

The Research & Development Taskforce

Pre-Budget Submission 2025–26

The Research & Development Taskforce (RDTF) is pleased to have the opportunity to put forward a 2025–26 Pre-Budget Submission that advocates for clinical trials reform.

Recommendation

The Research & Development Taskforce (RDTF) urges the Government to allocate ongoing and sustainable funding for the National One Stop Shop (NOSS) for clinical trials in the 2025–26 Federal Budget. Ongoing investment will ensure this vital initiative achieves its full potential, ensuring Australia remains globally competitive in clinical research and development (R&D), benefiting patients, industry, and the broader economy.

Government Leadership Driving Progress for Australian Clinical Trials

The RDTF welcomes the Government's commitment to advancing Australia's clinical trials environment through the allocation of \$62 million to support clinical trials, and a further \$18.8 million to progress the National One Stop Shop for clinical trials (NOSS) in the 2024–25 Federal Budget.¹ This funding represents a significant milestone after years of advocacy and stakeholder engagement to streamline clinical trials across Australia.

The NOSS is a digital platform designed to streamline approval and reporting processes for human research across Australia.² Since the allocation of funding in the 2024–25 Federal Budget, significant progress has been made under the leadership of Professor Ian Chubb and the Inter-Governmental Policy Reform Group (IGPRG) for health and medical research.

Achieving alignment across Australia's fragmented clinical trial landscape is no small feat. The IGPRG has brought together diverse stakeholders—spanning states, territories, public institutions, and private industry—through an extensive series of workshops, and established key working groups to ensure the platform is fit for purpose across the whole sector. This process has required significant coordination, negotiation, and compromise, reflecting years of advocacy and persistent effort. The various elements of the platform currently being tested, trialled, and refined mark a critical step toward realising the long-term vision of the NOSS.

The NOSS complements broader reforms aimed at strengthening Australia's clinical trial ecosystem. Alongside initiatives like the National Clinical Trials Governance Framework and the Human Research Ethics Committees (HREC) Quality Standard and Accreditation Scheme, the NOSS contributes to improving trial efficiency, reducing duplication, and expanding patient access to innovative therapies.

We acknowledge the progress that has been made towards the introduction of the NOSS and are fully supportive of its overarching goals of equity and access for clinical trial participants. To mitigate any unintended consequences, it will be critical for the views of all stakeholders, including both public and private clinical trial operators, to be considered to ensure the NOSS is fit-for-purpose and delivers upon its objectives.

To sustain the current momentum, continued funding is vital to move the NOSS from concept to full implementation. Building on the progress achieved will cement Australia's position as a leader in clinical research, attract global investment, and deliver faster access to life-changing therapies. Now is the time to ensure these efforts translate into lasting impact for patients and the broader health system.

Maintaining Momentum for Clinical Trials

Extensive consultations with diverse stakeholders, along with early testing and refinement of platform components, have demonstrated the Government's commitment to improving the clinical trials landscape. However, this progress risks stalling without sustained investment to see the initiative through to completion.

Ongoing and sustainable funding is essential to ensure the NOSS evolves to meet future needs, supports faster trial approvals, and attracts international sponsors. Without this commitment, we risk losing stakeholder confidence in the Government's commitment to clinical trials. A lapse in funding would jeopardise Australia's standing as a preferred destination for clinical research and disrupt the delivery of life-saving innovations to patients.

Failure to sustain this work also poses the risk of further fragmenting the clinical trials landscape. Without a national platform, jurisdictions will continue to develop disparate systems and processes that are not interoperable. This could lead to longer wait times for patients or, worse, deny them access to cutting-edge therapies. In contrast, regions like the European Union have already launched their Clinical Trials Information System (CTIS), harmonising clinical trial processes across member states and making it easier for sponsors to conduct trials³.

If Australia is to keep pace with global advancements, we must remain committed to building a single, streamlined clinical trial system. The NOSS is not only a pathway to more efficient research but also a critical tool to ensure Australian patients benefit from the latest medical breakthroughs. Sustained funding is not just a strategic investment—it is a vital step in delivering on the promise of better health outcomes for all Australians.

Why Clinical Trials Matter to Australia

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.⁴

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.⁵

The Economic Benefits of Clinical Trials

Beyond individual patient benefits, clinical trials play a pivotal role in supporting Australia's economy and its future, upon which innovative jobs, exports and productivity will rely. Bringing more clinical trials to Australia – including critical later stage trials, which have seen a more recent decline - will enhance the skills and capabilities of the Australian healthcare and research sector. Between 2016 and 2022, the number of Phase 1 and 2 trials grew in Australia by 54 per cent, whereas the number of phase 3 and 4 trials decreased by 2 per cent.⁶ In an increasingly competitive global environment, implementing the NOSS will help 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-skilled local jobs in science and research, including 400 jobs in Australian clinical trials directly. The MedTech industry also contributes \$1.4 billion annually to the Australian economy, approximately \$650 million resulting from foreign investment.⁷

The broader Australian health sector is comprised of 2,905 life science organisations, including 1,592 biotech and MedTech companies.⁸ There are close to 350,000 biotech jobs across Australia.⁹ The MedTech and biopharmaceutical industries combined contribute A\$5.5 billion to the economy, A\$8.2 billion in exports, and A\$2.1 billion in R&D investment.¹⁰

Conclusion

The RDTF recommends appropriate and sustainable funding of the NOSS in the 2025–26 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 the Research & Development Taskforce

The Research & Development Taskforce (RDTF) is a multi-sector collaboration between [Medicines Australia](#), [Medical Technology Association of Australia \(MTAA\)](#) and [AusBiotech](#). 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.

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 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.

About AusBiotech

AusBiotech is Australia's leading national and global advocate for life sciences. With a more than 3,000 strong industry led member network, we leverage our unique national convening power to support our members' growth – by building an Australian life sciences ecosystem that leads in development and commercialisation, to create high-quality, innovative life sciences companies.

¹ The National One Stop Shop Federal Budget Announcement 2024:

<https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/transforming-health-and-medical-research-in-australia>

² The National One Stop Shop - a national cross government platform for health-related human research 2024:

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

³ European Medicines Agency. Clinical Trials Information System: <https://www.ema.europa.eu/en/human-regulatory-overview/research-and-development/clinical-trials-human-medicines/clinical-trials-information-system>

⁴ MTP Connect. Australia's Clinical Trials Sector Report 2021:

https://www.mtpconnect.org.au/images/MTPConnect_2021_AustraliasClinicalTrialsSectorReport.pdf

⁵ Todd, AL., Nutbeam, D. More and better clinical trials in health care: focusing on people, not just systems and processes: <https://www.mja.com.au/journal/2023/218/5/more-and-better-clinical-trials-health-care-focusing-people-not-just-systems-and>

⁶ MTPConnect Clinical Trials Report. Available at:

https://www.mtpconnect.org.au/images/MTPConnect_2024_AustraliasClinicalTrialsSectorReport.pdf. Accessed November 2024.

⁷ Medical Technology Association of Australia. The Value of MedTech report 2023:

https://www.mtaa.org.au/sites/default/files/uploaded-content/field_f_content_file/the_value_of_medtech_report.pdf

⁸ Global Data research on behalf of AusBiotech 2024.

⁹ Global Data research on behalf of AusBiotech 2024.

¹⁰ MTP Connect. Medical Technology, Biotechnology and Pharmaceutical Sector Competitiveness Plan 2022:

https://www.mtpconnect.org.au/images/2022_MTPConnect_SectorCompetitivenessPlan.pdf