

Clinical trials in Australia

Roche Australia (Pharmaceuticals) policy position

Summary

- Clinical trials benefit Australia through providing patients with early access to medicines; enhancing translation of evidence into local practice; forging links between local and international researchers; driving investment; and raising the capability of our health system, yet our international competitiveness in attracting trials continues to decline.
- Issues with inconsistent trial costs, ethics and governance processes and patient recruitment all impact on Australia's competitiveness in attracting trials, and limit patients' ability to access novel treatments in areas of unmet medical need.
- Policy reforms to position Australia as an international research partner of choice are well documented in reports from the Clinical Trials Action Group, the McKeon Review and others, and Roche supports urgent action.

Background

The pharmaceutical industry's contribution to research in Australia is important for investment and jobs. Industry investment in active clinical trials was over \$1 billion in 2015¹. The Australian clinical trials sector supported at least 6,900 highly skilled jobs in 2015¹, the large majority requiring tertiary education levels. The industry growth centre, MTPConnect, has identified the potential for Australian trials to surpass \$2 billion of annual expenditure in the next 10 years, creating more than 6,000 new high-skilled jobs¹. Roche is a major contributor to this ecosystem, investing \$44 million in clinical research in Australia in 2017² and employing 110 local study staff who currently support approximately 119 local trials involving over 4,700 patients³. Roche's local trial staff also support Asia-Pacific regional trial activities.

Early access to new medicines through clinical trials has been estimated to save Australian taxpayers around \$100 million annually in hospital and Pharmaceutical Benefits Scheme (PBS) costs⁴, as well as providing patients with significant benefits from timely treatment. Other benefits include: enhanced translation of innovation into local healthcare practice; enhanced local clinical trial expertise; enhanced global profile and linkages for Australian researchers; and retention of researchers in the Australian public health system.

Roche position

Australia has recently experienced modest growth in pharmaceutical sponsored clinical trials of 2%¹. Roche continues to invest in Australian clinical research, yet in line with the broader industry, it is experiencing significant competition within the Asia Pacific region. Recent regulatory and clinical trial improvements in China have opened pathways for participation in global registration

trial programs, potentially reducing opportunities for Australian patients to participate. As of 2017, China contributes the largest number of patients to the Roche Asia Pacific regional clinical trial program for medicines⁵. Moreover, compared to countries with similar sector profiles such as Canada or the UK, Australia attracts 14% fewer phase III or later development clinical trials across all companies¹.

Roche appreciates the policy work that has occurred around Australia on this issue, including by the National Health and Medical Research Council (NHMRC), the Clinical Trials Advisory Committee (CTAC) and the Australian Health Minister's Council. Roche has been an active participant and leader of a number of industry working groups, such as the industry Research and Development Task Force, to support constructive projects at all levels of the system. Nevertheless, problems with Australia's competitiveness clearly remain and progress has been extremely slow. It is concerning that the opportunity for Australia to lead the Asia Pacific region in clinical trials continues to elude us. Persistent challenges are research costs, red tape around study start-up and slow recruitment.

Cost-shifting from the health sector to industry leads to wide variability in the cost of conducting trials, strongly discouraging investment. Industry reports show cost variations of up to 845% between different clinical trials sites for the same activity in the same study⁶, which suggests fair market rates are not being consistently applied. Cost competitiveness will also be challenged by Government moves to restrict the R&D Tax Incentive to small and medium enterprises (SMEs), based on the assumption that larger businesses are less responsive to financial incentives of this kind⁷. The recent Finkel, Ferris and Fraser (2016) review of the Incentive, and the subsequent Government response, made a number of recommendations that would more tightly focus eligibility on additional investment and restrict the amount that larger companies could claim⁸. In reality, larger companies such as Roche look at costs in a global context and may see Australia as less competitive without such incentives.

Timelines for setting up and completing trials are a disadvantage for Australia. Clinical trials are time-sensitive activities, as companies cannot register new medicines or indications, provide broad access and generate a return on investment until they are completed. Roche has found wide variability in time to study start-up in Australia, which imposes unacceptable risks. Despite significant Government work through the NHMRC to address the issue, approval by Human Research Ethics Committees (HRECs) remains fragmented and variable around the country. The time to complete an ethics review of a multi-centre clinical trial can exceed six months⁹. While mutual acceptance of ethical review in some states of Australia has expedited the process, many approvals are still required and the persistence of "slow" sites can still impact on Australia's performance and share of global trials.

Of greater concern is governance approval by institutions, where processes have been recognised as

inefficient. Many governance delays are due to inconsistent requirements, based on a poor understanding of essential and non-essential steps. Given the widely standardised nature of clinical trials, contractual discussions should not be a source of delays and is yet the biggest contributor to delays to activate a clinical trial and provide access to patients to clinical trial treatments in Australia.

Roche considers that the way forward has been mapped out by the industry Research and Development Taskforce, building on the 2013 McKeon Review¹⁰ recommendations and the Clinical Trials Action Group report⁴, which include:

- Coordinating with stakeholders to ensure national governance and ethics review processes are streamlined across Australia;
- Accelerating early access to Australian patients to clinical trial treatments;
- Providing training to key stakeholders on clinical trial conduct; and
- Ensuring that clinical trials are promoted to relevant patient advocacy groups to maximise patient participation in clinical trials.

Many of these recommendations have been endorsed by the Senate Select Committee on Funding for Research into Cancers with Low Survival Rates¹¹.

Roche believes that Australia has the potential to be a global leader in clinical trials activity and supports timely action to ensure that we deliver on this promise.

This position paper was adopted by the Roche Australia (Pharmaceuticals) Leadership Team on 24 September 2018 and entered into force the same day

¹ MTPConnect. 2017. "Clinical Trials in Australia: The Economic Profile and Competitive Advantage of the sector". Melbourne

² Data on file

³ Data on file

⁴ Commonwealth Department of Industry. 2011. "Clinically Competitive: Boosting the Business of Clinical Trials in Australia". Clinical Trials Action Group Report. Australian Government, Canberra

⁵ Data on file

⁶ Pharmaceuticals Industry Council. 2013. Letter to the Independent Hospital Pricing Authority. Canberra

⁷ Commonwealth of Australia. 2013. *Tax Laws Amendment (Research and Development) Bill 2013*. Explanatory Memorandum

⁸ Ferris B, Finkel A and Fraser J. 2016. "Review of the R&D Tax Incentive". Australian Government, Canberra

⁹ Pharmaceuticals Industry Council. 2013. "Survey of Research Governance Timelines in Australia". Canberra

¹⁰ McKeon S. 2013. "Strategic Review of Health and Medical Research". Australian Government, Canberra

¹¹ The Senate. 2017. "Select Committee into Funding for Research into Cancers with Low Survival Rates". Final Report. Canberra