INDUSTRY ADVISORY GROUP

Inter-Governmental Policy Reform Group (IGPRG) Sub-Committee

Communique – Meeting 02

11 December 2024

Background

Inter-Governmental Policy Reform Group (IGPRG)

In 2023 all Australian Health Ministers agreed to the establishment of an enduring Inter-Governmental Policy Reform Group (IGPRG), which will provide policy and operational oversight of key national health and medical research reforms. The IGPRG is responsible for delivering the broader policy program including the National One Stop Shop, implementation of the National Clinical Trials Governance Framework and the development of a quality standard and accreditation scheme for Human Research Ethics Committees.

National One Stop Shop Program

The National One Stop Shop effectively joins up the clinical trial and health research whole-of-life cycle into one operational system (from approval, registration and conduct through to the publication of results) supported by mutually agreed processes and policies. Ultimately, the National One Stop Shop will make it easier for patients, researchers and sponsors to find, conduct and participate in clinical trials and research in Australia.

IGPRG Sub-Committees

As part of its approved arrangements and structures, sub-committees will be established to support the IGPRG and its functions. Some Advisory Groups will focus on seeking views, perspectives and input from external and industry stakeholders, and cross-jurisdictional working groups will undertake operational activities and provide technical advice to IGPRG in support of its initiatives and reform agenda.

Update

The second meeting of the Industry Advisory Group (IAG) was held on 11 December 2024. The IAG is a sub-committee of the IGPRG. The IAG is chaired by Adjunct Professor Julie White.

The focus of the meeting was to discuss the health and medical research pipeline and IGPRG priority areas to inform the project.

National One Stop Shop (NOSS)

The Government is committed to implementing the National One Stop Shop to harmonise and streamline the regulatory and operating environment for health and medical research in

Australia. The Government announced funding in the 2024-25 Budget to progress essential technical work to inform the National One Stop Shop ICT solution. On 16 September 2024, a Request for Expression of Interest (REI) for delivering the National One Stop Shop ICT Solution was published on AusTender. The Government continues to work in collaboration with state and territory governments through the Inter-Governmental Policy Reform Group (IGPRG) to deliver the National One Stop Shop and related initiatives.

National Site-Specific Assessment (SSA)

The SSA is consistent with minimum requirements specified in the National Clinical Trials Governance Framework and all relevant legal or regulatory requirements, as well as being sufficient to provide decision-makers with confidence that patient safety and clinical standards are being maintained.

• National Clinical Trials Governance Framework (Governance Framework)

Effective implementation of the Governance Framework is the cornerstone of the national clinical trial reform agenda. The Department, under the auspice of the IGPRG, leads and maintains the implementation of the Governance Framework by providing consistent guidance and support for health services, accrediting agencies and the sector. The Governance Framework ensures clinical trial service is embedded in routine health service clinical and corporate governance systems and is considered core health service business.

Quality Standards and Accreditation Scheme for Human Research Ethics Committees (HRECs)

The public consultation on the draft Quality Standards and Accreditation Scheme for HRECs will take place in March 2025.

2025 Meetings

Four IAG meetings are planned in 2025. The next meeting is 9 April 2025.

Further information

Information is available on the <u>Australian Clinical Trials</u> website, or by emailing IGPRG@health.gov.au

Please contact the team in the Australian Government Department of Health and Aged Care to receive updates and presentations on the initiatives underway. These sessions can be tailored to meet your needs. Please email clinicaltrialspolicy@health.gov.au to arrange a session.