Australian Teletrial Program
Access to clinical trials, closer to home

Australian Teletrial Program

Response to questions on notice from Senator Louise Pratt; Senate inquiry into equitable access to diagnose and treat individuals with rare and less common cancers.

Version 1.0 13 March 2024

Australian Teletrial Program (ATP) response to Questions on Notices from Senator Louise Pratt following the Inquiry into equitable access to diagnosis and treatment for individuals with rare and less common cancers, including neuroendocrine cancer

Senator PRATT: *Perhaps you can take this on notice, and you might be able to direct us to where we answer this. In a constitutional sense, can the Commonwealth be the only body that regulates clinical trials if all the states repeal their laws, or is it the other way around? Do the states need to refer their powers? There are often political debates around—sometimes it can be something like the number of embryos that are left in a particular clinic. There can be quite politicised reasons, or sometimes very good reasons, as to why a state might think that a national model isn't—they still want to put their 2c worth in. Those governance models are really important. I'd be keen if you could take that on notice, and perhaps we could even hear back from the clinical trials reference group about that.*

The Australian Teletrial Program (ATP) thanks Senator Pratt for the opportunity to respond in detail.

1. **Governance model**

The Government's Research and Governance reform agenda acknowledges the operational and legislative differences between jurisdictions and institutions which creates barriers and delays to health and medical research, including clinical trials. Across the research industry, there is strong appetite for research and governance process improvement of clinical trials and their uptake, including teletrials.

While ATP is focused on teletrials, there is benefit in recommending continued harmonisation between states and territories legislative requirements for research ethics and governance. This benefit would be most impactful in sector wide initiatives, such as the National One Stop Shop and National Clinical Trial Governance Framework, with a flow on to the ATP. Senator Pratt's question is best referred to the Inter-Governmental Policy Reform Group (IGPRG), formally the Clinical Trials Project Reference Group. This will be raised via the Queensland IGPRG representative, Doctor Julie White.

Teletrial specific recommendation request:

The ATP asks the Senate to:

a. Support a recommendation to Government's Research and Governance reform agenda, acknowledging the teletrial partnership between primary and satellite sites with networked approvals/oversight. This would allow sites to collaborate immediately on components of the regulatory approval process that can be streamlined, while simultaneously encouraging site-specific assessment of local considerations.
b. Recommend greater standardisation of pharmacy, imaging, pathology, and other third-party services (fees and processes).
c. Endorse the ATP National Office's continued development and roll-out of standardised templates, guides and harmonisation of processes incorporating teletrial methodology.

2. **Recognition of the Regional Clinical Trial Coordinating Centers (RCCCs)**

Following the previous Senate Inquiry, Regional Clinical Trial Coordinating Centres have been established in six ATP jurisdictions. It is hoped the value of the centres has been

demonstrated in the ability to increase equity of access to, and participation in clinical trials for regional, rural and remote patients, not just in rare and less common cancers, but all disease types and conditions.

There is acknowledgment that considerable work is required that will extend beyond the current funding period of October 2026. The Regional Clinical Trial Coordinating Centres provide start-up support with the biggest enablers of teletrials - Clinical Trial Coordinators. Currently a lack of career progression, continuity of contracts and the need for proficient specialist knowledge of Clinical Trial regulatory, legal and Good Clinical Practice impacts recruitment and retention of this workforce. It could however, become a legitimate career pathway option particularly in regional, rural and remote healthcare settings.

Teletrial specific recommendation request:

The ATP asks the Senate to:

d. Advocate for ongoing financial support from state, territory and federal governments to support the National Office and RCCC workforce, digital improvements, data management and research culture development to continue embedding the teletrial model across Australia.
e. Recommend workforce stability by encouraging institutions to provide permanent funding for research governance and clinical trial operations, including permanent appointment to roles for workforce, prioritising those based in regional, rural and remote areas.
f. Recommend the creation of standardised role descriptions for research roles across jurisdictions, to create sector stability.
g. Influence and encourage cultural change by embedding exclusive time for clinician researchers within existing roles, rather than having it as an addition to clinical load and outside of working hours.
h. Endorse an "opt-out" instead of "opt-in" for teletrials as standard clinical trial design with funding bodies and sponsors.

Inquiry into equitable access to diagnosis and treatment for individuals with rare and less common cancers, including neuroendocrine cancer

Questions on Notice from Senator Louise Pratt, page 15.

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Answers due COB Friday, 15 March 2024

This been under consideration and action since the 1980's.

In 1989 (after the Baume Review) the Commonwealth enacted the *Therapeutic Goods Act*. This has provided a legislative framework for the regulation of clinical trials that use unregistered therapeutic goods. In particular, the Clinical Trials Notification (CTN) scheme has been an outstanding success in attracting trials to Australia. All jurisdictions already operate successfully within this Commonwealth-led legislation and framework.

Jurisdictions already comply with relevant national policies and processes, in addition to state and territory policies and processes.

However, no single entity controls all the levers for change. The Australian Government is leading national reforms in partnership with all state and territory governments to continue to improve the operating environment for clinical trials and research in Australia.

A streamlined, harmonised, effective, predictable and consistent operating environment is essential for a vibrant health and medical research eco-system. In recognition of this, all Australian Health Ministers recently agreed to the establishment of an enduring Inter-Government Policy Reform Group (IGPRG) that is responsible for developing, implementing and overseeing national reforms to improve, streamline and harmonise the operating environment for health and medical research, and to make Australia a preferred destination for research.

A key initiative currently underway to improve access to clinical trials, is the development of the National One Stop Shop for Health and Medical Research. The National One Stop proposal has been developed in collaboration with all Australian governments aiming to harmonise and streamline end-to-end health and medical research approvals, management, monitoring and reporting nationally. Together with other related national reforms underway,

the National One Stop Shop will make it significantly easier for participants, researchers, administrators and sponsors to find, participate in and conduct research in Australia.

In recent years, ethics approval has moved from institutional ethics review of clinical trials to national mutual acceptance, which is a networked approach. This is currently limited to public hospitals. However, there is a program of work currently underway, being led by the IGPRG, to expand this scheme to all organisations across Australia reviewing clinical trials.

In terms of local governance reviews and contractual obligations, work has been undertaken to develop and agree a single national Site Specific Authorisation (SSA) form as part of the national reform agenda and a recent Commonwealth Budget Measure. This single national SSA requirement has been endorsed by all jurisdictions for implementation via the National One Stop Shop. It will harmonise and streamline SSA requirements at the local level. However, to apply a networked approach to individual contractual requirements, further consideration of Commonwealth and State legislation would be required. For example, the *Commonwealth Corporations Act 2001* would need to be changed to remove the fiduciary obligations of directors and officers in relation to such things as risk assessment. This would have unintended consequences and would be unlikely to be supported.

Embedding clinical trials into routine business for health services is being supported by the implementation of the National Clinical Trials Governance Framework, as recently endorsed by all Health Ministers. This work has been progressed as part of the national reform agenda and the Encouraging More Clinical Trials in Australia budget measure, and falls within the remit of the IGPRG.