Australian Medical Research and Innovation Two Year Priorities

Title: Medical Engineering Research as an enabler for Medical Technology Innovation

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1. **What is the gap in Australia's health system to be addressed by this priority?**

Australia has the potential to greatly expand its capacity to develop new medical technologies that improve quality of care, and reduce overall cost of care; but this is currently hampered by a lack of funding to support clinician-led, STEM-enabled collaborative, multidisciplinary translational research focussed on medical technology innovation.

2. **How does your area of priority address either an existing or a new health or health system challenge?**

Cross-disciplinary research focussed on clinical outcomes – eg Medical engineering and digital health currently 'falls between the cracks' of the two major funding schemes – ARC and NHMRC, – hence this needs to be identified as a specific priority area, with targeted funding to support collaborative invention, translation and commercialisation of research directed at new medical technologies.

3. **Comment on which aims and objectives your priority is likely to meet.**

Research-engaged workforce; Leveraging and enhancing collaboration and integration; Translation pathway that maximises opportunities for success; preventions and cures of tomorrow; economic benefits; sustainable, high-quality care.

4. **Mandatory considerations – which of the mandatory considerations set out in the *Medical Research Future Fund Act (2015)* does your priority proposal address?**

☒ Burden of disease on the Australian Community
☒ How to deliver practical benefits from medical research and medical innovation to as many Australians as possible
☒ How to ensure that financial assistance provides that greatest value for all Australians
☒ How to ensure that disbursements complement and enhance other assistance provided to the sector

5. **Outline of priority proposal:**

The development of new medical technologies is inherently multidisciplinary, and requires the complementary expertise of clinicians, researchers and industry to come together as required at the different points along the innovation journey. If well coordinated, this collaborative approach has the potential to harness the existing but disconnected strengths in the Australian system – clinical expertise, high-quality enabling STEM research expertise, and industry-based product development and commercialisation expertise. The essential 'ingredients' are all present, but have not yet been adequately supported to come together, at scale, in an outcome-directed fashion.

Proposed Solution. Essential Elements for maximising Medtech Innovation

1. **Early clinician involvement in innovation – target major unmet needs**

ROI and impact can be greatly enhanced if the innovation process is guided at the outset by leading clinicians, health professionals and patient advocates, who have a deep understanding of the real unmet clinical needs that patients are encountering. These clinical champions should remain involved through the innovation process – ensuring 'pull-through' to final application, and development of technologies that meet real-world usage requirements. This also enhances the participation in

research by leading clinicians and hospitals, building a culture that constantly strives for the best possible outcomes for patients. Health professionals and administrators are also best placed to see the current inefficiencies in processes in the delivery of care – stimulating insights into how technologies could be developed and applied to improve both the quality, and efficiency of care delivery.

2. **Connect clinical needs to the problem solvers – STEM and Design researchers**

Whilst health professionals are best placed to identify clinical needs, complex challenges often require different types of expertise to be engaged to develop an effective solution. Rapid developments in science, engineering and IT are providing us with a new 'tool box' of enabling technologies that can be brought to bear on these clinical challenges. Facilitation is needed to help clinicians connect to STEM and design researchers best placed to solve the defined challenge. Forums of clinicians and STEM and design researchers are proving a fertile environment for parties to brainstorm and identify new ways that previously intractable problems can be tackled by latest STEM discoveries. However, this type of collaborative approach, which harnesses enabling STEM-research to target specific clinical needs, is currently not well supported by either of the major funding schemes.

3. **Integrate industry and commercialisation expertise to prioritise investment, enhance translational activities, and accelerate the path to product and clinical adoption**

The progression of a potential technology solution through to a successful new therapy, device or diagnostic requires a range of hurdles to be overcome – IP protection, manufacturability, regulatory approval, and a sufficient market and reimbursement pathway that warrants the downstream investment required. The ability to build a successful portfolio of medical technology innovations can be enhanced if these factors can be considered early in the R&D process. In the current system, these aspects are unfortunately viewed as elements that come after the research is done, when the IP is 'thrown over the fence' for some other player to commercialise. A much greater return on research investment can be achieved if this expertise, review and input is built into the earliest stages of research planning and prioritisation of investment decisions. This also provides the research team with options on how to structure their research direction to maximise potential impact. This model of early, independent commercial advice prior to investment in translational medtech research is used effectively in Singapore.

4. **Targeted funding for translational medtech research, and industry partnerships**

There are two distinct phases of R&D in medtech innovation, each requiring targeted initiatives. As noted above, there is the initial phase of clinician-led, STEM-partnered research to develop enabling technologies for the next generation of devices and diagnostics. There is then a need for funding and expertise to support the transition through Technology Readiness Levels 4 to 7. Whist some funding is available via the NHMRC Development scheme, this is a very low fraction compared to the overall pool of funding for research. It will be necessary to increase the proportion of funding in this domain if Australia is to significantly improve its track record for translation of excellent biomedical discovery research through to medtech products and clinical benefits.

There is also a need to integrate different types of expertise at this applied research phase, such as product development and regulatory expertise. These are skill sets which are not commonly found within the University, MRI or hospital sectors, but more commonly in industry, product development service firms or consultants. Funding mechanisms should be designed to incentivise the integration of this expertise. Three potential options include:

(i) Incentivise industry partnerships for medical technology development – eg Expand the MDPP model developed at Flinders Uni, or develop a clinical equivalent of the ARC Linkage scheme (The ARC Linkage scheme supports University-industry partnerships, but currently deems ineligible any projects which target a specific clinical outcome, thus eliminating those partnerships most related to medtech product development. This anomaly of eligibility that disadvantages the medtech sector has been removed in the ITRH and ITTC schemes, but remains in the Linkage scheme)

(ii) Provide a voucher scheme that enables medtech research teams to access external expertise, such as prototype manufacture, for translation and commercialisation

(iii) Build and support dedicated units that provide medtech commercialisation expertise and investment attraction to University/hospital clusters – eg akin to MERCI in Singapore, or the Blavatnik accelerator, or a medtech version of the M2 Venture Catalyst

Implementation: It is recommended that funding is implemented in a staged process.

1. Clusters: Bolster existing clusters of hospitals and research organisations that are focussed on medtech product innovation, translation and industry partnerships. This would enable established administration, infrastructure, and staff to be fully leveraged, allowing additional funding to be directed primarily to translational medtech project opportunities. Encourage a network of these 'nodes' in an Australian Medtech Innovation Initiative to enable sharing of best practice. (Nodes ready to implement include - VIC – MIME network including Monash Partners AHSC hospitals; SA - Flinders MDRI; NSW – UTS-Kolling Institute; with MTAA support, and connection to international SPARK network)

2. Sector-wide: Identify medical engineering, digital health, and clinical-STEM research collaboration as a priority area for investment, with specific funding allocated within either NHMRC, ARC or MRFF to support these cross-disciplinary, outcome-focussed and translational medtech research activities.

Feasibility: Feasibility of implementation has been demonstrated by the success of local models (Flinders Medical Device Partnering Program; MIME seed fund), which need to be scaled-up for greater impact, and by international models (UCSD GEM, MERCI, Blavatnik accelerator)

Risk	Mitigation
Broad involvement of clinicians	Pilot with established Uni-hospital clusters, eg MIME, MDRI, AHSCs. Foster network development.
Engagement by research community in translational research	Targeted funding for translational projects; prioritised by independent commercial/industry/clinical advisors, clear KPIs and tranched funding for projects.
Identification and integration of relevant commercial expertise for translation; effective industry engagement	Work closely with MTPConnect Expand MDPP program – (MIME-MDRI partnership to deliver expanded MDPP program across the 2 major manufacturing states)

6. What measures of success do you propose and what will be the impact on health care consumers?

Number of clinicians engaged in collaborative medtch projects with STEM researchers
New IP related to medtech products
Number of funded projects progressing from TRL 4 to 7
Nunber of projects progressing on commercialisation pathway via industry partnership or spin-out formation.
Number of technologies through to market approval and clinical utilisation.

7. Please outline any linkages your proposal has with stakeholders, policy agendas and other health and medical research funding agencies.

Stakeholders: MIME network (Monash University, Monash Partners Academic Health Science Centre partner hospitals – Alfred Health, Monash Health, Eastern Health, Peninsula Health, Cabrini Health, CSIRO, Hudson Institute, BakerIDI). Aligns with NISA, MTPConnect objectives, and Victorian State government medtech sector growth strategies. Related - Proposed SPARK program with MTAA.