

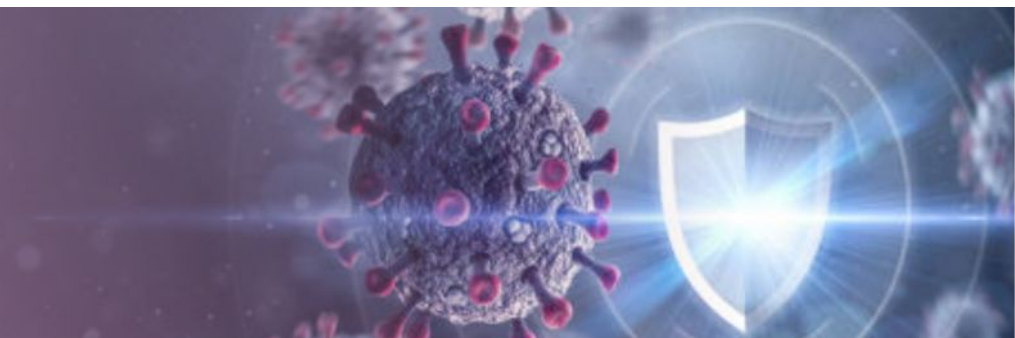


3:30 pm

## The vaccine value chain: opportunities and challenges in Australia

Jennifer Herz

Co-Founder & Director, Biointelect



# Inaugural Australian Vaccine Value Chain Conference, 21-22 May 2024



**Jennifer Herz**  
Co-founder and Strategic Advisor, Biointelect



**Branwen Morgan**  
Lead, Minimising AMR Mission  
Research Director, Health & Biosecurity, CSIRO



**John Skerritt**  
Enterprise Professor for Health Research Impact, University of Melbourne



**Jodie McVernon**  
Professor and Director of Doherty Epidemiology  
Head, VIDRL Epidemiology Unit, Department of Infectious Diseases



**David Grolman**  
Medical mRNA and Antiviral Lead, Pfizer Australia



**Ian Henderson**  
Executive Director, Institute for Molecular Bioscience, UQ



**Leanne Hobbs**  
Independent Consultant



**Alma Fulurija**  
Head of Strep A Vaccines Telethon Kids



# Tuesday 21<sup>st</sup> May 2024

8:00am – 8:30am	<b>Registration</b> Coffee, Tea and Refreshments
8:30am – 8:50am	<b>Opening of the Conference</b> Welcome to Country and Opening Remarks
8:50am – 10:15am	<b>Plenary 1:</b> The Vaccine Value Chain – What Do We Want for Australia?
10:15am – 10:45am	Morning Tea and Networking
10:45am – 12:00pm	<b>Plenary 2:</b> Preclinical Vaccine Development Capabilities in Australia: Governance, Skills and Talent
12:00pm – 1:00pm	Lunch and Networking Event
1:00pm – 2:15pm	<b>Plenary 3:</b> Clinical Trials and Infrastructure
2:15pm – 3:30pm	<b>Plenary 4:</b> Manufacturing: Supply, Demand and Sustainability
3:30pm – 4:30pm	Afternoon Tea and Networking
4:00pm – 5:30pm	<b>Plenary 5:</b> Enabling Policy and Regulation for Vaccines
6:00pm – 7:00pm	Pre-dinner Drinks <b>Venue:</b> Strangers Foundation Room, NSW Parliament <b>Pre-dinner remarks:</b> Leah Goodman, CEO Biointelect & The Hon Anoulack Chantivong MP Minister for Innovation, Science and Technology
7:00pm – 10:00pm	Dinner and Evening Networking

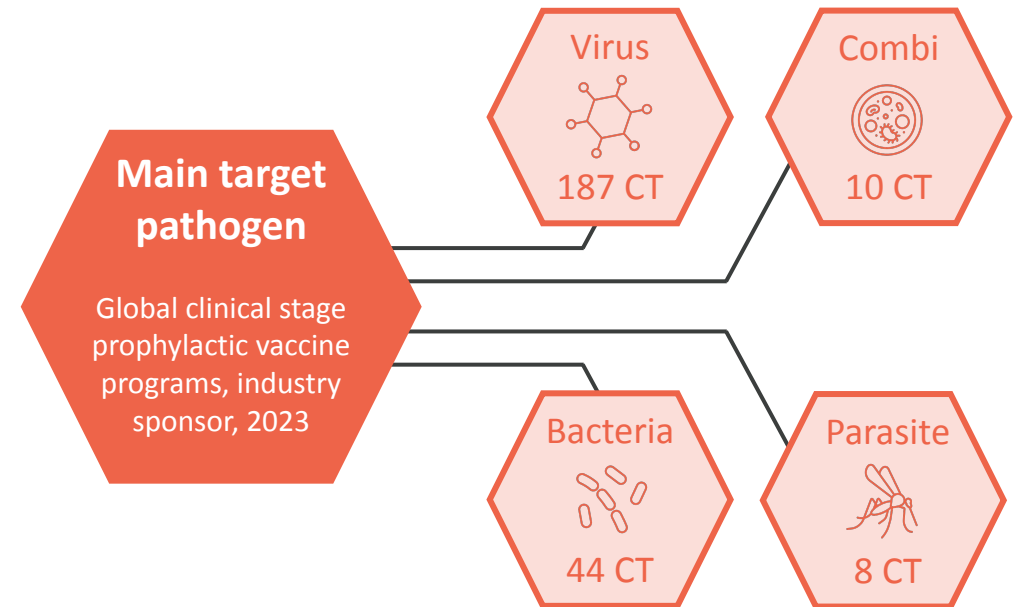
# Wednesday 22<sup>nd</sup> May 2024

8:00am – 8:30am	Coffee, Tea and Refreshments
8:30am – 9:45am	<b>Special Session:</b> How Can Australia Contribute to Advance CEPI's 100 Day Mission and the Regional Vaccine Manufacturing Collaborative?
9:45am – 11:00am	<b>Plenary 6:</b> Equity of Access and Uptake
11:00am – 11:30am	Morning Tea and Networking
11:30am – 12:45pm	<b>Plenary 7:</b> Market Access and Health Technology Assessment
12:45pm – 1:45pm	Lunch and Networking
1:45pm – 3:00pm	<b>Plenary 8:</b> Funding and Investment
3:00pm – 3:40pm	<b>Plenary 9:</b> Bringing it All Together/The Vaccine Value Chain
3:40pm – 3:50pm	<b>Closing Remarks</b> The Hon Anoulack Chantivong MP Minister for Innovation, Science and Technology
4:15pm – 5:30pm	<b>CSIRO Satellite Session:</b> Advancing Innovation in Australian Veterinary Vaccines

# Global vaccine clinical development pipeline

“ A substance used to stimulate the **production of antibodies** and **provide immunity** against one or several diseases, prepared from the **causative agent of a disease, its products,** or a **synthetic substitute,** treated to act as an antigen **without inducing the disease.** ”

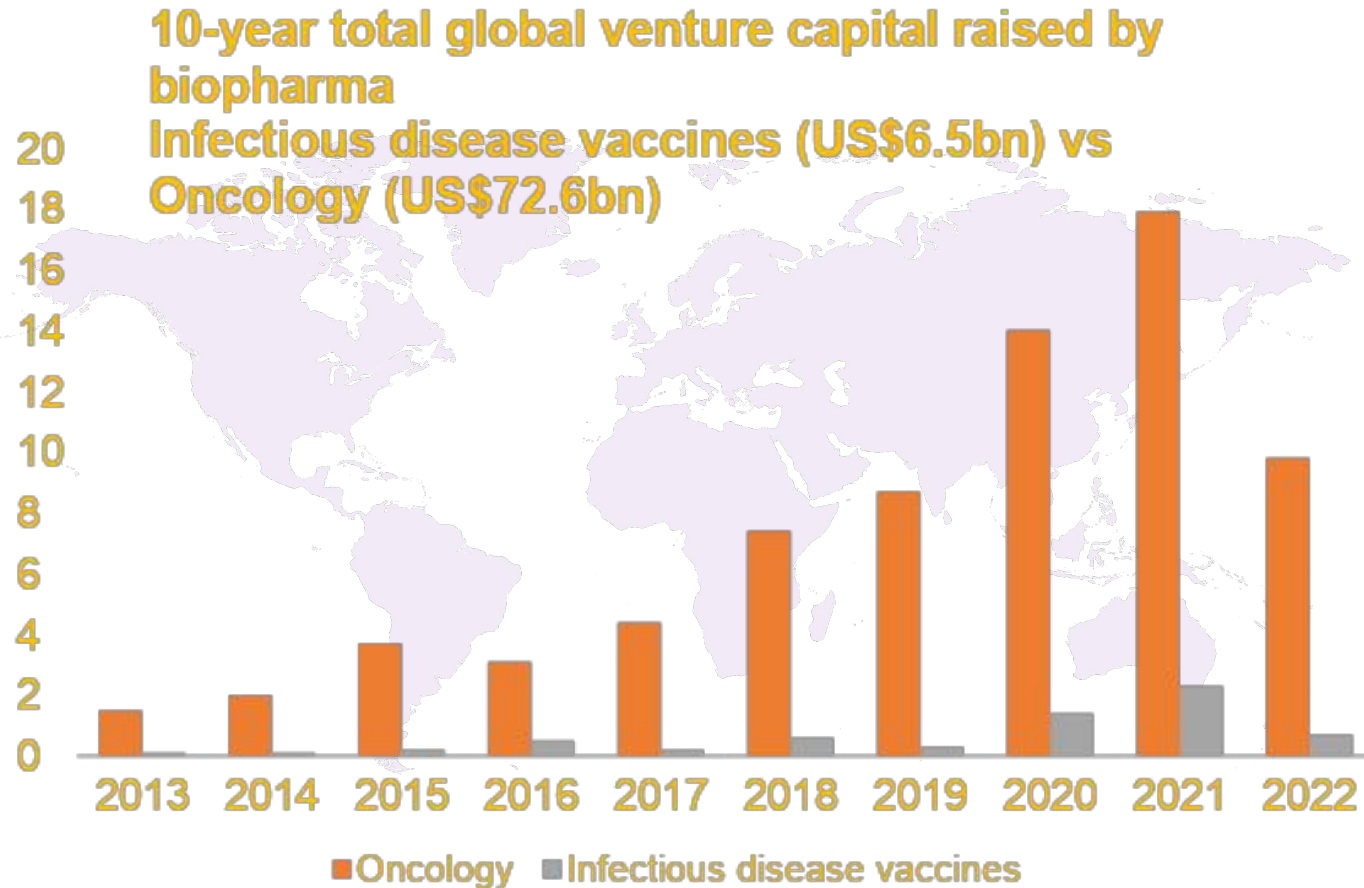
Summary of global vaccine clinical development pipeline	
34	Unique pathogens have a licensed and approved vaccine
15	Different vaccine modalities in clinical-stage development
31	Infectious diseases in the clinical pipeline for which there is no currently available approved vaccine



Reproduced with permission: David Thomas, CFA and Chad Wessel. The State of Innovation in Infectious Disease Vaccines and Prophylactic Antibodies. BIO Industry Analysis (December 2023).

Original presentation by J. Herz, 21 May 2024

# 3.4% global venture capital raised is for infectious disease vaccine development



Investment for infectious disease vaccines in Australia is fragmented and hard to quantify



- Medical Research Future Fund - \$22 B
- National Reconstruction Fund - \$1.5 B
- Clinical Trials Activity Initiative - \$750 M
- Biomedical Translation Fund - \$501 M
  - **\$0 awarded to ID vaccine development**
- Medical Res. Commercialisation Init. - \$450 M
- CUREator - \$7.21 M
  - **\$936K awarded to GPN Vaccines**

Reproduced with permission: David Thomas, CFA and Chad Wessel. The State of Innovation in Infectious Disease Vaccines and Prophylactic Antibodies. BIO Industry Analysis (December 2023).

Biomedical Translation Fund investee companies. <https://business.gov.au/grants-and-programs/biomedical-translation-fund/investee-companies>

Brandon capital: <https://brandoncapital.vc/2024/05/07/funding-australias-future-economy-cureator-deploys-7-21-million-to-propel-local-life-sciences-potential/>

Original presentation by J. Herz, 21 May 2024

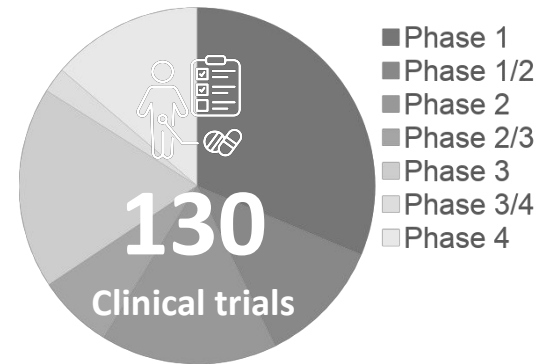
# Mapping Australia's vaccine pipeline since 2000 - Where are they now?



Source:  
**Espacenet**



Source:  
**Dimensions**



Source:  
**Global Data**



**Global clinical development success rates for infectious disease vaccines #**

Phase 1	Phase 2	Phase 3	BLA
49%	35%	67%	97%

**Cumulative Likelihood of FDA Approval (LOA) from Phase I # 11%**

Biointelect unpublished data

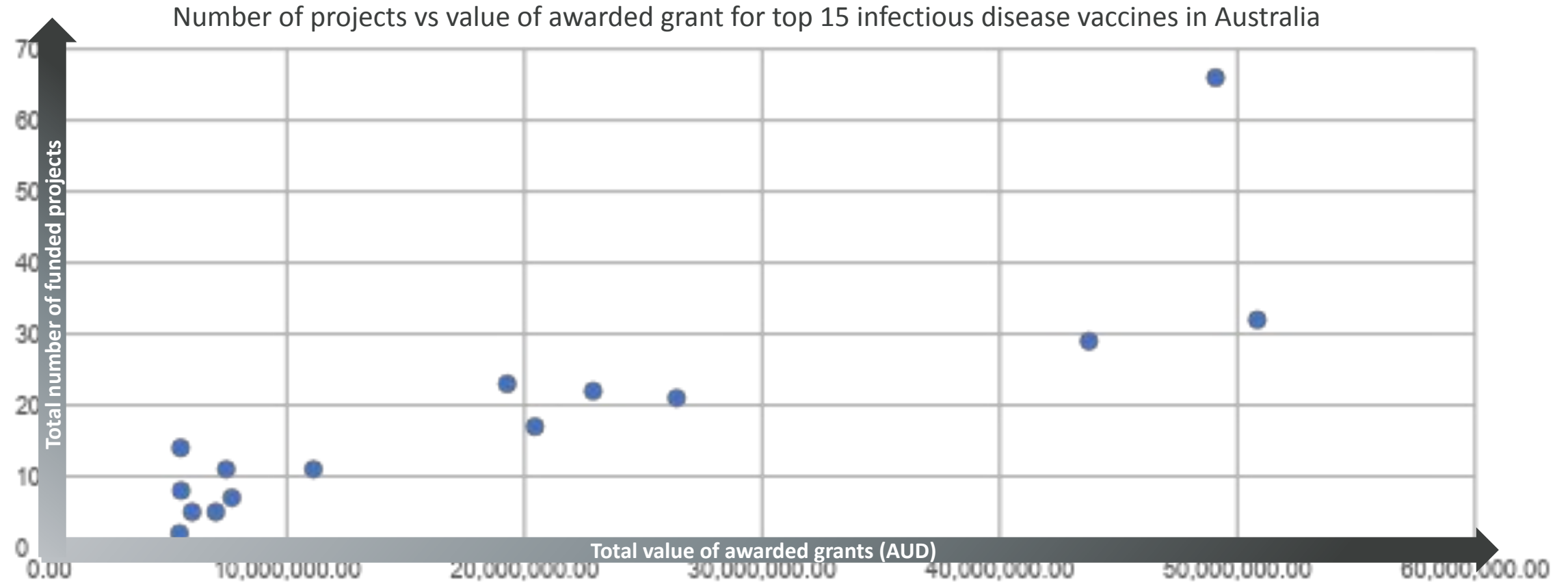
# Reproduced with permission: David Thomas, CFA and Chad Wessel. The State of Innovation in Infectious Disease Vaccines and Prophylactic Antibodies. BIO Industry Analysis (December 2023).

GARDASIL® - the HPV vaccine: Case Study. NHMRC. <https://www.nhmrc.gov.au/about-us/resources/impact-case-studies/gardasilr-hpv-vaccine>

Original presentation by J. Herz, 21 May 2024

## Total grant funding\* for infectious disease vaccines since 2000 is AUD\$ 642 M

*This dataset includes 524 projects targeting 58 different infectious diseases. AUD\$ 288 M (45%) was awarded to the top 15 infectious disease targets (shown below), while AUD\$ 293 M (46%) had an unspecified target.*

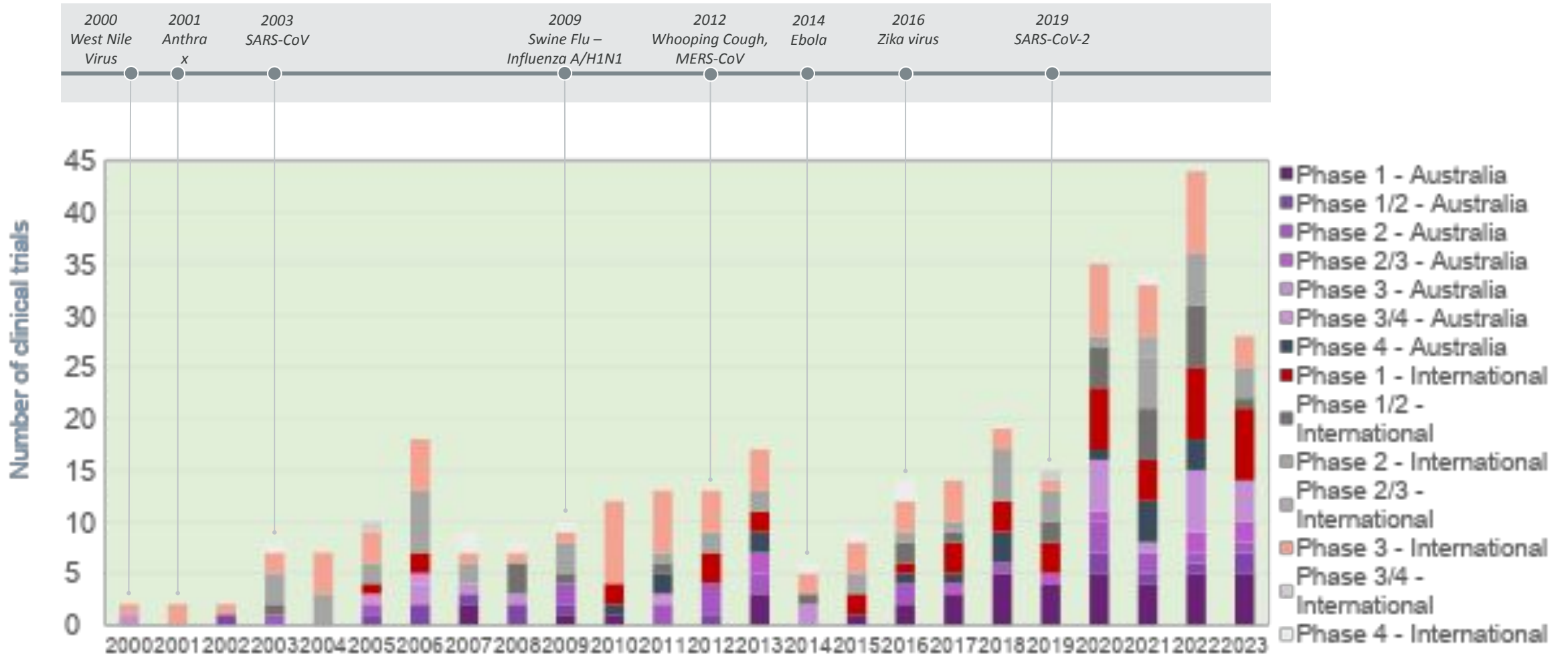


Own unpublished data from Dimensions database

Note\*: Grant applications awarded to Australian researchers working with an infectious disease vaccine mainly from NHMRC, ARC, NIAID, WHO, and others.

Original presentation by J. Herz, 21 May 2024

# 37% of all clinical trials in Australia with Australian clinical sponsor

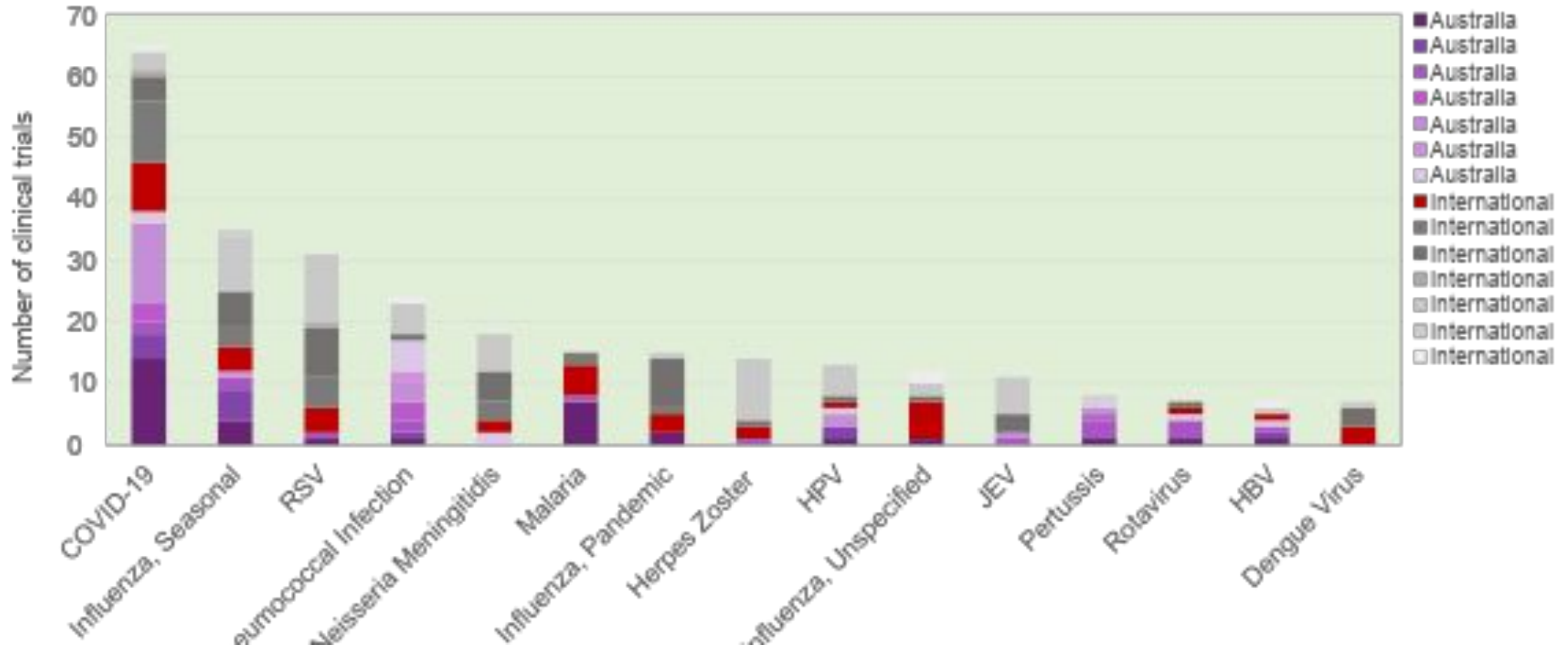


Own unpublished data from Global Data and Clinicaltrials.gov  
 Note: Australian subsidiaries of global pharmaceutical companies are categorised as International sponsors.  
 Original presentation by J. Herz, 21 May 2024



# Vaccine clinical trials in Australia by infectious disease target

Cumulative vaccine clinical trials between 2000 to 2023 for the top 15 infectious disease targets



Own unpublished data from Global Data and Clinicaltrials.gov

Note: Australian subsidiaries of global pharmaceutical companies are categorised as International sponsors.

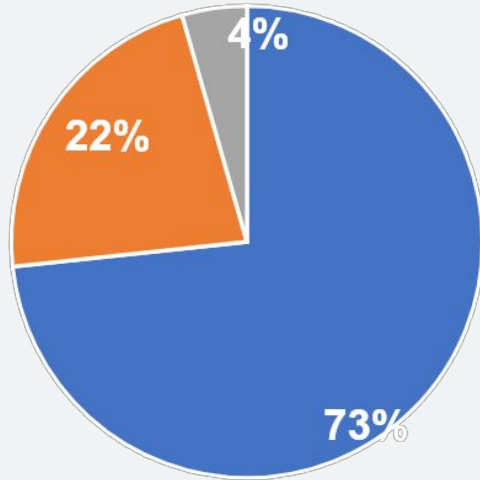
Original presentation by J. Herz, 21 May 2024

# Australia's vaccine development history and current state

Results from 30 respondents (10% response rate)



The target pathogen(s) for the vaccine candidate.

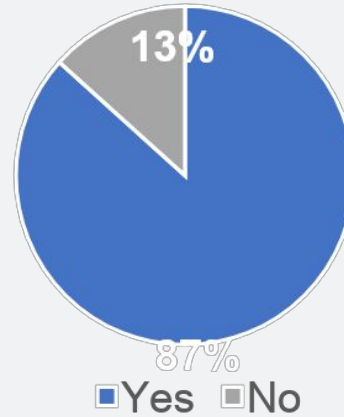


Virus: 73%

Bacteria: 22%

Parasite: 5%

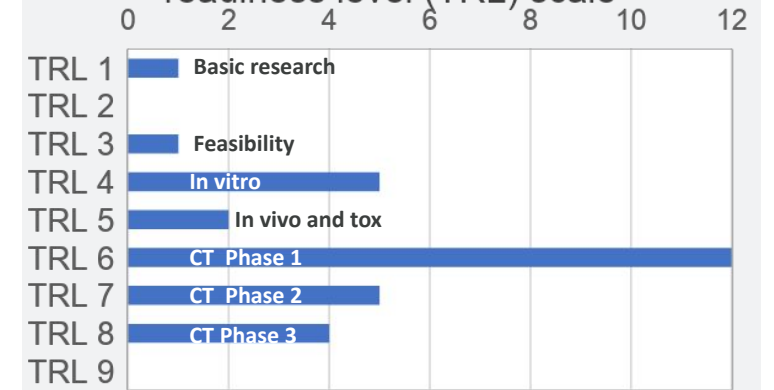
Was the vaccine project a collaborative effort with an industry partner?



**52%**  
involved government grant funding

**48%**  
involved industry funding sources

The highest attained development stage along the technology readiness level (TRL) scale



Count of responses

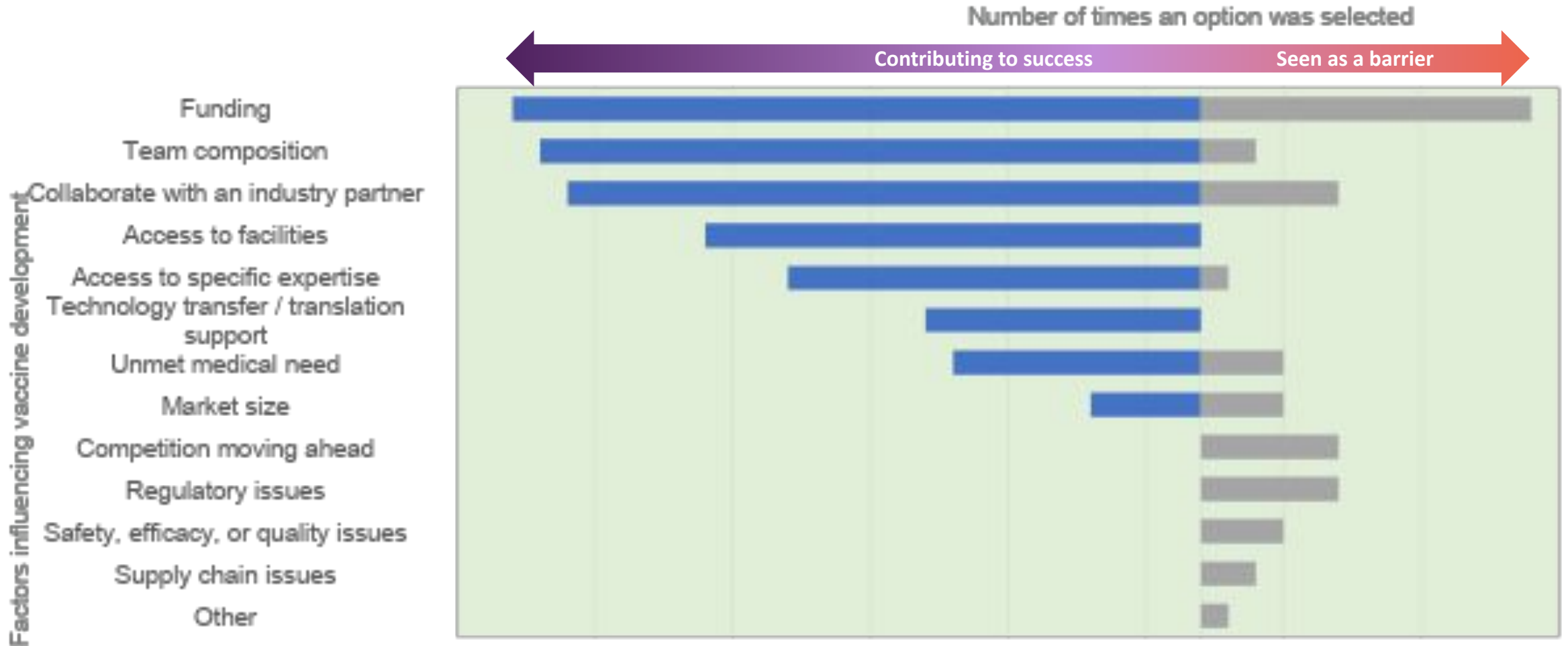
**79%**  
of respondents indicated the vaccine candidate is still in development

**3**  
respondents indicated a TRL 8

Own unpublished data

Original presentation by J. Herz, 21 May 2024

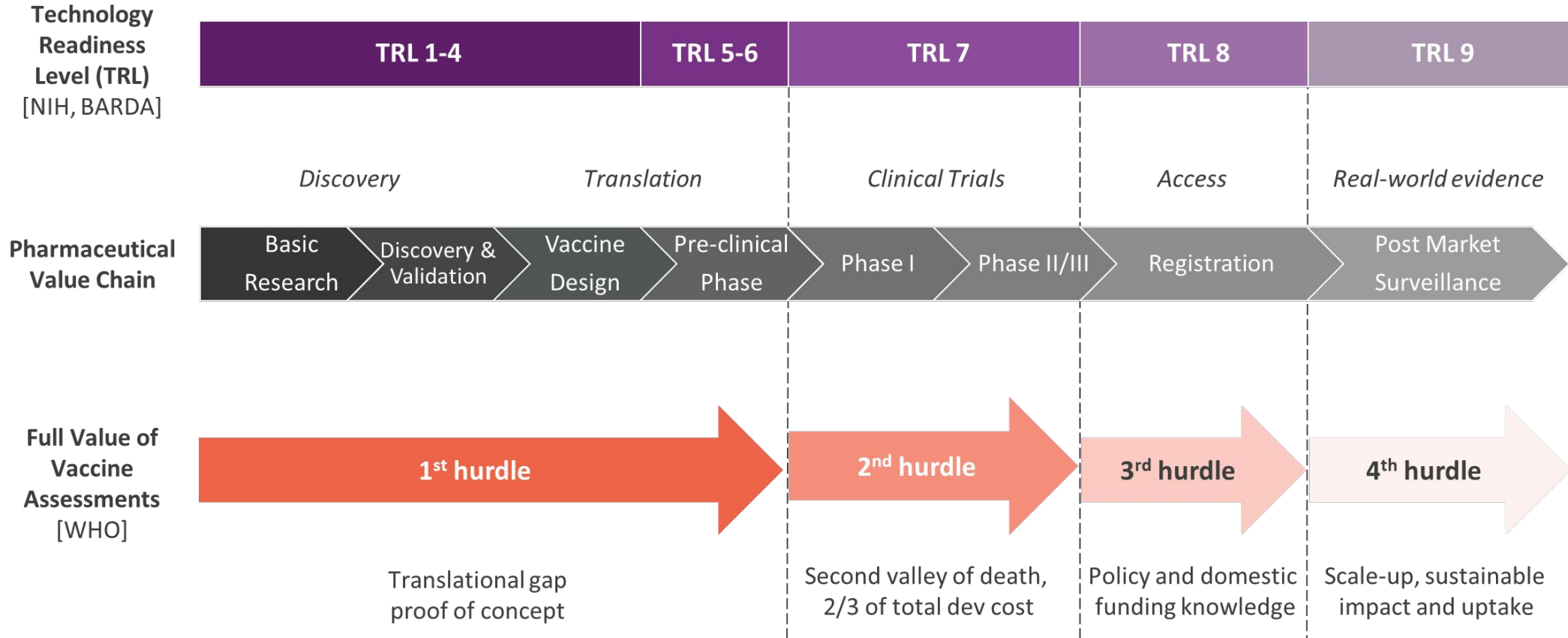
# Survey responses to factors influencing vaccine development in Australia



Own unpublished data

Original presentation by J. Herz, 21 May 2024

# Measuring vaccine translation and commercialization in Australia



NIH Centers for Accelerated Innovations. Technology readiness levels. URL: <https://ncai.nhlbi.nih.gov/ncai/resources/techreadylevels> (2019)

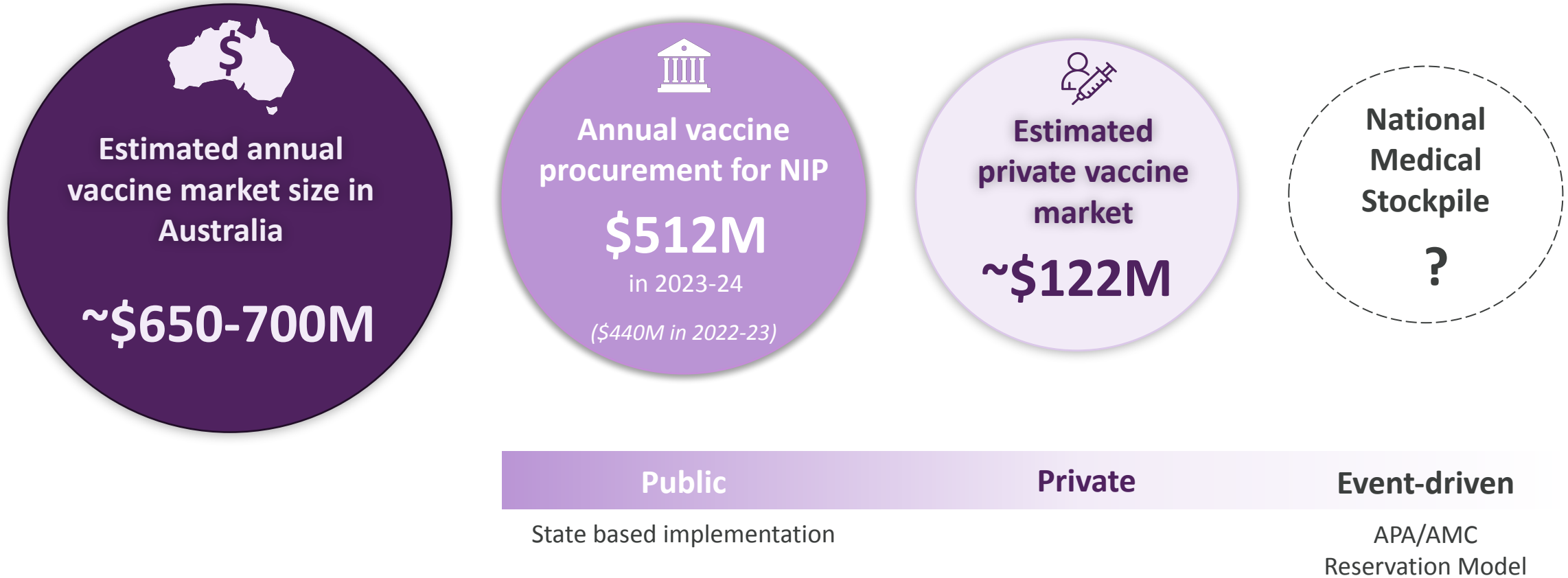
Piot P., et al. Immunization: vital progress, unfinished agenda. *Nature*. 575, pages119–129 (2019).

Arnouts, E., et al. Technology Readiness Levels for vaccine and drug development in animal health: From discovery to life cycle management. *Front Vet Sci*. 9 (2022).

Original presentation by J. Herz, 21 May 2024

# Australian vaccine market: estimated size

Excluding market size for COVID-19 vaccines



Australian Government DoHAC. Portfolio additional estimates statements 2023–24. Program 1.9 Immunisation. [https://www.health.gov.au/sites/default/files/2024-02/2023-24\\_health\\_portfolio\\_additional\\_estimates\\_statements.pdf](https://www.health.gov.au/sites/default/files/2024-02/2023-24_health_portfolio_additional_estimates_statements.pdf)  
AusTender Contract Data download. 6 May 2024. Filtered by Category "Drugs and Pharmaceuticals", Title including "Vaccine", Supplier is a Vaccine Manufacturer.

Original presentation by J. Herz, 21 May 2024

# Plenary 6: Equity of Access and Uptake

**Session Moderator:** **Rodney Pearce**  
Chair, Immunisation Coalition

This session delves deep into Australia's pivotal role and challenges in vaccine distribution and advocacy, drawing lessons from the COVID-19 pandemic and insights from CEPI. It also sheds light on the prevalent issue of vaccine hesitancy, with lessons learned from Australia's HPV campaign. Furthermore, the session examines adult vaccine uptake, particularly focusing on the unique challenges of delivering vaccines to underserved and hard to reach populations and the need for evidence informed approaches to privileging access to achieve equitable health outcomes.

- **Improving Vaccine Confidence, Equity and Uptake (in Australia and the Asia Pacific region)**

**Margie Danchin**

Group Leader, Vaccine Uptake, MCRI in addition to Deputy Chair, ARIA

- **Strategies to Increase Vaccine Uptake in Primary Care**

**Nigel Stocks**

Director, Australian Sentinel Practices Research Network

- **Pharmacy Role in Increasing Adult Vaccine Uptake**

**Chris Campbell**

General Manager, Policy and Program Delivery, Pharmaceutical Society of Australia

- **Achieving Equity in Underserved Populations**

**Kristy Crooks**

Aboriginal Program Manager and leads Public Health Aboriginal Team,  
Health Protection - Hunter New England

## Panel Discussion

Priorities to Improve Access, Uptake and Address Vaccine Hesitancy

## Session Objectives

- Delve into 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

- Identification of **barriers and opportunities** to improve vaccine uptake to enhance health outcomes and equity in Australia.
- Ideas for new **collaborative models** that could improve access.

# Plenary 7: Access and Health Technology Assessment

**Session Moderator:** **Katrina Lapham** Director, Strategic Market Access & Policy, Biointelect

This session presents the latest findings from the Health Technology Assessment (HTA) review and discusses the specific considerations of vaccines within the HTA framework. It delves into the challenges of access delays, related to evidence, systems and processes, offering a comparative perspective with overseas practices and emphasizing the community's viewpoint on the value of vaccines.

- **Perspectives on How Vaccines are Valued**

**Natalie Carvalho** Associate Professor of Health Economics, Melbourne School of Population and Global Health, University of Melbourne

- **Clinical Research Perspectives on HTA, Value of Vaccines and Evidence Generation**

**Michelle Giles** Professor, Department of Infectious Disease, University of Melbourne

- **Industry Perspectives On HTA Review Priorities for Vaccines**

**Andrew Thirlwell** Global Policy and Public Affairs, Australia, New-Zealand and Korea Lead, Pfizer

- **Reflections: PBAC, HTA and Vaccines**

**Michelle Burke** PBAC Member

## Panel Discussion

- How should vaccines be evaluated to understand their full value, perspectives and data challenges?

## Session 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 vaccine.

## Outcomes

- Identification of pain points and areas of improvement 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.

## Conclusion

Improving commercialization requires aligned data sets and implementing a framework to measure progress

### 1 National approach needed

- To attract overseas investment in innovation
- Strategic position in global supply chain
- Clinical trial networks: public private partnerships
- Better VPD Data to inform decision making

### 2 Invest in prevention: full value of vaccines

- Societal perspective needed, lower discount rate
- Recognise drivers of industry investment
- Industry collaboration to build skills and talent

### 3 Enabling policy & regulatory pathways

- Lessons learned from COVID experience
- Speed of new technology eg platform regulation
- One Health approach: synergies with animal health
- Recognise our leadership role in the region

### 4 Communication, education, equity of access

- Whole of life immunisation plan
- Need to address local and regional access barriers
- Strong engagement with community leaders key to have social licence and address hesitancy



# Acknowledgements



BIO for granting approval to use their data and *The State of Innovation in Vaccines and Prophylactic Antibodies for Infectious Diseases* report.



National Health and Medical Research Council for providing a dataset.



Policy Cures Research for discussions regarding data methodology.



GlobalData for use of the Drugs and Clinical Trials databases.



MTPConnect for assistance distributing the *Australian Vaccine Landscape* survey.



Therapeutic Innovation Australia for sharing data on manufacturing facilities.



Bellberry for looking at the clinical trial slides.

Linda van de Burgwal, PhD MBA, for data collection and review

Jacqui Wade, Carolyn Austin, Frances Ryan, and Esther S Pronker, PhD, for data collection, review of the data, and development of the slides.



## Q&A

# The vaccine value chain: opportunities and challenges in Australia

Jennifer Herz

Co-Founder & Director, Biointelect

