



Medical Technology
Association of Australia



*2011 Strategic Roadmap for Australian Research
Infrastructure*

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MEDICAL TECHNOLOGY FOR A HEALTHIER AUSTRALIA

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Contents

- 1. About the medical technology industry..... 4
- 2. 2011 Strategic Roadmap for Australian Research Infrastructure..... 4
- 3. Research and Development (R&D) 4
- 4. Clinical trials..... 5
- 5. Clinical registries..... 7
- 6. Conclusion 8
- 7. References 9

1. About the medical technology industry

The Medical Technology Association of Australia (MTAA) represents the manufacturers, exporters and suppliers of medical technology products in Australia. Medical technologies are products used in the diagnosis, prevention, treatment and management of disease and disability. Products range from consumable items such as wound care products and syringes, to high technology implantable devices such as cochlear implants, cardiac defibrillators and orthopaedic joints, diagnostic imaging equipment, and products which use biological materials.

The medical technology industry had sales in Australia of more than \$7.5 billion in 2009-10 and employs more than 17,500 people. It is strongly research-based, often working closely with healthcare professionals to design and develop products for improved patient benefit. MTAA represents companies supplying approximately 70% of all non-pharmaceutical medical products on the Australian market.

2. 2011 Strategic Roadmap for Australian Research Infrastructure

This submission is in response to the release in July 2011 by the Australian Government Department of Innovation, Industry, Science and Research of the *2011 Strategic Roadmap for Australian Research Infrastructure (Exposure Draft)*. MTAA supports innovative research in Australia and welcomes the opportunity to comment on the report and make specific recommendations. The capability area most relevant to the medical technology industry is "Promoting and Maintaining Good Health". Of relevance to the Australian medical technology industry, the 2011 Strategic Roadmap states that infrastructure is now required to support research into medical devices, drug delivery systems, diagnostics or surgical devices.

MTAA recommends:

- That the Strategic Roadmap expand on strategies to improve translational research in the health sector
- That the section dealing with Population Health Research Platforms be extended to include infrastructure to further enable clinical trials in Australia and the development of high quality data collection and sharing for the purpose of health research
- That mechanisms be developed to further support the collaboration between researchers and industry, including support for clustering.

3. Research and Development (R&D)

Medical technology companies invest a considerable portion of their revenue in R&D. It is estimated that high technology medical technology companies in the United States devote upwards of 20% of their revenue to R&D¹. Australian government expenditure on health and medical research as a percentage of GDP is within the 0.11%-0.12% band². The annual spend on R&D for the medical technology sector in Australia was \$388 million in 2008-09. This expenditure covers medical biotechnology, nanotechnology and biomedical engineering³. There were 18,000 medical technology patents filed in Australia between 2003 and 2009. However, only 7% of these patents were filed by Australian companies. The most

¹ USITC, "Medical Devices and Equipment: Competitive Conditions Affecting U.S. Trade in Japan and Other Principal Foreign Markets," March, 2007.

² Research Australia. Trends in Health and Medical Research Funding, April 2009.

³ Australian Bureau of Statistics (ABS). Research and Development. Businesses. 8104.9, 2008-09.

popular international patent classifications were 'diagnosis, surgery and identification', followed by 'blood vessel filters and prostheses' and 'devices for introducing media into and onto the body'⁴.

Australia has a trade deficit in medical technology. Nearly all medical technology products manufactured in Australia are exported, while the majority of medical technology products used in Australia are imported. In 2010, the value of medical technology imports was \$3.3 billion and the value of medical technology exports was \$1.2 billion⁵.

The 2011 Strategic Roadmap focuses almost exclusively on 'research'. The Roadmap should include mechanisms to improve translational research. The system as it stands has a focus on intellectual property (IP) sales and rewards universities without maximising returns that might be achieved through commercial engagement and product development.

Strategies for enhancing translational research could be included in the Translating Health Research section. This section covers the gap between scientific discovery and improved outcomes that impact on both the patient and the Australian economy. Developing new medical treatments, technologies and preventions will lead to the development of local manufacturing jobs in Australia and may have considerable export potential.

One way of encouraging translational research in Australia which may lead to an increase in the development of medical technology products is through the encouragement of partnerships between researchers, industry and funders. The United Kingdom Government, in its 2011 report⁶, *Plan for Growth*, has proposed a series of strategies to increase the collaborations between research bodies, funding partners and industry. Specifically the Government proposes to form new translational research partnerships from National Institute for Health Research (NIHR) Biomedical Research Centres⁷. The NIHR launched an open competition for funding with £775 million over five years in infrastructure to form the basis of new translational research partnerships.

Life sciences geographical clusters have been shown to be effective incubators for translational research efforts e.g. Medicon Valley in Denmark and Sweden. The UK report, *Plan for Growth*, also recognises the benefits of enhanced collaboration through the encouragement of clusters involving industry, medical facilities, universities and research institutions.

4. Clinical trials

The Population Health Research Platform section of the 2011 Strategic Roadmap outlines the need for integrated, national health-based data. MTAA suggests that the following information on clinical trials and registries is included within this section. Australia is a good location for clinical trials at any stage. Clinical trials are worth around \$1 billion to the Australian economy each year (including approximately \$450 million in foreign investment)⁸. There was rapid growth in the number of clinical trials being conducted in Australia from the early 1990s, however this growth hit a plateau and has started a downward trend in the last few years.

⁴ Griffith Hack, *Mind the gap: Medical technology innovation in Australia*, June 2010.

⁵ ABS - 5368.0 International Trade in Goods and Services, Australia, November, 2010.

⁶ HM Treasury and Department of Business Innovation & Skills. *The Plan for Growth*. March 2011

⁷ *Ibid* at page 94

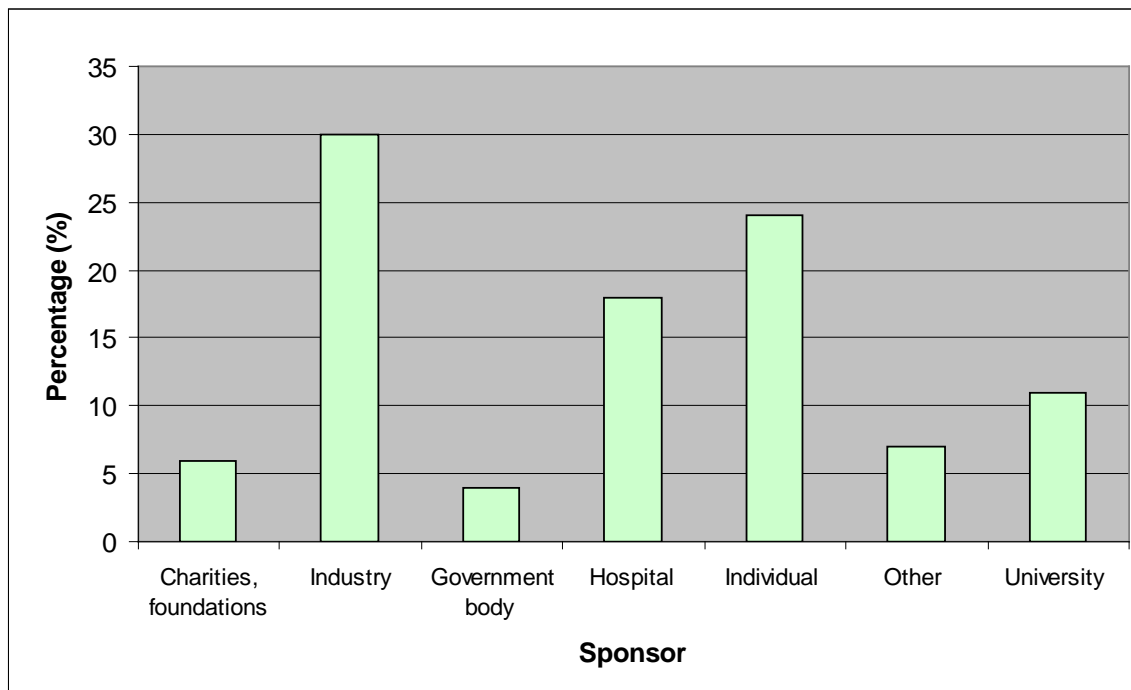
⁸ Australian Government. *Clinically competitive: Boosting the business of clinical trials in Australia*. Clinical Trials Action Group Report, 2011.

Australia faces increasing competition from countries in regions such as Asia, South America and Eastern Europe which can run clinical trials at a lower cost and have more volunteers. The United States has also been affected by the movement of clinical trials to developing countries. Costs and delays in gaining ethical approval may have also influenced a decline in Australia's competitiveness in this area. In March 2011 the Australian Government accepted the recommendations of the Clinical Trials Action Group which, it is hoped, will improve the speed of approval for new trials and streamline a national ethics approval process.

Information on clinical trials in Australia is available from an online register. The Australian New Zealand Clinical Trials Registry (ANZCTR) includes trials covering pharmaceuticals, medical devices, and treatment and rehabilitation therapies. Sponsors are responsible for registering trials and details of all trials in Australia are made available online. Almost 400 medical device trials were registered in Australia between 1999 and 2011. Of these, 68% had Australia as the primary sponsor and 73% conducted research in Australia. The primary purpose of medical technology trials was treatment (91%). The majority of clinical trials are sponsored by industry due to the expense and risk involved when bringing new products to market.

An Australian survey has addressed the value Australia derives from industry funded clinical research⁹. Survey respondents reported involvement in a total of 3,484 clinical trials and research projects, of which industry was the major funder. Six key categories were rated high or very high value by the majority of respondents: early access to medicines and improved outcomes; translation of evidence into clinical practice; enhancing Australian trial expertise; enhancing the global profile and research opportunities for researchers; provision of funding for research and academic projects; and retaining researchers in the public health system.

Figure 1: Primary sponsors of medical technology trials in Australia



⁹ Bourgeois, C. (2008). Value of Industry Sponsored Clinical Trials in Australia. Inaugural Survey of Investigator Perceptions on the Value of Industry Funded Clinical Research. NSW Clinical Trials Business Development Centre, on behalf of the Pharmaceuticals Industry Council (PIC).

Smaller Australian enterprises are often disadvantaged in generating clinical trial data because of lack of access within the public health system to facilities, medical professionals and patients. Further trials could be enabled through specific policies which provide dedicated access for technologies which indicate potential at the research phase.

5. Clinical registries

The section on Population Health Research Platforms section addresses the need for researchers to be able to access national, integrated population-based health data for developing diagnostic, preventative and therapeutic interventions and evaluating and improving clinical practice. MTAA suggests that the platform include clinical registries.

The Australian healthcare system holds within it vast amounts of data that are not uniformly merged. Clinical registries provide real-world data on clinical practice, patient outcomes, safety and the comparative effectiveness of different treatments (e.g. a pharmaceutical versus a device for the treatment of a cardiac condition). There are a number of different types of registries, for example device or procedure specific registries (which collect data on medical devices or surgical procedures), class registers (which collect data on all devices and procedures used in a specific class or intervention) and comparative registers (which look at a range of options for treating a specific disease, e.g. drug, surgical procedure or medical device)¹⁰. Registries are able to effectively collect large amounts of real world data to monitor safety and quality at a population level. In some cases registries provide benchmark data and enable clinicians to compare their outcomes to those of others.

The 2009 Federal Government review of health technology assessment (HTA) in Australia recommended the creation of registries for high risk implantable items and/or procedures¹¹. High risk devices include Class III and active implantable medical devices (e.g. implantable pacemakers). Recommendation 15 of the review recommends that data from registries be used to provide additional information for post-market surveillance of safety and efficacy. There is the potential for data from registries to be applied to future HTA.

A 2009 report by the National Health and Hospitals Reform Commission (NHHRC) also recommended that Australia have systems in place to “provide comparative clinical performance data back to health services and hospitals, clinical units and clinicians”(1). A recent article in the Medical Journal of Australia recommends that prioritization of registries in Australia focus on high cost areas of medicine (in particular areas where resources may be inappropriately used), sequenced care (treatment where positive outcome depends on a well-timed and well-performed sequence of events, e.g. trauma care), devices, procedures and drugs (medium to long-term monitoring where there is a need to establish safety) and areas where registries could be developed with relative ease to monitor disease or compliance(2).

Page 47 of the 2011 Strategic Roadmap states that Australia has a range of routine registers that relate to disease, treatment and devices. This is not the case. There are 28 registries operating across multiple sites in Australia, however there are very few national registries. Those registries with national coverage collect data on renal dialysis, joint replacements, breast implants and organ transplantation. The National Joint Replacement Registry (NJRR) is funded by industry, collects data on orthopaedic prostheses and is a doctor-led registry which achieved clinical buy-in via the Australian Orthopaedic Association (AOA) encouraging its members to comply. The NJRR reported 82,823 joint replacements in 2010. Since it was

¹⁰ Review of health Technology Assessment in Australia. Submission 39. Medical Technology Association of Australia. 22 May 2009.

¹¹ Commonwealth Government of Australia, Review of Health Technology Assessment in Australia, December, 2009.

established the NJRR estimates that it has reduced the number of unnecessary revision operations by 1,200 procedures per year.

The Australian Society of Plastic Surgeons (ASPS) maintains the Breast Implant Registry (BIR) to collect information relating to the patient, surgeon, procedural and implant data relating to breast implants.

There have been attempts to set up registries for cardiac and obesity procedures. The Australian Cardiac Procedures Registry (ACPR) was developed through a pilot project sponsored by the Australian Commission on Safety and Quality in Healthcare (ACSQHC), however a sustainable funding source has not yet been identified for future development.

Evans et al. (2) surveyed Australian registries that collect clinical outcome data. The authors found that the majority of registries require modifications to their procedures in order to provide useful and reliable information for quality improvement purposes. The biggest issues were failures to audit data, provide long term follow-up, collect data on major confounders, recruit more than 80% of the relevant population and capture data so that it can routinely link with other databases. For a clinical registry to have optimal results funding must be long-term and sustainable (for example, follow-up may need to continue for many years).

Guidelines and accompanying principles and technical standards for data collection and management of registries have been developed by the National Health and Medical Research Council (NHMRC) and outline the key indicators for registries(3). The accompanying Technical Standards and Architecture document outlines the technical aspects of data collection and management. The guidelines suggest best practice models to which registries should adhere and include process indicators (activities undertaken as part of the provision of care such as procedures undertaken), outcome indicators (measures used to assess effectiveness of treatment) and structural indicators (setting attributes, e.g. administrative processes that support care).

6. Conclusion

The 2011 Strategic Roadmap covers 'co-investment' and notes that "opportunities for industry co-investment in research infrastructure facilities should be clear and encouraged as a basis for closer research collaboration". Industry is a significant funder of clinical trials and the medical device registries in Australia. The development of infrastructure and support for co-investment should be encouraged.

Funding for R&D in Australia should support not only research, but also strategies for translational research. Strategies to encourage geographical clustering of research facilities, universities and industry should be developed.

Mechanisms to encourage clinical trials and the development of national clinical registries should be articulated. MTAA supports the suggestion that there be access to data not held in university institutions such as that from the Australian Bureau of Statistics (ABS), Australian Institute of Health and Wellbeing (AIHW), Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Schedule (PBS), where appropriate.

7. References

1. National Health and Hospitals Reform Commission: A Healthier Future For All Australians – final report June 2009. Canberra: Department of Health and Ageing, 2009.
2. Evans, S.M., Bohensky, M., Cameron, P.A., & McNeil, J. (2011). A survey of Australian clinical registries: can quality of care be measured? *Internal Medicine Journal*;41:42-8.
3. The NHMRC Centre of Research Excellence in Patient Safety. (2005). Guidelines for the establishment and management of clinical registries – Draft Guidelines Version 2, A Report prepared for the Australian Commission on Safety and Quality in HealthCare.