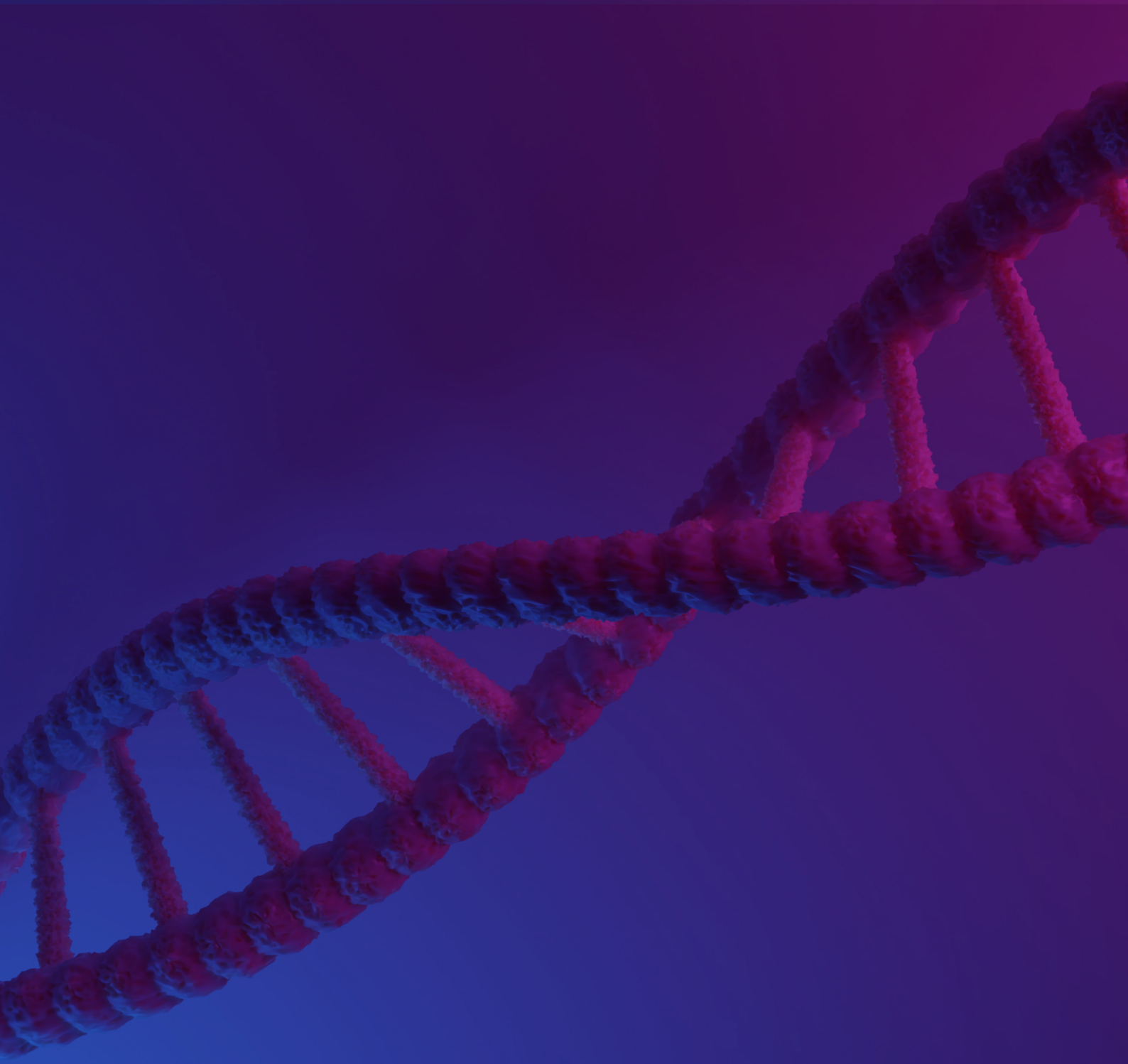

Roundtable: Response and resilience of the Australian life sciences sector

Biointelect

Pfizer

Executive summary

As the world emerges from the pandemic, it is critical to reflect on what has been learned and how to make strategic and sustainable investments for the future. Australia must identify and prioritise local investments, co-designed with stakeholders, and collaborating with the global life sciences sector. Effective investments have the potential to deliver benefits across the ecosystem, promoting discovery and early-stage research, clinical trials and the delivery of world class healthcare and preventive health for the wellbeing of all Australians.

Pfizer's white paper, Response and Resilience: Lessons Learned from Global Life Sciences Ecosystems in the COVID-19 Pandemic, highlights learnings from across the world of the favourable characteristics of the life sciences sector to respond to the COVID-19 challenge. A roundtable was held in Sydney on 25 March 2021 to discuss aspects of Australia's response to the pandemic.

The Australian life sciences sector is complex, built around core activities across the product development value chain, guided by a skilled workforce, funding and investment, regulatory and policy frameworks. Understanding our strengths, weaknesses and opportunities is fundamental to building resiliency and responsiveness to future threats. Figure 1 shows a simplified SWOT analysis of the Australian biomedical life sciences ecosystem, echoing key points raised during the roundtable discussion.

The following were identified as the priorities areas for future pandemic preparedness:

- Define areas of unmet need for future strategic investments into Signature Assets and establish catalyst models around common goals to ensure end-to end investment, collaboration and education in the life science sector.
- Develop a single front door for commercialisation with "lots of keys" and build partnerships around a common purpose between innovators and all expertise in the value chain, particularly early in product development.
- Leverage the Australian tele-trials model to drive forward the national agenda for harmonisation of clinical trial governance and ethics approvals as well as the broader implementation of digital technologies in clinical practice.
- Develop a more comprehensive and actionable national digital/health data strategy to enable patient-relevant outcomes to be captured, interpreted and applied to the next wave of technologies for regulatory and reimbursement purposes.
- Consider learnings from the pandemic to enhance speed, flexibility and collaboration in regulatory processes and provide government funding for TGA to expand its resource base and services.
- Support the implementation of the National Preventive Health Strategy through learnings from pandemic initiatives to enhance adult vaccination rates.
- Develop a national research agenda and industry-focused incentives for targeted commercialisation of research into areas of unmet need for Australians.

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Roundtable facilitated by Biointelect and sponsored by Pfizer Australia Pty Ltd.

Pfizer

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Biomedical Life Sciences Ecosystem "Framework"

KEY
Strengths
Weaknesses
Opportunities
Threats

VALUE CHAIN

Intellectual Property Protection

Regulatory Review and Approval

Basic R&D → Pre-clinical Testing → Clinical Trials Ph.1 → Clinical Trials Ph. 2/3

Specialized Research Infrastructure

Small-Scale/Pilot Manufacturing

Large-scale manufacturing

HTA/reimbursement

Sales & Mktg.

Distribution

Warehousing & Transportation

MARKET

Stockpiles → Government → Clinicians & Health System → Patient

Pharmaco vigilance

CORE ACTIVITIES

TALENT

R&D Personnel	Clinical Trials Management	Production & Business Operations	
Scientific knowledge & technical skills	Clinical knowledge & world-leading KOLs	Supply chain/distribution/PV expertise within multinationals	World class healthcare system
Bioinformatics skills (genomics); Product development & commercialisation expertise	Harmonisation of governance/ ethical requirements; Strategic design addressing reg/payer needs	QMS and manufacturing expertise in high-value therapeutics at a commercial scale	Health informatics and health economics; Health data and cybersecurity; RWD use in drug development

External Professional & Contracted Services

Attracting international highly skilled and experienced talent

R&D funding model for Australian universities (e.g., reliance on international income/talent)

Lack of targeted national research agenda and understanding of local unmet needs

CAPITAL

Investment in R&D (Public & Private)	Early-Stage Capital (Governmental, Private Equity or Industrial)	Production and Operations Capital (Industrial, Private Equity and Commercial Markets)

Established government funds for pre-clinical and clinical research (e.g., NHMRC, MRFF) and attractive R&D tax incentives

Prioritised and sustainable investment into research assets, workforce and sovereign manufacturing capability and capacity

Establishing catalyst model around common goals for end-to-end investment

Untargeted and uncoordinated investment with consequences on Australia's current position as one of the world leading destinations for R&D

POLICY & REGULATION*

Education · Government research funding · IP protection · Taxation policies · Liability regulations · Market Access · Public Health System Price policies

Workforce development · Government co-investment · Industry-focused initiatives · Production process regulations & quality controls

Speed, flexibility and collaboration across the value chain in regulatory and HTA processes

Rigid policies and regulation framework leading to limited patients access to novel therapies

CROSSCUTTING SUPPORTS

Figure 1 Simplified SWOT analysis of the Australian biomedical life sciences ecosystem

Modified from TEConomy Partners, LLC for Pfizer, Inc: Response and Resilience: Lessons Learned from Global Life Sciences Ecosystems in the COVID-19 Pandemic (2020) Figure 2; Sources for Australian information: MTP Connect: 'A Survey of Workforce Skills and Capacity in the Medical Technology, Biotechnology, Pharmaceutical and Digital Health (MTP) Sector'(2020).

Prioritised and sustainable investments

The COVID-19 pandemic has galvanised support for funding research projects and infrastructure in Australia. Strategic targeting and management of investments in basic research is required for this to translate into new vaccines and therapeutics that will ultimately benefit patients.

Innovative public-private partnership (PPP) models are used internationally to leverage financing across the life sciences sector, to pursue a common purpose and enhance pandemic preparedness. Box 1 describes the world's largest life sciences PPP, the European Innovative Medicines Initiative (IMI).[1]

PPPs are not a new concept in Australia, although they are underutilised in life sciences. National PPPs, with established hubs in states and territories and facilitated by cross-jurisdictional cooperation, should be explored to expand the capability and capacity of our life sciences infrastructure. Effective models would draw in not only private financing sources, but expertise and experience in the commercialisation of vaccines, therapeutics and other products.

The pandemic response leveraged existing expertise and networks in vaccine research, molecular genomics, gene sequencing and clinical trial alliances. Additional investments in capability and capacity in skilled workforce and infrastructure, will enhance our ability to respond to future threats. Ensuring that these investments are sustainable and will support research translation outside of pandemic conditions is key to this success.

Collaboration across the value chain to achieve commercialisation

The development of vaccines against COVID-19 in record time during the pandemic highlights the importance of effective collaborations in life sciences.[2, 3, 4]

There are many other excellent examples from the COVID-19 pandemic of collaborations within Australia, across our region and internationally, which should be documented and learned from. Box 2 describes several of these.

Pre-existing arrangements between research institutes, industry and governments are crucial to facilitating rapid cooperation during a pandemic and other emergency situations. The collaborations that were most successful in the pandemic (i.e., in vaccine development) had already established relationships and had in place robust agreements and clearly defined roles between the parties, allowing each to contribute to joint goals to their best capabilities and avoid duplication of effort. Such relationships take time to establish but provide clear benefits to research and commercialisation outside of pandemic conditions also.

BOX 1 - The Innovative Medicines Initiative (IMI) as a successful PPP model

The IMI was established in 2007 as a partnership between the European Union and European Federation of Pharmaceutical Industries and Associations (EFPIA). The overall goal to was to build a more collaborative ecosystem in the life science sector in Europe, in order to speed up the development of next generation vaccines, therapeutics and other products.

The IMI supports collaborative research projects that are aligned to it's Strategic Research Agenda and leverages networks of industrial and academic experts to boost pharmaceutical innovation in Europe.

Since its establishment, the IMI has not only provided significant funding to a wide range of collaborations (170 projects, involving over 5,000 participants), but has also helped to break down the barriers and cultural differences between industry and public sector institutions (universities and research institutes) in Europe. This type of "catalyst" model, focused around common goals, enables end-to-end, prioritised and sustainable investments, while maximising opportunities for collaboration.

1. https:/www.imi.europa.eu/
2. https:/www.csiro.au/en/Research/Health/Infectious-diseases-coronavirus/Fighting-the-virus/Vaccine-manufacture
3. https:/researchaustralia.org/covid-19/
4. https:/www.who.int/initiatives/act-accelerator/about

Product development that focuses on unmet patient needs requires engagement with patient representatives, regulators, and the healthcare system. Box 3 provides an overview of the Accelerated Access Collaborative (AAC), which is a single point of contact for innovators launching new products and programs in the English National Health Service (NHS). The AAC issues advice on areas of unmet need in the NHS population and how to best target innovations, aiming to increase investment and reduce wasted efforts and resources. It shows that innovation can be rapid and effective when supported by strong governance and reimbursement pathways and when there are shared visions, goals, and realistic expectations. [5]

Similar approaches should be explored for Australia. Key challenges remain in establishing strong academic-industry relationships in Australia.

These groups share a broad common purpose, to investigate and commercialise new vaccines, therapeutics, and products for patients. However, fundamental misalignment of incentives between academic researchers and industry leads to missed opportunities for research translation, towards this broad common goal. For example, funding for academic research comes predominantly from government and philanthropic sources, with grants that reward the generation of intellectual property, although such early filing is unattractive for future industry investment. Reliance on public funding sources, coupled with limited exposure to industry mentorship and expertise, generates an environment that is not conducive to commercialisation. Many of these issues are long-standing in the Australian life sciences sector and require comprehensive and targeted interventions.

BOX 2- Examples of local and international collaborations which enabled rapid development of therapeutics during COVID-19 pandemic

- **CSIRO, University of Queensland (UQ) and CSL** – In early 2020, CSIRO's biologics production facility produced and scaled-up the UQ protein-based vaccine candidate for COVID-19 for Phase 1 trials in record time. UQ also partnered with CSL for the large-scale production of the vaccine. Agreements between these organisations was already in place prior to the pandemic, which allowed the pandemic research program to begin within two weeks. While vaccine trials were abandoned in late 2020 due to "false-positive" HIV test results in Phase 1 trial participants, this effort demonstrates the importance of pre-existing relationships and agreements between collaborating entities, which enabled a rapid pivot to COVID-19 vaccine development.

- **University of Sydney (UoS) and various partners** – UoS was part of the consortium led by Fudan University, Shanghai, which released the world's first gene sequence of COVID-19 on 10 January 2020. UoS has also collaborated with Flinders University (SA) and US company, Oracle Cloud technology, to test a COVID-19 vaccine candidate.

- **Access to COVID-19 Tools (ACT) Accelerator** was a global collaboration to accelerate development, production and equitable access to COVID-19 diagnostics, therapeutics, and vaccines. Organised into four pillars of work (diagnostics, therapeutics, vaccines, and health system strengthening), it brought together governments, researchers, industry, philanthropists, public and global health organisations such as Bill & Melinda Gates Foundation, World Health Organisation (WHO), Coalition for Epidemic Preparedness Innovations (CEPI), Gavi vaccine alliance and others.

- **BioNTech SE (HQ: Germany) and Pfizer Inc. (HQ: USA)** – collaboration was already in place for mRNA development of influenza vaccines prior to the pandemic. When COVID-19 emerged, a small, confident and experienced group was able to rapidly pivot to COVID-19 vaccine development.

- **Sanofi (HQ: France) and GSK (HQ: UK)** – developing an adjuvanted vaccine for COVID-19, using innovative technology from both companies (S-protein COVID-19 antigen from Sanofi and adjuvant technology from GSK).

5. NHS England, https://www.england.nhs.uk/aac/what-we-do/how-do-we-do-this/; Catapult, https://ct.catapult.org.uk/about-us/

Technological advances

The COVID-19 pandemic has demonstrated the broad benefits of digitisation in the life sciences sector and highlighted the sector and general public's support for digital health initiatives. Digital health is a broad area and there is ongoing work to expand applications to improve patient outcomes across primary care, public hospital services and aged care.

The successful pilot and adoption of the Australasian Tele-Trials model applies digital technologies to facilitate participation in clinical trials for Australians in rural and remote areas. This supports greater equity of access to trials and world-leading innovative therapies – refer to Box 4,[6, 7, 8]. Australia, already known as a destination for high-quality clinical trials, is among the first adopters of tele-trials internationally.

BOX 3- Accelerated Access Collaborative (AAC) – the UK initiative designed to support the adoption of innovation

The NHS AAC is a partnership between patient groups, government bodies, and industry, working together to streamline the adoption of innovation (including medicines, diagnostics, devices, digital products, pathway changes and new workforce models). It provides a "single front door" for innovators, "demand signalling" to assist researchers, innovators and funders in understanding the needs of the NHS. Integrated horizon scanning, testing infrastructure and an agreed strategy to fund innovation (in consultation with stakeholders) provides a clear pathway for proving and implementing new technologies and programs.

Harmonisation of clinical trial governance and ethics processes, while continuing to focus on high-quality data capture, is critical to making Australia an exemplar for other countries. The National Clinical Trials Governance Framework[9] and the National Standard Operating Procedures for Clinical Trials, including Tele-Trials (as part of the National Tele-Trials Compendium) [10] are important examples of progress towards the goal of harmonised approaches to trial governance and ethics, although much work is still to be done to make this a reality across Australian trial sites.

BOX 4- Digitalisation of clinical trials

- **The Australasian Tele-Trial Model has increased access to clinical trials across Australia.** The Tele-Trial Model was initially developed by the Clinical Oncology Society of Australia (COSA) Regional and Rural Group in consultation with clinical trial sponsors, clinicians and regulators. The goal was to increase access to clinical trials for oncology patients living in rural and remote locations. COVID-19 accelerated the uptake of tele-trials in Australia in general, supported by the use of digital tools, including telehealth and remote monitoring. These tools enable patients from rural and regional centres (satellite centres) to be recruited and receive treatment closer to home through a link with primary trial centres. The model is currently used by states and territories, including Queensland, Victoria, South Australia, NSW and ACT.

- Syapse Learning Health Network - a global platform for sharing of Real-World Data (RWD). This global oncology network was developed by the Syapse, the US-based company in partnership with leading health systems, life sciences companies, and regulators to explore the use of RWD in improving the outcomes of cancer patients. Collection of data is enabled through additional incorporation of digital tools such as wearables and devices. The network currently aggregates data from over 1,300 clinicians, 450 hospitals across 25 states, enabling secure sharing of de-identified patient data between institutions. By using Syapse Learning Health Network's shared data, companies can better understand patient journey and treatment algorithms, further informing the design of clinical trials, as well as assisting with regulatory and reimbursement decisions.

6. Clinical Oncology Society of Australia: Australasian Tele-Trial Model (2016): https://www.cosa.org.au/media/332325/cosa-teletrial-model-final-19sep16.pdf
7. https://www.medicinesaustralia.com.au/policy/clinical-trials/tele-trials/
8. https://syapse.com/
9. https://www.safetyandquality.gov.au/sites/default/files/2020-02/national_clinical_trials_governance_framework_and_user_guide_-draft_for_pilot_2020.pdf
10. https://www.health.gov.au/resources/publications/national-standard-operating-procedures-for-clinical-trials

Greater utilisation of real-world data (RWD), wearable devices and electronic health records provide opportunities to improve the overall efficiency of clinical trial conduct, provide better data upon which to base reimbursement decisions and enhance patient care. International regulators and health technology assessment agencies have recognised these opportunities, which should be further explored in Australia. Box 4 describes a global precision oncology sharing network which uses RWD insights in streamlining clinical trial design and accelerating access to therapies for oncology patients.

Public confidence, privacy and security and system design are important considerations that must be addressed. COVID-related initiatives (e.g., widespread acceptance and use of the CovidSafe app for contact tracing; expansion of Australian Immunisation Register (AIR) to include mandatory reporting of adult vaccinations from July 2021 as part of the COVID-19 vaccine rollout) have demonstrated the potential to overcome these issues during unprecedented times, which may have created greater risk tolerance among the general public to data sharing and controls, including data linkage.

Substantial additional investments and policy actions are required to develop a more comprehensive and actionable national digital strategy that will optimise the collection, aggregation and analysis of health data in Australia for the benefit of patients.

BOX 5- Examples of Signature Research Assets leveraged for COVID-19 R&D in Australia

- The CSIRO's Biologics Production Facility was established under the National Collaborative Research Infrastructure Strategy scheme and administered by Therapeutic Innovation Australia. It provides assistance with optimisation, scale-up, production and purification of recombinant proteins in large quantities. CSIRO's biologics production facility rapidly produced and scaled-up the UQ protein-based vaccine candidate for COVID-19 for Phase 1 trials. New GMP-accredited Advanced Biologics Manufacturing Facility is expected to open by the end of 2021 to cost-effectively produce proteins (vaccines and anti-venoms) for Phase 1 and Phase 2 trials.

- Australian Centre for Disease Preparedness (ACDP) was initially established as Australian Animal Health Laboratory in 1985, to identify and respond to increasing threat of exotic pathogens, including those spreading from animals to humans. ACDP is one of the few facilities of Biosecurity level 4 (BSL 4) around the world to deal with zoonotic diseases. Since the start of the COVID-19 pandemic, the ACDP has been dedicated to preclinical work related to COVID-19 to speed up therapeutic and PPE development. In 2020, ACDP received substantial boost from the Australian Government, with a $220 million upgrade of the facility and additional $10 million to support COVID-19 specific work as required.

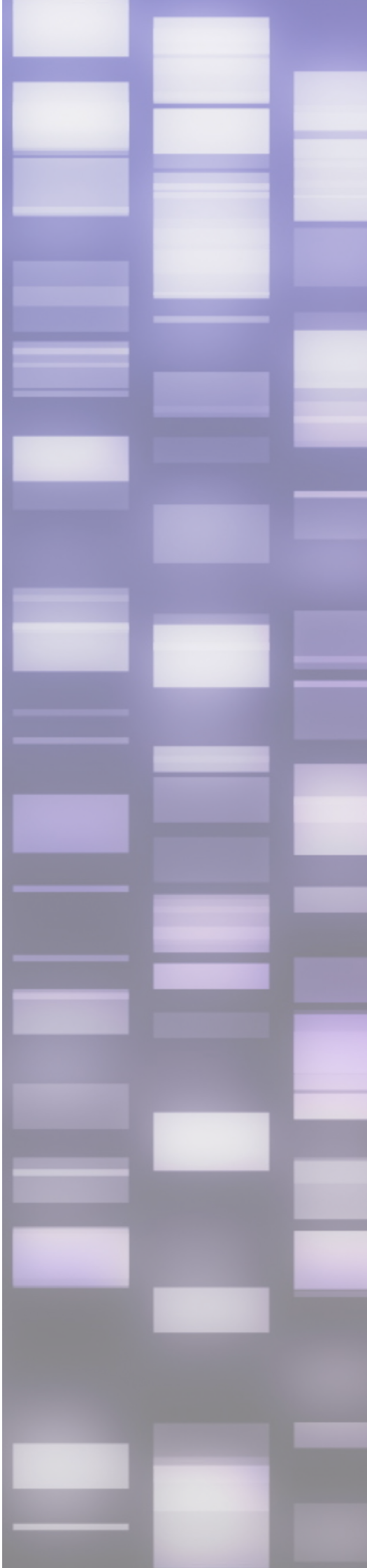
- The Peter Doherty institute for infection and Immunity and Burnet institute received more than $6 million in government funding in 2020 to lead Victorian consortium to develop novel diagnostics and point-of-care tests, new therapeutics and to support clinical trials and public health initiatives to reduce transmission of COVID-19. The Victorian Infectious Diseases Reference Laboratory (VIDRL) at the Doherty Institute was also the first laboratory outside of China to grow and share the virus. The consortium continues to work with local and international stakeholders to expedite development of therapeutics, diagnostics, clinical research and improve public health response to COVID-19.

Policies and regulation

Australia's regulatory response to the pandemic, including a pragmatic and thorough approach to the assessment of COVID-19 vaccines, has been a testament to how processes can evolve quickly when required. Key elements of this response are speed, flexibility, collaboration, and increased funding support for the regulator, while ensuring that public safety remains paramount. How best to adopt these principles into "business as usual" regulatory processes is an important consideration.

Achieving a high rate of vaccination against COVID-19 is imperative for Australia's recovery from the pandemic, which has highlighted the essential role of prevention in an effective health system. Australia invests just 1.34% of the health budget into public and preventive health (vs. 2-4% in most other OECD countries).

Our rates of childhood vaccination are world-leading, with approximately 95% of children fully vaccinated for vaccines included in the National Immunisation Program. Adult vaccination rates are understood to lag behind, with only around 55% - 75% of eligible adults vaccinated against pneumococcal, influenza and herpes zoster. Pandemic initiatives, such as mandatory reporting to the Australian Immunisation Register, provide opportunities for better monitoring, target-setting and accountability for increasing adult vaccination rates. The overall goal is to protect Australians against vaccine-preventable diseases.



Priorities areas for future pandemic preparedness

Prioritised and sustainable investment

1. Define areas of unmet need for future strategic investments in Signature Research Assets, such as the CSIRO's Biologics Production Facility, Australian Centre for Disease Preparedness, and world-class research institutes (see Box 5[11,12,13,14]).
2. 2. Establish catalyst models around common goals for end-to-end investment, collaboration and education in the life sciences sector.
3. Ensure that assets, capabilities and skills are tailored to the sector's needs beyond a future pandemic.

Collaboration across the value chain to achieve commercialisation

4. Develop a single front door for commercialisation with "lots of keys", considering initiatives similar to NHS England's Accelerated Access Collaborative
5. Build academic-CSIRO-industry partnerships around a common purpose, with benefits for all parties, considering international models such as the UK's Vaccine Manufacturing and Innovation Centre (VMIC) in UK. The VMIC is a first-of-its-kind not-for-profit organisation founded by academic institutions and supported by industrial partners to enhance UK preparedness and response capabilities for producing vaccines against emerging infectious diseases.
6. Work towards increasing interactions between innovators and all expertise in the commercialisation pathway (regulatory, IP, funding, market access, etc) early in product development.

Technological advances

7. Leverage the Australian tele-trials model to drive forward the national agenda for harmonisation of clinical trial governance and ethics approvals.
8. Develop a white paper that outlines a roadmap for the implementation of digital technologies in tele-trials and broader implementation in clinical practice which may inform a broader national clinical trial strategy.
9. Develop a more comprehensive and actionable national digital/health data strategy to enable patient-relevant outcomes to be captured, interpreted and applied to the next wave of technologies for regulatory and reimbursement purposes.
10. Continue to work with the regulator and leverage initiatives already in place to improve and expand the use of technological advances in GMP production and supply chain.

Policies and regulation

11. Consider learnings from the pandemic to enhance speed, flexibility and collaboration in regulatory processes
12. Provide government funding for the TGA, to expand its resource base, to enable expanded services by funding public good activities instead of cost-recovering from industry (currently 100% cost recovered from industry, with many necessary activities for public good only)
13. Support the implementation of the National Preventive Health Strategy through learnings from pandemic initiatives to enhance adult vaccination rates. Federal and state/territory governments should closely work together to ensure consistency in implementation approach and communication to public.
14. Develop a national research agenda and industry-focused incentives for targeted commercialisation of research into areas of unmet need for Australians. Models such as the NHS Accelerated Access Collaborative (AAC) could provide national leadership on unmet need, research priorities and their link to regulation/reimbursement and assist with the implementation of innovations into Australian healthcare system.

11 https:/www.csiro.au/en/research/health-medical/vaccines/Vaccine-manufacture
12 https:/www.csiro.au/en/about/facilities-collections/ACDP
13 https:/www.minister.industry.gov.au/ministers/karenandrews/media-releases/csiro-upgrading-world-class-facility-fight-diseases
14 https:/www.burnet.edu.au/news/1204_million_dollar_boost_to_covid_19_public_health_response

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