

MTPConnect
MedTech and Pharma Growth Centre

MEDTECH, BIOTECHNOLOGY AND PHARMACEUTICAL SECTOR COMPETITIVENESS PLAN

February 2018 Update



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2. Foreword

As an independent, not-for-profit organisation dedicated to fostering the growth of Australia's medical technology, biotechnology and pharmaceuticals (MTP) ecosystem, MTPConnect stakes its reputation on its ability to promote the development of the sector it represents.

Following the path set out in the Medtech, Biotechnology and Pharmaceutical Sector Competitiveness Plan (SCP), which we published in December 2016, the past year has seen satisfying progress in promoting our Sector Growth Priorities.

This SCP Update report documents the numerous successful projects we have contributed to in 2016/17, the first year of the SCP, and demonstrates our performance in building the organisation's profile and stimulating engagement with our programs. This Update report has been developed to be read in conjunction with the original SCP.

One of our most valuable contributions has been our ability to foster connections in the sector, increasing synergy between all participants ranging from industry to research to government. We have worked closely with established industry organisations to complement and add value to their successful activities. Our headline achievement has been the investment of over \$15 million into initiatives supporting the MTP sector, which have attracted more than \$31 million in co-contributions from industry. Other highlights have included MTPConnect's participation in the intellectual property review conducted by the Productivity Commission, the showcasing of Australian innovation and capabilities to an inbound Chinese Delegation of R&D companies and investors, and the release of a report highlighting the economic benefit of clinical trials to Australia and benchmarking the country's progress in developing this vital industry. We have worked with industry bodies and policy makers to streamline the regulatory environment, formalised agreements and signed memoranda of understanding with CRCs and industry organisations, as well as presenting Australia's value proposition onto the world stage and helping Australian industries prepare for the global market.

Benchmarks are crucial to measuring progress towards our own goals. Accordingly, in the first year of the Sector Competitiveness Plan, we have collected metrics on outcomes that define the success of the sector. At the same time, we have established a plan for further data collection and yearly reporting that will provide ongoing, quantitative assessment of our performance.

In the following pages, we also outline MTPConnect's future priorities. While working towards the goals set out for years 2 and 3 of the SCP, we will be pursuing five key imperatives that align with Australia 2030: Prosperity through Innovation – a plan for Australia to thrive in the global innovation race (2030 Plan), a report released by Innovation and Science Australia in January 2018. These priorities, to develop education, industry, regulation and policies, research translation and commercialisation, and culture, support our efforts to boost the fortunes of the MTP sector through the pursuit of our own Sector Growth Priorities.

We thank you for your engagement in our efforts to promote some of the industries that are most central to Australia's future growth, health and prosperity. We hope you will follow our activities in 2018 with interest, and look forward to providing you with future news of our achievements.

Bronwyn Evans

Chair
MTPConnect

Sue MacLeman

Chief Executive Officer
MTPConnect

3. Executive summary

MTPConnect is an independent, not-for-profit organisation that champions a sector-led approach to accelerating the growth of the medical technology, biotechnology and pharmaceutical (MTP) ecosystem in Australia. It has been established as part of the Australian government's Industry Growth Centres Initiative.

The Industry Growth Centres Initiative is an industry-led approach that drives innovation, productivity and competitiveness by focusing on areas of competitive strength and strategic priority.

The initiative is designed to help Australia transition into smart, high-value and export-focused industries. It enables national action on key issues such as collaboration, commercialisation, international engagement, skills and reform of regulation. It drives excellence rather than dependence, and will create an economy that ensures Australia's ongoing prosperity.

The MTPConnect Sector Competitiveness Plan (SCP) developed in 2016 outlined a 10-year vision for the MTP sector, focusing on the Sector Growth Priorities for achieving sustainable growth and increased competitiveness over that period.

The Sector Growth Priorities have been developed as a guide for the entire MTP sector and are long term in nature and remain relevant for the 2018 Sector Competitiveness Plan. The sector priorities also inform MTPConnect's goals and objectives. MTPConnect's role in the sector is defined around three key pillars, and four objectives outlined below.



Our three pillars

Taking Action

Undertaking highly targeted actions to foster connection and collaboration

1

Independent Voice

Listening to the sector to provide an independent voice to shape policy and regulatory renewal, and influence the direction of funding

2

Projects Investment

Jointly funding targeted, sector-led projects to address identified constraints and gaps

3

¹ Further information about the Industry Growth Centres Initiative is available at www.business.gov.au/industrygrowthcentres.

² pp14-29, *Medtech, Biotechnology and Pharmaceutical Sector Competitiveness Plan*, December 2016



MTPConnect's mandate as an Industry Growth Centre is focused on four key objectives:

1. Improving coordination and collaboration between research and industry, and within industry, to achieve stronger commercialisation outcomes.
2. Improving the management and workforce skills necessary for sector growth.
3. Improving the sector's capability to engage with international markets and access global supply chains.
4. Identifying opportunities to address regulations that are unnecessary or overly burdensome and are impeding growth.

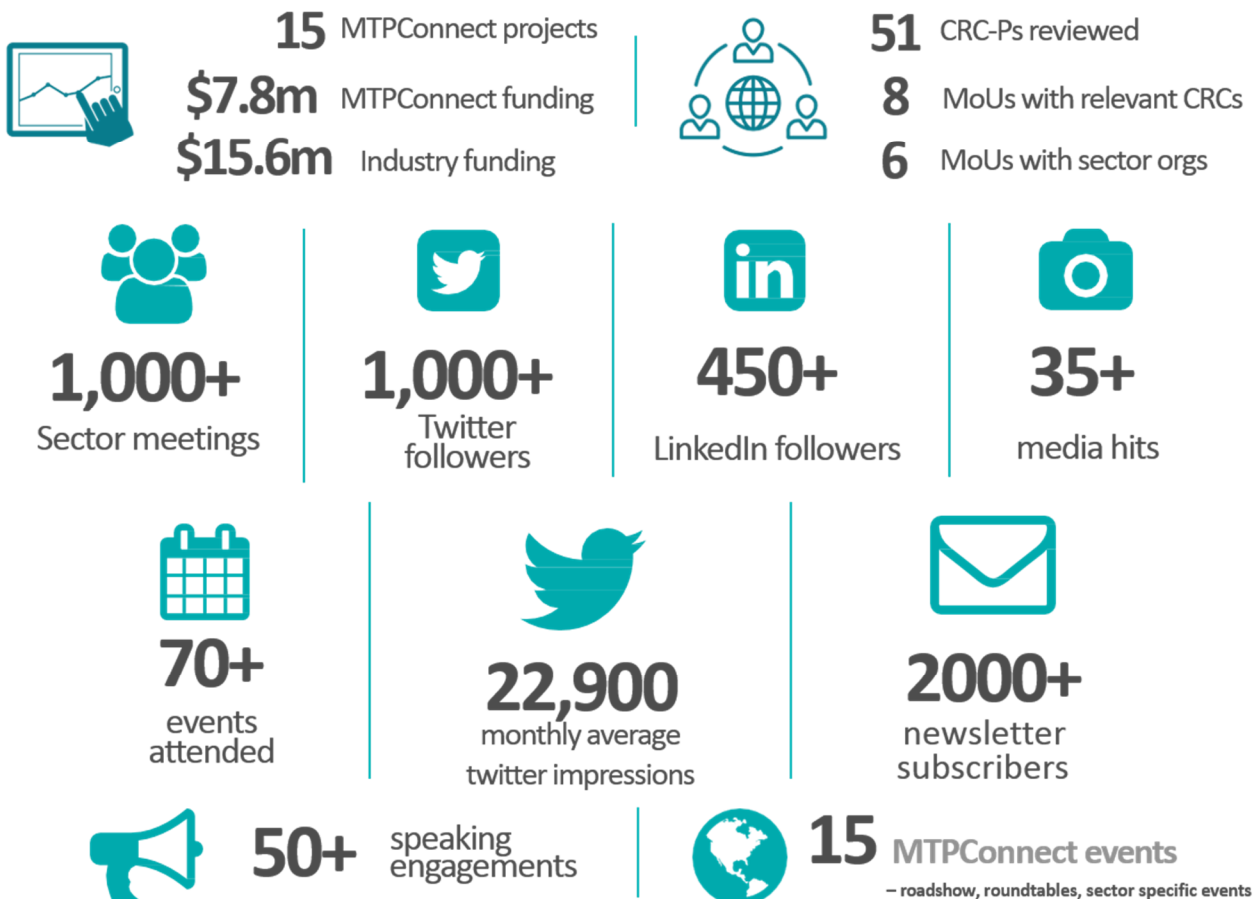
In the first year, 2016–17, MTPConnect laid the foundations for Australia to realise its potential advantages in the global MTP sector. The initial focus was on creating a deeper understanding of the barriers and constraints and undertaking actions expected to lead to rapid improvements. Activities for rapid impact include working with sector stakeholders to address regulatory hurdles, fostering better engagement of sector participants with each other and the international environment, building management and workforce skills, and improving access to information and education around development and commercialisation. We have assisted several entities with their competitive grant applications for translational and industry-focused product development, to promote better alignment with sector growth priorities. Our practice of providing feedback to both successful and unsuccessful grant applicants is helping researchers to improve their commercialisation focus.

MTPConnect has supported networking and engagement, forging stronger connections between research and industry to address knowledge gaps, and support enhanced commercialisation of sector innovations. In support of this objective, MTPConnect has held meetings, speaking engagements and events, and developed memoranda of understanding (MoUs) for collaboration with leading medical technology and pharmaceutical organisations, industry bodies, and Cooperative Research Centres (CRCs) to complement existing programs. The organisation has co-funded accelerator programs that support innovation and assist entrepreneurs in developing the workforce and management skills which are key to successful commercialisation. In particular, MTPConnect has focused on building connections between commercial and academic programs which formerly had limited contact. These connections are key to future collaboration between research and industry and addressing Australia's translation and commercialisation gap. The organisation has also worked to educate Australian companies on global industry best practice.

Consultation with the MTP sector identified a range of regulatory issues that were having a negative effect on the ability of small and medium sized businesses to grow and expand overseas. Over the past year, MTPConnect has engaged with the Therapeutic Goods Administration (TGA) to renew, harmonise and streamline these regulations.

This document reports on MTPConnect's year 1 progress in relation to the goals and priorities established in the 2016 SCP.

Spreading the word: Engagement and impact



Statistics as at 30 June 2017.



4. MTP Sector and growth priorities

4.1 Sector growth priorities

Australia's medical technology, biotechnology and pharmaceutical (MTP) sector has many strengths. If it is to remain sustainable and increase its contributions to Australia's economy and public health, it must continue to grow.

MTPConnect, as part of the Australian Government's Industry Growth Centres Initiative, helps to set priorities that are important to the growth of the MTP sector. While Australia has a vibrant research sector, its commercialisation productivity is behind that of other leading research countries. Australia's falling position in the Global Innovation Index 2017, which measures Australia's total innovation ranking including medical technology and pharmaceuticals, reflects this: we ranked 12th in innovation input but 30th in innovation output, having fallen from 22nd place in 2014.

MTPConnect's vision is for Australia to retain current and planned levels of expenditure in research and development (R&D) while achieving greater success in commercialisation. The MTP sector must create more products that reach the proof-of-concept phase and early-stage commercialisation; it must increase the number of medium to large companies that can claim late-stage product successes; and it must maximise the value of any intellectual property monetisation events along the way. The overall effect of these achievements would be greater employment and wealth creation for Australia.

The Sector Competitiveness Plan presented in 2016 identified seven Sector Growth Priorities that underpin this vision, each addressing specific elements of the MTP value chain:

Sector		Growth				Priorities
SECTOR GROWTH PRIORITIES		Basic research	Preclinical research & development	Clinical development	Manufacturing	Market access, marketing, sales and service
P1	Identify and invest in Knowledge Priorities focused on current and future market needs					
P2	Create a highly productive commercialisation environment from research to early clinical trials and proof-of-concept					
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 digitally enabled MTP solutions: devices and data analytics*					
P6	Position Australia as the preferred partner for emerging Asian markets					
P7	Support advanced manufacturing as a part of the Australian innovation ecosystem					

Note: * Some of the technologies and solutions within P5 do not fit the traditional MTP value chain and will have much shorter development and implementation pathways

The Sector Growth Priorities and their objectives are detailed in the [2016 MTP Sector Competitiveness Plan](#).



There are a number of constraints and gaps that must be overcome to achieve the Sector Growth Priorities. While we have seen improvement in all of these (from policy, funding and focus, regulation, global supply chains, commercialisation and collaboration, and skills) we still have work to do in further closing the gaps. Please refer to the original SCP for a more comprehensive discussion of these constraints and barriers.

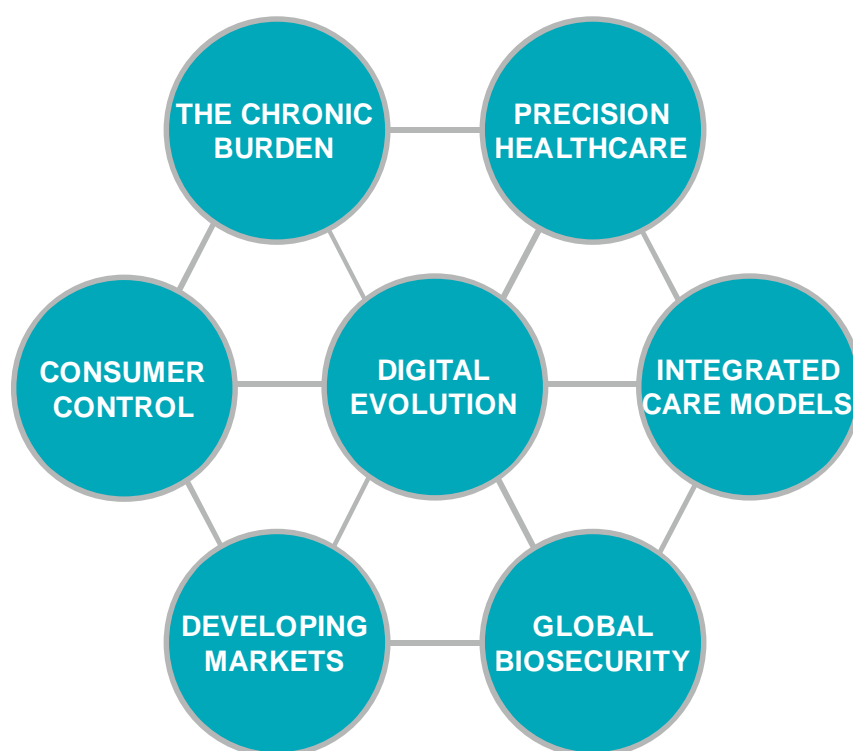
4.2 Global megatrends

The MTPConnect Sector Competitiveness Plan and Sector Growth Priorities address three key areas that are vital to the sector's growth. These are:

1. expected future challenges and opportunities.
2. identified areas for regulatory renewal.
3. knowledge priorities, which align the sector's research needs with market requirements and the goal of optimising commercialisation opportunities.

In doing so, the plan takes into account global megatrends---the overarching social, economic, environmental, technological and geopolitical forces that will shape the future. Such megatrends are often disruptive; they change existing business models and present opportunities and challenges for organisations. Seven megatrends have been identified that will significantly affect the Australian MTP and broader healthcare sector over the next 20 years:

Megatrends

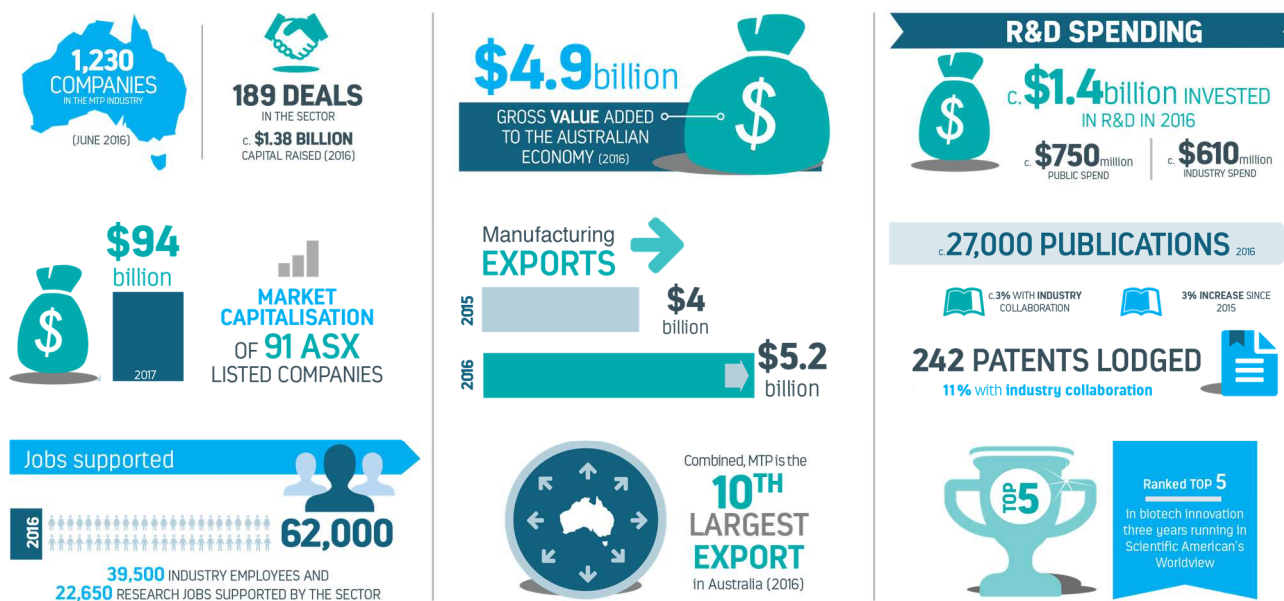


These megatrends are described in detail in the MTPConnect Sector Competitiveness Plan issued in December 2016.

4.3 Sector metrics

MTPConnect has invested in creating a consistent set of sector wide metrics to track and measure sector competitiveness and growth over the long term. Prior to this effort, a consistent and holistic set of metrics for the entire MTP sector did not exist. MTPConnect will continue to measure and report these key metrics to provide a transparent measure of sector progress and performance over time.

Australia's vibrant medical technology, biotechnology and pharmaceutical sector at a glance

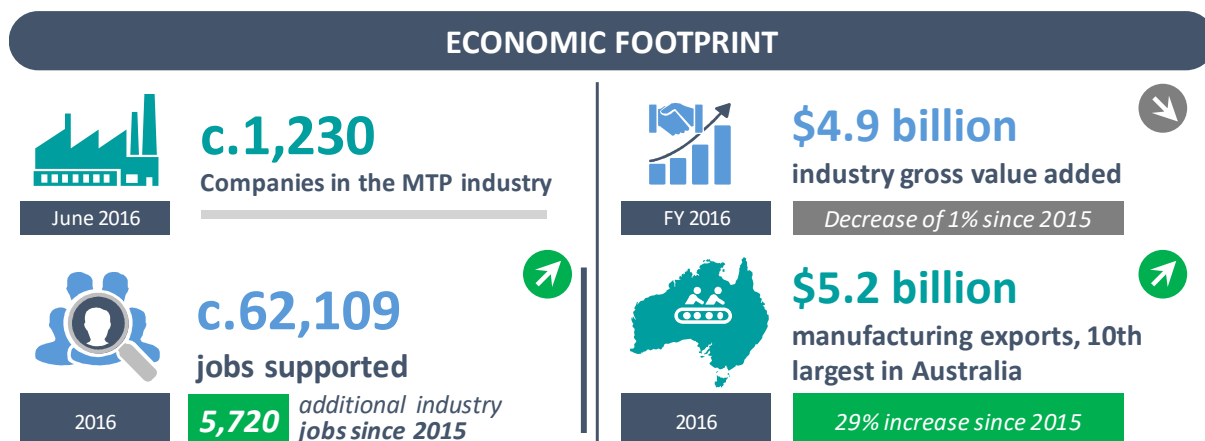


*Data collected by MTPConnect and L.E.K. Consulting 2017

Trends in the MTP sector

Economic footprint

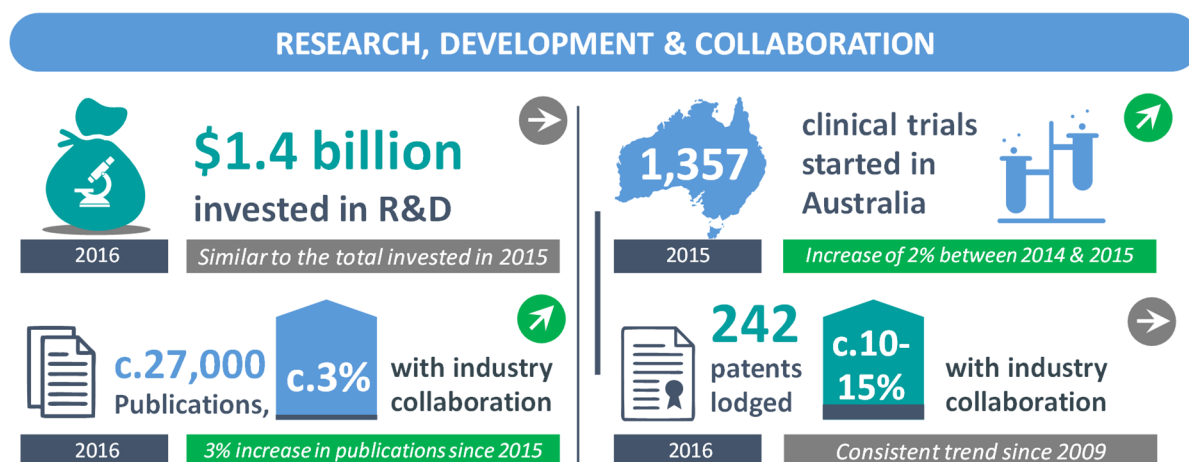
At an economic level, the sector is comprised of 1,230 companies, generates employment for over 62,000 employees and delivers \$4.9 billion of gross value added. The sector is the 10th largest export sector in the Australian economy. The sector is moving in a positive direction, generating 5,720 additional industry jobs and export growth of 29% between 2015 and 2016.



R&D Activity and Collaboration

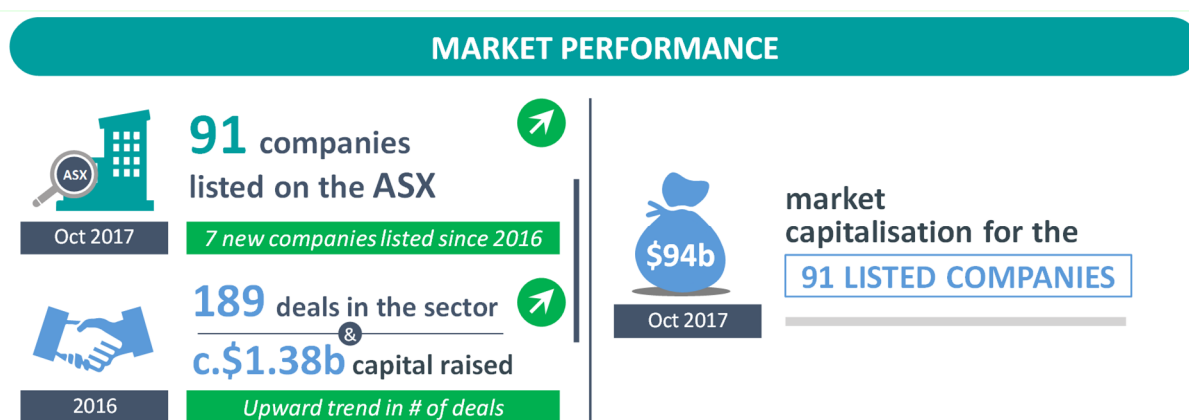
The level of R&D activity has been increasing in recent years. The number of publications from research organisations, and the number of clinical trials, has been growing steadily at rates of 7.7% and 2.2% p.a. respectively from 2012 to 2015. While the value of R&D investment has remained largely flat between 2010 and 2016, both the Medical Research Future Fund (MRFF) and the Biomedical Translation Fund (BTF) are likely to result in increasing public grants and R&D investment from 2017 onwards.

While research activity has been steadily increasing, collaboration between researchers and industry needs to improve. The proportion of publications that involve collaboration with industry has been consistent at c.2.8% and below the levels experienced in countries with a high innovation index.



Market Performance

The level of commercial and deal activity is also following a positive trajectory as measured in the number of publicly listed MTP companies, deal activity and funds raised in the sector. Australian companies raised \$1.38 billion in 2016 through capital raising and IPOs.





5. MTPConnect goals and actions

5.1 How MTPConnect supports sector growth

The Medical Technologies and Pharmaceuticals Growth Centre, MTPConnect, was formed as a not-for-profit company in November 2015 as part of the Federal Government's Industry Growth Centres Initiative. The organisation was established to champion an industry-led approach to the development of the MTP sector and to drive innovation, productivity and competitiveness by focusing on areas of competitive strength and strategic priority.

MTPConnect plays an integrating role across the sector, driving regulatory and policy change; coordinating activities between sector participants; facilitating deeper collaboration between research organisations, healthcare service providers and industry; and accelerating the development and progress of innovative companies.

MTPConnect's Role



Our three pillars

Taking Action

Undertaking highly targeted actions to foster connection and collaboration

1

Independent Voice

Listening to the sector to provide an independent voice to shape policy and regulatory renewal, and influence the direction of funding

2

Projects Investment

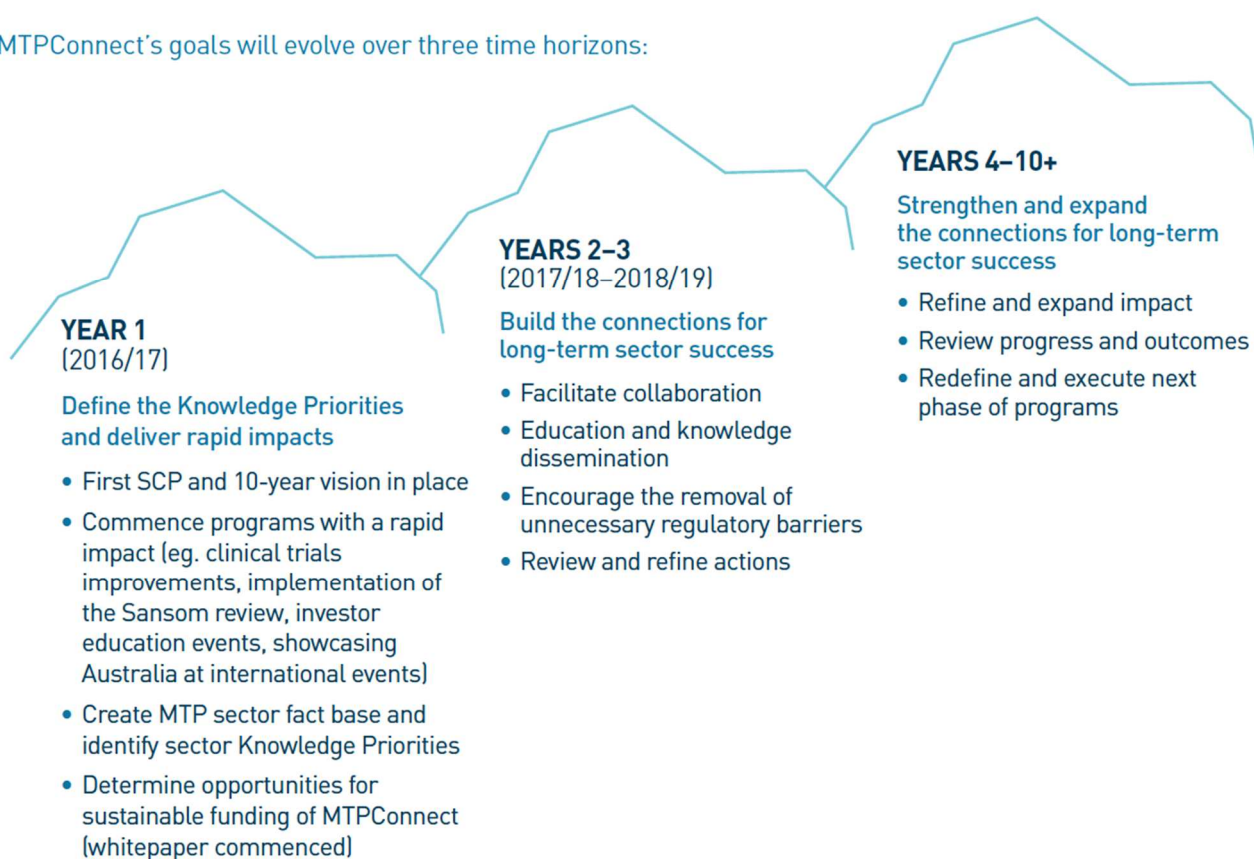
Jointly funding targeted, sector-led projects to address identified constraints and gaps

3

Within these three pillars, MTPConnect's specific goals and actions will evolve over the next 5 to 10 years as the organization grows in maturity and creates the necessary connections for success. The goals outlined in the 2016 SCP and captured on the following pages reflect the near term and longer term goals MTPConnect has been working towards.



MTPConnect's goals will evolve over three time horizons:



5.2 Year 1 update

In the 2016-17 year, MTPConnect has supported the creation of educational tools, workforce and skills development programs, and commercialisation resources for the MTP sector. In parallel, we have brought together academic and industry players to create better relationships for commercialisation, and worked to streamline and modernise regulation impeding growth in the sector. Below, we outline some of the key achievements so far in relation to these areas of focus.

Stronger ties: Improving coordination and collaboration

Australia needs practising clinicians, industry, and researchers to be closely linked if the MTP sector is to create commercially viable outputs that are focused on practical health applications or needs. MTPConnect engages with the sector through meetings, speaking engagements and events, and by developing memoranda of understanding (MoUs) for collaboration. It has also used the Project Fund Program to co-fund projects that improve engagement between research and industry, including commercialisation training and development accelerators.

Projects to date have included the Bridge Program, The Actuator: Australia's National Medtech Accelerator, ANDHealth: The National Digital Health Accelerator, the Perth-based Centre for Entrepreneurial Research and Innovation, and the National Medical Device Partnering Program.



National Medtech Accelerator – The Actuator

This national medical-devices accelerator is to assist around 10 companies each year that are commercialising discoveries made in universities, research organisations and hospitals. The Actuator gives assistance on IP, regulation and legal aspects of commercialisation in dedicated co-working spaces in three states, and is planned to expand in the coming year.

National Digital Health Accelerator – ANDHealth

Each year, this accelerator will help roughly seven early-stage companies in developing an evidence-based digital health product. ANDHealth will assist these companies with contributions towards specialist advice as well as mentors to develop their product for future investment. The first cohort of six evidence-based digital companies has been recruited, and all 55 applicants have been given feedback and assistance where applicable.

The National Medical Device Partnering Program (NMDPP)

MTPConnect supported the national expansion of this scheme piloted in Adelaide. Companies with a medical device product, at any stage in its life cycle, are partnered with designers and engineers at a university or research institute to develop their device. This support can be used to produce a proof of concept, technical or aesthetical progress, or a small clinical trial. The companies involved get an improved device, and the students and researchers get the experience of working on a real-life technical challenge.

In June 2017, MTPConnect released a report on the economic benefits of clinical trials in Australia. The organisation is also funding the Clinical Trials in Australia project, where over 28 companies in the MTP sector partner to select a number of projects to commit to in working collaboratively towards improving the clinical trials industry in [Australia](#).

MTPConnect continues to engage with the sector on the current constraints and barriers to growth, and on potential solutions that will drive change.

2016-17 highlights

- 200 students across Victoria participated in an event to connect students with 55 industry representatives at Medtech and Biotech Mingle Melbourne (with RMIT and the Ribit job-matching platform created by CSIRO-Data61)
- 8 MoUs signed with Cooperative Research Centres (CRCs)
- 6 MoUs signed with leading medical technology and pharmaceutical organisations and industry bodies to drive sector awareness, understanding of MTPConnect Sector Growth Priorities, collaboration and Project Fund participation
- Involved in precinct taskforce to attract medical investors to Gosford Health and Wellbeing Precinct
- Brought together over 100 sector participants to collaborate on commercialisation projects



Greater capability: Improving management and workforce skills

The Australian MTP sector faces the ongoing challenge of developing, attracting and retaining talented researchers, business development and managerial staff in a competitive international environment. In addition, it faces a shortage of skills in enabling disciplines such as bioinformatics, health economics, regulatory affairs and data analytics.

MTPConnect has used the Project Fund Program to co-fund projects to improve management and workforce skills in the sector, including the following:

The IMNIS MedTech-Pharma and STEM Program

MTPConnect is helping ATSE expand this scheme to a national level. The scheme is designed to encourage regular communication, with career coaching and industry networking just two of the opportunities available to these PhD students.

The program was increased to include 141 students at 11 universities across four states (VIC, NSW, QLD and SA) in 2017, with the expansion to the remaining states planned in the coming year.



The Bridge Program

Initiated by 15 organisations in the MTP sector, including multinational pharmaceutical companies, this program has engaged and trained up to 200 mid-career researchers and SME employees on pharmaceutical commercialisation. The first cohort of 101 students has completed the course, culminating in a three-day residential and attendance at the AusBiotech conference. The second cohort for this program is currently being recruited.

The Centre for Entrepreneurial Research and Innovation (CERI)

This project, which is part of the national Accelerating Australia project, involves 19 universities and companies, and brings together entrepreneurs to form multidisciplinary teams. Accelerating Australia sponsored 10 students to attend the SPARK design course in Japan, transforming their mindsets and developing opportunities for them.

In addition, MTPConnect has presented a number of training sessions and discussions with the Department of Industry, Innovation and Science Entrepreneurs' Programme and Accelerating Commercialisation.



2016–17 highlights

- Industry mentors connected with 141 PhD students.
- Engagement between 150 MTP manufacturers, interested sector participants, and international representatives of the Pharmaceutical Inspection Co-operation Scheme, including the United States Food and Drug Administration (FDA), the British Medicines and Healthcare Products Regulatory Agency (MHRA), and the Australian Therapeutic Goods Administration (TGA), as well as industry leaders and government representatives.
- Partnered with MedTech's Got Talent 2017 providing entrepreneurs and start-ups with workshops, mentoring and training to help with pitching, commercialisation, branding and development of medtech innovations.

Less red tape: Identifying opportunities to streamline regulations

Unnecessary or over burdensome regulations impede the growth of industry. Following the Sector Competitiveness Plan, MTPConnect is working with the sector to:

- Support industry engagement with TGA on the Sansom Review of Medicines and Medical Devices Regulations.
- Streamline clinical trials regulation to enhance Australia's attractiveness in a global marketplace.
- Share international best practice for 3D-printed medical device regulation and market access.
- Share international best practice on precision medicines to ensure rapid regulatory review, approval and access.
- Share technology trends emerging in the future technologies area (including digital solutions).
- Support industry engagement with the TGA for medicinal cannabis product approval and access.

Intellectual Property Review and the MTP Sector

The Australian Government engaged the Productivity Commission to undertake a 12-month public inquiry into Australia's intellectual property system, releasing the Intellectual Property Arrangements report. MTPConnect worked with the Department of Industry, Innovation and Science to highlight and provide insight on issues relevant to the sector, including data exclusivity; patent term extensions; the use of renewal fees as a policy lever; differences between generics, biosimilars and biologics; opportunities to strengthen innovation patents and the need to remain globally attractive for business.

³ <http://www.medtechchallenge.com/>



International engagement and excellence: Improving the sector's capability for international engagement and access

The Australian MTP sector operates within a global market, and companies need to develop their products with the world in mind. As well as sending delegations to international events, MTPConnect has used the Project Funds Program to co-fund projects that improve international engagement.

Activities to date have included a comprehensive global investment education program for the Australian life science sector, including companies, investors and researchers. This project is coordinated by AusBiotech, a key industry organisation in the MTP sector, with partners including ASX, Dibbs Barker, WE Buchan and KPMG, to provide companies with the training and access to be competitive on a global scale, and educate the investment sector in Australia and overseas about the opportunities in Australia. The first of three documents to come out of this project has been launched—Roadmap to a Successful IPO for Life Science Companies—an investment series tour to China has been hosted, and a course on pitching to investors provided.

Monash University is also leading a project to extend the Canadian Centre for Regenerative Medicine (CCRM) to Australia. This will involve exploring the CCRM's networks in Canada, Japan and Europe, as well as exposing Australian experts and research to the CCRM community to spur progression of and investment into Australian innovations.

MTPConnect executives travel domestically and internationally to attend and present at conferences and exhibitions, developing the market presence of MTPConnect and the Australian MTP sector, and fostering relationships and partnerships.

MTPConnect continues to work closely with Austrade to showcase Australian success stories and the world-class research and development capability Australia has to offer. Activities in this area have included the BioKorea mission, the Minister for Trade's mission to Japan, the European Innovation delegation in April 2017, the inbound investment mission from China in May 2017, and the BIO International Convention held in San Diego in June 2017, at which MTPConnect developed strategic linkages.



Engagement highlights

MTPConnect delegates participated at the following events.

- The Medtech Conference, 2016
- BioKorea 2016 and 2017
- BIO 2016 and 2017
- Japan mission with Steven Ciobo, the Minister for Trade, 2017
- Australia Business Week in India, 2017
- Asian Investment Series (Singapore, Hong Kong and China), 2017
- Chief scientist's innovation delegation to Europe 2017
- Medical Fair India, 2017
- BioEurope 2016
- TCI conference, 2016



Building the future: Laying the foundations for long-term impact

Sector fact base and knowledge priorities

To measure and track the development of the MTP sector, MTPConnect has developed a database of statistics and measures of collaboration and impact that can be remeasured in future years [see Figure on p9]. The fact base consolidates data from the R&D Tax Incentive office, Entrepreneurs' Programme and the Australian Bureau of Statistics. We have collaborated with Medicines Australia and the Medical Technology Association of Australia to include relevant sector metrics for medtech and biotech as well. A clinical trials report contains year-on-year statistics for the clinical trials industry, which can be built on for future years.

Access and resources

Objective-based activities were supported by a range of education and access tools for the sector. In the past year, this included an education portal containing information on product development and commercialisation progress, and resources available to address the continuum of innovation, including key regulatory, IP, legal, quality and manufacturing aspects. MTPConnect is also working with key stakeholders like the TGA to provide better resources that can be linked into MTPConnect's web portal, and has begun consultations with the TGA on a regulatory education strategy for SMEs. MTPConnect has also included information to inform sector participants to the funding opportunities in their area and the related application guidelines.

Sustainable funding

MTPConnect continues to explore options for ongoing funding and investment to sustain the organisation past the four-year period of initial funding from the Department of Industry, Innovation and Science.

The exploration of possible options was intended to ensure that MTPConnect does not duplicate existing efforts or initiatives in the sector, and that funding options would enhance the organisation's reputation and fulfil its larger objectives while generating income.

Government funding provides an important endorsement, helping to maintain MTPConnect's reputation along with its unique capacity to foster collaboration between government and the MTP sector.

Project Funds

A key achievement to date has been the investment of over \$15 million into initiatives supporting the MTP sector, which have attracted more than \$31 million in co-contributions from industry. See appendix for further details of all project initiatives co-funded by MTPConnect and sector participants.



6. Future areas of focus

MTPConnect's goals for years 2 and 3 of the Sector Competitiveness Plan will build on the organisation's excellent reputation and address the need to forge connections crucial to the long-term success of the sector, to facilitate collaboration, to promote education and the dissemination of knowledge, to encourage the removal of unnecessary regulatory barriers, and to review and refine actions being taken.

MTP-sector metrics have been collected and a plan for yearly reporting established. Ongoing arrangements are in place for the collection of data on six broad outcomes that define the success of the sector.

The majority of MTPConnect's actions to date, and those planned in future, focus on commercialisation and have been directed to address Sector Growth Priorities 1 to 4, with projects funded in line with the goal of addressing all of the priorities. These actions will be reviewed on a regular basis and amended as needed to ensure that they address the sector's evolving needs.

Facilitate collaboration

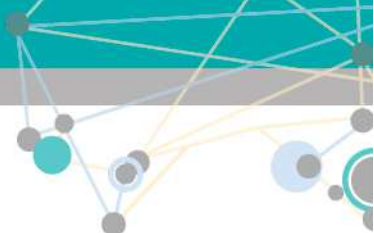
Building on a strong basis of connections already forged with the Australian MTP sector, and through its positioning as a coordination point for MTP-sector stakeholders, MTPConnect will continue to facilitate and foster collaboration between parties within and relevant to the MTP sector through delivery, attendance at and sponsorship of key meetings and events.

Specific actions include:

- Holding and co-badging forums to connect researchers, industry and end users (clinicians, state departments) and to identify unmet medical needs.
- Working with sector participants to identify and optimise relevant grant applications (including advice on possible consortium members) to align proposals and ensure that they address areas of unmet need in industry commercialisation.
- Ongoing engagement with clinical research centres to assist with research translation and commercialisation, and to celebrate successes.
- Support, promote and host networking events between research and industry, including linking health and biotech incubators to share best practices.
- Focusing on Asia to promote the Australian MTP sector, and to establish Australia as the Asia-Pacific hub for MTP.
- Ongoing collaboration with Austrade, support and delivery of trade missions, and international travel to showcase and forge connections with the Australian MTP sector, and between the sector and its counterparts and markets abroad.

Educate and disseminate knowledge

MTPConnect plays a key role in aggregating, curating and disseminating critical information that assists stakeholders and participants to connect with opportunities, resources and initiatives available in the sector. This helps to ensure students and researchers are given the skills necessary for commercial success, and to support successful commercialisation for SMEs.



Specific actions include:

- Engaging with funding bodies to encourage inclusion of commercialisation factors in sector rankings and grant assessment criteria, and encouraging increases to translation and commercialisation-focused grant programs.
- Engaging with sector participants, funding bodies and universities to highlight the need to focus training and development in digital priority skill areas.
- Sector and government engagement on development and focus of VET and skills-training packages specifically applicable to the MTP sector.
- Developing case studies showcasing successful translation of focused research into commercial outcomes, national and international best practice, and positive stories of the MTP sector's contribution to society.
- Encouraging greater focus of research spending on Knowledge Priority areas with recommendations for focus areas and links to commercialisation outcomes.
- Ongoing work to establish best practice graduate and internship programs that link researchers and industry to encourage exchange of information and skills, drive SME employment, and promote roles in advanced manufacturing.
- Showcasing funding and grant opportunities from government schemes to the sector through meetings and presentations.
- Promoting programs to support the early stages of start-up and company formation.
- Driving investment through promotion of the benefits of investing in the Australian MTP sector.
- Developing an SME education program to maximise negotiated funding outcomes, out-licensing arrangements or divestment.
- Coordinating with Austrade on a consolidated calendar for marketing and promoting the Australian MTP sector to the global market, particularly in Asia, and organising and supporting both outbound and inbound missions.
- Providing advice, guidance and connections to international market experts to help prepare Australian companies for international expansion.



Encourage the removal of unnecessary regulatory barriers

In line with the recently released 2030 Plan, MTPConnect is continuing its close engagement with the Australian Government to create a more flexible regulatory environment that fosters innovation. MTPConnect will continue its close work with the sector to understand the restraints and barriers that exist and develop recommendations and actions to overcome hurdles to drive further collaboration and commercialisation.

Specific actions include:

- Holding roundtables and “future forums”, and delivering white papers on future trends and significant growth areas including digital health, precision medicine and 3D printing, to help government develop appropriate responses and identify areas for regulatory renewal.
- Working with government to ensure it takes a long-term view of regulation and policy affecting the industry.
- Ongoing support and development of the Australian clinical trials industry, building on sector roundtables and the MTPConnect economic profile and competitive advantage report.
- Working with the Australian Digital Health Agency and other peak bodies to encourage better data linkages for e-health records, clinical trials, standards and regulation.
- Encouraging better linkages across public and private data sets to develop Australia’s data assets into a platform for commercial success.
- Working with the TGA to position Australia as the go-to for regulatory best practice in South-East Asia, taking the lead to harmonise regulatory regimes and help Australian exporters.

Review and refine actions

The MTPConnect team and board meet at monthly, quarterly and yearly intervals to report on and review actions and deliverables, ensuring their alignment with MTPConnect’s role, its 10-year vision for impact according to primary metrics, and the Sector Growth Priorities.

The MTPConnect business plan is currently under review and is due for submission to the Department of Industry, Innovation and Science in the second quarter of 2018.

MTPConnect will be undertaking a sector survey to gauge sentiments, understanding and perceptions of the impact, benefits and services of MTPConnect and its projects. This survey will also help to identify further opportunities for programs and development, and to guide future strategy and programs.

7. Appendix: Projects co-funded by MTPConnect to address sector priorities

Project Title	Brief description of project	Consortium members (Lead in Bold)
Industry Mentoring Network in STEM (IMNIS) program	Aiming to narrow the cultural gap that exists in Australia between business and academia through the Industry Mentoring Network in STEM (IMNIS) program, developing and delivering a national mentoring program linking PhD students with qualified industry mentors.	Australian Academy of Technology and Engineering. AusBiotech
The Actuator	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.	STC Australia. Artesian Venture Partners
Upgrade CSIRO Protein Production Platform	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.	CSIRO. Monash University
BioFab3D@ACMD	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 with a vision to build biological structures such as organs, bones, brain, muscle, nerves and glands.	St Vincent's Hospital (Melbourne) Limited. University of Melbourne, University of Wollongong, Swinburn University of Technology, RMIT University, Stryker Australia Pty Ltd
ANDHealth	Creating an integrated ecosystem for the development & commercialisation of evidence-based digital health products.	ANDHealth. Murdoch Children's Research Institute, Planet Innovation, Curve Tomorrow, Royal Children's Hospital, HealthXL, GP2U Telehealth Pty Ltd, AusBiotech, RMIT University, Novartis Pharmaceuticals
Comprehensive Global Investment Program for Life Sciences	Development of a comprehensive global investment education program for the Australian life science sector - companies, investors and researchers.	AusBiotech Ltd. ASX, Dibbs Barker, WE Buchan, KPMG
Australian Centre for Regenerative Medicine	CCRM Australia, an Australian hub of Canada's Commercialization Centre for Regenerative Medicine (CCRM), will support the development of foundational technologies to accelerate the commercialisation of regenerative medicine products and therapies.	Monash University. CSIRO, CCRM Canada, Cell Therapies, St Vincent's Institute of Medical Research, AusBiotech Ltd

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Hit ID platform	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.	Cancer Therapeutics CRC Pty Ltd (CTx). UniQuest, Walter and Eliza Hall Institute (WEHI), Children's Cancer Institute (CCI), Griffith University / Compounds Australia
Pilot Implementation of the Australasian Tele-Trial Model	Clinical Oncology Society of Australia (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.	Clinical Oncology Society of Australia (COSA). Rare Cancers Australia, Cancer Voices Australia, Australian Institute of Tropical Health and Medicine (AITHM), Garvan Institute of Medical Research, The Walter and Eliza Hall Institute of Medical Research (WEHI), Icon Group, c/- Icon Consolidated Holdings P/L, St John of God Hospital, Medicines Australia, AbbVie Pty Ltd, Janssen, Novartis Pharmaceuticals Australia Pty Ltd, Pfizer Australia Pty Ltd
National Medical Device Partnering Program (NMDPP)	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.	Flinders University. CSIRO, STC Australia, Medical Technology Association of Australia
Vaccine research in Australia: Landscaping capabilities and relevant service	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. Delivery of Australia's first national Vaccine conference.	Vaxine Pty Ltd. Mylexa Pty Ltd, Australian Respiratory and Sleep Medicine Institute Ltd
The Bridge Program	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.	Queensland University of Technology (QUT). Abbvie, Amgen, Australian Private Equity & Venture Capital Association Limited, Bristol-Myers Squibb Australia, Medical Research Commercialisation Fund, Boehringer Ingelheim, Celgene, CSL Limited, Janssen-Cilag, Macquarie University, Medicines Australia, Merck Sharp & Dohme (Australia), Mundipharma, Novartis Pharmaceuticals

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Accelerating Australia	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.	Centre for Entrepreneurial Research and Innovation (CERI). The University of Western Australia, Monash University, University of Sydney, SPARK Co-Lab Ltd, University of Technology Sydney, Proteomics International Limited, Orthocell Ltd, St John of God Healthcare, Avita Medical, Adelaide University, Murdoch University, Curtin University, Edith Cowan University, Harry Perkins Institute of Medical Research, Telethon Kids Institute, Lion's Eye Institute, Ear Science Institute of Australia, Perron Institute for Neurological and Translational Science Limited
Biofabrication Institute	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.	Queensland University of Technology. Hear and Say, Metro North Hospital and Health Service
Clinical Trials: Impact and Quality (CT:IQ)	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.	Bellberry Limited Australian Clinical Trials Alliance Limited (ACTA), The George Institute for Global health (TGI) & George Clinical (GC), NHMRC Clinical Trials Centre (CTC), with over 25 expressions of interest from industry and other key stakeholders
Australia-China Life Sciences Partnership Program	To increase awareness and opportunities for communication, collaboration and commercialisation between the life sciences sector in Australia and China. It will also deliver high quality, collaborative research and industry projects as well as valuable data analytics on commercial engagement between the two countries.	AusBiotech Ltd. Asialink Business, China BlueSky Partners, FB Rice, KPMG, King & Wood Mallesons, Therapeutic Innovation Australia
AMMRF Technical Voucher Fund	The scheme will fund vouchers to support MedTech R&D by providing easy and discounted access to Australian Microscopy and Microanalysis Research Facility (AMMRF) microscopy services, reducing existing barriers to use.	The University of Sydney. University of Queensland, University of Western Australia, University of NSW, University of Adelaide, University of South Australia, Australian National University, Flinders University
Ab-initio pharma Formulation and GMP product manufacturing services for clinical trials in Australia	Establishment of a Ab-initio, a unique pharmaceutical product design, formulation, manufacturing and training facility that provides cost effective solutions for small-to-medium enterprises, academics, clinicians and larger pharma for early phase clinical trials in Australia.	The University of Sydney. Sydney Local Health District NSW, ARCS Australia

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ClinTrial Refer Australia Improve integrated platform development	Developing a new IT platform connecting doctors and patients to recruiting trials across research networks. This project will integrate 19 ClinTrial Refer derivative apps, create one combined database, new search functions, enable electronic referrals, link to ANZCTR and build a national solution to trials recruitment.	South Eastern Sydney Local Health District and Sydney Local Health District. University of Sydney, Linear, Australian Clinical Trials Alliance (ACTA), Australian New Zealand Clinical Trials Registry (ANZCTR), ClinicalTrials Connect, Research4 Me, Amgen, Canteen
Accelerating Australia – Stage 2	Facilitating translation of biomedical research through entrepreneurial experience courses and support services, to improve collaborating across sectors, organisations and disciplines to identify promising biomedical products and assist in bringing them to production.	Centre for Entrepreneurial Research and Innovation (CERI). The University of Western Australia, Monash University, The University of Adelaide, The University of Melbourne, University of Technology Sydney, The University of Sydney, SPARK CoLab, Western Australia Orthocell, Avita Medical Ltd, Proteomics International, Murdoch University Australia, Curtin University, Edith Cowan University, Macquarie University, Harry Perkins Institute of Medical Research, Telethon Kids Institute, Lions Eye Institute, Ear Science Institute Australia, Perron Institute for Neurological and Translational Science Australia, St John of God Healthcare, SPARK Global USA, Linear Clinical Research, Cook Medical, Translational Research Institute, Illawarra Health and Medical Research Institute, University of Wollongong , RMIT, The University of Newcastle, Centre for Nanoscale BioPhotonics, ASCEPT, Knowledge Translation Australia
The Bridge Tech Program	Providing mid-career, senior entrepreneurs and scientists with access to relevant, specific commercialisation training, medtech conferences and internships. The program will be delivered by companies, universities and industry operating in the sector through online mediums, residential training, and networking events.	Queensland University of Technology. Siemens Healthcare, Stryker, Cook Medical, Hydrix, IDE Group, Flinders University, Magnetica, Cicada Innovations, Ellume, The Actuator, Immunexpress
Certara-Monash University Industry Fellowship Program	The Certara-Monash University Industry Fellowship Program will identify and develop the next generation of industry-experienced drug development pharmaceutical scientists with real world drug development experience through training in clinical pharmacology, pharmacometrics and regulatory science, who will help shape the future of the biotech and pharmaceutical industry.	Certara Australia Pty. Ltd. Monash University

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Building clinical trial capability and capacity to grow the MTP Sector	The MTP clinical trials sector is constrained in growth through lack of appropriately skilled and experienced workforce participants. This project aims to train and connect graduates with MTP clinical trial companies to equip them with job ready skills to meet this MTP sector gap.	ARCS Australia Ltd. QuintilesIMS Pty Ltd, Novotech Ltd, Clinical Network Services (CNS) Pty Ltd, PPD Australia Pty Ltd, George Clinical Pty Ltd, OnQ Recruitment Pty Ltd, Seerpharma Pty Ltd, UNSW, Sydney, University of Sydney, Monash University, St Vincent's Hospital, Pharma to Market Pty Ltd, Sydney Partnership for Education, Research, and Enterprise (SPHERE)
Enabling Precision Cancer Clinical Trials: A molecular profiling platform for the Australian clinical trials industry	This project will enable Australian SMEs to enhance clinical trials through access to the Garvan Institute's molecular profiling platform; including a clinically-accredited tumour genomic test, an analysis platform, and patient-matching capabilities to facilitate recruitment and optimise treatment.	The Garvan Institute of Medical Research. NHMRC Clinical Trials Centre, NSW Early phase Clinical Trials Alliance (NECTA), Genome.One, Linear Clinical Trials, Illumina Technology
Clinical Trial Assist – facilitating clinical trial recruitment in general practice	To provide funds for a feasibility study to develop and evaluate a model to support clinical trial feasibility assessment and patient recruitment in Australia by utilising a large general practice network and data set.	VentureWise Pty Limited. NPS Medicinewise Group, Prospection, The George Institute
Accelerating precision therapies through digital infrastructure for adaptive trials and trial-ready cohort studies	A feasibility study for the development of national digital infrastructure to support adaptive clinical trials and 'trial-ready' natural history cohort studies for a number of rare diseases. The digital study will improve efficiencies in drug evaluation through trial enrolment, data collection, and enabling analysis for novel trial designs.	Murdoch University. Telethon Kids Institute, Deakin University, RPH Medical Research Foundation, University of Western Australia, Shiraz Pharmaceuticals, Linear Clinical Research, Barwon Health, St John of God Subiaco, WA Department of Health, The Australian Atherosclerosis Society (AAS), Foundation for Angelman Syndrome Therapeutics Australia (FAST), MNDi Foundation, Princess Margaret Hospital, Life Science Innovation Forum for Rare Disease (APEC Economies), Cystic Fibrosis
The Healthy Living Design Hub	Funding to work with medtech companies to create customer-focused health solutions, offering real life testing for new health technology products and services. Programs focus on user-centered interactive design, translating ideas from concept to prototype with clear paths to market and long-term product development planning.	Swinburne University of Technology. Central Queensland University (CQU), Metro Trains Australia Pty Ltd, Cairns Taipans (NBL), CSIRO, Thermal Hyperformance Pty Ltd, Richmond Football Club Ltd. (AFL), Planet Innovation Pty Ltd

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Training Programs for the Biologics and Biomedical-based Industry Sector	The design and creation of training programs for companies associated with the R&D and advanced manufacturing of biologic medicines and biomedical sciences. The training program will improve the knowledge and skills base necessary for advancement of Australian industry in this sector.	Australian Institute for Bioengineering and Nanotechnology, University of Queensland. Abbvie, Australian Red Cross Blood Service (ARCBS), ACYTE Biotech, Avipep, CSL Ltd, LuinaBio, Patheon Biologics
Installation of robotic sterile finished product clinical trial manufacturing capability	Support for Pharmaceutical Packaging Professionals to add a fully robotic, sterile vial-filling line to manufacture Phase II and III products, to their facility, which can then be used by Australian companies to locally produce product for clinical trials.	Pharmaceutical Packaging Professionals Pty Ltd. Clinical Network Services
Operationalise the Centre for Commercialisation for Regenerative Medicine Australia (CCRM Australia)	Accelerating the commercialisation of Australian regenerative medicine therapies and related products, building on the 2016 Project Fund Program supported development of CCRM Australia as a hub, via training; fostering increased collaboration between industry and academia, both locally and globally; and nurturing local regenerative medicine companies.	Monash University. Australian Regenerative Medicine Institute (ARMI), CCRM (Canada), Bioplatforms Australia (BPA), Cell Therapy Manufacturing CRC, Australian National Fabrication Facility (ANFF), ReNerve Pty Ltd, Cynata Therapeutics Ltd, Regeneus Ltd, Australian Red Cross Blood Service, Therapeutic Innovation Australia (TIA), Industry Mentoring Network in STEM (IMNIS), Australian Institute for Musculoskeletal Science (AIMSS), Scinogy Pty Ltd, Bioforum (CCRM Israel), Ear Science Institute, CSIRO, Cell Therapies Pty Ltd, St Vincent's Institute of Medical Research, AusBiotech Pty Ltd
National MTP+D Live Showcase: Searchable, trackable, public pipelines for medtech, pharmaceutical and digital health innovations	Cataloguing and tracking of publicly accessible, searchable online showcase of the MTPD innovations under development in Australia. Investors, practitioners and consumers can follow the progress of any innovation as the showcase is updated in real time using a humanized machine learning system.	Health Innovate Pty Ltd. Health Horizon, Hospital and Health Services IP Ltd, Novartis Pharmaceuticals Australia, ANDHealth, Health Informatics Society of Australia (HISA), Medical Technology Association of Australia (MTAA), Medical Software Industry Association (MSIA), Better Health, Healthcare and Treatment Global Impact Cluster, (University of Newcastle) Melbourne Academic Centre for Health (MACH), QUT Biomedical Industry Group
A cloud-based AI digital health platform (Hospital 4.0) applied to nationwide cardiovascular clinical decision support.	Implementation of an Artificial Intelligence digital health platform to eliminate avoidable/preventable errors in health care services by automating best practice clinical guidelines and delivering real time guidance to clinical decision makers, with initial focus on cardiovascular services in rural/remote SA.	Integrated Cardiovascular Clinical Network (iCCnet), Country Health SA Alcidion Corp. Adelaide, AstraZeneca Australia Macquarie Park, Cardihab Pty Ltd Fortitude Valley, Chamonix Health Solutions Adelaide, Medical Communications Associates Pty Ltd, Medi - Map Ltd Christchurch, SysLinx Pty Ltd Adelaide, Flinders University, University of South Australia



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The Bioprint Facility for Translational Science and medicine in the MTP Sector	This project will allow SMEs to engage with the BioPrint facility and technical experts at the University of Wollongong to establish a world first facility to enable the development of bioinks and customised bioprinting systems for targeted clinical applications.	University of Wollongong. SMR Automotive Australia Pty Limited, Sydney Eye Bank, St Vincent's Hospital (Melb), Lincoln Consulting Group
Establishment of an MTP competency based, manufacturing skills development facility/training hub and early stage clinical trial manufacturing facility.	This project will establish a medtech/pharma clinical manufacturing training hub to enable the translation of innovative, investigational products into clinical studies. Additionally, the project establishes a “turn-key” early stage clinical product manufacturing facility for a wide-range of clean to sterile medtech products at the Translational Research Institute (TRI) in Brisbane.	Translational Research Institute. PharmOut, Eurofins AMS