

Inquiry into approval processes for new drugs and novel medical technologies

House of Representatives standing committee
on health, aged care and sport

Medicines Australia's recommendations for research & development.

Medicines Australia leads the research-based medicines industry of Australia. Our members discover, develop and manufacture prescription medicines, biotherapeutic products and vaccines that bring health, social and economic benefits to Australia.

Clinical research trials are the pivotal phases of Research and Development. Australia currently holds a strong international reputation as a location for clinical trials, but they can be conducted anywhere, including outside Australia. Sustaining this reputation is increasingly challenging as international competition for placement of clinical trials has already begun to erode Australia's advantage.

Enhanced R&D support is associated with improved development, production and access to medicines and vaccines, a factor highlighted by the Australian and global response to the COVID-19 pandemic.

Australia has historically been a reliable destination for quality clinical research, but we must continue to demonstrate superiority against other international benchmarks.

In light of programs like the EU's Horizon Europe, for example, one of whose goals is reaching the earlier stages of drug development more rapidly, with a total budget of AUD\$5 billion, Australia must speed up time to initiation of and pace of recruitment for clinical trials.



It is no secret that targeted **Research and Development programs** in advanced economies lead to greater productivity, jobs and growth.



Australia already has one of the **lowest levels of support for R&D in the OECD** and for a decade, the nation's productivity has languished, jobs and wages have stagnated as has growth.²



Now, the nation faces the challenge of a **sustained downturn in consumer confidence and business investment.**

Australia should double domestic clinical trial activity and expand access to regional areas, generating economic activity. As a priority, there should be one harmonised platform to authorise and oversee clinical trials.

Recommendations:

- Work with industry to review the impact of the revised R&D tax incentive (RDTI) on pharmaceutical innovation, clinical trials and innovative manufacturing to identify where further changes are warranted.
- Consider potential for the Medical Research Future Fund (MRFF) to be linked or mirrored to the EU's Horizon Europe scientific research project.
- Update public health policies to harmonise Human Research Ethics Committee and Site Specific Assessment submissions into one Australian online platform.
- Develop and launch a National Community Awareness Campaign for clinical trials.
- In consultation with industry, invest in and develop a national standard approach for clinical tele-trials in rural, remote and regional areas.
- Invest in and adopt modernised digital technologies and practices to position Australia as the premier destination for international clinical trials.

Australia should aspire to be at the forefront of healthcare, compared against leading international benchmarks. **Enhanced Research and Development support** as well as safe harmonised arrangements to make **Australia a world leader as a site for clinical trials** are two of the keys.



In 2019, there were **1,820 ongoing trials in Australia**: a **22% increase on 2015**. This contributes an estimated **\$1.1 billion a year to the economy**. This figure could easily be doubled over the next 5 years by industry working with governments to create the right settings to realise this ambition.



MA's members contribute approximately **\$9 billion to the Australian economy**, directly and indirectly supporting the employment of **23,000 Australians**.



Domestic manufacturing of pharmaceutical products generate **\$1.6b in exports**.



Our members initiate **1,000 clinical trials** annually helping **33,000 Australians** get early access to emerging therapies.