Response to Genomic Policy Framework consultation

InGeNA consulted with our members and our Consumer Advisory Group to develop this response. Our response is an integration of the issues and feedback provided.
We heard from large multinationals through to scaling organisations in the development of this work. It was a rapid consultation turnaround given the timelines.

Thank you for the opportunity to engage with the consultation and provide this written report. We look forward to ongoing engagement in the process of the policy framework development.

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General Questions

1. How does your organisation/the constituents you represent currently engage with Health Genomics?
InGeNA represents the genomics industry in Australia, including biotechnology, diagnostics, health informatics, and pharmaceutical companies. is Australia's peak body for genomics and personalised healthcare, bringing together industry leaders across diagnostics, therapeutics, software, data, and analytics. Our members range from large multinationals to innovative startups, all working to accelerate the adoption of genomics and ensure it is embedded in Australia's health system. Members of InGeNA engage in Health Genomics via providing genomic data for clinical trials, personalised medicine, genomic screening, polygenic risk scores, reproductive carrier screening.

InGeNA collaborates closely with stakeholders, including our own consumer advisory group, to ensure that personalised healthcare benefits all Australians. We advocate for genomics to is embedded in our health system in a sustainable way and can achieve clinical and efficiency benefits that improve prevention, and enhance quality of life.

Our role focuses on supporting the integration of genomic technologies into healthcare through partnerships with health systems, regulatory bodies, and clinicians. InGeNA also advocates for policies that encourage innovation and adoption of cutting-edge genomic solutions, while working alongside a patient advocacy group to ensure patient needs are at the forefront. Although InGeNA is not directly involved in research, we facilitate industry participation in genomics-related developments and implementation.

2. What do you see as the major priorities for embedding Health Genomics in Australia, currently and in the future?

- **Workforce Development:** A critical priority is developing a workforce that is well-versed in genomics and precision medicine. Healthcare professionals, from general practitioners to specialists, need targeted education and ongoing training in genetic testing, interpretation, and treatment.
- **Collaboration with Industry:** Strengthening mechanisms for collaboration between healthcare providers, government, and industry is vital to ensuring seamless adoption of genomic innovations.
- **Fostering Homegrown Innovation:** Attracting investment in Australian-grown genomic technologies and ensuring these innovations are integrated into the health system will help Australia remain competitive in the global genomics market.
- **Access to World-Class Treatments:** Ensuring Australians have access to world-leading treatments in genomics and precision medicine, including gene therapies and personalized drug treatments.
  Through mechanisms including: Expansion of MBS items for genomics to create equitable access and National screening programs.

- **Infrastructure for Genomics and Precision Medicine:** Put in place the necessary infrastructure that are suitable for a federated healthcare system. This includes data management platforms, bioinformatics platforms, data storage solutions, and high-quality laboratories—to support the future of genomics and precision medicine in Australia. Ensure data security and sovereignty.

3. How would you like to see these priorities realised?

- **Workforce Training and Support:** Introduce government-supported education programs and professional development opportunities for healthcare workers to gain competency in genomics, genetic testing, and precision medicine.
- **Public-Private Partnerships:** Establish stronger collaboration frameworks that allow industry and public healthcare providers to co-develop and implement innovative genomic technologies.
- **Investment in Innovation:** Provide incentives for domestic and international investment in Australian genomic startups and biotechs, promoting local innovation while ensuring access to global advances in genomics.
- **Sustainable Funding Models:** Develop clear and sustainable funding models that support equitable access to genetic testing and world-class genomic treatments across Australia.
  Increase in grant funding for translational research projects (bench to bedside). Funding for cutting edge genomic capabilities so that Australian patients benefit from advancements in genomics.
  Consistent federal and state funding of clinical genomics: Whilst MSAC assesses funding of new tests for the entire population, in practice State powers over funding of public hospitals means that public pathology services may not be able to claim the MBS. Genomic testing is an expensive and rapidly growing

part of a pathology service's offering, and we are observing that some hospital budgets are not accounting for this expanding area of cost. This has the potential to lead to inequity of access for public patients where budgets are exhausted, and will continue to get worse if not addressed. This could extend to: Promoting improved, equitable access to genomic services across all regions of Australia, including rural and underserved populations. Funding for widespread infrastructure and training in these regions to support equity in care and quality of life for impacted patients.

- **Building Future-Proof Infrastructure:** Invest in modern, secure, scalable and sustainable genomic information management **systems** that are healthcare interoperable.
  Genomic **data** must be: FAIR (Findable, Accessible, Interoperable and Reusable).
  Ensure that there is responsible governance for the use of genomic data for clinical care and research.
  Currently there is no requirement and mechanism for FAIR data and this creates huge waste in the system and will fail to ensure we can scale and deliver a genomic health benefits to Australians.
    - Invest in advanced genomic data storage, interoperability, and secure sharing solutions to enable clinical use and research integration. Create a national platform that ensures genomic data is securely available for clinical decision-making and innovation in treatments.
      Set policy around cybersecurity and interoperability of systems processing and storing genomic data.

  Ensuring that realisation of benefit to improve the quality of life, choices, options, wellbeing is why genomics is so important.
  Increasing access with a well-resourced workforce etc will improve the diagnosis yield and hopefully the experience within the health system however the greatest realisation of benefit will be the ability to keep people out of the health system through improved care and support across their life course and across their holistic health and wellbeing journey. Screening and diagnostics are the gateway to this.
  The involvement of consumers and the lived experience community in collaboration with industry is fundamental to ensuring that the genomics benefits are realised. Understanding the consequences and unintended consequences of genomics implementation to ensure effectiveness and sustainability that are explicitly linked to quality of life improvement is critical and must drive implementation towards a fully integrated genomics health and wellbeing service.

4. Do you think the Strategic Priorities of the National Health Genomics Policy Framework should still remain the broad priorities for the new framework?

Yes, the broad priorities from the previous framework are still relevant but should be enhanced. supports the five pillars identified in the previous strategy, but activities across these areas need to be designed with a clear implementation objective and endpoint. Identifying dependencies and prioritisation across activities will be important. We encourage a pragmatic approach to identifying activities to ensure that they lead to clearly identified goals.
We suggest a stronger focus on implementation and scale-up within the health system, with a lower emphasis on research funding within the genomics strategy.

Establishing clear, long-term goals for health genomics
Ensuring equitable access to genomic services that are clearly linked to improved health outcomes should be a key goal for the NHGPF. Goals should be quantifiable, and linked clearly to areas where the benefit of genomic testing has been demonstrated. Australia has a world class health system however we are up to 10 years delayed in the implementation of the benefits of genomics. We can take action to work collaboratively with industry, government and university/research institutions to accelerate adocoption linked with quantifiable objectives should align to areas such as cancer and rare disease where genomic testing has well-established benefits. Setting clear goals (such as, for example, offering somatic genomic testing to all patients with advanced [Stage 2+] cancer) would establish clarity about the volume of testing likely to be conducted, which in turn would inform implementation planning for funding, provider infrastructure, and so forth. Specific, measurable targets for the next 3, 5 and 10 years will enable a detailed focus on implementation, which in turn could drive collaborative efforts between industry and health providers to create services to deliver to this goal.

Specifically:

- **Workforce Development:** There must be a stronger focus on equipping healthcare professionals with the skills to interpret and apply genomic data in clinical practice.
- **Industry Collaboration:** There should be clearer pathways for industry and healthcare systems to work together, particularly in integrating new genomic technologies into everyday healthcare.
- **Future-Proofing Infrastructure:** The framework should include a future-oriented approach to developing infrastructure designed for our federated healthcare system that supports genomics and precision medicine, ensuring that data is secure, interoperable, and available for use in clinical care.
- **Access and Equity:** Strengthen the emphasis on making world-class genomic technologies and treatments available to all Australians, ensuring no one is left behind, particularly those in rural and underserved areas.
  Importantly we need to focus on why we are doing this – to improve the health outcomes of all Australians. improving the quality of life, choices, options, wellbeing is why genomics is so important. the greatest realisation of benefit will be the ability to keep people out of the health system through improved care and support across their life course and across their holistic health and wellbeing journey. Screening and diagnostics are the gateway to this.
- **Addressing sustainable financing of genomics**

Currently, genomic testing is provided through a combination of private (self-funded) testing, MBS-subsidised testing, testing provided as part of a public hospital service, and testing conducted as part of research projects.

- Reduce funding complexity: Although this is similar to other areas of health care in Australia, it is likely that what tests are available through which funding or access pathways is more complex in genomics than in other areas of health service delivery.

The NHGPF is an opportunity to establish clarity about how genomic testing is currently and should be funded. Serious consideration should be given to creating clarity about health genomics being funded predominantly through existing health financing systems - chiefly through the MBS and hospital payments through the National Health Reform Agreement (NHRA). Ensuring that health financing is the main mechanism through which health genomics are provided will encourage greater availability of genomic testing through multiple providers, which will increase access to testing and encourage greater competition between suppliers (both of services and of genomic technologies). This would align to Australia's existing health system financing, including for other pathology services, and encourage more routine use of clinical genomic testing across the health system.

Overall, a stronger focus on implementation and scale-up within the health system, with a lower emphasis on research funding within the genomics strategy.

- Consistent federal and state funding of clinical genomics: see above While the Medical Services Advisory Committee (MSAC) assesses tests for nationwide funding, state control over hospital budgets often prevents public pathology services from claiming the Medicare Benefits Schedule (MBS). With the rising costs of genomic testing, some hospitals aren't budgeting for this, leading to unequal access for public patients, especially when funds run out. This issue may worsen unless addressed, and solutions could include promoting equitable access to genomic services, especially in rural and underserved areas, and funding infrastructure and training to support care in these regions.

5. Are there any specific priorities or areas within these priorities that the new framework should be focused on? If so, why?

- **Workforce Development:** We need to ensure Australia has a genomically literate workforce capable of using advanced diagnostic tools and precision medicine. Training programs should be scaled up, and ongoing support provided for healthcare professionals.
- **Collaboration Mechanisms with Industry:** Streamlined processes for working with industry, particularly around introducing new genetic tests and treatments, are essential to keep Australia at the cutting edge of health genomics.
- **Attracting Investment in Innovation:** The framework should prioritise creating the right conditions for fostering and adopting homegrown genomic technologies, allowing the industry to flourish locally while maintaining access to global innovations.

- **Robust and effective funding mechanisms:**
  We should look at ROHPG a federal grant funding scheme as a relevant model that has delivered scale of imaging rollout (https://www.health.gov.au/our-work/radiation-oncology-health-program-grants-scheme). Approved laboratories doing genomic testings in Australia, could use this to buy secure Genomic Information Management infrastructure that meets the requirements of secure, scalable, interoperable. It would help labs significantly uplift their genomic data infrastructure so that work can be done to connect up genomic data across labs and jurisdictions for clinical reuse. Further work on Pathology Ordering could be done to further streamline genomic testing and lay foundations for a genomic test directory. This will then allow connections to be built with research infrastructure.
  Currently there are no requirements or mechanisms for labs to have FAIR data (Findable, Accessible, Interoperable and Reusable) which causes a lot of waste and does not enable genomics to scale in Australia.
  Considering reform to MBS item utilisation for genomics
- A key gap in understanding the current state of genomic testing in Australia is the lack of clear data on provision of testing services. Currently, MBS items do not fund testing in public hospitals for public patients. In some cases, clinicians working in public hospitals may refer patients for genomic testing through a "right of private practice" which can attract MBS benefits. Although RDA does not currently have access to data quantifying this, it is likely that current practice means that some genomic testing is MBS reimbursed in public hospitals, some is MBS reimbursed in private pathology providers, and some is funded through activity-based public hospital funding. Particularly considering the close linkage between genomic testing and the use of high-cost drugs funded through the Pharmaceutical Benefits Scheme, there may be merit in considering whether targeted reform of MBS utilisation in public hospitals could improve equity in access to genomic testing by enabling all genomic testing to be reimbursed through Medicare, irrespective of provider. This would require complex reform, including some legislative and regulatory change, with change required both in activity based funding and MBS items. The advantage of shifting all genomic testing to the MBS would be the capacity to monitor test access and utilisation; consistent national funding via the MBS would highlight utilisation differences between locations and jurisdictions (states and territories) and potentially highlight areas with lower (under) or higher (potentially over) utilisation.

- **A National Genomic Test Directory**: A step forward in terms of person-centred delivery of clinical genomics would be to mirror much of NHS England's approach to genomics, and in particular the implementation of a regularly updated National Genomic Test Directory. A move to such a system would also reduce the demand on MSAC to assess new genomics – currently their largest area of new submissions. The UK's National Health Directory provides a framework for periodic review of appropriate (including assessment of effectiveness and clinical utility) biomarkers to be included. This allows for tests to be added and potentially removed.

6. What are the major barriers to embedding Health Genomics into the Australian Healthcare system?

- **Workforce Gaps:** A shortage of healthcare professionals with expertise in genomics and precision medicine is a significant barrier. Upskilling the current workforce and training the next generation is critical.
- **Lack of Integration with Industry:** While there are promising genomic innovations, there are limited pathways to collaborate with industry and bring these innovations into widespread clinical use. Clearer mechanisms for public-private partnerships are needed.
- **Data and Infrastructure Gaps:** Australia lacks the necessary infrastructure to handle the vast amounts of genomic data being generated. We need scalable and sustainable systems that are healthcare interoperable and able to be connected with research infrastructure.
- **Funding Models:** Current funding models are inadequate for supporting the widespread use of genomic testing and treatments, particularly in non-metropolitan regions.

7. What are the opportunities that remain to be captured through integrating genomics into healthcare? How can we capture these?

- **Precision Medicine in Oncology and Chronic Diseases:** Expanding the use of genomics in cancer treatment, pharmacogenomics, and chronic disease management could transform care by providing more personalized, effective treatments.
  Nationally consistent approach to managing genomic data across laboratories will enable existing genomic data to be easily found and reused (where appropriate), avoiding duplication of expensive genome sequencing, and leveraging existing genomic information for improved patient care and reduction in healthcare costs due to unnecessary duplication of MBS testing.
- **International Leadership:** Australia can become a leader in precision medicine by fostering an environment that supports local innovation and attracts global investments. Capturing these opportunities will require robust investment, regulatory flexibility, and streamlined industry partnerships.
- **Expanding Access:** Ensuring equitable access to genomic testing and treatments across all regions of Australia will help reduce healthcare disparities and improve health outcomes. A targeted approach to rural areas is crucial. Genomics is key to a preventative and proactive approach- the prevention and earlier detection of disease through screening programs to reduce the healthcare burden (cost minimisation) and prevent the need to use PBS

8. What evidence or data is available to identify obstacles and/or monitor success of embedding health genomics in Australia?

- **Workforce Competency Data:** Surveys or audits of the current genomic knowledge base within the healthcare workforce can highlight gaps in training and readiness for genomic integration.

- **Patient Outcomes Data:** Tracking patient outcomes in areas where genomics is integrated into clinical practice—such as cancer care—can provide insight into the clinical utility and cost-effectiveness of genomic interventions.
- **Health Economic Analyses:** Economic assessments that quantify the cost-effectiveness of genomic testing versus standard care models, particularly in rare diseases and oncology, can inform decision-making and policy development.
  Pathology Technology Australia report. Australia is up to 10 years behind and these delays have an economic and societal impact. Examples of the delays for access is summarised in the HRD access and innovative genomic tests for children and newborns case studies. Documented from page 36 in this report: *https://pathologytechnology.org.au/wp-content/uploads/2023/08/Unleashing-the-Hidden-Potential-of-Pathology-Technology-Report.pdf*
  The effectiveness of current programs that demonstrate the impact of Genomic testing are in place. However, the benefits are in programs rather than in sustainable and long term healthcare. Examples of these include the ZERO Childhood Cancer Program and the Omico program. This needs to be translated beyond programs and to leverage data for healthcare outcomes and improvement of Australians.

9. Do you have any suggestions on what government(s) can do to better support the integration of genomics into the Australian health system?

- **Facilitate Industry Collaboration:** Governments should implement frameworks that enable more effective collaboration between industry and healthcare providers, particularly around the adoption of new technologies.
- **Workforce Support:** Introduce and fund nationwide genomics training programs for healthcare professionals and ensure continuous education opportunities in this rapidly evolving field.
- **Invest in Infrastructure:** Governments need to prioritise funding for genomics-specific infrastructure to provide modern secure, cloud, genomic data infrastructure that is interoperable with healthcare and sustainable. This will future-proof the health system and ensure seamless integration of precision medicine. Leverage existing significant investment in the development of genomic information management systems designed specifically for federated healthcare systems.
- **Incentivise Innovation:** Create incentives that attract both local and global investment in Australia's genomics sector, ensuring that our domestic innovations can compete on the world stage while maintaining access to international developments.
- **Consistent federal and state funding of clinical genomics**
- ***A National Genomic Test Directory***
- **Universal access to Comprehensive Genomic Profiling for Australian** cancer patients at the point of diagnosis. We believe that equitable access to CGP will significantly reduce barriers to biomarker testing and access to precision oncology medicines in Australia. Our current health technology assessment system evaluates medicines and their associated tests in parallel, which results

in significant delays for both the medicines and tests to receive reimbursement. With universal CGP, we envisage that access to treatments will be expedited, as patients access a test de-linked from a reimbursement submission for a medicine. In the lab, CGP will improve efficiencies by removing multiple small panels on different instruments; and lastly, a single CGP assay will reduce the risk of test failures and avoid the need for multiple genetic tests which exhaust tumour DNA - therefore increasing the patient's likelihood of finding a matched treatment for their diagnosis. There needs to be a transition plan of national projects such as Zero Childhood Cancers and PrOSPeCT into the MBS. Reimbursement of this testing requires an understanding of CGP being a multi-indication predictive and prognostic tool that doesn't fit easily into MSAC's current assessment framework. This will also rely on: a) Integration of CGP and genomics into routine clinical care, standardisation of funding and frameworks to incorporate genetic information (metro/regional) i.e. supporting standardisation for genetic testing and counselling pathways nationally. b) enhanced education and training support for registrars/HCPs regarding genomics and driving community awareness.

10. Is there anything your organisation or constituents are doing to support the use of genomics or the integration of genomics into the health system? How could governments support you to better do this?

InGeNA works to promote the use of genomics through advocacy, education, and collaboration with healthcare stakeholders. Our members develop genomic technologies, precision medicine solutions, and diagnostic tools aimed at improving healthcare outcomes. We also work closely with our patient advocacy group to ensure that patient needs are considered.

Governments could support us by:

- **Enhancing Collaboration Platforms:** Creating formal platforms where industry, healthcare providers, and policymakers can collaborate more effectively on genomic integration.
- **Supporting Industry-Led Innovation:** Provide funding or tax incentives that encourage further investment in genomic technologies developed within Australia, ensuring that these innovations can be rapidly adopted in the health system.
- **Ensuring Access:** Support equitable access to these innovations across all populations, ensuring that regional and underserved communities benefit from the latest advancements in genomics and precision medicine.

Industry specific Questions

1. What are the major limitations to how industry can participate in health genomics in Australia currently?

- **Regulatory Barriers:** The current regulatory landscape can slow down the approval and adoption of innovative genomic technologies. Long approval times

and complex regulatory pathways make it difficult for industry to introduce new products and services quickly. Current regulatory frameworks do not fully account for the fast-paced nature of genomics innovations. The extended approval process for diagnostic tools, therapeutic applications, and data-driven analytics delays industry participation in advancing personalised healthcare.

We should seek to leverage other HTA markets' assessments of genomic tests and fast-track their approvals locally, saving time, money and delivering quicker access to patients.

- **Limited Integration with Healthcare System:** Industry struggles to integrate their genomic solutions within the public healthcare system due to a lack of streamlined processes for public-private collaboration.
- **Lack of appetite for public private partnerships to further implementation** Provide mechanisms for industry to collaborate and accelerate implementation of genomics. Emphasise funding and support towards implementation rather than R&D.
- **Lack of clear long term goals and objectives for health genomics that are linked to improved health outcomes for Australians.**
  Specific, measurable targets for the next 3, 5 and 10 years will enable a detailed focus on implementation, which in turn could drive collaborative efforts between industry and health providers to create services to deliver to this goal.
- **Funding and Reimbursement Issues:** Lack of sustainable funding and reimbursement models for genomic testing and treatments limits widespread adoption and hinders industry participation.
  Lack of incentives, and investment into genomic data infrastructure for healthcare. Without the foundations, precision medicine and research from genomic testing will not be possible at scale in a sustainable or safe way.

  Lack of consistent federal and state funding of clinical genomics: State powers over funding of public hospitals means that public pathology services may not be able to claim the MBS. Genomic testing is an expensive and rapidly growing part of a pathology service's offering, and we are observing that some hospital budgets are not accounting for this expanding area of cost. This has the potential to lead to inequity of access for public patients where budgets are exhausted, and will continue to get worse if not addressed.

2. Can you describe these limitations and the impact they have on industry (if not already answered above)?

- **Lack of clear, long-term goals for health genomics**
  These should be linked to benefits – health economic impact for Australians, reduced diagnostic odyssey and associated costs, reductions in low benefit care, shift to a prevention based healthcare system.
  The impact to industry is that we are not delivering benefits to Australian healthcare and low benefit care is instead using up the healthcare budgets. We need to shift the system in collaboration and input from industry about the healthcare benefits for the next 3, 5 and 10 years. This will have a detailed focus

on implementation, which in turn could drive collaborative efforts between industry and health providers to create services to deliver to this goal.

- **Regulatory Delays:** Long approval times create financial burdens for companies, particularly smaller enterprises, making it difficult for them to compete or innovate. It also delays patient access to new therapies and diagnostic tools.
- **Limited Public-Private Collaboration:** Without strong mechanisms for collaboration, innovations in health genomics often remain siloed, preventing large-scale impact. Industry players, especially startups, face challenges in scaling their technologies within public health systems.
- **Funding Constraints:** The absence of clear funding mechanisms for genomics services makes it risky for companies to invest heavily in the Australian market. It also limits companies' ability to innovate and grow, impacting patient access to cutting-edge genomic solutions.
- **Slower Market Entry:** Regulatory hurdles delay market entry, making it difficult for both large multinational companies and local startups to introduce new genomics technologies in Australia.
- **Barriers to Scaling Innovations:** Without clear pathways for integrating genomic data across the healthcare system, companies face difficulties in scaling innovative solutions, impacting their ability to contribute to personalised healthcare effectively.
- **Reduced Investment Potential:** The lack of predictable funding and reimbursement for genomic tests reduces genomic data infrastructure and industry confidence and limits investment in Australia's genomics ecosystem, curbing growth in personalised healthcare.
- **High cost of delaying access to tests and treatments.**
  The economic impact has been evaluated in a recent Pathology Technology Australia report. Australia is up to 10 years behind and these delays have an economic and societal impact. Examples of the delays for access is summarised in the HRD access and innovative genomic tests for children and newborns case studies. Documented from page 36 in this report:
  https://pathologytechnology.org.au/wp-content/uploads/2023/08/Unleashing-the-Hidden-Potential-of-Pathology-Technology-Report.pdf

3. Are there any issues/barriers relating to health practitioner literacy in genomics (if not already answered above)?

Yes, the lack of genomic literacy among healthcare practitioners is a significant barrier. Many practitioners are not fully equipped to interpret genomic data or apply precision medicine approaches in clinical settings. This creates a gap between the availability of genomic technologies and their actual use in patient care, slowing down the broader integration of genomics into healthcare.

There is lack of integration and literacy when we look at the whole pipeline of developing health practitioners.

There is lack of literacy in the other parts of the health system workforce to direct how to implement genomics effectively and set up effectively for clinical workforce as well. We

note this issue when we are working with literate health practitioners who deal with poor clinical workflows for genomics and hence hinders even early adopters to take this up.

4. Are there differences between local and international companies in how they engage with health genomics in Australia?
Yes, there are significant differences in how local and international companies engage with health genomics in Australia.

- Local Companies: These companies are often highly innovative, frequently emerging as spin-offs from universities and research institutions. However, they face substantial challenges:
    - Limited Access to Funding: Investment in genomics in Australia is more constrained compared to other life sciences sectors, making it difficult for local startups to secure adequate resources for development.
    - Limited Market Size: The local market is relatively small, which restricts opportunities for these companies to gain traction.
    - Challenges in Procuring Local Contracts: Local companies often struggle to secure contracts or procurement deals within the Australian health system. Procurement policies are not favourable toward Australian-made products, making it difficult for local innovators to validate their technologies domestically. There is “no right door” and it is very obscure and ad hoc about how to procure into the Australian market – this wastes valuable time and resource for scaling organisations who need to scale and gain customers quickly to succeed. This in turn hampers their ability to scale internationally. As a result many will turn to overseas growth opportunities as these are easier than local opportunities.
    - Risk of Losing Innovation Early: Because of these hurdles, many local companies fail to gain the traction necessary to scale, resulting in promising innovations being lost at an early stage or being acquired by international firms.
- International Companies: These companies generally have greater resources but still face challenges:
    - Some international companies have dedicated market access teams, which help navigate the complexities of Australia's healthcare system. However, not all companies have these specialised resources, making it difficult to enter the Australian market efficiently.
    - International companies face the same slow approval processes that hinder timely market entry, limiting the ability to rapidly introduce cutting-edge genomic tests and treatments.
    - Alignment with Global Models: International companies could benefit from a regulatory environment that more closely mirrors models like the UK Cancer Drugs Fund, which fast-tracks access to genomics-based technologies. Implementing such a model in Australia would allow both local and international companies to reduce time-to-market for their genomic solutions.

5. Are there differences between local and international companies in how they benefit from health genomics in Australia?

- **Local Companies:** Local companies face greater hurdles in securing funding and achieving broad adoption within the Australian healthcare system. While they are better positioned to create tailored solutions for the Australian market, they often struggle with scalability.
  Poor procurement practices for innovative companies makes it harder for them to gain benefit.
- **International Companies:** International companies may benefit more quickly from established global networks and larger resource pools, but their products often face longer regulatory processes and the challenge of adapting to the specifics of the Australian healthcare landscape.

6. Do you have any suggestions on how the government can better support industry in Australia to engage with/benefit from health genomics?

- **Adopt Accelerated Approval Models**: Australia could benefit from adopting a model similar to the **UK Cancer Drugs Fund**, which accelerates the approval of innovative genomic tests and treatments. This approach would allow for faster market access for critical genomic technologies, helping companies bring innovations to patients more quickly. The UK's model offers conditional funding while further evidence is collected, a system that could be adapted to fast-track genomics innovations in Australia.
  The ROHPG scheme is a model example that is a mechanism to enable approved services to access funding for infrastructure. This would provide incentives for labs to significantly uplift their genomic data infrastructure and foster an interoperable genomic data ecosystem across the country that is required for precision medicine, and could then be used to develop innovative research infrastructure solutions.
- **Improve Procurement Processes for Australian-made Products**: The government should reform procurement policies to ensure better support for **local innovations**. Currently, local genomics companies face significant challenges in securing even small-scale contracts within the Australian healthcare system. Improved procurement processes that prioritize Australian-made products would allow local companies to validate their technologies domestically, providing them with the credibility needed to scale internationally.
- **Simplify Regulatory Pathways**: The slow and complex regulatory approval process in Australia hinders both local and international companies. The government could introduce a more streamlined process for genomics innovations, which would reduce time-to-market and increase the competitiveness of Australian genomics globally. By aligning with faster regulatory frameworks like those in the UK and the US, Australia could become more attractive to investors and innovators.
- **Facilitate Industry and Health System Collaboration**: Creating more **public-private partnerships** could enhance the adoption of genomics within the Australian healthcare system. These collaborations would help align industry innovations with healthcare needs, ensuring that genomic technologies are integrated into clinical practice more efficiently.
- **Investment and Reimbursement Support**: Introducing **targeted funding programs** for genomics companies, particularly local startups, would encourage more innovation. Additionally, **flexible reimbursement models** that account for the rapid

evolution of genomic technologies would enable both local and international companies to engage more effectively with the health system.

- **Support Workforce Development:** Government should also fund programs to upskill healthcare professionals in genomics, which would drive broader adoption of genomic technologies developed by the industry.

7. What would need to change for industry to benefit from a growing market in health genomics in Australia?

- **Adopt Accelerated Access Models Similar to the UK**: Australia could implement a system similar to the **UK Cancer Drugs Fund**, which accelerates the approval of new genomic tests and treatments. This model allows innovative products to enter the market while gathering additional evidence on their effectiveness. Such a fast-track approval process would help both local and international companies bring genomic innovations to patients more rapidly, benefiting the industry by shortening time-to-market and reducing regulatory delays.
- **Streamline Regulatory and Approval Processes**: Australia's current regulatory processes are slow and can significantly delay the introduction of genomics-based technologies. By simplifying these processes and aligning with international standards—such as those in the UK and other global markets—Australia could create a more favourable environment for innovation, making the market more attractive to both local and international investors.
- **Expand Access to Funding**: Investment in genomics is currently limited in Australia, particularly compared to other life sciences sectors. The government could introduce **incentives for private and public funding**, as well as tax incentives to attract more investment in this space, similar to the UK's **Innovate UK** and other funding schemes aimed at driving innovation in health technologies. Increasing the availability of funds for genomics companies would enable them to scale more effectively within Australia and internationally.
- **Enhance Reimbursement Models**: The reimbursement landscape needs to be more flexible and adaptable to accommodate emerging genomic technologies. This would provide companies, particularly those dealing with cutting-edge precision medicine, with a clearer path to market entry and sustainable revenue. The UK's approach to managing reimbursement through their fast-track models could be an example for Australia to follow.
- **Increase Industry Collaboration with Healthcare Providers**: Encouraging **stronger partnerships between the healthcare sector and industry** would ensure genomic innovations are integrated into clinical settings more effectively. By fostering collaboration, companies can better align their innovations with the needs of the healthcare system, accelerating adoption and creating more opportunities for growth.
- **Enhanced Data Infrastructure:** Improved infrastructure for data management and sharing, particularly around genomic data, would allow for better integration of industry innovations into the healthcare system and support advancements in precision medicine.

8. What could the government do to attract more investment in the health genomics industry in Australia?

- Review international models that have been successful

- Attract multinational pharmaceutical organisations to fund companion diagnostics
- **Incentivise R&D:** Offering tax incentives and grants for research and development in the genomics sector would attract both domestic and international investment. This includes incentivising clinical trials and pilot programs in genomics.
- **Promote International Collaboration:** Establish trade and innovation agreements with countries that lead in genomics research to facilitate international partnerships and attract foreign investment.
- **Create an Innovation-Friendly Environment:** Governments could reduce regulatory red tape and make it easier for companies to test and introduce new genomic solutions by creating innovation-friendly zones or frameworks within the healthcare system.
- **Align with Global Regulatory Standards**: Aligning Australian regulations with faster-moving markets like the UK and the US would make it easier for companies to bring their genomic technologies to both domestic and international markets. Harmonised regulations would reduce barriers to entry and increase Australia's appeal as a global hub for genomic innovation.
- **Highlight Success Stories:** Showcasing successful implementations of genomics within Australia—especially where industry and healthcare providers collaborate—could attract both investors and global industry players.

9. What are the key points of evidence or data that we can look to see if/how much industry contributes to the success of health genomics in Australia?

- **Economic Impact Reports:** Tracking investment levels, job creation, and contributions to GDP from the genomics industry could serve as a key indicator of how much industry is contributing.
- **Clinical Adoption Rates:** Data showing how many genomic tests or precision medicine treatments are adopted into routine clinical practice, and whether these are developed by local or international companies.
- **Collaborative Projects:** The number of collaborative projects between industry, government, and healthcare providers (e.g., genomics trials, precision medicine pilots) could highlight industry's role in driving the success of genomics in healthcare.

10. What are the key points of evidence or data that we can look to see if/how much industry has benefited from the success of health genomics in Australia?

- **Industry Growth Metrics:** Growth in the number of companies, startups, and investments in the genomics space in Australia could indicate how much industry is benefiting from health genomics.
- **Revenue and Market Penetration:** Increased revenue for companies providing genomic solutions or services, as well as market penetration data showing their uptake within the healthcare system, could be used to assess the industry's success.
- **Job Creation in Genomics:** The creation of new jobs, particularly high-skilled roles in genomics, biotechnology, and precision medicine, would reflect how the industry is benefiting from a growing genomics market.

Example issues of concern for industry

disparity between TGA regulations and what is listed on the MBS and used in clinical practice (eg: There is no single TGA approved (ARTG listed) assay/workflow that matches the MBS funded Lung NGS panel). This is because NGS is still broadly a LDT and these are regulated by NATA. Noting that there is an existing TGA consultation on CDx however this is likely to make things even more challenging.

Additional information

In the UK, the *Cancer Drugs Fund* (CDF) provides a useful model for how Australia could potentially accelerate approvals for genomic tests by adapting a similar framework. The UK removed *complex technologies* (CTX) from the standard NICE (National Institute for Health and Care Excellence) approval process, particularly focusing on therapies and tests that fall under precision medicine, including genomics.

Key Aspects of the UK Model:

1. **Separate Approval Pathway for Complex Technologies (CTX):**
    - By removing CTX from the standard NICE process, the UK has created a faster approval mechanism for genomics-based tests and precision medicine treatments, which would otherwise take longer to evaluate under traditional frameworks.
    - This pathway allows rapid access to innovative treatments, such as genomic tests, by focusing on conditional approvals based on early data, often while gathering further evidence of long-term clinical efficacy.
2. **Accelerating Access Through Interim Funding and Usage:**
    - In the UK's CDF model, genomic tests can be fast-tracked into clinical use while additional data is collected. For example, the test may be funded and used for a specific population or condition, even if full evidence is still being gathered.
    - This allows for real-world data collection to support future NICE appraisals while ensuring that patients can access life-saving genomic testing early.
3. **Flexible Reimbursement Models:**
    - The CDF supports flexible reimbursement models, which is critical for adopting new and evolving technologies. The NHS engages in value-based pricing negotiations with manufacturers of genomic tests, enabling pricing adjustments as new data emerges.
    - This removes the financial burden from patients and allows the health system to accommodate the high initial costs of novel tests, making adoption smoother for the industry.

Potential Application to Australia:

Australia could benefit from a similar approach, where:

- **Genomic tests** and precision medicine approaches could be fast-tracked under a separate approval pathway, bypassing or simplifying existing TGA or MSAC processes that might take years.

- **Interim approvals and funding** could be granted for genomic tests, with the condition that data will be collected in real-world clinical settings to ensure safety and efficacy while the technology is already in use.
- **Public-private partnerships** could be formed to bring cutting-edge genomic tests into the healthcare system rapidly, while allowing for ongoing adjustments based on evidence gathered over time.

Benefits for Australian Industry:

- **Accelerated Market Entry:** By adopting a model similar to the UK's, Australian companies can introduce genomic tests to the market more quickly, supporting local innovation and attracting international investments.
- **Reduced Delays in Approvals:** Genomic and precision medicine innovations often outpace regulatory frameworks, and a flexible approval process would reduce bottlenecks, helping patients access world-class treatments faster.
- **Data-Driven Decision-Making:** Real-world evidence gathered during the interim approval phase can inform the long-term integration of genomic tests into the healthcare system, providing industry with valuable data to refine their products.

Such a model could significantly boost Australia's position in health genomics, providing a platform for cutting-edge genomic testing while fostering industry growth.