



Medical device clinical trials in Australia – current challenges and call-to-action

When are clinical trials for medical devices required?

- To demonstrate safety and effectiveness of novel higher risk devices or after significant changes to higher risk devices to obtain or maintain regulatory approval
- To assess the cost effectiveness and comparative effectiveness of medical technologies for reimbursement purposes

Why are clinical trials important for Australia?

- Clinical trials are vital for advancing research and development of novel and high-tech medical technologies
- Clinical trials provide patients with access to new promising treatments with a potential to save or prolong their life, or improve their quality of life
- Clinical trials are an opportunity for doctors to learn about latest methods of treatment and to improve healthcare in general
- Clinical trials contribute to the knowledge economy with \$1.1 billion in gross expenditure and supported approximately 6,900 largely tertiary qualified jobs in 2015, with employment figures projected to grow to over 12,000 by 2025¹

Challenges faced by industry-sponsored clinical trials:

- A lack of harmonisation across states and territories regarding ethics approval and governance processes and documentation requirements that increases bureaucracy with no added value;
- Lack of technical expertise specific to certain technologies within ethics committees;
- Slow start-up times which have a direct negative effect on product development timeliness and costs of running clinical trials; less than half of clinical trials in FY15 completed the ethics and site approval process within the 60-day goal¹;
- Low patient recruitment rates, which in turn drives higher cost per patient; this is caused in part by low public awareness and engagement of medical practitioners and a lack of a nationally harmonized framework for clinical trials¹;
- High fixed and specialist costs incurred by medical device companies, which is an issue for start-ups, small and medium size entities¹;

Opportunities in advancing clinical trials in Australia:

- Maintain the current CTN (clinical trials notification) scheme
- Maintain the R&D incentive for medical technology companies that develop products and conduct clinical trials in Australia

¹ Clinical Trials in Australia: The economic profile and competitive advantage of the sector, MTPConnect and L.E.K., June 2017 https://www.mtpconnect.org.au/Attachment?Action=Download&Attachment_id=54

- Set up an Australian Coordinating Body for clinical trials along with a nationally harmonized scheme for clinical trials
- Improve and expand the ANZ Clinical Trials Registry

MTAA is encouraged by the recent announcements regarding Federal Government funding:

- \$248 million to support clinical trials for Australian patients with rare cancers and rare diseases, and unmet need clinical trials and registries program;
- \$6 billion in the 2018-19 Budget to fund Australia's health and medical research sector, including \$3.5 billion for the NHMRC, \$2 billion in disbursements from the Medical Research Future Fund and \$500 million from the Biomedical Translation Fund;
- \$1.3 billion National Health and Medical Industry Growth Plan, to improve health outcomes for hundreds of thousands of Australians, create tens of thousands of new jobs, and develop the next generation of Australia's global leading industries;
- \$7 million to support states and territories to redesign their trial systems to make it easier for researchers and companies to conduct clinical trials;