inGeNA

Industry Genomics Network Alliance

DISCUSSION PAPERS

Precision Health Roundtable

The future state of precision health in Australia by 2030, what we need to do to get there and what are the priority areas

September 2022

AIDH

AUSTRALASIAN INSTITUTE OF DIGITAL HEALTH | inGeNA Industry Genomics Network Alliance

InGeNA is a united voice for Australian industry partners contributing to the rapidly developing field of genomics.

Auspiced by the Australasian Institute of Digital Health (AIDH), InGeNA strives towards bringing a shared perspective on critically important areas underpinning the future of genomics.

InGeNA's members and partners share a single vision for genomics in healthcare: better health outcomes, healthcare value and affordability, and a trusted, equitable and ethical genomics ecosystem.

Supported by MTPConnect MedTech and Pharma Growth Centre

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Introduction to the Precision Health Roundtable

Genomics and precision health relates to all Australians, with 22.8 million Australians expected to use genomics to improve wellness and/or as prevention healthcare. This impact ranges from the 6-8% of children born in Australia with a rare genetic condition to the 1 in 2 Australians who will be diagnosed with cancer in their lifetime. Precision health is at a crossroads and there is an opportunity to move forward together to build on the existing work, informed by the views of other stakeholders in the genomics value chain.

Industry Genomics Network Alliance (InGeNA)

InGeNA is a united voice for Australian industry partners contributing to the rapidly developing field of genomics. The Alliance partners share a vision for Australia's leadership in the adoption of genomics in healthcare. InGeNA was formed by a group of industry organisations, hosted by the Australasian Institute of Digital Health (AIDH), to bring a shared perspective on critically important areas underpinning the future of genomics. Our vision is to realise the full potential of genomics to personalise healthcare. We believe we can achieve this by harnessing the collective skills and expertise of industry to integrate genomics into healthcare to deliver:

- Better health outcomes
- Healthcare value and affordability
- A trusted, equitable and ethical genomics ecosystem

Collaboration across the key sectors of diagnostics/pathology, technology and pharmaceuticals will ensure long and far-reaching benefits for Australian health consumers. We believe:

- Collaboration with other organisations in the healthcare sector is critical, as together we can collectively ensure long and far-reaching benefits for Australian health consumers.
- InGeNA can be the leading industry voice, providing guidance to government, media and stakeholders.

Together we have developed a strategy that focuses on four key pillars:

- **Quantifying the benefits of genomics:** Build the evidence base on the value of genomics to the economy, society and patient care
- **Access and equity:** Advocate for patient equity and access to personalised healthcare
- **Workforce:** Advance industry skills and development to build a workforce for the age of precision health
- **Data and technology innovation:** Drive the value of genomics information management and national data infrastructure to support advanced care

The momentum behind precision health will herald significant changes in the health sector. There will be a great deal of activity over the next year or two as we collectively look to greater adoption of precision health to improve health outcomes for Australians. The review of Health Technology Assessment (HTA) processes that will be undertaken by Medicines Australia and the Government, and the announcement of plans to establish Genomics Australia are but two of these.

To achieve the best outcomes for patients, it is important that we have a clear collective vision of what this future might look like.

Delivering precision health by 2030

There has been a great deal of stakeholder engagement in recent years looking at the future of precision health and genomics in particular. The *National Health Genomics Policy Framework* [1] published in 2017 and its associated *Implementation Plan* set out a focus on five areas for governments and the sector. 2018 saw the publication of *The Future of Precision Medicine in Australia* [2] by the Australian Council of Learned Academics, which explored the challenges and opportunities for precision health and its use. InGeNA has released a series of reports over the last 12 months covering issues including the benefits of genomics,

improving access, understanding the impacts of genomic data, and how we can assess and improve the capabilities of Australia's genomics workforce.

InGeNA has been discussing with our valued partners in recent months how industry can support and coordinate with the broader sector to deliver better patient outcomes through clinical genomics. The ARCS Conference earlier this year helped solidify this conversation with the recognition that there would be value in hosting a Roundtable event to discuss the solutions and priorities for delivering on the promise of precision health by 2030.

Objective for the Precision Health Roundtable

The goal is to identify the future state of precision health in Australia by 2030, what we need to do to get there and what are the priority areas. To ensure that all parties have a voice, InGeNA has invited attendance from organisations across patient advocacy, government, clinical delivery, research, and industry – we all have a role in achieving this goal. The focus of the day will be on tangible, practical solutions that can incrementally lead to our aspiration for a future where patients benefit from clinical genomics.

The output of the roundtable will be an initial communique on the day, followed by a report to be provided to Commonwealth, state and territory governments and the relevant Departments. The report will outline recommendations for implementing precision health to deliver benefits to Australians and the Australian health system by 2030.

Approach to the Roundtable

To focus discussion and debate, a set of five themes were identified that build on the work InGeNA has done in areas underneath its strategic pillars and other topics related to how we can progress towards a precision health ecosystem. These themes are:

- Strengthening governance through stakeholder engagement to support the integration of genomics
- Improving national access to genomic testing through the Medical Benefits Schedule (MBS)
- Harmonising data quality, standardisation, sharing and governance
- Understanding the national infrastructure requirements for clinical implementation
- Building a learning healthcare system delivering precision medicine based on genomic technologies

Attendees will be asked to indicate topics in which their organisation has an interest as part of the RSVP. The organisers will allocate people to the themes guided by this information while achieving a balance of representations across all five topics.

This set of short summary papers has been provided to set the scene for the discussion themes and pose several questions for discussion. InGeNA encourage attendees to canvas their organisation for responses to these points. Attendees will need to have read the brief discussion papers ahead of time and to arrive prepared to build on conversation and contribute to the questions.

Next steps

We thank you in advance for your participation and hope the following discussion papers will provide useful information and pose leading questions to get you ready for this event. InGeNA publications referenced in this document can be found at our website: www.ingena.org.au.

We also invite you to contribute ideas about your work and points you'd like to see discussed at the event.

Strengthening governance through stakeholder engagement to support the integration of genomics

The potential of genomic-based care to improve the lives of Australians is significant. It is having, and will continue to have, a transformational impact on where, when and how healthcare is delivered.

Despite the significant benefits genomic-based care can deliver, integrating genomics into healthcare is extremely challenging given the broad ranging impact it can have, and this complexity is made even more so by the fragmented nature of the Australian healthcare system.

The complexity and the breadth of challenges (for example ethical, legal, funding, infrastructure, research and workforce considerations) means that a collaborative and partnership-based approach would be beneficial as no single entity could adequately address the issues on their own.

Significant investment in progressing genomics has been made nationally and jurisdictionally. At a national level, efforts to integrate genomics into healthcare have now reached a critical juncture which allows stakeholders to consider the level and type of engagement that would be of value to them and to progressing genomics in Australia. Specifically:

1. The national policy framework (the National Genomic Health Policy Framework [NHPF]) guiding the activities required to implement genomics in Australia has expired and is due for review
2. The intergovernmental architecture under which the NHPF for genomics was being progressed has been replaced by a greatly rationalised operating structure
3. The previous Australian Government committed to establishing Genomics Australia to guide implementation of genomics in Australia

Further information is outlined in the Background section below.

As this paper outlines, stakeholder engagement in the public sector is key to good governance which supports government deliver on its priorities. In this national context, stakeholders include:

- State/Territory governments
- other public sector entities
- consumer organisations
- the private sector
- healthcare professionals
- the genomics technology industry
- academic and research institutions
- private citizens who have an interest in this area.

There are likely to be upcoming opportunities for stakeholder input into:

a) The review of the NHPF or, if this has occurred, the development or implementation of policy / program / service under the updated iteration of the Framework
b) Informing genomic priorities and / or policy / program / service development or implementation under Genomics Australia

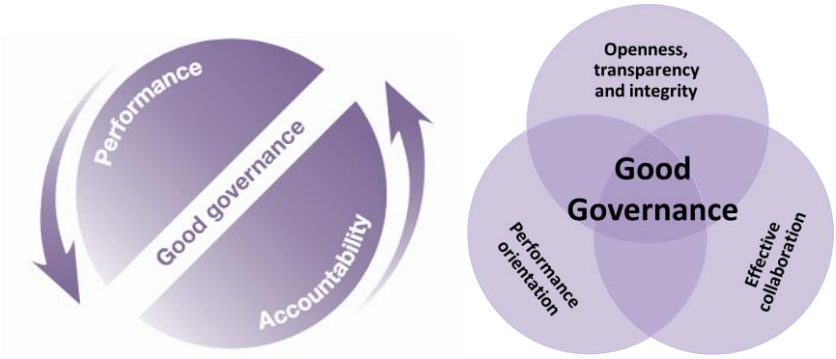
Providing insights into the benefits of stakeholder engagement and the engagement needs of different stakeholders would help inform the Australian Government to develop a stakeholder engagement strategy as it seeks to coordinate the implementation of genomics across Australia.

Governance in the public sector

There are various definitions of governance and the principles which underpin good governance, but governance is fundamental to helping organisations to deliver on their purpose. Good governance has also been identified as essential for policy success [3, p. 250].

In the public sector, governance refers to the arrangements and practices that enable an entity to set its direction and manage its operations to achieve expected outcomes and discharge its accountability obligations. In simpler terms, it has been defined as referring to *"the way things get done, rather than just the things that are done"* [4, p. 7]

Governance expectations for Commonwealth entities are enshrined in the *Public Governance, Performance and Accountability Act 2013 (The PGPA Act)* [5]. The Act establishes a system of governance, performance and accountability, including meaningfully informing Parliament and the public and working cooperatively to achieve common objectives, where practicable.



Adapted from ANAO Public sector governance: strengthening performance through good governance

Good governance promotes public confidence in government and its agencies and focusses on performance to deliver on objectives and accountability to provide visibility of results to others such as the Parliament and the community. Other fundamentals of good governance include openness, transparency and integrity, engaging constructively with stakeholders and effective collaboration, including partnerships outside government [4, pp. 8, 10, 17–18].

The importance of stakeholder engagement in a governance framework

Stakeholder engagement is important as it aligns with contemporary public expectations and enables informed policy development and implementation. Working collaboratively (across entity, jurisdictional and sector boundaries) is also important as the contribution of multiple parties can enhance policy outcomes sought by government for the community. Good governance requires the identification of stakeholders and engagement through appropriate information, consultation and engagement mechanisms [4, pp. 1, 16].

The ANAO states: *"Constructive stakeholder relationships, together with suitable information and analysis to support decision-making and resource allocation, position an entity to set appropriate priorities, make informed decisions and develop well targeted programs and services. Many stakeholders are willing to contribute expertise and resources in providing advice to assist in the design and delivery of programs and services".*

Stakeholder engagement frameworks

5 levels of stakeholder engagement have been incorporated into the Department of Health's stakeholder engagement framework, with engagement methods suitable for each level of engagement and engagement principles [6]. These offer useful insights as to how engagement may occur during different stages.

The principles of engagement outlined in the Department's Framework are:

a) Purposeful engagement underpinned by an understanding of what the Department wants to achieve
b) Inclusive engagement where relevant stakeholders are identified, and engagement is made easy
c) Timely engagement where stakeholders are involved from the start and agree on how and when to engage
d) Transparent engagement where engagement is honest, and expectations clarified
e) Respectful engagement where expertise, perspectives and needs of stakeholders are acknowledged and respected

The 5 levels of engagement and potential methods of engagement:

Inform	Consult	Involve	Collaborate	Empower
Inform or educate stakeholders in one way communication	Gain information and feedback from stakeholders to inform decisions made internally. Limited two-way communication - ask questions, stakeholder provides answers	Work directly with stakeholders throughout the process to ensure that issues and concerns are understood and considered. Two-way/multi-way communication where learning takes place on both sides	Partner with stakeholder and/or stakeholder groups for the development of mutually agreed solutions and joint plan of action Two-way/multi-way communication where learning, negotiation and decision making on both sides. Stakeholders work together to act	Delegate decision-making in the hands of the stakeholders on a particular issue Stakeholders are enabled/equipped to actively contribute to the achievement of outcomes
Method of engagement	**Method of engagement**	**Method of engagement**	**Method of engagement**	**Method of engagement**
• Fact sheets • Websites • Public presentations • Annual report	• Surveys • Focus groups • Meetings	• Multistakeholder forums • Advisory panels • Consultative committees • Workshops • Participatory decision-making	• Reference groups • Joint projects • Multistakeholder initiatives • Partnerships	• Integration of stakeholders into governance structures (e.g., as members or shareholders on particular committees)

Adapted from Department of Health Stakeholder engagement framework (2018).

Background on National efforts to integrate genomics into healthcare in Australia

The National Health Policy Framework 2018-2021 and Implementation Plan

In recognition by Australian governments of the transformational impact of genomics in healthcare and an effort to implement genomics consistently across Australia, a national framework was developed under the Council of Australian Government (COAG) arrangements. The *National Health Genomics Policy Framework 2018-2021* [1, pp. 2, 41–42] outlines a blueprint for coordinated action by governments, health professionals and others such as industry to work in partnership to embed genomics into healthcare [7, p. 2].

The Framework focussed on 5 priority areas of activity (see Attachment 1 on page 11).

The Policy was supported by an Implementation Plan which explained how the 5 priorities above would be progressed and allocated responsibilities across the jurisdictions using the COAG structures in place at the time (i.e., the Clinical Principal Committee (CPC), the Australian Ministers' Advisory Council (AHMAC) and the COAG Health Council) (see Attachment 2 on page 12).

The implementation plans to be developed and progress with the priority activities could not be publicly found.

Governance under the Framework

Both the Framework and the Implementation plan noted the need for clear governance arrangements and stakeholder engagement.

The Implementation Plan noted that genomics was a shared responsibility between the Commonwealth and the States and across a range of portfolios. It also noted that: *"Governance arrangements are to be consultative and transparent. This includes openly sharing and, where practicable, inviting comments on documentation such as terms of reference, project plans and progress reports. Where possible, co-design principles will be adopted in driving specific activities under each action. AHMAC and CPC will make decisions on how, and from whom, they seek advice on an as-needed basis."*

Specific actions in relation to governance outlined in the Implementation Plan include:

- an independent evaluation by Governments of the Framework and the effectiveness of the governance arrangements in 2020
- developing s performance framework to guide and monitor the implementation of genomics into healthcare

It is unclear whether a review of the Framework or governance arrangements has occurred or whether it was delayed, most likely by COVID-19.

Replacement of COAG with new Federal relations architecture

In October 2020, the COAG arrangements were replaced by a new intergovernmental relation architecture to enable more agile and timely responses to relevant issues, central to which is the National Cabinet. See Attachment 3 on page 13. The changes were implemented following the Conran Review [8].

The new structure provides for the following (based on the Conran review):

- only a few committees to report to National Cabinet and are therefore covered by Cabinet operating principles
- expert advisory groups which, depending on need, may report to National Cabinet or Health Ministers Meetings but otherwise have no reporting line
- establishment of a Health Ministers Meeting to replace previous health related groups and limit the number of issues dealt with to 2-3 priorities per year.

At the time of writing, a review of relevant websites indicates that:

- The National Cabinet Reform Committee on Health is focussed on job creation
- The Health Ministers meetings which for 2021-22 are focussed on:
    - COVID
    - implementation of the National Health Reform Agreement (NHRA)
    - workforce
    - aged care
    - the National Disability Insurance Scheme
    - a dental strategy.

It is unclear whether, or if, genomic activities are being undertaken under this new structure. They could be undertaken under an Expert Advisory Group or potentially the Gene Technology Committee, which may or may not exist.

Establishment of Genomics Australia

In March 2022, the then Health Minister announced the establishment of Genomics Australia to guide the future of genomic health and medicine over the next 10 years. Genomics Australia is intended to commence as a non-statutory body within the Department of Health with an advisory board to become a statutory body in the future. Professor Kathryn North will be the inaugural chair of Genomics Australia.

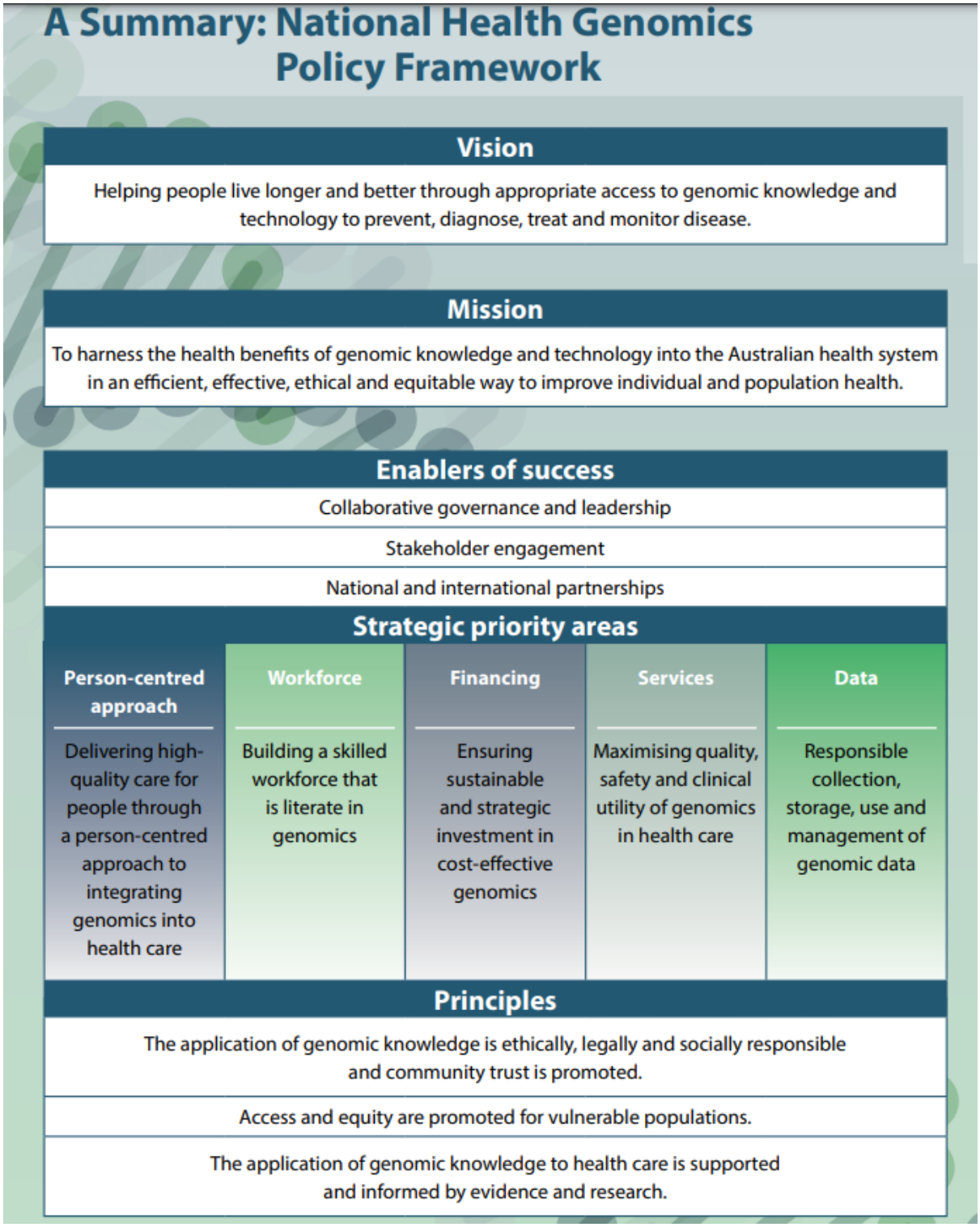
Progress with implementation is unclear.

Discussion points:

1. How can your contribution help progress the implementation of genomics in Australia?
2. Why is contributing to the development or implementation of policy, programs or services related to genomics important to you / your organisation / your sector important?
3. Using the stakeholder engagement levels and methods outlined in this paper as a guide:
    a. how can the value of your/ your organisation's / your sector's contribution be maximised?
    b. What engagement would you like to see around the review or the next iteration of the National Health Genomics Policy Framework?
    c. What engagement would you like to see around the priorities and activities around the establishment of Genomics Australia?
4. If you would be happy to only remain informed, what level of transparency around genomics activities would you require?
5. Are there any other points you would like to raise?

Attachments

Attachment 1: Summary of the National Health Genomics Policy Framework



Attachment 2: Extract from Genomics Policy Implementation Plan around governance structure

Effective governance is essential for driving and coordinating implementation of the National Framework. To ensure that all governments are involved, and work is taken forward in a cohesive way, it is appropriate for the governance arrangements to be established under the AHMAC structure.

AHMAC is the advisory and support body to the COAG Health Council (CHC). It operates to deliver health services more efficiently through a coordinated or joint approach on matters of mutual interest. AHMAC is responsible for providing effective and efficient support to CHC by:

- advising on strategic issues relating to the coordination of health services across the nation and, as applicable, with New Zealand; and
- operating as a national forum for planning, information sharing and innovation.

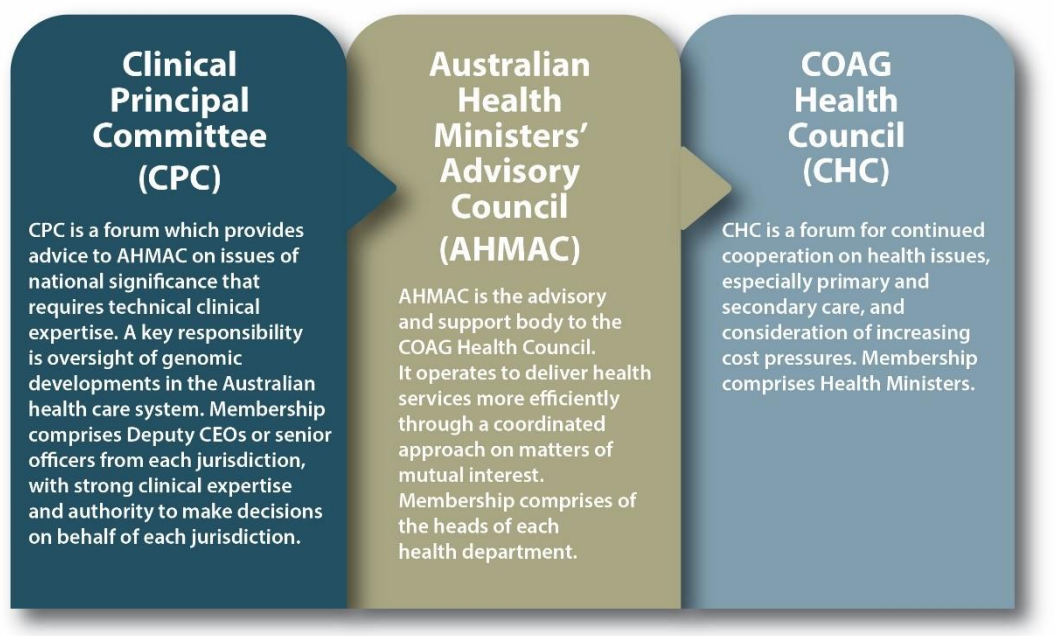
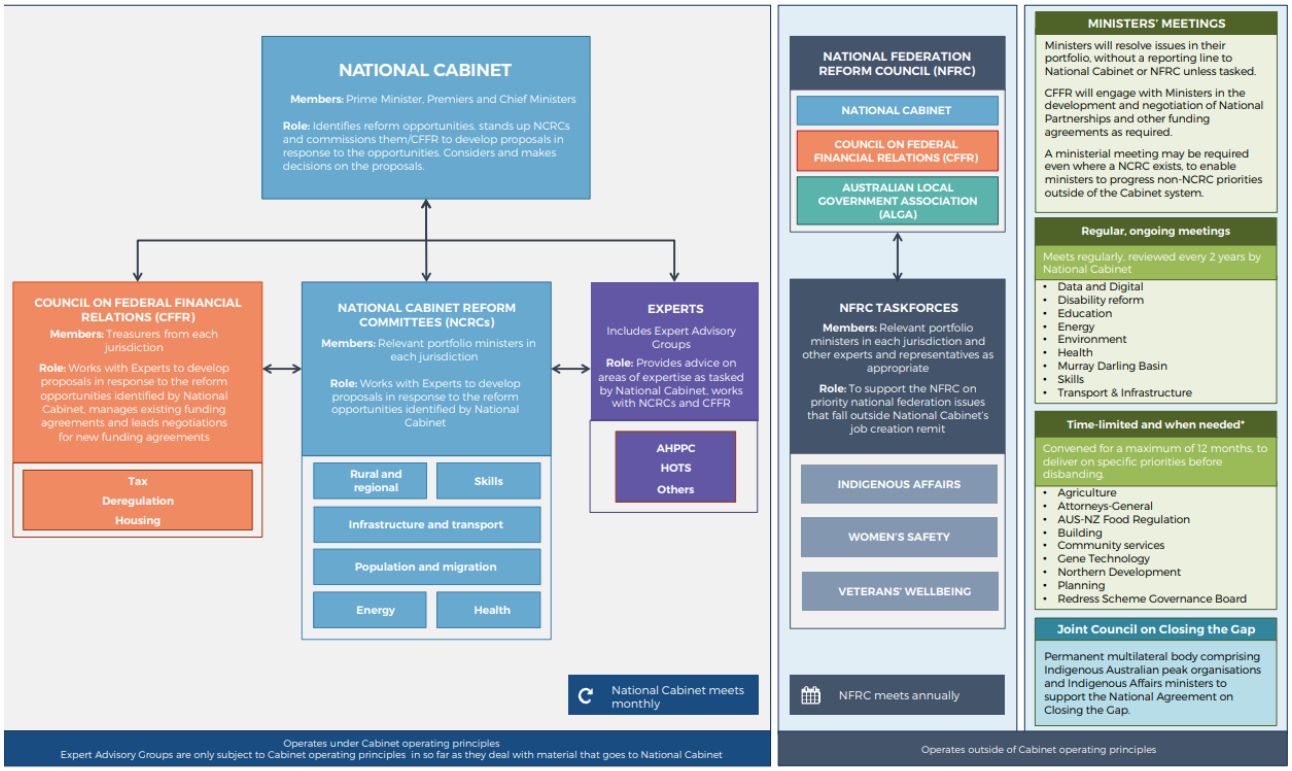


Figure 1: Explanation of governance structure

AHMAC has four principal committees, which manage the business of AHMAC and provide advice. One of these is the Clinical Principal Committee (CPC). AHMAC membership includes chief executives from all departments of health, while CPC membership consists of senior medical officers. Depending on the nature of the implementation action, it may be relevant for other principal committees (for example the Health Services Principal Committee) to be involved in noting or endorsing particular implementation actions.

Attachment 3: New Federal Relations Architecture – effective October 2020

AUSTRALIAN FEDERAL RELATIONS ARCHITECTURE



Improving national access to genomic testing through the Medical Benefits Schedule (MBS)

Background

Equitable access to precision medicine is one of InGeNA's strategic priorities. In this context, InGeNA members are of the view that faster, equitable and affordable access to comprehensive genomic testing is required to ensure more Australians can realise the benefits that precision medicine and its enabling technologies (including cell, gene and targeted medicines) can bring.

Under Australia's fragmented healthcare system, achieving consistent and affordable access to genomic tests nationally (and therefore equitable access to testing and healthcare) relies on them being listed on the MBS. However, the MBS only provides for a fraction of genomic tests being conducted in Australia, with expenditure in 2016 accounting for fewer than 30 genetic or genomic tests compared to around 1,700 such tests being performed by laboratories in Australia with costs being met by State or Territory Governments, private healthcare providers or consumers [9].

Furthermore, access to comprehensive genomic profiling (testing for 250 – 500 genes) is mostly only offered in the clinical research setting or at the patient's own expense (around $1,200 - $6,000) [10, p. 36].

Listing on the MBS relies on:

a) a health technology assessment (HTA) being conducted to assess the comparative safety, clinical efficacy and cost-effectiveness of the technology (or service) proposed for listing,
b) a positive recommendation by the Medical Services Advisory Committee (MSAC), an independent non-statutory committee comprising experts including medical specialists, pathologists and economists, and
c) acceptance of the MSAC recommendation by the Health Minister.

HTA has been defined as defined as a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle to inform decision making to promote an equitable, efficient, and high-quality health system [11].

Based on their experience, InGeNA members were of the view that faster MBS listing could be achieved if HTA methods and processes for genomic tests were improved. It therefore commissioned HTAnalysts to develop a White Paper to identify existing issues with these and potential solutions [12].

The HTA White Paper

The White Paper was developed following input from a literature review and an extensive consultation process involving stakeholder workshops and a separate independent industry expert review. The stakeholder workshops involved over 60 stakeholders, including consumers, laboratories, clinicians, Department of Health officials, MSAC members and industry representatives. A copy of the White Paper can be found at https://ingena.org.au/access-equity/.

As the perspectives on the issues varied between stakeholders, it was difficult to align on priority issues and collaborative actions to address these. It became clear that:

- many issues identified were not exclusive to genomic technologies
- several initiatives were underway to reform MSAC processes, but these was not visible to stakeholders
- it is difficult to separate HTA methods and processes from reimbursement / pricing issues and the MBS structure does not easily accommodate for managed entry arrangements such as those which exist for the PBS to contain costs and manage evidentiary uncertainty to be easily invoked

Noting the differing views on what the issues were between stakeholders, the key challenges, which all contribute directly or indirectly to delays in access, included:

- the length, complexity and efficiency of the MSAC process
- poor transparency of MSAC decision making, post-MSAC processes and MSAC reform initiatives
- significant delays in MBS listing after an MSAC recommendation
- the difficulty faced by patients in engaging with the HTA process and ensuring equal representation across disease states
- difficulty in meeting evidentiary requirements (noting this was a key area where views differed)
- the narrow definition of value in the context of determining whether a technology is deemed cost-effective
- the fragmentation of funding responsibilities for genomics across jurisdictions

The White Paper made recommendations for action around the above issues, including gathering quantitative evidence of the issues, and seizing opportunities to collaborate on current Government – industry reform initiatives which are also working on the identified issues relating to the MSAC process and HTA.

Opportunities to progress the HTA White Paper recommendations

Since the White Paper was finalised, some recommendations have been implemented in initiatives led outside InGeNA (e.g., including an industry representative on MSAC, a commitment to horizon scanning).

InGeNA has focussed its efforts on collaboration, particularly with Medicines Australia given the forthcoming HTA Review committed to by the Government, and is considering how the White Paper recommendations will be progressed given the rapidly evolving policy environment in relation to HTA and genomics.

The complexity of evaluating genomic tests as part of HTA and the uncertainty associated with the evidence impacts on the timelines for the MSAC processes, with a full HTA requiring assessment by 2 subcommittees as well as MSAC and around 2 years to complete. In practice, the MSAC timelines are often much longer as the Committee seeks to address concerns about the uncertainty around the evidence. Key sources of uncertainty for genomic tests include small patient populations and the multiple potential conditions that a genomic test can be used for, leading to multiple clinical pathways and health outcomes that need to be considered.

While the more complex issues are being considered by InGeNA, there is an opportunity to build on the issues identified around patient engagement in the MSAC process and the value of information provided by a genomic test. Given genomic testing and subsequent gene therapy is increasingly being targeted at severe, degenerative conditions, it is also important to discuss opportunities to accelerate listing once an MSAC decision is made (i.e., once the more complex elements of the MSAC process have been completed). These opportunities are outlined further below.

Strengthening the consumer voice in informing MSAC decision making

During the HTA White Paper consultations, patients, patient representatives and medical professionals expressed disappointment in the lack of opportunities to engage early, continuously and meaningfully throughout the entire MSAC process, with current engagement limited to a written submission.

They outlined that a single consumer representative on the MSAC (and its subcommittees) could not effectively represent patients with the broad range of diseases which genomic tests can detect and that there was a lack of opportunities for patients to be educated and engaged in the HTA process.

Additionally, patient support groups found it difficult to submit written applications, particularly for complex applications and did not have adequate funding to contract a consultant to assist them with the application.

The MSAC definition of value has been found to be narrow.

Given the experience of many participants at the roundtable, either as a patient or providing genomic-based care during the patient's health journey or as part of the MSAC process, there is an opportunity to consider

the value that genomic testing can bring to individuals, both related to health and beyond and how these benefits can be captured to inform the MSAC process.

Discussion points:

1. What value has genomic testing brought to you / your family / your patient?
2. If you have not been able to have a genomic test, what benefits do you think this would offer?
3. Thinking about the value that genomic testing can bring, how could that information be captured and what would be required?
4. How could that information be presented as part of the HTA process?
5. What has your experience been in providing submissions to the MSAC: what worked well; what could have worked better; what were the outcomes?
6. Have you ever considered putting in a submission to support an MSAC application but didn't? What were the reasons?
7. What support would you need in preparing a written submission to the MSAC?

Accelerating MBS listing after an MSAC recommendation

Once the MSAC has made a recommendation, the Minister must give formal approval before an MBS listing can occur. Experience indicates this process normally takes 12 – 24 months.

There is limited information on the post-MSAC processes beyond the information on the website which states:

- Once the MSAC has considered an application at an MSAC meeting, its advice will inform a decision by the Minister of Health in relation to public funding.
- New policy proposals will be developed by the department and include liaison with central agencies and the applicant/clinical experts where relevant.
- The department will provide advice to the Minister on MSAC deliberations and seek authority to put forward the new policy proposals through the Budget or Mid-Year Economic Fiscal Outlook (MYEFO) process.
- The Budget is brought down by the Treasurer on the second Tuesday of May each year.
- The Government also provides a Mid-Year Economic Outlook which updates information contained in the Budget, by the end of January each year.
- The Government will decide whether public funding should be granted based on MSAC advice and advice from the department.
- There are no specific timeframes for listing on the Medicare Benefits Schedule (MBS) as the decision to list is subject to government consideration. However, once approved, the department will implement the decision of Government through amendment to regulations and/or other instruments for the listing of the recommended service on the MBS.

Discussion points:

1. What has the impact of delayed or no access to testing been for you / your family / your patient?
2. What can earlier testing mean for you and your condition / your family / your patient?
3. What information would you like to see published in relation to an application once an MSAC recommendation has been made and it has entered the "post-MSAC" process phase and why?

Data quality, standardisation, sharing and governance

The collection, management and exchange of genomic data into healthcare delivery is critical to supporting better person-centred care, driving value to the health system and to building a thriving research ecosystem. The delivery of mature genomics information management which supports the integration of genomics into mainstream health care requires a comprehensive and collaborative approach.

A unified approach to genomic data in Australia to ensure clinical implementation of genomic technologies is effectively supported by coherent national approach to:

- legislative and regulatory requirements that support privacy and consent mechanisms while still encouraging data sharing
- funding arrangements that acknowledge the cost of infrastructure and processes that support efficient collation and sharing data with security and privacy
- harmonised approaches to dealing with genomic data between state and territory public health bodies and following international practices, and supporting a viable and sustainable industry
- working across healthcare systems to ensure that other activities are pragmatic, implementable and consistent in support early and equitable access to care for all Australians.

For detailed background please refer InGeNA's White Paper *Genomics Data in Australia* [13] which can be accessed at https://ingena.org.au/data-innovation/.

Diversity of genomics data and participants

Genomics is inherently complex and involves the coordination and collaboration of organisations within a diverse ecosystem [14]. As illustrated in Figure 2, there are five broad phases in the delivery of genomics:

- Sampling, through which the individual or related party provides a biological sample in readiness for processing. This may include use of a biobank for the sample.
- Processing of the sample using the relevant technology to produce the raw genomic data. The type of data produced will vary on the technology used.
- Analysis of this data to identify genomic variants or other markers of genetic significance.
- Interpretation of the clinical significance of the analysed sample.
- Application of this information for clinical diagnosis or treatment options, or as part of a program of research or development.

Figure 2: The phases of activity in the genomics value chain

Exome or genome sequencing can produce large volumes of sequencing data requiring bioinformatics pipelines to identify genomic variants, while other technologies may produce comparatively smaller datasets that require less intensive processing.

Solutions to deliver these capabilities are provided by a range of industry participants, including:

- organisations providing sequencing and other technology products or services
- bioinformatics solutions, commonly cloud-based, to support processing, analysis and exploration of the data
- specialist organisations developing diagnostic tools or biomarker solutions for use in the interpretation or application phases
- solutions for managing the data in on-premises, cloud or hybrid solutions
- pharmaceutical and biomedical organisations who rely on genomic data to support research into new pharmaceutical products, therapies or diagnostic tools
- organisations translating research into clinical practice through clinical trials.

Organisations addressing these capabilities range from multinational companies with a broad range of interests to small and medium organisations targeting specific sector requirements.

Other participants in the genomics ecosystem include:

- individuals, who must be the primary beneficiary of genomics technologies
- academic and research groups, who improve genomic technologies and provide the evidence required to support the wider adoption of clinical genomics
- clinicians within public and private health establishments who rely on genomics to support prevention, diagnosis and treatment decisions
- public and private diagnostic providers who incorporate genomics into the suite of services provided
- clinical colleges and professional groups responsible for setting professional standards for clinicians
- governments who provide funding within policy, legislative and regulatory frameworks.

All these groups must work together to deliver sustainable genomics data capabilities.

Discussion points:

1. Are there other types of data that need to be considered?
2. Are there other participants that need to be considered?

Status of genomic data in Australia

The importance of genomic data for clinical care and economic value is recognised by many publications and projects, and will be influenced by others, including:

- the Future of Precision Medicine in Australia report [2]
- the National Health Genomics Policy Framework and Implementation Plan 2018-2021 [15]
- the NAGIM Blueprint [16]
- recognition of the importance of Indigenous Data Sovereignty and other ethical considerations [17]–[19]
- the Australian Genomics project developing recommendations for implementing NAGIM [20]
- inclusion of big data in Australia's Digital Economy 2030 strategy [21]
- inclusion of genomics in the Commonwealth Digital Health Blueprint [under development]
- Australia's National Digital Health Strategy which is due in 2022 [22]
- projects undertaken within Melbourne Genomics, including delivery of a clinical genomics platform [23]
- work by David Thomas and OMICO [24]

Discussion points:

1. Are there other significant publications or projects of national significance that need to be included?

A national approach to genomic information management

The *Blueprint for a National Approach to Genomic Information Management* (NAGIM Blueprint) [25] is a digital genomics blueprint developed for the Project Reference Group on Health Genomics, under the *National Health Genomics Policy Framework Implementation Plan* [15].

The Blueprint delivered principles and guidelines from evaluating the current jurisdictional, operational, and technical landscape in Australia. The NAGIM Blueprint concluded that a standards-based approach, using a federated cloud or hybrid model, would be the most appropriate strategy for a national approach to genomic information management in Australia. The Blueprint also included a proposed roadmap of activities, as relevant to data infrastructure, genomic medicine, governance, and genomic research.

The proposed NAGIM research ecosystem

Australian Genomics is developing recommendations for implementing NAGIM in a research context. They have undertaken pilot projects to develop and encourage adoption of standard approaches and tools supporting the collection, storage and use of genomic data in Australia. The goal was to identify the best combination of components that can serve as the basis for long-term national research infrastructure.

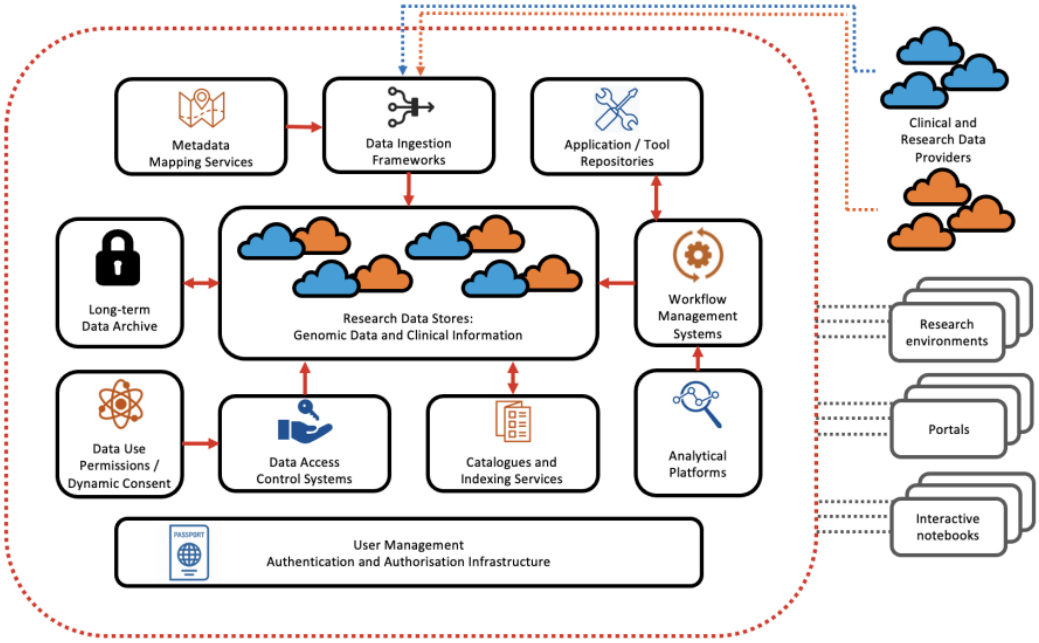


Figure 3: Schematic of Australian Genomics' proposed NAGIM Research Ecosystem

This was based on addressing five key capabilities identified in the NAGIM Blueprint:

- Federated frameworks
- Standards-based approaches
- Interoperability across systems
- Alignment with international data sharing initiatives
- Cloud-based or hybrid solutions

Discussion points:

1. How would this research ecosystem support or influence the work your organisation is doing?

Critical infrastructure pillars

Following this work, Australian Genomics have released draft recommendations for implementing an ecosystem for genomic research based on the NAGIM approach [26]. This has identified three 'critical pillars' for NAGIM-enabled infrastructure:

- **Interoperability:** able to interact with other systems to seamlessly exchange and make use of information
- **Scalability:** able to accommodate growth and manage / process large-scale datasets
- **Extensibility:** able to accommodate new additions and expand functionality.

Following from Australian Genomics consultation on NAGIM, InGeNA raised some further consideration from an industry translational medicine functionality and implementation perspective, to ensure patients can equitably gain access to the diagnostics and treatments/interventions that genomics and related innovations. These include:

- **Useability** (relevance, usability and clinical utility): able to satisfy the known requirements of end-users as 'fit-for-purpose' operationally in clinical, translational and research settings
- **Sustainability:** as the diversity of data types required to support genomics evolves the issues of costs and the funding for clinical and research and administrative data providers is sustainable.

Recommendations for implementation

The project has also identified eight key recommendations released for sector feedback. These are:

1. Governance, Coordination and Workstreams to Progress the NAGIM Roadmap

   Appoint a coordinating body, governance and working group(s) to manage, monitor and report on the parallel work streams established to progress a national approach to genomic information management in Australia.

2. Architectural Foundations for an Integrated Australian NAGIM Infrastructure

   Commence building the architectural foundations, and the core genomic data management infrastructure, for a federated NAGIM research ecosystem. This should include progressing foundational 'End-to-End' (ETE) genomic platforms and integrations between them, delivered as a pilot to inform design of the production-level operations and capabilities.

3. Clinical Information Systems, Priorities, and Intersections

   Establish alignment and intersections of the NAGIM research ecosystem with Australian jurisdictional clinical systems, and progress clinical priorities. This should include national regulatory frameworks for clinical data sharing, minimum requirements for clinical data collection, standards for security and privacy for progressing federated clinical settings, and clinical infrastructure pilots.

4. Data Governance and Ethical, Legal and Social Considerations

   Identify and address the governance and legal requirements, and ethical and social considerations, associated with a federated NAGIM ecosystem. This should include national frameworks and agreements for data sharing; management of culturally sensitive collections and Indigenous data sovereignty; and critically, consideration of data donor consent (research, clinical), autonomy and privacy.

5. Key National Services for NAGIM

   Establish the key national services required to operate a federated NAGIM ecosystem in Australia. This should include an Australian digital researcher identity and access service, and national user support services.

6. Data Standards and Harmonisation

   Achieve sector agreement to establish the data standards, data harmonisation processes and data ingestion procedures to be adopted across the federated NAGIM ecosystem. This should include use of standards developed through the Global Alliance for Genomics and Health (GA4GH), HL7, and other international standards.

7. Production Operations

   Establish the strategy and requirements for successful transition of pilot NAGIM infrastructures to production platform(s), and an operational federated NAGIM ecosystem. This should include competitive tender for mature system-level operations, consolidation of academic and industry partner networks, and a long-term sustainability model.

8. Innovation in NAGIM

   Invest in a sustained strategy of innovation with evaluation and incorporation of new technologies to apply to the NAGIM ecosystem. This should be progressed separately to core data management and user support services, with a dedicated budget to support future proofing of the ecosystem to new technology and data demands.

Discussion points:

1. How will your organisation support or be supported by these recommendations?
2. Where do you see industry having the biggest impact/contribution across the proposed recommendations and activities?

Understanding the national infrastructure requirements for clinical implementation

The COVID-19 pandemic led to increased awareness and attention from the government, media and the public around molecular testing in Australia. Whilst this led to increased demand and investment in molecular microbiology, there are still significant gaps in molecular genetic testing for complex human inherited diseases and cancer.

To build a national infrastructure around complex genomic testing in Australia, InGeNA has identified three main pillars, logistics, facilities and technology, which are further split into six categories (Fig. 1), for consideration and further discussion at this roundtable meeting.

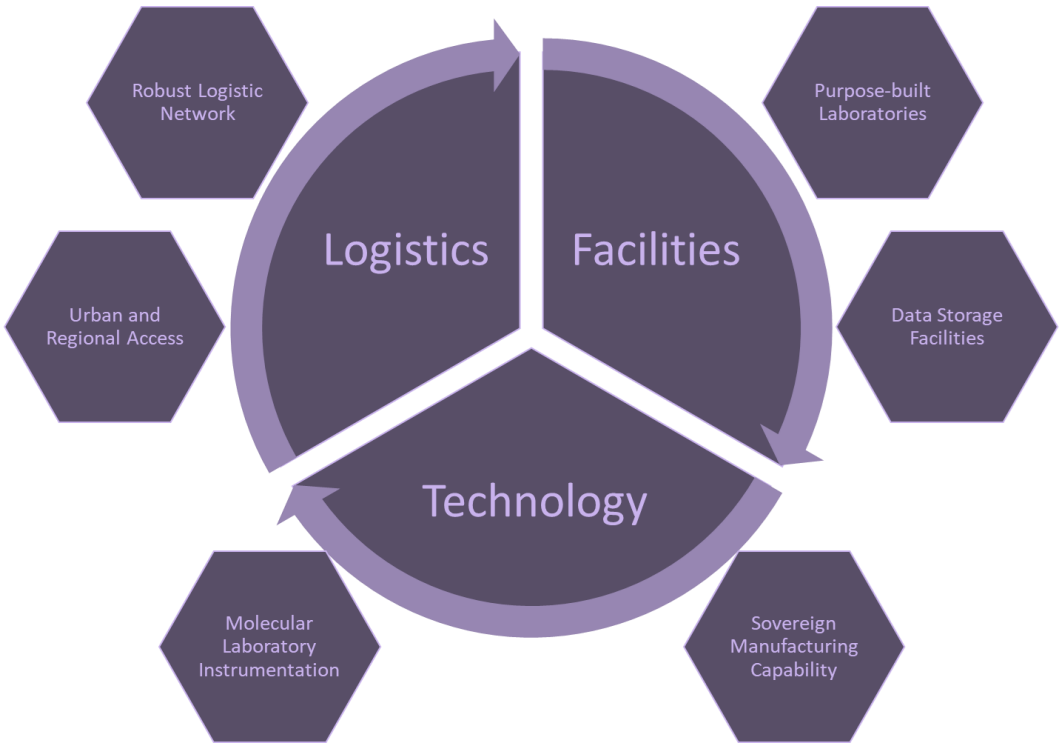


Figure 4: The three pillars and six categories for successful genomic testing implementation in Australia

Logistics

This pillar comprises the need for a robust logistic network and regional access to testing. To provide seamless genetic testing in Australia, we must first have a robust logistic network which enables patient samples to be collected, processed and sent to laboratories in a timely manner, irrespective of the location of the patient. Regional sample logistics and timely processing of results are imperative. A significant and perhaps unique challenge for Australia is our vast land and low population density, making it difficult to service the healthcare and testing needs of regional and remote communities. Urban logistic networks, however, are much more advanced and provide timely sample transport to laboratories. The private pathology industry has significant investments in sample logistics and have a robust national network, as demonstrated during the COVID pandemic where patient results were obtained typically within 24h from sample collection.

Over the last 10 years, direct to consumer companies have provided genetic testing via a postal service where samples are self-collected and sent back to the laboratory for processing. The Australian national bowel

screening program (since 2006), and more recently, the national cervical screening programs are available to the public by self-collection methods. Whilst similar self-collection programs could be implemented for various inherited genetic tests, molecular testing of cancerous tumours remains a challenge, although liquid biopsy from blood samples collected in any pathology collection centre could be a useful monitoring tool.

Discussion points:

1. How can we deliver a quality national logistics network for genomic testing? (Leverage private pathology expertise? How can we improve regional access?)
2. Is it feasible for complex genomic testing to be routinely performed regionally?
3. How can we improve regional access to complex genomic testing? (e.g., Self-collection of samples)
4. Which factors have the potential to expedite sample logistics?

Facilities

This pillar comprises purpose-built laboratories and data storage facilities. Additional specialised genomic testing laboratories and data storage facilities are needed to cope with the anticipated increased demand and must achieve timely, quality and cost-effective patient sample results.

Whilst Australia is a world leader in genomic research with numerous translational research facilities across the country, there is insufficient investment in clinical testing laboratories and cloud-based computing capability with the capacity to deliver high-throughput molecular genetic testing. In addition to the need for increased infrastructure, to deliver high quality complex genomic testing, specialised and highly trained personnel are required. Although this topic is to be covered in detail in the 'Workforce' stream, it should be considered here whether investment should be made with a centre of excellence approach, where a complete specialised clinical and diagnostic team work together to deliver expert care. This approach is already in place in Victoria within Melbourne Health where the VCCC specialise in cancer care whilst the VCGS specialise in inherited diseases.

A challenge to implementation of additional facilities across Australia would be the ability to service rural and remote communities given the clinical expertise required, sample testing volumes and overall cost. Therefore, would state-based centralised testing sites and centres of excellence be a more viable option?

Discussion points:

1. What are the pros and cons of having state-based centralised testing sites?
2. Would a 'centre of excellence' approach be suitable to deliver expert care?
3. What are the challenges and legal requirements of implementing state-based vs federal data storage facilities?
4. How can clinical practice be harmonised across states and territories to deliver equitable care?

Technology

This pillar comprises molecular laboratory instrumentation and sovereign manufacturing capability. Implementation of highly automated and high-throughput processing instrumentation will drive down costs and increase efficiencies whilst local manufacturing capabilities will help protect Australia from potential future global supply-chain shortages.

Whilst Australia is known as a global leader in development of IP, there has historically been challenges in capitalising and keeping manufacturing of novel technologies in Australia. Should there be a focus on local manufacturing from international suppliers, or should there be new investment in our own technology and manufacturing?

Given the rapid rate of development of genomic technologies, increased capacity of sample processing and the reduced cost of testing, what measures should be taken to invest in suitable mid-long term testing solutions?

Discussion points:

1. Does Australia have the IP and technological capability to manufacture complex genomic testing instrumentation?
2. How do we future-proof investments in technology given this is a rapidly advancing field?
3. How do we ensure instrumentation redundancy, variety of suppliers and flexibility to adapt to evolving testing requirements?
4. How do we secure reliable and ongoing supply of laboratory products?

Building a learning healthcare system delivering precision medicine based on genomic technologies

The full implementation of precision medicine led by genomic technologies in the healthcare system will rely not only on the efficient development of precision medicines and new technologies, but also on the ability to have a Learning Healthcare System that integrates evolving and new technologies into clinical practice in a timely and equitable manner. As our healthcare system transitions from a specialist and disease-centred system to a learning healthcare system, the competencies and capabilities of the various workforces servicing this sector also need to change.

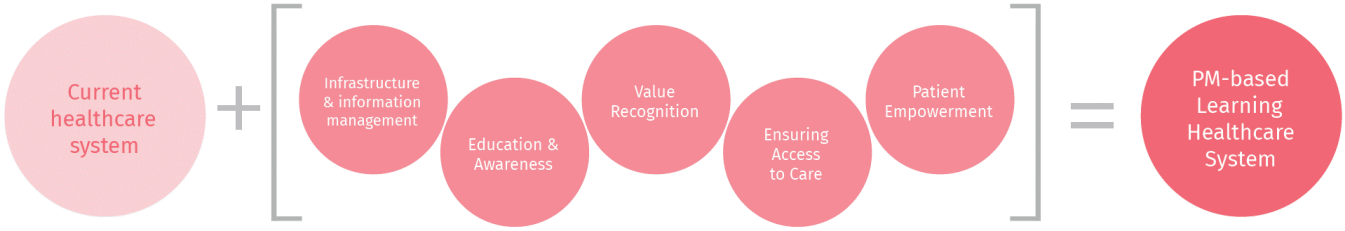


Figure 5: Moving to a learning health system based on precision medicine

Since the sequencing of the human genome, there has been a steady rise in the impact of genomics in the practice of medicine. In the past few years there has been a significant increase in the understanding of the genetic basis of many rare, inherited diseases with an increasing focus by the pharmaceutical, biotechnology, therapeutics industries in developing treatments and potential cures for these diseases. Furthermore, the identification of technologies and biomarkers for early detection of disease, monitoring of response to treatment and their use as companion diagnostic tools to identify optimal therapies has grown significantly. This has led to the development and application of precision medicine rather than reliance only on the traditional one-size-fits-all approach to therapeutic product development.

Multi-omics profiling, digital and molecular biomarkers, model-based data integration, artificial intelligence, biomarker-guided trial designs, patient-centric companion diagnostics and real-world evidence integration have been identified as key components of the translation of genomics technologies into the healthcare system. The need for a precision medicine-based learning healthcare system has been identified as integral to support the transfer of emerging genomic knowledge and applications into improved clinical care, and the translation from research to clinical practice. Multiple forces drive the future of medical science development including international regulatory convergence, advanced manufacturing, the rise of biosimilars, new science and technology external to genomics, the digital revolution and the cost of new medicines. A further factor to consider is that it is difficult for stakeholders including patients, medical practitioners, healthcare workers, regulators and payers, as well as medical, technology and pharma industry companies, to keep abreast of the rapidly changing requirements for keeping up to date with this evolving ecosystem.

Industry consultation and publication review confirms that current knowledge and awareness of genomics technologies and precision medicine within the healthcare provider community is inconsistent, knowledge resources are scarce and not regularly updated, workforce training for new technologies is insufficient, medical, pharmacy and other higher education curricula are outdated, and government policies and support need strengthening.

In 2021, InGeNA undertook a research project to determine the capabilities and competencies required by the medical technology and pharmaceutical (MTP) industry workforce to ensure that the workforce is confident and capable of integrating genomic information and/or technologies into their everyday work practice, and that the environment fosters a culture of continuous learning to deliver genomic scientific,

technology, and healthcare integration innovations across the MTP industry by 2025. The report *InGeNA Precision Medicine Workforce Competency Framework* [27] and corresponding *Competency Framework* tool are available at https://ingena.org.au/workforce.

This Discussion Paper will focus on three aspects of workforce:

- skills and competencies
- collaboration
- education channels

Skills and Competencies required to implement genomics

In building such a health literate workforce, education is a critical pillar in the integration of precision medicine into a learning healthcare system. Education of consumers and practitioners, and the MTP workforce will be required.

Competency Domains

For members of the MTP industries these four domains are relevant:

- medical science and technologies
- translation and clinical application,
- governance and regulation, and
- professional practice.

Note that patient and societal consideration should be considered for each domain and central to all functions.

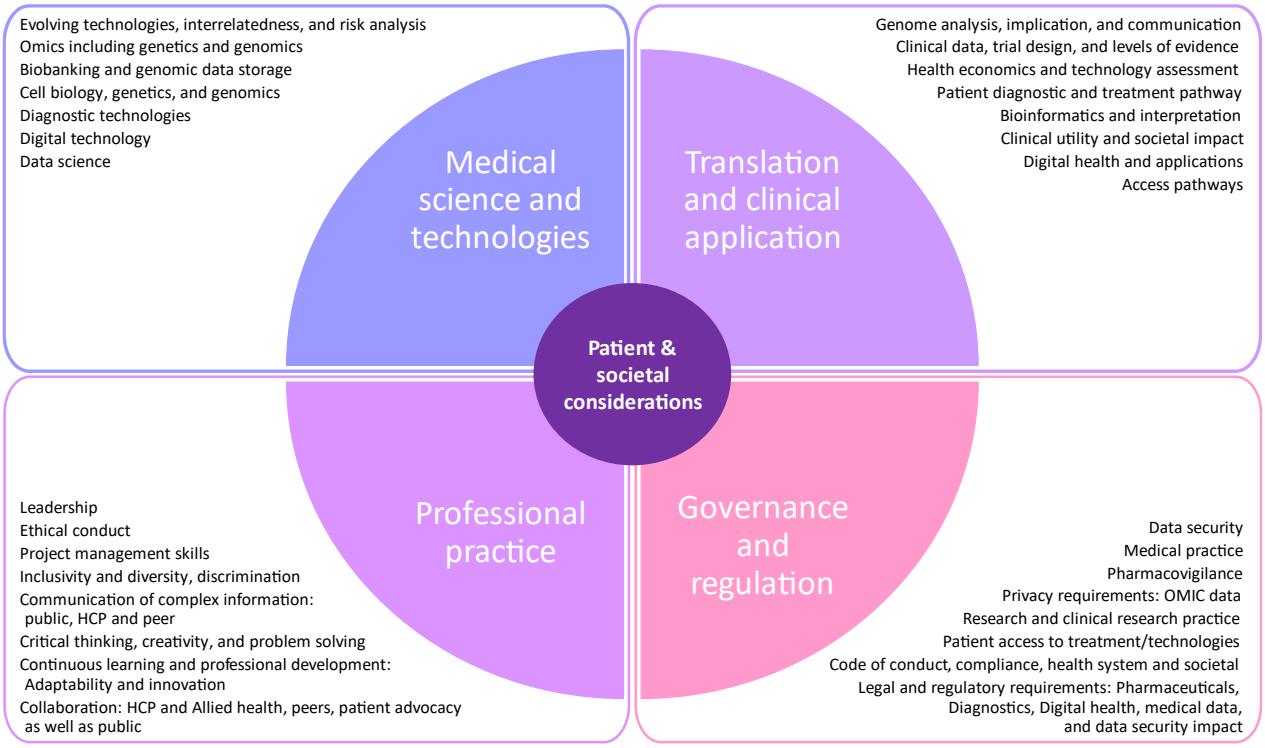


Figure 6: Domains and competencies

Continuous learning mindset

Education curricula and methods of learning are adapting to support the continuous learning mindset needs as technologies and systems continually evolve. Strongly focusing on 21st-century skills development in digital and information literacy, collaboration and teamwork, analytical and problem-solving skills, flexibility and adaptability, creative and critical thinking, leadership, initiative, and self-direction, it is critical that education from secondary to tertiary education and across s healthcare system is addressed.

Discussion points:

1. Are the Domains outlined in the Framework relevant for your workforce?
2. Do we have a healthcare system organisational culture that reflects a continuous learning mindset? How do we discuss/ develop a continuous learning mindset and the 21st century skills needed to imbed that into our healthcare culture, given the uncertainty and complexity that brings?

Collaboration

Stakeholders in the health sector will need to work together to ensure these future workforce competencies are defined for the relevant stakeholders needs and attainable to ensure that implementation of genomics into the healthcare ecosystem is sustainable and effective. There are significant benefits of broad stakeholder collaboration for the wider healthcare ecosystem, the Australian economy and especially for the individual patient to allow early and equitable access to precision healthcare interventions.

Common language

Building resources that support a common technical or medical language to enable more efficient and effective implementation of precision medicine and in particular OMICS technologies. Active inclusion of these resources in training for the industry will further support collaboration, understanding, and importantly the fundamental aspects of trust and respect needed across stakeholders to enable collaboration.

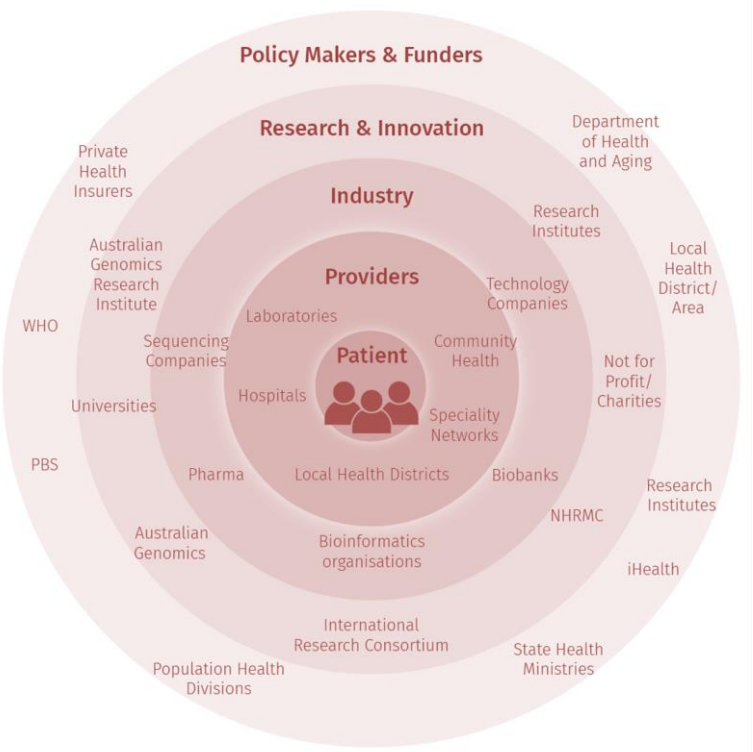


Figure 7: Genomics ecosystem stakeholders

Stakeholder collaborations

Including patients and carers needs and insights in all aspects of their care across the R&D continuum, from early development to implementation into the health system, requires a system that is collaborative and actively inclusive. Fostering constructive and sustainable collaborations across the stakeholders and across the multiple medical, scientific and technology disciplines involved is critical to implementing genomics.

Discussion points:

1. Is there an accepted "Common Language" for genomics in Australia (or globally) if not, would establishing a national "common language" for genomics be of value?
2. How can we support effective collaboration between stakeholders and evolving healthcare system, including medical colleges, allied health, consumer organisations, and government and state decision makers on workforce? What actions can drive this?

Genomics workforce training and education

Members of the genomics workforce have qualifications that range from medicine, allied health, life and bio-medical sciences, as well as engineering, business, and law. Provider education and training for healthcare professionals in Australia is overseen by many institutions including tertiary education providers, agencies, Royal Colleges, and specialist education providers. The delivery of precision medicine will rely heavily on cross –discipline expertise where completion of an accredited degree is not essential to practice, and it is sometimes not possible to have an accredited degree in the competencies required, because the capability and competency needs are evolving, and no formal courses are available yet.

Internationally and locally, higher education courses in science and other non-accredited areas are available to meet some needs of the workforce, however it is difficult to have new programs and topics such as genomics and precision health added to highly regulated higher education programs. Many higher education providers are also looking at developing shorter courses and micro-credentials, which might be suitable for meeting the training needs. Increased collaboration between industry, healthcare providers and academia, as exemplified by the NHS in the UK, could lead to development of such courses.

Discussion points:

1. What options could be considered to speed up the introduction of precision health capabilities in tertiary education for healthcare practitioners, healthcare service providers and industry, research and innovation, and for government and regulators?
2. To support a workforce capable of implementation and sustaining precision medicine, is there a role to introduce genomic technology education into secondary education?

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Precision Medicine Competency Framework for Industry

Domain	Subdomain
Patient & Societal considerations:	
	Every Sub Domain should include consideration of the patients' needs and the impact on society
Medical science and technologies:	
	Cell Biology, genetics, and genomics
	OMICS including Genetics and genomics
	Diagnostic technologies
	Digital technology
	Data science
	Biobanking and genomic data storage
	Evolving technologies, interrelatedness, and risk analysis
Translation and clinical application:	
	Patient diagnostic and treatment pathway
	Clinical data, trial design and levels of evidence
	Digital health and applications
	Genome Analysis, implication, and communication
	Bioinformatics and Interpretation
	Clinical Utility and societal impact
	Health Economics and technology assessment
	Access pathways
Governance and regulation:	
	Code of conduct and compliance, health system and Societal impact
	Patient Access to treatment/technologies
	Research and clinical research practice
	Medical practice
	Pharmacovigilance
	Legal and Regulatory requirements: Pharmaceuticals, Diagnostics, Digital health, medical data, and data security
	Data security
	Privacy requirements: OMIC data
Professional practice:	
	Ethical Conduct
	Critical thinking, creativity and problem solving
	Leadership
	Communication of complex information: public, HCP, peer
	Inclusion & diversity, discrimination
	Collaboration: HCP and Allied health, peers, patient advocacy as well as public
	Continuous learning and professional development: Adaptability and innovation
	Project management skills

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