Clinical trials in Australia

Roche Australia (Pharmaceuticals) Policy Position

Summary

- Clinical trials benefit Australia through providing 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.
- Policy reforms needed to improve Australia's competitiveness are well documented in reports from the Clinical Trials Action Group, the McKeon Review and others, yet progress is slow.
- Roche supports urgent action to address inconsistent trial costs, ethics and governance processes and patient recruitment, to position Australia as an international research partner of choice.

Background

The pharmaceutical industry's contribution to research in Australia is important for investment and jobs. Private investment in clinical trials in Australia reached over $630 million in 2010, directly employing over 1,400 individuals[1]. Industry funds 68% of clinical trials in Australia and a further 5% are collaborative trials involving industry[2]. Roche is a major contributor, investing over $36 million in clinical research in Australia in 2014[3] and employing over 100 local study staff who currently support approximately 145 local trials involving over 2,000 patients[4]. Roche's local trial staff also support 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) costs[5], as well as providing patients with significant benefits from timely treatment. Other benefits identified by Australian trial investigators are: enhanced translation of evidence into local practice; enhanced local clinical trial expertise; enhanced global profile and linkages for Australian researchers; and retention of researchers in the Australian public health system[2]. Health research and development has also been estimated to deliver a return in health benefits of $2.17 for every dollar invested[6], which suggests industry investment returns nearly a billion dollars in health to Australia every year[7].

The benefits of medical research and a strong local biopharmaceuticals industry have been acknowledged by the Government through the proposed Medical Research Future Fund and the Industry Innovation and Competitiveness Agenda[8].

Roche position

While industry-funded research and development continues to grow globally[9], Australia has experienced a decline in clinical trials. New trial activity fell by 27% between 2007 and 2010, and again by 10% in 2013[10], with the local industry struggling to attract global trials to Australia.

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. Whilst 17% of all current Roche trial patients in the region are located in Australia, for trials initiated in 2014, Australia accounted for only 6% of patients in the region, with our share declining relative to markets such as South Korea[11].

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 in all relevant consultations and supports constructive projects at all levels of the system. Nevertheless, problems clearly remain and progress has been extremely slow. It is concerning that the opportunity for Australia to lead the region in clinical trials continues to elude us.

Cost of trials

Investment in clinical trials is subject to competition globally and Australia needs to compare favourably with the rest of the world. Australia's significant expertise in healthcare, research and clinical trials is attractive, but competitiveness in cost and efficiency is also important.

Australia should be able to compete with other developed, high-quality markets for clinical trials. KPMG's Competitive Alternatives report rated Australia's R&D costs as lower than the USA, Japan and Italy, while somewhat higher than Canada and the UK[12]. For a recent trial conducted by Roche in South Korea and Australia, per-patient costs were similar[13]. Thus if trials were managed more efficiently, Australia could be cost-competitive with other developed markets.

Yet 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 study[14], which suggests fair market rates are not being applied. Roche supports initiatives through the Independent Hospital Pricing Authority (IHPA) and CTAC to develop a list of standard costs.

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 kind[15]. In reality, larger companies such as Roche look at costs in a global context and may see Australia as less competitive without such incentives.

Ethics committee and governance approvals

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 average time to complete an ethics review of a multi-centre clinical trial now takes more than six months in 30% of cases[14]. 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 be linked to the declining share of Australian patient enrolments seen in Roche trials[11].

Fragmented IT systems and paperwork requirements also pose challenges, a concern raised by the McKeon Review in 2013[16]. Many systems remain "inefficient, inconsistent and manual", with wide variation and incompatibility between states and even hospitals within the same state [16]. Roche notes that action is urgently needed to resolve these long-standing and well-documented issues.

Of greater concern is governance approval by institutions, where delays may take over a year in the worst cases[17]. In one recent Roche study, ethics approval in Australia was completed before South Korea, but study start-up was delayed by governance approval timelines nearly 30% longer on average[18]. Many of these delays are due to inconsistent requirements, based on a poor understanding of essential and non-essential governance steps. Given the widely standardised nature of clinical trials, contractual discussions should not be a source of delays.

Roche endorses the 2013 McKeon Review recommendations[16], building on the earlier Clinical Trials Action Group report, which include:

- An online approval workflow system for trials;
- Establishment of 8–10 national ethics committees;
- A national clinical trials liability insurance scheme; and
- A national clinical trials office.

Roche considers that, to be most effective, a national clinical trials office should be a dedicated statutory body with buy-in and involvement from health and industry portfolios at both state and federal levels.

Roche advocates for Australia-wide standardisation of templates, systems, processes and governance officers' job descriptions to ensure that ethics and governance approvals are fit-for-purpose and efficient. One possible avenue is a site accreditation process to promote adherence to best practice and timelines. For this reason, Roche supports initiatives such as the NHMRC "Clinical Trials Ready" plan, which would raise clinical trial standards and support capacity-building in the sector.

Recruitment

Timely recruitment of Australian patients into clinical trials remains a challenge. Roche supports initiatives such as a national clinical trials portal that would increase awareness among patients of the existence of clinical trials and provide the opportunity for earlier access to new treatments. A

strong base of enrolments into trials would also increase Australia's competitiveness.

Business environment

In addition to streamlining processes, Roche encourages policy makers to consider the broader environment for pharmaceuticals in Australia. Access and public reimbursement challenges are inextricably linked to the ability of a country to continue to attract studies. For example, Roche has invested heavily in trials in new therapies for melanoma in Australia, given its high incidence here and significant local expertise. However, with medicines funding challenges impacting our ability to launch our melanoma franchise in Australia, we are unlikely to be able to continue to attract clinical trials in this field. As pharmaceutical companies assume responsibility for treating patients until public reimbursement is available, the increasingly unpredictable nature of access decisions means this is a significant risk.

Roche considers that Australia has the potential to be a 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 15 May 2015 and entered into force the same day

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[1] Pharmaceuticals Industry Council (PIC). 2012. "2011 Survey of Privately Funded Clinical Research Activity". Sydney

[2] Bourgeois C. 2009. "Value of Industry Sponsored Clinical Trials in Australia". Report prepared for PIC, Sydney

[3] Data on file

[4] Data on file

[5] Medicines Australia (MA). 2014. "Submission to Senate Economics References Committee Inquiry into the Australian Innovation System". Prepared for Senate Economics References Committee, Canberra

[6] Access Economics. 2008. "Exceptional Returns: The Value of Investing in Health R&D in Australia II". Prepared for the Australian Society for Medical Research, Sydney

[7] MA. 2011. "Keeping Clinical Trials in Australia: Why Action Is Needed Now." Occasional Paper No. 3. Canberra

[8] Australian Government. 2014. "An Action Plan for Australia's Future", media release, access from https://www.pm.gov.au/media/2014-10-14/action-plan-australias-future, 14/01/15

[9] PHRMA. 2014. "2014 profile – Biopharmaceutical research industry", accessed from http://www.phrma.org/sites/default/files/pdf/2014_PhRMA_PROFILE.pdf, 16/12/14

[10] MA. 2014. "New figures show clinical trial red tape reductions critical". Media release, 24 June 2014

[11] Data on file

[12] KPMG. 2014. "Competitive Alternatives". 2014 Edition. KPMG Canada

[13] Data on file

[14] MA. 2014. "Proposed removal of red tape affecting the Australian Medicines Industry". Submission to the Parliamentary Secretary to the Prime Minister, Canberra

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

[16] McKeon Review of Health and Medical Research. 2013. Australian Government

[17] PIC. 2013. "Survey on research governance timelines in Australia". Sydney

[18] Data on file