Summary of Recommendations of *The New Frontier - Delivering better health for all Australians* (Zimmerman report)

The Zimmerman report was released in November, 2021, the result of an inquiry into the approval processes for new drugs and novel medical technologies in Australia. The report put forward 31 recommendations. Australian Genomics' priorities, projects and model of operation align with many of the recommendations.

About Australian Genomics

Australian Genomics is an Australian Government initiative supporting genomic research and its translation into clinical practice. Through broad engagement and a national collaborative approach, it achieves two key objectives: to improve efficiency, reach and timeliness of genomic research projects, and to support Commonwealth State and Territory health departments in the implementation of genomics research outcomes by refining and communicating evidence to inform policy development.

Australian Genomics engages with current and emerging government policy and priorities to identify gaps and opportunities, to support policy and action for integrating genomic technologies into the health system. By interfacing with consumers, governments, industry and global genomics initiatives, Australian Genomics drives change and growth in the sector.

Summary of recommendations and relevant Australian Genomics activity

Recommendation 1: The Committee recommends the Australian Government establish a Centre for Precision Medicine and Rare Diseases within the Dept of Health.

- To enhance Dept of Health capacity to provide Australians with timely access to new drugs and novel medical technologies
- To provide advice to Dept of Health and AMRAB, education and training
- Advice to governments on the establishment of a dedicated regulatory Health Technology Assessment pathway for cell and gene technologies

Australian Genomics acts in an advisory role to governments. For example, Australian Genomics coordinated the Scientific Strategy Committee convened in 2019 to identify strategic research priorities for the MRFF Genomics Health Futures Mission. Through the National Implementation Committee, Australian Genomics advises on the progress and outcomes of translational genomic research. A similar model could be adopted by a Centre for Precision Medicine and Rare Diseases.

The Australian Genomics 'future diagnostic technologies' working group is establishing a living map of emerging health technologies.

Genomicsinfo.org.au is a resource for patients and publics on genomics and health. Australian Genomics has also overseen the delivery of genomic workforce education and training opportunities through the clinical flagships. These have been delivered in multiple formats including education workshops, facilitation of multi-disciplinary team meetings to review genomic testing results (e.g. variant prioritisation and interpretation), and internships.

Recommendation 2: The Health Technology Assessment (HTA) process for cell and gene therapies be simplified

- establish a jointly funded national genomics testing program to provide equitable access to genomic testing nationwide. As part of the program, governments should ensure the provision of genomics counselling for all patients.

There is an opportunity to build upon Australian Genomics nationally coordinated approach; network of clinical and diagnostic genomic services; and national network of clinical sites.

Our work on the capacity and development of the Genetic Counselling workforce can be leveraged, in collaboration with the Human Genetics Society of Australasia (HGSA).

Recommendation 3: Establish an Office of Clinical Evaluation

- To serve a "living evidence" function to ensure HTA is based on the most up-to-date global health practices

There is an opportunity to leverage Australian Genomics' national network of experts and international collaborations to inform clinical evaluation.

Recommendation 5: Develop a labour market and skills strategy to expand the number of health economists in Australia.

Australian Genomics has championed the inclusion of health economic evaluation in genomic research, encouraging all clinical genomic research studies to build in up front health economic research applicable to the individual study cohort. Australian Genomics offers support and consultation with leading health economists in the development phase of research proposals. Australian Genomics' health economists have developed novel approaches to economic assessments, incorporating empirical measures of public and patient preferences to interventions.

Recommendation 6: Educate and engage with patients, clinicians, industry and the public and develop education campaigns on all aspects of the regulation and reimbursement system.

Broader education and engagement will be essential for patient participation in the HTA MSAC system (recommendation 28). Patient engagement would be facilitated by consumer and patient support groups, which Australian Genomics has strong relationships with through its Community Advisory Group, Involve, genomicsinfo, and targeted cohort projects.

Recommendation 16: Formation of an international Health Technology Assessment consortium

Opportunity to leverage Australian Genomics' leadership roles in international health consortia (inc. Global Alliance for Genomics and Health), active collaborations (inc. NHS England), and the Economics of Genomics and Precision Medicine (Econ-Omics) special interest group within the international Health Economics Association.

Recommendation 21: expand the newborn screening program based on new understandings of genomic testing for conditions and international best practice (while not in the terms of reference for this inquiry, the Committee recognises and supports the calls from rare disease patient groups for more funding for treatment pathways for actionable disorders across states and territories, where identified through newborn screening.)

Opportunity to build upon Australian Genomics' nationally coordinated approach; network of clinical and diagnostic genomic services; and national network of clinical sites in collaboration with public health units.

The application of genomics in NBS is a sensitive and important topic and requires broad community consultation and evidence-based approaches informed by existing policies[1]. NBS is the subject of one research stream of the most recent Genomic Health Futures Mission funding opportunity (2022) and Australian Genomics is partnering with proposals in this stream, and has committed to funding the coordination of a national collaboration of centres of excellence in genomic NBS 'GenSCAN'.

Recommendation 22: Implement with urgency the harmonisation of Human Research Ethics Committee (HREC) and Site-Specific Assessment submissions into one Australian online platform and enable parallel review by HRECs and Research Governance Offices.

Australian Genomics has published on the challenges and need for harmonization of research HREC/governance processes[2], after establishing a national network of 32 recruitment sites nationally.

Recommendation 23: development of a national clinical trial register

Australian Genomics has participated in the Australian Commission on Safety and Quality in Health Care consultations on development of a clinical trials governance framework and the Australian Research Data Commons Health Studies National Data Asset program, lending strong support to the progression of national federated and linked datasets and registers. Data linkage and sharing leads to better access to trials for patients, better health outcomes, and amplifies the value of collected health data.

Recommendation 24: modernising digital technologies and practices to position Australia as the premier destination for international clinical trials. This would include developing national standards for the use of e-consent, esignature, and electronic medical records.

Australian Genomics has developed participant platforms[3] that facilitate engagement, dynamic consent and quality of data capture and an e-consent strategy that facilitated

[1] Newborn Bloodspot Screening National Policy Framework ISBN: 978-1-76007-364-0; Population Based Screening Framework, ISBN: 978-1-76007-370-1
[2] Med J Aust 2019; 211 (10): doi: 10.5694/mja2.50397
[3] *Eur J Hum Genet* **29,** 687–698 (2021). https://doi.org/10.1038/s41431-020-00782-w

continued research participant recruitment throughout the COVID-19 pandemic when hospital clinics were minimised. Australian Genomics supported projects have developed standard clinical data capture instruments including an electronic family pedigree tool. Importantly, Australian Genomics has socialised the use of these innovative digital tools with the multiple stakeholders involved.

Recommendation 25: standard operating procedures to support and strengthen the capacity to conduct clinical tele-trials in rural, regional and remote areas.

Australian Genomics clinical flagships and the Mackenzie's Mission Australian Reproductive Carrier Screening Study have expanded geographical recruitment though innovative approaches, including the use of regional clinics, tele-health and e-consent.

Recommendation 27: Develop additional reforms to data exclusivity timeframes to support research and development into new drugs and novel medical technologies in areas of unmet need. Consider future funding initiatives for novel drug discovery and support research and development partnerships in Australia.

There is an opportunity to build upon Australian Genomics nationally coordinated approach; network of clinical and diagnostic genomic services; and national network of clinical sites. Australian Genomics engages with industry through the Industry Genomics Network Alliance. (InGeNA).

Recommendation 28: Integrate the patient voice upfront into the Health Technology Assessment system, including consider making patient evidence compulsory for certain application.

Involve Australia is a community-led project in Australian Genomics to develop guidelines to optimize consumer involvement in research. This recommendation is linked with recommendation 6: better educating and involving patients in HTA processes.

Recommendation 29: The independent Health Technology Assessment Review reassess relevant aspects of the Health Technology Assessment process to ensure there are future pathways for treatments and therapies that do not fit neatly into the current system such as rare cancers, antimicrobials, orphan drugs, and precision medicines.

Australian Genomics experiences the challenges to implementation of novel and innovative medical services and technologies into the health system; the complexity of which is exacerbated by the shared responsibility of funding between Commonwealth and State governments. Australian Genomics is mapping translation pathways. Early engagement with government in translation research may support the transition to the health service.