

Medicines Australia submission to the NSW Health Capabilities Consultation

24 August 2022

Medicines Australia welcomes the opportunity to provide feedback on the NSW health system capability assessment and foreign direct investment potential in the sub-sector of Clinical Trials.

Medicines Australia is the peak body representing the innovative, research-based, medicines industry in Australia. Our members discover, develop and manufacture medicines and vaccines that help people live longer, healthier lives and bring social and economic benefits to Australia.

Through clinical trials, the medicines and medical technology industry can provide a mechanism for consumers to gain early, no-cost access to innovative treatment across a broad range of diseases.¹ They can also provide the evidence for reimbursement pathways, such as through the Pharmaceutical Benefits Advisory Committee (PBAC), that further increases access of these treatments to Australians.²

Australia's medical research sector makes a significant contribution to the economy. For every \$1 invested in medical research in Australia, \$3.90 is returned to the broader economy. In addition, the sector employs more than 32,000 people directly, with a further 78,000 in the downstream medical technologies and pharmaceuticals sector.³

In 2019, \$1.4 billion were invested in clinical trials, with industry investment accounting for approximately 79% of this expenditure. Although considered to be an underestimation, there were at least 8000 Australian jobs supported by the clinical trials sector in 2019. Through clinical trials, hospitals can receive funding for resources, such as study site personnel, academic projects, and opportunities are provided to retain specialised researchers.⁴

Clinical trials conducted in NSW make up one of the largest portions (28%) of total clinical trials in the country, second only to Victoria (30%).⁴ Medicines Australia recognises the NSW's investment into the

¹ Medicines Australia, R&D Taskforce position paper: One Stop Shop & Clinical Trials Front Door, 2021

<https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2021/12/20211207-Medicines-Australia-RDTF-Clinical-Trials-position.pdf>

² Australian Government Department of Health, The Pharmaceutical Benefits Advisory Committee Guidelines: Section 2 Clinical evaluation, 2016

<https://pbac.pbs.gov.au/section2-clinical-evaluation.html>

³ KPMG, Economic Impact of Medical Research in Australia, a KPMG study commissioned by the Association of Australian Medical Research Institutes (AAMRI), 2018

<https://aamri.org.au/wp-content/uploads/2018/10/Economic-Impact-of-Medical-Research-exec-summary.pdf>

⁴ MTPConnect, Australia's Clinical Trials Sector, 2021

<https://www.mtpconnect.org.au/reports/clinicaltrialsreports2021>

new Clinical Trials Management System (CTMS) and appreciates the ambition to expand its clinical trial capabilities and make it more attractive for foreign direct investment.⁵

However, when multinational biopharmaceutical companies are considering investing in clinical trials in Australia, they do not only look at NSW's capabilities but all of Australia's clinical trial landscape. As a federation of states, there are separate processes for jurisdiction-specific and therapy-specific approvals and authorisations. There are also separate processes for Therapeutic Goods Administration (TGA) notifications and registration on the Australian and New Zealand Clinical Trials Registry (ANZCTR).⁶

This fragmentation of different research ethics and local site authorisation systems between states and territories have created long-standing challenges with duplication, delays, and a heavy administrative burden on potential sponsors. Delivering a multicentre trial in Australia across state and territory borders continues to involve significant duplication of effort, complexity, and inconsistency in approach with variable and unreliable return on contracted participant numbers in the agreed timelines.¹

As a result, Australia is less competitive than emerging and established markets on clinical trial measures of timely and efficient trial start-up, cost, and the capacity to recruit trial participants. To remain internationally competitive, clinical trials must be able to commence quickly and efficiently across many clinical trial centres around Australia, as well as compete internationally with other countries on a cost basis.⁶

This lack of international competitiveness in the clinical trials sector is a missed opportunity. Australia has one of the highest-ranking health systems globally⁷, which can facilitate a wide range of clinical trials. Additionally, Australia has a diverse population⁸, which means outcomes from clinical trials conducted here can be applied to a broader population and address the issue of the lack of diversity in clinical trials.⁹

Greater harmonisation of clinical trial governance and regulatory processes would help increase Australia's attractiveness to multinational sponsors and foreign direct investment.¹ The Australian Commission on Safety and Quality in Healthcare (the Commission) are overseeing the consultation and development of a National One Stop Shop and Clinical Trials Front Door - a national platform for health-related human research.⁶

⁵ NSW Health, Clinical Trial Management System (CTMS), 2022

https://www.hnehealth.nsw.gov.au/research-office/research-ethics/clinical_trial_management_system_ctms⁶ Australian Commission on Safety and Quality in Health Care, The National One Stop Shop - a national platform for health-related human research, 2022

⁶ Australian Commission on Safety and Quality in Health Care, The National One Stop Shop - a national platform for health-related human research, 2022

<https://www.safetvandquality.gov.au/our-work/health-and-human-research/national-one-stop-shop-national-platform-health-related-human-research>

⁷ Morgan Liotta, Australia ranks high in global health system comparison, RACGP, 2021

<https://www1.racgp.org.au/newsgp/professional/australia-ranks-high-in-global-health-system-compa>

⁸ Australian Bureau of Statistics, Cultural diversity: Census, 2021

<https://www.abs.gov.au/statistics/people/people-and-communities/cultural-diversity-census/latest-release#:~:text=27.6%20per%20cent%20of%20the,during%20the%20Census%20collection%20period.>

⁹ Gray II DM, Nolan TS, Gregory J, Joseph JJ, Diversity in clinical trials: an opportunity and imperative for community engagement, The Lancet, 2021

[https://www.thelancet.com/journals/langas/article/PIIS2468-1253\(21\)00228-4/fulltext](https://www.thelancet.com/journals/langas/article/PIIS2468-1253(21)00228-4/fulltext)

The primary objective of the One Stop Shop is to ensure the Australian clinical research environment is efficient, cost-effective and operates to world's best practice now and in the long-term. The Clinical Trials Front Door will make it easier for patients, researchers, industry representatives and sponsors to find, conduct, participate and invest in high quality and ethical research in Australia.⁶

Medicines Australia, in collaboration with Medical Technology Association of Australia and AusBiotech, have formed the Research and Development Taskforce (RDTF). The RDTF consists of research and development experts, particularly in clinical trials, and is working closely with the Commission, the Department of Health and Aged Care, and Australian Clinical Trials Alliance (ACTA), to support the focus and investment in the National One Stop Shop and Clinical Trials Front Door.¹⁰

Although NSW is well-equipped to conduct clinical trials, the lack of harmonisation in the sector nationwide is a barrier for multinational sponsors to fully embrace Australia's potential as an innovation destination. The establishment of the National One Stop Shop and Clinical Front Door can increase Australia's attractiveness for foreign direct investment and global competitiveness in clinical trials, and continue to provide benefits to the Australian population and economy. As a majority of clinical trials in Australia are conducted in NSW, it is imperative that NSW strongly supports the implementation of the National One Stop Shop and Clinical Front Door.

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¹⁰ Medicines Australia, Research & Development Taskforce (RDTF), 2022
<https://www.medicinesaustralia.com.au/policy/clinical-trials/research-development-task-force-rdtf/>