MTAA Submission Paper National Reconstruction Fund Consultation

Medical Technology Association of Australia

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Contents

Medical Technology Association of Australia

The Medical Technology Association of Australia (MTAA) is the national association representing companies in the medical technology (MedTech) industry. MTAA aims to ensure the benefits of contemporary, innovative and reliable medical technology are delivered effectively and sustainably to provide better health outcomes to the Australian community.

MTAA represents manufacturers and suppliers of 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 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.

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.

Executive Summary

MTAA welcomes the opportunity to comment on the NRF Consultation Paper. Australia has a proud record in medical device technology (MedTech) innovation and the NRF represents a significant opportunity to lay a further foundation for industry growth in decades to come. MedTech is an industry as diverse as its technologies, ranging from MRI machines to implants, digital devices and surgical instruments, as it is in the companies that work in it.

As well as representing companies from startups to multinationals, MTAA acts as a partner in delivering the Clinical Trial Commercialisation (MedTech) program run by MTPConnect. This program supports commercialisation of local innovative technologies. This submission incorporates perspectives from the MTAA Industry Development Working Group, consisting of member companies involved in local manufacturing initiatives, R&D activities, and commercialization of medical technologies.

The importance of Medtech was underscored during the COVID-19 pandemic when local and overseas companies mobilised to manufacture ventilators in anticipation of need. MedTech is an exciting industry but its value multiplies through its effect on improved health and supporting emergency response. MTAA believes that no part of MedTech should be excluded from NRF investment upfront, but the diversity of investments considered on their merits.

The response on the NRF mandate focuses on specific opportunities to invest in manufacturing capabilities and to establish fund settings that will address the current underinvestment and outflow of capital from MedTech. Included in this response is a report prepared by Ballistic Ventures that MTAA hopes provides important insights on the current investment landscape in MedTech.

Innovation in MedTech is always dependent on a broader ecosystem which includes regulatory, reimbursement, procurement and R&D incentives. This paper points out areas of improvement in these intersecting areas.

MTAA looks forward to further engaging with the Department on the development of the NRF.

Definition Questions

1. What types of projects or investments should the Government direct the NRF to focus on, or not invest in, within each of the seven priority areas to achieve the NRF's purpose?

Medical device technology (MedTech) has exciting future globally and in Australia. MedTech covers a broad spectrum of technologies including medical hardware and, increasingly, medical software and both in combination. Supply chains and markets vary from the global to the local. Australia already has a strong track record in medical devices, most notably Cochlear and ResMed, which have shown what is possible. MedTech typically has lower hurdles for entry than biopharmaceuticals, which means it can be a more realistic option for investment in Australia which may lack the critical mass to routinely crack biopharmaceutical markets. The clinical community is necessarily heavily involved in medical device innovation due to its 'hands on' nature, which is advantageous for Australia, since Australia's clinicians and health researchers are highly regarded worldwide. Given the demonstrable opportunities, MedTech should be a key focus of the NRF. However, investments should not be limited to simply manufacturing capital investment, as this risks missing the opportunities of digital health. Furthermore, while a strong focus will naturally be smaller Australian innovators, global companies will play a necessary role in the expansion of value-adding activities in Australia, and their skills have flow on effects for the sector as a whole.

2. How should industry 'transformation' and 'diversification' be defined and measured for each of the seven priority areas?

'Transformation' should mean future looking. It is important investments are in process technologies and product types that are likely to endure into the long term. For example, 3-D printing will continue to advance and become the norm in manufacturing of medical devices. However, each iteration of printing technology will bring further benefits. This also means that the technology can be leveraged broadly across the ecosystem. 'Diversification' should include types of companies, types of technologies, and therapy areas. Startups and early stage companies should be recognised for their potential but the risk can be significant and in MedTech the product may vary in its global penetration if it does come to market. In order to achieve an effective return, investments in more mature local and global companies will need to be considered in addition. Diversification means avoiding picking a particular narrow set of technologies or therapeutic areas. However, Australia needs to be careful not to try to do everything, when it is 2% of the world market. Some specialisation will make senses. The NRF should be aware of growing opportunities to manufacture MedTech that must be supplied regionally due to custom requirements where the competition pool for investment is therefore smaller.

3. How should 'value add' be defined and measured in relation to relevant priority areas?

Calculating the value-add resulting from the maintaining and promoting investment in Australia rather than overseas is notoriously difficult. However, it should be understood that patents, capital and skills are all very mobile and a key consideration of value is investment that occurs that wouldn't otherwise have remained here. There is great value well beyond the manufacturing and investment in having a company domiciled in Australia. If the NRF investments result in a substantial MedTech industry base going forward, this would justly be considered a major success.

There are other significant spill over effects of investments in MedTech, particularly the upside of early access for Australian patients and clinicians to health innovation, as companies with local investments will typically undertake clinical trials and early launches in home markets. Furthermore, the NRF must consider the importance of sovereign capability in local MedTech manufacturing for emergency preparedness and supply chain resilience. There is a precedent, given the disruption experienced during Covid-19, to prioritise investing in a local MedTech manufacturing capability to prepare for future health emergencies. During the pandemic, MTAA members (including Stryker and Circuitwise) were relied upon to locally manufacture key items including PPE, ventilators, testing kits and ICU equipment as part of the Government's Health Industry Coordination Group – a collaborative arrangement bringing government and industry together to secure supply of critical health technologies.

4. How much detail should be provided on each of the priority areas? How should greater detail and the need for flexibility be balanced?

The TGA definition of medical devices in Section 41BD of the *Therapeutic Goods Act* 1989 provides a useful definition of the focus of the majority of MedTech investments. There may be supportive digital health devices that don't meet this definition, but it should not include investments in medical data systems or health informatics.

Investment needs and opportunities

5. What are the opportunities for value-add, growth and diversification in each of the priority areas?

Australia has a vibrant, if underfunded, startup sector in MedTech. Investment in these companies at key milestones has the opportunity to allow these companies to scale and develop the increasingly demanding data needed to demonstrate safety and efficacy to regulators and payers. This sector already has a natural diversity built into it without requiring this to be explicitly cultivated. However, as noted, startups alone do not represent the opportunity for the MedTech sector. MedTech typically does not launch globally and Australian-based companies can benefit from investment that allows capacity and capability for further launches in conducive markets, generating additional revenue for return investment. This may include expanding manufacturing capability or conducting further trials to generate evidence necessary for regulatory or reimbursement agencies. These types of issues typically limit the ability of SMEs to expand. The opportunity to attract investment from global companies with targeted investments should not be underestimated. These investments are typically large and may include R&D (as undertaken by Stryker recently) or manufacturing. As noted, these often revolve around the increasing custom device needs of regional markets that involve bespoke requests from clinicians for patient matched technology.

6. What are the manufacturing capabilities needed to support each priority area?

Examination of Manufacturing 4.0

There will be a need to be an increase focus on industry 4.0 concepts such as automation and use of digital twin as manufacturing activities that should be expanded locally. These advanced manufacturing solutions should be carried out in manufacturing hubs that should be located strategically in areas where there are low property prices and labour costs to make it worthwhile for companies to invest. An example would be focus on the Albury/ Wodonga region between Sydney and Melbourne, Newcastle and Wollongong in NSW, Geelong and Dandenong in Victoria, the Princess Alexandria Hospital precinct and Gold Coast region in Queensland and the Tonsley precinct in South Australia. Furthermore, given the high complex nature of these facilities in terms of their activities, there is less of an incentive for such companies to offshore these activities as it could occur great cost to do so.

As an illustration, Vaxxas is an Australian company that follows this trajectory. The recent investment of government funding into a state-of-the-art Biomedical Manufacturing Facility in Queensland will allow Vaxxas to develop their High Density Microarray Patch, a needle free technology. Once set up, the facility is expected to employ up to 110 high skilled biomedical

experts and manufacture enough needle-free vaccines to deliver 300 million doses - exemplifying the precise manufacturing Australia can continue to grow domestically.

Aligning sovereign capability with sustainability

In addition to bolstering sovereign capability, the NRF investment mandate will involve allocating funds to achieve desirable social outcomes, such as environmentally sustainable policies. Product stewardship is an area of increasing focus for the Federal Government, with the Minister for Environment and Water's recent inclusion of healthcare plastics on the National Product Stewardship priority list. There is an opportunity in MedTech to bolster local manufacturing to strengthen supply chains but also factor in sustainability principles.

The NRF should examine technologies that focus on reprocessing/reusing certain medical technologies, such as medical single use items, as this could reduce the amount of medical waste being diverted to landfill. It also generates a highly specialised manufacturing capability where certain medical waste can be reused in clinical settings.

Once established, such local capabilities can also be leveraged to unlock export market opportunities, as there are other countries regionally that are transitioning their economic activity to be more sustainable. Having an NRF support sector that is being able export reusable or environmentally-friendly devices presents an opportunity for Australia to be a leader within the region.

Mapping of existing Medtech manufacturing capability

To help understand how the NRF can be best placed to invest in the medical technology space, MTAA recommends the Department undertake a Medtech manufacturing ecosystem landscape assessment involving a gap analysis and future capability trends. This should involve leveraging existing information on the medical technology device requirements and manufacturing capability already being collected by MTPConnect and the Advanced Manufacturing Growth Centre and supported by relevant future oriented patent landscape mapping initiatives.

There is already an existing local manufacturing capability that should be grown to achieve sufficient stockpiles of essential medical devices. This would involve investing in activities that could include:

- Electronics manufacturing
- Injectional moulding
- Manual (low volume) and automated (high volume) assembly.
- Glass manufacturing.
- Sterility treatment – all types

7. What are other capabilities needed to support each priority area?

TGA support for Australian SME medical device companies

The TGA can play a critical role in supporting Australian companies to develop regulatory dossiers that meet local and international obligations. Unfortunately, the heavy reliance of the TGA on industry fees and the consequent underfunding of the TGA means this capability is emaciated and it urgently needs bolstering. The TGA should be viewed as an important agent of MedTech industry development. Access to this capability should not attract fees.

Harnessing the workforce capability support mechanisms in the MedTech ecosystem

Once emerging concepts have achieved technology and engineering proof of concept through small volume manufacturing, the next challenge is to lower unit production costs through accessing networks of local small – medium sized component suppliers. Unfortunately, this is where many companies are forced to relocate offshore to access such capabilities.

Organisations such as the Australian National Fabrication Facility (ANFF), which is funded as part of the National Collaborative Research Infrastructure Strategy are key levers in building the local manufacturing capability in Australia. ANFF has the ability not only provide the equipment to support development of new products, and improvements to current production methods, but is important is training new workers to possess high end manufacturing capabilities.

By enhancing access to such initiatives, Australia is able to grow a highly specialised workforce capable of undertaking R&D and advanced manufacturing activities. This is turn helps support more local manufacturing remaining in Australia but also encourage foreign direct investment from larger companies as there would be a workforce of sufficient to support any major investment new in manufacturing or R&D facilities.

The NRF could fund a technology voucher program to allow companies to access these capabilities. Such a program would operate in a similar manner to the Investment NSW Tech Voucher Program.

8. What are the strategic priorities for supply chains / enabling inputs in each priority area?

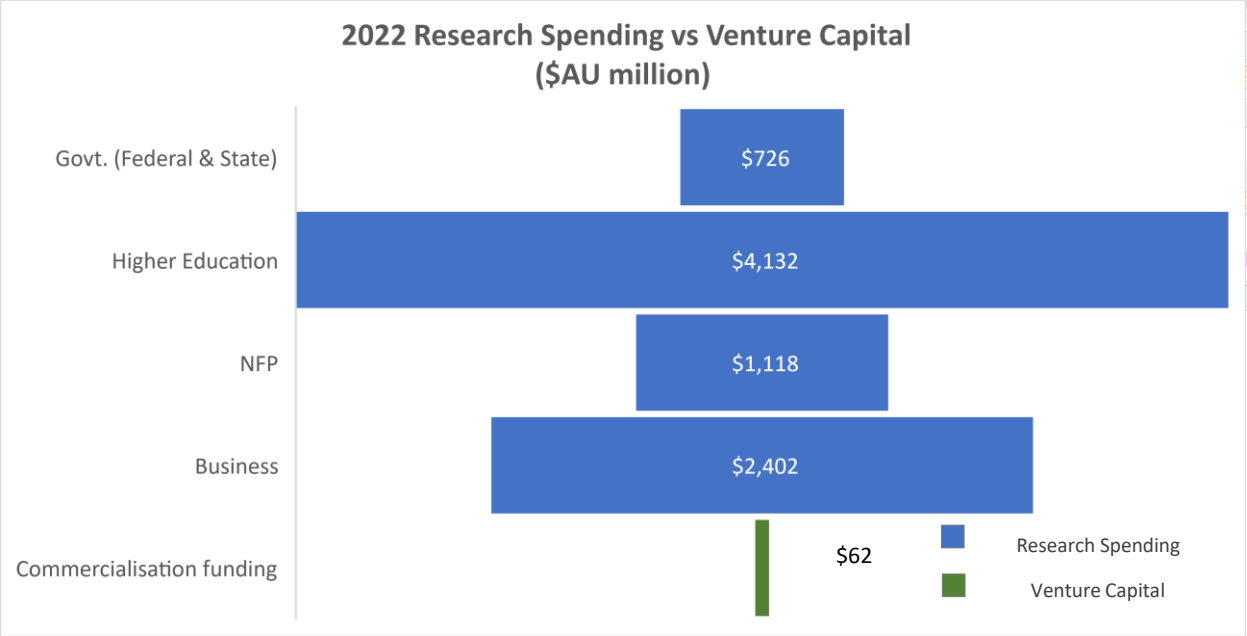
There are no current supply chain or material input limitations to the growth of MedTech in Australia.

9. What are the gaps in or barriers to private sector investment in each of the priority areas?

Lack of appetite to invest in MedTech

A current challenge in the MedTech sector is the level of risk aversion to investing in the medical devices sector. The Australian Medical Device Venture Investment report identified that MedTech represented 46 of 182 deals (25.3%) and $255million of the $1.7billion of venture capital invested (14.6%) into the health and medical technology sector. In addition, a significant amount of MedTech venture capital is flowing offshore. Approximately 38% (AU$96 million) of Australian medical device venture capital identified over the past 5 years, flowed into deals where the company was headquartered outside of the country (e.g., Bivacor, EBR Systems, Alimetry etc.). This capital also represented a little over 30% (14/46) of all medical device deals completed over the period (See Appendix)[1].

Another challenge has been historically large volumes of funding allocated for medical research and not enough dedicated to venture capital needed to commercialise research. This is clearly seen in the following Chart. The funds should instead be redirected to encourage more private investment activity so more companies and grow locally. Providing funding to local industry players that have the ability commercialise research, rather than a reliance on university commercial schemes, is beneficial as it diversifies the risk of relying on the tertiary sector manage commercialising innovative technology.



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

10. How can the NRF help build or encourage stronger pathways for Australian developed innovation and research, and encourage additional private investment in priority areas?

Approaches to encourage stronger pathways for Australian developed innovation and research and encourage additional private investment is referred to other questions throughout the MTAA response.

11. How could the NRF consider Government policy priorities in performing its investment function?

As part of its investment function, the NRF could consider how local medical technology manufacturing industries are able to support key policy priorities in healthcare. For instance, how locally manufactured items lead to improve patient outcomes and savings to the hospital system. In addition, the NRF could consider the need to establish essential devices manufacture locally, including considerations about the National Medical Stockpile to ensure health emergency preparedness.

Returns, financial instruments and working with other investors

12. What factors and considerations should inform the portfolio rate of return for the NRF?

The NRF should use the Capital Asset Pricing Model which is used extensively in corporate finance to identify assets with different risk/ return profiles and their different costs of debt and equity capita respectively. It sets the framework to explore why digital health and pharmacology startups attract funding over medical devices.

In addition, the NRF should avoid non-investment return evaluation criteria as these distort commercial decision making and market efficiency. However, it is important that there are goals outlined in the investment mandate of the particular economic or social problems the Fund needs to address – e.g. more reusable medical devices or medical devices that are designed to be sustainable.

How to measure the rate of return

It is important to note there are different costs of capital across the different medical manufacturing sectors: pharma, biotech and medical devices. Each have their own unique traits in terms of their commercialisation pathway.

Models of evaluating risk and rates of return in private capital markets should be reviewed and an approach applied to the NRF. The CAPM model is a fundamental principle of corporate finance and can be used to measure rates of return. Ultimately, having an approach to determine the initial cost of capital and comparing the real return verses expected return for an investment helps optimise construction of investment portfolios that will efficiently maximise return for the least amount of risk needed.

When exploring potential rates of return in the medtech sector, further investigation is required to analyse the return profiles of key sub-sectors:

- Digital health: Often considered capital and intellectual property 'light' with shorter development and regulatory approval times (relative to other device sectors)
- Pharmacology: A structured regulatory approval process with deep capital investment and intellectual property development creating long timeframes to market yet with significantly high pay-offs leads to creation of a portfolio approach associated with traditional venture fund investment
- Implantable and wearable medical devices of varying approval requirements, as well as deep intellectual property and capital development requirements, typically requiring technology and market validation, yet with lower returns relative to pharmacology sub-sector

13. What factors and considerations should inform the setting of acceptable but not excessive level of risk? Should the acceptable level of risk differ between priority areas?

Using the Capital Asset Pricing Model should provide a clear indicator of the variation in the cost of capital/acceptable risks due to nature of project and ability to ensure capital preservation vs outperformance returns. This in turn will help an established benchmark of return based on comparable global transactions in markets.

14. What types of concessional offerings would be preferred if these were offered (for example, lower interest rates) and why?

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There are several concessional offerings that could be adopted as part of the NRF

- Non-recourse loans (debt) with equity level interest rates capitalised (rather than regular repayments)
- Longer term duration debt
- Longer term holding equity
- Consider capital gains tax offsets for co-investment by private investors
- Guarantees like those offered by the Small Business Administration in the US would be a welcome addition to our environment here. This would get Australia's banks providing growth capital to SMEs again

15. What factors drive or constrain co-investment (for example, by industry, financial sector or domestic or offshore investors) and how should these be taken into account?

The main factors that impact on co-investments are risk and return profiles of medical devices and lack of local investor experience investing in this space. Furthermore, this is compounded by a lack of opportunities of local exits for medical device deals.

16. What are the mechanisms and types of finance which will best attract co-investment from the private sector? How can the NRF best crowd-in investment?

Fund of Fund models

To enable crowding-in of investment into Australian MedTech, the Government should examine Evergreen Fund and Fund models that the NRF could implement. A 'fund of funds' is a pooled investment fund that invests in other types of funds. Essentially, it is a portfolio containing different underlying portfolios of other funds. The NRF, through a fund of funds approach could create a mechanism to crowd in private investment. This approach could attract new investors and build investments from existing investors, and with its crowd-in potential, offer a further opportunity to local assets grown in Australia remain here longer.

An additional benefit of the fund of fund model enables hyper focus on specific areas to build centres of excellence, as well as recognising the different cost of capital considerations across the seven priority areas, each with unique risk/ return profiles.

Supported by Evergreen fund model

Venture Capital and Private Equity fund structures are traditionally raised in the closed-ended manner, through limited partnerships with end dates. These fund structures have limited time to deploy capital and gain investor returns – time frames often shorter than those associated with commercialising the deep technologies associated with medical devices. This closed end fund structures partially explain the emphasis of the local venture capital investment ecosystem on later stage deals, as characterised in the table below:

Invested (AU$ M)	2018	2019	2020	2021	2022	Total
Accelerator/Incubator	0.34	0.04				0.38
Seed Round	0.35	2.94	5.21	0.73		9.23
Early-Stage VC	4.41	4.1	2.48	28.94	12.01	51.94
Later Stage VC	45	45.65	1.38	27.71	73.8	193.54
Total	**50.1**	**52.73**	**9.07**	**57.38**	**85.81**	**255.09**

A less common alternative to this is an open-ended/evergreen fund, an ongoing structure that continues indefinitely. The core advantage of such funds is that they have more flexibility. Without an end date and with the ability to raise more capital, they can truly focus on long-term capital appreciation for investor, as well as enable capital allocation to longer term deep technology research commercialisation. Challenges do exist with ongoing underlying asset valuation, particularly when allowing existing investor exits or enabling new investors to enter. One example growing in broad activity is CSIRO's Main Sequence Ventures (MSV). Unfortunately, this fund does not invest in regulated medical devices. The MSV model does demonstrate the ability to attract co-investment by private institutional and strategic (corporate) capital within more traditional closed end fund structures.

Financing arrangements for smaller companies

For smaller companies, financial arrangements that make it easier for companies to stay afloat and grow will then encourage additional private sector co-investment. This is important for early stage medical device companies as they are generally unable to meet debt service requirements. Some potential arrangements could involve the NRF using SAFE notes (Simple Agreement for Future Equity) which is a financial instrument that does not immediately default to debt and carries no interest. Instead, it can either be converted to equity at a later point, the amount is repaid or it can be converted during a liquidity phase. In terms of deploying debt financing, medium sized medical technology companies would be better suited to taking on debt to scale up their operations.

Another alternative scheme currently adopted by NSW Medical Devices Fund is to provide a form of grant funding that converts to a loan scheme with interest once the startup reaches profitability and repays the value of the grant – however the specific terms and able to be negotiation on a case-by-case basis.

Policies that encourage Early Venture Capital investment in MedTech

The NRF should review and adopt policies that sustain VC risk appetite investing in startups. This is clearly a challenge in Australia which is currently more risk averse when investing in the Early VC space of medical devices. Australian Medical Device Venture Investment Summary Report (January 2023), between January 2018 and January 2023 of the $AU1.7billion VC invested in health and medical technologies, only 4% was for seed stage and 32% early stage. In contrast 64% was directed towards late stage venture capital.

Private equity co-investment models involving global companies

There is an opportunity to encourage additional investment from global companies through formation of co-investment arrangements. This would involve larger companies in addition to providing funding through the NRF, also contributing additional equity finance to the fund through a separate arrangement with the fund manager. This allows these companies more exposure to certain deals involving small to medium sized medical technology companies they may see as of strategic interest.

Foreign Direct Investment Opportunities with global companies

While seeming counterintuitive, involving global medical technology industry companies is an opportunity to leverage the initial NRF and strengthening sovereign capabilities. Finance provided to global companies via the fund incentivise foreign direct investment to stimulate growth of critical, local Medtech companies to grow and manufacture locally. This could occur by providing these companies access debt financing to help them offset large capital investments that are required to build manufacturing facilities in tandem with some tax-deductible benefits (capital and equipment offsets). Large global companies would then also directly invest their own funds to supplement the debt financing provided to build critical infrastructure and hire key personnel.

Adjusting Tax Incentives to promote co-investment

R&D

To encourage more co-investment from global companies to support growing a local manufacturing capability, further augmenting the R&D tax incentive will increase local research and development activity in Australia. For larger companies, especially those that conduct clinical trials (such as Medtronic, Boston Scientific and Biotronik) providing a larger tax offset will ensure more core R&D activities are able to take place domestically.

Providing employers with a tax offset for employing tertiary educated employees in a dedicated R&D function is an investment attraction tool that drives employment rather than offering 'big corporate' relocation assistance or concrete and glass buildings

Furthermore, the R&D tax incentive should also be structured to facilitate the development of partnerships to conduct key R&D activities. Companies may have to incur additional legal expenses to provide proof they are still eligible for the R&D incentive if they are partnering with a larger company. This could involve an SME partnering with a global company in undertaking R&D activity and ensuring eligibility criteria is modified to reflect joint R&D ventures.

Early stage Venture Capital

An increase in the tax offset currently provided investing in the ESIC (Early Stage Innovation Company) and ESIC's modified capital gains tax treatment would help encourage more investing in early seed stage medical technology companies, identified as an area of weakness in the Australia medical technology investment landscape. According to the Australian Medical Device Venture Investment Summary report 2023, currently (2023) we invest <AU$350 million a year into the medical device sector, when on average Australia would require at least AU$660 million to sustain and graduate 10 innovative companies a year (see Section 5 of Appendix) .

Complementary reforms

17. What are the non-financial barriers preventing businesses from making the most of opportunities for value-add, growth and diversification in the priority areas?

Home markets are more relevant for MedTech than biopharmaceuticals because overseas clinicians and payers will often want to see a device has success in the company's local market before considering it. Regulatory, reimbursement and procurement all play a key role in market access.

Regulatory Barriers

While there is an imperative to maintain safety and quality in regulatory requirements, there also needs to be a consideration of the approval times and the costs medical companies are required to navigate to reach market. Currently, Australia often takes longer to provide premarket approval for high-risk devices when compared to its overseas counterparts such as the USA and Canada. Proposed significant increases in TGA fees will further compound these concerns.

Reimbursement Barriers

Medtech is typically paid for by 3rd party payers, usually governments or insurers. In Australia, public hospitals can use new medical devices as soon as they are approved for use by the TGA, although they are limited by hospital budgets. In contrast, the path for uptake of new technologies in the private sector, especially private hospitals, is more complex. Implanted devices need to be listed on the Prostheses List which may involve lengthy assessment. Innovation is often rejected. Furthermore, the process to get procedures funded through the MBS where devices can be used is prolonged with indefinite timeframes for government approval. Consequently, overseas markets may appear more attractive both for launch and investment.

Procurement

Procurement processes by state and territory hospitals may disincentivise local innovation in several ways including requiring tenders of broad portfolios instead of niche devices by small companies, not paying for new innovation or paying simply the lowest price instead of considering important value adds (value-based procurement).

The government can also consider strategic approaches to procurement that serve multiple goals. To support the initial investment activity of the NRF in local medical technology company manufacturing, the Government should adopt a targeted tender program that prioritises procuring local medical technologies that are of critical importance to Australia's national interest. As noted earlier, these can include devices that will help Australia prepare for future national health emergencies. In terms of implementation, MTAA recommends this targeted tender program be aimed at specific, defined areas of sovereign priority to be filled by Australian medical technology manufacturers. This would follow the model used at the height of the pandemic to

resolve supply chain challenges around ventilators and PPE. This would require development of a priority list, based on required capabilities in the event of future supply chain stress.

While serving a critical health need, these targeted tender programs would also provide an opportunity for government and private industry to co-invest in sovereign capability. Simultaneously, a sustainable value proposition is built for that capability in Australia with a local customer, in the form of government health procurement. The program would also contain criteria requiring tender applicants to show how the capability could become competitive over time against overseas competition, both in local and export markets

It is important for the Government examine and potentially make additional reforms to other levers to help support the objectives of the NRF because of the interdependencies between the NRF and these levers. A consistent theme across the MTAA membership is that existing regulatory and reimbursement hurdles that make it more unappealing to grow and expand manufacturing activity in Australia.

Identifying smaller businesses with robust Quality Management Systems to invest in
Another important consideration is NRF targeting startups and smaller companies with a clear plan regarding how they intend to grow their local business footprint. This would require these companies to have a clearly defined QMS that is ideally tailored to the industrial designer. Companies with a strong understanding inhouse of the various aspects of a company's QMS (design, manufacturing, supplier management, risk management, complaint handling, clinical data, storage, distribution, product labelling and more) will provide and encourage investment (from angel investors and VCs) in the company's business activities. Historically, there have been problems that medical technologies, irrespective of their efficacy, lack of clarity on the QMS to adopt (because it is outsourced without an intention to bring this knowledge inhouse) or only decide on the QMS too late in the growth phase of the company, resulting in an inability to bring the product to market and commercialise it.

Migration policy
Skilled migration visas need to easier and faster to obtain in priority areas such as medical technology manufacturing can help develop the workforce capability to growth the industry when funding is allocated in certain projects.

18. Are there non-financial mechanisms that could support priority areas and the objectives of the NRF?

This is addressed in our response to question 17

19. How could the NRF work alongside other complementary reforms to best deliver on the Government's policy priorities?

This is addressed in our response to question 17

20. To what extent are other levers required to support the objectives of the NRF (for example, skills, trade, supply chains)?

Information on peer comparison transactions and other valuation approaches
Enhance access to private investor capital through access to global information on peer comparison transactions (through sources as Pitchbook or CB insights) on comparable devices in early-stage commercialisation to help identify opportunities to invest in Australian medical technology startups. This will help relevant general partners (GPs) assigned to the NRF to identify and evaluate worthwhile deals to invest in. Furthermore, there will be a need to introduce novel valuation techniques (such as real options modelling) for the medical technology sector. Currently, the limited capacity to use an array of tools to determine the value of investing in medical technology opportunities, means there is a reluctance by fund managers to contribute finance to the sector.

Fund manager choice
As highlighted in the Australian Medical Device Venture Investment Summary Report (January 2023, see Appendix) there is currently no clear fund manager with a highly specialised understanding of the medical technology sector. Existing venture Capital vehicles are more focused on Life Science and Pharmaceutical investments than they do for Medical Device investments.

This is thought to be largely structural based on portfolio models that require few but very large exits (the returns are significantly higher in pharma and biotech), rather than the more frequent but smaller exits seen with Medical Devices (the returns are of a smaller magnitude relative to pharma and biotech).

Furthermore, it should be noted that the major venture capital funds in the current Australian ecosystem have traditionally been more focused in investing in companies at the growth stage rather than early investment stage and also prioritised investing in.

In addition, a substantial proportion of Australian venture capital for medical devices has been flowing offshore. Approximately 38% ($AU96 million) of Australian medical device venture capital identified over the past 5 years has flowed into deals where companies were headquartered outside of the country

There needs to a be a critical appraisal of the existing fund managers operating in the medical technology ecosystem to help determine the most appropriate group selected to manage the NRF investments.

MTPConnect are a natural candidate, given their extensive networks in the medical technology space and that they possess deep specific insights within Australia's medical technology sector with strong global connections. MTPConnect have reviewed over 1,200 propositions, yet only invested in 15% of these due to funding constraints. However, there would be a need to build MTPConnect capital market capabilities across venture capital and private equity.

MTPConnect has developed significant sector insights experience and networks in evaluating medical device concepts. This positions MTPConnect to be able to provide medical technology sector specific capability in identifying and screening potential NRF investments.

In many ways, MTPConnect presents the natural fund management capability, with strengthened capital markets capabilities, to become the specialist medical devices capability for the NRF.

One proposition to access deep sector experience and capability is for MTPConnect and MTAA to form a joint venture with venture capital and private equity fund management specialists. MTAA will leverage co-investment by industry members as strategic investors into early stage (TRL 1-3) and mid-stage (TRL 4 – 6) projects on an aggregate basis (evergreen fund model), with the opportunity to invest directly into their preferred mid-stage projects.

In order to ensure the NRF is fulfilling a mandate to invest in local and innovate companies that can conduct manufacturing activities to build sovereign capability, it needs to act as a catalyst at the earlier stage by becoming a co-investor and offering co-investors beneficial capital gains tax positions (for instance) to draw private monies into the earlier stages.

21. How does the NRF, with other private and Government settings, drive the right ecosystems for sustainable industry growth?

- Tax incentives for Foreign Direct Investment (FDI) – providing the right tax incentives for larger global companies will encourage investment in conducting Australian based R&D and local manufacturing. The patent box policy announced in the previous budget which provided a lower tax rate on patent derived income for medical and biotechnology companies would be an ideal policy to increase FDI activity. Other tax incentives would be increased capital gains tax offsets for losses in early stage investments to continue sustained investment in this space
- Providing the right tax incentives to facilitate manufacturing activities taking place in areas where the labour and property costs are relatively low.
- A combination increased training of local university graduates with high specialised technical training to help support advanced manufacturing activities

- Tax incentives to locate manufacturing in geographical areas with lower labour and property costs

Building capability to gather high quality clinical evidence for novel technologies

An important non-financial mechanism to leverage would be to involve Key Opinion Leaders within the medical technology space to be more actively involved in collaborations between industry and universities. KOL would include leading clinicians that may use and evaluate novel medical devices in clinical and or research settings.

How:

Increasing KOLs involvement within the health innovation precincts in building key clinical evidence can happen in several ways. They can support collecting clinical data and reviewing aspects of the technology being developed.

Benefits:

i) It increases clinician awareness and understanding of the latest innovative technologies through building the evidence base

ii) It builds the expertise of clinicians to appraise and evaluate novel technology that is transferable to other domains (regulatory, reimbursement)

Outcome:

By increasing this level of collaborative activity, this in turn should then be able to then build a key group of decision makers with sufficient knowledge and expertise to support a program dedicated to assessing novel technology pathways.

22. APPENDIX

Australian Medical Device Venture Investment.

Summary Report (January 2023)

The following report discusses venture investments made into Australian medical devices over the past 10 years (2013 – 2023). Specifically, this report seeks to highlight the level of investment in medical devices and investment activity at different stages of the technology value chain, with contrast drawn against health and medical technology investments more broadly.
Raw data was sourced from Pitchbook and is correct on the 31st January 2023.
Search terms were guided by the authors previous experience as the Chief Innovation Officer and Head of Investment Strategy at Cicada Innovations and the manager of a MedTech corporate venture vehicle, Nanosonics Investments. Further guidance was gleaned from Ben Armstrong's LinkedIn article "Healthtech in Australia: A venture capital perspective" (22 March 2022).

Search Criteria: AirTree Ventures; Archangel Ventures; Artesian Capital Management; Bioscience Managers; Blackbird Ventures; Brandon Capital; Brenteca; Carthona Capital; Flying Fox Ventures; Folklore Ventures; Giant Leap; Horizon 3 Biotech; IP Group Australia; Main Sequence Ventures; OIF Ventures; OneVentures; Right Click Capital; Square Peg Capital; Uniseed;
Inclusions: Healthtech, Health IT, Life Sciences, Pharmaceuticals, Diagnostics, Medical Devices, Software as a Medical Device (SaaMD), Medical Device Manufacturing / Tools, Venture Capital, Corporate Venture, Private Equity, PIPE.
Exclusions: Angel investors, High Net Worth (HNW) investors, Foreign Venture Capital investors, State and Federal grants (including the NSW Medical Devices Fund).
Note: Accelerator / Incubator refers to external investments and not those made though program participation.

1. State of the Nation

The Australian Venture Capital industry invested AU$2.1billion (236 deals) into 108 unique health and medical technologies from January 2013 to January 2023. The data is heavily skewed towards the past 5 years, suggesting a growing maturity in both data collection and the Australian health and medtech sector. Whilst this report will refer to some 10-year figures, the focus of any analysis will be the contemporary 5-year data.

From January 2018 to January 2023 the data suggests venture investments of AU$1.7billion (4% Seed-Stage, 32 % Early-Stage VC, 64% Later-Stage VC, 0.2% PE/PIPE) into 182 deals (21% Seed-Stage, 39% Early-Stage VC, 35% Later-Stage VC, 1% PE/PIPE).

Table 1a illustrates the shift in deal completion resulting from post-COVID19 austerity, rising interest rates and reduced LP appetite. Table 1b. clearly shows the transition towards fewer and later-stage investments in 2021 and 2022.

Medical Devices represented 46 of 182 deals (25.3%) and $255million of the $1.7billion of venture capital invested (14.6%) into the health and medical technology sector (Table 2a).

Table 1a.

Number Completed Investments	2018	2019	2020	2021	2022	2023	Total
Accelerator/Incubator	**2**	**5**	**1**				**8**
Diagnostic		2					2
Health IT		1					1
Life Science / Pharmaceutical		1					1
Medical Device	2	1	1				4
Seed Round	**7**	**10**	**10**	**8**	**3**		**38**
Diagnostic				1			1
Health IT	1	4			1		6
HealthTech	1		2	2	1		6
Life Science / Pharmaceutical	2	1	2	3	1		9
Medical Device	1	4	5	1			11
Medical Manufacturing	1						1
SaaMD	1	1	1	1			4
Early Stage VC	**13**	**18**	**17**	**15**	**8**		**71**
Diagnostic		1	2	2			5
Health IT	3	1	5	1			10
HealthTech	2	4	2	5	3		16
Life Science / Pharmaceutical	5	8		4	3		20
Medical Device	3	3	6	3	2		17
SaaMD		1	2				3
Later Stage VC	**10**	**12**	**9**	**15**	**16**	**1**	**63**
Diagnostic	1	2	1	1	1	1	7
Health IT	1	2	4	4	3		14
HealthTech			1	1	1		3
Life Science / Pharmaceutical	4	4	2	5	7		22
Medical Device	2	4	1	3	4		14
Medical Manufacturing	1			1			2
SaaMD	1						1
PE Growth/Expansion			**1**				**1**
Health IT			1				1
PIPE					**1**		**1**
Health IT					1		1
Total	**32**	**45**	**38**	**38**	**28**	**1**	**182**

Table 1b.

Medical Device Investments	2018	2019	2020	2021	2022	2023	Total
Accelerator/Incubator	2	1	1				4
Seed Round	1	4	5	1			11
Early-Stage VC	3	3	6	3	2		17
Later-Stage VC	2	4	1	3	4		14
Total	**8**	**12**	**13**	**7**	**6**	**0**	**46**

Table 1c.

Invested (AU$ M)	2018	2019	2020	2021	2022	2023	Total
Accelerator/Incubator	**0.34**	**0.34**	**0.00**				**0.68**
Diagnostic		0.10					0.10
Health IT		0.10					0.10
Life Science / Pharmaceutical		0.10					0.10
Medical Device	0.34	0.04	0.00				0.38
Seed Round	**13.67**	**5.04**	**9.08**	**26.28**	**8.58**		**62.65**
Diagnostic				2.10			2.10
Health IT	0.77	1.10			2.08		3.95
HealthTech	0.57		2.30	6.81	1.50		11.18
Life Science / Pharmaceutical	7.10	0.00	1.14	14.72	5.00		27.96
Medical Device	0.35	2.94	5.21	0.73			9.23
Medical Manufacturing	3.86						3.86
SaaMD	1.02	1.00	0.43	1.92			4.37
Early-Stage VC	**64.56**	**178.56**	**97.04**	**195.81**	**31.05**		**567.02**
Diagnostic		0.00	4.16	1.41			5.57
Health IT	14.03	0.00	19.16	22.30			55.49
HealthTech	8.69	68.15	64.21	104.23	2.00		247.28
Life Science / Pharmaceutical	37.43	106.31		38.93	17.04		199.71
Medical Device	4.41	4.10	2.48	28.94	12.01		51.94
SaaMD		0.00	7.03				7.03
Later Stage VC	**110.62**	**178.71**	**72.76**	**335.21**	**410.97**	**5.46**	**1113.73**
Diagnostic	26.00	11.02	2.26	0.00	11.20	5.46	55.70
Health IT	3.80	32.82	31.95	116.29	82.07		266.93
HealthTech			8.74	0.00	6.88		15.62
Life Science / Pharmaceutical	21.01	89.22	28.43	163.02	236.99		538.67
Medical Device	45.00	45.65	1.38	27.71	73.80		193.54
Medical Manufacturing	8.31			28.19			36.50
SaaMD	6.50						6.50
PE Growth/Expansion			**3.46**				**3.46**
Health IT			3.46				3.46
PIPE					**0.00**		**0.00**
Health IT					0.00		0.00
Total	**189.19**	**362.65**	**182.34**	**557.30**	**450.60**	**5.46**	**1747.54**

Table 1d.

Invested (AU$ M)	2018	2019	2020	2021	2022	Total
Accelerator/Incubator	0.34	0.04				0.38
Seed Round	0.35	2.94	5.21	0.73		9.23
Early-Stage VC	4.41	4.1	2.48	28.94	12.01	51.94
Later Stage VC	45	45.65	1.38	27.71	73.8	193.54
Total	**50.1**	**52.73**	**9.07**	**57.38**	**85.81**	**255.09**

2. Venture Capital Flowing Offshore

Approximately 38% (AU$96 million) of Australian medical device venture capital identified over the past 5 years, flowed into deals where the company was headquartered outside of the country (e.g., Bivacor, EBR Systems, Alimetry etc.). This capital also represented a little over 30% (14/46) of all medical device deals completed over the period.

Deals into overseas headquartered companies had a strong bias towards Later Stage VC (AU$81million) which supports a growth story but also suggests a further $AU14.9million in Seed and Early-Stage capital was funnelled offshore, representing 24% of all Seed and Early-Stage deals. (Note: This data is biased by the search criteria, with IP Group Australia, Brandan Capital, One Ventures and Horizon 3 all making significant investments into offshore headquartered companies).

Table 2a.

Invested (AU$ M)	2018	2019	2020	2021	2022	Total
Accelerator/Incubator		0.04				0.04
Seed Round			1.7			1.7
Early-Stage VC			2.31		10.86	13.17
Later Stage VC	8	45.65		27.71		81.36
Total	**8**	**45.69**	**4.01**	**27.71**	**10.86**	**96.27**

3. Venture Capital Deals into Domestic Companies

32 venture deals were completed into medical device companies headquartered in Australia between January 2018 and December 2022, representing AU$159million in capital allocation.

The data indicates a clear weakness in the funding continuum for Seed Stage medical devices, which represent only 5% of all Australian medical device capital, throttling the translation and commercialisation of innovative medical devices. The average investment made at Seed-Stage was AU$940,000, which for most seed startups represents 12-18 months of capital runway.

State-based distribution (Table 3d) of venture capital into medical devices paints an interesting picture that highlights formal venture capital is only part of the overall story. Victoria witnessed the largest deployment medical device venture capital (55%) with a little over $87million invested during the reported period. QLD was the next most active state, receiving 19% of medical device venture capital. NSW companies received surprisingly little formal venture given the medical device activity seen in the state.

The data does miss some companies like Medlogical Innovations and Atmo Biosciences, who were successful in raising Seed to Early-Stage financings in 2022 from HNW individuals despite a lack of venture capital activity.

Table 3a.

Invested (AU$ M)	2018	2019	2020	2021	2022	Total
Accelerator/Incubator	0.34					0.34
Seed Round	0.35	2.94	3.51	0.73		7.53
Early-Stage VC	4.41	4.1	0.17	28.94	1.15	38.77
Later Stage VC	37		1.38		73.8	112.18
Total	**42.1**	**7.04**	**5.06**	**29.67**	**74.95**	**158.82**

Table 3b.

Deals Completed	2018	2019	2020	2021	2022	Total
Accelerator/Incubator	2					2
Seed Round	1	4	4	1		10
Early-Stage VC	3	3	3	3	1	13
Later Stage VC	1		1	1	4	7
Total	**7**	**7**	**8**	**5**	**5**	**32**

Table 3c.

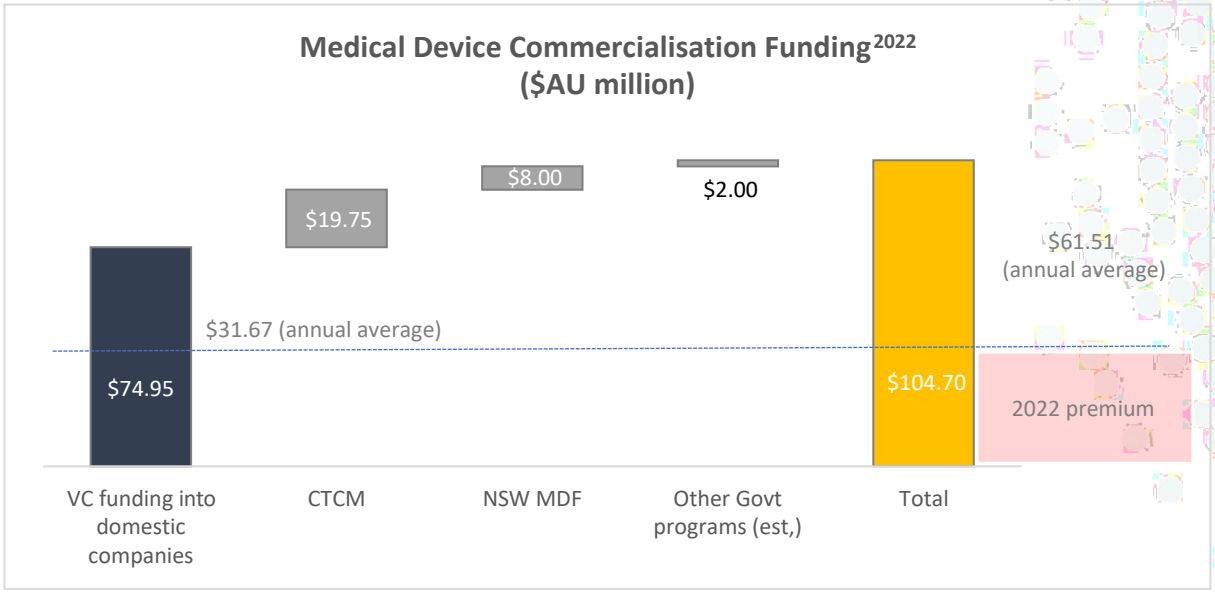
Deal Metrics	Avg Deal Size ($M)	% Capital Invested	% Deals Completed
Accelerator/Incubator	0.17	0%	6%
Seed Round	0.94	5%	31%
Early-Stage VC	4.85	24%	41%
Later Stage VC	18.70	71%	22%

Table 3d.

Invested / State ($M)	NSW	QLD	VIC	WA	Total
Accelerator/Incubator		$0.14	$0.20		$0.34
Seed Round	$4.28	$0.47	$2.78		$7.53
Early-Stage VC	$1.27	$5.50	$32.00		$38.77
Later Stage VC		$23.98	$52.38	$35.82	$112.18
Total	**$5.55**	**$30.09**	**$87.36**	**$35.82**	**$158.82**

A focus on 2022 provides further insight into the non-private funding available for medical device commercialisation, with ~29% originating from government programs like the CTCM managed by MTPConnect of the NSW Medical Devices Fund (MDF). The NSW MDF invested AU$78 million into 43 innovative medical devices from 2013 – 2020, resulting in over AU$790 million in capital from private and professional investors. Objectively, little of this value-added investment was made by Australian venture capital.

Chart 1.



Note: 2022 was an outlier. The average annual VC funding into domestic companies over the period was AU$15 million.

4. Balancing Research Spending with Venture Capital

Research Australia reports that AU$8.4billion is spent on health and medical research (HMR) each year, priming the innovation funnel with technologies that will one-day change patients' lives.
AU$2.3billion in federal government funding was invested into universities and medical research institutes (2021-2022) though initiatives like the National Health and Medical Research Council and the Medical Research Future Fund (Table 4a.).
29% of HMR expenditure (AU$2.4billion) was seen in the business sector, with 13% of all business research and development focused on health and medical R&D (2019-2020), with a greater focus on the development aspect than pure research (Table 4b.).

Table 4a.

NHMRC Funding	$870 million
ARC Funding contribution to HMR (10%)	$81 million
Research Block Grants contribution to HMR (34%)	$680 million
MRFF	$646 million
Total	$2,277 million

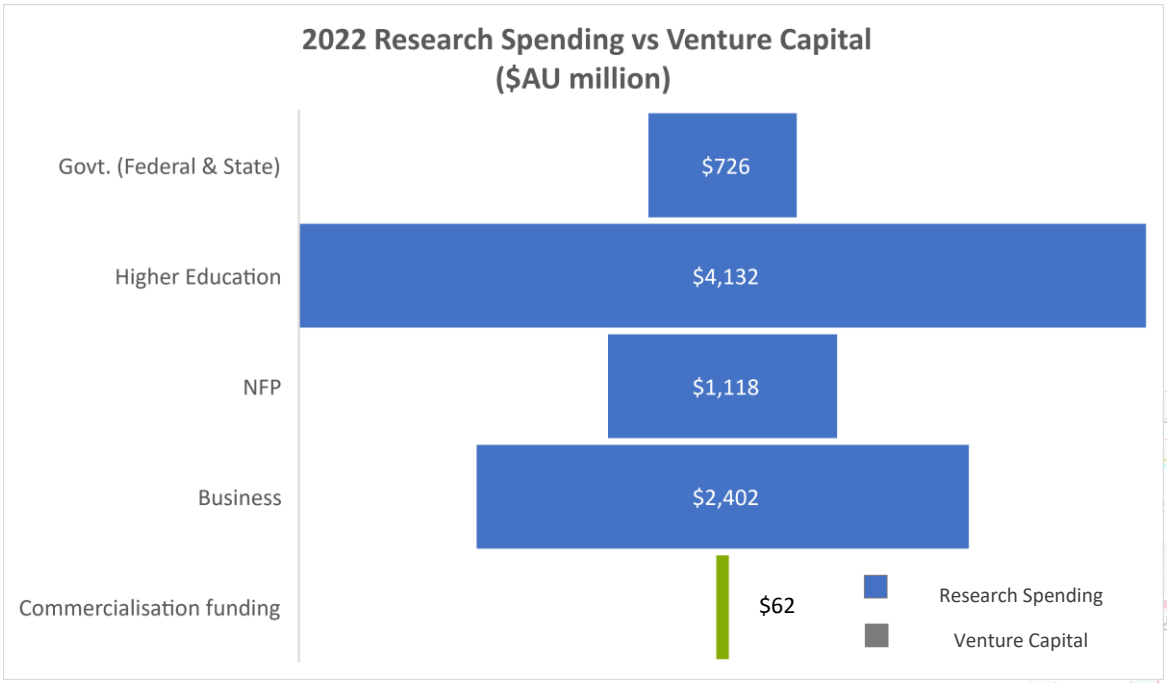
Source: Australian Government Science Research and Innovation Budget Tables 2021-22- estimated expenditure for 2021-22

Table 4b.

Aust. Govt. (including agencies)	States & Territories	Higher Education	Not For Profit	Business	Total ($M)
128	598	4,132	1,118	2,402	8,378
2%	7%	49%	13%	29%	100%

The magnitude of this investment appears poorly matched against that of Australian Venture Capital investment into the HMR sector at an average of AU$350 million per annum (4% of research spend), with medical device investments trailing at AU$25 million per annum and those with Australian headquarters on receiving an average annual investment of AU$32 million from the venture industry.
2022 was an outlier with significant later stage VC invested, bringing the total annual investment to AU$75 million, 5 times the average of AU$32 million invested per annum. When controlled average VC funding, the total commercialisation funding available from formal VC and government programs is AU$45 million per annum.

Chart 2.


2022 Research Spending vs Venture Capital
($AU million)
Govt. (Federal & State)
Higher Education
NFP
Business
Commercialisation funding
$726
$4,132
$1,118
$2,402
$62
Research Spending
Venture Capital

5. How much Venture Capital is required?

The average investment required for a US medical device startup prior to its acquisition / IPO is closely linked with its regulatory pathway. A weighted average venture investment of ~US$45 million (AU$66 million) is required over the life of a medical device company, to cross the startup valley of death, commercialise and achieve a financial exit for their backers (Table 5a.) On this basis, Australian venture investments would need to exceed AU$660 million per annum to sustain and graduate 10 innovative companies a year. Today (2023) we invest <AU$32 million a year into the domestic medical device sector suggesting that Australian innovations whither on the vine or that the top end of the value chain is serviced almost entirely overseas.

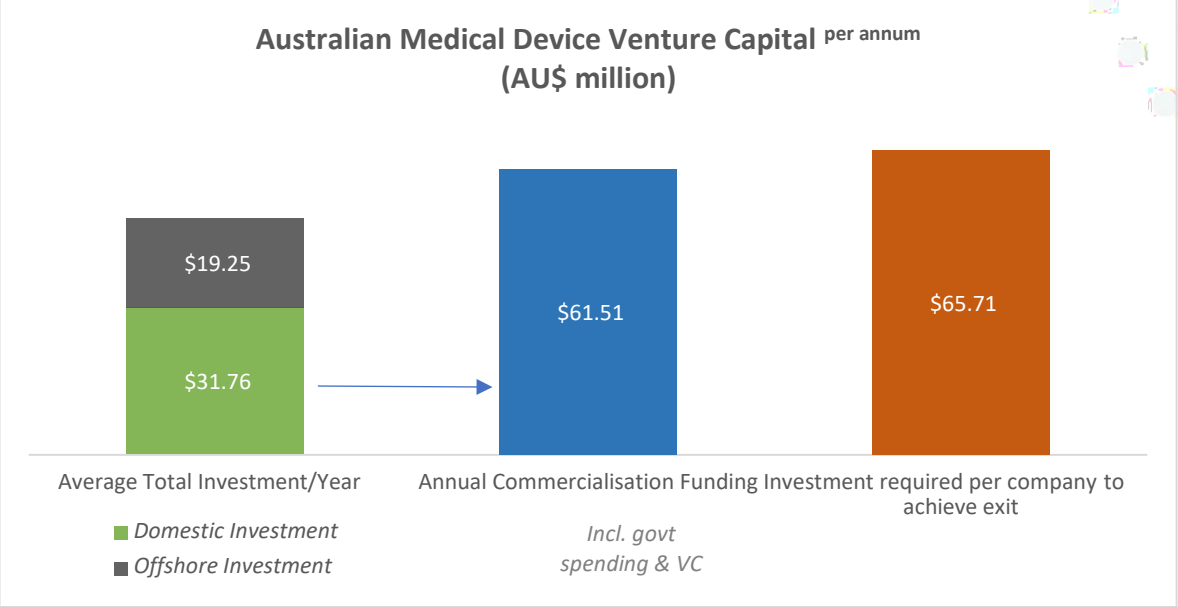
Table 5a.

			Median					
Regulatory Pathway	**n**	**Dominant Stage**	**Invested** (US$ M)	**Upfront Return** (US$ M)	**Upfront Multiple**	**Total Deal Size** (US$ M)	**Total Deal Multiple**	**Time (Years)**
510k	39	On Market	$41	$110	2.7x	$130	3.2x	8.1
De Novo	4	On Market	$46	$360	7.8x	$435	9.5x	8.8
PMA	31	Pre-Market	$51	$200	3.9x	$315	6.2x	6.7

Source: 2015 – 2019 Data, Silicon Valley Bank Annual Healthcare Reports 2018 & 2019

The following chart contrasts all annualised Australian medical device venture capital investment identified in the search against annual commercialisation funding for medical devices. The quantum of funding available nationally appears to be less than the forecast funding required to achieve 1 company exit (company life-cycle) per year in Australia.

Chart 3.



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7. Summary

Australian venture capital struggles to sustain the commercialisation of health and medical innovations generated by the Australian research and business sectors.

Medical devices receive disproportionally little capital from existing venture vehicles, and this is more acute at the Seed stages of investment.

Existing Venture Capital vehicles have a greater appetite for Life Science and Pharmaceutical investments than they do for Medical Device investments. This is thought to be largely structural based on portfolio models that require few but very large exits, rather than the more frequent but smaller exits seen with Medical Devices.

Significant amounts of the capital allocated to medical devices is invested into Later-Stage companies and those who have headquartered outside of Australia.

There appears to be a state-based disparity in the distribution of medical device venture capital that is inconsistent with translational research spend and the volume of IP generated.

The average quantum of commercialisation funding available, including government commercialisation funding and medical device venture capital, is less than that required to commercialise and exit 1 company per year in Australia (where exit is defined as a financial return for investors / backers allowing for the recycling of capital). This sub-scale financial ecosystem presents a challenge for the medical device ecosystem, government targeted growth sectors and investors.

Ben Wright
Ballistic Ventures Pty Ltd.
January 2023

Commissioned by Innovation Venture Partners Pty Ltd for use by MTAA in supporting their submission to the NRF Consultation Process