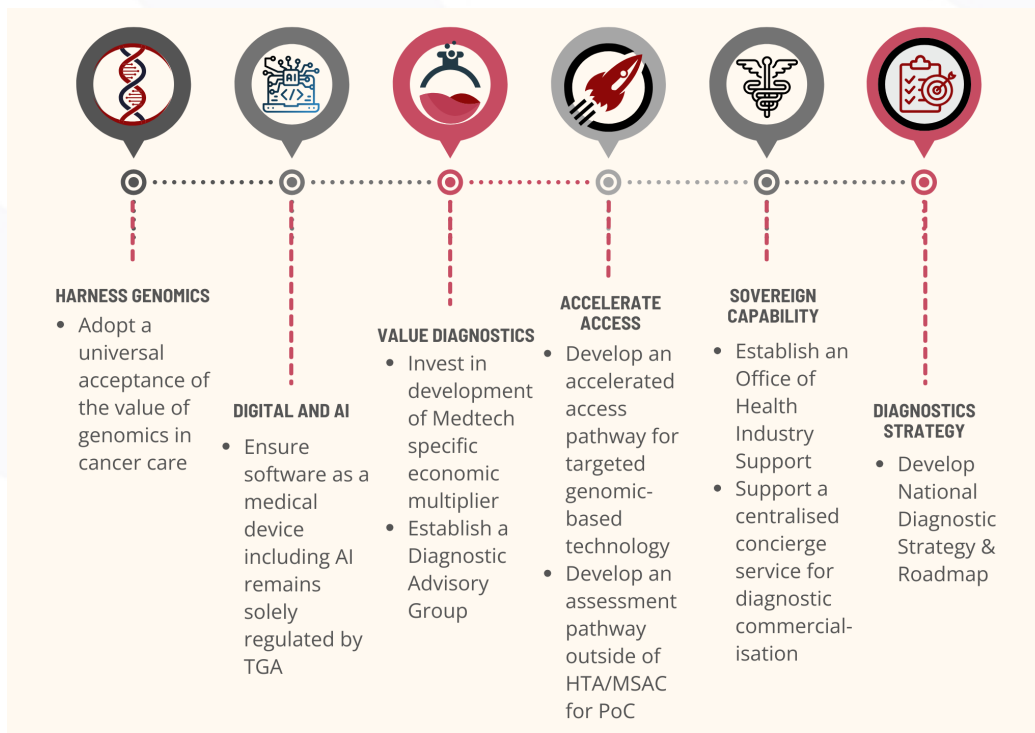


## Summary

Australia has the capacity to transform our current activity-based, sickness model of healthcare to a predictive, preventative and personalised, wellness-based model. Recommendations here provide key next steps to this end including strategic investment in genomics, point-of-care technology, and digital enablers.

Utilising a broader health economic lens encompassing value-based health, and recognising critical sovereign capability requirements, Australia can avoid its healthcare system falling rapidly behind comparable economies. Health is becoming less affordable and accessible for many. We must act now. Encompassing the immediate, short, and long-term activities outlined in this document, Pathology Technology Australia invites policy makers to lead the change.



## Introduction

Pathology Technology Australia (PTA) is the peak industry body representing the manufacturers, distributors, and importers of the technology responsible for more than 95% of pathology testing in Australian laboratories, hospitals and the community. Our membership includes almost all the manufacturers and suppliers of genomic testing technology, point of care technology, and other disruptive and high-medical need technology solutions that are currently under-utilized in the Australian healthcare setting. We have a clear view of the technological advancements being developed and their strong impact on quality of life. Our members partner with clinical and research institutes to develop, install, train, and maintain the range of tests and supporting infrastructure that screen for risk, enhance diagnosis, target treatment, support patient management decisions, and monitor a patient's ongoing health.

Progressive economies around the world are adopting technologies such as genomics, point of care testing, and digital health systems to improve health outcomes and reduce the burden of disease on their economies. There are also existing and beneficial tests that have been TGA approved for years yet are either partially funded or not funded at all, so are out of reach to most Australians. It is time to recognise the value of investing in pathology technology-driven solutions to address our most pressing healthcare challenges.

# Change Pillars

## 1. Adopt Point of Care Technology for Universal Access to Healthcare

Australia's geography and diverse population needs require a diversity of healthcare tools and resources to provide access to universal healthcare. An approach which meets people where they are and brings healthcare and related testing closer to the patient is possible. Adoption of pathology technology outside of centralised, high-volume laboratory settings can support an increase in the scope of practice to empower clinical nurse practitioners, pharmacists and other trained health workers with critical information to augment their delivery of effective healthcare services.

Targeted Point of Care (PoC) testing will reduce inequalities in accessing healthcare, reduce gaps in healthcare outcomes of rural and under-served populations, and increase scope of practice for appropriately trained healthcare workers:

- a. Develop an **assessment pathway outside of HTA/MSAC for PoC technology reimbursement**
  - o Australia has a very limited offering of funded PoC tests, with only 6 different analytes, compared to over 30 in Germany and Switzerland. Many of the PoC tests offered in other jurisdictions are not funded through standard HTA pathways. In Australia, the limited reimbursement fees determined for PoC tests funded outside of First Nations health services are a reflection of the MSAC HTA process that is not set up to accurately assess the full value chain of providing PoC testing for target populations and healthcare challenges.
  - o Reducing the barriers of PoC test assessment in cases with a clinically proven central laboratory equivalent, removing the direct cost-effectiveness comparison with high-volume testing, and devising assessment criteria that encompasses the full value chain of the use of PoC testing will enable the government to fully capitalise on the use of PoC tests to address broader national health goals.

## 2. Harness Genomics for Predictive, Preventative & Precision Health

Australia does not yet provide timely and equitable access to genomic-based testing in predictive, preventative or personalise healthcare. There is growing frustration within the community at the limited access to timely, funded genomic testing to support a variety of cancers including breast cancer, ovarian cancer, lung cancer, and gynaecological cancers.

PTA believes the following initiatives will lead to more equitable and timely access to genetic testing and bring Australia's healthcare system more in-line with like economies around the world in the delivery of genomic-based healthcare:

- a. Adopt a **universal acceptance of the value of genomics in cancer care**
  - o We have moved away from the 1970's models of non-specific radiation and chemotherapy and are now in an era of personalised medicine to treat cancer. The more we learn about cancer the more we realise that *all* cancers are unique. An immediate short term policy objective should ensure **all cancer patients access fully funded and timely genetic testing** to determine the most effective treatment options available.
- b. Develop an **accelerated access pathway** for targeted genomic-based technology
  - o Strategic, agile, and self-reflective models such as that used in the UK genomic test directory could be adapted to Australia, utilising a conditional-funding approach for high-clinical need tests. Data generated during the conditional period could then be used to validate ongoing funding, either through the standard HTA process or alternative funding pathways.

### 3. Digitalisation to Drive Productivity

Productivity gains in pathology services are, and will continue to be, derived using digital and artificial intelligence (AI)-driven tools and infrastructure. It is essential that our regulatory and funding mechanisms can effectively assess and/or evolve to match the evolutionary pace of these key efficiency drivers. Further priority is needed to develop and support the data infrastructures required to utilise these tools in a cost-effective and nationally universal manner. This will require national coordination to overcome State/Territory silos, and cross sector/service silos that will limit the utility of data-driven insights and solutions.

It is critical that the pathology technology industry and specialised service providers that develop and deliver these tools remain intimately involved in policy making and decision impacting this space.

- a. Our immediate and strong recommendation is that software as a medical device including those that are AI enabled, be ringfenced from the National AI Guardrails and regulated solely by the TGA.
- b. Funding digital health applications will likely require mechanisms outside the current MBS processes to extract the greatest value.
- c. Awareness and training for health consumers and health professionals will be an important building block for the effective adoption of the benefits and efficiencies.

### 4. Apply Broad Health Economics Metrics for Value-Based Healthcare

[Unleashing the Hidden Potential: Reframing Pathology Technology's Role in Australian Healthcare](#) identified over \$7 BILLION in value forgone over the last two decades from delays in funding critical pathology technology already cleared by the TGA.

The Pathology Review (due to report June 2025) will, in part, investigate the systemic barriers and opportunities related to the use of innovative and disruptive pathology technologies. Similarly, the HTA Review Report, incorporates a small proportion of diagnostic technology as it relates to the delivery of medicines. Further to this activity, PTA believes the following initiatives will lead to more timely, equitable, and cost-effective use of pathology technology in Australian healthcare:

- a. Establish a **Diagnostic Advisory Group** with stakeholders including healthcare professionals and laboratory service providers, patient advocacy groups, industry bodies, and Government representatives to coordinate on the most efficient and effective utilisation of diagnostics.
  - i. In the short term, the Group could identify currently available, but underutilised, high-medical value tests and technology for accelerated pathways through funding and adoption processes
  - ii. Utilise the Group to advise on R&D priority pathways to fulfill unmet medical needs and national health strategies
  - iii. Draw on the Advisory Group for the formation of a National Diagnostics Strategy
  - iv. Use the Advisory Group in an ongoing capacity to provide input on future direction of the Strategy and horizon scanning activities with linkage to national healthcare missions
- b. Develop a **National Diagnostics Strategy and Roadmap**
  - i. The World Health Organisation outlined recommendations for the Seventy-sixth World Health Assembly to strengthen diagnostics capacity (February 2023) recognizing that “diagnostic services are vital for the prevention, diagnosis, case management, monitoring and treatment of communicable, noncommunicable, neglected tropical and rare diseases, injuries and disabilities.” The first recommendation *urges* signatory nations “to consider the establishment of national diagnostics strategies, as part of their national health plans, that include regulation, assessment and management of diagnostics and development of integrated networks to tackle all diseases and medical challenges, avoiding current silos often observed.”

## 5. Drive Sovereign Capability to De-Risk Healthcare

Australia relies almost exclusively on international manufacturers and suppliers for diagnostic products, importing 97% of all pathology technology, making us unacceptably vulnerable to future pandemics and external shocks. With more than 70 percent of all medical diagnostic and management decisions based on these tests, and 100 percent of cancer diagnoses, it is essential that we have a cohesive strategy for sovereign capability in this space. While Australia is in the top 95 percentile for medical innovation, we are in the bottom 5 percentile for manufacturing. Within the unique, almost 100 per cent government funded market of diagnostics, commercialisation of local innovations is particularly challenging without clear market signals and a path for in-market funding.

While initiatives related to the National Reconstruction Fund, and government wide “Buy Australian” activities can help boost local manufacturing and commercialisation of Australian innovation, more is required. The following initiatives will specifically address the unique challenges within the medical technology and diagnostics sector. They will provide sovereignty and security to critical health sector needs, boost local and national economies, and improve the return on investment for the significant (around \$6bil per year) outlay in medical research funding:

- a. Invest in the **development of a medtech sector-specific economic multiplier**
  - o Procurement remains a fundamental barrier to the long-term success of local innovators in the medtech space. Government purchasing contracts form a substantial segment of the medtech market and are often decided on cost-based assessments that do not adequately calculate the secondary economic benefits of buying locally manufactured products and services. When the US state of Kentucky’s General Assembly introduced an economic multiplier to guide procurement to better understand when locally preference would benefit residents, manufacturing output for the state increased 36%
- b. Establish an **Office of Health Industry Support (OHIS)**
  - o Emulating the Department of Defence Industry Support (ODIS) model that links Australian small and medium enterprises to the defence needs of Australia. ODIS engages with state and territories to link local industry to deliver capability that equips and sustains the Australian Defence Force.
  - o An OHIS could:
    - i. Link national health programs to SMEs capable of delivering suitable technology.
    - ii. Work with the end users of the technology and the SMEs to maximise innovative technology outcomes.
    - iii. Provide specialist business advice to SMEs on health technology requirements, supporting access to health procurement programs (state and commonwealth).
    - iv. Taylor grants to SMEs developing technology addressing high unmet or poorly met medical needs.
    - v. Provide specialised services for local SMEs to navigate regulatory and funding pathways.
    - vi. Link health strategy, horizon scanning, and align with State and Territory health strategy as well as industry peak bodies
    - vii. Leverage advice from an Australian Diagnostics Advisory group to link innovation development to nationally important health missions and programs – establishing a pull rather than push market signal.
- c. Support a **centralised concierge service for diagnostic commercialisation**
  - o Providing a one-stop, training and mentoring program for promising diagnostic technology innovators to evolve towards successful commercialisation would serve to boost sovereign capability in key MedTech areas.