National Health and Medical Research Strategy Consultation Team
Department of Health, Disability and Ageing
GPO Box 9848
Canberra ACT 2601

Dear Consultation Team,

Submission to the Draft National Health and Medical Research Strategy Consultation

On behalf of the life sciences industry R&D Taskforce, we express our support for the Draft National Health and Medical Research Strategy and provide feedback on areas impacting the clinical trials sector.

The R&D Taskforce (RDTF) is a collaboration of innovative life sciences leaders across the membership of AusBiotech, Medicines Australia and the Medical Technology Association of Australia. As the pre-eminent group representing industry in the sector, we work to advance the research and development environment in Australia to encourage greater investment in R&D, to ensure Australia's R&D policy settings are globally competitive and, most importantly, to ensure Australians can access cutting edge treatments through clinical trials.

We commend the Strategy's Vision, for impactful research, healthier Australians, and a stronger nation. We recommend strengthening the Vision, to recognise the role of commercialising health innovations in the health of Australians. The proposed Values of impact & sustainability, quality & integrity, equity, collaboration & partnership are well-aligned with the needs of the health and medical research sector. Similarly, the Goals outlined in the Strategy are ambitious and appropriately focused on driving national prosperity, leading the world in health outcomes, delivering equity, securing a resilient health system, and strengthening regional and global partnerships.

While we support the proposed Focus Areas, we recommend a greater emphasis on the actions and associated timeframes which will support **clinical trials** as a key component of the Focus Area "Embed research processes that are modern, efficient, and consumer centred." Clinical trials are a cornerstone of the healthcare system, playing a pivotal role in the research and development of new medicines, vaccines, medical devices, and diagnostics. Not only do they provide patients with early access to potentially life-saving treatments, they also contribute to the expansion of medical knowledge, and improve health outcomes across the board. Hospitals and clinics conducting clinical trials often deliver better care, adopt new treatment strategies more rapidly, and achieve lower mortality rates. Beyond individual patient benefits, clinical trials also drive economic growth, creating high-skilled jobs and attract foreign investment.

In this context, the role that the pharmaceutical, medical technology and biotechnology sectors play in contributing to a strong research ecosystem via company led medical research, public–private partnerships, investment in advanced manufacturing capability, and co-funding of translational research should not be overlooked. The draft Strategy could be strengthened by more explicitly recognising our sectors' vital contribution to Australia's health and economic future including the contribution to the economy via investment in clinical trials from industry. While it references "biotech and medtech," it currently lacks a dedicated roadmap for medicines development, regulatory reform, and market access, as well as a clear plan to attract foreign investment into Australian based health R&D and manufacturing.

The Strategy may also benefit from referencing potential reforms to accelerate regulatory approval and health technology assessment processes, which are key to ensuring timely patient access and building investment confidence. Further clarity around mechanisms to operationalise sovereign manufacturing capability would be helpful, particularly given that Australia imports over 90% of its prescription

medicines. Additionally, referencing partnerships with economic policy bodies such as the Productivity Commission could help align health research with broader national productivity and industry growth goals.

Expanding or complementing initiatives like QUT and MTPConnect's Bridge Program and BridgeTech, Flinders University's Medical Device Partnering Program (MDPP) and NSW Health's commercialisation training programs delivered by Cicada Innovations, which equip researchers with commercialisation and investor engagement skills, will enhance the Strategy. In addition to these programs, we'd encourage the strategy to consider ways to strengthen collaboration between industry and research, enabling each sector to maximise their respective skill sets and complement the other, with a focus on translation. There is a focused role for peak industry bodies, including the RDTF's sponsors, to proactively facilitate the proposed collaboration and implementation of targeted global engagement initiatives, such as in-bound corporate research and outbound export market development activities. A single program may not be sufficient; a national framework could help embed commercialisation capabilities, investor readiness, and international market engagement across the research ecosystem. Without these measures, Australia risks losing competitiveness in attracting global biopharmaceutical investment and translating research into accessible medicines and technologies.

We strongly endorse the **Workforce** Enabler as critical to supporting and embedding clinical trials into the healthcare setting. Workforce development will be pivotal in ensuring clinician researchers have the necessary training, resources, and protected time to conduct high-quality trials. Beyond the clinician researcher, without the support of clinical study coordinators or clinical research nurses, the work to communicate with potential participants and the operational aspects of delivering the Australian piece of large multinational clinical trials would not be possible.

From an infrastructure perspective, the **National One Stop Shop (NOSS)** will be a critical enabler of modern, efficient, and consumer-centred research processes. The NOSS will streamline clinical trial operations, reduce administrative burdens, and improve access to trials for diverse populations, including those in regional, rural, and remote areas. It will be important that the implementation of the NOSS does not negatively impact start-up timelines, particularly for early phase trials conducted by the private sector.

In addition to the NOSS and the Human Research Ethics Committee Quality Standard and Accreditation scheme, which is expected to support a much-needed Single Ethical Review process, we desperately need quality, streamlined, efficient and time-bound Research Governance Processes within the public healthcare setting. The current disjointed, unpredictable and time absorbing process are eroding the many other benefits that Australia has to offer to multinational industry partners who are comparing our performance with emerging markets such as Brazil, Argentina and Türkiye to name a few. Given the importance of the NOSS among the Clinical Trials reforms, and notwithstanding the recent well-received announcement of a further $13.6M for clinical trials, we strongly urge the Federal Government to allocate funding to the implementation phase in the 2026-27 Federal Budget.

Successful implementation of these priorities will enhance Australia's capacity to deliver impactful research, improve health equity, and strengthen the healthcare system.

We support the establishment of the National Strategy Advisory Council to ensure transparent oversight, strategic coordination, and accountability for the implementation of the National Strategy. To fully unlock the potential of Australia's life sciences industry, and maximise its contribution to national health, productivity and security goals, we call on the Federal Government to establish a whole-of-government Australian Life Sciences Council to provide national coordination across the innovation lifecycle, from early-stage research through to clinical trials, translation, development and commercialisation.

Key indicators to measure success of a focus on clinical trials should include:

- Growth in the number and diversity of clinical trials conducted in Australia.
- Increased participation in clinical trials across the board, and additionally by underserved populations, including regional, rural, and remote communities.
- Workforce metrics, such as the number of clinician researchers supported and trained and the number of clinical study coordinators and clinical research nurses employed in Australia
- Infrastructure metrics, including the operational efficiency of the NOSS
- Implementation of a Single Ethics Review for all clinical trials, irrespective of the location of the clinical trial site
- Speed to start-up of clinical trials (HREC submission to First Subject Enrolled) in the top 5% of countries, which includes the Research Governance processes

These metrics should be measured at short-term (1–3 years), mid-term (4–7 years), and long-term (8–10 years) intervals.

The National Strategy has the potential to significantly influence the volume and nature of industry sponsored clinical trials by enabling greater integration of clinical trials into healthcare settings. For it to have a positive impact, sustained investment in workforce development, Research Governance processes and infrastructure, particularly the NOSS, will be essential.

Thank you for the opportunity to provide feedback on the Draft National Health and Medical Research Strategy. We look forward to seeing the Strategy drive transformational change in health and medical research across Australia. The RDTF, Medicine Australia, MTAA and AusBiotech stand ready to work together with the Department of Health, Disability and Ageing towards finalising the Strategy.

Yours sincerely,

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MTAA	AusBiotech	Medicines Australia