

National Reforms to Clinical Trials

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



Dear colleagues,

I hosted IGPRG in June with this important [message](#) from Minister Butler. He thanked the IGPRG members for their work on the national reform agenda. The reforms aim to see improvements in the health care of Australians wherever in the nation they may live, and that aspiration is underpinned by health and medical research.

Regards,

Ian



National reforms video

A [video on national reforms in health and medical research](#) has been published on the Australian Clinical Trials website. It provides an overview on reforms to support clinical trials in Australia and why they are important. The video is intended for anyone new to the reform agenda and work of IGPRG.

Australian Clinical Trials website update

The [website](#) is an important channel for providing information on the national reform agenda.

Information on the [Industry Advisory Group](#) and [Stakeholder Advisory Group](#), sub-committees supporting the IGPRG, has recently been published.



National One Stop Shop - Update on engagement approach

Pre-delivery design workshops with representatives from across the sector contributing insights and helping to refine business requirements and workflows.

Based on feedback from stakeholders, future workshops will involve smaller groups of subject matter experts selected for their alignment with the specific topic under discussion. To date this has focused on each of the jurisdictions, TGA, OGTR and PHRN.

Five workshop waves have been completed for: system personas, user registration, organisational profiles, ethics applications, project and application initiation, feasibility assessment and SSA applications. Outputs from each wave are reported to [IGPRG](#) and Research Operations and Technical Working Group (ROTWG). ROTWG provides advice to IGPRG for the national reform initiatives to improve the clinical trials operating environment. It is focused on technical and operational requirements.

In coming months, we will also seek input from the private sector, CROs, universities and community representatives. The pre-delivery design phase is on track to be completed by year end.

SCRS Follow-up ANZ Webinar: NOSS Q&A - 12 August 2025 9:00am - 9:45am (AEST)

The **Society for Clinical Research Sites** is hosting a webinar following the presentation on NOSS at the Australia-New Zealand Site Solutions Summit. [Submit](#) questions about the National One Stop Shop and [register](#) for the webinar.

National SOPs

The National Standard Operating Procedures for Clinical Trials in Australia (National SOPs) is currently undergoing renewal. The [current version](#) was published in 2021.

The Therapeutic Goods Administration (TGA) will soon invite public feedback on its proposed annotations to the ICH E6(R3) Guideline for Good Clinical Practice: Principles and Annex I. The consultation is expected to be announced in the coming weeks on the [ICH Guideline for Good Clinical Practice](#) webpage and promoted through TGA's [social media channels](#).

Once the TGA releases its annotations, these will be reviewed and considered. Following this, a draft update of the National SOPs will be circulated to our large network of stakeholders for feedback.

If you would like to contribute to the renewal of the National SOPs, please email your contact details to: ClinicalTrialsPolicy@health.gov.au quoting *National SOPs review* in the subject title.

WHO Global Action Plan for clinical trial ecosystem strengthening (GAP-CTS)

The World Health Organization (WHO) has published the [Global action plan for clinical trial ecosystem strengthening \(GAP-CTS\)](#). The plan outlines nine priority actions to support countries and stakeholders reform and sustain clinical trial systems that are fit for purpose, inclusive and locally led.

Anchored in WHO's 2024 Guidance for best practices for clinical trials, GAP-CTS addresses persistent disparities in trial activity and access, especially in low- and middle-income countries, and calls for systemic improvements to trial funding, design, coordination and ethical oversight.

The nine actions are designed to:

- strengthen national leadership and governance of research systems
- enhance engagement with patients, communities and the public
- address barriers faced by under-represented populations
- adopt innovative designs and digital technologies
- accelerate access to training for the research workforce
- improve regulatory and ethics review efficiency
- integrate trials into health systems and routine care
- improve research transparency via trial registries
- expand international collaboration across regions and sectors.

IGPRG-led national reforms align with these actions.

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