

Evidence Summary



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Our Research Ethics and Governance Network

The appointment of a coordination team to maintain the Australian Genomics research protocol and manage ethics and governance processes has had a significant positive impact on the start-up times and ongoing management of clinical flagship projects.

Background

Australian Genomics has undertaken an ambitious goal to recruit research participants into clinical flagships through more than 30 sites across every state and territory in Australia.

The value of this approach is in providing equitable access to research genomic testing for all Australians, and also to ensure the systems and processes required for delivery of genomic medicine are piloted throughout Australia, using and fostering local expertise.

To achieve this goal Australian Genomics initiated the necessary research ethics and governance applications through the National Health and Medical Research Council's National Mutual Acceptance scheme. This scheme was introduced to streamline multi-site human research ethics approvals for projects navigating the different jurisdictional requirements of the states and territories.

Under the scheme, ethical and scientific review of the project is undertaken by one certified Human Research Ethics Committee (HREC), and then subsequent governance review of the project for jurisdictional compliance is performed by each clinical site where the research will be carried out.

While we support the need for robust review of research involving humans, this two-step process for obtaining ethics and governance often impacts the initiation of research projects by increasing the administrative requirements for researchers and increasing the time taken to obtain approvals for study commencement.

Project aims

Australian Genomics established a national coordination network of staff to manage the administration for obtaining and maintaining ethics and governance approvals in 30 public and one private hospital in Australia.

Coordinators managed the overarching ethics requirements while locally employed Project Officers worked with site Research Governance Offices (RGOs) to gain the approvals required to recruit participants at each site. Weekly meetings of the national network via teleconference have been an important platform to solve issues and share ideas and learnings relating to multi-jurisdictional research processes.

Key findings

[Australian Genomics has now achieved ethics and governance approvals to recruit participants into clinical flagships spanning every state and territory in Australia.](#)

This has come at a significant cost in terms of both time and salary expenditure ([Haas et al, 2019](#)), but the role of the coordination network has been recognised both within and externally to the organisation as an essential mechanism for making the study operational.

The coordination team manage ongoing study Protocol amendments and have established good

Acknowledgement

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working relationships with HRECs and RGOs. Australian Genomics is fortunate to have been funded for a five year term, as the shorter three year funding cycle would not logistically allow for research programs to aspire to a national approach to recruitment.

Importantly, in a system where lengthy legal reviews are common, we have established a suite of research contracts; a Multi-Institute Research Agreement with 34 institutions, and a research collaboration agreement serving 20 institutions.

More recently we have complied with current standards to implement a Medicine’s Australia Clinical Trials Research Agreement, which has been approved for use in four states.

Potential impact

The appointment of a coordination team to maintain the Australian Genomics research protocol and manage ethics and governance processes has had a significant positive impact on the start-up times and ongoing management of clinical flagship projects.

Eighteen months passed between the time the initial ethics application preparation began to the first site being live for recruitment.

In contrast, the most recent clinical flagship projects added to the study received all the necessary approvals to start recruiting participants in as little as three months.

This facilitates projects in meeting study timelines and budgets, maintaining momentum of research teams and reducing the administrative burden on clinical investigators.

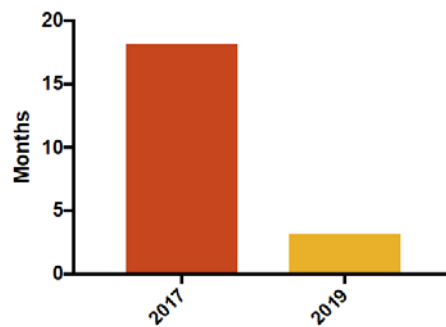


Fig. 1 Time to launch new clinical flagships

Conclusion

The Australian Genomics coordination team has established a research ethics and governance network to facilitate clinical genomic research across Australia.

This network ensures short start-up times for new clinical flagships and provides researchers with a wealth of experience in meeting ethical and governance requirements for establishing genomic research projects working within the Australian system.

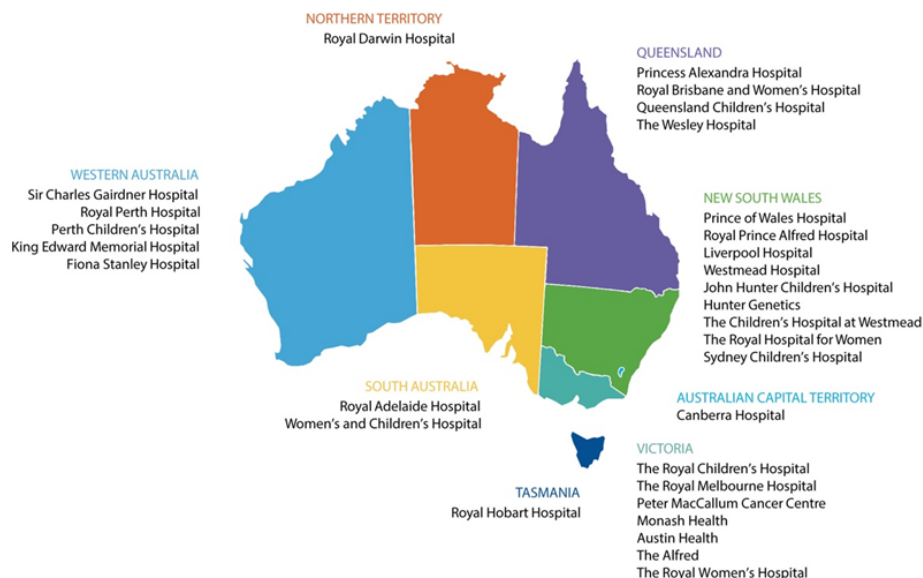


Fig. 2 Clinical recruitment sites, Australian Genomics, October 2019