Flinders UNIVERSITY

medical device PARTNERING PROGRAM
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How can we optimise translation of health and medical research into better health and wellbeing?

ToR #4. The relationship between business and the research sector, including opportunities to improve Australia's capacity to capitalise on its investment in health and medical research through commercialisation and strategies for realising returns on Commonwealth investments in health and medical research where gains result from commercialisation.

ToR #8. Opportunities to improve national and international collaboration between education, research, clinical and other public health related sectors to support the rapid translation of research outcomes into improved health policies and practices. This will include relevant international comparisons.

Summary

While Australia has excellent strengths and capabilities in health and medical research, the translation of that research into practice has been more difficult. Our clinicians have ideas and needs, our scientists have solutions, our engineers have technologies, and our industry is willing to engage. However the path to connect them is unclear. Grant funding support is valuable but insufficient. Two successful models are presented both of which provide a structured mechanism for engagement between relevant stakeholder groups. These models demonstrate that when the appropriate mechanisms are in place, medical device innovation and health and medical research translation can be achieved.

Introduction

It is widely accepted that Australia undertakes some of the world's best research and development, and that the Commonwealth Government provides significant support to enable this activity. It is also true that as a nation we can improve on the translation of that research into outcomes that will result in better health and wellbeing for all. An important part of achieving successful translation is in providing an environment for beneficial collaboration and a mechanism for developing relationships.

Typically, development of medical devices is protracted and requires collaboration of multi-disciplinary skills across specialty fields. With the current economic and funding environment, there are increasing challenges for small companies to engage in research and innovation and most are unable to afford appropriate in-house research resources. Meanwhile, University research programs are generally technology driven rather than market or end-user driven. A demand-driven approach that moves through a structured collaborative pathway leads to better outcomes for all stakeholders.

Barriers in translation of health and medical research: medical devices and beyond

The underlying issues which slow and even stifle our ability to translate research and development into real-life outcomes are many and varied. The following list provides a summary of the issues

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preventing effective translation of research in the field of medical devices, and which may also be relevant to other industries and research disciplines.

- Lack of clear entry point and process: Clinicians with new ideas, companies with product ideas and researchers with technologies do not have a clear pathway for engagement with each other to allow the dissemination and development of medical device ideas.
- 'Corporate culture' differences between research organisations and industry: Different funding sources, motivations, and rewards lead to differing expectations and difficulties in negotiation, particularly in relation to Intellectual Property (IP) and time-frames for development.
- Lack of collaborative and cross-disciplinary approaches in early phases of development: Competition between research institutions; lack of collaboration within institutions and between research disciplines; little or no clinical and commercial feedback; all combine to result in research activity which bears little relevance to the end-user and development pathways which do not include the best 'expert' advice in the critical early stages.
- Lack of collaborative engagement between research and industry: Industry is often regarded as an outlet for licensed technologies from research institutions, rather than a valuable partner in the research and development phases of a project.
- Industry characteristics: The Australian medical device industry is dominated by small to medium enterprises (SME), and as a result, companies are both cost and time sensitive, and require a clear, cohesive, low-risk strategy for engagement with research institutions.

Models for facilitated engagement: overcoming obstacles to translation of research

The Medical Device Partnering Program (MDPP)[1] led by Flinders University has been operating successfully for almost 4 years and is a collaborative program that brings together key players to develop medical devices and aged care solutions to improve health care. The Medical Device Partnering Program links relevant researches from the three South Australian Universities and disability research organisation (NovitaTech) with end-users, clinicians and industry to develop technically advanced medical device and assistive technology solutions.

The program provides access to specialist multidisciplinary teams comprised of experienced researchers, clinicians and business advisors, who assess projects based on their technical feasibility, clinical need, commercial advantage and economic viability at early stages of development. The project may then proceed to a discrete research phase, involving specialist advice, or facilitated partnering that will assist the idea to move further along the translation pathway. The program has provided assistance such as proof of concept studies, prototype development, technical advice, end-user focus groups, and facilitated partnerships with manufacturers and investors. Furthermore, the program offers regular education events and networking opportunities for participants, providing additional avenues for collaboration and partnership building.

[1] http://www.flinders.edu.au/mdpp/

Despite having been developed independently, the Medical Device Partnering Program model shows remarkable similarities both in philosophy and concept to the highly successful Center for Integration of Medicine with Innovative Technology (or CIMIT) model[2] that has been operating in Boston, US, for almost 15 years. CIMIT "*fosters collaboration among world-class experts in translational medicine, science and engineering, in concert with industry, foundations and government, to rapidly improve patient care by catalyzing the discovery, development and implementation of innovative solutions to pressing clinical problems*"[3]. CIMIT's leadership attributes the success of their program to the provision of effective facilitation; for every dollar spent on research, an additional 50c is spent on facilitation. CIMIT's external reviewers (scientific, medical and industry leaders) "*have applauded this budget tactic as the single characteristic most important to CIMIT's success with advancing projects and careers*"[4].

The key to the success of both programs is the ability to bring together experienced and expert multidisciplinary teams from all stakeholder groups in early stages of projects. Successful innovation and translation is achieved by:

- Functioning as a 'portal' for industry and researcher engagement which also incorporates expert clinical and business advice and facilitates partnering across established networks. The programs provide access to expert multidisciplinary teams across research institutions and within research institutions, in a targeted and supported manner.
- Providing a clear and cohesive model of engagement between research and industry which allows all parties involved to understand the process and manage expectations resulting from diverse 'corporate cultures' at early stages in the relationship.
- Involving experienced and expert multidisciplinary teams in early stages of development together with experts in clinical and business fields, allowing market forces to shape the research and development process, ultimately resulting in a product which is technically advanced and also relevant to the end-user.
- Simplifying legal arrangements around intellectual property combined with a clear model for engagement resulting in a low-risk offering for SMEs, whilst retaining value for research institutions.
- Providing expert business advice at early stages of development together with on-going networking and education events to assist program participants to build some of the essential commercialisation skills necessary and establish relationships.

Conclusion

When mechanisms for facilitated engagement between stakeholders are in place, medical device innovation and health and medical research translation can be achieved.

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[2] CIMIT: A Prototype Structure for Accelerating the Clinical Impact of Research on Novel Technologies by John A. Parrish, M.D. and Ronald S. Newbower, Ph.D. Available at http://www.cimit.org/images/cimit-model.pdf
[3] http://www.cimit.org/
[4] As footnote 1, page 7