MTPConnect
MedTech and Pharma Growth Centre

MTPConnect Business Plan FY2022

1 SEPTEMBER 2021

Australian Government
Department of Industry, Science, Energy and Resources

Industry Growth Centres

INTRODUCTION

The Business Plan from MTP-IIGC Ltd (trading under the name MTPConnect) is provided to the Department of Industry, Science, Energy and Resources (DISER) as a contracted deliverable as detailed in the Funding Agreement signed by MTPConnect and DISER on 18 December 2015 and in the three Variations to the Funding Agreement signed on 3 May 2016, 15 January 2019 and 22 April 2021.

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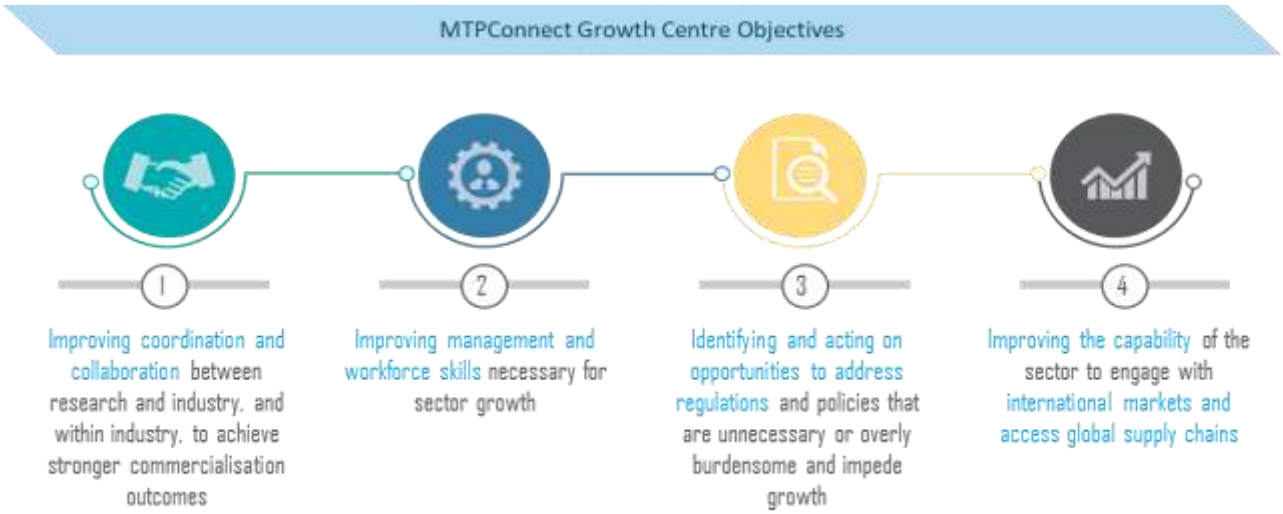
EXECUTIVE SUMMARY

MTPConnect is an independent, not-for-profit Growth Centre (GC) driving connectivity, innovation, productivity and competitiveness in Australia's medical technology, biotechnology and pharmaceutical (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. In this way, we are building a more resilient and competitive medical products manufacturing sector.



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

- **Deploying strategic initiative funding.** MTPConnect now delivers more than $180 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 40 collaborative projects, engaging over 180 consortium members. MTPConnect-funded projects have achieved demonstrable results, including 294 technologies being invented or progressed, 203 patents/trademark applications and licenses, 84 start-up companies, 801 direct and indirect jobs being created and $103.5 million of investment flowing into incubator companies (at 30 June 2020)

MTPConnect's GC work is complemented by five Medical Research Future Fund (MRFF) programs worth nearly $170 million:

- BioMedTech Horizons (BMTH) - $45 million
- Biomedical Translation Bridge (BTB) - $22.3 million

- Researcher Exchange and Development within Industry (REDI) - $32 million
- Targeted Translation Research Accelerator (TTRA) - $47 million
- Clinical Translation and Commercialisation – Medtech (CTC-M) – $19.8 million[1]

The BMTH program has committed $41.7 million to support 46 projects across four funding rounds, while over the three funding rounds of the BTB program, $16.3 million has been committed to support 21 projects. These included projects funded through a dedicated COVID-19-related round which have moved into the clinic and on to the market.

Through the REDI initiative, more than $22 million has so far been committed to training and skills programs, with 13 partners and selected providers delivering more than 2,215 new training, mentoring and industry placements across Australia addressing key skills gaps in medical product development and commercialisation. The first four fellows selected through the REDI fellowship program have commenced working with their industry partners on priority research translation projects.

The TTRA program has completed an extensive needs assessment process to determine the expert and consumer priority areas for targeted translation research in diabetes and cardiovascular disease and launched EOIs for two new research centres and the first round of research projects. More than $25 million is scheduled to be committed to projects and initiatives in September 2022.

The CTC-M program is the newest of our suite of MRFF programs that will see funding allocated to help medical devices and digital health technologies move into the clinic.

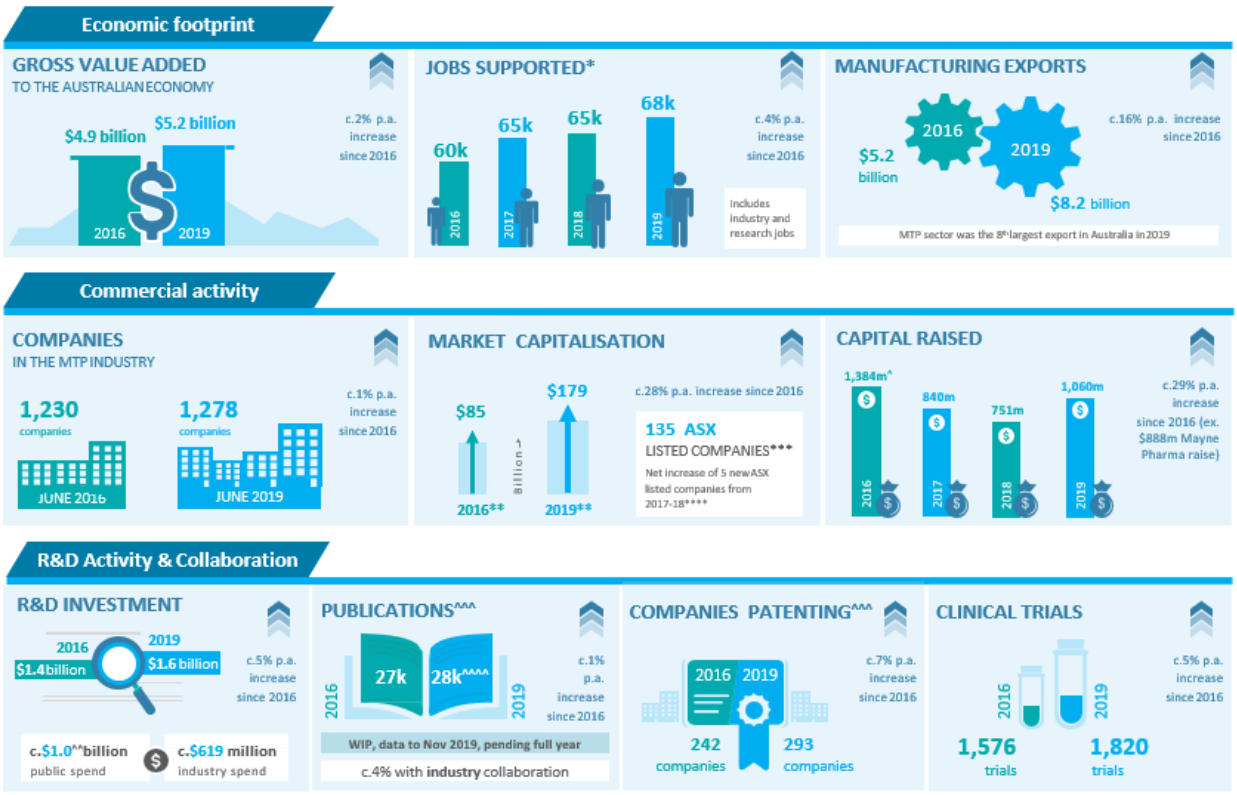
Together, these GC and MRFF programs enable MTPConnect to foster commercialisation and collaboration and address the skill gaps and key constraints identified across the sector. They position MTPConnect as a major funding body supporting the translation of highly promising health and medical research into medical products over the next four years.

[1] On 20 August 2021, it was announced that a fifth MRFF program, the $19.75 million Early Stage Translation and Commercialisation Support Grant to support early clinical development of medical devices with commercial potential, had been awarded to MTPConnect.

MTP Sector success since 2015

MTPConnect's 2020 Sector Competitiveness Plan (SCP) revisited the MTP sector's Knowledge Priorities, Sector Growth Priorities and regulation reform agenda, and reviews the growth achieved by the sector between 2015 and 31 December 2019, the period prior to the emergence of the COVID-19 pandemic. The SCP documented robust growth across many key metrics including Gross Value Added which grew steadily at 2 per cent p.a. since 2016 and manufacturing exports which grew 16 per cent since 2016 to be worth $8.2 billion, making the MTP sector the 8th largest export segment in Australia.

MTP sector progress on specific data analysis 2015 to present, MTPConnect's 2020 SCP



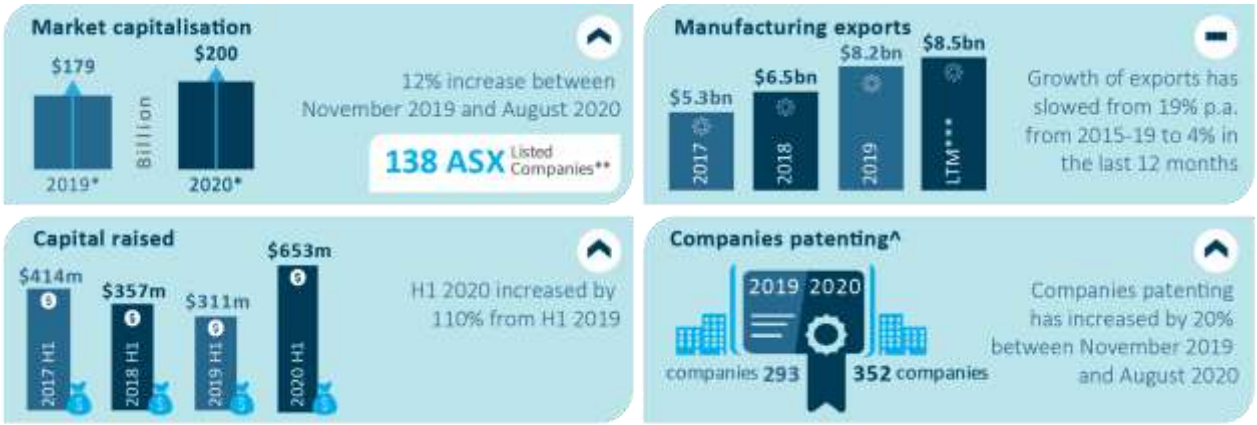
Notes:
* Due to the volatile nature of quarterly employment metrics, the industry job portion of the presented figures is calculated as a rolling 2-year average of the quarterly data. In the 2019 SCP, industry jobs was calculated as an annual average.
** 2016 market cap as at June 2016, 2019 market cap 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.

2020 and 2021 have been dominated by the emergence of the COVID-19 global public health emergency. With participants in the MTP sector on the frontline for research, diagnosis, management, prevention and treatment of infectious diseases, MTPConnect leveraged its expertise and extensive industry networks to play a critical role in supporting Australia's response to COVID-19, including deploying a fast-tracked round of the BTB program to specifically target COVID-19 projects (medical devices, diagnostics, prophylactic or therapeutic approaches) that could achieve an impact in less than 12-months.

We partnered with L.E.K. Consulting to conduct interviews with senior sector leaders to understand the burden of the pandemic and lockdown restrictions, with results published in three COVID-19 Impact reports, launched in June and September 2020. These reports found that in the first eight months of 2020,

performance against the key metrics of manufacturing exports, market capitalisation of ASX-listed companies and capital raised continued to follow the upward trajectory identified in the 2020 SCP.

Manufacturing exports grew to be worth $8.5 billion in 2020, up from $8.2 billion at the end of 2019, while MTP companies were able to raise much-needed liquidity to strengthen their balance sheets, taking advantage of positive investor sentiment towards the sector during the pandemic, with $653 million of capital raised by listed MTP companies in the first half of 2020, an increase of 110 per cent from H1 2019. The number of companies patenting rose 20 per cent between November 2019 and August 2020, likely due to efforts to find products and solutions in response to COVID-19.



Notes: * 2020 market cap at 31 August 2020, 2019 market cap at 30 November 2019.
** The list of ASX-listed MTP companies was updated to reflect five new listings, one new inclusion to the MTP sector list and three de-listed since November 2019.
*** LTM is the last 12-months to June 2020
^ Data provided by Clarivate Analytics.
Source: Thomson Reuters, ABS, Bioshares, Clarivate, L.E.K. Consulting analysis

MTPConnect 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 and a further nine-months of funding allocated in the October 2020 budget, MTPConnect's DISER Growth Centre funding expires on 30 June 2022.

MTPConnect has always held a focus on long-term sustainability. A detailed sustainability assessment was initiated in 2019/20 and included a study of unmet market need in the MTP sector and potential market platforms to defragment opportunities around intellectual property. The assessment included MTPConnect's market role, business model, commercial model, platform model and cost, as well as strategy and technology analysis and market testing.

MTPConnect has taken substantial steps 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 a suite of MRFF programs worth nearly $170 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 four years) to support MTPConnect's activities to develop the burgeoning MTP ecosystem in WA.

These programs, along with other initiatives to diversify revenue sources and retaining access to the unspent GC funding MTPConnect will hold at the end of June 2022, form key pillars of MTPConnect's strong plan to transition to a sustainable model. The Government has approved an additional one year for Growth Centres, including MTPConnect, to spend any unspent grant funds remaining at 30 June 2022 in the following financial year, to 30 June 2023. This flexibility was agreed by the Government in recognition it would assist a smooth transition to self-sustaining funding models.

MTPCONNECT'S VISION FOR THE MTP SECTOR

MTPConnect's vision is for Australia's MTP sector to create more medical 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. This vision was developed through a series of extensive sector consultations in 2016 and 2019.

The Australian MTP sector has the potential to be a significant contributor to improving patient outcomes and 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, mRNA, big data and analytics, while the ability to develop products and services tailored to consumers with digital connectivity and integration is becoming increasingly feasible, alongside a rise in consumer awareness of their overall health and wellbeing.

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

The megatrends, knowledge and sector priorities detailed in the 2020 SCP continue to shape 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.

The Global Biosecurity Megatrend and COVID-19

The MTP sector is on the frontline for research, diagnosis, management, advanced manufacturing, prevention and treatment of infectious diseases and, as has been demonstrated throughout 2020/21, is critical for responses to pandemics and global biosecurity threats.

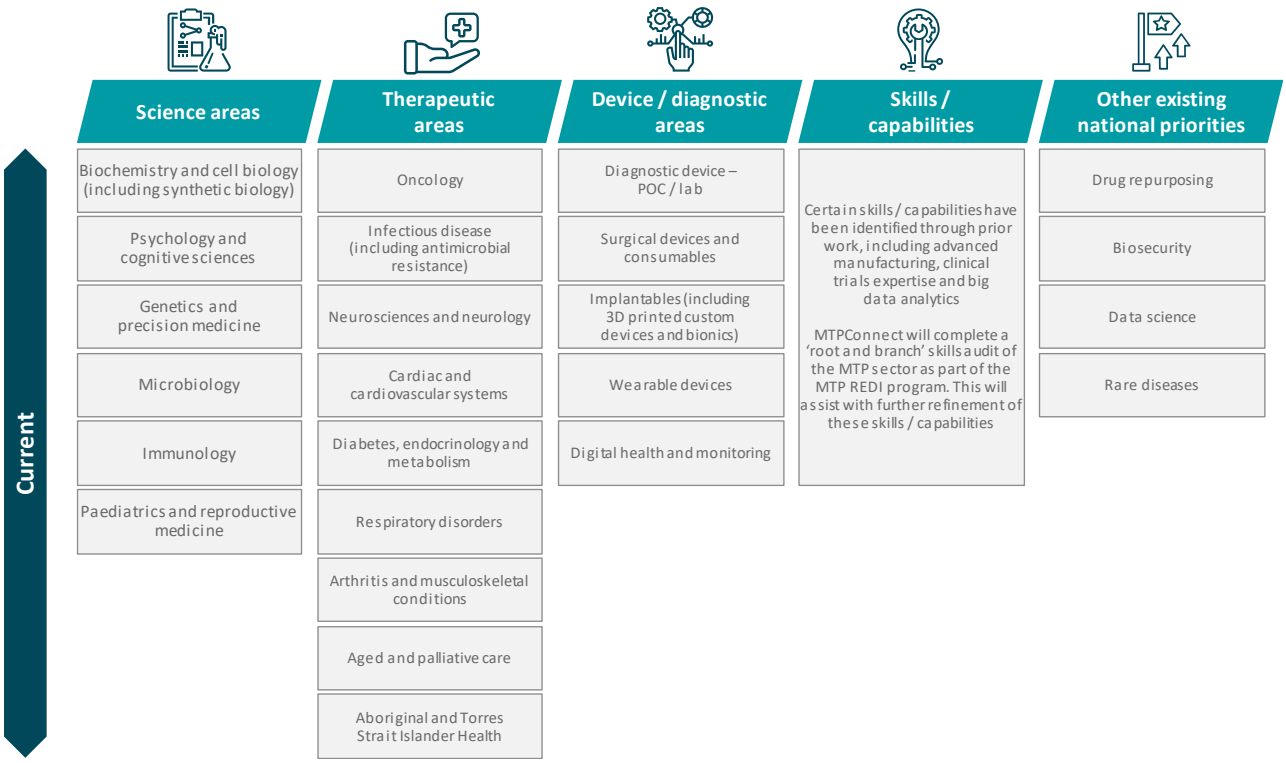
Many Australian researchers, start-ups and SMEs are working in vaccine design and manufacture, diagnostics and imaging, bioprocessing technologies, ventilation technology, telemedicine, infection control and protection and immune system directed therapies. In the early stages of the pandemic, industry input into Commonwealth Government Taskforces was integral to securing essential supplies of ventilators, testing kits and personal protective equipment supplies required by the healthcare system.

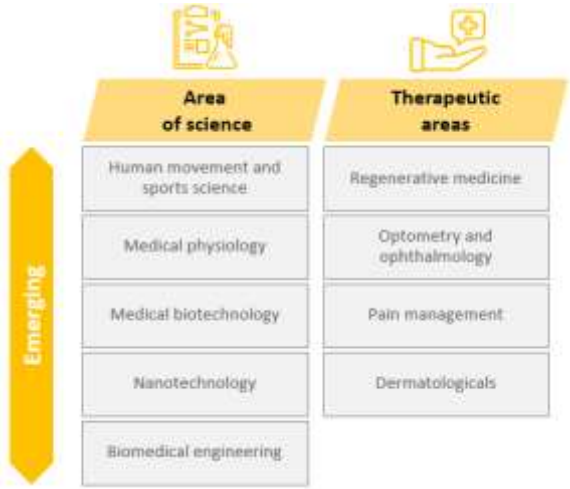
MTPConnect has leveraged its expertise and extensive industry networks to play a critical role in supporting Australia's response to COVID-19. This has included close involvement in the Taskforces and Working Groups and state interagency COVID-19 committees, as well as membership of the CSIRO Health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





Current and Emerging Knowledge Priorities, MTPConnect's 2020 SCP

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 FY22. The table below lists the sector priorities and demonstrates their alignment with the four GC objectives.

Sector Priorities		Growth Centre objectives: Improving coordination and collaboration	Improving management and workforce skills	Identifying opportunities to address regulations	Improving access to global supply chains & markets
P1	Align investment in Knowledge Priorities 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	✓✓	✓✓✓	✓✓	✓✓✓

Key: ✓✓✓ Greater focus on addressing particular Growth Centre objective
✓ Less focus on addressing particular Growth Centre objective

With a continuing focus during 2021/2022 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:

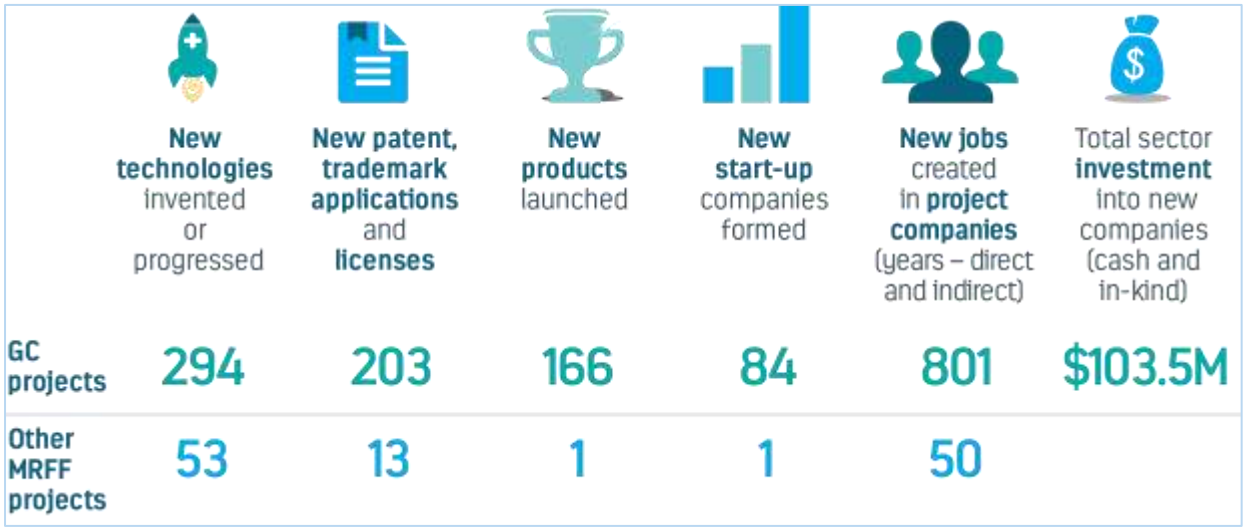
- Create more products that reach the proof-of-concept phase and early-stage commercialisation
- Increase the number of companies that have late-stage product successes
- Maximise the value of any IP monetisation events.

HOW MTPCONNECT IS ACHIEVING THE PROGRAM OBJECTIVES

As stated in MTPConnect's Funding Agreement with the Commonwealth, the IGC Initiative aims to encourage the commercialisation of new products; enhance workforce skills; reduce red tape; and forge closer links with global supply chains. It also focuses on building a more resilient and competitive medical products manufacturing sector. 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

The images below provide a summary of the impact of MTPConnect supported activities against the objectives to June 2020 (see the MTPConnect FY2020 Annual Report for more details).



Objective 1: Collaboration and Commercialisation

In 2020, Australia ranked 23rd on the Global Innovation Index. For innovation inputs – research – we ranked 13th in the world, yet for innovation outputs – commercialised products – we ranked 31st. In Harvard University's 2019 Economic Complexity Index, which measures the diversity and sophistication of national exports, Australia ranks 86th in the world. These measures highlight the opportunity for Australia to boost the translation and commercialisation of sophisticated medical products that are derived from our health and medical research and drive the creation of high-paying jobs which will underpin economic growth and resiliency. 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, BTB, REDI and TTRA funding across a wide range of project areas, ranging from 3D anatomical printing and precision medicine to clinical trials, advanced manufacturing, industry mentoring and targeted skills training programs.

MTPConnect will continue to strategically deploy capital from and manage projects supported by its five funding schemes. In alignment with the Modern Manufacturing Strategy (MMS), these funds and the projects and activities they support 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.

With the ongoing rollout of the MMS and the Medical Products Roadmap, MTPConnect will continue to support manufacturing in the MTP sector. Key activities include the deployment of a new voucher program to boost medical products manufacturing in Western Australia. Through our WA Life Sciences Innovation Hub, we have made available funding of $450,000 and launched a contestable program for SMEs. Successful applicants will be announced early in FY22.

Round 4 of the BMTH program, which has a focus on manufacturing and medical technologies, will also be finalised early in FY22. We will provide funding to support the development of pre-commercial prototypes, fast-tracking the steps to commercialisation ready for advanced manufacturing and clinical trials activity. Successful applicants will be announced early in FY22 and will be project-managed by MTPConnect throughout the financial year.

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).[2] Applications to these programs are still 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.

Through our REDI program, we have consistently heard that clinician innovation and commercialisation skills are not where they should be and, with support, have the potential to significantly impact the development and translation of new medical products. The UK's Clinical Entrepreneur Program (CEP) has helped increase clinician translation with 427 innovations, 246 start-ups formed and 1,371 jobs created by just over 500 clinical entrepreneurs. These new medical products have helped 34.6 million patients in the UK in the first four-years.

As a priority activity for FY22, MTPConnect is scoping an Australian version of CEP with relevant stakeholders such as health providers, government, leading clinicians and medical colleges. Following extensive stakeholder engagement, we are aiming to develop a fit-for-purpose, Australia-focused CEP that

[2] Although Growth Centres will no longer formally review ARC ITRP program applications, MTPConnect will continue to engage with applicants to help develop competitive applications.

will encourage and support Australian clinicians to commercialise their ideas and innovations to deliver better health outcomes. We expect to launch an Australian CEP during FY22.

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.

With COVID-19 restrictions likely to continue impacting businesses and organisations in the sector for most, if not all of FY22, we will continue to deliver a program of virtual seminars, summits and events to provide networking and partnering opportunities. We will also provide sponsorship support for the key Australian and international conferences that are critical for our sector to network, create partnerships and grow; including the AusBiotech conference and events held by MTAA, ARCS and MA.

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. 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 will continue providing additional financial support for the Bridge and BridgeTech programs in 2021-22, 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 5,214 companies, universities, research organisations and industry associations.

This year we will continue to expand this focus to ensure that the sector's skills keep pace with changing needs by continuing to deliver on our $32 million REDI initiative. 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 GSK Australia, 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.

Training partners Seer Pharma, ARCS Australia, Biointelect and Cicada Innovations have recently been appointed to deliver targeted education and training programs across Australia, while the REDI Fellowship

Program, which has so far seen four fellows appointed, will continue to rollout across FY22, providing up to $250,000 per fellow, per annum to working in industry on priority projects.

Over the last 12-months, MTPConnect delivered three reports that have identified key workforce skills gaps in our sector. This year, as part of our REDI program, we will deliver a fourth report highlighting the emerging skills gaps in precision medicine and genomics, sovereign supply/manufacturing (especially cell and gene therapies, biologics and mRNA), and the defence sector in the broader health system. As part of this, we will engage with a range of industry, research, clinical and defence experts.

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.

This year, MTPConnect's will work with the Therapeutic Goods Administration (TGA) and other agencies to explore Australia's regulatory regime for gene and cell therapies. Through a range of stakeholder engagements and small roundtables, MTPConnect will assess whether there are genuine stakeholder concerns around the regulatory pathways as they relate to clinical trials and manufacturing and the interaction between the TGA and the Office of the Gene Technology Regulator (OGTR) for both/either clinical trials or commercial application of gene therapies.

MTPConnect will continue its work on Antimicrobial Resistance (AMR) through the Australian Antimicrobial Resistance Network (AAMRNet), an industry body that was established by MTPConnect in 2020 as a GC Project Fund project. AAMRNet provides a unified voice to support and promote Australia's role in the global fight against the growing threat of drug resistant infections through a coordinated set of policies/activities on research and development (R&D), regulation, commercialisation, surveillance and stewardship. As the only body in Australia able to provide whole-of-sector representation, AAMRNet is uniquely placed to promote Australia's role in the fight against AMR and help inform government priorities and strategies. Following on from the release of our 'Fighting Superbugs' report in 2020, MTPConnect and AAMRNet, in partnership with CSIRO, will undertake three new pieces of work:

1. Conduct an audit of Australia's current capabilities in AMR R&D as a crucial first step in developing the whole-of-government approach required to foster greater collaboration and leverage the industry knowhow that will enhance Australia's ability to commercialise early-stage AMR research and maximise the impact of Australia's AMR R&D efforts. It is anticipated that the audit will be completed in mid-FY22.
2. Measure the impact of AMR on human morbidity and mortality in Australia
3. Develop a business case that sets the groundwork for the establishment of a Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) endorsed AMR Accelerator in Australia.

With matching funding from CSIRO secured, the AAMRNet AMR Accelerator would work with Australian grant applicants to improve the quality of applications, increasing their likelihood of success and facilitate foreign direct investment (FDI) through the promotion of Australian fee-for-service capabilities to overseas companies seeking to access Australian expertise, capabilities and infrastructure.

MTPConnect will also continue to play a leadership role in other key areas, including drug repurposing of medicines and supply chain resilience. We will also deliver a leading, relevant and forward-looking report examining the status of Australia's medicinal cannabis industry, a significant and growing player in the

medical products sector. The report, commissioned by MTPConnect, is being developed in partnership with Deloitte Access Economics. To be released in FY22, it will provide an evidence base to articulate the current size of Australia's medicinal cannabis industry, as well as future estimates for the sector and will serve as a valuable resource to inform policymakers, industry and consumers.

COVID-19 has revealed the importance of pandemic preparedness, biosecurity and medical countermeasures. It has also revealed opportunities for researchers and SMEs to address pipeline gaps with high quality R&D with the potential for global commercialisation. MTPConnect has worked with DMTC and Austrade to develop an investment value proposition to attract FDI into the Australian biologics sector. It involved evaluating the Australian landscape in cell, CAR-T, gene and antibody therapies and assessing Australia's competitiveness relative to key international markets.

Building on, and in alignment with, this ongoing foundational work, and the work being undertaken through the REDI program to examine skills gaps impacting sovereign supply/manufacturing and the defense sector, MTPConnect will work to overcome the siloed nature of Australia's university, MRI, SME and defence/national security sectors to effectively identify needs and opportunities that can be met by new horizons biotech research conducted in Australia. This work will be ongoing in FY22.

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 will continue 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 will continue to partner with Austrade and peak bodies such as AusBiotech and MTAA to put Australian MTP stakeholders in front of international customers and investors. Since our establishment, we have led or directly supported more than 25 trade missions involving 850 companies. Our GC project partners have been involved in 119 inbound and outbound trade missions.

With the transition to virtual trade delegations and meetings, we will continue to support AusBiotech's Digital Bio initiatives. We will also 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, BioJapan, the MedTech Conference and the BIO international convention to ensure Australia is well-positioned to respond internationally in the post-COVID-19 era.

With the increasing reliance on online events and meetings, MTPConnect will continue to provide seminars and resources to support start-ups and SMEs to partner effectively at virtual conferences when seeking new strategic partnerships for funding or collaboration. These activities will build on the success of our Skills Summit delivered in FY21 which brought together a panel of industry experts who shared their first-hand experiences with participants. Key sessions were made widely available to the sector through the MTPConnect podcast series.

We will maintain our Memoranda of Understanding (MoUs) that have been established with international groups such as the Medical Alley Association (USA) and Confederation of Indian Industry (India) to strengthen international relationships.

MTPCONNECT'S PRIORITY ACTIONS

As outlined in the October 2020 federal budget and at Senate Estimates in June of 2021, MTPConnect, and the other Growth Centres, must transition to a sustainable model by 30 June 2022 when funding of the Growth Centres formally ends. MTPConnect's priority action for FY2022 will be the development and implementation of a Transition Plan to allow MTPConnect to become self-sustainable in the absence of DISER funding.

However, should a model for sustainability not be identified, approved and initiated by October 2021, in order to meet our operational and employee obligations ahead of the expiration of our Funding Agreement on 30 June 2022, MTPConnect will commence wind-up proceedings. At the same time as we transition, MTPConnect will continue to support the MTP sector and build on our achievements since inception and address the key challenges of the sector. MTPConnect's priority actions can be broadly categorised into three themes:

During 2021/2022, 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 FY22 strategic initiatives will be monitored using our program logic and data matrix, on the back of a largely supportive performance review in 2019 (the Nous Review) and the 2020 ACIL Allen Assessment (yet to be released).

Additional impact assessment will be provided by measuring levels of engagement with MTPConnect's social media, digital channels and podcast series.

Growth Centre Objective 1: Improving Coordination and Collaboration

MTPConnect will continue to play 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, BTB and TTRA funding Secure and deliver additional non-GC sourced funding to key initiatives in the sector Help ensure high quality MTP projects are funded by assisting entities with CRC, CRC-P, ARC ITRP program pre-submission review and mentoring. Bring together recipients of MTPConnect's GC, BMTH and BTB funding, and industry leaders in collaboration and skills summits	Develop and release policy papers on antimicrobial resistance and medical cannabis 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 Continue to refine Knowledge Priorities consider market pull or science push (e.g. biosecurity defence, medical countermeasures) when refreshing our SCP Continue to monitor, assess and promote international best practice approaches to funding SMEs	Develop programs that link large research-intensive Multinational Companies to Australia's researchers/SMEs through the REDI fellowships Maintain activity in existing state-based hubs (WA, NSW, VIC, QLD) and explore establishing a new hub in SA Maintain communications and engagement with the general public, including patients Collate and report on a consistent set of sector metrics on behalf of the sector Continue to deploy Guidance And Impact Tracking System (GAITS) software through BMTH/BTB program participants Support TTRA Centres to undertake Partnering Summits	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 Continue working with accelerators, including ANDHealth, the MedTech Actuator, 10X Accelerator and Cicada Innovations

Growth 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. Through the 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
Deploy REDI funding to expand training programs with proven partners (e.g. GSK Australia, 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 in precision medicine and genomics, sovereign supply/manufacturing (especially cell and gene therapies, biologics, and mRNA) and the defence sector Bring together recipients of MTPConnect's GC, BMTH and BTB funding and industry leaders in collaboration and skills summits	Review and address skills gaps in precision medicine and genomics, sovereign supply/manufacturing (especially cell and gene therapies, biologics, and mRNA) and the defence sector, with findings to inform REDI program analysis 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 and events and promote achievements	Continue ongoing REDI work to establish best practice industry placement, internship and fellowship programs that link researchers and industry Promote an SME education program to maximise negotiated funding outcomes, out-licensing arrangements or divestment Develop a business case to attract and deploy an Australia-focused Clinical Entrepreneurs Program (CEP)

Growth Centre Objective 3: Regulatory and Policy Environment

MTPConnect has been involved in several 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, regenerative medicine and mRNA. 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
Continue using the Project Fund Program to co-fund projects to improve regulation and clinical trials in Australia. Continue the support of a national Regenerative Medicine sector 'catalyst' collaboration body to advance the development of Australia's RM sector Continue the support of InGeNa as the national Genomics 'catalyst' collaboration body to	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, industry developments and megatrends to inform policy development (e.g. gene and cell therapy regulations, AMR issues and medical cannabis) 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 Infectious Disease Resilience Roadmap

advance the development of Australia's genomics sector Continue the support of AAMRNet as the national Anti-Microbial Resistance 'catalyst' collaboration body to advance the sector	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 with protracted COVID-19 restrictions in place, driving a need for new ways to be globally connected. To achieve this objective, MTPConnect will continue to leverage its virtual platforms and infrastructure to promote Australia's capabilities internationally and foster connections between international companies and institutions and Australian businesses and researchers.

MTPConnect key priority activities and deliverables to address Growth Centre Objective 4

Provide industry thought leadership through an independent voice	Taking direct action – Promote and connect Australia globally
Continue to work with Austrade to support opportunities for Australian developers and producers Work with AusBiotech to help coordinate, fund and recruit delegates to attend the BIO2022 Conference	Continue to 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 BIO2022, the MedTech conference) Subject to COVID-19 restrictions, continue to attend and present at focused conferences and exhibitions domestically and internationally to develop the Australian MTP sector's in-market presence (including virtual attendance) including 2021 MedTech Conference, Bio Japan, Bio Korea Continue to evaluate global best practice around international engagement strategies and translate into Australian initiatives, including the NHS Clinical Entrepreneurs Program Provide advice, guidance and connections to international market experts to help prepare Australian companies for international expansion

ACTIVITIES AND MILESTONES – FY2022

FY2022 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 (1/4/2021 to 30/6/2021)	31 July 2021	Report submitted to DISER
2	MTPConnect Transition Plan	30 September 2021	Transition Plan submitted to DISER
3	MTPConnect Business Plan	30 September 2021	Business Plan submitted to DISER
4	MTPConnect Quarterly Report Q1 (1/7/2021 to 30/9/2021)	31 October 2021	Report submitted to DISER
5	MTPConnect 2020-2021 Annual Report	31 October 2021	Report submitted to DISER and, once approved by the Commonwealth, published on MTPConnect website
6	MTPConnect Quarterly Report Q2 (1/10/2021 to 31/12/2021)	31 January 2022	Report submitted to DISER
7	Updated Sector Competitiveness Plan for 2020 - 2021	28 February 2022	SCP submitted to DISER and, once approved by the Commonwealth, published on MTPConnect website
8	MTPConnect Quarterly Report Q3 (1/1/2022 to 31/3/2022)	30 April 2022	Report submitted to DISER
9	MTPConnect Final Growth Centre Report (2015-2022)	22 September 2022	Report submitted to DISER

MEMBERS REGISTER

MTPCONNECT LTD

ABN: 53 608 571 277

As of 1 April 2021, the members in Medical Technologies and Pharmaceuticals Industry Innovation Growth Centre are, or have been:

Member	Date joined	Date ceased	Comments
Mr Alex Fowkes	November 2020		MTP-IIGC Ltd director
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 June 2021: 0

BUDGET

In-Kind Contributions for FY2022

MTP-IIGC Ltd (trading as MTPConnect) has five 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
Mr Alex Fowkes	Currently paid at approximately 50% of market rate – other 50% donated as in kind.	
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.	
TOTAL		**$185,744**

Entity	In-kind contribution	In-kind value
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		**$60,000**

Cash Contributions for FY2022

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

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

Other Participants	Contribution value for FY2022
DoH BMTH funding	$20 million to be deployed in FY2022 as grant and operating funds.
DoH BTB funding	$5.3 million to be deployed in FY2022 as grant and operating funds.
DoH REDI funding	$10 million to be deployed in FY2022 as grant and operating funds.
DOH TTRA funding	$19m million to be deployed in FY2022 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 23	31 Aug 2021	$1,250,000
Payment 24	30 Nov 2021	$1,250,000
Payment 25	28 Feb 2022	$1,250,000
Payment 26	31 May 2022	$1,250,000
TOTAL		**$5,000,000**

MTPConnect Project Funding Cash Contributions

To date, 40 projects have been contracted, with over $23.4 million of matched funding committed and $22.3 million of matched funding and $15.4 million of in-kind evidenced by projects so far. Growth Centre projects will continue into FY22 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	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
FY 2016 Carried over to FY 2017 with DISER permission	$1,400,000	$1,671,993	$1,988,704	$5,047,656	$3,554,479	$2,035,199	$1,301,969
FY 2017	$3,200,000						
FY 2018	$8,000,000						
FY 2019	$3,000,000						

Expenses Budget

Tables of MTPConnect's FY22 expenditure budget and cash summary are included below. This budget has been approved by the MTPConnect Board but is subject to future business requirements.

MTP-IIGC LTD (MTPConnect) Business Plan - DISER – FY 2022	
Operating Income	**FY 2022**
Grants - operating expenses	$5,000,000
Other Income	$0
Total Income	**$5,000,000**
Operating Expenses	
Travel Expenses	$73,900
Office & Administration	$421,310
Accounting, Audit and Legal	$209,500
Employment, Board and Consultants	$2,318,975
Sector Sponsorship and Communications	$341,000
Sector Support Projects	$560,000
Sector Competitiveness Plan and Sustainability	$500,000
Total Operating Expenditure	**$4,424,685**
Profit/Loss from Operating Activities for the period	**$575,315**
Project & Activity Funding	**FY 2022**
MTPConnect Activities	$0
Project Funds (FY2021)	$1,392,978
Total Project & Activity Expenditure	$1,392,978
Profit/Loss from Project Activity for the period	**($1,392,978)**

MTP-IIGC LTD (MTPConnect) Business Plan - DISER – FY 2022 Cash Summary	
Cash Summary	**FY 2022**
Opening Balance	**$6,347,528**
Inflows	$5,000,000
Outflows	$5,817,663
Closing Balance 30 June 2022	**$5,529,864**

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.

Growth Centre Projects – Completed

PROJECT TITLE	COMPANY NAME	BRIEF DESCRIPTION OF PROJECT	OUTCOMES (FY2020)	KEY OBJECTIVES			
				1. Collaboration	2. Skills	3. Regulation	4. Global
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.	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.		1		
The MedTech Actuator	The Actuator Operations	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.	Thirty-two new companies have been supported, creating over 53 new technologies and $25million of investment.	1			
BioFab3D@ACMD	St Vincent's Hospital Melbourne	Support for BioFab3D@ACMD, a robotics and biomedical engineering centre, embedded within a hospital. Researchers, clinicians, engineers and industry partners will work alongside each other to build biological structures such as organs, bones, brain, muscle, nerves and glands.	Since the start of the project the BioFab3D centre has trained over 233 individuals and progressed 21 new technologies. The centre is also being used by two MedTech start-ups.	1			

PROJECT TITLE	COMPANY NAME	BRIEF DESCRIPTION OF PROJECT	OUTCOMES (FY2020)	KEY OBJECTIVES			
				1. Collaboration	2. Skills	3. Regulation	4. Global
ANDHealth	ANDHealth	Creating an integrated ecosystem for the development and commercialisation of evidence-based digital health products.	Supported 10 evidence-based digital health product companies, which has created 188 new jobs, an investment of $30.5million, and treated over 91,000 patients. Additional funding for five-day training course was granted in December 2018, which has been delivered to additional audiences with other sponsors in FY2020.	1			
Comprehensive Global Investment	AusBiotech Ltd	Development of a comprehensive global investment education program for the Australian life science sector - companies, investors and researchers.	This project held 13 events with over 1,300 attendees and supported one inbound and five outbound trade missions. While the direct continued benefits are not known, the indirect benefits are being seen through increased investment into MTP companies.				1
Australian Centre for Commercialisation of Regenerative Medicine (CCRM) - Stage 1	Monash University	CCRM Australia, an Australian hub of Canada's Centre for Commercialisation of Regenerative Medicine (CCRM) will support the development of foundational technologies to accelerate the commercialisation of regenerative medicine products and therapies.	Ten regenerative medicine product companies are collaborating internationally to advance their product commercialisation. Five collaboration events with over 500 attendees as well as the support of three inbound and three outbound trade missions.	1			
Hit ID platform	Cancer Therapeutics CRC Pty Ltd (CTx)	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.	New storage infrastructure and 310,000 compound bank to allow fast screening of compounds to determine new target drug formulations. Six screenings have already been performed since the project's completion.	1			

PROJECT TITLE	COMPANY NAME	BRIEF DESCRIPTION OF PROJECT	OUTCOMES (FY2020)	KEY OBJECTIVES			
				1. Collaboration	2. Skills	3. Regulation	4. Global
Pilot implementation of the Australasian Tele-Trial Model	Clinical Oncology Society of Australia (COSA)	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.	The Tele-Trials Consultation Guide has been approved for National Mutual Acceptance (NMA) and is now available as generic national documents. Six clinical trials have commenced with 81 patients recruited, 75 of whom are rural.	1			
Medical Device Partnering Program (MDPP) - Stage 1	Flinders University	Initial scoping of the rollout of a national Medical Device Partnering Program (MDPP) to bring together research, clinical and industry partners in a streamlined process for collaboration and product development.	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.	1			
Vaccine research in Australia: Landscaping capabilities and services	Vaxine	Project to assist in landscaping Australia's vaccine research capabilities and relevant services for use by the whole MTP sector in a searchable database. The project will also host Australia's first national vaccine conference.	A better-connected Australian vaccine community, engaging through events and in person. Ten events have been held with over 350 attendees. Two products have been developed and five pre-clinical and one clinical trial have commenced.	1			
The Bridge program	Queensland University of Technology (QUT)	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, and direct exposure to industry practitioners in the scientific, legal, financial, clinical, regulatory and reimbursement disciplines that contribute to the commercialising of medicines.	Four hundred and seventy-six early-career researchers have been trained in pharmaceutical commercialisation. A FY2020 survey revealed five new products launched, six licenses negotiated and seven start-up companies formed since the project started. This project is now funded through the BTB fund.		1		

PROJECT TITLE	COMPANY NAME	BRIEF DESCRIPTION OF PROJECT	OUTCOMES (FY2020)	KEY OBJECTIVES			
				1. Collaboration	2. Skills	3. Regulation	4. Global
Accelerating Australia - Stage 1	Centre for Entrepreneurial Research and Innovation (CERI)	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.	Governance developed to allow network of translational activities in the future as well as pilot training programs. Training was delivered to 194 peoples. 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.		1		
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.	Specifications for a bioFabrication centre, with industry partners engaged. At least eight children recruited to a pilot project investigating biofabrication of ears.	1			
Clinical Trial : Impact and Quality (CT:IQ)	Bellberry Ltd	A 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.	Five sector-wide, industry-led projects are complete, including checklist and additional information for clinical trial design and an investigation onto electronic consent. The consortium has presented its projects at nine events to over 1,000 attendees.	1			
Australia-China Life Sciences Partnership Program	AusBiotech Ltd	The Australia-China Life Sciences Partnership Program aimed to increase awareness, and thus, opportunities for communication, collaboration and commercialisation between the life sciences sectors in Australia and China.	A free-to-use database was generated. Uptake was lower than expected and the project was terminated.				1
Microscopy Australia - Technical Voucher Fund	University of Sydney	The scheme will fund vouchers to support MedTech R&D by providing easy and discounted access to microscopy services. It is designed to reduce barriers and provide industry with access to analytical tools and Microscopy Australia's experts.	Six vouchers have been issued to SME's, progressing three product concepts and one clinical trial.	1			

PROJECT TITLE	COMPANY NAME	BRIEF DESCRIPTION OF PROJECT	OUTCOMES (FY2020)	KEY OBJECTIVES			
				1. Collaboration	2. Skills	3. Regulation	4. Global
ClinTrial Refer - Improve recruitment to all clinical trials in Australia	South Eastern Sydney Local Health District.	ClinTrial Refer is a mobile smartphone and web-based platform connecting doctors and patients to recruiting clinical trials across research networks. This project will develop a new IT platform to integrate the 19 derivative apps, create one combined database, create new search functions, enable electronic referrals, link to ANZCTR and build a national solution to trials recruitment.	A single 'ClinTrial Refer' application has been launched on Apple and Android platforms and has been loaded with active trials. Over 60 individuals have been trained on how to load clinical trials and the app has seen an increase of over 2,300 users since its new launch.	1			
Accelerating Australia – Stage 2	Centre for Entrepreneurial Research and Innovation (CERI)	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.	Commercialisation training and support for at least 949 individuals (students and clinicians from 20 partner universities and companies) - resulting in 120 new technologies, 25 new jobs and $6.5million of investment into the companies. Improved collaboration between universities and companies within each state node.		1		
The Bridge Tech program	Queensland University of Technology (QUT)	The Bridge Tech program will enable Australia to more effectively capitalise on its world-class 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.	Three Hundred and thirty-one early career researchers have now trained in medical device commercialisation. As of June 2020, this has resulted in eight new companies, four products launched and 12 pre-clinical or clinical trials. Networks have developed between participants and industry. This project is now funded by the BTB fund.		1		
CRITERIA - Building clinical trial capability and capacity.	ARCS Australia Ltd	This project aims to connect MTP companies with appropriately trained graduates to equip them with job ready skills to meet this gap.	ARCS have trained 52 graduates in all aspects of pharmaceutical medicine and clinical research through 44 training events. 40 graduates of the CRITERIA program now have jobs within the clinical trial industry.		1		

PROJECT TITLE	COMPANY NAME	BRIEF DESCRIPTION OF PROJECT	OUTCOMES (FY2020)	KEY OBJECTIVES			
				1. Collaboration	2. Skills	3. Regulation	4. Global
Enabling precision cancer clinical trials for SME's.	The Garvan Institute of Medical Research	To 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.	To date the project has trained over 400 individuals. The project team has processed over 1,250 samples and engaged with six Australian-based SMEs including 4 clinical trials.	1			
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 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.	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.	1			
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.	The open-source adaptive clinical trial platform has been developed and it being used with three rare disease populations (motor neurone disease, cystic fibrosis and Angelman syndrome) and a separate project has been commenced to use the system for COVID-19 clinical trial analysis.	1			
Training programs for the biologics and biomedical-based industry sector.	Australian Institute for Bioengineering and Nanotechnology, the University of Queensland	The project will 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.	Four hundred and ninety participants received training during the project, this was a mixture of in-person training and access to an e-learning platform. One additional clinical trial has commenced from the trainees.		1		

PROJECT TITLE	COMPANY NAME	BRIEF DESCRIPTION OF PROJECT	OUTCOMES (FY2020)	KEY OBJECTIVES			
				1. Collaboration	2. Skills	3. Regulation	4. Global
Installation of robotic sterile clinical trial manufacturing capability	Pharmaceutical Packaging Professionals Pty Ltd	This project creates a fully robotic, sterile vial-filling line to manufacture Phase II and III products.	Project was terminated due to lack of progress as a result of company relocation.	1			
Operationalise the Centre of Commercialisation for Regenerative Medicine (CCRM Australia)	Monash University	To accelerate the commercialisation 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.	CCRM Australia has completed a pilot mentoring program, launched a regenerative medicine database and hosted national online seminars. Over 400 attendees have attended, training, collaboration and information events.	1			
National MTP+D Live Showcase: Searchable, trackable, public pipelines for medtech, pharmaceutical and digital health innovations	Health-Innovate Pty Ltd	To catalogue and track publicly exposed MTPD innovations under development in Australia. The catalogue will be publicly and globally accessible and kept up to date using a humanised machine learning system.	A learning platform following at least 1,200 Australian products has been developed and has been showcased at the World Hospital Congress. It can be used to demonstrate trends and funding focus opportunities.	1			
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. 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 customised bioprinting systems.	A new facility (TRICEP - Translational Research Initiative of Cellular Engineering and Printing) has been established at Wollongong. Ten new products have been developed within the facility, with two new start-up companies formed. TRICEP supported over 100 inbound and outbound missions through speakers and facility tours.	1			
Establishment of an early-stage product manufacturing facility and training hub	Translational Research Institute	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.	Improvements in the cleanroom facilities are now complete with over 60 individuals trained using the facilities, four companies using the facilities and three clinical trials commenced - treating 120 patients.	1			

PROJECT TITLE	COMPANY NAME	BRIEF DESCRIPTION OF PROJECT	OUTCOMES (FY2020)	KEY OBJECTIVES			
				1. Collaboration	2. Skills	3. Regulation	4. Global
ASIALINK	Asialink Business	Developed 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.	Two guides have been launched and well received, one in Melbourne with 46 attendees and the second as an online seminar.				1
National Expansion of the MDPP Stage 2	Flinders University	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.	A MDPP has been established in Victoria and supported by the Victorian Government. Additional funding for the ongoing program has been provided in South Australia by the South Australian Government. Discussions are progressing with Tasmania, Queensland, New South Wales and Western Australia. A MedTech facilities mapping exercise is complete, with a user interface designed, and will be launched in FY2021.	1			

Growth Centre Projects – Ongoing

PROJECT TITLE	COMPANY NAME	BRIEF DESCRIPTION OF PROJECT	OUTCOMES (FY2020)	KEY OBJECTIVES			
				1. Collaboration	2. Skills	3. Regulation	4. Global
Upgrade CSIRO protein production platform	CSIRO	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 postgraduate study.	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. Twenty postgraduates will be trained in the production systems.	1			
Formulation and GMP product manufacturing services for clinical trials in Australia	Ab Initio Pharma and the University of Sydney	To establish 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. Postgraduates trained in production system.	Facility has been designed. Build to begin and Installation of machinery planned for FY2021.	1			
Certara-Monash University Industry Fellowship Program	Certara Australia	The Certara-Monash Fellowship Program in drug development and pharmaceutical science will identify and develop the next generation of pharmaceutical scientists. The program will be located at Monash University's Faculty of Pharmacy and Pharmaceutical Sciences and will involve a combination of academic coursework, hands-on industry training and research.	Four postdoctoral fellows have been appointed and started their training. Feedback from academic and industry mentors is positive with respect to the skills being learnt by the fellows and their impact on the projects they are involved in.		1		
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, 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 South Australia; however, the infrastructure will be	Initial health data has been uploaded and presented on a platform, which has allowed panels of experts to quantify clinical guidance principals. Clinical AI algorithms have been developed and the team is developing user interfaces, while collecting a year's worth of comparison data to prove the system.	1			

PROJECT TITLE	COMPANY NAME	BRIEF DESCRIPTION OF PROJECT	OUTCOMES (FY2020)	KEY OBJECTIVES			
				1. Collaboration	2. Skills	3. Regulation	4. Global
		commercially scalable to other diseases, across Australia and beyond.					
IMNIS Stage 2	ATSE	To continue with PhD mentoring activities, develop an alumni program and pilot rural and remote mentoring.	This IMNIS program has connected over 217 students from 14 universities to an industry mentor. The rural pilot has been positive, with six mentees from JCU and CQU in Queensland connecting with mentors remotely. Thirty-six mentees have gained employment in industry across both projects.		1		
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.	Established in FY2021	1	1	1	1
Regenerative Medicine (RM) Catalyst Body	AusBiotech	This project will build on the Regenerative Medicine Advisory Group report, 'Regenerative medicine: Opportunities for Australia' (MTPConnect, LEK, 2018) and investigate and analyse the Regenerative medicine sector in all four Industry Growth Centre (IGC) pillars.	Established in FY2021	1	1	1	1
Genomics National Alliance (InGeNA)	The Australasian Institute of Digital Health	The project addresses the need for a central group to represent Industry across the genomics value chain (diagnostics, bioinformatics, cloud, data, pharma and technology), and provide a combined and compelling voice. To develop genomics policy and to work collaboratively with research, government and service providers across the genomics and health sectors. To focus on enabling access and improved outcomes for Australians as well as the economic strength and capability of Australia to be a global leader in genomics and deliver precision health at a population level.	Established in FY2021	1	1	1	1

PROJECT TITLE	COMPANY NAME	BRIEF DESCRIPTION OF PROJECT	OUTCOMES (FY2020)	KEY OBJECTIVES			
				1. Collaboration	2. Skills	3. Regulation	4. Global
Australian Cardiovascular Alliance (ACvA)	Australian Cardiovascular Alliance	To map the capabilities and resources specifically available to support cardiovascular medtech development in Australia. By creating an online searchable portal, the project will improve collaboration and promote the development of medical devices for cardiovascular disease in Australia. The Project will also develop a clinical trial service to support research groups locally and internationally to set up cardiovascular-related clinical trials for medical devices in Australia. This service hopes to increase the number of Australian patients receiving life-saving treatment for their cardiovascular conditions.	Established in FY2021	1			1

MTPConnect
MedTech and Pharma Growth Centre

CONTACT US FOR FURTHER

INFORMATION

PHONE +61 3 9070 8298

EMAIL info@mtpconnect.org.au

HEAD OFFICE Ground floor, Suite 2
155 Cremorne Street
Cremorne VIC 3121
Australia

See our website for other locations

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