STRATEGIC EXAMINATION R&D Review

April 2025

Medical Technology Association of Australia Ltd
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ABOUT MTAA

The Medical Technology Association of Australia (MTAA) is the national association representing manufactures and suppliers of medical technology (MedTech) used in the diagnosis, prevention, treatment and management of disease and disability. The MedTech industry is diverse, with medical products ranging from frequently used items such as syringes and wound dressings, through to high technology implantable devices such as pacemakers, defibrillators, bone and joint replacements, and other prostheses. MedTech also includes hospital and diagnostic imaging equipment used in all settings, from the smallest rural clinic to the largest multi-site hospital, such as ultrasound and magnetic resonance imaging (MRI) equipment, as well as digital solutions such as software as a medical device (SaMD).

MTAA's membership encompasses a diverse range of Medtech companies. These include

- emerging start-ups seeking to commercially translate Australia's world class research into market leading concepts
- growth stage Australian owned companies pushing into SE Asian and other global export markets
- established global Medtech companies actively conducting clinical Investigations, bringing an array of first in human studies to Australia.

MTAA members provide all of Australia's healthcare professionals with essential product information, continuing education and training to ensure safety and to optimise the effective use of MedTech. Our members design, manufacture and circulate virtually every medical product used in the management of disease, disability and wellness in Australia. MTAA aims to ensure the benefits of contemporary, innovative and reliable MedTech are delivered effectively and sustainably to provide better health outcomes for the Australian community

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Overview of MTAA's response to the Strategic Examination of the R&D review

The Medical Technology Association of Australia (MTAA) consulted with multiple small, medium and large member companies regarding their perspectives on what an integrated, sustainable, dynamic and impactful R&D system looks like.

The Strategic Examination of R&D is a far too narrow, academic research, technology supply side focused review of opportunities to create impact for the wider community. This review must consider the demand side of research **Commercialisation** as too much Australian academic research occurs in isolation. In isolation with respect to global markets, customers and prospective industry partners and from capital markets seeking to fund the short- and long-term retirement plans of Australians.

When examining the Terms of Refence for this review, aspects such as determining how to maximise value of existing R&D investments, strengthening linkages between research and industry to address barriers to meaningful collaboration, or driving greater R&D investment by industry, risk oversimplifying the issues and solutions to address Australia's gradual global decline in R&D performance as solely related to improving academic R&D activity and technology push factors.

To further improve Australia's R&D performance, demand side factors are essential to affect systemic change to improve Australia's public profile as a nation with a highly advanced R&D ecosystem. This requires examining the barriers and opportunities around both R&D and commercialisation and how Australia can better address these respective activities through appropriate policy reform

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MTAA's Key Recommendations

Key take aways for each respective question is provided to help identify and provide solutions to improve Australia's current R&D and commercialisation performance.

Consultation Questions	Key Take Aways
Q1	Integrates responses from Q2-10.
Q2	University barriers related to limited identification of needs prior to undertaking R&D and develop more collaborative IP sharing arrangements. Current government regulatory, procurement and reimbursement policy settings have long approval timeframes and don't incentivise local R&D sufficiently as part of these policies, inhibiting more local R&D/commercialisation activity to be conducted as part of their approving MedTech products. Gathering metrics to benchmark regulatory and reimbursement approval timeframes would help incentivise improving these policy settings to encourage more local R&D and commercialisation activity. Strengthening R&D tax incentive and reforming privacy legislation so more companies (local and global) are incentive to do more research activities (such as clinical trials).
Q3	Addressing the policy settings that acts as inhibitory barriers to more R&D and commercialisation, will organically promote a culture of innovation excellence Industry and academia should have formal partnerships where curriculum design factors in the markets needs from industry in relation to R&D and commercialisation roles Increased educational awareness of a variety of roles in Australian MedTech that intersect with R&D and commercialisation. Examine and empower government agencies to promote and provide more financial assistance to MedTech companies
Q4	More venture capital should reallocate to enable commercialisation experts in the private sector the ability to translate R&D being generated in academia Having limited flexibility in the number and nature of partnerships related to the eligibility criteria in grant applications can have a substantial impact of success rate commercialising MedTech concepts. An opportunity to leverage Australia's diaspore that works in MedTech to generate more export market opportunities for local Australian innovation.
Q5	Developing human centred design programs where clinical immersion is the foundation for inventing and implementing a MedTech concept – setting up these programs should involve liaising with global counterparts to see how the program could be set up in Australia and if Australian universities can become affiliates of existing programs.

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Consultation Questions	Key Take Aways
	Encourage more researchers to be involved in customer discovery activities with industry to identify specific problems that will help lead to focused technology and product development roadmaps.
Q6	The Australian IP activity for medical technology is promising but the next phase in terms of leveraging this IP is critical to generate future economic and social benefits. Training researchers to understand commercialisation requirements, encourage and incentivise private commercialisation specialists to translate more research
Q7	Addressing the key policy barriers impacting R&D will create incentives for companies to undertake more of these activities – developing, diversifying and sustaining the Australian R&D and commercialisation workforce in the process.
Q8	Cultural appropriateness of MedTech research needs to be promoted in clinical trial research, with consideration of alternative trial designs that promote inclusiveness Industry can collaborate with First Nations people to develop a framework on how MedTech research can incorporate principles related to Indigenous data sovereignty – tying in both needs of First nation's people and researchers.
Q9	Governments must always be aware that MedTech is a globally competitive sector, and Australia can only incentivise business leaders to invest in Australia through improving existing policy settings Introduce procurement policies that incentivise purchasing local MedTech solutions for a minimal viable production run, factoring in the ability of those solutions to be scaled globally as well
Q10	For medical technology there are a range of metrics proposed that consider both technology push and demand side pull factors. Assessing MedTech progress across each of should help in determining how effective policy reforms have been to lift Australia's R&D and commercialisation performance.

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Question 1: What should an integrated, sustainable, dynamic and impactful Australian R&D system look like?

As articulated in MTAA's responses to subsequent questions, examining both supply and demand factors together will allow for the following in the Australia R&D system for MedTech:

Connected and engaged: Proactive global, regional and local market, supply chain and end user engagement initiatives, such as incorporating various customer discovery and related human centred design principles as modules into thesis driven academic training prior to commencing literature review exercises.

Integrated: stronger partnerships between entities undertaking R&D and industry partners undertaking commercialisation. From MTAA's perspective, this involves building an understanding of unmet needs, barriers to uptake and adoption and the process to bring concepts to fruitful commercial, adoption in the market involving industry, and identifying who can best commercialise the research through proactive industry engagement initiatives, such as patent landscape mapping and researcher/ manufacturer discovery study tours.

Sustainable: Synergies between R&D and commercialisation create a value chain of activity from discovery all the way to a market ready product. Any proceeds can then be reinvested into future R&D activities.

Dynamic: If all parts of the R&D sector have a strong baseline understanding across the ecosystem of both R&D and commercialisation requirements about each stage in the commercial journey for MedTech (identifying a market need, attracting capital at the early stages, through to understanding regulatory and reimbursement requirements) this provides researchers and industry with a singular vision of identifying unmet meets that can lead to speedier design, development and commercialisation.

Impactful: By considering both MedTech R&D and commercialisation activities, meaningful metrics can be formed that accurately benchmark the local and global impact of Australia's R&D system in terms of economic value and social benefits. As outlined in Q10, including of demand side metrics such as: the average days to approve a MedTech product, proportion of tenders awarded to local innovation, proportion of venture capital allocated in earlier funding round for MedTech projects, will provide the necessary incentives for Australia to become more competitive and lifts its R&D and commercialisation performance.

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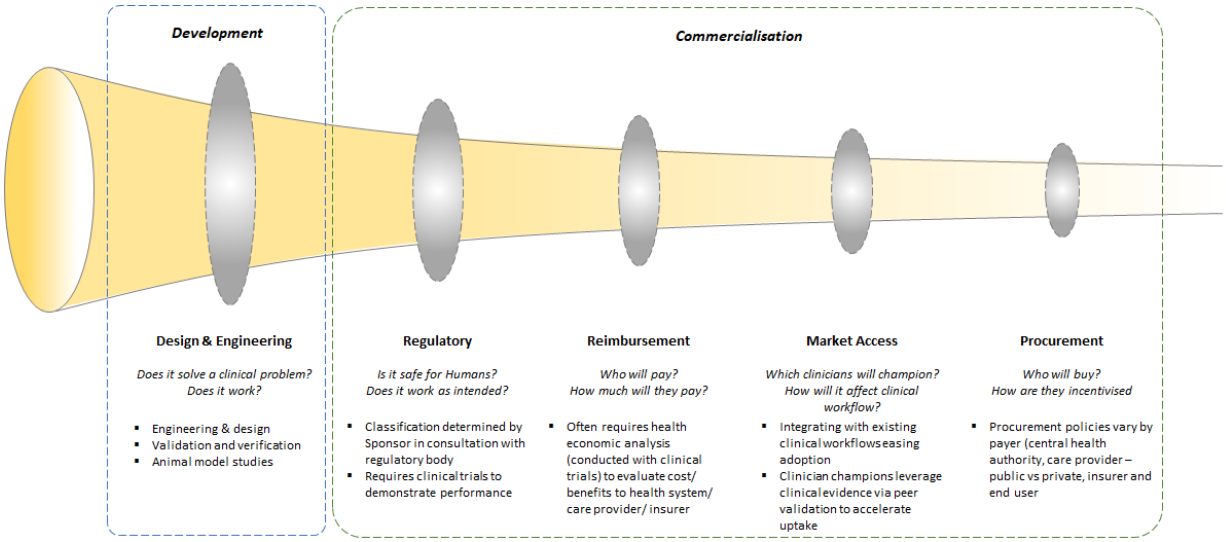
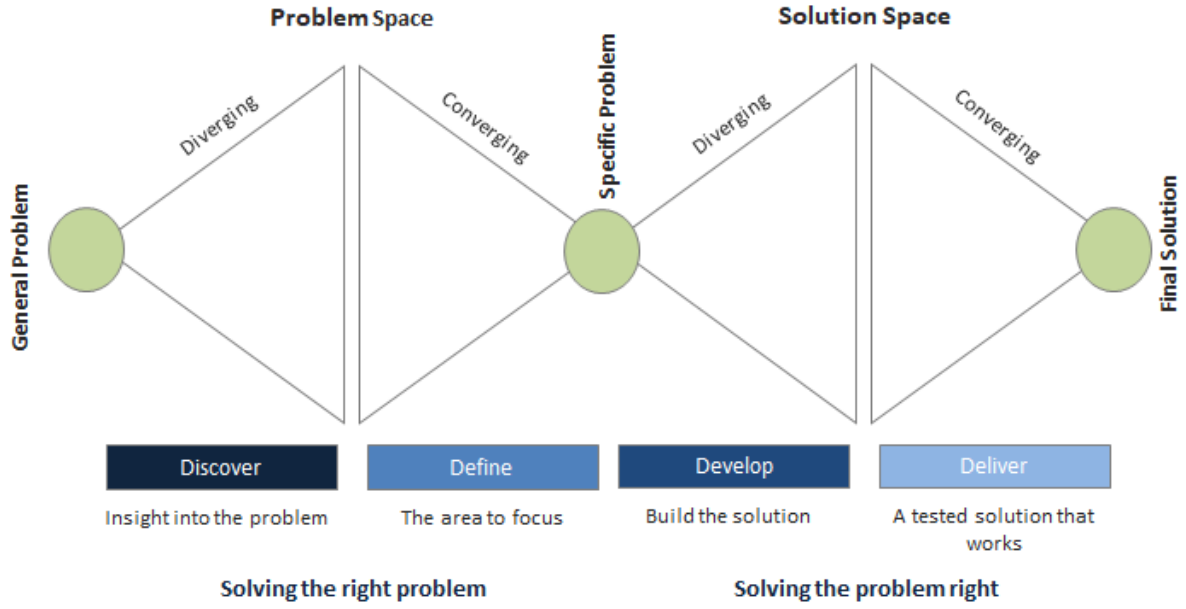
Question 2: What government, university and business policy settings inhibit R&D and innovation why?

MedTech R&D innovation and commercialisation occurs across a continuum of activity (as illustrated below). Currently, both R&D and commercialisation are hampered by a range of university, government and business demand side policy settings, spanning the design and engineering priorities, medical device regulation, reimbursement, market access public procurement (as well as competitiveness of the R&D tax incentive). An explanation is then provided for how each type of policy setting inhibit greater R&D and commercialisation, with suggestions on policy improvements also provided where applicable.



University Barrier – Traditional early career researcher training drives insular convergent thinking

The traditional literature review process, fundamental to early career researcher training through thesis-based PhD and master's degrees, drives an insular thought process to converge on common concepts, often unrelated from real world applications. Potential approaches to encourage divergent thought is to create funded opportunities for proactive global, regional and local market, supply chain and end user engagement initiatives, such as incorporating various customer discovery and related human centred design principles and market/ industry problem and opportunity mapping (such as patent landscape analysis) as modules into thesis driven academic training prior to commencing literature review exercises. This approach leverages the Double Diamond approach to problem discovery and solution definition to progress research beyond its initial discovery phase.



Intention

- Focus attention on areas that are of interest to industry partners, global markets, and funding schemes
- Leverage areas of relative research and patent strength to address underserved patient communities
- Reduce competition for early to mid career researchers

University Barrier – IP arrangements

The one-sided nature of IP agreements that generally favour universities is a key barrier. The upfront IP requirements including requests to implement licensing fees and ownership rights, has meant challenges for industry partners to readily commercialise research. Negotiations between technology transfer offices and prospective industry partners are often adversarial due to misaligned views of value creation and further capital investment requirements to achieve commercial impact. This coupled with the fact that there is a high degree of untapped commercialisation capability in the private sector leads to missed opportunities to develop more market ready products that could be used and sold in Australia. Instead of universities enforcing inflexible IP sharing agreements upfront, relinquishing some IP to industry partners would enable two benefits:

1. Increasing the successful probability of commercialising the initial discovery research
2. Developing a royalty arrangement post commercialisation that provides a sustainable revenue source for academic future research.

Australia risks undertaking large amounts of research with no clear pathway to develop these into market ready products without alternative IP sharing and access arrangements. This then invariably leads to MedTech R&D being diverted offshore where other jurisdictions reap future economic value of locally developed R&D.

University Barrier - Design and Engineering for a clinical problem

MTAA members repeatedly noted R&D across the tertiary sector is focused on developing the technology first and then focusing on the application of the technology as a secondary consideration. However, medical technology research needs to start with specific problem first because without a clear need, this reduces the chance to successfully translate R&D into tangible solutions that can scaled up across the health care system. As outlined later in our submission, there have been successful clinical immersion problems that help address the engineering design challenges and increase the chances for the technology to be successfully commercialised.

Government Barrier – Medical Device regulation

In terms of medical device regulation, members have reported obtaining timely medical device regulatory approval for their products through the Therapeutic Goods Administration (TGA) has historically been challenging, relative to other bodies such as the EU and FDA. Whilst upholding clinical safety and efficacy standards is paramount, long approval lines may deter companies to invest more in R&D in Australia because the path to market, especially for higher-class medical devices, is slower in Australia relative to other jurisdictions. If a company wants to commercialise their research, there is a significant opportunity cost incurred wanting to obtain Australian regulatory approval, whereas in the same amount of time they could have achieved regulatory approval and sales in UK and US, which also have the advantage of a larger market size.

To address these challenges, gathering metrics on relative performance of approval timeframes across different jurisdictions can help identify areas where the Australian Government could review and improve processes to strike the right balance in the regulatory approval process between safety and time access to technology. The industry could help share aggregated data on average regulatory approval timeframes to help in benchmarking approval timeframes in Australia with other jurisdictions.

Government Barrier – reimbursement approval

For medical technologies in Australia, getting reimbursement in the private health system is a prolonged process and deters more companies investing in local research that can be taken all the way to market in Australia. Extensive evidence requirements currently result in an imbalance between getting sufficient evidence to demonstrate comparative clinical effectiveness and ensure patients with private health insurance can access the best technologies. As an example, for certain orthopaedic implants to be listed on the Prescribed List (the list of medical devices and human tissue products for which private health insurers are required to pay minimum benefits) a 2 year follow up rule must be satisfied. This means that that for a certain number of patients with devices implanted, companies must provide clinical data with at least a 2 year follow up period. Such requirements then create an additional barrier by increasing the time and costs to obtain data for reimbursement consideration. This means innovative technology only reaches private patients years later (and is longer the most innovative technology when it finally reaches patients).

Similarly to addressing regulatory approval timeframes, having league tables that chart approval process times for reimbursement decisions, helps assess how Australia's fares globally. This then supports recalibrating evidence requirements, so processes are streamlined to facilitate speedier, but still rigorous, reimbursement approval and access to patients.

Government Barrier – public procurement

Another challenge is limited consideration of local R&D activity in public procurement processes for MedTech. Public procurement practices still focus on obtaining MedTech products at lower prices to meet annual budgetary targets. However, the focus on lower prices has meant limited consideration procuring innovative MedTech products developed through Australian R&D. Local innovative technology might be at a higher price point and generate a range of health and financial value adds across the health system but procurement policy frameworks are not designed to encourage purchasing of innovative technology. Instead, existing processes, such as the inclusion of alternative offers where suppliers can demonstrate additional benefits of their product, are simply considered but do not lead to changes in purchasing behaviour by procurement agencies.

In addition, procurement agencies increasing focus on consolidating suppliers they want to purchase from indicates prioritising narrowing medical device choice but providing no clear demand signals that

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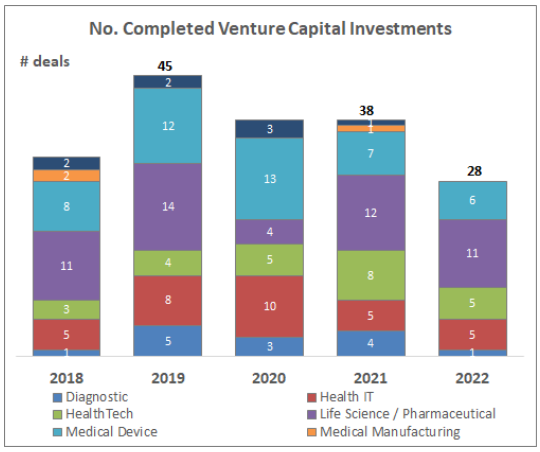
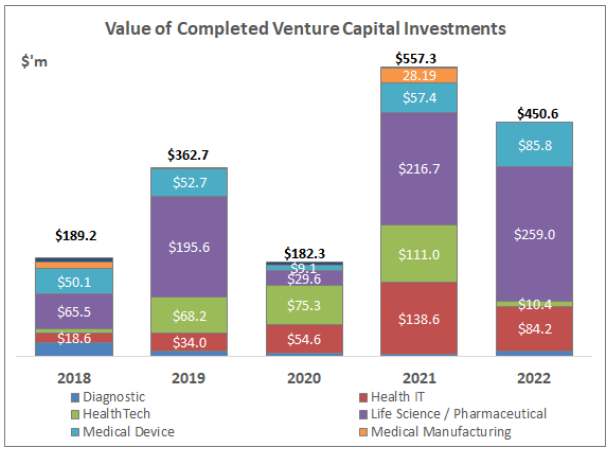
Australian innovation should be genuinely considered. Without a clear pathway that incentivises procurement of medical technologies that have incorporated local R&D, Australian research will continue to develop up to a point before being transferred offshore to be commercialised and lose future economic benefits.

Business Barrier – limited venture capital allocated to MedTech projects and limited awareness of MedTech as a distinct asset class

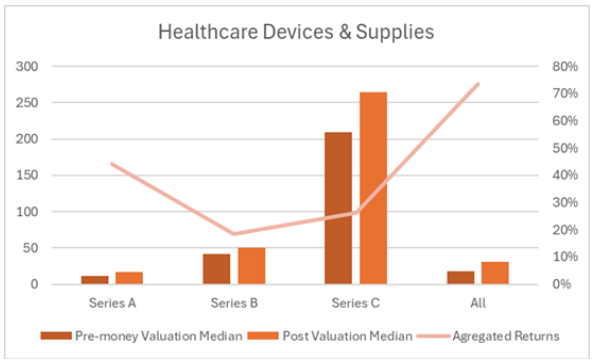
There has historically been limited investment in MedTech ventures in private markets. Examining historical data collected between 2018-2022 shows the number of deals completed and value of deals involving MedTech is still relatively low compared to pharmacology. In both graphs below, both the number of investments and total value for MedTech receives a relatively small share of private capital investment.

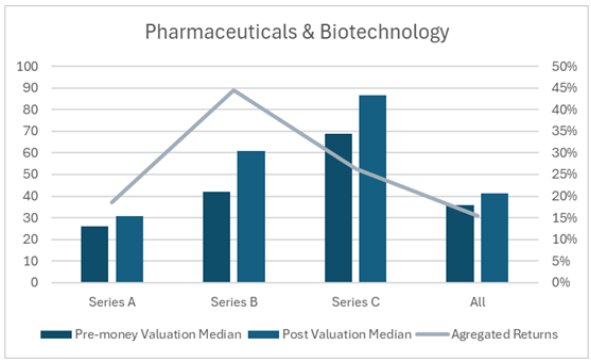




[1]Source: Australian Private Capital Market Overview: A Preqin and Australian Investment Council Yearbook 2023

Furthermore, Medtech as an early stage, alternative investment asset class is poorly understood by general venture funders. Medtech is often grouped together with pharmacology under the broad banner of life sciences.





Observations[2]:

- Since 2018, Australia's Healthcare Devices sector delivered 74% returns across Series A-C, compared to 15% in Pharmaceuticals. Series A returns alone were 44% versus 19%.
- In later-stage Series C, Healthcare Devices show a significant lead, with a median post-valuation 3.04 times higher than that of Pharmaceuticals.

[1] Source: Australian Private Capital Market Overview: A Preqin and Australian Investment Council Yearbook 2023

[2] Series A-C Valuations in Oceania since 2018 in Healthcare Devices vs Pharma. Pitchbook

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The two asset classes are very different, based on the typical trade sale exit point[3]. Pharmacology is typically a binary 'bet' at the research phase (Series A funding) on a large outcome. In contrast, Medtech is a cumulative bet, increasing in probability of success, through the Research, Development and Commercialisation Phases, requiring c.A$65m before acquisition. As an asset class it delivers overall higher portfolio returns, provided commercial capabilities at each phase are discretely accessed.

However, those who do understand the Australian MedTech innovation ecosystem, currently find more attractive investment returns elsewhere due to the regulatory and reimbursement hurdles lowering investment returns due to delays in reaching market and generating patient impact.

Business Barrier – current R&D tax incentive design

The current R&D tax incentive's design in it is current form is an important policy lever that has benefitted existing MedTech R&D activities to date (eg clinical trial activities). However, there should be an examination and adjustment of the scheme to further assist increased MedTech R&D activity in Australia.

In its current form, the eligibility criteria around core and non-core R&D activities is not sufficient to attract more substantial investment from larger global companies that have the ability to allocate funds across an array of different markets with appealing tax incentive policies (such as Singapore for example).

There is also no clear linkage between the R&D tax incentive and major manufacturing initiatives the Government wants to develop a strong national capability in (eg to support medical manufacturing under the NRF). This limits interest from industry who need certainty around future long term sustainable financial returns conducting more R&D and commercialisation activity in Australia. There could be an opportunity to implement an adjustable tax offset rate if tied to key manufacturing priorities to create that demand pull from MedTech companies to invest in Australian R&D and commercialisation.

Business Barrier – Privacy requirements not standardised

Another evolving challenge for companies that may want to undertake more extensive clinical trial activity is navigating privacy legislative requirements regarding collecting and storing data. Each state has slightly different regulations, meaning larger global companies that have a decentralised approach to conducting clinical trials (where data is gathered in Australia and then is collected offshore to be stored and analysed) must comply with additional local requirements. The lack of standardisation disincentivises companies to want to scale up operations because of the cost inefficiencies in the process this creates.

Key takeaways:

- University barriers related to limited identification of needs prior to undertaking R&D and develop more collaborative IP sharing arrangements.
- Current government regulatory, procurement and reimbursement policy settings have long approval timeframes and don't incentivise local R&D sufficiently as part of these policies, inhibiting more local R&D/commercialisation activity to be conducted as part of their approving MedTech products. Gathering metrics to benchmark regulatory and reimbursement approval timeframes would help incentivise improving these policy settings to encourage more local R&D and commercialisation activity.
- Strengthening R&D tax incentive and reforming privacy legislation so more companies (local and global) are incentive to do more research activities (such as clinical trials).

[3] https://www.mtpconnect.org.au/Category?Action=View&Category_id=203

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Question 3: What do we need to do to build a national culture of innovation excellence, and engage the public focus on success in R&D and innovation as a key national priority?

There are a range of factors that help promote a national culture of innovation excellence and engage public focus on R&D. These involve addressing the current business regulatory policy settings, establishing closing working relations between industry and academia on R&D workforce development , and policies that promote global export opportunities for local Australian medical technology innovation.

Culture is tied to address inhibitory R&D and commercialisation policy settings

Addressing the current inhibitory policy settings will organically create a strong innovation culture where research is readily able to target specific problems, industry is encouraged to partner in commercialising academic research, and streamlined regulatory and procurement processes should allow for the technology to reach the Australia public/private healthcare system in a reasonable time.

In terms of engaging the public focus on success in R&D and innovation as key national priority, being able to successfully commercialise more MedTech products in Australia could generate a visceral impact on why it's critical to invest in Australian MedTech R&D and commercialisation - as it would address both the power of R&D and access to R&D innovation. The recent positive public media attention for BiVACOR's total artificial heart, invented by Queensland-born Dr Daniel Timms, highlights the public support for MedTech R&D (even though BIVACOR is being commercialised offshore). However, if such innovations through the right regulatory, reimbursement and procurements settings could be locally developed, commercialised and accessed by Australian patients more quickly, this could lead to more great public focus on the transformative impact of Australian MedTech to support high quality and equitable healthcare systems.

Partnerships promote workforce development that leads to a national culture of innovation excellence

The culture of innovation excellence also requires better connections between the tertiary sector and MedTech industry in developing the future MedTech workforce to attract the best talent to develop and commercialise future concepts into amazing products that improve patient outcomes. For example, other jurisdictions have done well in creating courses that integrate university learning and opportunities to apply learnings in an industry setting. In Ireland, for example, graduates completing a biomedical engineering take placements during the later part of their degree with an established MedTech company and go through a series of rotations. The industry connection assists with shaping the university curriculum in such a way that its helps with developing future graduates with the right set of skills to fill key jobs with an R&D and commercialisation requirements.

Furthermore, have industry partners should work with universities to increase awareness of the vast array of opportunities for graduates to participate in the MedTech workforce. This is key to having a systematic way of attracting talent to support further R&D and commercialisation activities. As

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highlighted in MTAA's Value of MedTech report [4]the sector directly employs 17,000 people spanning a diverse array of roles including that in their respective ways support the ecosystem, including

- Clinical Trials
- General and corporate management
- Information technology
- Professional and Consulting Services
- Supply chain and logistics

Sustaining the MedTech workforce (and healthcare workforce) more broadly is critical to ensure that MedTech R&D and commercialisation be continued. It is important to note that clinicians are also innovators, so by examining key trends in the healthcare workforce (retention rates in jobs, average age of the clinical workforce by role) we are also support the broader workforce integral in R&D and commercialisation.

Export Market opportunities

Another policy lever that should be examined and will help support grown a culture of local innovation excellence and increase public focus of R&D as a national priority are the potential export market opportunities for Australian MedTech across the Asia-Pacific region. The could involve:

- government entities such as Austrade to organise business forums that show off the innovation of MedTech developed in Australia[5]
- government entities such as Export Finance Australia, increasing level of support for Australian MedTech through allocating finance using bonds, guarantees or trade-credit arrangements to help companies de-risk doing business, a. with the SE Asian region. Due to the multiple costs exporting medical technologies (freight costs, registering with the TGA, IP protection etc) and combined with potential uncertainty of certain Asian customers ability to pay, there is a need for a range of reliable financial options.
- Collaboration involving industry associations (eg MTAA) and the TGA and AusTrade in educating local companies on path to conformity assessment recognition for key SE Asian region markets (eg Malaysia)

Key takeaways:

- Addressing the policy settings that acts as inhibitory barriers to more R&D and commercialisation, will organically promote a culture of innovation excellence
- Industry and academia should have formal partnerships where curriculum design factors in the markets needs from industry in relation to R&D and commercialisation roles
- Increased educational awareness of a variety of roles in Australian MedTech that intersect with R&D and commercialisation.
- Examine and empower government agencies to promote and provide more financial assistance to MedTech companies

[4] Nous: MTAA Value of MedTech Report; pg 61

[5] MTAA submission: Australia's Southeast Asia Economic Strategy to 2040 consultation

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Question 4: What types of funding sources, models and/or infrastructure are currently missing or should be expanded for Australian R&D?

What programs currently supports MedTech R&D
There are a range of government programs investing in Australian R&D focusing on MedTech, which is important in progressing key discovery research to examine new technology models or applications. These include:

- medical research focused grants through Australian Research Council and National Health and Medical Research Council
- Research translation grants, such as the Australian Economic Accelerator (AEA)
- complex grants such as through the Industry Growth Program & Coo-operative Research Centre grants
- bespoke grants (such as Invest Victoria) and investment funds (Breakthrough Victoria, National Reconstruction Fund) which incentivise increasing R&D activity within a certain geographic region

However, there are areas where existing funding models could be modified or considered to support Australian R&D and commercialisation.

Q: What is missing that would benefit R&D? A: clear performance metrics for translation programs
With respect to Australian Accelerator Program, members have reported having clearer and more robust performance metrics to accurately measure the proportion of products being successfully commercialised.

Q: What is missing that would benefit R&D? A: Venture Capital reallocation to commercialisation
There is limited venture capital in commercialising Australian medical technology R&D activity. Under the existing funding arrangements, Australia is investing in R&D programs, but these programs do not leverage all the commercialisation capabilities across the entire ecosystem to create additional economic and social value in Australia. This is because structurally across the R&D ecosystem, there is an overreliance on university commercialisation schemes/offices to undertake this work.

This generally leads to fewer research projects being spun out as separate commercial entities earlier from universities, which can then be commercialised by industry experts

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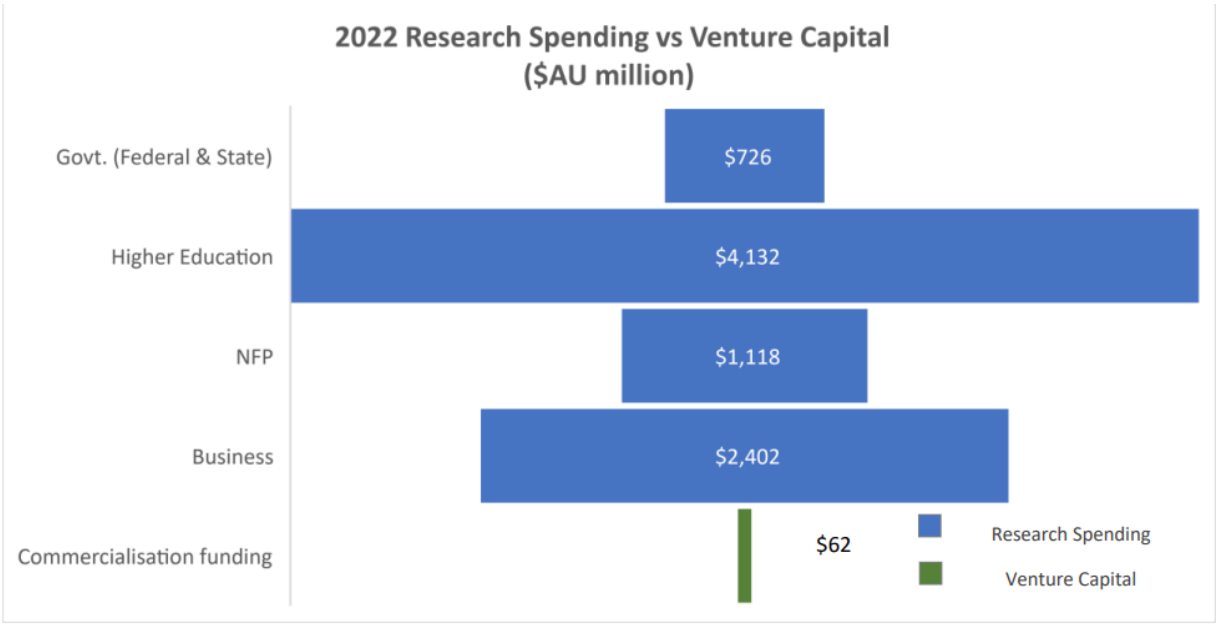

2Australian Medical Device Venture Investment Summary Report (January 2023)

1 Australian Medical Device Venture Investment Summary Report (January 2023) pg 6

2 Australian Medical Device Venture Investment. Summary Report (January 2023), Chapter 1: State of the Nation pg 2

[6]Australian Medical Device Venture Investment Summary Report (January 2023)

These factors combined then concentrate risk by expecting both R&D and commercialisation to be successfully undertaken across the tertiary sector – even though commercialisation requires different capabilities to discovery research. Instead, the government should strategically invest in R&D and commercialisation as discrete activities and allocate funding to more private entities specialising in commercialisation.

A model that should be implemented for MedTech research to increase Australian R&D and commercialisation would be:
Step1: Spinning out a promising MedTech R&D project and related intellectual property to become a distinct legal commercial entity.
Step 2: Provide government/grant funding to industry commercialisation experts from industry to complete the translation of the research.

Q: What is missing that would benefit R&D? A: Having translation funds that consist of smaller specialised VC funds
The existing translation funds that support MedTech research being commercialised (eg Biomedical Translation Fund) consist of larger established venture funds that are geared to investing in projects that will make sizeable returns (such as pharmacology projects). This does not align with the investment strategies needs for of medical device projects as outlined in (Q2, pg9).

As a solution, establishing/modifying a translation program based on the principles of the previously operational Innovation Investment Fund (IIF) [7] program from the late 1990s could ensure more successful commercialisation for MedTech projects can occur:

The Funds were structured in a way that it consists of multiple smaller funds (Eg 10 VC funds) compared to a few well-established funds. Having funds organised this way is critical in diversifying venture

[6] Australian Medical Device Venture Investment Summary Report (January 2023)
[7] Management of the Innovation Investment Fund Program, Australia Audit National Office (2002)

funding to earlier stages during seed funding and Series A rounds for MedTech research projects – critical as MedTech projects needing consistent funding at each stage of the commercialisation journey to maximise probability of commercial success (cumulative bet).

Q: What is missing that would benefit R&D? A: Restrictive eligibility criteria in grant funding

Another barrier to facilitating increased R&D investment is limited flexibility in the partnership arrangements when applicants apply for grants. The preference to award grants to multiple partners may down the line create a commercialisation complexity if there is a change in the commercial relationships between grant partners. As an example, in Europe, where this strong encouragement to have partners as part of grant applications, this could involve having a startup and contract manufacturer initially being approved to receive funding. However, as the startup becomes more mature and the manufacturer involved becomes the main supplier to the company, a deterioration in this relationship then would make it challenging at this stage in the commercialisation journey to progress or find an alternative arrangement (potentially more complicated is there are additional IP arrangements that were predetermined when applying for the grant).

Q: What is missing that would benefit R&D? A: Alignment on how grants address all key stakeholder needs

A recurring theme from engaging members was how grant applications were put together in the lead up to applying for funding. Member companies reported multiple instances where universities are geared to complete applications to satisfy short term discovery research priorities such as sustaining staff and laboratory operating costs while not considering if the research will address a market need. Without this clear alignment across academic, clinical and industry partners, this impacts on appetite for industry to sign on as partners in future grant applications.

Q: What is missing that would benefit R&D? A: Clearer government directives to procure and fund activities linking commercialised products to national priorities

Governments should more clearly communicate how procuring critical technology will support local needs and priorities, especially in Health and Defence sectors. As an example, funding tenders and purchase orders aimed at building technology and commercial supply chains here in Australia using locally developed Australian MedTech research.

Q: What is missing that would benefit R&D? A: leveraging the skills of the diaspora to support export market opportunities and build referred trust

Australia's multicultural population brings with it a workforce that has a strong understanding of different cultural contexts from around the world. There should be a way to incentivise leveraging the skills of the people who both have strong MedTech research and commercial skills and come from culturally and linguistically diverse groups (CALD) to promote Australian medical R&D concepts to potential export markets.

One approach could be industry liaison officers from the Australian MedTech sector, collaborating with government agencies like Austrade to co-design materials and set up events to connect local innovators with key markets and build referred trust . For example, if these liaison officers establish key connections in another country, these overseas contacts would then engage with their local business partners and introduce them to Australian MedTech companies. Simply by association with a local overseas contact (referred trust), the Australian MedTech company could accelerate building of a business relationship with the overseas customer.

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Key takeaways:

- More venture capital should reallocate to enable commercialisation experts in the private sector the ability to translate R&D being generated in academia
- Having limited flexibility in the number and nature of partnerships related to the eligibility criteria in grant applications can have a substantial impact of success rate commercialising MedTech concepts.
- An opportunity to leverage Australia's diaspore that works in MedTech to generate more export market opportunities for local Australian innovation.

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Question 5: What changes are needed to enhance the role of research institutions and businesses (including startups, small businesses, medium businesses and large organisations) in Australia's R&D system?

Challenges with current approach to R&D
The way Australian MedTech R&D system is set up currently focuses on researchers developing technologies without intentionally factoring in an understanding of clinical needs for these types of technologies. Instead, there is a need for more MedTech research teams to learn about the unmet clinical needs in the market first before undertaking research activities.

Focusing on clinical immersion models
By immersing researchers in an environment where they experience the actual problems within the health system first, this will then help support research that has a higher chance of being commercialised. This is a very well-established approach in the Irish MedTech sector through the BioInnovate Program based at the University of Galway. This program is based on the Stanford BioDesign Innovation Fellowship and is an affiliate of the Standford program.

Administered by Enterprise Ireland (agency responsible for the development and growth of Irish enterprises in world markets), BioInnnovate was initially established in 2011 with the aim of anchoring the medical device sector in Ireland by educating and training future entrepreneurs. To date the programme has trained 150 Fellows and led to 33 companies - 23 of which are high potential start-ups.

The Program has three key phases Identify, Invent and Implement.

Phase 1 – Identify
In the first phase, there is an understanding of the demand and supply side factors impacting research (distinctions between market pull and technology push). Teams are created bringing together people with different skill sets (doctors, engineer, marketing etc) and then sent to different hospital sites as part of the clinical immersion experience. Teams spend 4 weeks in a hospital setting followed up 4 weeks in a clinic.

By the end of Clinical Immersion, participants will have identified and documented hundreds of potential healthcare challenges. Teams then filter down the hundreds of clinical needs identified during Clinical Immersion. This stage is about refining and prioritising the most pressing, impactful problems, honing their focus on the most promising opportunities.

Phase 2 – Invent
Teams start ideating potential solutions to the clinical problems they've identified. Solutions proposed factors in how to bring a new technology to market, including, product design development, clinical trials strategy, regulations and reimbursement. Teams collaborate to ensure the filtered and identified needs align with regulatory requirements and are commercially viable within healthcare systems.

Phase 3 – Implement

This is where teams develop essential business skills, including business planning, fundraising, and strategies for scaling their solutions. The aim is to prepare participants for the commercial realities of launching a MedTech product, ensuring they are equipped to attract investment and build sustainable businesses.

The Australian MedTech system should try and emulate more of these types of programs which focus on integrated professional teams and training researchers to have strong understanding of the unmet needs as a foundation for research. While some of these activities are offered as a subject in universities (eg clinical immersion unit in the UNSW Biomedical Engineer course) these type of programs could be scaled up and offered as formal program supported by government agencies (eg Invest NSW/VIC)

Key takeaways:

- Developing human centred design programs where clinical immersion is the foundation for inventing and implementing a MedTech concept – setting up these programs should involve liaising with global counterparts to see how the program could be set up in Australia and if Australian universities can become affiliates of existing programs
- Encourage more researchers to be involved in customer discovery activities with industry to identify specific problems that will help lead to focused technology and product development roadmaps.

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Question 6: How should Australia support basic or 'discovery' research?

Strengths with MedTech discovery research

Australia has very strong discovery MedTech research capabilities and reputation that should continue to be supported. This is reflected, in one sense, by the degree of MedTech intellectual property activity in Australia. Based on the recent Australian 2024 IP report the life sciences sector leads other fields for the number of standard patent applications received each year. In 2023, there were 3,690 Australian standard patent applications for Medical Technologies, second to the 3945 applications for Pharmaceuticals, and substantially higher that the 1,718 applications for Organic Fine Chemistry and 1, 694 applications for computer technology. In terms of domestic patenting in Australia, standard patent applications by residents had increased by 2.4% in 2023 to 2556 in total and has remained fairly steady in the level of output. Of domestic patents by Australian applicants filed, Medical Technology was the second highest at 8.1% (after civil engineering but before transport ad compute technology)[8]

Opportunities to further MedTech leverage discovery research

However, while its helpful to see strong discovery research and IP generation, there needs to be a way to also leverage the commercial value of basic/discovery research. As referenced previously, examining ways to:

- develop programs that train researchers to understand unmet clinical needs first as the basis of discovery research but also be aware about the set of activities across the R&D and commercialisation continuum
- to diversify funding to allow more private entities that specialise in commercialisation to support leveraging discovering research into commercially successful products
- reallocating venture capital across the public and private sector away from R&D to more commercialisation-based activities

Key takeaways:

- The Australian IP activity for MedTech is promising but the next phase in terms leveraging this IP is critical to generate future economic and social benefits.
- Training researchers to understand commercialisation requirements, encourage and incentivise private commercialisation specialists to translate more research

[8] IP Australia (2024) Australian IP report

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Question 7: What should we do to attract, develop and retain an R&D workforce suitable for Australia's future needs?

Firstly, the ability to establish a sustainable R&D workforce requires making the necessary adjustments to previously discussed barriers that are impeding R&D innovations. These include streamlining regulatory and procurement processes, in addition to ensuring there are appropriate R&D tax incentive policies in place. Once these changes in the regulatory environment have been implemented this then creates incentives for MedTech companies to invest more substantially in Australian facilities and the workforce to support Australia's R&D activity. Without these changes, many MedTech operations in Australian will focus on sales and marketing with limited scope for R&D roles. This then means that university graduates from the tertiary sector with strong research and engineering skills invariably either shift into other sectors for work in Australia or will move overseas to look for R&D role.

Key takeaways:

- Addressing the key policy barriers impacting R&D will create incentives for companies to undertake more of these activities – developing, diversifying and sustaining the Australian R&D and commercialisation workforce in the process.

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Question 8: How can First Nations knowledge and leadership be elevated throughout Australia's R&D system?

Increasing First Nation's participation in clinical trial activity and developing frameworks that empower First Nation's communities to have a stake in data governance arrangement involving MedTech research are two key activities that can elevate First Nation's knowledge and leadership across the R&D system.

Involving First Nations people to participate in more MedTech clinical trials

One key area is promoting more Indigenous participation in MedTech clinical trials to addresses key unhealth public health needs. First nation's people are overrepresented with chronic health conditions and experience poorer health outcomes relative to the rest of the Australian population. However, the ability to increase First Nation's representation in clinical trials faces challenges stemming from ethical concerns arising from historical mistrust of researchers and sometimes exclusion of certain individuals. To foster more First Nation participation, cultural appropriateness of MedTech research needs to be encouraged and addressed. As an example, clinical trial uptake could be increased through more alternative designs[9], such as delayed start design trials, especially if a randomised control trial is not ethically appropriate and the aim is to ensure all participants have access to the intervention. This then aligns with the cultural values around inclusion, important for engagement with First Nations communities in research activities.

Indigenous Data Sovereignty Principles for MedTech research

Another area to consider with fostering stronger engagement of First Nation's participants in the medical research R&D ecosystem is how to minimise the potential misrepresentation of data collected through a Western medical research paradigm which may not necessarily align with First Nations world views, experiences or priorities. Data collected through research generated about First Nations's participants, is protected with a Western legal framework of privacy and licencing law. This data is collected and used primarily by researchers, government departments and statistical agencies to perform analysis and make key public health decision – but this use has an impact on broader social perceptions of First Nation's people responsibilities in addressing persistent health challenges [5]

This has given rise from researchers and Indigenous leaders of a need to protect First Nations people against misuses of data, through Indigenous Data Sovereignty[10]. This requires First Nations data to be managed in accordance to laws, practices and customers of a particular community/nation state. It is not a singular concept by vary on practices of different First Nation's communities and First Nation managed services. Industry could collaborate with government and academic in developing frameworks that better incorporates IDS principles that facilitate more research, industry and First Nation MedTech research.

[9] Umaefulam, V., Kleissen, T., & Barnabe, C. (2022). The representation of Indigenous peoples in chronic disease clinical trials in Australia, Canada, New Zealand, and the United States. *Clinical Trials*, *19*(1), 22-32.

[10] Trudgett, S., Griffiths, K., Farnbach, S., & Shakeshaft, A. (2022). A framework for operationalising Aboriginal and Torres Strait Islander data sovereignty in Australia: Results of a systematic literature review of published studies. *EClinicalMedicine*, *45*.

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Key takeaways:

- Cultural appropriateness of MedTech research needs to be promoted in clinical trial research, with consideration of alternative trial designs that promote inclusiveness
- Industry can collaborate with First Nations people to develop a framework on how MedTech research can incorporate principles related to Indigenous data sovereignty – tying in both needs of First nation's people and researchers.

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Question 9: What incentives do business leaders need to recognise the value of R&D investment, and to build R&D activities in Australia?

Business leaders in MedTech do see intrinsic value in R&D. The lifecycle of medical devices is relatively short and there is a continual need to innovate to compete. However, many MedTech companies operate globally and can choose which markets to invest in R&D in. To ensure Australia can attract for investment for MedTech R&D, the right incentives need to be implemented, which involves address the existing key barriers, as referenced in previous questions (medical device regulation, public procurement processes, IP arrangements, R&D tax incentive policy)

Consider preferential procurement models, in which concepts developed in Australia through collaboration between clinicians and researchers focus on local problems and have global economic potential receive purchase orders for minimally viable production runs. Procurement is worth far more than grant funding as there is business certainty for companies based on agreed volumes and timeframes.

Key takeaways:

- Governments must always be aware that MedTech is a globally competitive sector, and Australia can only incentivise business leaders to invest in Australia through improving existing policy settings
- Introduce procurement policies that incentivise purchasing local MedTech solutions for a minimal viable production run, factoring in the ability of those solutions to be scaled globally as well

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Question 10: What should be measured to assess the value and impact of R&D investments?

In terms of metrics that could be used to measure the value and impact of R&D investment there needs to be a consideration of assessing success in addressing the barriers to R&D and commercialisation to measuring progress

Clinical Trials

There could be a league table that outlines level of industry based clinical trial activity for clinical trial sites across the public and private sectors. Specific metrics could be adopted to assess how each performance, including:

1. Number of new trials and breakdown by trial phase, and by sponsor type
2. Overall study start-up timeline (regulatory timeline)
3. Ethics and governance approval timeline
4. Human Research Ethics Committee (HREC) approval timelines
5. SSA/site assessment timeline
6. Trial recruitment: actual and planned number of participants recruited
7. Site recruitment: actual and planned number of participants recruited
8. Total inbound (internal and external) investment annually.

Medical Device Workforce

- Breakdown of various roles as a % of total workforce including: R&D, manufacturing, quality, regulatory, supply chain and logistics
- Average age of the healthcare/MedTech workforce per year, to determine sustainability of workforce

Medical Device Regulation and Reimbursement approval

- Assessing average regulatory and reimbursement approval times for different class devices see if there is reduction in average approval times. Could stratify this to comparing approval timelines for local MedTech and approval times for global MedTech to understand if reforms around regulatory approval support for R&D being commercialised in Australia.

Public Procurement Processes

- Assess if the adding local R&D incentives (more weighting as part of evaluation criteria in tenders) translates to more local suppliers being awarded contracts and/or being included on tender panels
- Assess number of new MedTech RFPs request local R&D content that include any form of local development (not just for companies originating in Australia) as a consideration in evaluation
- Assess the number smaller procurements (Eg less than $150, 000), which preclude need for state standardised agreements are being used by local health services are to pilot innovations based on Australian R&D

R&D tax incentive

- Tracking number of smaller MedTech companies are claiming the R&D tax incentive and for what activities

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Venture Capital

- % of funding reallocated to industry partners that specialise in MedTech commercialisation
- % of funding allocated at seed, Series A, B,C stages compared to current baseline
- % of VC deals investing in local Australian MedTech headquarter in Australia

Key takeaways:

- For MedTech there are a range of metrics proposed that consider both technology push and demand side pull factors. Assessing MedTech progress across each of should help in determining how effective policy reforms have been to lift Australia's R&D and commercialisation performance.

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