

Pharmaceuticals Industry Council

Local priority – Global partner

Survey of Research Governance Timelines in Australia



Survey of Research Governance Timelines in Australia

April 2013

By: **Omar Ali Khan** Medicines Australia
Carlo Maccarrone GlaxoSmithKline
Annette Jones Boehringer Ingelheim
Deborah Monk Medicines Australia
Linda Nielsen Sanofi

Introduction

Slow start up times are regularly identified by clinical trial sponsors as one of the most important reasons why Australia is losing its competitive edge against other countries.^[1] In a 2010 pharmaceutical industry survey, 38 per cent of respondents reported that it took them more than 6 months to initiate a clinical trial in Australia, while a further 25 per cent said that it took them between 4 and 6 months.^[2]

Despite ongoing reforms, the time it takes to start a clinical trial in Australia is not getting shorter, and sponsors are increasingly citing the lengthening research governance approval timelines as the cause of the problem. In November 2012, the Pharmaceuticals Industry Council's Research and Development Taskforce (RDTF) conducted a survey to collect data on the efficiency of research governance processes in Australia. The results show that, on average, research governance reviews add 49 calendar days to study start up in Australia. In 2011, the Clinical Trials Action Group, which was set up by the Australian Government to help improve Australia's competitiveness as destination for global clinical trials investment, recommended a **combined** 30-day best practice benchmark for both ethics and research governance reviews.^[3]

This survey only captures part of the total activity in Australia and the data was provided by sponsors instead of institutions where these clinical trials were actually reviewed. This data does not account for the date the governance application was submitted to an institution, but rather the overall approval time. However, the results presented here align well with anecdotal evidence from various other sources and, at the very least, reconfirm the need for sponsors, investigators, site staff, research governance officers and other relevant stakeholders to work together to make it more efficient to initiate clinical trials in Australia.

Methods

The survey was sent by email to 45 companies currently conducting clinical trials in Australia. They were asked to provide the date on which the following events occurred for each Australian site involved in a clinical trial commenced by their company between 1 July 2011 and 30 June 2012:

- Human Research Ethics Committee (HREC) approval
- Site Specific Assessment (SSA) approval
- Principal Investigator (PI) certification, CTN
- HREC certification, CTN
- Approving Authority certification, CTN (and)
- Sponsor certification, CTN

For our analysis, we focused on the length of time between HREC approval and SSA approval. We also compared how long it took for different sites involved in two randomly selected multi-centre clinical trials to complete this process.

Tasmania, Northern Territory and the ACT were mostly excluded from our analysis due to the small number of data points. Otherwise, each state's share of the reported activity reflected their (known) share of the total activity in Australia.^[4]

Results

19 companies responded to the survey. These included 13 "pharmaceutical companies", 4 "contract research organisations" and 2 "biotechnology companies". Collectively, respondents provided data on 271 sites participating in 105 individual clinical trials. The respondents had previously reported a combined expenditure of approximately \$227 million on clinical trials in 2010.^[5]

According to the our analysis (Figure 1), the national median for the length of time between HREC approval and SSA approval is 33 days, whilst in 75 per cent of the cases, this process is completed within 66 days. Compared to the national benchmarks, this sample set showed that sites located in Western Australia and Victoria appear to be among the most efficient in the country when it comes to completing research governance reviews. Nationally, however, only about 30 per cent of governance reviews are completed within 30 days; Figure 2.

Figure 1

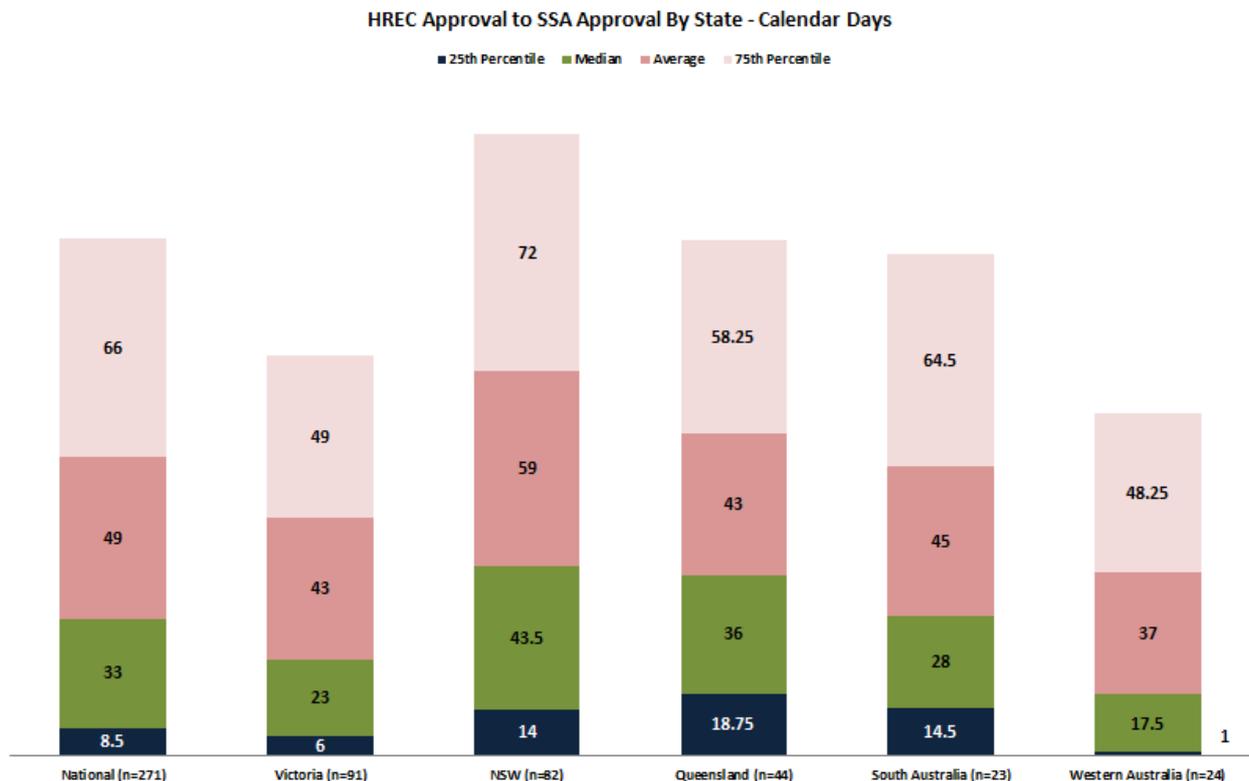
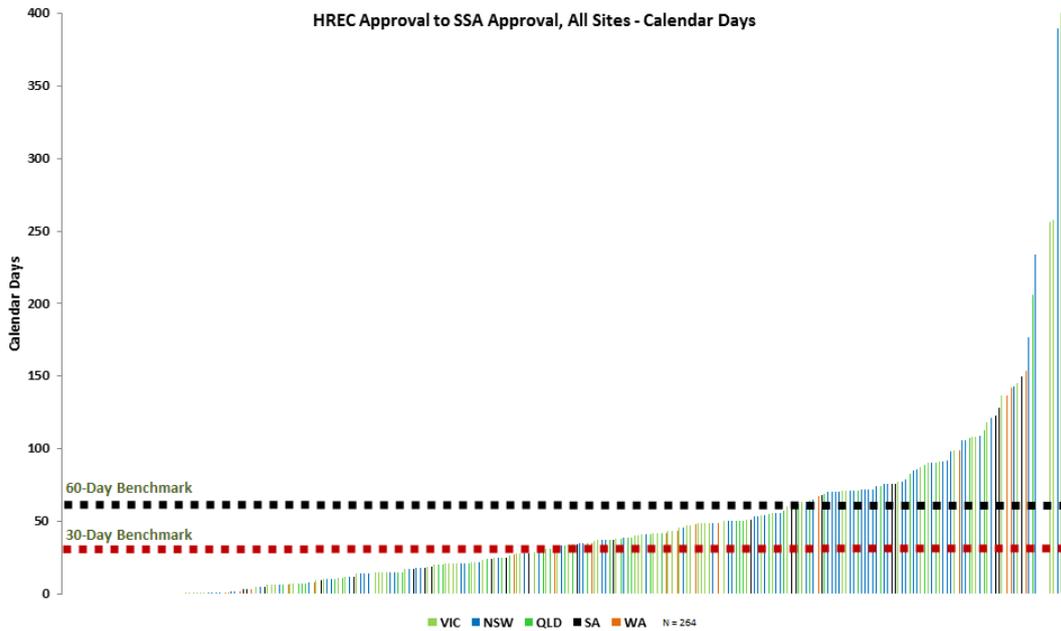


Figure 2



We also analysed how long it took for individual sites involved in two randomly selected multi-centre clinical trials to complete a governance review. As Figures 3 and 4 show, there was significant variation in timelines among participating sites.

Figure 3

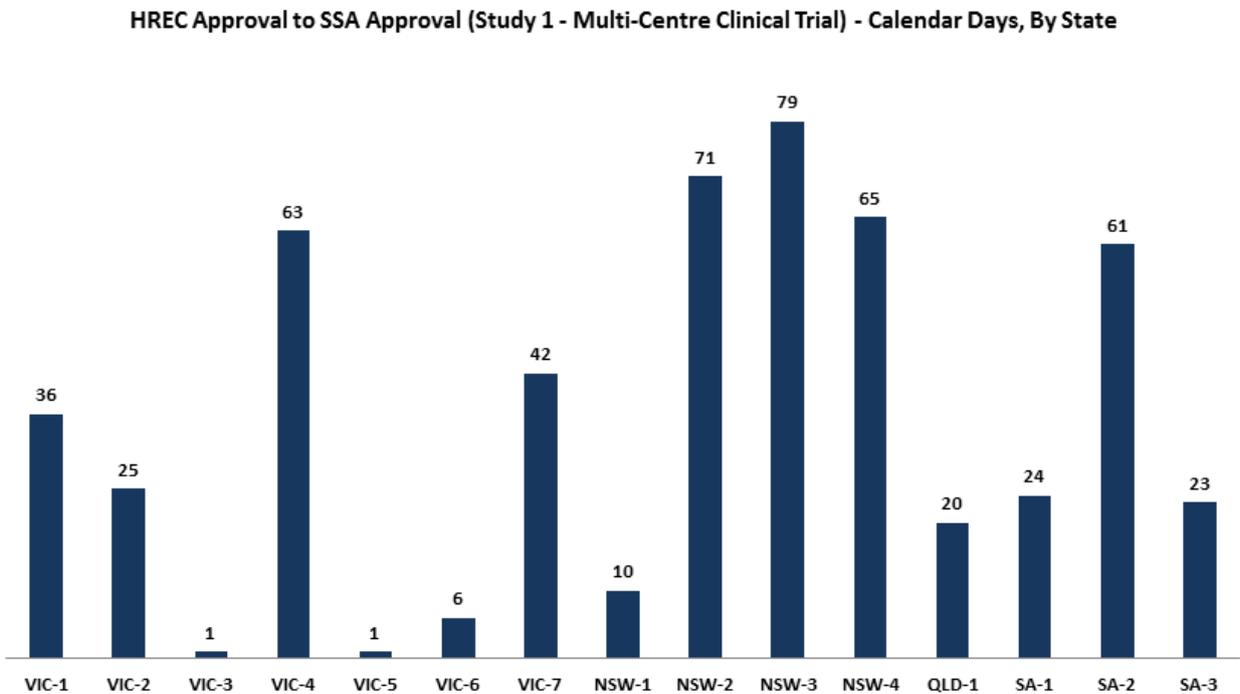
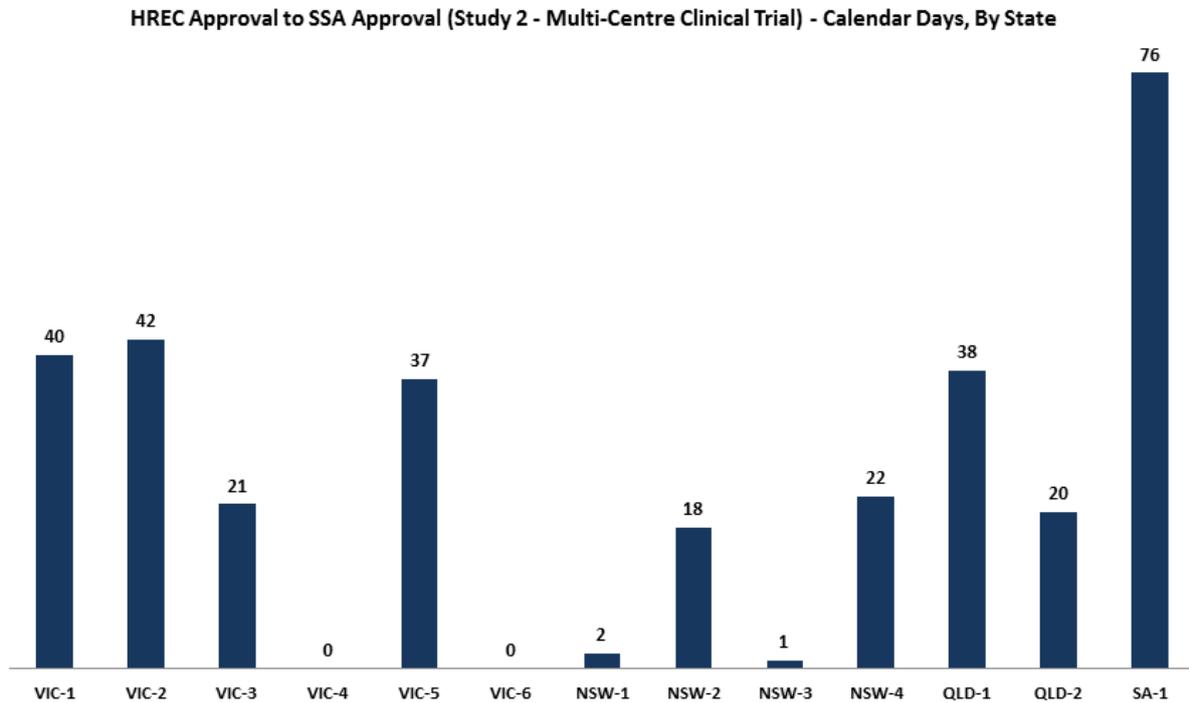


Figure 4



Discussion

Australia's competitiveness as a destination for global clinical trials investment is clearly under threat. Between 2008 and 2007, the number of new clinical trials declined by an alarming 34 per cent and despite a welcome increase in 2011, there were still around 26% fewer clinical trials initiated in 2011 compared to 2007.^[6] According to several industry surveys^[7], the main reasons for this decline are:

- low patient recruitment rates;
- high and unpredictable costs; and
- slow study start up times, which is the focus of this paper.

Historically, sponsors cited ethics reviews as the cause of the delays in study start up in Australia. This has changed in recent years; trial sponsors now identify "research governance" as the main issue, which is not surprising. Victoria, New South Wales and Queensland, which together account for approximately 80% of all clinical trial activity in Australia, have implemented numerous reforms since 2007 to streamline the ethics approval process (especially for multi-centre clinical trials).^[8] Research governance, on the other hand, has not received the same attention and this is reflected in the data presented here.

In 2010, the Australian Government established the Clinical Trials Action Group to "help cement Australia's position as a good place to conduct clinical trials". In its final report, the Action Group made 11 recommendations, aimed mostly at improving patient recruitment and making the process of initiating and conducting clinical trials in Australia significantly more efficient and cost effective. One of the key recommendations was for the relevant authorities to ensure a maximum combined 60-day timeframe or a combined 30-day best-practice timeframe for both ethics and research governance reviews.^[9] It is useful to note that the timeframes described in this articles do not include the time it took respondents to obtain ethics approvals, which would have added at least 30

days to overall timelines in most cases. As our survey shows, the national median for governance reviews alone is currently 33 days.

Clinical trials are an indispensable and, in many cases, the most expensive and time-consuming component of the drug development process.^[10] Over the past decade, the bio-pharmaceutical industry has initiated over 7,500 clinical trials in Australia in over 30 therapeutic areas such as oncology, pulmonology and neurology.^[11] This type of activity is important not only for the massive investment it brings to Australia -- around \$650 million in 2010 alone -- and the thousands of high-paying jobs it supports.^[12] It is also important for the role it plays in improving Australia's healthcare system.^[13] Among other things, clinical trials provide early and often free access to new healthcare technologies, which is estimated to save Australian tax-payers more than \$100 million each year in hospital and medicine costs.^[14]

Of course, there are a number of challenges sponsors, study coordinators, investigators and research governance officers face in trying to reduce governance review timelines; for example, a lack of standard procedures, delayed submission for governance review relative to HREC submission date and insufficient resources. But regulatory delays not only cause delays in patient access to new treatments, they also delay the development of new medicines and divert a company's resources away from actual R&D to meeting inefficient regulatory requirements. All this just highlights the central importance of relevant stakeholders, including industry, working in partnership to make it more efficient to initiate clinical trials in Australia and in doing so, ensuring that this country remains a leading destination for global investment in clinical trials for decades to come. It also highlights the need for more accurate and transparent reporting on timelines by institutions themselves in order to consistently and reliably track their performance and efficiency.

Notes

- [1] Commonwealth of Australia, 2012, Strategic Review of Health and Medical Research in Australia, Consultation Paper.
- [2] Pharmaceuticals Industry Council, 2010, 2nd Benchmarking Survey of Privately Funded Clinical Research Activity in Australia.
- [3] Commonwealth of Australia, 2011, Clinically Competitive: Boosting the Business of Clinical Trials in Australia.
- [4] Therapeutic Goods Administration, September 2012, Half-Yearly Performance Report, Clinical Trials (Medicines).
- [5] Pharmaceuticals Industry Council, 2012, Survey of Privately Funded Clinical Research Activity in Australia.
- [6] Therapeutic Goods Administration, 2012, Half-Yearly Performance Report, Clinical Trials (Medicines).
- [7] Pharmaceuticals Industry Council, 2009, Inaugural Benchmarking Survey of Privately Funded Clinical Research Activity in Australia.
Pharmaceuticals Industry Council, 2010, 2nd Benchmarking Survey of Privately Funded Clinical Research Activity in Australia.
- [8] State Governments of Victoria, New South Wales and Queensland, 2011, Monitoring and Reporting Framework: Mutual Acceptance of Ethical and Scientific Review for Multi-centre Clinical Trials Conducted in Public Health Organisations in New South Wales, Queensland and Victoria.
- [9] Commonwealth of Australia, 2011, Clinically Competitive: Boosting the Business of Clinical Trials in Australia.
- [10] Jorge Mestre-Ferrandiz et. al., The R&D Cost of a New Medicine, Office of Health Economics, 2012.
- [11] Therapeutic Goods Administration, 2012, Half-Yearly Performance Report, Clinical Trials (Medicines).
- [12] Pharmaceuticals Industry Council, 2012, Survey of Privately Funded Clinical Research Activity in Australia.
- [13] NSW Clinical Trials Business Development Centre, 2009, Inaugural Survey of Investigator Perceptions of the Value of Industry Funded Clinical Research.
- [14] Senator the Hon Kim Carr, 2011, Speech at the Medicines Australia Parliament Dinner on 2 March 2011.