



Medical Technology
Association of Australia

Clinical Trials Action Group Discussion Papers:

1. Developing a Clinical Trials Roadmap
2. Developing Key Performance Measures for Clinical Trials
3. Ensuring the Rapid Uptake of Streamlined Ethics, Scientific and Governance Review Process
4. Strategies to Improve Patient Recruitment
5. Developing an Information and Communications Technology (ICT) Strategic Plan for Clinical Trials

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Medical Technology for a Healthier Australia

About the medical technology industry

MTAA represents the manufacturers, exporters, importers and distributors of medical technology products in Australia. Medical technologies are products used in the diagnosis, prevention, treatment and management of disease and disability.

The medical technology industry in Australia has an annual turnover of \$6.0 billion (2007/2008), earns an export income of \$1.3 billion (2007/2008) and employs in excess of 17,500 people. Local manufacturing produces earnings of \$2.6 billion. The medical technology industry invested \$160 million in research and development in Australia in 2007/2008¹.

MTAA estimates that \$1.6 billion is spent on medical technologies in the private hospital system in Australia with a further \$2.8 billion spent in the public health system².

There are 9,492 products listed on the Prostheses List at February 2009, of which 87% are listed by member companies of MTAA. There are a total of 25,993 (non-dental) medical devices listed on the Australian Register of Therapeutic Goods (ARTG) (at September 2008) by 1,710 sponsors.

The Australian market for medical technology is approximately 2% of the global market. Because of its small size, this means that companies developing innovative technologies will always need to consider the potential return on investment in making a decision as to whether to bring a technology into Australia or invest in development of a new technology in Australia.

Understanding medical technology

Medical technology refers to the diagnostic or therapeutic application of science and technology to improve the management of health conditions. Technologies may encompass any means of identifying the nature of conditions to allow intervention with devices, pharmacological, biological or other methods to increase life span and/or improve the quality of life³.

The range of medical technologies is far-reaching and includes diverse products:

- cardiac devices such as implantable defibrillators and catheters for ablation of atrial fibrillation
- implantable orthopaedic joints and intraocular lenses
- diagnostic tests for general pathology such as cholesterol and glucose, and infectious disease tests such as HIV and hepatitis

¹ MTAA estimate based on Australian Bureau of Statistics Report 81040DO012_200607

² This figure does not include major medical equipment in the public health system

³ Wikipedia. Wikipedia definition of medical technology. Retrieved 15 April 2009 from http://en.wikipedia.org/wiki/Medical_technology.

- diagnostic tests such as markers for HER-2 antibodies for breast cancer and K-RAS gene for bowel cancer
- radiology imaging equipment such as positron emission tomography and computed tomography x-ray scanners
- human tissues such as human heart valves, corneas, bones (part and whole) and muscle tissue.

There are fundamental differences between the medical technology and pharmaceutical sectors. While many of the differences relate to shorter and more rapid product development timeframes, perhaps the most germane to this consideration of the Clinical Trials Action Group is the development of clinical evidence for regulatory approvals and the need for clinical investigations. *(Please note: The difference in terms, clinical trials for pharmaceutical products vs clinical investigations for medical technology was proposed as part of the international standard ISO 14155 Parts 1 and 2 (2003) to help distinguish between these types of studies.)*

The issues being addressed in the five papers released by the Action Group are equally relevant to the medical technology and the pharmaceutical sectors. Ensuring a sustainable medical technology sector in Australia, both in terms of the development and manufacture of the medical technology in this country, as well as importing the technology will be influenced by the planning for viable clinical trial and clinical investigation networks.

MTAA would welcome the opportunity to participate in subsequent discussions resulting from the review of the submissions to the papers released by the Clinical Trials Action Group.

Comments on Discussion Paper One

1. The need for clinical investigation data to support the development of safe and effective medical technology is just as relevant to multi-national companies as it is to small companies. It is therefore necessary to consider the support of these activities in any “Road Map” for both ends of this spectrum. Small companies face difficulties with access to investigators and the relative high costs of this work in Australia. Many of these domestic companies carry out their clinical investigations overseas for these reasons. Many overseas-based companies encounter delays conducting clinical investigations in Australia.
2. The “Road Map” needs to consider the roles and responsibilities for the industry sector in advocating and promoting Australia for clinical trials and investigations.
3. Other factors should be considered which could influence the success of these initiatives such as gauging the interest of trial sites in Australia. Accreditation programs by the NHMRC for site and sponsor training, for example, may be another way to improve the competitiveness and attractiveness of Australian

study sites.

4. Central coordination of clinical investigations will be of great assistance to the medical technology sector. This would then lead to streamlining processes in governance approval, training and education in GCP and the application of ISO 14155 Parts 1 and 2 (2003), training HRECs and monitoring timelines for the studies, for example.

Comments on Discussion Paper Two

1. In considering the question of how clinical trial and clinical investigation information could be used to improve Australia's attractiveness as a destination for international clinical study investment MTAA makes the following suggestions. The same suggestions may also encourage more Australian-based companies to conduct this research in this country.
 - a. An accreditation program for training in clinical trials and clinical investigations for the industry and research staff should be adopted.
 - b. The publication and availability of the results of any audits of clinical trial or investigation programs needs to be implemented.
 - c. Accreditation of the infrastructure supporting clinical trials and investigations within the Australian Council on Healthcare Standards framework should be encouraged and developed.
 - d. The development of surgical training facilities for animal and cadaver studies should be developed.
 - e. Promotion of clinical research as one of the drivers for improvements in effective evidence-based medical practices should be encouraged to counter the argument that such research is just seen as another cost in the healthcare system.
 - f. Doctors should be encouraged to dedicate time to research in the public hospital system.
2. For the "Four Pillar Model" developed by the Research and Development Taskforce (RDTF) to describe key factors which could be used to determine a country's attractiveness to global decision makers as a site for conducting clinical trials or investigations, MTAA provides the following comments and suggestions:
 - a. MTAA supports the concept of the Four Pillar Model.
 - b. A consensus needs to be achieved on how the quality of the clinical trials and investigations sectors in Australia can be appropriately measured against comparable factors in other countries.
 - c. To improve the timeliness of clinical trials or investigations, alternatives to the current structures and relationships for HRECs need to be considered in light of overseas experience. For example, could HRECs independent of hospitals be a viable alternative?
 - d. In terms of the value or cost of clinical trials or investigations, the costs of reviews, and more notably the costs of governance reviews, should be transparent and consistent across Australia, without being excessive.

- e. To boost the capacity of the clinical trials and investigations sector, effective ways to promote, encourage and monitor recruitment need to be implemented.
3. In considering the scope to include clinical trial and investigation performance information into hospital and related care in health system performance indicators, the following points are suggested.
 - a. While MTAA appreciates the need to develop measures that could be used to compare the overall performance of the clinical trials or clinical investigation sector with similar sectors overseas, the development and promotion of such measures should not be done at the expense of sound scientific practice.
 - b. The MTAA supports the HoMER initiatives and the benefits which could be accrued for the medical technology sector. It would be expected that a streamlining of the number of committees with appropriate expertise to review the potentially multi-faceted nature of clinical investigations could result.
 - c. The timelines for ethics committee reviews should be tracked by the NHRMC and the results published.
 - d. Governance review timelines should be tracked by a central agency and the results published.
 4. Other examples of clinical investigation performance measures include:
 - a. The collection of costs relating to ethics committee deliberations, governance of studies, start-up issues and archiving procedures.
 - b. The development of guidelines to identify institutional overheads that relate to the complexity of the clinical investigation.
 - c. The production of a national schedule of fees such as study start-up fees, pharmacy dispensing fees as well as other standard activities related to the conduct of a trial or investigation.
 5. Possible lessons or implications for the clinical trials/investigations environment in Australia include:
 - a. Recruitment for investigations would be enhanced by improving investigators expertise in discussing and arranging patient consent and the resources needed to identify appropriate study subjects.
 - b. Standardised clinical investigation agreement templates should be adopted and promoted for use within Australia.
(NOTE: MTAA, in conjunction with the VMIA and various State health departments are currently working towards this end.)
 - c. Study related procedures should be separated from the legal obligations relating to the investigation protocols through the adoption of standardised patient consent forms and procedures.

Comments on Discussion Paper Three

In considering the need to ensure the rapid uptake of streamlined ethics, scientific and governance review processes, the following observations and comments are provided.

HRECs:

1. The National Ethics Application Form (NEAF) is widely accepted at public hospitals but this is not reflected in the private hospital system. The knowledge and experience of ethics committees within the private hospital is quite variable and can add to delays.
2. Standardising review processes is extremely valuable as competencies and processes vary widely.
3. Standardised procedures should be considered to help ethics committees operate such as increasing the frequency of meetings of the committees and establishing set timeframes for the submission of research proposals and subsequent meetings.
4. The acceptance of standardised clinical trial and investigation agreements and consent forms and by all HRECs would reduce delays in approvals.
5. Increasing the role of the NHMRC to consider reasons why particular hospitals may not wish to implement particular clinical investigations should be encouraged.
6. As with the UK model, consideration should be given to the situation where a sponsor can directly contact an HREC after the initial approval by that committee.
7. A central coordination and monitoring role for the HoMER system should be adopted after the investigations and trials have been conducted for activities such as monitoring of timelines and adjudication of HREC complaints.
8. A centralised IT platform would allow the tracking of HREC approvals, recording serious adverse events, identifying new research sites, and tracking study timelines.

Governance review:

1. Standardised clinical investigation agreement templates should be adopted and promoted for use within Australia.
(NOTE: MTAA, in conjunction with the VMIA and various State health departments are currently working towards this end.)
2. Private hospitals should be encouraged to accept standardised clinical research agreement templates.

3. Training and education programs should be developed to help all parties, including research and governance staff understand clinical research requirements and related agreements.
4. MTAA supports concurrent reviews by HRECs.
5. Mechanisms should be developed so that governance officers and sponsors of investigations or trials can liaise directly to expedite the resolution of issues.
6. State health departments should be encouraged to monitor or even enforce appropriate governance reviews of studies to improve the consistency of these reviews.

Comments on Discussion Paper Four

A number of suggestions that could be incorporated in strategies to improve patient recruitment are:

1. Identify doctors who could champion the benefits and advantages of conducting clinical investigations in Australia so that they could discuss them with their peers at society meetings and medical conferences.
2. As study nurses can often be the first contact for study recruits, a program should be developed for nurse educators to equip study nurses with the necessary liaison skills for this role.
3. Improved information networks need to be developed to accommodate the need to identify patients who fit study eligibility criteria which may only be able to be assessed based on the patient's condition at the time of surgery.
4. The publication of trial information on an appropriate website could assist members of the public consider self-referral to various investigations or trials.
5. Access to epidemiological data at a hospital level would assist the medical technology industry with study site selection.
6. The awareness of clinical trials and clinical investigations among the general public would assist in the understanding and value of this activity.
7. The use of electronic medical records for patients would help with the identification of patients for particular studies.

Comments on Discussion Paper Five

In developing an information and communications technology strategic plan for clinical trials and investigations, the following points should be noted:

1. While an eHealth approach has many potential benefits and advantages, such initiatives have to consider how the data could be used to assist Australian companies undertake their clinical research if the results are needed as part of requirements for overseas regulatory authorities. For example, the eHealth proposal would not currently meet the requirements for Part 11 compliance for the FDA in the United States.
2. The proposal to manage clinical trials and presumably clinical investigations using an integrated IT management system appears to be ambitious. MTAA considers that the sharing of data relating to healthcare data and records, remote monitoring of patients, trial approvals and longer term monitoring of patients should be implemented before the suggested IT management system is considered.