponsorship and Communications	\$483,966
Sector Support Projects	\$420,000
Sector Competitiveness Plan and Sustainability	\$1,732,000
Total Operating Expenditure	\$5,299,009
Profit/Loss from Operating Activities for the period	(\$267,254)

Project & Activity Funding	FY2021
MTPConnect Activities	\$0
Project Funds (FY2021)	\$1,338,360
Total Project & Activity Expenditure	\$1,338,360
Profit/Loss from Project Activity for the period	(\$1,338,360)

MTPConnect Industry Growth Centre Projects

MTPConnect Industry Growth Centre Projects

The following table provides an overview of MTPConnect's GC projects. More information can be found at mtpconnect.org.au/projectfundprogram

Growth Centre Objective addressed by Project



Improving Collaboration and Commercialisation



Management and Workforce Skills



International Markets and Global Value Chains



Regulation Reform

FINISHED PROJECTS

Industry Mentoring Network in STEM (IMNIS) program ATSE

Project description: Aiming to narrow the cultural gap that exists in Australia between business and academia through the Industry Mentoring Network in STEM (IMNIS) program, that will develop a national mentoring program linking PhD students with qualified industry mentors.

Outcomes: 400 industry knowledgeable PhD students have been trained. Over 80% of mentees maintain contact with their industry mentor after their one year program has ended.



MedTech Actuator

The Actuator Operations Ltd

Project description: To leverage Australia's existing industry and research capabilities in the acceleration of new high-value, medical device technology development opportunities through a number of focused, 15-month actuator programs.

Outcomes: 24 new companies have been supported, creating over 55 new jobs with over \$8.7M of investment.



BioFab3D@ACMD

St Vincent's Hospital (Melbourne) Limited

Project description: Support for BioFab3D@ACMD, a robotics and biomedical engineering centre, embedded within a hospital. Researchers, clinicians, engineers and industry partners work alongside each other with a vision to build biological structures such as organs, bones, brain, muscle, nerves and glands.

Outcomes: Since the opening of the BioFab centre last year, 94 individual have worked within the centre. The Centre is also being used by two MedTech start-ups.



Comprehensive Global Investment program AusBiotech Ltd

Project description: Development of a comprehensive global investment education program for the Australian life science sector - companies, investors and researchers.

Outcomes: This project has held 13 events with over 1300 attendees and has supported one inbound and three outbound trade missions.



Australian Centre for Regenerative Medicine Monash University

Project description: CCRM Australia, an Australian hub of Canada's Commercialization Centre for Regenerative Medicine (CCRM) will support the development of foundational technologies to accelerate the commercialization of regenerative medicine products and therapies.

Outcomes: 10 regenerative medicine product companies that are collaborating internationally to advance their product commercialisation. 5 collaboration events with over 500 attendees as well as the support of three inbound and three outbound trade missions.



Hit ID platform

Cancer Therapeutics CRC Pty Ltd (CTx)

Project description: Build on a national framework to provide Australian drug discovery organisations access to a comprehensive Hit ID platform that includes: a fit for purpose drug discovery library (up to 300,000 compounds); an ultra-high throughput screening facility; fragment based drug design capability; and a state of the art software platform for in silico drug discovery.

Outcomes: New storage infrastructure and 310,000 compound bank to allow fast screening of compounds to determine new target drug formulations. 6 screenings have already been performed since the project completion.



National Medical Device Partnering Program (NMDPP) **Flinders University of South Australia**

Project description: Initial scoping of the roll out of a National Medical Device Partnering Program (NMDPP) to bring together research, clinical and industry partners in a streamlined process for collaboration and product development.

Outcomes: A National program is in place across all States with appropriate guidelines and governance determined.

A lead for each State has been identified and is driving the program.



Vaccine research in Australia: Landscaping capabilities and relevant service

Vaxine Pty Ltd

Project description: Project to assist in landscaping Australia's vaccine research capabilities and relevant services for the use by the whole MTP sector in a searchable database. Australia's first national Vaccine conference.

Outcomes: A better connected Australian vaccine community, engaging through events and in person. Eight events / seminar have been held with over 100 attendees.

5 pre-clinical and one clinical trial has started as a result of these collaborations.



The Bridge Program

Queensland University of Technology (QUT)

Project description: A consortium of 15 companies, universities and industry associations that aims to transfer practical skills on pharmaceutical commercialisation through online and residential training in drug discovery and development. Direct exposure to industry practitioners in the scientific, legal, financial, clinical, regulatory and reimbursement disciplines that contribute to the commercialising of medicines.

Outcomes: 299 early careers researchers have been trained in pharmaceutical commercialisation. A 2019 survey revealed 30 products developed and 16 patent applications since participants training ended. This project is now funded through the BTB fund.



Accelerating Australia – Stage 1

Centre for Entrepreneurial Research and Innovation Limited (CERI)

Project description: A national consortium for translational medical technology and pharmaceuticals research and training. Small grant offered for scoping / development project on governance and national collaboration work.

Outcomes: Governance developed to allow network of translational activities in the future as well as pilot training programs. 194 people took part in training courses. The trainees invented 19 new medical technology opportunities and have since won commercial grants, seed funding, placements in accelerator programs, established companies and filed patent applications.



Clinical Trial Assist – facilitating clinical trial recruitment in general practice

VentureWise Pty Limited

Project description: To identify, develop and evaluate a model to support clinical trials in Australia by providing access to the leading clinical data set in Australia to: (1) guide clinical trial protocol development; (2) assess feasibility of protocols and recruitment; (3) facilitate direct patient recruitment; and (4) engage the general practice sector.

Outcomes: 52 GP's attended education 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.



National MTP+D Live Showcase: Searchable, trackable, public pipelines for medtech, pharmaceutical and digital health innovations

Health-Innovate Pty Ltd

Project description: To catalogue and track publicly exposed MTPD innovations under development in Australia. By the end of the year-long collaborative campaign the catalogue will be publicly and globally accessible and kept up-to-date using a humanized machine learning system.

Outcomes: A learning platform following at least 1200 Australian products has been developed and has been showcased at the World Hospital Congress. The progress of the products is automatically kept up to date and can be used to demonstrate trends and funding focus opportunities.





Improving Collaboration and Commercialisation



International Markets and Global Value Chains



Management and Workforce Skills



Regulation Reform

FINISHED PROJECTS (continued)

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

University of Wollongong

Project description: Create a facility to expedite the development of commercial opportunities in 3D bio-printing. It will provide the technical expertise and facilities to enable the development of commercial opportunities identified with/by the clinical partners, the partner SMEs and other industries for the production of relevant biomaterials, formulations of bioinks or customized bioprinting systems.

Outcomes: A new facility (TRICEP - Translational Research Initiative of Cellular Engineering and Printing) has been established at Wollongong. Four companies have progressed their product development within this facility so far, two of which have had \$2.3M of investment. Three additional companies are in discussions with TRICEP.



Installation of robotic sterile finished product clinical trial manufacturing capability

Pharmaceutical Packaging Professionals Pty Ltd

Project description: PPP currently supports manufacture of clinical trial products for Australian biotech companies and medical research institutes. Whilst PPP can manufacture non-sterile products for Phase I, II and III, they are limited to Phase I for sterile products. This project proposes adding a fully robotic, sterile vial-filling line to manufacture Phase II and III products.

Outcomes: This project was terminated by MTPConnect.



ONGOING PROJECTS

Upgrade CSIRO Protein Production Platform

CSIRO

Project description: Aiming to upgrade the CSIRO (Clayton) protein production platform to human GMP capability for pilot-scale (<=200L) for a variety of expression systems (mammalian/yeast/ bacterial) as well as scale-up of cells. Will include a training program for post graduate study.

Outcomes: This project will deliver and commission equipment for a facility to produce small volumes of cells for Phase II and Phase III human clinical trials. 20 post graduates will be trained in production system.



ANDHealth

ANDHealth

Project description: Creating an integrated ecosystem for the development & commercialisation of evidence-based digital health products.

Outcomes: Supported 10 evidence-based digital health product companies, which has created 88 new jobs, an investment of \$15.8M, and treated over 24,000 patients. Additional funding for 5-day training course was granted in Dec 2018.



Pilot Implementation of the Australasian Tele-Trial Model Clinical Oncology Society of Australia (COSA)

Project description: COSA has developed a national guide for implementation of the Australasian Tele-Trial Model in consultation with clinical trial sponsors, clinicians, health administrators and regulatory bodies. This project will 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: Five tele-trial model cancer trials cluster are in place with patients recruited to four clusters so far.



Biofabrication Institute

Queensland University of Technology (QUT)

Project description: 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 8 children recruited to a pilot project investigating biofabrication of ears.



Clinical Trial: Impact and Quality (CT:IQ)

Bellberry Ltd

Project description: Clinical Trial Improvement Initiative - based on the CTTI (US) model with a vision for a whole of sector approach to improve the quality, efficiency and impact of clinical trials.

Outcomes: Five sector wide, industry led projects are underway. These project engage and benefit the entire clinical trials sector.



Australia-China Life Sciences Partnership Program AusBiotech Ltd

Project description: The Australia-China Life Sciences Partnership Program aims to increase awareness and opportunities for communication, collaboration and commercialisation between the life sciences sector in Australia and China. This will utilise the in-market knowledge and expertise of the program's consortium partners to develop an interactive platform and training programs as well as leveraging the MTPConnect-funded Global Investment Program to deliver high quality, collaborative research and industry projects as well as valuable data analytics on commercial engagement between the two countries.

Outcomes: A free-to-use database with facilitated connections benefitting at least 20 businesses with knowledge and connections.



Microscopy Australia – Technical Voucher Fund University of Sydney

Project description: The scheme will fund vouchers to support medtech R&D by providing easy and discounted access to the range of Microscopy Australia services. It is designed to reduce barriers and provide industry with:

- access to analytical tools and experts with problem solving capabilities
- funds tailored to SME and large companies' research needs
- better links between universities and industry – more engagement opportunities

Outcomes: Six vouchers have been issued to SME's. This has facilitated both research investigations and international clinical trials work.



Ab-initio pharma | Formulation and GMP product manufacturing services for clinical trials in Australia The University of Sydney

Project description: To provide bespoke pharmaceutical products that meet regulatory and quality control standards. To establish a unique manufacturing and training facility that provides cost effective manufacturing solutions for Small Medium Enterprises, academics, clinicians and larger pharma for early phase clinical trials in Australia.

Outcomes: Installation of a production facility to produce small volumes of solid fill product for Phase II and Phase III Human clinical trials. 20 post graduates trained in production system.



ONGOING PROJECTS (continued)

ClinTrial Refer – Improve recruitment to all clinical trials in Australia

South Eastern Sydney Local Health District

Project description: ClinTrial Refer is a mobile smartphone and web-based platform connecting doctors and patients to recruiting clinical trials across research networks. Successful as a template, there are currently 19 derivative pilot apps. ClinTrial Refer Australia will develop a new IT platform to integrate the derivative apps, create one combined database, create new search functions, enable electronic referrals, link to ANZCTR and build a national solution to trials recruitment.

Outcomes: A single 'ClinTrial Refer' application has been launched on Apple and Android platforms and has been loaded with active trials. Initial feedback is very positive.



Accelerating Australia – Stage 2

Centre for Entrepreneurial Research and Innovation (CERI)

Project description: Accelerating Australia is a national consortium of biomedical research institutions, universities, healthcare providers and companies. It facilitates translation of biomedical research through experiential entrepreneurial courses, brokerage and early stage commercialisation support services. Collaborating across sectors, organisations and disciplines to identify and reduce hurdles in our biomedical translation ecosystem to the benefit of all.

Outcomes: Commercialisation training and support for at least 462 individuals (students and clinicians from 20 partner universities and companies) - resulting in 66 new technologies, 11 new jobs and \$3.2M of investment into the companies. Improved collaboration between universities and companies within each State Node.



The Bridge Tech Program

Queensland University of Technology

Project description: To enable Australia to more effectively capitalise on its world class medical technology—medical device research sector by providing mid-career and senior entrepreneurs and scientists with relevant, specific commercialisation training. The program will be delivered by companies, universities and industry operating in the sector through online mediums, residential training and networking events.

Outcomes: 114 early careers researchers trained in medical device commercialisation. As of June 2019 this has resulted in eleven new technologies being progressed with eight of these in pre-clinical or clinical trial. Networks have developed between participants and industry. This project has been moved to the BTB fund.



Certara-Monash University Industry Fellowship Program

Certara Australia Pty. Ltd

Project description: The Certara-Monash Fellowship Program in drug development and pharmaceutical science will increase sector-wide capabilities through consistent, scalable, expert-led, industry focused training of Post-Doctoral Fellows. The national program will identify and develop the next generation of pharmaceutical scientists who will help shape the future of the biotech and pharmaceutical industry. The program will be located at Monash University Faculty of Pharmacy and Pharmaceutical Sciences and will involve a combination of academic coursework, hands-on industry training, and research.

Outcomes: The initial three post doctoral fellows have been appointed and started their training. Applications are open for the additional 2 fellows.



CRITERIA – Building clinical trial capability and capacity

ARCS Australia Ltd

Project description: The MTP Sector is constrained in growth through lack of appropriately skilled and experienced workforce participants, particularly for conducting Clinical Trials. This project aims to connect MTP companies with appropriately trained graduates to equip them with job ready skills to meet this gap.

Outcomes: ARCS have trained 52 graduates in all aspects of pharmaceutical medicine and clinical research. At the end of the initial training program, over 75% of graduates gained full-time employment within the Australian clinical research industry. ARCS will mentor all graduates until the end of the project.



Enabling Precision Cancer Clinical Trials: A molecular profiling platform for the Australian clinical trials industry and SME's

The Garvan Institute of Medical Research

Project description: This project will deliver a molecular profiling platform to increase capacity in Australia's clinical trial sector, and increase the attractiveness of Australia to the international pharmaceutical industry. The platform includes a clinically-accredited molecular test for cancer trials, a genomics data platform to support clinical trials, and patient-matching capabilities to facilitate recruitment.

Outcomes: To date the project has trained over 200 individuals and identified 400 individuals who have been referred via patient matching for clinical trials and focussed therapies. This project will have at least 5 SME companies engaged with the platform by its conclusion.



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

Queensland University of Technology

Project description: To develop digital infrastructure to support adaptive clinical trials and 'trial-ready' natural history cohort studies. The open-source solution will enable seamless capture and linkage of clinician-entered and patient-reported data with health system administrative data, improving efficiencies for assessing and connecting eligible patients to trials, supporting the efficient systematic capture of data for trials, and for enabling real-time Bayesian analysis for novel trial designs. It is specifically intended to facilitate capture of clinical evidence to inform the licensure and funding of new therapeutic products.

Outcomes: The open source adaptive clinical trial platform is in development with 25 individuals trained in its use. A further 300 people have been to information seminars. The databases are established for three initial rare disease populations, and are being populated.



Training Programs for the Biologics and Biomedical-based Industry Sector.

Australian Institute for Bioengineering and Nanotechnology, University of Queensland

Project description: The project seeks to design and create training programs for industry associated with the R&D and advanced manufacturing of biologic medicines and more broadly for industry associated with biomedical sciences. The training program fills a gap in the required knowledge and skills base necessary for advancement of Australian industry.

Outcomes: At least 227 individuals have received training so far. This is a mixture of in-person training and access to an e-learning platform.



Operationalize the Centre for Commercialisation for Regenerative Medicine Australia (CCRM Australia)

Monash University

Project description: This project will see CCRM Australia accelerating the commercialization of Australian regenerative medicine technologies, therapies and related products. This is achieved by fostering increased collaboration between industry, clinicians and academia, both locally and globally; and nurturing local regenerative medicine companies for the international market.

Outcomes: CCRM Australia has completed a pilot mentoring program, launched a regenerative medicine database and will coordinate a national conference in 2020. Partner companies are collaborating to advance their product commercialisation and apply for grants together.



A cloud-based AI digital health platform (Hospital 4.0) applied to nationwide cardiovascular clinical decision support.

Integrated Cardiovascular Clinical Network (iCCnet) CHSA,

Project description: The consortium will implement a Cloud Artificial Intelligence digital health platform by invoking AI risk stratification (triage) and delivering real time guidance to clinical decision makers, via notifications and escalations. The initial clinical focus will be on chronic disease services in rural/remote SA, however, the infrastructure will be commercially scalable to other diseases, across Australia and beyond.

Outcomes: Initial health data has been uploaded and presented on a platform to allow the health team experts to determine clinical guidance principals. Machine learning will then be based on these guidance principals.



Improving Collaboration and Commercialisation



International Markets and Global Value Chains



Management and Workforce Skills



Regulation Reform

ONGOING PROJECTS (continued)

Establishment of a MTP competency based, manufacturing skills development facility/training hub and early stage clinical trial manufacturing facility.

Translational Research Institute

Project description: This project will establish a medtech/pharma clinical manufacturing and training hub at the Translational Research Institute (TRI) in Brisbane to enable the translation of concepts into products for clinical studies.

Outcomes: Improvements in the cleanroom facilities are progressing with delivery of the final equipment due in December. Interest from the MedTech sector is strong with over 130 individuals attending four information sessions.



ASIALINK

Asialink Business

Project description: To 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: All three reports are being developed and will be launched between December and February. Information and Asia-linked networking events are planned.



National Expansion of the MDPP Stage 2

Flinders University of South Australia

Project description: To expand the Medical Device Partnering Program nationally. It builds on the review and scoping work undertaken in 2017 and 2018, funded by MTPConnect, and seeks to establish the foundations for national operations.

Outcomes: A MDPP has been established in Victoria and supported by the Victorian State government. Additional funding for the ongoing program has been provided in South Australia by the SA State government. Discussions are progressing with Tasmania, Queensland, NSW and WA. National guidelines and processes have been established.



IMNIS Stage 2

ATSE

Project description: To continue with the PhD mentoring activities, develop an alumni program, a rural pilot and remote mentoring.

Outcomes: IMNIS programs have connected over 240 students from 32 organisations in the MTP sector to an industry mentor. The Alumni program has had its first event. The rural pilot is progressing with Queensland as the pilot location.



Improving Collaboration and Commercialisation



International Markets and Global Value Chains



Management and Workforce Skills



Regulation Reform



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