DIAGNOSTIC TESTING SOVEREIGN CAPABILITY & SUPPLY CHAIN RESILIENCE

PRELIMINARY FINDINGS

October 2022

ADAPT
Australian Diagnostics Action Plan Team

MTPConnect
MedTech and Pharma Growth Centre

PATHOLOGY TECHNOLOGY AUSTRALIA

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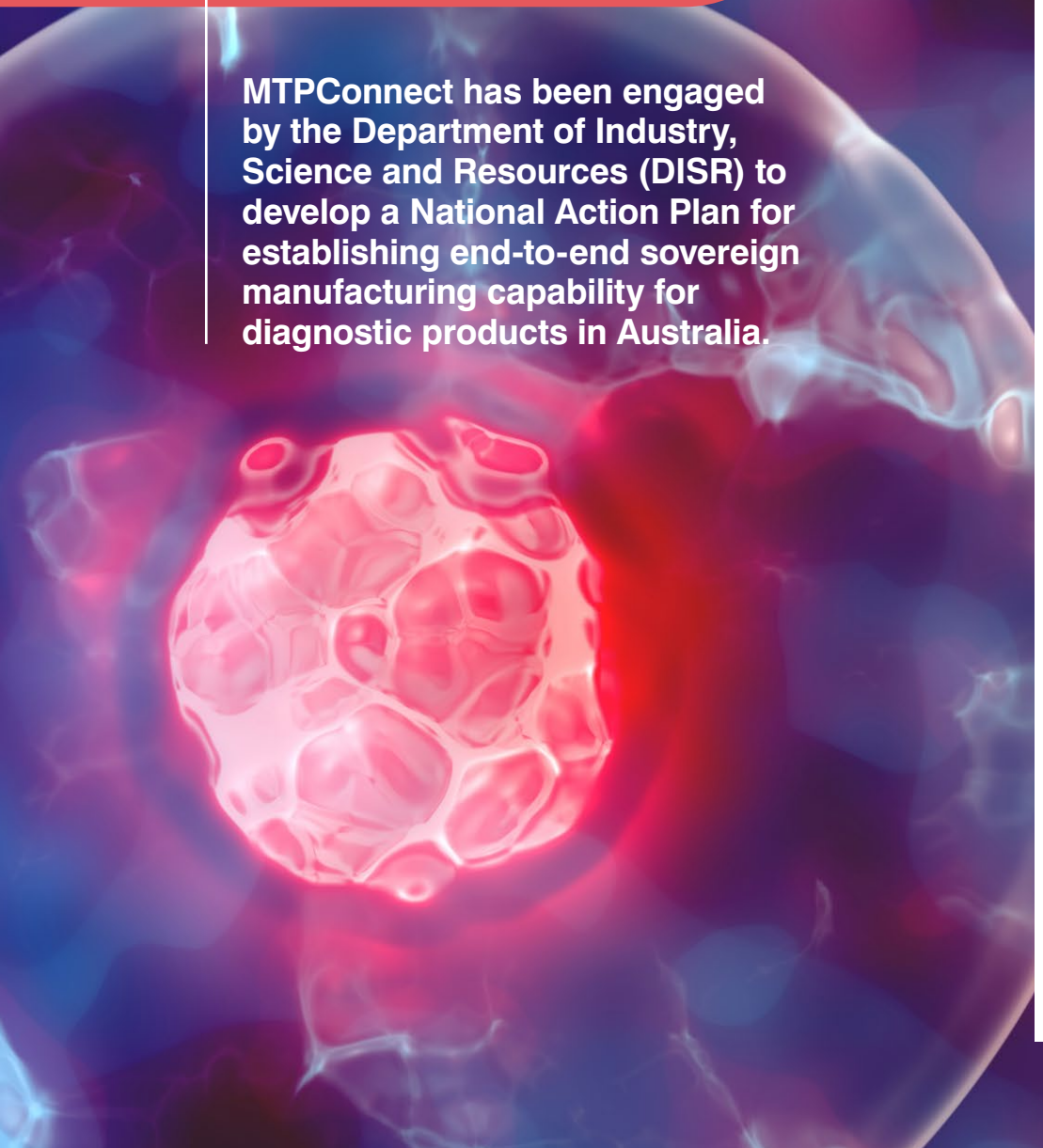
MTPConnect MedTech and Pharma Growth Centre

PATHOLOGY TECHNOLOGY AUSTRALIA

1 BACKGROUND

MTPConnect has been engaged by the Department of Industry, Science and Resources (DISR) to develop a National Action Plan for establishing end-to-end sovereign manufacturing capability for diagnostic products in Australia.



The project is being delivered in partnership with Pathology Technology Australia (PTA) and is being supported by **HT**ANALYSTS.

A five-person External Advisory Group has been convened to guide the project, with members including:

- **Dr Sean Parsons – Ellume**
- **Dr Paul MacLeman – AdAlta**
- **Kylie Sproston – Bellberry**
- **Professor Chris Molloy – Medicines Discovery Catapult (UK)**
- **Jo Root – Consumers Health Forum of Australia**

To better understand the diagnostics testing landscape – including the current value chain, manufacturing capabilities and supply chain resilience – MTPConnect, PTA and **HT**ANALYSTS have been reviewing the current landscape and conducting interviews across Australia, with a diverse range of stakeholders, to gain insights into the current barriers and opportunities across the value chain.

This will facilitate the development of a National Action Plan, outlining key issues and providing actionable next steps for providing Australia with sovereign diagnostic product manufacturing capabilities, expected to be delivered to government in April 2023. This will also include an analysis of supply chain security and resilience for diagnostic products that will continue to be imported into Australia. Recommendations in the National Action Plan will be extensively consulted and stress tested.

The project team is working with a wide-ranging group of key stakeholders, engaging the sector to gather insights and understanding of the challenges with developing, commercialising, manufacturing and supplying IVDs in the Australian market.

Purpose and scope

Currently, **more than 97 percent of the in vitro diagnostic (IVD) products used in Australia are imported** and, as a result, much of this technology is manufactured offshore, exposing Australia to supply shortages during periods of high demand and stress on global supply chains. While it is unrealistic for Australia to be fully self-sufficient in all aspects of health technologies and consumables, recent geopolitical pressures have revealed an underlying need to develop and produce IVD products reliably and sustainably. In addition, as we look to the future, there is further risk that other events could impact trade[1].

Recent geopolitical pressures have revealed an underlying need to develop and produce IVD products reliably and sustainably.

For example, the Australian Strategic Policy Institute estimates that 80 percent of global trade is carried via sea and that between 20 percent and 33 percent of that trade moves through the contested waters of the South China Sea[2].

For over 50 years, Australian innovators have developed some of the world's most important medical products – in areas such as vaccines, sleep therapy, blood plasma medicine and correction of hearing loss, and most recently in tests for contagious disease, drug-resistant micro-organisms, and rapid tests. For example, scientists from The University of Queensland developed the world's first cervical cancer vaccine[3].

Australia should be looking to bring the best of the outside world to our shores and the best of Australia to the outside world. By fostering sovereign capability and resilience we can create economical value, advance health outcomes and improve health security for all Australians.

Australia has the scientific and technical capability to develop and manufacture innovative diagnostic products at the frontier of the world's health needs. From lateral flow tests, such as the COVID-19 rapid antigen test (RAT), to tests for influenza and other respiratory infections; point-of-care tests for common infectious diseases; tests to detect septicaemia, heart conditions, diabetes and kidney disease; nucleic acid (deoxyribonucleic acid [DNA] and ribonucleic acid [RNA]) based tests for contagions, early cancer detection, inherited disorders and drug-resistant infections – all of these are within the capability of Australian researchers, pathology technology developers and manufacturers to produce.

The COVID-19 pandemic has raised awareness that access to diagnostic products is crucial to controlling emerging infectious disease. It has also uncovered the consequences of having an internationally dependent and reactive healthcare ecosystem. Thus, for IVD products that will continue to be imported, understanding the supply chain is critical, particularly as over 70 percent of all medical diagnosis and management decisions rely on pathology test results, as do 100 percent of cancer diagnoses.

There are clear security, health and economic imperatives to establish, retain and strengthen supply resilience and sovereign manufacturing capabilities for key diagnostic products. Given that Australia is heavily reliant on imports for the majority of our IVD and pathology testing needs, we need to harness our leadership position in research and development (R&D) to ultimately become a regional centre of excellence in developing and manufacturing key diagnostic technologies to improve our sovereign manufacturing capability.

Australia is heavily reliant on imports for the majority of our IVD and pathology testing needs.

A focus on the full manufacturing value chain, including the pre-production, production and post-production phases, will drive creation of high-tech and high-paying jobs, generate export income and protect the health of Australians in times of serious threat. This is especially true for medical products that cannot be easily stockpiled, as is the case for most IVD test consumables, which have a short shelf life and rigid storage temperature requirements.

MTPConnect's programs delivered on behalf of the Medical Research Future Fund and other initiatives are supporting late preclinical and early clinical medical product development, translation and workforce skills development. However, more can be done to address barriers faced by innovative manufacturers in Australia when gaining access to the local market.

To find solutions to these issues, a truly end-to-end approach is needed and may be achievable with relatively simple changes to perspectives, structure and funding. However, to propose solutions, a detailed understanding of the landscape, barriers and opportunities is needed.

To find solutions to these issues, we need to understand and validate the following:

- **Local barriers to manufacturing** IVD products in Australia, including market access pathways, and potential opportunities to overcome them.
- **Availability of critical products**, including components and raw materials for IVD products.
- **Gaps in the skilled workforce** in the IVD sector.
- **Supply chain resilience** for diagnostic products, raw materials and consumables that are imported, and opportunities to minimise supply chain disruptions.

In vitro diagnostics

The National Action Plan will focus on IVD products, as well as the associated services and software in Australia. According to the Therapeutic Goods Administration (TGA), a medical device is defined as an IVD if it is a *'reagent, calibrator, control material, kit, specimen receptacle, software, instrument, apparatus, equipment or system, whether used alone or in combination with other diagnostic goods for in vitro use'*[4].

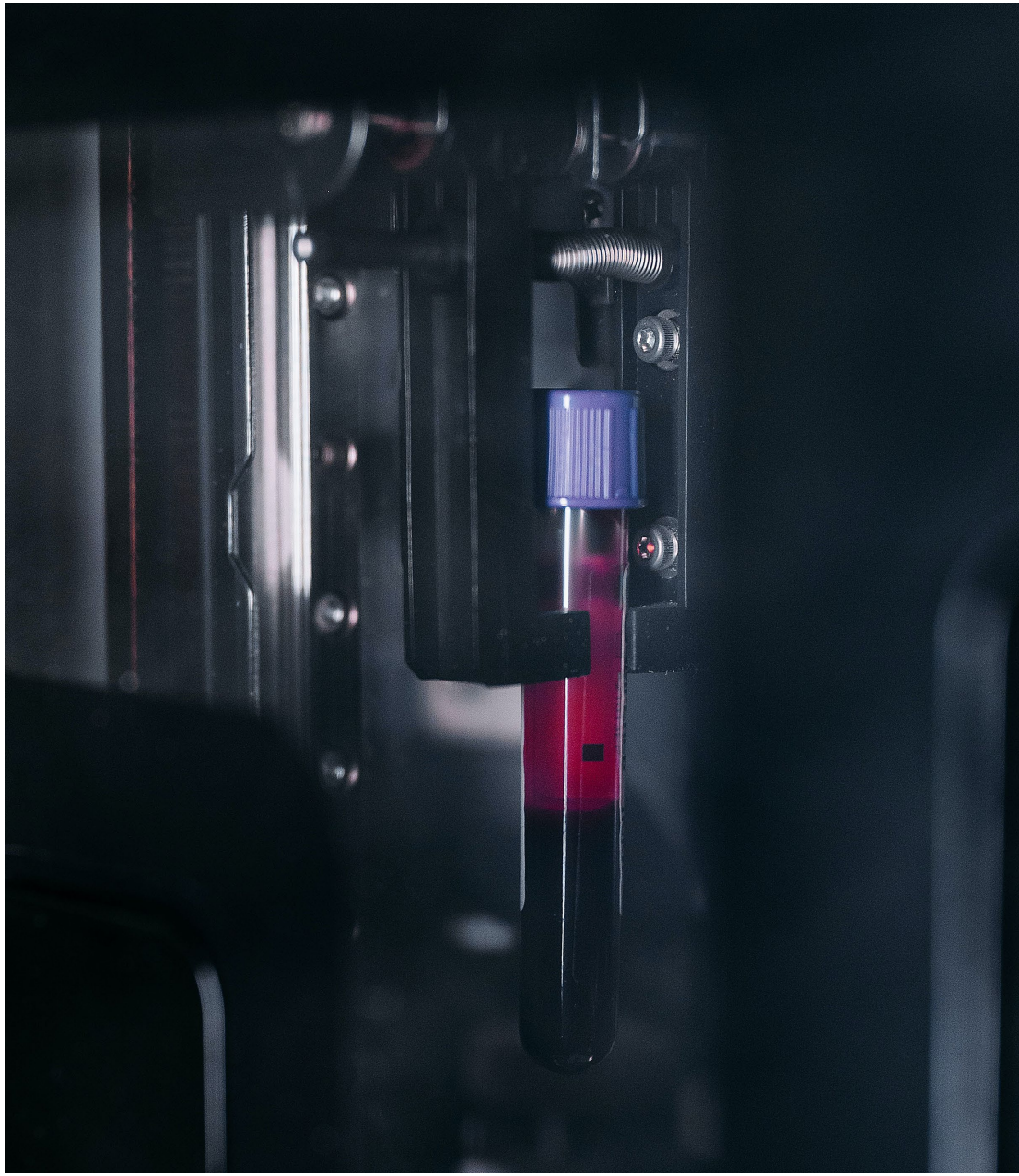
These can be further classified into six key categories, including:

1. **Biomarkers**
2. **Devices**
3. **Genomics**
4. **Point-of-care**
5. **Self-testing**
6. **Software as a medical device**

This definition provided by the TGA excludes products that are not intended for therapeutic use (i.e. drug tests used for sport, alcohol or illicit drugs)[5]. IVDs not intended for therapeutic use, as well as medical imaging devices, are out of scope for the National Action Plan.

The value of in vitro diagnostics

IVDs are a crucial contributor to the Australian healthcare system, facilitating medical discoveries and transforming patient care and overall health outcomes. From genetic tests that inform targeted cancer treatments to blood analyses to identify the right antibiotic, IVDs play a vital role in detecting, diagnosing, treating and managing a broad range of health conditions[6].



IVDs are indispensable for routine patient management, as the value of IVDs lies predominately in prevention. Appropriate testing allows for early-stage interventions, reducing late-stage healthcare expenditure[6] and ultimately increasing the chances of better treatment outcomes. Regional, rural and remote general practices, as well as mobile health providers, also see the value in IVDs supporting fast, portable and accurate diagnoses to enable faster and more effective clinical support for patients[7].

Furthermore, diagnostics (e.g. lateral flow tests) is a platform technology that can be easily adapted in times of need. Thus, having this sovereign capability will position Australia to respond to threats more holistically and efficiently.

Over the last 20 years, the diagnostic landscape has rapidly scaled because of accelerating innovation, such as real-time access to data and simplified collection processes[5, 8]. These advances have seen IVDs being produced more quickly and accurately with greater cost-effectiveness, accessibility and simplicity of use[8].

Worldwide, the market for IVDs is robust and projected to grow to approximately AU$150 billion by 2024[9], driven by four key factors[8]:

1. Growing ageing population
2. Rise in chronic and infectious diseases
3. Increasing population of point-of-care and in-home personalised testing
4. Growing use of automated instruments.

Sovereign capability will position Australia to respond to threats more holistically and efficiently.

Sovereign Manufacturing Capability

There continues to be debate on what sovereign capability means, but it is clear that strong manufacturing and reliable and robust supply chains are key in realising overall improvements and enhancing resilience[10].

Sovereign capability primarily relates to ensuring a degree of self-sufficiency and security for a nation, reducing vulnerability due to external dependency in key areas of national interest, such as population health. This is especially true for medical products that cannot be easily stockpiled, as is the case for most IVD test consumables, which have a short shelf life and rigid storage temperature requirements.

Until now, Australia has focused on a goal of sovereign capability in the area of defence. However, COVID-19 has forced policymakers to pay greater attention to sovereign capability in other areas, particularly healthcare[10]. Australia has high healthcare operational capability, being able to deliver high-quality care through strong services and research sectors, but low industrial capability, being unable to locally manufacture healthcare technologies – a weakness exposed during the pandemic[10].

Sovereign capability means establishing and retaining manufacturing capabilities for key IVD products, ensuring a degree of self-sufficiency and security for Australia. To achieve this, sovereign capability must encompass all the adjacent functions to research, develop, retain and sell IVD products. In areas where Australia is not able to be fully self-sufficient, robust supply chains are vital in realising overall improvements and enhancing resilience.

A recent analysis of supply chain management in the construction industry identified 10 key characteristics that inform sovereign capability. They include design management, risk management, inventory management and logistics management[11]. Sovereign manufacturing capability is thus more than just manufacturing, and instead encompasses all the adjacent functions to make, maintain and dispose of products.

Sovereign manufacturing does not necessarily mean Australia must increase the number of local manufacturing companies to be fully self-sufficient in all aspects of IVD products. It instead means, in areas where we are not manufacturing products, increasing and supporting the capability of existing local manufacturers to ensure supply is available at times of need[10]. This National Action Plan will therefore include an analysis of supply chain resilience to determine which products and materials Australia is heavily reliant on importing, to ultimately identify the availability of substitute and alternative products and materials.

The benefits of sovereign manufacturing capability stretch beyond strengthening Australia's sovereignty and self-sufficiency to include:

- Increased economic growth
- Greater participation in international value chains
- Increased employment opportunities and diversification of skills
- Ready supply of products
- Industrial capability, which can be maintained and redirected in crises
- Retention and growth of manufacturing skills.

Above all, advanced manufacturing and reliable, robust supply chains are key in ensuring overall improvements to the healthcare system and in protecting the health and wellbeing of Australians.

2 ONGOING INITIATIVES

To understand what gaps the National Action Plan will fill for establishing end-to-end sovereign manufacturing capability for diagnostic tests in Australia, it is important to understand the work that is currently underway.

The Australian Government is moving to establish a $15 billion National Reconstruction Fund, with $1.5 billion earmarked for medical manufacturing. The National Reconstruction Fund, currently under development, aims to boost domestic manufacturing capabilities for medicines, vaccines and diagnostic tests.

The Minister for Industry and Science, the Hon. Ed Husic MP, has noted[12]:

> **"There is nothing more important than the health and wellbeing of Australians. As we navigate a rapidly changing world, being able to produce medicines and vaccines onshore for our community and our global trade partners in Asia, the Pacific and beyond can only hold us in good stead."**

As part of the former Australian Government's strategy to help manufacturers scale up, become more competitive, resilient and build scale in the global market, two key documents were developed:

1. Medical Products National Manufacturing Priority road map[13]
2. Sovereign Manufacturing Capability Plan[14,15]

Although the Medical Products National Manufacturing Priority road map and the Sovereign Manufacturing Capability Plan are no longer active, both uncovered manufacturing challenges and potential opportunities that could be leveraged.

Medical Products National Manufacturing Priority Road Map

The former Modern Manufacturing Strategy identified that economic conditions must be optimised to improve manufacturer's competitiveness, particularly in:

Skills: Although the Australian workforce is highly skilled, industry stakeholders identified skill gaps such as those required to design, test and manufacture medical products.

Procurement: For many products, it is governments that are the key customers. Having well-functioning and streamlined systems for supplying multiple entities and levels of public health systems can be critical for many medical products manufacturers to be sustainable..

Regulation: The ability to navigate regulation effectively and efficiently is a key enabler of competitiveness for new businesses and products to enter the market. The regulatory differences between states and other countries impact on the market access for high-quality Australian products.

Energy: Affordable energy and energy technology is critical for medical products manufacturers, particularly when they play a role in supporting human and animal health and delivering critical medical supplies.

Competition: Capital is highly mobile in the medical products sector and many countries are aggressively targeting private sector investment. Therefore, it is important to get the economic conditions right to attract investment.

Furthermore, the three primary barriers identified by the former medical products taskforce that limit commercialisation for many small and medium enterprises (SMEs) include:

1. Difficulties in translating research into competitive products
2. Obstacles in integrating local and international supply chains
3. Challenges in establishing the conditions that enable collaboration.

Potential opportunities

To help Australian manufacturers commercialise and increase their scale in the medical products sector, three areas of co investment were identified in the report:

- Helping manufacturers finalise translation of their research in Australia, to provide a pathway to full-scale Australian production.
- Helping manufacturers access and integrate with local and international supply chains, enabling them to get competitive products into global markets.
- Supporting the development of vibrant manufacturing ecosystems through collaborations that increase the commercialisation of innovative ideas and expand manufacturing output.

Sovereign Manufacturing Capability Plan

The Sovereign Manufacturing Capability Plan focused on six critical products including biopharmaceuticals and personal protective equipment which were identified as necessary for Australians' health, safety and wellbeing in a crisis.

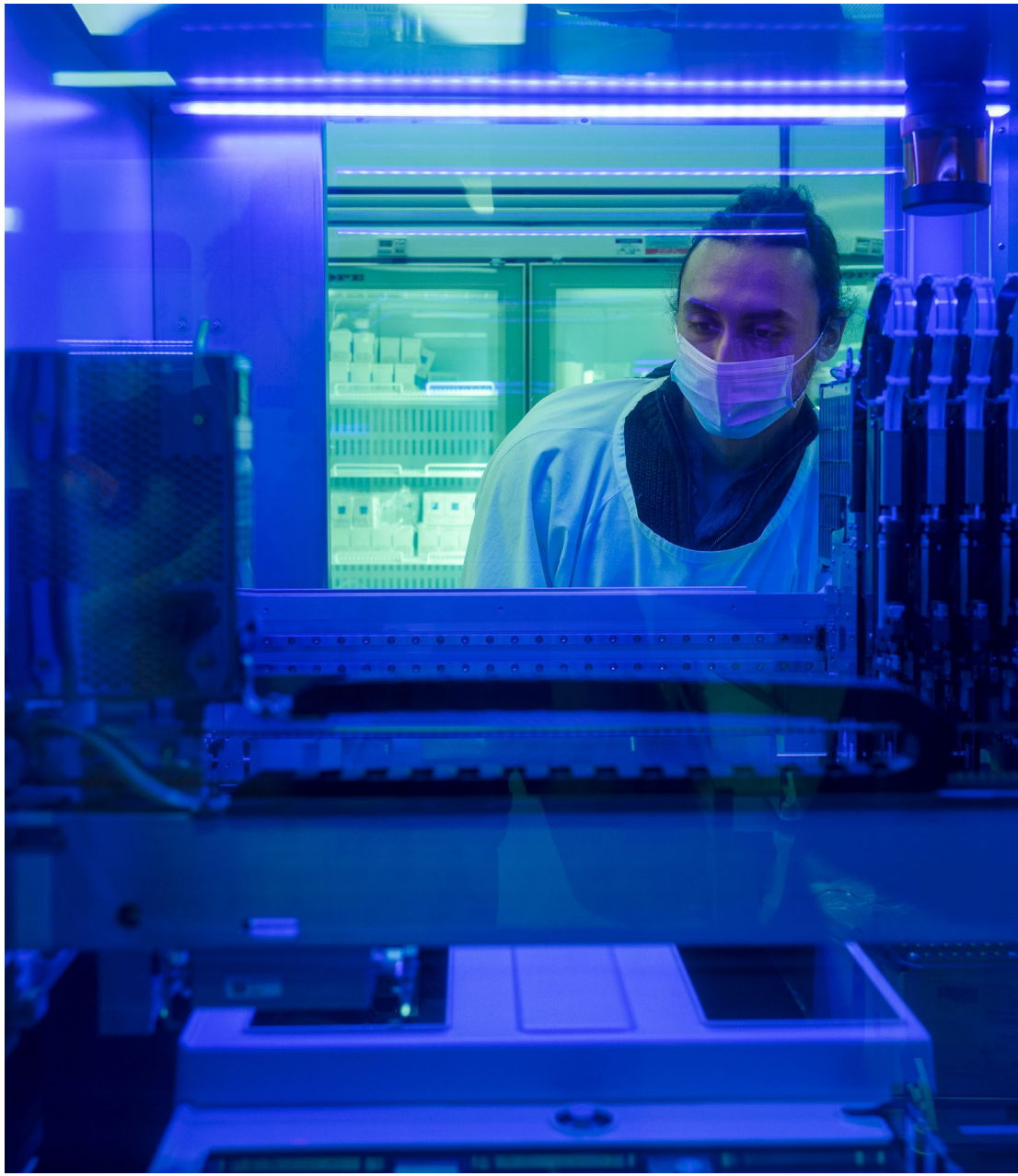
Barriers or vulnerabilities in the supply chain that were identified were as follows:

- Lack of suitable alternatives for some products
- Limited adaptability of manufacturing processes (notwithstanding some personal protective equipment activity during COVID-19)
- Limited holding of stock by businesses
- Lack of availability of packaging
- Lack of skilled workforce
- Poor end-to-end visibility across supply chains
- High level of regulation.

Potential opportunities

Opportunities to address supply chain vulnerabilities were as follows:

- Enhancing existing and growing emerging manufacturing capabilities that build on Australia's niche capabilities and/or competitive advantages.
- Developing substitutes or alternatives for a critical product.
- Strengthening supply chain transparency, which may include incentivising uptake of digital technology capability or implementing a system to track and trace chemical supplies.
- Building the capability of the existing and future workforce, such as establishing a training centre of excellence.



3 CONSULTATION PROCESS

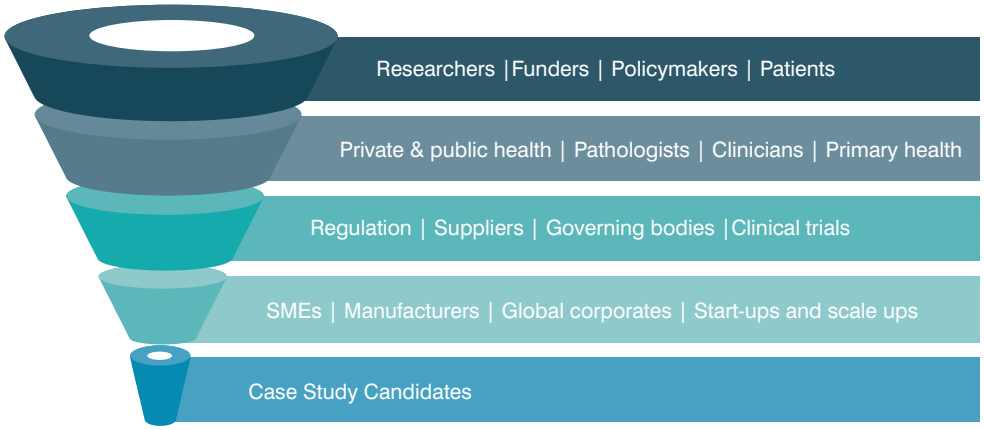
To gain a comprehensive understanding of Australia's current diagnostic testing capability and supply chain resilience, MTPConnect, PTA and HTANALYSTS are undertaking extensive interviews with stakeholders across the value chain in Australia, including participants from multiple geographical locations across the entire diagnostic life cycle.

A phased engagement framework is being used to analyse the current status, strengths, gaps and support required to establish Australia as a regional centre of excellence for diagnostic technology development.

Stakeholder mapping was carried out to ensure a diverse range of stakeholders are consulted. A cross-section of the stakeholder funnel (Figure 1) is being consulted at each stage.

Stakeholders include, but are not limited to, researchers, funders, pathologists, regulation, governing bodies, SMEs, manufacturers, global corporates, start-ups, and scale ups.

Figure 1: Stakeholder mapping using a funnel approach



Stakeholder engagement involves three phases:

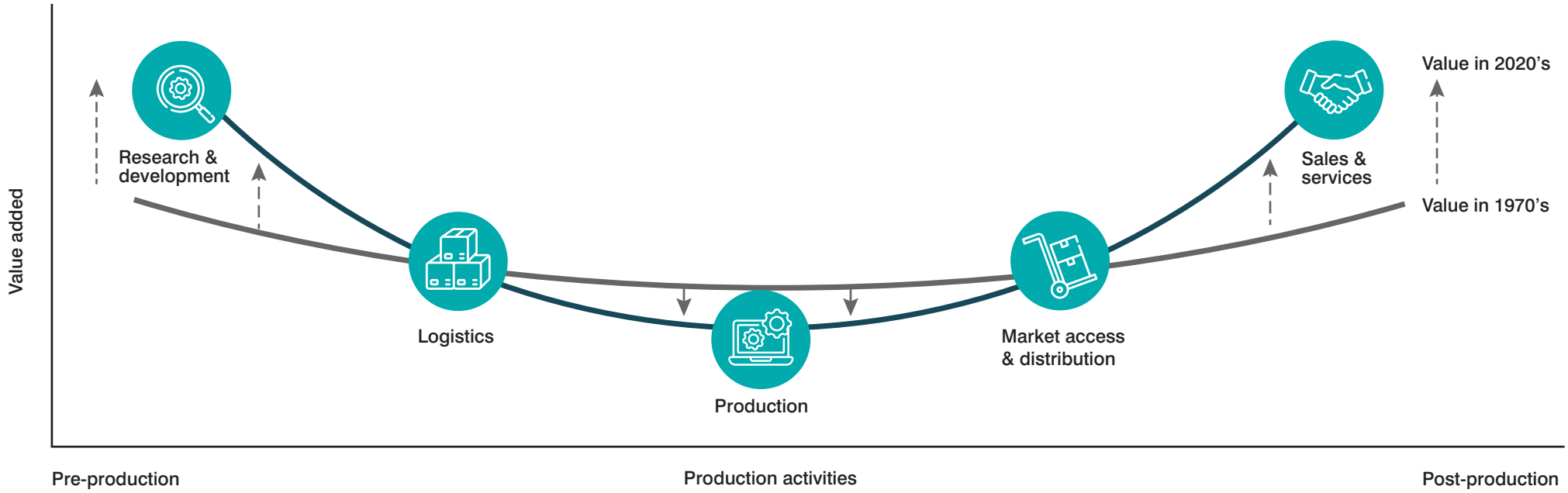
- **Phase I:** Interviews focused on identifying priority and urgent issues within the diagnostic testing landscape, informing this preliminary findings report.
- **Phase II:** Interviews will focus on developing recommendations for the gaps/challenges identified during Phase I.
- **Phase III:** Post interview analysis will involve testing the suitability and viability of the National Action Plan recommendation.

Phase I interviews are underway. These discussions have followed a rigorous and structured approach to facilitate a thematic analysis at the completion of Phase I in October. Phase I interviews covered two key topics:

1. **Sovereign manufacturing capability for IVD products in Australia:**
   This discussion is guided by the manufacturing smile curve to identify barriers and opportunities across all sections of the supply chain. The manufacturing smile curve includes R&D, logistics, production, market access and distribution, as well as sales and services.

2. **Supply chain resilience:**
   This discussion aims to identify critical/priority products, raw materials and components that continue to be imported within the diagnostic landscape, as well as potential strategies to improve the manufacturing capabilities of these products and materials in Australia.

Figure 2: Schematic of the manufacturing smile curve



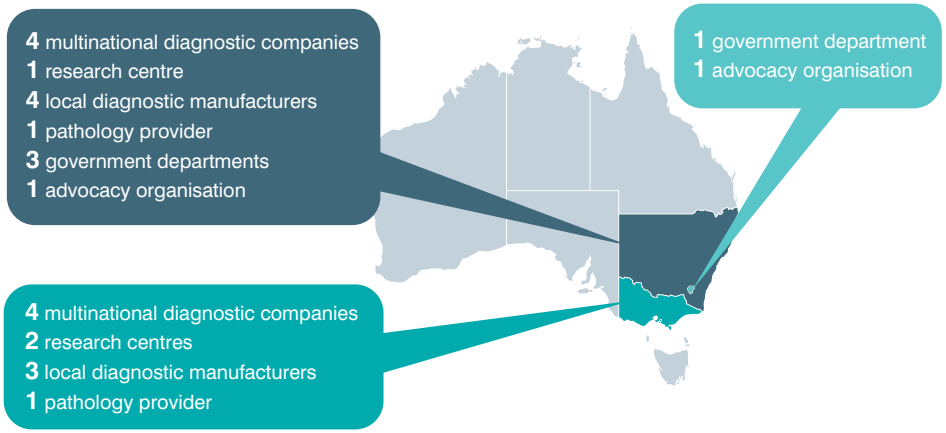
Key stakeholders in Phase I will be followed up with a survey to capture where Australia's imported IVDs are sourced and the potential alternative that may exist if needed – an activity that has never been mapped in Australia.

4 PRELIMINARY FINDINGS

Preliminary findings have been developed from Phase I interviews in three states and focus mainly on manufacturing capabilities. Further research on the supply chain resilience topic will continue through Phase II and III and will inform the recommendations in the final report.

These findings are based upon 26 interviews from Phase I which were conducted across New South Wales, Australian Capital Territory and Victoria up until September 2022. These were carried out with eight multinational diagnostic companies, seven local diagnostic manufacturers, four government departments, two pathology providers, three research centres and two advocacy organisations. Data from the remaining three states will be analysed in the final report.

Figure 3: Breakdown of the 26 stakeholders interviewed as part of the Preliminary Findings Report



Stakeholders interviewed to date have agreed on the importance of IVDs for the health of Australians, particularly in terms of early diagnosis and prevention and in times of serious threat (such as during the COVID-19 pandemic). By manufacturing and becoming the centre of excellence, Australia can create high-tech manufacturing jobs and generate export income, all as a by-product of protecting the health of Australians. Australia has also been identified by stakeholders as a 'premium market' to produce reliable and high-quality products. Australian-manufactured IVD products were also described as having good market appeal in the Asia-Pacific region, as well as globally, due to perceptions of safety, quality and reliability and the halo of the 'Brand Australia'. If the market conditions are right, it is therefore feasible to create economies of scale in exporting for manufacturers.

Sovereign Manufacturing Capability

From the stakeholder engagement process, a clear consensus emerged that Australia is vulnerable to supply chain disruptions driven by geopolitical instability, which means it is critical to improve sovereign manufacturing capabilities, as well as the resilience of the supply chain.

However, despite the presence of some Australian companies developing, manufacturing and selling diagnostic tests locally and overseas, the current environment is perceived to be unfavourable by a range of stakeholders.

The key barriers identified to date are summarised in Figure 4 (p.21), according to the following five categories:

1 Research & development

The main barriers identified include the inability for a company or individual to scale up a product, following R&D. Once proven, many do not have the skills, knowledge or expertise to navigate the next steps through to successful production and sales in Australia. There is also a lack of Australian venture capital investment to support the commercialisation of products. As a result, many companies exit the country or individuals sell their intellectual property overseas. Because of how often this scenario occurs, the post-R&D phase is often termed the 'valley of death' by individuals in the sector.

Government research grants are readily available, particularly for universities and academics. Although these grants are important, the outputs can often be focused heavily on the number of research papers produced and a lack of support is provided beyond the development and design of a product. When providing grants, additional requirements to be successful in the IVD setting are not considered. In the IVD setting, time from development to design and production may take three to seven years. Often the investment does not provide the end-to-end support required and thus fails to have the desired effect. In some cases, the academic entities receiving research funds have been unable to connect with companies that have the requisite manufacturing and quality expertise; in other cases, the companies have struggled to access clinical samples or data to complete validation testing.

For example, one SME was unable to access samples locally and was required to purchase blood samples from the US for US$110 (A$170) per sample, which was considered expensive, particularly for an SME.

For SMEs, it was identified that there are limited laboratory or manufacturing spaces available to design, test and validate products.

Preliminary outcomes to explore through further consultation:

- Establish a manufacturing hub to connect academic entities, SMEs or manufacturers with the services and resources they need to navigate across the manufacturing smile curve.
- Establish communal laboratory spaces that start-ups or SMEs can hire and utilise.
- Facilitate and provide access to biobanks, samples, control material, clinical data and clinical trials for product testing and validation.
- Foster partnerships across the manufacturing smile curve to facilitate the final stages of validation, approval and adoption.

2 Logistics

Increasing logistics costs are making it more difficult for Australian manufacturers to produce IVD products locally. The cost to both import raw materials and export finished products internationally is high. For example, one stakeholder described spending approximately 9 cents on shipping for every COVID-19 swab, which was described as significantly higher than the cost of manufacturing. Despite this, companies that are focused on reducing their environmental impact highlighted the importance of having a manufacturing facility in Australia, if there is a market available for the sale of these locally manufactured products.

Some stakeholders also raised the disconnect between Australian Biosecurity Import Conditions (BICON) and TGA emergency authorisation during the COVID-19 pandemic. BICON import permits are often complex to navigate for inexperienced companies. Raw materials required for local IVD manufacturing were being held by border control officers, delaying development and production and reducing the impact of TGA prioritisation of the review of COVID-19 IVDs.

Preliminary outcomes to explore through further consultation:

- Improve the effectiveness and use of the current Export Market Development Grants.
- Increase local availability of key raw materials.

3 Production

Government grants are available for both R&D and production, and although valuable, these grants were described by some companies as ‘laborious’. The information, time and resources required to apply for a grant and then the reporting requirements after receiving the grant make it difficult to realise the value. Many companies chose not to apply for particular grants for these reasons.

The need for Australian manufacturers to compete in global markets in order to be sustainable has been raised several times to date. Unless the IVD product is unique, Australian manufacturers need to be able to develop and manufacture products at a low cost. However, human resource, energy and logistics costs in Australia result in higher prices, significantly reducing cost competitiveness.

Preliminary outcomes to explore through further consultation:

- Long-term strategic commitment to manufacture specific or priority IVD products.
- Establish a central hub for medical device manufacturing with all the facilities and expertise for medical devices for companies to provide their blueprints.
- Map national imperatives for IVD innovation and production and then have a process where local providers can work with the government on strategies to enhance this.
- Prioritise multiuse and adaptable platform technology.

4 Market access & distribution

The TGA leads the way in regulation and reform, maximising safety and efficacy of products registered for Australians. However, regulatory challenges still exist for local companies that have managed to overcome the R&D challenges.

While the TGA has established processes of industry engagement, including establishment of SME Assist, some companies, especially those with limited experience of the IVD framework, have articulated that they find it difficult to meet the validation testing and information required for TGA product registration on the Australian Register of Therapeutic Goods (ARTG). In other cases, navigating the requirements for quality certification, registration and reimbursement for companies has caused extensive delays.

Importantly, government grants and funding initiatives into R&D are not aligned with broader procurement. Local market conditions are not viable by way of the Medicare Benefits Schedule (MBS) rebate levels and 'buy local' mandates in procurement processes.

MBS rebate levels are low, particularly in comparison to the UK and US; some IVD products are not able to be reimbursed and often new and innovative products are not reimbursed at all. MBS reimbursements for IVDs are paid to the accredited pathology provider or general practitioner, and not the technology provider, so there is little left for manufacturers. This is different to the pharmaceutical table, where the technology provider negotiates the reimbursement and the service provider (pharmacist) gets a fee.

Preliminary outcomes to explore through further consultation:

- Additional TGA support and advice for researchers and industry to facilitate product registration, with consideration of funding options to support resource increase.
- Health Technology Assessment review may be able to enhance the environment for sovereign manufacturing of IVDs.
- Regular horizon scanning to identify, fund and accelerate the development, introduction and purchasing support of innovations.
- Increase reimbursement for IVD products, such as rapid and point-of-care testing in the community.
- Grants and support directly related to regulatory approval and reimbursement.

5 Sales & services

For many products, it is governments that are the key customers, and the misalignment between government grants and procurement means homegrown products are not being purchased and new products (i.e. those that result from the grants) are not being supported. Where the government chooses not to 'buy local', products are sold or manufacturing is moved overseas closer to the primary customers. During the COVID-19 pandemic, some companies' experience has shown that overseas products were preferred in the Government procurement process when it came to locally developed and produced polymerase chain reaction (PCR), rapid and point-of-care tests. A recent example of this occurred in New South Wales, where a diagnostics company rapidly produced high-quality, tested and validated PCR COVID-19 RATs. The company approached the federal and state governments to gain support to manufacture in Australia and was unsuccessful. The company has since set up manufacturing facilities in the US, where it has been supported by the US Government, and now sells tests in the US market.

Preliminary outcomes to explore through further consultation:

- 'Buy local' mandates or de-risking procurement of new, innovative IVD products.
- Legislate a percentage of locally sourced IVDs from the commonwealth stockpile, to ensure companies are not solely reliant on foreign-produced goods.
- Similar to the US military, there may be a legislation that companies can only sell products to the government for the best price to avoid corruption.

Figure 4: Overview of preliminary findings for manufacturing capability

1 Research & development

- Difficult to navigate, fund and source patients for clinical trials
- Funding into R&D does not align with Australian Government procurement
- Lost R&D tax incentives for companies that return ≥$20 million annually
- Academics or researchers are not well equipped or have knowledge on how to translate and commercialise products. There is also a limited number of industry players in R&D
- No pathway to full-scale production and sales in Australia
- Limited independent laboratory spaces available
- Current ethics processes are time-consuming with a duplication in processes across sites

2 Logistics

- High costs of importing or exporting products or raw materials
- Importing simple raw materials is difficult and product quality needs to be tested upon arrival
- Lack of storage space for products or materials imported
- Lack of global sea and airfreight
- Disconnect between BICON and TGA emergency use authorisation
- Supply chain challenges resulting in market shortages

3 Production

- Difficult to forecast production demand and sales with changing government regulations and a lack of long-term commitments to procurement
- Current incentives for manufacturing do not match company needs
- More economically viable to set up manufacturing offshore
- Inability to produce all raw materials or products because of environmental impacts
- Government grants can be time-consuming
- If the majority of customers are overseas, more cost-effective to manufacture close to the customer

4 Market access & distribution

- The centralised government procurement process (often from overseas) is impacting local suppliers
- Low reimbursement for services or products in Australia, leaving little for manufacturers
- The assessment process is also inequitable for new and innovative technologies
- TGA is under-resourced for providing advice to industry to facilitate product registration
- Duplicative reimbursement and regulation processes increasing time to market

5 Sales & service

- Misalignment between health policy and procurement. The Australian Government is not prioritising Australian-made IVDs
- Australia's market is small and thus for Australian manufacturers to be successful, an international market is needed
- Australian companies are reluctant to switch to local providers
- Difficult to be cost-competitive with large multinationals
- Lack of communication regarding policy changes between government and companies

What is the impact?

- Companies or individuals will sell their intellectual property (IP) overseas and exit the Australian market
- Difficult to be cost-competitive on a global scale. Less security in product or raw materials being imported
- Manufacturing facilities are established overseas, fewer jobs are created and the number of products exported is reduced
- Products to market are slow or they never reach Australian customers
- Manufacturing facilities are moved or are established closer to the customer (overseas)

If these barriers can be overcome through an end-to-end approach, Australia can realise the benefits of increased jobs, retention of skilled individuals, secure products, more control over quality and ultimately **better health outcomes for Australian citizens**

5 OVERSEAS EXAMPLES

The project is also exploring best practice from around the world to inform the National Action Plan.

The Manufacturing Technology Centre

The Manufacturing Technology Centre (MTC)[16] was established in the UK in 2010 as an independent research and technology organisation with 'the objective of bridging the gap between academia and industry – often referred to as "the valley of death"'.

In 2011, MTC opened a manufacturing facility, making it one of the largest public sector investments in UK manufacturing. MTC is involved in R&D, training, advanced manufacturing management and factory design. Thus, partnerships can be established with entrepreneurs and SMEs across the UK supply chain to increase productivity and bring concepts to market. MTC is able to do this by improving productivity, reducing costs, embedding innovation and de-risking the use of technology.

CASE STUDY

MTC helped Albert Jagger – a vehicle hardware supplier – to re-shore a product range, that a competitive marketplace had led them to purchase from China, to their UK engineering facility.

MTC created a project plan to evaluate the financial, performance, technology and training needs to profitably re-shore products.

MTC assisted in ensuring resilience of supply chains, reduced production costs and increased productivity within the UK.[17]

Research and Development Tax Incentives

The UK Government supports innovative PCR businesses by incentivising them to invest in R&D – allowing companies to claim an enhanced corporation tax deduction or payable credit on their research and development costs. In 2021, the UK Government committed to a review of these tax incentives to ensure they are internationally competitive and effectively target activities that drive good outcomes for the UK economy[18].

Life Sciences Innovative Manufacturing Fund

As part of the Global Britain Investment Fund, the Life Sciences Innovative Manufacturing Fund (LSIMF) was granted £354 million, which will support life sciences manufacturing[19]. The LSIMF will provide £60 million in capital grants for investment in the manufacture of human medicines, medical diagnostics and medical devices.

The fund's objectives are as follows:

1. Creating economic opportunity through investments that will provide high-wage, high-skilled jobs.
2. Deploying cutting-edge innovations (at both pilot and commercial scale), which can be embedded in either the product itself or within the manufacturing process.
3. Increasing health resilience, either through increased domestic capacity or by providing flexible capabilities and ability to be re-deployed in some way in a future health emergency.
4. Minimising impact on the environment, which might include reduction in input resources or using alternative input materials to become more sustainable or support the government's net-zero target.

Rapid Acceleration of Diagnostics (RADx)

During 2020, as the COVID-19 pandemic began spreading globally, the National Institutes of Health (NIH) – in partnership with the Biomedical Advanced Research and Development Authority (BARDA) and other US Government organisations – launched the Rapid Acceleration of Diagnostics (RADx) initiative to speed innovation in the development, commercialisation and implementation of technologies for COVID-19 testing[20].

Supported by US$1.5 billion government funding, RADx established four programs to rapidly scale testing to provide accurate, reliable and accessible tests across the US[21]. These successfully reduced the development timeline from years to months[21].

1. **RADx Tech:** With an allocated budget of US$666 million, the program aimed to speed the development, validation and commercialisation of innovative point-of-care and home-based tests. Via a 'shark-tank' challenge, approximately 100 companies were matched with technical, business and manufacturing experts. Today, the program has enormous potential to impact the response to other pandemics[21, 22].
2. **RADx Underserved Populations (RADx-UP):** This program was created to understand and reduce the disparities in COVID-19 morbidity and mortality. Data from more than 125 government-supported research projects (budget US$512 million) helps policymakers develop effective COVID-19 testing strategies[22, 23].
3. **RADx Radical (RADx-rad):** Supported by a budget of US$187 million, the program supports innovative and non-traditional diagnostic approaches to address current gaps in COVID-19 testing and surveillance[22].
4. **RADx Advanced Technology Platforms (RADx-ATP):** This program supported advanced and late-stage COVID-19 testing technologies that were nearly or already FDA-approved to rapidly scale and expand. This program had a budget of US$191 million[22].

CASE STUDY

The huge success of the RADx program has been highlighted by several local Australian diagnostic manufacturers throughout Phase I interviews.

One company shared that they participated in a networking call with the NIH, where a group of nearly 30 experts provided support and advice. They emphasised the advantages of this opportunity and stated that it would be great if there was a similar networking program in Australia.

South Korea's Biotechnology Industry

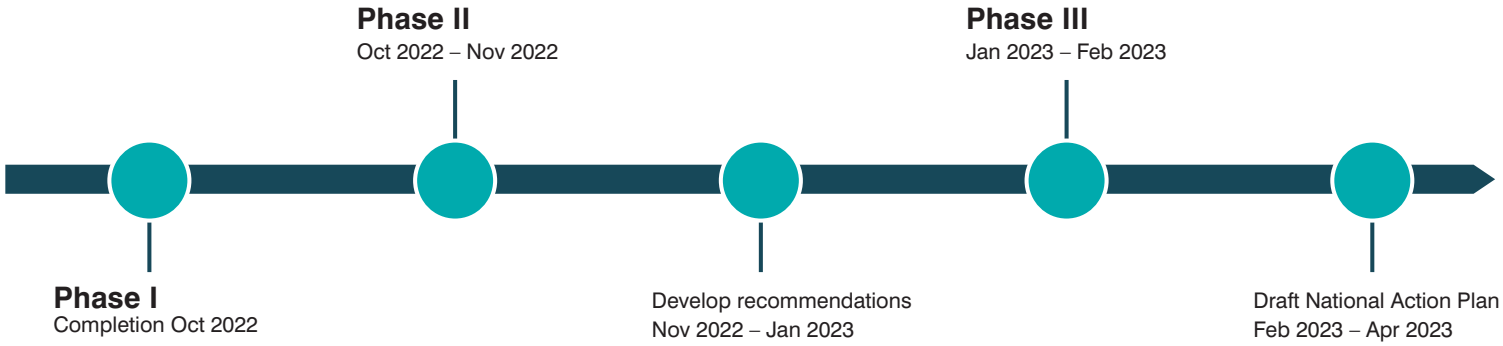
South Korea is one of the leaders in R&D in the Asia-Pacific region and has been highlighted as a key international example by stakeholders for its ability to quickly bridge the gap between R&D and development of innovative IVDs[24]. South Korea's success in IVD translation could be attributed to the following factors:

1. South Korea has established a clinical trial powerhouse with a total of 166 clinical trial centres. This facilitates an accelerated clinical trial approval system for medical devices[25].
2. South Korean regulatory systems are harmonised with international regulations, which enables the Ministry of Food and Drug Safety (MFDS) to effectively manage medical devices[25].

6 NEXT STEPS

Stakeholder consultation in Phase I was completed by mid-October 2022, with Phase II beginning soon after. Phase I provided a deep understanding of the key barriers to sovereign manufacturing capability in Australia, while Phase II will focus on developing recommendations to these barriers. The final phase will include testing suitability and viability of the recommendations to ensure each is actionable and attainable.

Figure 5: Timeline and next steps for the project



The final report (National Action Plan), which will include actionable next steps for providing Australia with sovereign diagnostic product manufacturing capabilities, is expected to be delivered to government in April 2023.

Connect with the team via the below details:

Email: diagnostics@mtpconnect.org.au

Website: www.mtpconnect.org.au/programs/diagnostics

Working group

MTPConnect is an independent, not-for-profit organisation focused on growing Australia's medical technology, biotechnology, pharmaceutical and digital health (medical products) sector. MTPConnect forges stronger connections between research and industry and maximises opportunities for Australians to make scientific and technological breakthroughs that are successfully translated and commercialised.

MTPConnect works to increase collaboration and commercialisation, improve management and workforce skills, optimise the regulatory and policy environment and improve access to global supply chains and international markets.

In this way, MTPConnect is building a more resilient and competitive medical products manufacturing sector.

PTA is the peak body representing manufacturers and suppliers of about 95 percent of all tests and technology used in pathology laboratories, hospitals, general practice and for self-testing.

PTA members develop and manufacture tests and testing technology, and conduct clinical trials and validation testing to meet the requirements for inclusion on TGA's Australian Register of Therapeutic Goods (ARTG); they also train doctors and scientists in the use of this technology, provide technical support to maintain devices operating at their optimum and maintain the supply chain – all of which makes pathology possible.

The member companies of PTA strive to provide tests and testing technology that deliver the highest quality, accessible and affordable healthcare services to all Australians.

HTANALYSTS has been providing boutique impact measurement and communication services for 20 years. It strives to make a powerful impact on society by driving human-centric outcomes. Its purpose is to have a powerful impact on the health of society by connecting people with the best treatments in the fastest amount of time.

Originally founded in 2002, **HT**ANALYSTS has grown to become a leader in healthcare and impact assessment consulting, providing services to the healthcare industry. In recent years, its scientific rigour has proven valuable for those outside the traditional pharmaceutical world, and this has seen the company grow its capabilities to include expertise in social impact measurement, government services, healthy ageing and disability.

HTANALYSTS has extensive experience working with numerous stakeholder groups to develop a comprehensive understanding of complex topics such as health technology assessments, genomics, climate change and unintended pregnancies.

Abbreviations

ADAPT	Australian Diagnostics Action Plan Team
ARTG	Australian Register of Therapeutic Goods
BARDA	Biomedical Advanced Research and Development Authority
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DISR	Department of Industry, Science and Resources
EAG	External Advisory Group
HTANALYSTS	Health Technology Analysts
IVD	In vitro diagnostic
LSIMF	Life Sciences Innovative Manufacturing Fund
MBS	Medicare Benefits Schedule
MMS	Modern Manufacturing Strategy
MTC	Manufacturing Technology Centre
PCR	Polymerase chain reaction
PTA	Pathology Technology Australia
RADx	Rapid Acceleration of Diagnostics initiative
RAT	Rapid antigen test
R&D	Research and development
SMEs	Small and medium enterprises
SCRI	Supply Chain Resilience Initiative
TGA	Therapeutic Goods Administration

Glossary

Consumables	Supplies required for the manufacturing process that do not form part of an end product.
End-to-end	Production process that takes a product from its beginning (R&D) to its end (service) – i.e. across the smile manufacturing curve.
In vitro diagnostic (IVD)	A reagent, calibrator, control material, kit, specimen receptacle, software, instrument, apparatus, equipment or system, whether used alone or in combination with other diagnostic goods for in vitro use[4].
Manufacturing	Process of turning raw materials into finished goods through the use of tools, human labour, machinery and chemical processing.
Manufacturing smile curve	Includes R&D, logistics, production, market access and distribution, as well as sales and services.
Raw materials	Inputs that are used in the manufacturing, transformation or assembly process of an end product.
Sovereign capability	Relates to ensuring a degree of self-sufficiency and security for a nation, reducing vulnerability due to external dependency in key areas of national interest[10].
Stakeholder	A stakeholder is any government, organisation, medical, academic group or person that has a direct interest in the process and outcome.
Value chain	Involves the various business activities and processes needed along the manufacturing smile curve to create a product or service.

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