

National Reforms to Clinical Trials

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December 2025 edition

Message from Professor Ian Chubb AC FAA FTSE FACE FRSN Chair, Inter-Governmental Policy Reform Group (IGPRG)



Dear colleagues,

This has been a busy year - marked by collaboration and a shared commitment to improving outcomes across our sector through the national reforms. I thank you all for your hard work and commitment.

I have enjoyed working with you. I look forward to 2026. Together I think we can get there.

Best wishes,

Ian

National One Stop Shop (NOSS) update

NOSS is set to transform the translation end of the health and medical research spectrum by the introduction of a single national platform designed to streamline research processes. It will make it simpler for researchers, consumers and sponsors with the aim of building on Australia's reputation as provider of first-rate medical research and clinical services, and their application to new therapies provided to more Australians.

NOSS will deliver a streamlined, predictable, and consistent operating environment.

To ensure NOSS is user-centric and meets the needs of researchers, sponsors, and participants, we have conducted extensive stakeholder engagement to inform the design and implementation of the platform.

- **Discovery:** Over 60 technical workshops were completed in 2024 with jurisdictional representatives and subject matter experts.
- **Pre-delivery design:** Throughout 2025, we hosted pre-delivery design workshops. We have heard from stakeholders across the sector whose insights have shaped the business requirements and system workflows.
- **Approach to Market:** We conducted a Request for Information (RFI) for the NOSS ICT solution. The RFI closed on 14 November 2025.

We extend our sincere thanks to all stakeholders across the sector who participated throughout 2025 – including jurisdictions, regulators, private sector, CROs, consumer representatives and others. Their contributions have been invaluable. The engagement in the workshops, requirements review, documentation feedback and experience sharing has been critical to progressing the business case for future funding. Shout out to Alex and the AlphaPlus team for their valued contributions.

Highlights from recent conferences

AusBiotech – October 2025

Presented on the national reforms to improve health and medical research at the AusBiotech International Conference and attended the clinical trials sector networking dinner.

MTAA MedTech – October 2025

Presented on the national reforms to improve health research at the MTAA MedTech Conference. It was great to engage the medical device and tech sector on how national reforms could help attract more device trials to Australia.

Pan-Canadian Clinical Research Summit – October 2025

At the Pan-Canadian Clinical Research Summit, hosted by the Clinical Research Association of Canada, we engaged on a panel discussing best practice ethics in human research and shared Australia's progress to develop an accreditation scheme for Human Research Ethics Committees (HRECs) and their host institutions.

ACTA Clinical Trials and Registries Symposium – November 2025

Delivered a presentation showcasing NOSS and the new Health and Medical Research Strategy for Australia at the ACTA Clinical Trials and Registries Symposium.

ARCS Clinical Summit – November 2025

Presented insights on the national reforms in health and medical research at the ARCS Clinical Summit, emphasising streamlined processes and improved collaboration across sites.

HREC Conference – November 2025

Presented an update on the accreditation scheme for HRECs and their host institutions at the Australian and New Zealand Human Research Ethics Committee Conference (hosted

by Health Translation Queensland). The conference brought together leading voices to discuss the future of health and medical research governance.

Research & Development Taskforce – November 2025

Met with the Research & Development Taskforce to discuss NOSS and progress advancing reform efforts.

These engagements reflect a strong commitment to building a more efficient, transparent, and collaborative research ecosystem across Australia.



Photo: Linda Cristine (DHDA) presenting at the ARCS Clinical Summit 2025

Photo: Prof Ian Chubb (Chair, IGPRG) presenting at the ARCS Clinical Summit 2025

National Standard Operating Procedures for Clinical Trials (National SOPs)

We are updating the National SOPs to reflect Therapeutic Goods Administration (TGA) annotations to the [ICH E6\(R3\) Guideline for Good Clinical Practice: Principles and Annex I](#).

The TGA annotations are essential in our review of the National SOPs to ensure alignment with legislation governing clinical trials in Australia. We will circulate draft updated National SOPs to stakeholders for feedback in early 2026.

Australian Clinical Trials Initiative

The recently launched Australian Clinical Trials Initiative (ACTI) is a coordinated, national effort to promote the clinical trials sector through global trade missions.

ACTI will encompass 25 events over the next year helping Australian firms diversify and build greater access to key international markets.

This \$1 million initiative includes funding from the Australian



Government's Accessing New Markets Initiative, which has been designed to help Australian businesses respond to an increasing level of global economic uncertainty by building the resilience and diversification of Australia's export markets.

ACTI sees government collaborating with industry for a national goal, bringing together federal agencies, state governments, and national peak industry bodies to promote Australia internationally as an attractive clinical trials destination.

Some events have already taken place. The forward pipeline of events will provide an opportunity to work with Austrade to promote our research capabilities and position Australia as a key destination.

Events will continue across Europe, North America, the Middle East, and Asia-Pacific next year.

Photo: Munish Sharma
(Austrade) and Jaspreet
Sidhu (DHDA) at the launch
of ACTI at the 2025
AusBiotech International
Conference

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We acknowledge the Traditional Owners and Custodians of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to Elders both past and present.

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