

The Research & Development Taskforce

Pre-Budget Submission 2024–25

The Research & Development Taskforce (RDTF) is pleased to have the opportunity put forward a 2024–25 Pre-Budget Submission that advocates for clinical trials reform. The RDTF is a multi-sector collaboration between [AusBiotech](#), [Medicines Australia](#), and the [Medical Technology Association of Australia \(MTAA\)](#). The membership consists of research and development experts, particularly in clinical trials, and offers a unique industry perspective to stakeholders across Federal and State Governments as well as the broader health and research and development sector.

Recommendation

The Research & Development Taskforce urge the Government to provide appropriate and sustainable funding to the National One Stop Shop for clinical trials in the 2024–25 Federal Budget, so that Australian patients get access to the latest medical therapies and for the country to remain a globally competitive R&D destination, benefiting both Australian patients and the economy.

The National One Stop Shop

The National One Stop Shop (NOSS) for clinical trials is a digital platform that will provide a coordinated system of approval and reporting processes for human research, including clinical trials in Australia. Through two years of consultation with more than 1,000 stakeholders, the Australian Commission on Safety and Quality in Healthcare has built a proof-of-concept for the NOSS, which has the backing of a broad range of industry groups and State Governments across Australia.¹ Appropriate and sustainable funding is required in the 2024–25 Federal Budget to make it a reality.

Beyond a digital platform, the NOSS is an opportunity within the broader clinical trial and medical research reform underway, that will provide a single, harmonised, end-to-end process across the different jurisdictions. The life sciences sector has been advocating for harmonisation since the Federal Government established a Clinical Trials Action Group in 2009, co-chaired by then Parliamentary Secretary for Health, Mark Butler and the Parliamentary Secretary for Innovation and Industry, Richard Marles.

Importantly, clinical trials provide patients with access to innovative treatments at no cost, easing the burden on the public healthcare system and reducing costs for the Australian Government. In 2019 alone, 95,000 patients participated in clinical trials, underscoring the significant impact on healthcare affordability.² This strategically aligns with the Government's *Cheaper Medicines initiatives*, which aim to mitigate the cost-of-living pressures by reducing co-payments for medicines and promoting 60-day prescriptions.³

Increasing clinical trial activity through the NOSS will also align seamlessly with the Australian Government's *Measuring What Matters National Wellbeing Framework* that will track our progress towards a more healthy, secure, sustainable, cohesive, and prosperous Australia.⁴

A harmonised clinical trial environment through the NOSS that can ensure efficient clinical trial startups will attract more clinical trials to be conducted in Australia, and with it, benefits to the health of Australians and the economy.

Why Australia needs the National One Stop Shop

Australia's federated clinical trials environment is fragmented with states and territories (even individual area health services and hospitals) having different approval processes and systems for clinical trials. This fragmentation has been likened by our international colleagues to conducting trials in multiple countries and makes Australia less attractive for companies to conduct trials.

Australia is a good destination for clinical trials, with excellent healthcare facilities, world-class researchers, a diverse population, and strong legal frameworks with robust IP protections. However, the complex regulatory environment for trials in Australia can act as a barrier for companies looking for efficient and cost-effective locations.

Harmonising these processes through the NOSS will ensure patients get access to the latest medical therapies and Australia remains globally competitive as an R&D destination, benefiting both Australian patients and the economy.

Action is needed to ensure Australia remains a preferred destination for clinical trials

Failure to allocate funds to the NOSS poses significant risks to both patients and the broader healthcare landscape. Without adequate funding for the NOSS, Australia's clinical trial landscape will fragment further as each jurisdiction continues to develop their own systems and processes that are not interoperable. Australian patients will experience prolonged wait times or, worse, miss out on the opportunity to access cutting-edge medical therapies.

Additionally, the lack of sustainable funding for the NOSS may lead to a decline in clinical trial activity. Biopharmaceutical and medical technology companies may prioritise conducting trials in countries with more efficient and streamlined systems. In 2022, the EU launched their own 'One Stop Shop', the Clinical Trials Information System (CTIS). The CTIS harmonises clinical trial processes between European Union Member States, European Economic Area countries and the European Commission, making it easier for sponsors to conduct trials.⁵

If Australia is to keep pace with the changing global landscape, we too, need a single, efficient, and streamlined clinical trial systems across the country.

Background: Clinical Trials

The Health Benefits of Clinical Trials

Clinical trials are a fundamental part of the healthcare system. They play a critical role in the research and development of new medicines, vaccines, medical devices, and diagnostics. Clinical trials not only offer patients early access to potentially life-saving treatments at no cost, but they also contribute to the expansion of medical knowledge.⁶

Australia has world-class researchers renowned globally for being adaptive, collaborative, and open to new technologies and ways of thinking. Through R&D and clinical trials, Australia has generated globally transformative medical innovations like the human papillomavirus vaccine Gardasil®, the Cochlear bionic ear implant, and Recell® Spray-On Skin.

Patients participating in clinical trials also learn more about their health, play a more active role in decision making, and have better health outcomes. Hospitals that conduct clinical trials tend to provide better care, have more rapid uptake of newer treatment strategies and technologies, and have lower mortality rates.⁷

The Economic Benefits of Clinical Trials

Beyond individual patient benefits, clinical trials play a pivotal role in the economy of the future, which innovative jobs, exports and productivity will rely. Bringing more clinical trials to Australia will enhance the skills and capabilities of the Australian healthcare and research sector. It will encourage greater inbound foreign investment in clinical trials and the broader health ecosystem, including creating more jobs in health and research.

The Medical Technology Association of Australia's 2023 Value of MedTech Report revealed clinical trials support the economy by providing more than 8,000 high-level local jobs in science and research, including 400 jobs in Australian clinical trials directly. The medtech industry also contributed \$1.4 billion annually to the Australian economy, approximately \$650 million resulting from foreign investment.⁸

Further, the Australian biotech industry includes over 1,400 companies, of which around 80 per cent are small and medium, non-revenue generating companies, and employs over 260,000 people, with 178 companies listed on the ASX.⁹ The medtech and biopharmaceutical industries combined contribute A\$5.5 billion to the economy, A\$8.2 billion in exports, A\$2.1 billion in R&D investment, and support upwards of 73,000 jobs in industry and research.¹⁰

Conclusion

The RDTF recommends appropriate and sustainable funding of the NOSS in the 2024–25 Federal Budget. The RDTF is committed to work collaboratively with the Government to support its development and implementation. Investing in the NOSS is not just a commitment to the health and well-being of Australians but also an economic imperative, fostering innovation, creating jobs, and positioning Australia as a global leader in research and development.

About AusBiotech

AusBiotech is Australia's biotechnology organisation, working on behalf of 3,000 members for more than 37 years to promote the global growth of Australian biotechnology. AusBiotech covers the life sciences, including therapeutics, medical technology (devices and diagnostics), and agricultural biotechnology sectors, as well as the pipeline of development from early research to market.

About Medicines Australia

Medicines Australia leads the research-based medicines industry of Australia. Our members discover, develop and manufacture prescription pharmaceutical products, biotherapeutic products and vaccines that bring health, social and economic benefits to Australia. Our members invest in Australian medical research and take local discoveries and developments to the world.

About the Medical Technology Association of Australia

The Medical Technology Association of Australia (MTAA) is the national association representing companies in the medical technology industry. MTAA aims to ensure the benefits of modern, innovative, and reliable medical technology are delivered effectively to provide better health outcomes to the Australian community.

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