AUSTRALIA'S

Vaccine Value Chain

CONFERENCE©

A call for urgent action to maximise Australia's impact on the global vaccine value chain

Conference Outputs

Biointelect

This conference outputs document reports the key 'takeaway messages' from the plenary sessions of Australia's Vaccine Value Chain Conference©. It highlights expert recommendations that were distilled from the sessions and endorsed by the conference program committee and major sponsors.

Recognising the urgent need for global action to enhance the R&D pipeline and translation of new vaccines into use, it is critical for Australian stakeholders to build upon the momentum of Australia's Vaccine Value Chain Conference and codesign an actionable roadmap to achieve meaningful progress in Australia.

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Foreword

There are many aspects of the value chain of vaccines which covers discovery through to implementation. However, our understanding of the challenges, barriers, and levers to streamline this value chain across stakeholders is fragmented and sometimes siloed due, in part, to Australia's federated system.

This was evident in our response to the COVID-19 pandemic where novel vaccines were developed globally in record time. Australia's public health ecosystem pulled together, but the gaps in vaccine development, clinical trials, manufacturing, equity & access became clear.

Since then, many lessons have been learnt. This has led to significant investment by State and Territory and Federal Governments, the private sector, and philanthropy into different parts of the vaccine and infectious disease ecosystem.

While Australia has numerous scientific strengths, such as in discovery research, the knowledge and experience to translate discoveries to improve the health of the community requires greater access to data, and additional resources and know-how along the value chain. Access to funding and a skilled workforce remains limited across the ecosystem, which affects our ability to translate infectious disease and immunological research into vaccine products.

With less than two per cent of the Australian health budget spent on prevention, we currently place much greater emphasis on treating rather than preventing disease. Lengthy funding review processes for vaccines, triggered by industry applications, and followed by tendering for the National Immunisation Program, delays vaccine access and may create disincentives to launch new vaccines in Australia. We need to develop preventative health strategies that accelerate and fund routine vaccines as well as those that minimise the risk of disease outbreaks.

Australia has a world-leading track record in childhood immunisations programs. Among adults, vaccine fatigue, vaccine hesitancy, equity of access and uptake are all current issues of concern for the immunisation community, with consumer engagement and knowledge of vaccines forever changed since COVID-19. Australia also has an important leadership role to play in the Global Southern Region to support our more vulnerable neighbouring countries.

Recent breakthroughs like mRNA technology have revolutionised the speed of vaccine development and allow new diseases to be quickly targeted and may also facilitate streamlined regulatory and developmental pathways.

There are expansive opportunities for Australia as a Southern hemisphere centre of real-world safety and effectiveness studies of vaccines. This would simultaneously strengthen our understanding of the impacts of vaccines on public health outcomes in Australia while contributing to the global evidence base.

We need to ensure that all aspects of policy and regulation, including health technology assessments and vaccine funding, keep pace with global developments. Some targets may not be commercially attractive and may require public-private partnerships to support commercialisation and access for the most vulnerable populations.

With large infrastructure investments being made in Australia to increase manufacturing capabilities, fund discovery and translational research, and to grow the healthcare sector, it is essential to unite stakeholders within the vaccine value chain. This will boost our ability to collaborate and build innovation capacity with the goal of maximising the health and economic benefits to Australia and our region.

Australia's Vaccine Value Chain Conference© was a first of its kind, invitation-only event, which brought together 217 key decision makers across industry, academia, Government, non-profits, and health care providers to determine key recommendations for overcoming gaps and bottlenecks across the ecosystem.

International initiatives

On a global scale, the **Wellcome Trust** produced a discussion paper which examines why the ecosystem of infectious disease research and development (R&D) fails to meet people's needs and sets out potential routes for reform and key areas for discussion.[1] This paper identified several recurring failures including empty R&D pipelines, barriers during clinical development & registration, limitations in supply chains and products not appropriate, accessible or affordable for the communities that need them.

The paper calls for urgent reform and ambitious change in four key areas:

1. **Equitable and comprehensive priority setting in R&D, driving more balanced allocation of resources into research across different products and disease areas.**
2. **Streamlined clinical trial and regulatory approaches, building capacity and speeding up the time taken for products to be approved for use.**
3. **Strategic scale-up of geographically diverse and sustainable manufacturing capacity, supporting product supply approaches that align to global need.**
4. **Centring access and affordability while incentivising innovation, embedding these principles throughout product development to achieve better health outcomes.**

The **WHO R&D Blueprint for Epidemics** aims to accelerate the development of medical countermeasures. In June 2024 the WHO released "Pathogens prioritization, a framework for epidemic and pandemic research preparedness". It stresses the need for international collaboration and emphasises the critical need for investments in research, development, and innovation on an international scale.[2]

The Australian Vaccine Value Chain Outcomes are also consistent with this decentralised collaborative approach. Rapid local action will ensure Australia can effectively contribute to the global value chain.

Executive Summary

In May 2024, the Department of Health & Aged Care released a Consultation Paper - Towards Australia's National Immunisation Strategy 2025-2030.[3] The paper sought comments on the proposed vision, mission and six priority areas for the National Immunisation Strategy.

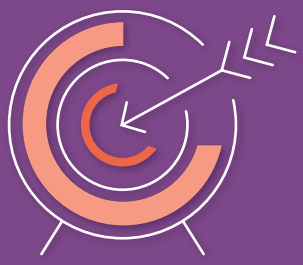
The consultation paper noted the importance of partnerships which support collaboration between levels of government, immunisation providers and experts, the vaccine industry and, importantly, the Australian people.

In addition, the paper acknowledged that the development of Australia's next National Immunisation Strategy (2025-2030) comes at a time when there is a rapidly shifting immunisation landscape. This includes significant technological advances, fluctuating community sentiment, and some recent concerning declines in childhood and adult vaccination coverage.

Of concern is that First Nations people have lower coverage than the rest of the Australian population for almost every vaccine.

There is a call to action to global health stakeholders across the infectious disease ecosystem to drive action and create change. The Australian Vaccine Value Chain Conference created a unique opportunity to consult on many of the priorities outlined in the consultation paper and reflect our local ecosystems first response to that call.

The Conference outputs cover the end-to-end value chain with detailed recommendations which have been grouped into three core themes:



Defining a coherent vision and alignment

a. National co-ordination and prioritisation of objectives

b. Community engagement along all stages of the value chain

01

Enabling needed capacities

a. Exploration of innovative funding models to achieve research translation and commercialisation

b. Subject matter training in specific skills and knowledge

c. Regulatory review and governance

d. Infrastructure investments to catalyse growth across the entire ecosystem

02

Development of metrics to assess progress towards goals

a. Process Evaluation – Is more translation happening?

b. Outcome Evaluation – Is disease burden being averted?

03

Australia's Vaccine Value Chain Conference© — Session Objectives, Outcomes, Key Issues and Recommendations

Plenary 1: The Vaccine Value Chain – What Do We Want for Australia?

Objectives

- Showcase and examine the concept of the end-to-end global vaccine value chain.
- Outline progress related to vaccine commercialisation in Australia.
- Explore and gain insights and learnings from successful international models.

Outcomes

- Identification of barriers and enablers for vaccine research, development and access in Australia.
- Understand how all the parts of the vaccine ecosystem interact together.
- Generation of ideas and insights from overseas on where Australia should "play to win".

Australia's vaccine value chain faces several critical issues that need addressing. First, there is an urgent need for nationwide policies to support the entire value chain, particularly through end-to-end stage-gated funding for vaccine development and commercialisation. This requires State and Territory funding programs to align nationally with clear objectives and Key Performance Indicators (KPIs). Additionally, systems that capture nationwide funding allocations and track the progress of funded projects by infectious disease and technology type are necessary, to monitor and deliver national, meaningful solutions.

Successful product development hinges on a sustainable network that brings together multiple stakeholders, provides catalyst funding for projects and training, attracts investment, leverages funding from various sources, advocates for vaccine development, and fosters industry and community engagement along with downstream manufacturing.

Lessons from overseas highlight barriers such as access to assays, manufacture of GMP batches, preclinical efficacy studies, and IND enabling toxicology studies. In addition, international examples highlighted the importance of a community of expertise across academia, CROs, government, and industry (with successful examples of this being the UK Vaccine Network and the Boston biotech hub).

Given that every disease and vaccine are different, the development pathway may need to adapt, necessitating alternative pre-clinical efficacy and toxicology studies, a flexible development process, and an understanding of pathogen evolution. National collaboration is essential to harness capabilities and respond as necessary to deliver national public health solutions and preparedness.

CRO: Contract Research Organization
GMP: Good Manufacturing Practices
IND: Investigational New Drug (US Food and Drug Administration)
LMIC: Low- or Middle-Income Countries

BactiVac, was established in August 2017 by The University of Birmingham, England, with an aim to accelerate the development and use of vaccines against bacterial infections, particularly in LMICs. This is a critical role, given that antimicrobial resistances (AMRs) cause approximately five million deaths annually and is a growing global crisis.[4] This case study illustrates how BactiVac exemplifies successful product development through a sustainable network that integrates multiple stakeholders, catalyst funding, advocacy, and industry engagement, while overcoming various barriers in vaccine development.

CASE STUDY

BactiVac – A Success Story in Accelerating Vaccine Development

Building a Sustainable Network

BactiVac's success hinges on its robust and multidisciplinary network. By bringing together experts from academia, contract research organisations (CROs), government bodies, and industry, BactiVac fosters a collaborative environment. This network facilitates the exchange of knowledge, skills, and best practice, which are essential for overcoming scientific and economic barriers in vaccine development.

Catalyst Funding and Training

To propel innovative vaccine projects and training initiatives, BactiVac provides catalyst funding. This funding has been crucial in initiating early-stage research projects that can attract further, larger grants. Additionally, by offering training opportunities, BactiVac ensures that the next generation of researchers and professionals are well-equipped to continue advancing the field of vaccinology.

Attracting and Leveraging Investment

BactiVac has successfully attracted investment from various sources, including governmental and non-governmental organisations. By leveraging these funds, BactiVac has been able to support a wide range of projects aimed at developing new vaccines and improving existing ones. This financial support is critical for addressing both the scientific challenges of identifying effective antigens and the economic challenges posed by the lack of commercial viability.

Advocacy and Community Engagement

Raising awareness about the importance of bacterial vaccines is a core aspect of BactiVac's strategy. The network actively represents the interests of its members to a broad range of stakeholders, including policymakers, funding bodies, and the general public. Through subsidised network meetings and workshops, BactiVac promotes interaction and collaboration among members, fostering a sense of community and shared purpose.

Overcoming Barriers to Vaccine Development

BactiVac has effectively navigated several common barriers in vaccine development:

- **Access to Assays and GMP Manufacturing:** By collaborating with international partners, BactiVac has improved access to critical resources such as assays and facilities for manufacturing Good Manufacturing Practice (GMP) batches.
- **Preclinical Efficacy Studies and IND Enabling Toxicology Studies:** BactiVac has leveraged expertise from networks like the UK Vaccine Network and the Boston Hub to conduct necessary preclinical studies, ensuring the safety and efficacy of candidate vaccines.
- **Flexible Development Pathways:** Recognising that every disease and vaccine may require a unique development pathway, BactiVac emphasises the need for flexibility. This includes adapting preclinical efficacy and toxicology studies and understanding pathogen evolution to stay ahead of emerging threats.

Recommendations

- Implement an Australian national standard framework to measure translation and commercialisation of vaccine products. The Technology Readiness Level (TRL) grading system is recommended and already adapted for vaccine products, serving as standard practice for organisations such as US BARDA, US NIH, and US FDA. Locally, it is utilised by DMTC and for CRC-P funding. However, a consistent approach across all stakeholders in the value chain is needed.

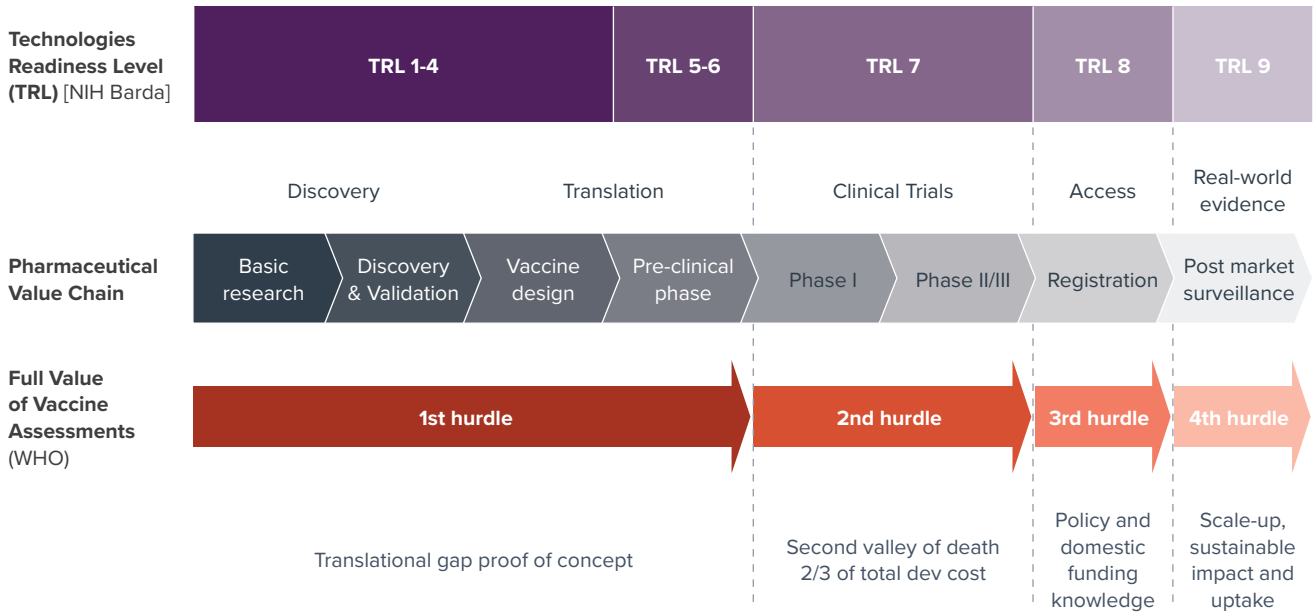


Figure 3: Examples of frameworks for measuring vaccine translation and commercialisation in Australia.
Adapted from J. Herz presentation: **Australian Vaccine Value Chain.**

- Create a national vaccine development network to facilitate knowledge sharing, coordination and collaboration as well as provide a more efficient framework for accessing the necessary expertise. It could also align with a national research strategy. A public private partnership model should be considered.

  It is recommended that the national network:

  - include access to an expert network (including international);
  - support development of vaccines for public health priorities as well as for industry and leverage funding from donors and philanthropy as well as the private sector;
  - have a strong governance framework and be inclusive and transparent.
- Revise major medical research grant funding data capture to include more specific data fields to measure research translation and product development milestones by disease target and

BARDA: The Biomedical Advanced Research and Development Authority (An American integrated, systematic approach to the development of the necessary vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies such as chemical, biological, radiological, and nuclear accidents, incidents and attacks; pandemic influenza, and emerging infectious diseases).
CRC-P: Cooperative Research Centres Projects; **DMTC**: Defence Materials Technology Centre;
FDA: Food and Drug Administration; **NIH**: The National Institutes of Health.

Plenary 2: Preclinical Vaccine Development Capabilities in Australia: Governance, Skills, and Talent

Objectives

- **Showcase research opportunities to optimise preclinical vaccine development.**
- **Highlight Australia's unique strengths and success in vaccine development.**
- **Acknowledge gaps, challenges in funding, skills, and governance to improve preclinical vaccine development.**
- **Spotlight successful local and international models as exemplars for change.**

Outcomes

- **Identification of actionable opportunities and solutions that can be acted upon to optimise Australia's pre-clinical vaccine development capabilities.**
- **Understand key barriers for academia in translating research into the clinic and unique strengths for vaccines.**
- **Understand industry objectives and the types of partnerships they are seeking, how they see Australia's contribution to global R&D and opportunities for growth.**
- **Understand the different government perspectives in protecting military and civilian health in Australia as well as implications for regional security.**

The preclinical portion of Australia's vaccine value chain faces several challenges related to development capabilities, particularly in governance, skills, and talent. While Australian academia excels in research and discovery, and the industry excels at translating research into product development and commercialisation, these strengths need better integration to ensure successful product outcomes. Importantly, there is limited opportunity in academia to access product development expertise and advice, which hinders progress in vaccine development. Australia's current focus on investigator-led grants and a few successful research translation case studies, combined with insufficient emphasis on tracking commercialisation progress, undermines a product development approach and inhibits a fail-fast culture that learns from clinical trial setbacks. Improving rapid, accurate preclinical triage of vaccine candidates and conducting thorough analyses of failures would enhance candidate selection and clinical success rates. Crucially, research aimed at understanding the mechanisms of action, the failure, and the side effects of many vaccines is lacking. Moreover, the commercial viability of some vaccines often does not align with their societal impact, highlighting the need for non-commercial funding solutions to address global health priorities.

The Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) is a global non-profit partnership dedicated to accelerating the development of antibacterial products to treat and prevent infections by drug-resistant bacteria, which are a leading cause of death worldwide. Based at Boston University, CARB-X manages the world's most scientifically diverse early development pipeline for new antibiotics, vaccines, rapid diagnostics, and other critical products. CARB-X's mission is to accelerate a diverse portfolio of innovative antibacterial products towards clinical development and regulatory approval, focusing on the most dangerous bacteria identified by the WHO and CD.

CASE STUDY

CARB-X - Success in Accelerating Antibacterial Innovation Through Strategic Partnerships

CARB-X deploys a comprehensive support model

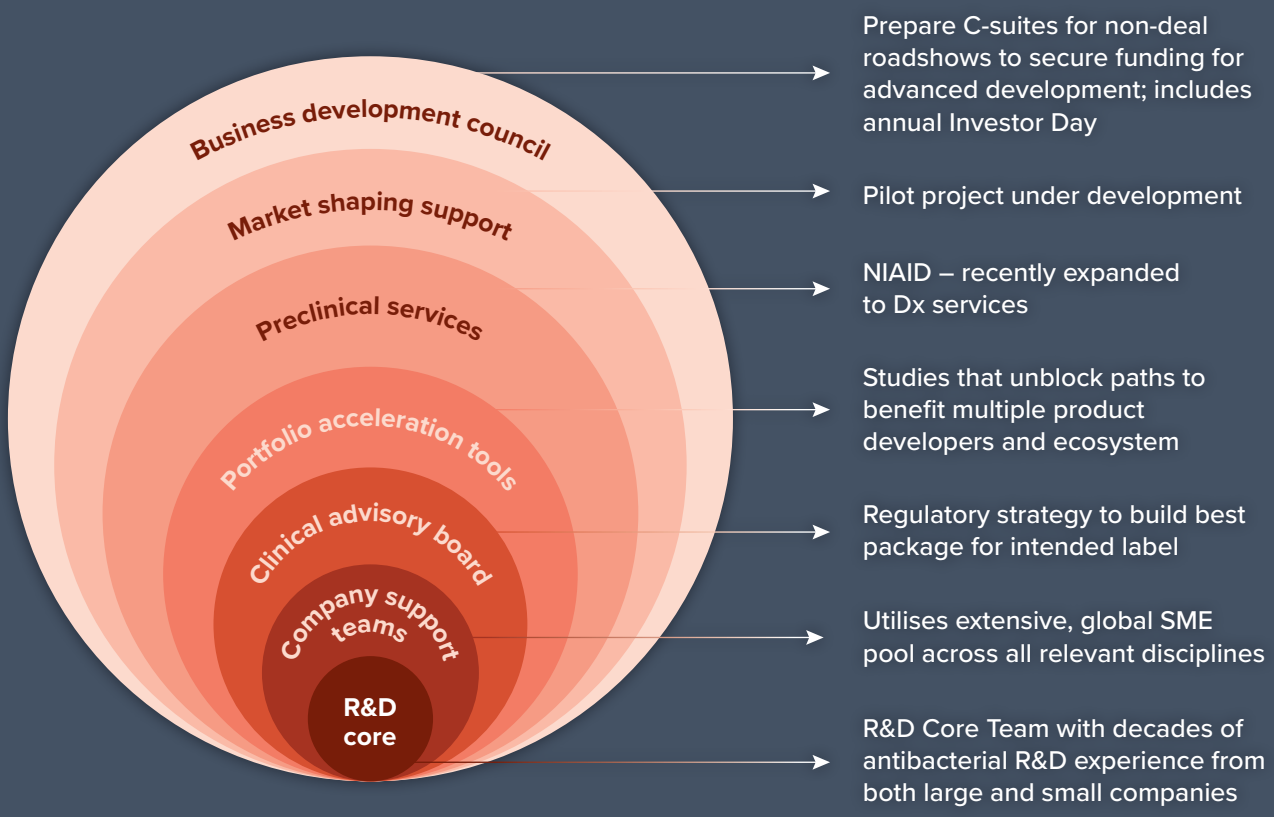


Figure 4: CARB-X deploys a comprehensive support model.

At the centre is the R&D Core Team, made up of experts with years of experience in antibacterial R&D from both large and small companies. Surrounding the core are Company Support Teams, which provide specialised help using a global pool of Subject Matter Experts (SMEs). The Clinical Advisory Board offers advice on clinical development and regulatory strategies. The Portfolio Acceleration Tools layer includes studies and resources that help multiple product developers and the ecosystem. Preclinical Services provide vital support in early product development. Market-Shaping Support prepares the market for new antibacterial products with pilot projects. The Business Development Council helps C-suite executives secure funding through non-deal roadshows and an annual Investor Day. Recently, NIAID services were expanded to include diagnostic services. This model supports the development of antibacterial products with a comprehensive, multi-layered approach.

Adapted from presentation by R. Alm, **Accelerating the Development of Novel Tools against AMR**.

CARB-X: Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator
CDC: Center for Disease Control (US)
WHO: World Health Organisation

Recommendations

- Develop partnerships with existing funding models that are industry led and focused on product development or replicate such models locally. Examples include: Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X), the Biomedical Advanced Research and Development Authority (BARDA) Acceleration Network – Therapeutics and Vaccines Hub, Coalition for Epidemic Preparedness Innovations (CEPI) or enabling preclinical services such as those offered by National Institute of Allergy and Infectious Diseases (NIAID).
- Enhance current models by providing access to subject matter experts.
- Create a national Vaccine Development Partnership to act as a central coordinating entity, provide administrative and project management support as well as create a subject matter expert network, international expertise to address local skills gaps e.g. in vaccine quality (chemistry, manufacturing, and controls CMC), Toxicology, GMP manufacture, etc.
- Establish an academic track for teaching vaccine development to students that includes bringing in external commercial experts and incentivising support for large-scale, innovative, next-generation technology.
- Promote internationally the unique success and capability of Australian vaccine R&D, including clinical trials, to attract industry investment.
- Develop a national pitch book with a catalogue of capability and contact points. This could be achieved by the funding of a national network with a coordinating body as a single front door.
- Develop new approaches to management of intellectual property to overcome barriers to collaboration and product development.
- Create standardised models and training to enable public and private collaborative partnerships to be established rapidly.

BARDA: The Biomedical Advanced Research and Development Authority (An American integrated, systematic approach to the development of the necessary vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies such as chemical, biological, radiological, and nuclear accidents, incidents and attacks; pandemic influenza, and emerging infectious diseases).

CARB-X: Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator

CEPI: Coalition for Epidemic Preparedness Innovations

GMP: Good Manufacturing Practices

NIAID: National Institute of Allergy and Infectious Diseases

SME: Subject Matter Expert

Plenary 3: Clinical Trials and Infrastructure

Objectives

- Outline Australia's contribution to regional and global clinical trials and key areas of strength.
- Understand the different requirements of clinical trial Sponsors making decisions on where to conduct clinical trials.
- Explore opportunities to grow Australia's global share of vaccine trials and develop new clinical trial models that could ensure greater inclusion of under-served populations.

Outcomes

- Identification of opportunities to leverage Australia's existing strengths in clinical trials by growing our global reach and impact especially in Phase III trials.
- Recognition of Australia's expertise in tropical disease, and opportunities arising from our southern hemisphere location (as a complement to clinical trials for respiratory diseases conducted over the respective winter seasons)
- Comprehension of industry objectives and the types of partnerships they are seeking, how they see Australia's contribution to global clinical trials and opportunities for growth.
- Appreciation of Australians regional role and opportunities to increase impact on public health in our neighboring countries.
- Identification of where Australia has true competitive advantages that can be harnessed for clinical trials to attract industry investment.

Clinical trials in Australia are sponsored by industry and non-industry parties. Collaboration challenges result in redundant and overlapping activities and competition between states, highlighting the need to map capabilities and streamline efforts for enhanced cooperation. Academic sites must better understand sponsors' goals and timelines, recognising the differing decision-making drivers of small biotech firms, established pharma, and NGOs. This includes adhering to feasibility and proposal requests within required timeframes, starting trials quickly, and meeting recruitment targets amid competitive enrolment environments.

Standardising costings for visits and procedures across Australia, as exemplified by the UK's interactive tool (the UK's standardised, national approach to costing and contracting for commercial contract research), would provide consistency, transparency, and more accurate costings, considering factors like trial site distance from communities. Simplifying processes for sponsors by offering a single point of contact and reducing multiple rounds of review and changes can decrease complexity and cycle time. Expanding access to subjects for phase II and III vaccine clinical trials requires partnerships between public and private sites. Additionally, the regulatory burden for trials conducted under hospital care poses a significant hurdle for research, while the lack of funding for virus isolation, sample collection, storage, sharing, and patient consent processes hampers research and collaboration. Currently, funding primarily covers MBS tests like PCR, limiting broader research initiatives.

The recent budget announcement by the Federal Government has provided funding to continue the development of the National One Stop Shop for Clinical Trials and Human Research. This Program aims to transform health and medical research in Australia, by making it easier for patients, researchers, and sponsors to find, conduct and participate in clinical trials and research.[5]

Australia has significant tropical disease expertise, and opportunities arising from our southern hemisphere location (as a complement to clinical trials for respiratory diseases conducted over the respective winter seasons) and emerging macro trends in the impacts of climate change on the incidence of infectious diseases in Australia and our region. In addition, there are opportunities to increase access to clinical trials for underserved populations as well as for endemic diseases affecting countries in the region. National and regional vaccine clinical trial networks that focus on specific populations are needed.

Growth in Australian vaccine trials 2000-2023

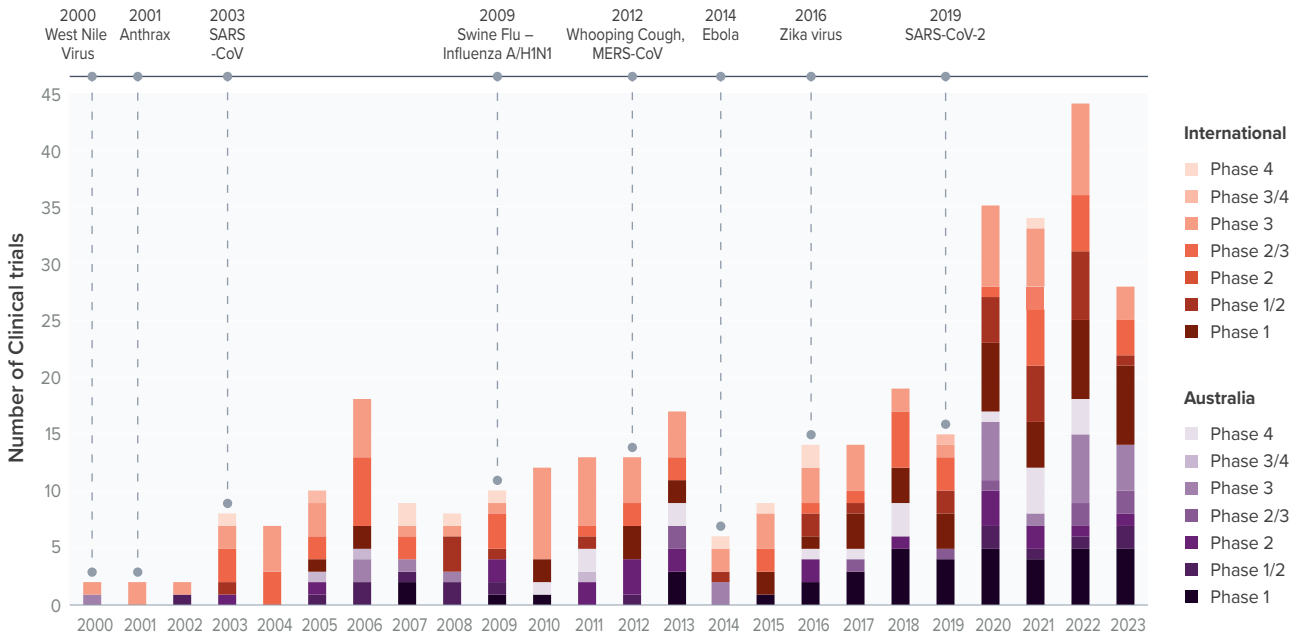


Figure 5: Growth in Australian vaccine trials 2000-2023.

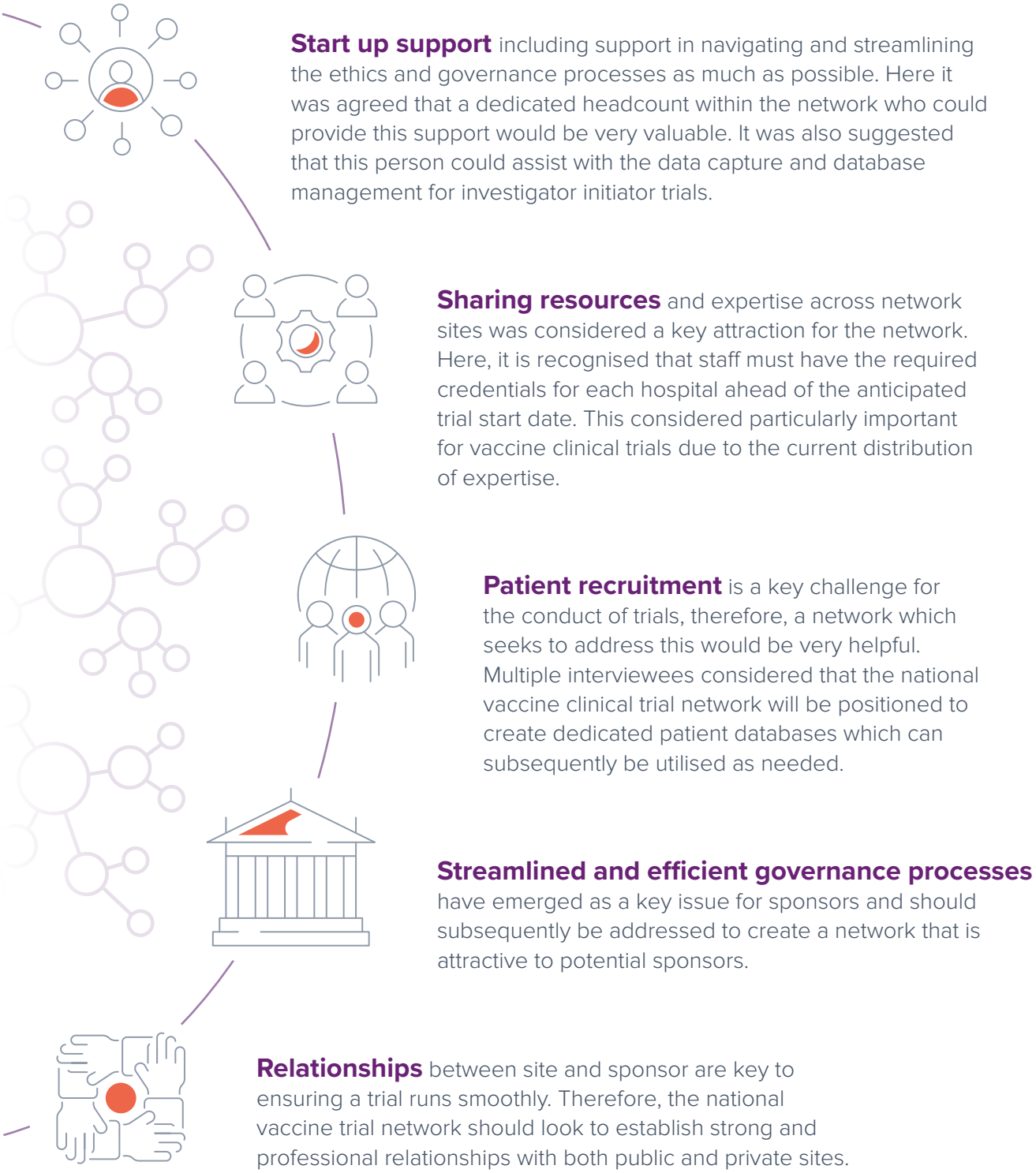
Adapted from J. Herz presentation: **Australian Vaccine Value Chain.**

Sources: Own unpublished data from Global Data and Clinicaltrials.gov.
Note: Australian subsidiaries of global pharmaceutical companies are categorised as International sponsors.

MBS: Medicare Benefits Schedule
PCR: Polymerase Chain Reaction
RWE: Real-World Evidence

Benefits and potential services of a national vaccine clinical trial network

The concept of a national vaccine clinical trial network was welcomed by all participants who saw it as an opportunity to provide a range of valuable services, including:



Start up support including support in navigating and streamlining the ethics and governance processes as much as possible. Here it was agreed that a dedicated headcount within the network who could provide this support would be very valuable. It was also suggested that this person could assist with the data capture and database management for investigator initiator trials.

Sharing resources and expertise across network sites was considered a key attraction for the network. Here, it is recognised that staff must have the required credentials for each hospital ahead of the anticipated trial start date. This considered particularly important for vaccine clinical trials due to the current distribution of expertise.

Patient recruitment is a key challenge for the conduct of trials, therefore, a network which seeks to address this would be very helpful. Multiple interviewees considered that the national vaccine clinical trial network will be positioned to create dedicated patient databases which can subsequently be utilised as needed.

Streamlined and efficient governance processes have emerged as a key issue for sponsors and should subsequently be addressed to create a network that is attractive to potential sponsors.

Relationships between site and sponsor are key to ensuring a trial runs smoothly. Therefore, the national vaccine trial network should look to establish strong and professional relationships with both public and private sites.

Figure 6: Benefits and Potential Services of a National Vaccine Clinical Trial Network.
Biointelect unpublished data

Recommendations

- Create a national vaccine clinical trial network for adult, paediatric and special populations. This should fund a coordinating body that can act as a single point of contact for sponsors conducting clinical trial feasibility and cover both investigator-led and industry-sponsored trials. The clinical trial network should be linked to a product development network to enable translation to the clinic.
- Build on the National One Stop Shop to create streamlined solutions for vaccines: (1) Develop national templates for costing vaccine trials with standardised inputs at a country level. (2) Develop standardised contracts to reduce duplication.
  An example being the UK Clinical Research Network model: The Future of Clinical Research Delivery: 2022 to 2025 implementation plan - GOV.UK (www.gov.uk)
- Create a national One Health Surveillance System (OHSS) to improve access to Real-World Evidence (RWE) surveillance data by linking public and private labs, allowing development of models using vaccine impact data to understand the value of the vaccine.

Plenary 4: Manufacturing: Supply, Demand and Sustainability

Objectives

- Understand the goals of the National Reconstruction Fund and the Medical Science Co-Investment plan.
- Review Australia's existing vaccine manufacturing capabilities.
- Understand the global vaccine supply chain, lead times and constraints to inform how Australia can act to secure supply.
- Discuss government, biotech, local and global manufacturers' perspectives on vaccine supply, demand and sustainability.
- Highlight funding and investment opportunities for vaccine manufacturing in Australia.

Outcomes

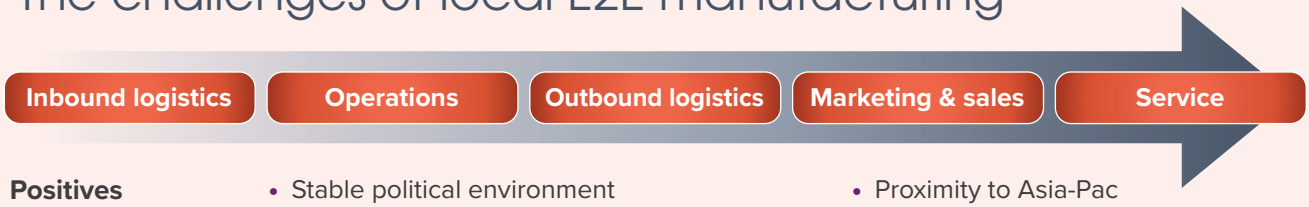
- Comprehension of the challenges and central issues surrounding the supply and demand dynamics of vaccines.
- Identification of realistic goals for development of sovereign capability that delivers a robust and resilient ecosystem.
- Understanding of the strategic position of Australia in the global supply chain, in the context of both local and regional needs.

Even with CSL, Moderna, Sanofi and BioNTech facilities coming online Australia's vaccine value chain faces significant issues regarding manufacturing capacity, capability and sustainability. Major weaknesses include gaps in manufacturing translation, such as the capability and skills to required regulatory standards within Australia.

The scarcity of Australian third-party services for GMP manufacturing stifles innovation and weakens links within the supply chain. In terms of early-stage development in readiness for Phase I and Phase II studies, this sometimes necessitates process development and manufacturing activities to be conducted offshore, which has knock-on implications for the utilisation of grant funding and R&D tax incentives. When local manufacturing process development activities have been undertaken, a lack of critical mass and shortages in the workforce skills leads to redundant efforts.

On the positive side, Australia benefits from several strengths, including the TGA, strong intellectual property frameworks, and a robust clinical trials sector. Additionally, there are government incentives, such as the Research and Development Tax Incentive (RDTI), as well as a diverse population and a stable political environment which provides a solid foundation for expanding manufacturing capabilities. However, it's important to note that the demand for Australian-made products alone is not sufficient to sustain local manufacturing businesses. Furthermore, during the pandemic, investments in mRNA manufacturing capability were made by State and Federal Government, and Industry. The recent Federal Governments "Australia's RNA Blueprint" showcases the opportunities, constraints and barriers that must be addressed to ensure a coordinated capability.[6]

The challenges of local E2E manufacturing



Positives	• Stable political environment • Strong regulatory framework • Educated workforce • Strong research and innovation ecosystem	• Proximity to Asia-Pac • Strong IP protection • Government partnerships
Challenges	• Proximity to major markets • Proximity to key suppliers • Smaller biotech ecosystem	• Some regulatory complexity • Foreign government incentives

Figure 7: Challenges of end-to-end (E2E) manufacturing in Australia.
Adapted from C. Larkins presentation: **Vaccine Manufacturing: Supply, Demand and Sustainability**

We will capture **more value** from Australia's world-leading **medical science** sector by

Increasing industrial capability and capacity

Supporting commercialisation

Improving our international competitiveness

Areas of investment **opportunities**

Digital Health

Medical devices

Complex therapeutics

Sustainability

Advancing our **capabilities**

Skills and capability availability

Supply chain diversification

Demand

Research translation and commercialisation

Collaboration and co-ordination

Regulation and business settings

Figure 8: From Medical Science Co-investment Plan, Australian Government Department of Industry, Science and Resources. https://www.industry.gov.au/publications/medical-science-co-investment-plan (2024).

The Commonwealth government has also committed to delivering a Future Made in Australia to boost investment and productivity, create jobs and seize the opportunities of a shifting global economy. However, relying solely on pandemic vaccine production is not sustainable; there is a need to develop capacity for seasonal or routine manufacturing of a range of vaccines for both Australia and the region to ensure long-term viability of Australian industry and deliver on the promise of the R&D pipeline.

The Medical Science Co-investment Plan outlines investment opportunities for government and industry to leverage Australia's strengths and target areas with high economic potential.[7] Vaccines are a high priority however to achieve the goals of the Medical Science Co-Investment plan we must strike the right balance between sovereign capability and optimising Australia's strategic place in diverse global supply chains. Manufacturing investments should also consider regional needs for vaccines against endemic diseases, as well as, military and civilian health threats, and emerging infectious diseases.

Global initiatives such as CEPI's Regionalized Vaccine Manufacturing Collaborative (RVMC) and the US BARDA's rapid response network create new opportunities for Australia to achieve this and emphasise the need for international collaboration.

Recommendations

- Establish manufacturing and translation facilities capable of delivering product to GMP.
- Facilitate exchange programs overseas to upskill local manufacturing teams in clinical development and industry. Consider nationally recognised training accreditation scheme and address recruitment and retention challenges including the Visa restrictions.
- Map Australian capability and conduct needs assessment and gap analysis for critical vaccines and pipeline technologies to inform NRF strategy. This should focus on building greater supply chain resilience in partnership with manufacturers.
- Create a fit-for-purpose Australian fill and finish network, including commercial scale fill and finish for sterile injectables.
- Prepare students for industry workforce by equipping universities with the capacity to train students in the transition from research laboratory to cleanroom and GMP manufacture.
- Develop commercial real estate/shared facility with cold chain capability that can be used for other Australian manufacturing and repurposed during high-demand times.
- Create a subject matter expert network in regulatory and quality aspects to support early-stage projects
- Modify grant eligibility to use international expertise where capability does not exist in Australia.

BARDA: The Biomedical Advanced Research and Development Authority (An American integrated, systematic approach to the development of the necessary vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies such as chemical, biological, radiological, and nuclear accidents, incidents and attacks; pandemic influenza, and emerging infectious diseases).

CEPI: Coalition for Epidemic Preparedness Innovations

GMP: Good Manufacturing Practices

NRF: National Reconstruction Fund

Plenary 5: Enabling Policy and Regulation for Vaccines

Objectives

- Review the National Immunisation Programme and determine how perspectives have changed after the pandemic.
- Delve into the enabling regulations for cutting-edge platform technology and highlight the potential of mRNA, viral vector, and other new technologies for human and animal vaccines.
- Understand goals for vaccine surveillance, program evaluation, and vaccine safety monitoring and explore data gaps.
- Discuss the relationship between evidence-based evaluation, public and animal health policies and the regulation of vaccines.

Outcomes

- Identification of policies and regulations that are predicted to improve the vaccine value chain, and opportunities for alignment between human and animal health.
- Identification of data gaps and collaborative models that may provide solutions.
- Comprehension of the constraints of industry, regulators, and policy makers.

During the COVID-19 pandemic, Australia's response to vaccine production and dissemination highlighted a shared purpose between sponsors and the TGA which was crucial for population-wide immunisation. Additionally, Australia's Medicines and Medical Devices Review (MMDR) recommendations implemented in 2016-18 has facilitated the evolution of regulatory pathways.

Several key lessons arose from the pandemic. Flexibility and adaptability were vital in updating regulations for COVID-19 variants, and building a global coalition by equipping key influencers proved effective. However, the need to truncate timelines became evident, as traditional schedules were not optimal for the needs of community.

High quality Real-World Evidence (RWE) provided critical insights and feedback, while the recently established provisional and priority approval pathways demonstrated the feasibility of fast-tracking vaccines, positioning Australia as a model for future pandemics.

Lastly, communication to the public needs further improvement, particularly in clarifying that new pathways do not compromise safety, and in addressing vaccine misinformation within current regulatory frameworks.

The wins and opportunities

What worked well

Shared purpose
Between Sponsors & TGA

New pathways
In place were understood & ready to use

New ways created efficiencies
Pandemic ways of working beneficial to full registration process i.e., GMP “virtual” and “hybrid”

New ways adopted for variants
Flexibility & adaptability enacted by approaching COVID variant updates as platform technology

Build Global Coalition
Identify influencers, equip and activate them

Learnings

Recalibrating time
Classic timelines don’t apply during pandemic

RWE Critical
Pandemics provide unique human exposure & feedback compared to waiting for Phase 3 RCT results

Global education
Provisional pathway is now fully understood by Global colleagues placing Australia well for future use

Public communication needs improving

- That pathway is not a safety shortcut
- Educating about the science and responding to vaccine misinformation is challenging for Sponsor’s under current regulatory frameworks

Figure 9: The Wins and Opportunities.
Adapted from C. Tucek-Szabo presentation: **Industry Perspectives on Pandemic Learnings and Enabling Regulatory Pathways**

Streamlining and simplifying regulatory processes to align with international standards, such as enabling platform regulation pathways, will accelerate access and promote global harmonisation for new platform-based technologies in Australia. Australia is taking the lead with RNA with the recent release of The RNA Strategy “Australia’s RNA Blueprint” (July 16, 2024) which sets out actions that governments, academia, and industry could take to support development of Australia’s RNA sector. One of the five goals is to lead RNA platform regulation and guidance development.[6]

In May 2024 the FDA released its draft Platform Technology Designation Program for Drug Development: Guidance for Industry.[8] This guidance describes the process for requesting and receiving a platform technology designation, which would provide an expedited pathway for the development of drugs or biologics that utilise a platform technology to standardise the development, manufacture, or processing of the finished product. This approach could therefore be followed for other vaccine platforms such as viral vector vaccines and protein subunit vaccines.

Refined regulatory pathways, such as those based on platform technology and other expedited pathways accelerate the development and approval of mRNA products in Australia. The use of platform technologies is advantageous because they allow for a standardised approach to developing and manufacturing mRNA vaccines and therapeutics, which can be applied across different diseases and conditions with minimal modifications. This standardisation reduces development and regulatory costs, speeds up patient access, and allows for agile responses to pandemics and for new mRNA products treating cancers and rare diseases.[9] These streamlined pathways were validated by the extensive experience and confidence gained from the rapid development and deployment of mRNA vaccines during the COVID-19 pandemic.

The need to transform mRNA platform regulation

Take learnings from MMDR and COVID-19 to prepare for the future health challenges and new technologies

mRNA Platform Technologies are versatile and efficient

- mRNA-LNP products leverage a common development process across various disease settings, (respiratory diseases, pandemics, rare diseases, and cancers)
- Platform approach accelerates the production of treatments and vaccines for patients and consumers.

Taking a platform approach can streamline regulatory reviews

- Experience from mRNA COVID vaccines emphasises the need for a robust mRNA platform specific regulatory framework that adapt across multiple treatments, enabling timely and predictable approvals
- Establishment of a framework requires knowledge-sharing and consensus
- Key to quick response to health crises, allowing rapid deployment of vaccines and treatments.

Leadership and collaboration

- Cross-sector roundtable established in October 2023 to review platform technologies
- Taking learnings from MMDR to prepare for the future – collaboration and co-design have benefits for evolving regulatory frameworks

Figure 10: The need to transform mRNA platform regulation.
Adapted from C. Tucek-Szabo presentation: **Industry Perspectives on Pandemic Learnings and Enabling Regulatory Pathways**

By leveraging this past success, regulatory bodies can optimise pathways for future mRNA products, ensuring quicker responses to public health threats and unmet medical needs. Additionally, a consensus around platform approaches would provide a predictable development pathway, benefiting academic and commercial groups, regulators, and ultimately, patients.

A proactive and strategic approach is needed to address vaccine hesitancy and promote the value of vaccines. Evidence must be co-developed with culturally appropriate context for communities, including Culturally and Linguistically Diverse (CALD) and First Nations peoples, as trusted community voices are more effective than top-down communication methods. Adopting a One Health approach to surveillance, prevention (including vaccines), and response is essential for health security, although complex challenges in the animal vaccine pipeline make securing investment difficult. Data gaps on the burden of vaccine-preventable diseases (VPDs) and the real-world impact of vaccines hinder national investment decisions. Pandemics highlight the importance of vaccine impact and system gaps, underscoring the need for nationally coordinated systems that provide harmonised and informative data reporting on infection outcomes, including vaccine and risk group status. Government investment and strategic private sector partnership are needed to ensure that the data products used are harmonised, of appropriate quality and report to informative endpoints.

While Australia has strong surveillance capabilities, current information systems are outdated for the digital age and strategic investment in technical capacity is needed, supported by appropriate cross-sectoral governance and privacy frameworks. Enhancing public trust in vaccines through global education and effective communication is crucial. Parallel issues in animal health, including regulation, access, logistics, and hesitancy, also impede optimal vaccine uptake and impact.

Recommendations

- Infectious disease surveillance – a nationally co-ordinated approach to development of a One Health Surveillance System (OHSS) is required.
- Develop novel platform regulation pathways, such as those for mRNA, and other expedited pathways urgently to streamline product development and review and to accelerate access.
- A national approach is needed to address data gaps in VPD surveillance to enable burden assessment, and ongoing evaluation of vaccine risks and benefits.
- Actively engage in partnership with grass roots community leadership to co-optimise communication with the public.
- Public and private sector collaboration is needed to generate surveillance data and high-quality RWE within and between human and animal health sectors.
- Establish a working group to explore barriers, synergies, opportunities for collaboration and appropriate governance structures to enable integrated surveillance and knowledge sharing between human and animal health sectors.

CALD: Culturally and Linguistically Diverse

RWE: Real-World Evidence

VPD: Vaccine Preventable Disease

Special Session:
How can Australia contribute to CEPI's 100 day mission and the RVMC?

Objectives

- Update on CEPI's 100 day mission and the new Regionalised Vaccine Manufacturing Collaborative. Explore relevant case studies that have either been funded by CEPI or are seeking funding.

Outcomes

- Identification of opportunities for Australia to optimise its contribution to the region in terms of relevant research for low-and middle-income countries, manufacturing infrastructure and capabilities, and strengthening collaboration with the region.

Effective optimisation and collaboration is essential for better preparedness, but challenges exist, such as working with CEPI to understand their evaluation framework, decision-making processes, and timelines, exacerbated by communication difficulties due to distance. Opportunities lie in creating centralised networks for developing new delivery platforms and contributing to a regionalised vaccine manufacturing framework, which still requires substantial work in terms of collaboration and education.

Australia's focus should extend beyond its borders, tapping into regions like Africa and Asia for greater benefits. CEPI's investment in multiple vaccine platforms for emerging infectious diseases enhances credibility, yet Australian grant funding often falls short of covering the full suite of IND-enabling activities needed to make vaccine candidates attractive to strategic partners and private funders. Additionally, many vaccine targets still lack licensed vaccines, highlighting the need for continued efforts and collaboration in this area.

> We believe that by bolstering global manufacturing capacities, particularly in underserved regions, will improve the speed, scale and access of vaccine manufacturing.
>
> **~ F.Kristensen**

> There's a great opportunity to build on Australia's strength in the vaccine ecosystem. You know you have amazing strengths around innovation, clinical trial capacities, regulatory science, but also policy and diplomacy work.
>
> **~ F.Kristensen**

Eight Pillars of the RVMC Framework

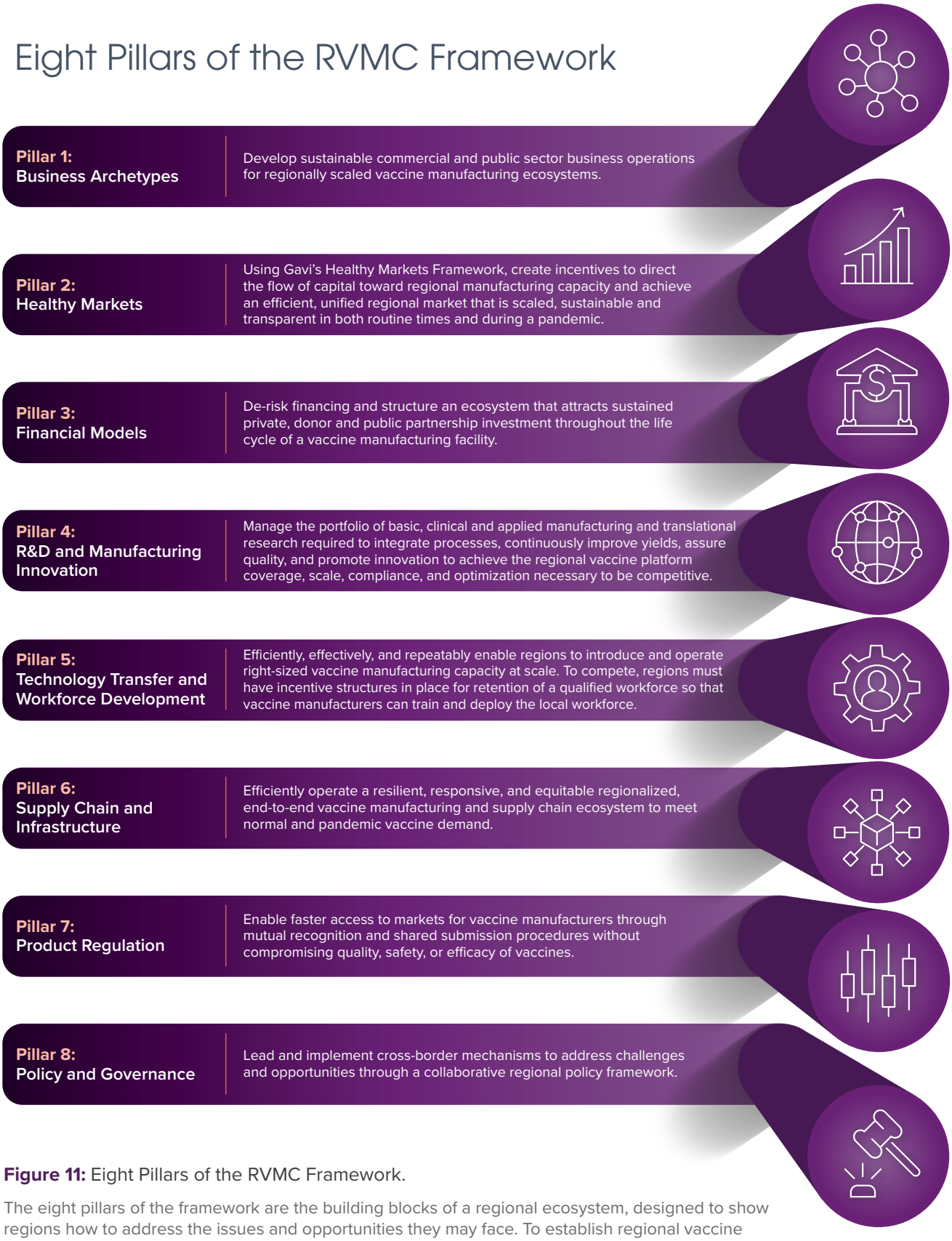


Figure 11: Eight Pillars of the RVMC Framework.

The eight pillars of the framework are the building blocks of a regional ecosystem, designed to show regions how to address the issues and opportunities they may face. To establish regional vaccine manufacturing in a truly self-sustaining way, regions will need to work on achieving the aims of all these pillars: Implementation of the pillars must be synchronized and adapted to regional needs and ambitions. Regionally contextualised roadmaps will need to focus on economic sustainability and innovation to ensure equity. As regions execute against their roadmaps and advance along their respective journeys towards maturity, they can also apply the lessons learned for vaccine manufacturing to other industries, turning regional self-sufficiency for pandemic response into more general and truly sustainable economic development.

Vision for a scalable response to fit the outbreak

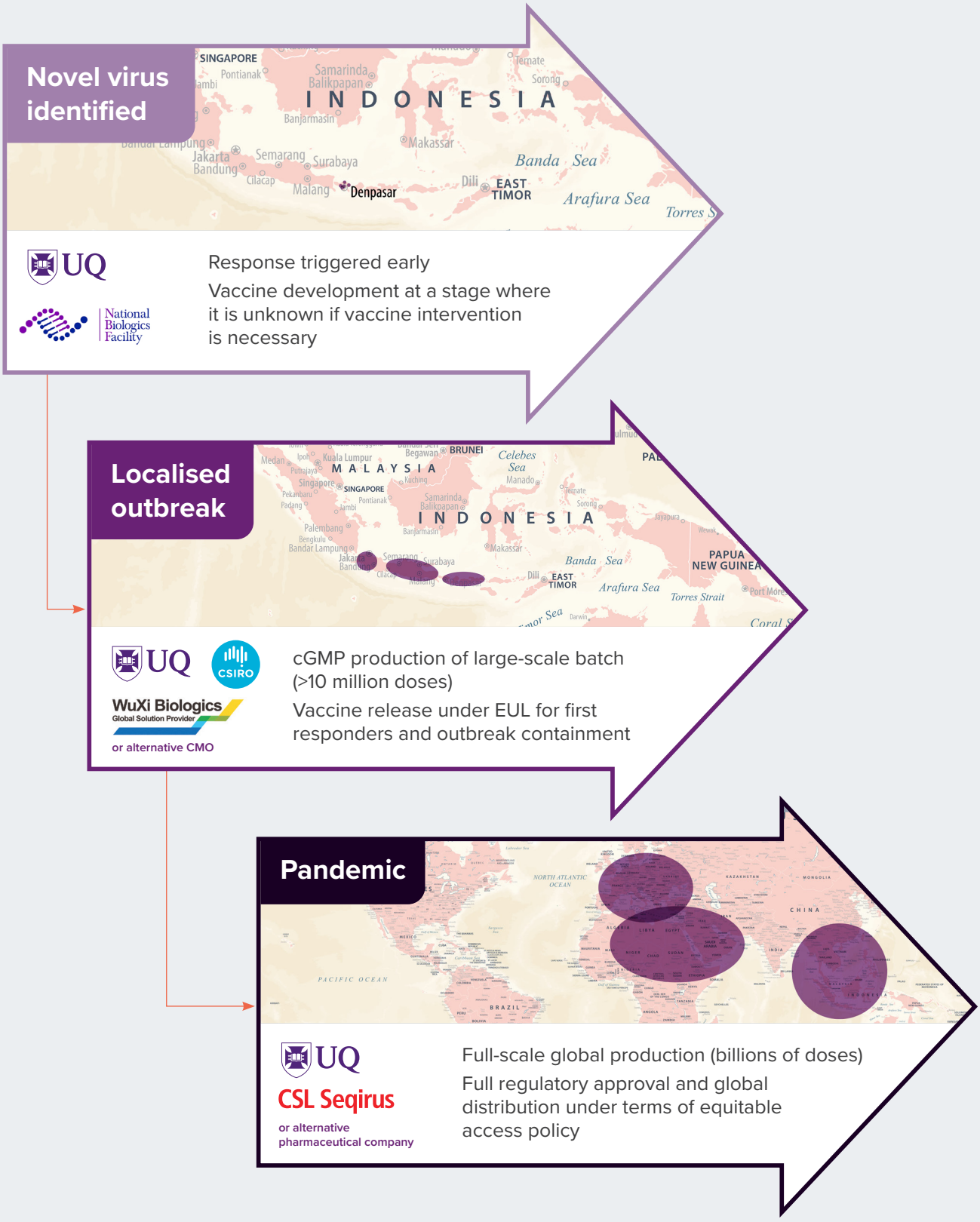


Figure 12: Vision for a scalable response to fit disease outbreak.

Adapted from K. Chappell presentation: **The Molecular Clamp Platform: A broadly applicable platform for rapid production of subunit vaccines to safeguard against future viral outbreaks**

Recommendations

- Develop a national capability map of laboratory services and biobanks. Disease X surveillance – linking of public and private laboratories.
- Project Management and Product Development/Regulatory Overview training and support for working with CEPI – templates, training on KPIs
- Education materials should be developed on manufacturing and quality to inform researchers and funders and ensure they prepare early
- Re-engage with CEPI on Regionalised Vaccine Manufacturing Collaborative (RVMC), Map Australian capability (with DMTC) and develop Asia Pacific Regional Strategy.
- Create a national vaccine development partnership and seek co-investment from CEPI and BARDA, focus on bridging the gap to enter the clinic (CMC, Toxicology etc).

BARDA: The Biomedical Advanced Research and Development Authority (An American integrated, systematic approach to the development of the necessary vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies such as chemical, biological, radiological, and nuclear accidents, incidents and attacks; pandemic influenza, and emerging infectious diseases).

CEPI: Coalition for Epidemic Preparedness Innovations

DMTC: Defence Materials Technology Centre

KPIs: Key Performance Indicators.

RVMC: Regionalised Vaccine Manufacturing Collaborative

Plenary 6: Equity of Access and Uptake

Objectives

- Explore Australia's pivotal role and challenges in vaccine access, distribution, and uptake including addressing vaccine hesitancy.
- Highlight vaccine uptake and challenges to delivering vaccines in underserved and hard-to-reach populations.
- Showcase national initiatives that improved adult vaccine uptake and hear from different providers.

Outcomes

- Identify of barriers and opportunities to improve vaccine uptake to enhance health outcomes and equity in Australia.
- Generate ideas for new collaborative models that could improve access.

Australia's vaccine value chain faces several key issues concerning equity of access and uptake, especially in the context of community engagement and vaccine hesitancy post pandemic.

Globally, vaccination rates and vaccine confidence have dropped to their lowest level since 2008, necessitating strong community engagement for education regarding trials and vaccine uptake. Public mistrust is more directed toward the government and industry rather than healthcare providers, indicating that trusted voices within the community are essential for effective communication.

Improving patient care and access, including financial support, can enhance vaccination rates. Inconsistencies in vaccination strategies between states must be addressed for a unified national approach. Local implementation activities must however be tailored, and clear, and open discussions with community leaders are crucial, as a "one-size-fits-all approach" is ineffective. The WHO framework helps understand vaccination drivers, highlighting social processes, beliefs about vaccine safety, access issues, and practical barriers such as cost and appointment availability (Figure 13).[10]

A global decline in vaccination post-COVID-19, fuelled by social media, reduced trust in government, political polarisation, and vaccine fatigue, contrasts with the stable trust in healthcare workers. Significant barriers exist for First Nations people, requiring urgent action to address these issues.

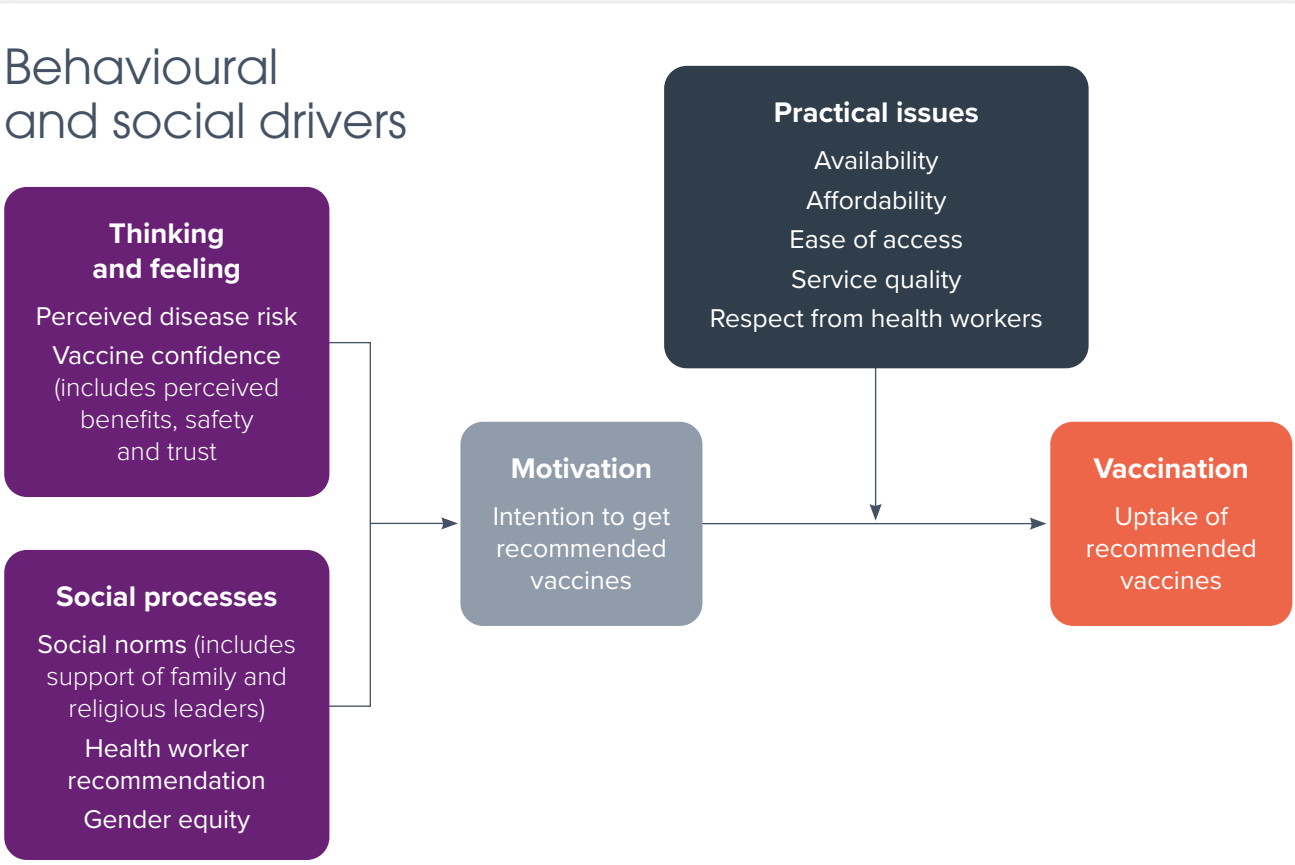


Figure 13: Behavioural and Social Drivers of Vaccine uptake.

Adapted from the **WHO Framework for measuring drivers of uptake**.

State-based recommendations and unique vaccine-preventable diseases (VPDs) relevant in Australia but not included in the National Immunisation Program (NIP) add complexity for providers, making it challenging to understand all recommendations and risk groups. To address this, the next national immunisation strategy should explicitly include adult vaccination targets, with corresponding policy levers, both at a national level and for specific target groups.

Currently, specific targets exist only for infant and childhood vaccinations, which significantly influences prioritisation and behaviour. This strategy should be part of a united, intentional initiative with the overarching goal of building vaccine confidence across all Australian communities. This should prioritise using evidence-based communication strategies such as champions, grass roots community leadership, and allowing industry to engage in more open and meaningful education dialogue.

On the following page is a Case Study of a successful vaccine campaign in Hunter New England (HNE) which implemented an Aboriginal governance model during the COVID-19 pandemic, establishing the Public Health Aboriginal Team (PHAT) to provide culturally informed leadership and oversight, leading to significant increases in vaccination rates among Aboriginal and Torres Strait Islander communities through strategic, multiagency collaboration and community-centred approaches.[11,12]

CASE STUDY

Hunter New England Region

Northern New South Wales, Australia

Hunter New England (HNE) is a large geographical area in New South Wales, Australia, with approximately 72,000 Aboriginal and Torres Strait Islander residents. In March 2020, the local Public Health Incident Command System embedded an Aboriginal governance model to provide cultural oversight and insight into the local COVID-19 incident command system (Crooks et al., 2023). The model ensured the local pandemic response was culturally informed and inclusive of Aboriginal people's voices and perspectives. The Aboriginal governance model enabled the establishment of the Public Health Aboriginal Team (PHAT) for COVID-19 that provided strategic and operational leadership, advice, and guidance for the local pandemic response. The PHAT coordinated three strategic and multiagency governance groups: (a) the HNE Aboriginal Governance Group on COVID-19; (b) the HNE Aboriginal Data Governance Group; and (c) the HNE Aboriginal Vaccination Steering Committee. These governance groups fostered and promoted transparent, two-way communication to support effective engagement (Crooks et al., 2023). As Indigenous data sovereignty is paramount, the Aboriginal Data Governance Group provided cultural oversight to ensure COVID-19 data were reported and interpreted through a cultural lens (Crooks et al., 2023). Importantly, an accountability framework was implemented so that response teams ensured that everyone had the opportunity to receive culturally appropriate support (Crooks et al., 2023). This involved the PHAT staff providing holistic care and follow-up telephone support to the case and their contacts and family members, including education, referral to testing and vaccine clinics, provision of personal and household items, and referral to local support services.

The PHAT, in partnership with the HNE Immunisation Team, activated the HNE Aboriginal Vaccination Steering Committee in October 2021 with the support of the local executive for emergency management, the Health Services Functional Area Coordinator, to respond to low initial COVID-19 vaccine uptake and the coverage gap between Aboriginal and non-Indigenous residents, and enable the development and implementation of locally informed and determined COVID-19 vaccination strategies. Situational reports were provided by PHAT to inform consensual decision-making by the Committee. The Committee consisted of Aboriginal and Torres Strait Islander health leaders, practitioners, and clinicians, as well as non-Aboriginal emergency management and immunisation leaders and clinicians. In the 5 weeks following the establishment of the Committee, 29,751 vaccinations were administered. This was achieved by working in partnership with key internal and external stakeholders including HNE Local Health District, Aboriginal Community-Controlled Health Organisations, the Australian Royal Flying Doctor Services, universities, and the Primary Health Network to offer a variety of accessible options ranging from large pop-up walk in clinics, after hours and weekend clinics, to more personal at home visits. The Team also offered transport, developed culturally appropriate and targeted information and messaging, and engaged local public health experts to have conversations with community members who were undecided to have the COVID-19 vaccine. Rather than expecting community members to register online to have the vaccine to then book in to receive it, the Team removed the barriers and challenges that Aboriginal and Torres Strait Islander often face when accessing health care, by taking the vaccine to the communities through localised and tailored vaccination strategies. This governance approach to a pandemic response had not previously existed in New South Wales and provided a model for embedding culturally and community-responsive insights to improve outcomes for Aboriginal and Torres Strait Islanders.

Case study wording from: Clark, K., Crooks, K., Jeyanathan, B., Ahmed, F., Kataquapit, G., Sutherland, C., Tsuji, L. J. S., Moriarity, R. J., Spence, N. D., Sekercioglu, F., Liberda, E. N., & Charania, N. A. (2024). Highlighting models of Indigenous leadership and self-governance for COVID-19 vaccination programmes. AlterNative: An International Journal of Indigenous Peoples, 20(1), 250-258. https://doi.org/10.1177/11771801241235418. Kimberley region (Western Australia, Australia)

Original Case Study Publication: Crooks K, Law C, Taylor K, et alEmbedding Aboriginal cultural governance, capacity, perspectives and leadership into a local Public Health Unit Incident Command System during COVID-19 in New South Wales, AustraliaBMJ Global Health 2023;8:e012709.

Barriers to getting vaccinated

Information and education

- Too much information causes confusion and mistrust
- COVID-19 vaccine development
- Need for multiple doses
- Conspiracy theories

Mistrust

- COVID-19 vaccination process
- Feelings of being controlled
- Inconsistent and changing information

"a lot of people don't think vaccines are safe and they don't trust vaccination"

Personal and community factors

- Past negative experiences of getting vaccinated
- Fear of needs
- Family influence
- Cultural influence

Access and logistics

- Rural and remote access
- Transport
- Stock availability
- Lack of GP appointments
- Long waitlists
- Drop-in vaccination clinics stopped

Communication

- Vaccine incentives perceived as bribery
- Not tailored, targeted, timely or localised

Figure 14: Barriers to getting vaccinated

Adapted from K. Crooks presentation: **Achieving Equity in Underserved Populations**

Recommendations

- Track drivers of vaccinations by identifying metrics to evaluate the most effective interventions and leverage the expertise of social scientists; Enable the public to use methods that work: e.g. SMS reminders for appointments increased vaccinations.
- Develop and expand on a community-based vaccine champions model to enhance communication with the public, engage early and focused on the needs of Culturally and Linguistically Diverse (CALD) populations.
- Develop a plan for whole of life immunisation that includes all providers to reach all communities. Improved coordination of all national stakeholders for consistent messages is needed. Reminders and incentives improve uptake.
- Engage early with communities to increase diversity in clinical trials populations and get consumer buy-in early and for increased participation/uptake.

Plenary 7: Market Access and Health Technology Assessment

Objectives

- Outline how vaccines are evaluated in Australia and overseas from a health economic perspective and understand the full value of vaccines to society.
- Explore the HTA review, its priorities and considerations for vaccines from payer, clinician researcher, and industry perspectives.
- Understand the current system and identify bottlenecks, data gaps and opportunities for change.

Outcomes

- Identification of pain points and areas of improvement and focus that are predicted to drive better access to vaccines for the Australian community.
- Reach a common understanding on the full potential value of vaccines and explore ideas for collaborative models to generate new data and real-world evidence.
- Understand the relevance of market attractiveness as a pull mechanism to drive industry investment.

Figure 15: Word cloud of AVVCC audience poll responses to "What is the value of vaccines?"

To further illustrate the value of vaccines, below represents the concepts of vaccination value with respect to the impact the COVID-19 pandemic has had on society.[13–15]

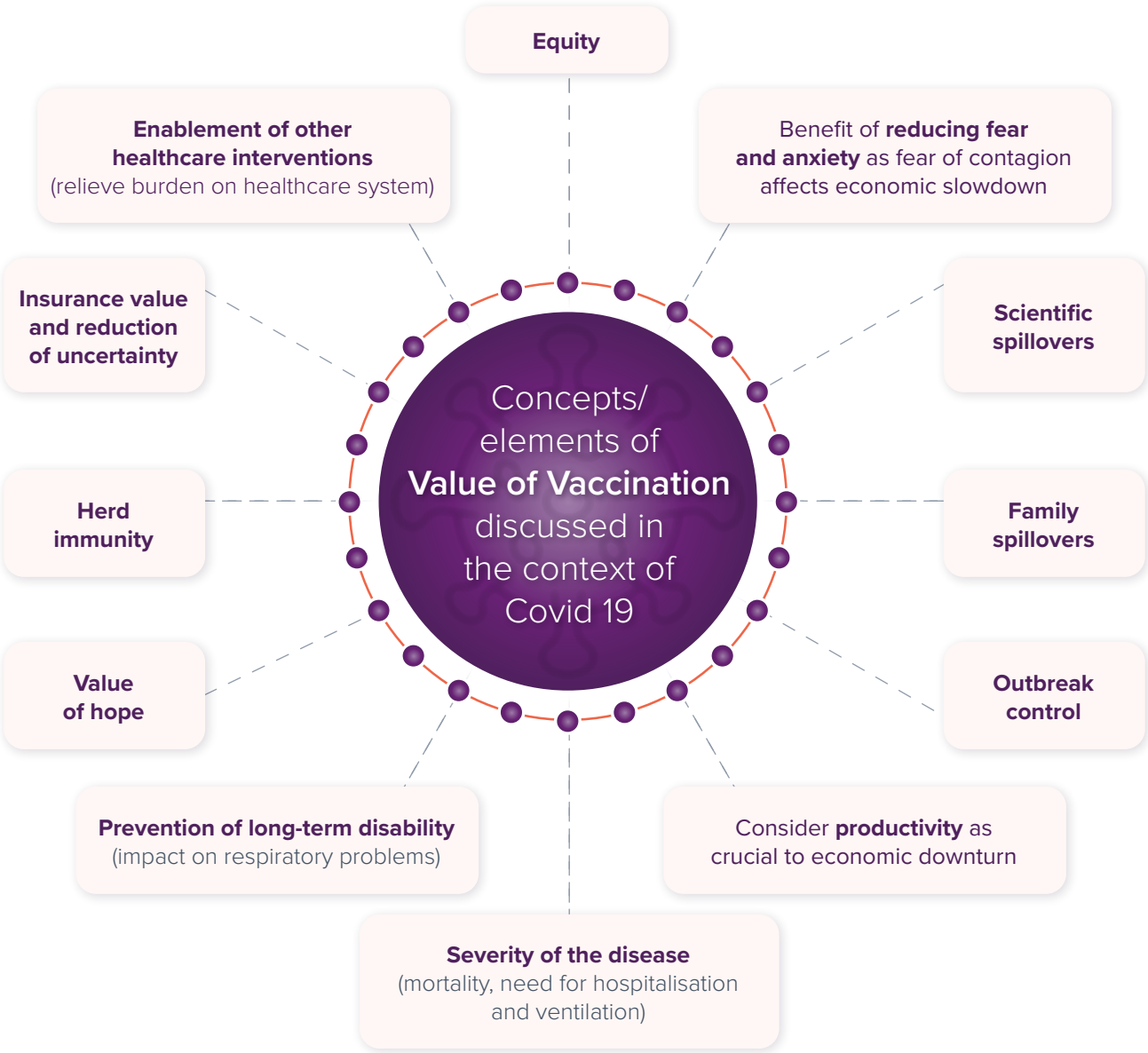


Figure 16: The Value of Vaccination in the context of COVID-19

Adapted from Beck, E. *et al.* Capturing the value of vaccination within health technology assessment and health economics: Literature review and novel conceptual framework. *Vaccine* 40, 4008–4016 (2022).

Australia's vaccine value chain faces significant challenges in market access and health technology assessment (HTA). Stakeholders share a vision of optimising the time for Australians to access new vaccines while ensuring thorough evaluations, as outlined in the recent Strategic Agreement between the Australian Government and Medicines Australia. Economic evaluation is crucial for assessing value for money, requiring consistency in methods across vaccine and non-vaccine-related interventions; however, willingness to pay for vaccines also sends an important signal to vaccine developers regarding the feasibility of commercialising a vaccine.

Australia is currently undertaking a review of HTA which is considering the methods and processes for vaccine funding. The following issues were raised in the plenary session as key focus areas for HTA reform:

- The current focus in HTA in Australia is narrow, and does not capture the broader societal perspectives that have been proposed in the literature and in evaluations overseas.
- Access timelines for publicly funded vaccines in Australia are lengthy, due to a multi-step process involving ATAGI review, PBAC review, and a tender process before NIP listing, taking an average of 1,355 days – almost 4 years – from TGA ARTG listing to NIP rollout.
- PBAC standard discount rate of five per cent is high by international standards, which affects the evaluation of vaccines more than medicines, as benefits accrue over a long period after administration of the vaccine.
- Requirements for local data and evidence that are not proactively met through investments in data capture and analysis to understand local epidemiology of infectious diseases where horizon scanning has identified that vaccines will soon become available.

Vaccine assessment processes are long, with multiple reviews and decision making

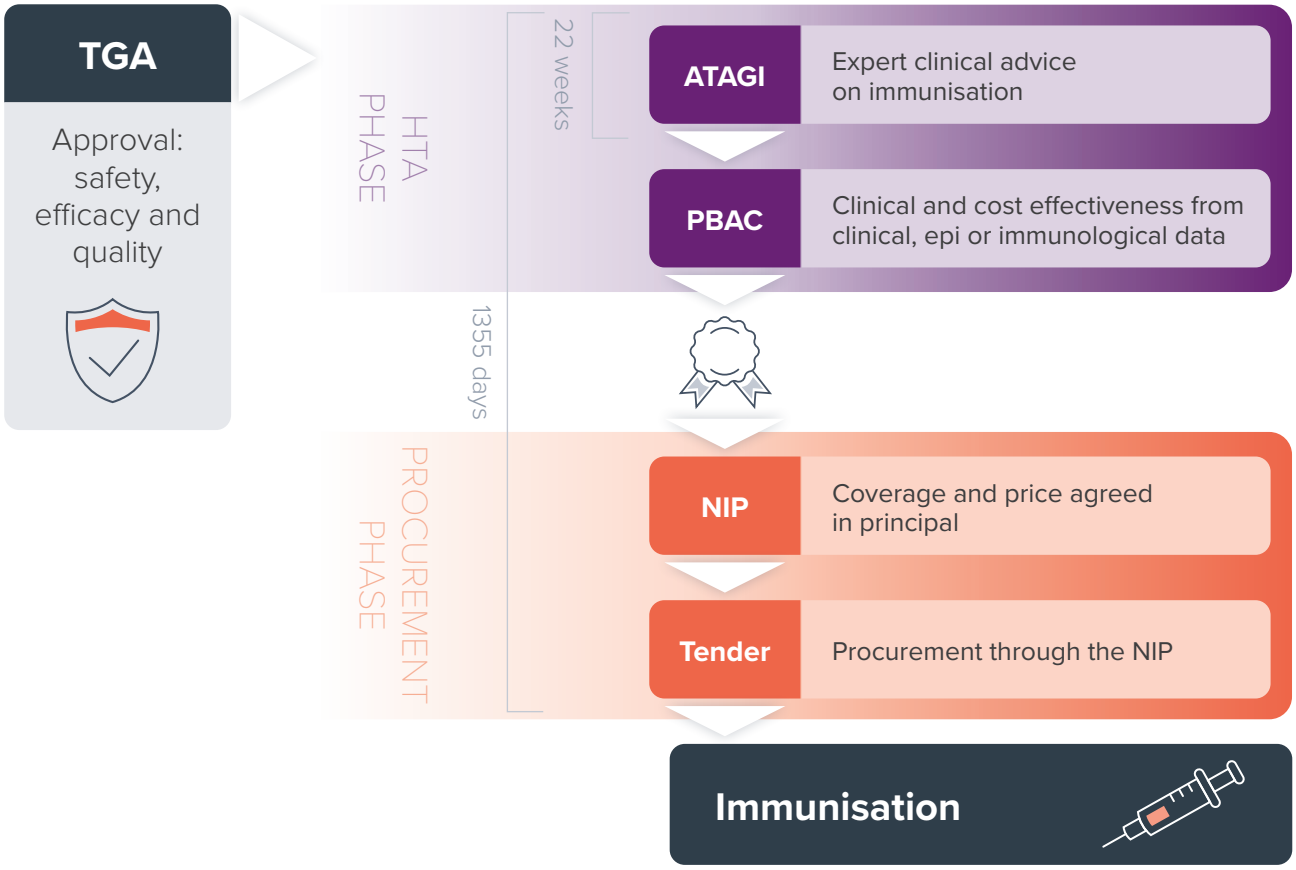
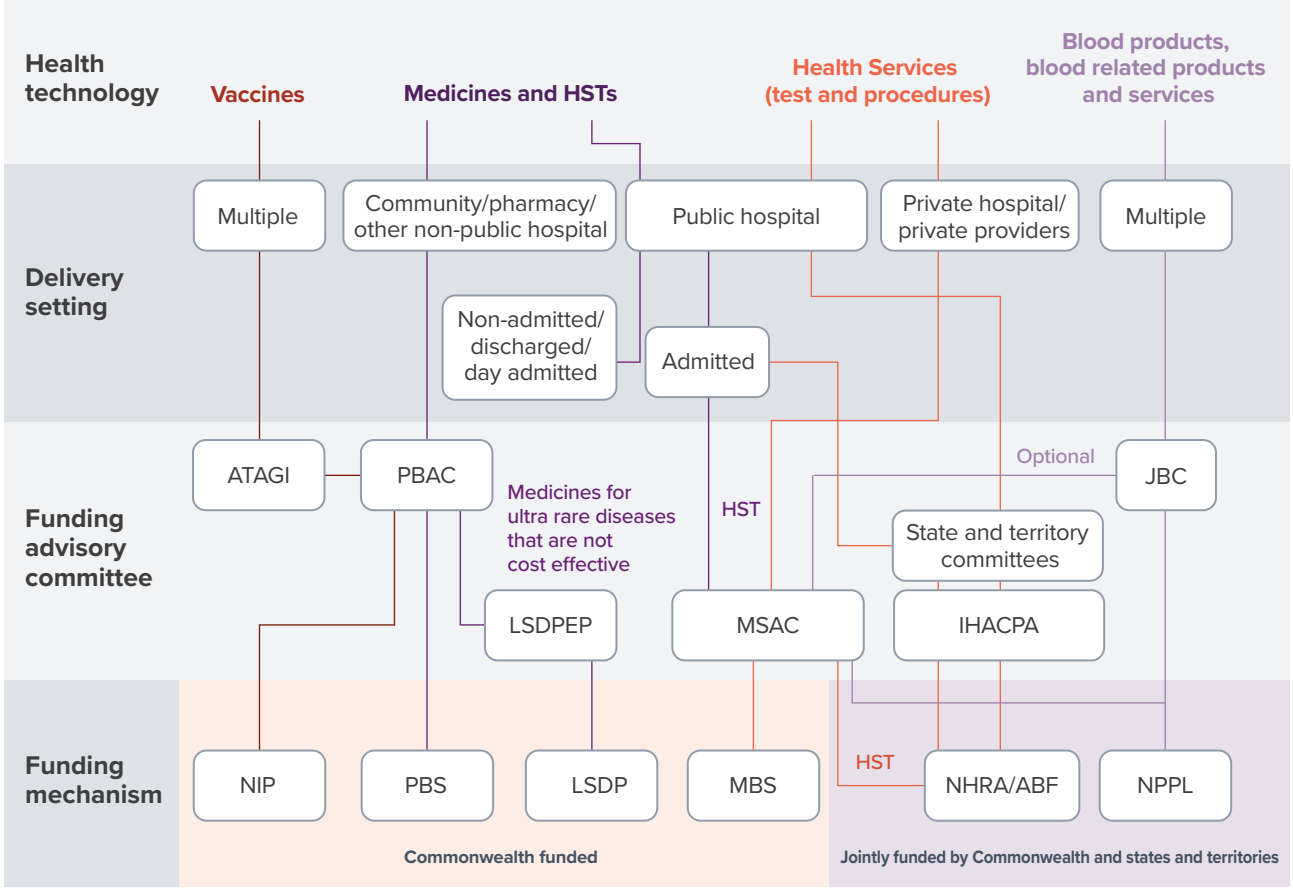


Figure 17: Vaccine assessment processes are long, with multiple reviews and decision making.

Adapted from A. Thirlwell presentation: **Valuing Vaccines Industry Perspectives on HTA for Vaccines**

Health Technology Assessment (HTA) pathways for assessing value of vaccines

Funding pathways for Commonwealth funded health technologies



Vaccine sponsor

Medical evidence
- RWE, RCT, burden of disease data

Economic evidence
- CEA, BIM based on RWE and RCT data

JCVI

Technical and economic committee

Evaluation and decision/recommendation on the medical and economic benefit of vaccine and inclusion of NIP. Evaluates CEA, RWE, RCT evidence sources

Implementation

Devolved UK governing bodies

Figure 18: Health Technology Assessment (HTA) pathways for assessing value of vaccines.

Adapted from N. Carvalho presentation: **Perspectives on how vaccines are valued.**
Left from: **HTA Policy and Methods Review** (2024) (Draft paper)[16], Right from: **Chicoye et al.** (2023) Vaccine 41(38).[17]

To this latter point, investments in generating high-quality real-world evidence and facilitating rapid access to harmonised, informative datasets and near real time data linkage at a national level are necessary. The UK's JCVI serves as a case study enabling rapid real-world evidence studies to inform vaccine recommendations. Moreover, Australia's role in supporting new vaccine launches and attracting investment in the region is critical. Finally, appropriate governance models, disclosure, and transparency can ensure collaboration is not hampered by conflicts of interest, and without precluding experts from working with the industry in this small community.

Recommendations

- Ensure that vaccine-specific issues and methodologies that affect the evaluation of vaccines (which have long-term and broad societal benefits) are specifically addressed in Australia's response to the Health Technology Assessment (HTA) review. This includes more efficient evaluation timelines, adopting broader value frameworks, investing in real world evidence (RWE) and reducing the base case discount rate. HTA should be aligned to overarching government policy for preventive health and aim to maintain Australia's position as a priority launch country for new vaccines.
- Establish a co-funded engagement partnership model for industry to collaborate with academia and government to generate real-world data and evidence in a timely manner to inform HTA decision making (e.g. IMI's RESCEU for RSV).
- Explore opportunities to incentivise greater industry investment in R&D in Australia through enhancing the access environment, including more efficient pathways, timelines and broader decision frameworks that capture the true value of vaccines.

ATAGI: Australian Technical Advisory Group on Immunisation
ARTG: Australian Register of Therapeutic Goods
HTA: Health Technology Assessment
ICER: Institute for Clinical and Economic Review
JCVI: The Joint Committee on Vaccination and Immunisation
NIP: The National Immunisation Program
PBAC: The Pharmaceutical Benefits Advisory Committee

Plenary 8: Funding and Investment

Objectives

- Outline and update investment strategies available for vaccine commercialisation and innovation in Australia.
- Understand the barriers and enablers for private equity, venture capital and industry investment decisions.
- Discuss investment challenges when there are limited commercial returns.
- Stimulate appetite for Public-Private partnerships within Australia.

Outcomes

- Identification of funding and investment gaps, levers to attract funding, industry investment, and examples of new partnership models that will ensure optimal outcomes for Australia and the broader region.

Australia's vaccine value chain faces critical challenges in funding and investment. To enhance market attractiveness, Australia must address its current small market size and high costs by streamlining processes, creating a one-stop-shop, and developing a cohesive national strategy. Grant funding eligibility and criteria can be too narrow, hindering product development from reaching maturity for private sector investment, thus misaligning medical research policy with industry policy goals. Could retaining more value chain components domestically, instead of outsourcing late stages of clinical research and manufacture, generate approximately 10,000 jobs?

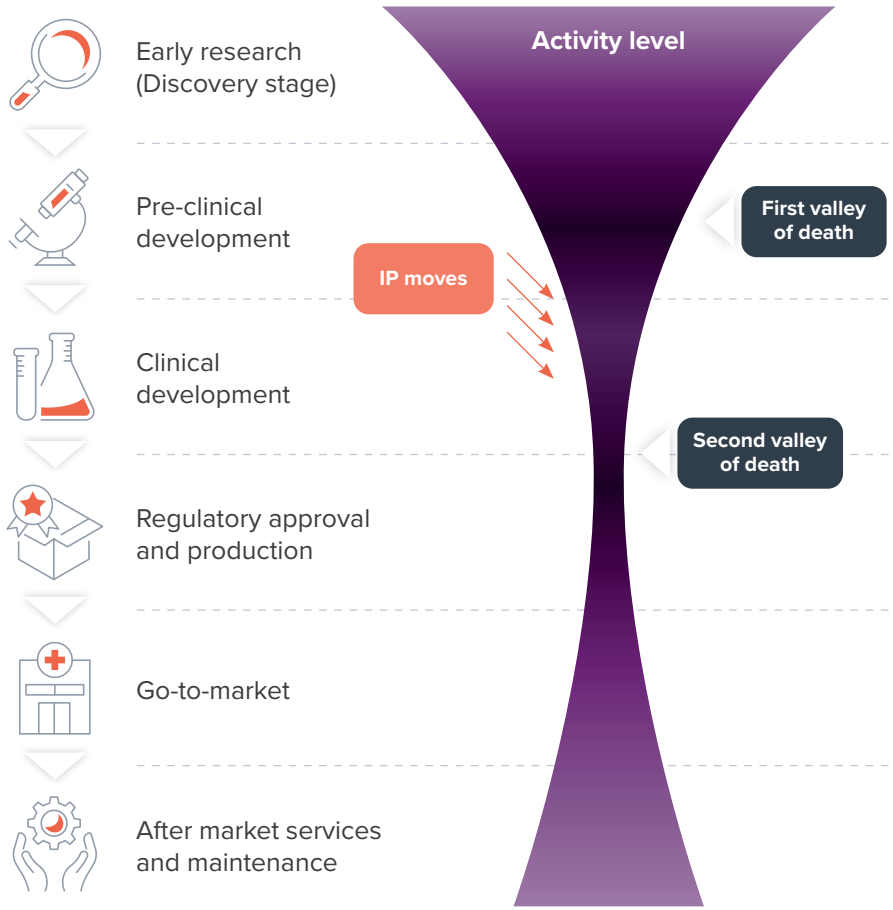
Greater participation in global clinical trials, particularly phase 3 and trials of seasonal respiratory vaccines, would leverage Australia's diverse population. Additionally, the protracted timeline from TGA registration to funding needs urgent reform, as exemplified by the five-year delay for a recent shingles vaccine despite robust data, and the average delay of almost four years.

All MRFF grant opportunities encourage partnering, particularly between companies or industries, partnering with other organisations or researchers to improve the potential research impact and translation into practice.

~ Pru Glasson

TGA: Therapeutic Goods Administration
MRFF: Medical Research Future Fund
NHMRC: National Health and Medical Research Council
KPIs: Key Performance Indicators
TRL: Technology Readiness Levels
DFAT: Department of Foreign Affairs and Trade

How do we retain a greater proportion of the value chain?



- Strong public investment in basic research (~$1.5bn per year)
- Opportunity to capture more of the middle phases of development and the value lost offshore
  - Australia's participation in 36% of global trials (45% of Phase III) results in 8,000 direct jobs and $1.4bn invested. Multiplier effect estimated as 1-6x (MTP Connect 2019)
- Some recent wins – One Stop Shop, Medica Co-Investment Plan
- Can addressing time/value to reimbursement serve as a catalyst for increased trial investment and footprint?

Is there another ~10,000 direct jobs and $1-2bn+ of value creation readily accessible?

Figure 19: How do we retain a greater proportion of the value chain?

Image adapted from **Australian Government Medical Science Co-Investment plan** and P. Desbiens presentation: **How Industry Makes Investment Decisions**

Recommendations

- Create a national Product Development Partnership (PDP) for vaccine development (government funding needed) to accelerate both for profit and public good vaccine development.
- Seek co-investment funding from CEPI RVMC and the BARDA Acceleration Network (BAN) for Vaccines for a strategic approach to capability and capacity building that includes international collaboration.
- Consider more industry-led targeted funding from MRFF and NHMRC that is focused on new technology development with accountability for achieving KPIs and TRL milestones. This needs to allow international collaboration to address the local skills gaps. Consider pull incentives for diseases with limited commercial return or for Australian priority pathogens.
- Ensure cross portfolio (Health, Industry, Defence, DFAT) collaboration to align on shared strategic goals of a sustainable vaccine commercialisation industry, regional security, and public health mission to improve access and uptake for Vaccine Preventable Diseases (VPDs).

Plenary 9: The Vaccine Value Chain: Bringing it All Together

Bottlenecks and gaps in the vaccine value chain

The discussions and recommendations from Australia's Vaccine Value Chain Conference underscore the critical need for a coordinated and strategic approach to enhance Australia's vaccine ecosystem. One important issue to address is market attractiveness. Currently, Australia's market is very small and less appealing for investors due to high capabilities and costs. Establishing a one-stop-shop and a national strategy could significantly streamline processes and make Australia a more attractive destination for vaccine development and commercialisation.

Moreover, aligning medical research policies with industry goals is crucial. Grant funding eligibility and criteria are sometimes too narrow and may not support product development to the point where private sector investment is viable.

By broadening grant funding and creating a supportive environment for product development, Australia can retain more of the value chain domestically. This could potentially generate 10,000 jobs and reduce the need to send research offshore.

Additionally, there is immense value in leveraging Australia's diverse population to enhance participation in global clinical trials, particularly phase III clinical trials. This approach not only strengthens Australia's position in the global market but also ensures that the vaccines developed are effective across different demographics.

Addressing the lengthy period from TGA registration to NIP funding in Australia is another critical area for improvement. The extended timeline hampers timely access to new vaccines. A recent study found that the timeline from ARTG listing to NIP rollout was almost four years. Streamlining this process is essential to ensure that Australians can access new vaccines promptly.

Furthermore, retaining a higher proportion of the vaccine value chain within Australia would not only create job opportunities but also foster innovation and self-reliance. By focusing on strategic investments, streamlined HTA processes, and community needs, Australia can strengthen its vaccine value chain, ensuring robust participation in the global market and better health outcomes for its population.

ARTG: Australian Register of Therapeutic Goods

NIP: National Immunisation Program

TGA: Therapeutic Goods Administration

Recommendations

1. Defining a Coherent Vision and Alignment of Purpose

A. National co-ordination and prioritisation of objectives

Immunisation Strategy Priority Area	Recommendation	AVVCC Plenary Session
3	Ensure cross portfolio (Health, Industry, Defence, DFAT) collaboration to align on shared strategic goals of a sustainable vaccine commercialisation industry, regional security, and public health mission to improve access and uptake for Vaccine Preventable Diseases (VPDs).	P8
6	Create a national vaccine development network to facilitate knowledge sharing, coordination and collaboration as well as provide a more efficient framework for accessing the necessary expertise. It could also align with a national research strategy. A public private partnership model should be considered. It should include access to an expert network (including international). It should support development of vaccines for public health priorities as well as for industry and leverage funding from donors and philanthropy as well as the private sector. It should have a strong governance framework, be inclusive and transparent.	P1
6	Enhance existing models by access to subject matter experts (SMEs), a national Vaccine Development Partnership could act as a central coordinating entity, provide administrative and project management support as well as create an SME network and vaccine community, international expertise would be needed to address local skills gaps e.g., in CMC, Toxicology, etc.	P2
4	Promote Australia's unique capabilities internationally for vaccine R&D, including clinical trials infrastructure and expertise, access to special populations, biobanks, laboratory capability, etc. to attract industry investment. A national pitch book should be developed with a catalogue of capability and contact points. Funding of a national vaccine value chain network with a coordinating body as a vaccine single front door could achieve this.	P2

DFAT: Department of Foreign Affairs and Trade

6	Create a national Vaccine Clinical Trial Network -adult and paediatric plus special populations. This should fund a coordinating body that can act as a single point of contact for sponsors conducting clinical trial feasibility and cover both investigator led and industry sponsored trials. The clinical trial network should be linked to the product development network to enable translation to the clinic. Develop national templates for costing vaccine trials and standardising contracts.	P3
6	Develop a national capability map of laboratory services and biobanks. Disease X surveillance – linking of public and private laboratories.	CEPI

B. Community engagement along all stages of the value chain

Immunisation Strategy Priority Area	Recommendation	AVVCC Plenary Session
2	Actively engage in partnership with grass roots community leadership to Co-optimise communication with the public.	P5
2	Track drivers of vaccinations by identifying metrics to evaluate the most effective interventions; Enable the public to use methods that work: e.g., SMS reminders for appointments increased vaccinations.	P6
2	Develop and expand on a community-based vaccine champions model to enhance communication with the public, engage early and focused on the needs of Culturally and Linguistically Diverse (CALD) populations.	P6
2	Develop a plan for whole of life immunisation that includes all providers to reach all communities. Improved coordination of all national stakeholders for consistent messages is needed. Reminders and incentives improve uptake.	P6
2	Engage early in clinical trials process with communities to increase diversity in clinical trials populations and get consumer buy-in early and for increased participation/uptake.	P6

2. Enabling Needed Capacities

A. Exploration of innovative funding models to achieve research translation and commercialisation

Immunisation Strategy Priority Area	Recommendation	AVVCC Plenary Session
3	Develop partnerships with existing funding models that are industry-led and focused on product development, or replicate such models locally (e.g., Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X), the Biomedical Advanced Research and Development Authority (BARDA) Acceleration Network – Therapeutics and Vaccines Hub, Coalition for Epidemic Preparedness Innovations (CEPI)), or enabling preclinical services such as those offered by National Institute of Allergy and Infectious Diseases (NIAID).	P2
6	Consider more industry led targeted funding from MRFF and NHMRC that is focused on new technology development with accountability for achieving KPIs and TRL milestones. This needs to allow international collaboration to address the skills gaps here. Consider pull incentives for diseases with limited commercial return or for Australian priority pathogens.	**P8**

B. Subject matter training in specific skills and knowledge

Immunisation Strategy Priority Area	Recommendation	AVVCC Plenary Session
5	Establish an academic track for teaching vaccine development to students that includes bringing in external commercial experts and incentivising support for large-scale, innovative, next-generation technology.	P2
5	Prepare students for industry workforce by equipping universities with the capacity to train students in the transition from research laboratory to cleanroom and GMP manufacture.	P4
6	Provide project management and product development/regulatory overview training and support for working with CEPI – templates, training on KPI's. Education materials should be developed on manufacturing and quality to inform researchers and funders and ensure they prepare early.	CEPI

C. Regulatory review and governance

Immunisation Strategy Priority Area	Recommendation	AVVCC Plenary Session
3	Facilitate creation of a subject matter expert network in regulatory and quality to support early-stage projects with Chemistry Manufacturing & Control (CMC) plan (international network needed) and modify grant eligibility to enable use of international experts where capability does not exist in Australia.	P4
3	Develop novel platform regulation pathways, such as those for mRNA, and other expedited pathways urgently to streamline product development and review and to accelerate access.	P5
3	Ensure that vaccine-specific issues and methodologies that affect the evaluation of vaccines (which have long-term and broad societal benefits) are specifically addressed in Australia's response to the Health Technology Assessment (HTA) review. This includes more efficient evaluation timelines, adopting broader value frameworks, investing in real world evidence (RWE) and reducing the base case discount rate. HTA should be aligned to overarching government policy for preventive health and aim to maintain Australia's position as a priority launch country for new vaccines.	P7
3	Build on the National One Stop Shop to create streamlined solutions for vaccines: Develop national templates for costing vaccine trials with standardised inputs at a country level. Develop standardised contracts to reduce duplication. An example being the UK Clinical Research Network model:The Future of Clinical Research Delivery: 2022 to 2025 implementation plan - GOV.UK (www.gov.uk)	P3
3	Explore opportunities to incentivise greater industry investment in R&D in Australia through enhancing the access environment, including more efficient pathways that, timelines and broader decision frameworks that capture the true value of vaccines.	P7
3	Explore standard models provide training to enable public and private collaborative models to be established more rapidly. Different approaches to management of intellectual property can create barriers to collaboration.	P2

D. Infrastructure investments to catalyse growth across the entire ecosystem

Immunisation Strategy Priority Area	Recommendation	AVVCC Plenary Session
6	Facilitate exchange programs overseas to upskill local manufacturing teams in clinical development and industry. Consider nationally recognised training accreditation scheme and address recruitment and retention challenges including the Visa restrictions.	P4
6	Establish manufacturing and translation facilities capable of delivering product to GMP.	P4
6	Map Australian vaccine manufacturing capability and conduct needs assessment and gap analysis for critical vaccines and pipeline technologies to inform NRF strategy.	P4
6	Create a fit-for-purpose Australian fill and finish network, including commercial scale fill and finish for sterile injectables.	P4
6	Develop commercial real estate/shared facility with cold chain capability that can be used for other Australian manufacturing and repurposed during high-demand times	P4
6	Re-engage with CEPI on Regional Vaccine Manufacturing Collaborative (RVMC), Map Australian capability (with DMTC) and develop APAC strategy.	CEPI

HTA: Health Technology Assessment

ICER: Institute for Clinical and Economic Review

NRF: National Reconstruction Fund

3. Development of metrics to assess progress towards goals

A. Process Evaluation – Is more translation happening?

Immunisation Strategy Priority Area	Recommendation	AVVCC Plenary Session
4	Implement an Australian national standard framework to measure translation and commercialisation of vaccine products. The Technology Readiness Level (TRL) gradings are recommended and already adapted for vaccine products and standard practice when used by US BARDA, US NIH, US FDA and locally this system is used by DMTC and for CRC-P funding but it needs a consistent approach across all stakeholders in the value chain.	P1
4	Revise major medical research grant funding data capture to include more specific data fields to measure research translation and product development milestones by disease target and technology type.	**P1**

BARDA: The Biomedical Advanced Research and Development Authority (An American integrated, systematic approach to the development of the necessary vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies such as chemical, biological, radiological, and nuclear accidents, incidents and attacks; pandemic influenza, and emerging infectious diseases).

CRC-P: Cooperative Research Centres Projects

DMTC: Defence Materials Technology Centre

NIH: The National Institutes of Health

FDA: Food and Drug Administration

IMI: Innovative Medicines Initiative

RESCEU: Respiratory syncytial virus consortium in Europe

RSV: Respiratory syncytial virus

VPD: Vaccine Preventable Disease

B. Outcome evaluation – Is disease burden being averted?

Immunisation Strategy Priority Area	Recommendation	AVVCC Plenary Session
2	Establish a working group to explore barriers, synergies, opportunities for collaboration and appropriate governance structures to enable integrated surveillance and knowledge sharing between human and animal health sectors	P5
4	Establish a co-funded engagement partnership model for industry to collaborate with academia and government to generate real -world data and evidence in a timely manner to inform HTA decision making (e.g., IMI's RESCEU for RSV)	**P7**
1	Create a national One Health Surveillance System to improve access to RWE surveillance data by linking public and private labs, allowing development of models using vaccine impact data to understand the VALUE of the vaccine.	P3
1	Establish a nationally co-ordinated approach to development of a One Health Surveillance System (OHSS) for infectious disease surveillance.	P5
1	Develop a national approach to address data gaps in VPD surveillance to enable burden assessment, and ongoing evaluation of vaccine risks and benefits.	P5
1	Encourate public and private sector collaboration to generate surveillance data and RWE within and between human and animal health sectors.	P5

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MACQUARIE University

CEPI

Australian National University

NCIRS National Centre for Immunisation Research and Surveillance Australia

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Appendix

I. List of Institutions of Attendees

360Biolabs

ACT Health

Adelaide University

Alfred Hospital / Monash Health

Amsterdam University

Animal Medicines (AMA)

Apiject

Australian Government Department of Health and Aged Care

Bactivac

Bellberry

BioDiem

Biocelect

Biointelect

Brasone Advisory

Burnet Institute

CARB-X

CR20

CSIRO

Centenary Institute

Cmax

Cube

DFAT

DMTC Health Security Systems Australia

Department of Health and Aged Care

Department of Industry, Science and Resources

Doherty Clinical Trials

Doherty Institute

GPN Vaccines

GSK

Garvan Institute

Griffith University

Hunter Medical Research Institute

ILIAD Biotechnologies

Immunisation Coalition

Influenza Centre / VIDRL

International Vaccine Institute

Investment NSW

MTP Connect

Macquarie University

Mater

Medicines Australia

Melbourne University

Moderna

Monash University

Murdoch Children's Research Institute

NHMRC

NSW Health

NSW Medical Research

NSW Ministry of Health

National Centre for Immunisation Research and Surveillance

Nexus

Novavax

Office for the Minister for Health and Ageing, Parliament House, Canberra

Office of the NSW Chief Scientist and Engineer

PBAC

PPD

PSA

Partnerships for African Vaccine

Pfizer

Policy Cure Research

Pop-Up Health

QIMR Berghofer Medical Research Institute

SA Dep of Trade and Investment

Sanofi

Sementis Ltd

Seqirus

TGA

Technovalia

Telethon Kids Institute

The University of New South Wales, School of Biomedical Sciences

Therapeutic Innovation Australia

UTS

University of Adelaide

University of Melbourne

University of Queensland

University of South Australia

University of Sunshine Coast

University of Sydney

VIC-Department of Health

VIC-Department of Jobs, Skills, Industry and Regions

VIDRL Epidemiology

Vaccinology and Immunology Research Trials Unit, W&C Hospital Adelaide

Vaxxas

Viral Vector Manufacturing

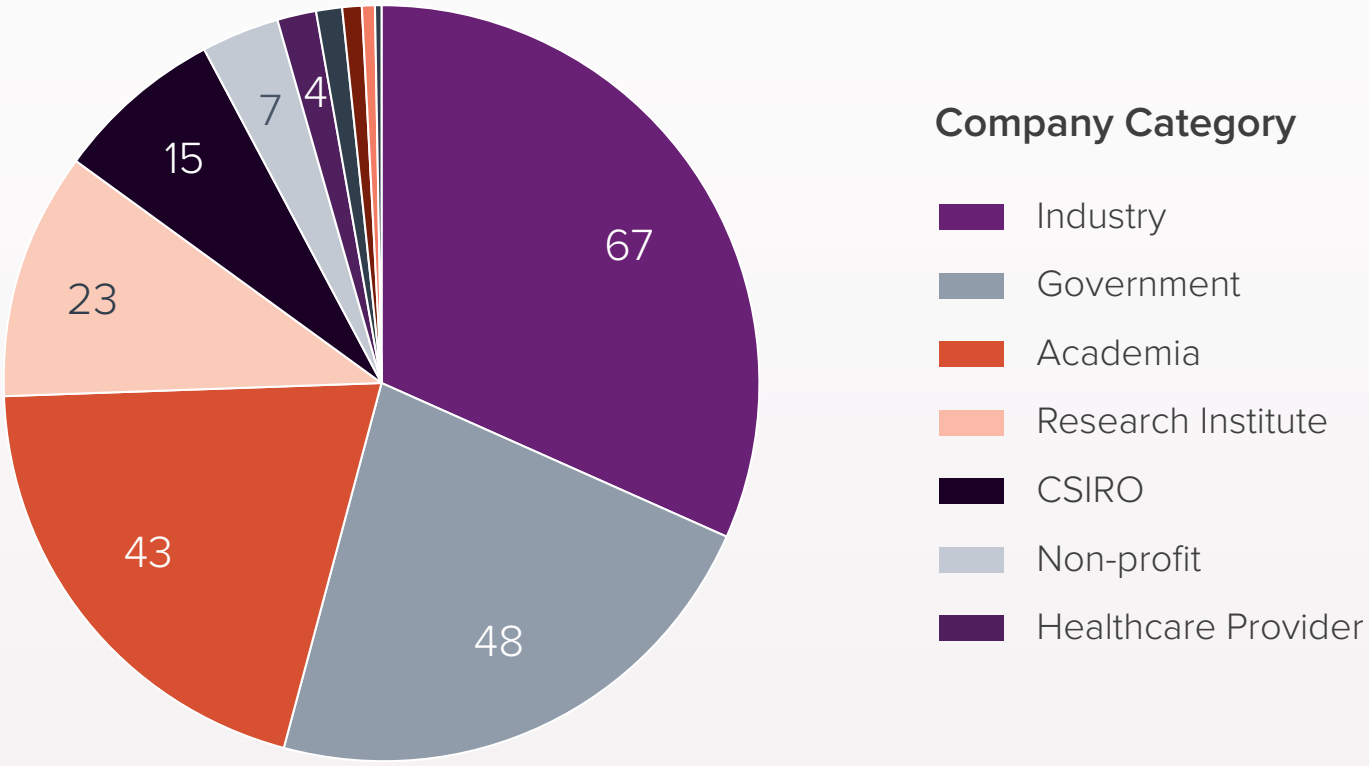
Virologist

Vironovative BV

Walter and Eliza Hall Institute of Medical Research / WEHI

Westmead Clinical School, Institute for Clinical Pathology and Medical Research

II. Breakdown of registered attendee by type



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Glossary

Abbreviation	Expansion
AMR	Antimicrobial Resistance
ARTG	Australian Register of Therapeutic Goods
ATAGI	Australian Technical Advisory Group on Immunisation
BARDA	Biomedical Advanced Research and Development Authority
CALD	Culturally and Linguistically Diverse
CARB-X	Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator
CDC	Center for Disease Control (US)
CEPI	Coalition for Epidemic Preparedness Innovations
CRC-P	Cooperative Research Centres Projects
CRO	Contract Research Organisation
DFAT	Department of Foreign Affairs and Trade
DMTC	Defence Materials Technology Centre
FDA	Food and Drug Administration (US)
GMP	Good Manufacturing Practices
HTA	Health Technology Assessment
ICER	Institute for Clinical and Economic Review
IMI	Innovative Medicines Initiative
IND	Investigational New Drug (US Food and Drug Administration)
LMIC	Low-or Middle-Income Countries
MBS	Medicare Benefits Schedule
NIH	The National Institutes of Health
NIP	National Immunisation Program
NRF	National Reconstruction Fund
OHSS	OneHealth Surveillance System
PCR	Polymerase Chain Reaction
PDP	Product Development Partnership
RDTI	Research and Development Tax Incentive
RESCEU	Respiratory syncytial virus consortium in Europe
RSV	Respiratory syncytial virus
RVMC	Regionalized Vaccine Manufacturing Collaborative
RWE	Real-World Evidence
SME	Subject Matter Expert
TGA	Therapeutic Goods Administration
TRL	Technology Readiness Level
VPDs	Vaccine-Preventable Diseases
WHO	World Health Organisation











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