

Australia's vaccine legacy: Time for a boost? Mapping an innovation system in a fragmented data environment

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ARTICLE INFO

Keywords:

Vaccine
R&D
Innovation system
Innovation
Infectious diseases
Australia

ABSTRACT

Global vaccine development relies on a decentralised, collaborative approach where national and international capabilities interact. Policy alignment and resource pooling are essential to ensure the efficacy and efficiency of innovation programs. Yet empirical mapping of national vaccine innovation systems is limited. This paper presents a focused case study of Australia's historical vaccine innovation system (2000–2023), analysing patterns in inventive activity (642 patents), public R&D funding (522 awarded grants), and clinical trial registrations (349 clinical trials).

Findings show episodic increases in patenting activity, including a surge during the COVID-19 pandemic, demonstrating responsiveness of the innovation system. Second, a positive aggregate association between public R&D funding and inventive output is visible in distinct disease areas, including influenza, malaria, and HIV. However, these domestic investments only partially translate into Australian-sponsored clinical trial activity. Much of the clinical trials volume, particularly for seasonal diseases, is driven by international sponsors that leverage Australia's attractive R&D environment and its unique position in the Southern Hemisphere.

Importantly, the attempt to follow individual vaccine “assets” along the value chain revealed that public datasets are too fragmented and heterogeneous for one-to-one linkages. This limitation is emphasised in the framing of the findings and consequently the data are presented descriptively, highlighting both strengths and constraints of available public databases for mapping vaccine innovation.

The analysis contributes to understanding Australia's national vaccine innovation system and provides a foundation for future work, while underscoring the need for consistent unique identifiers across publicly available datasets to enable end-to-end tracking. A sustained and aligned focus on national research priorities in a global context could further enhance Australia's contribution to global health security and stimulate growth in its biotechnology sector. To support this, a system based on the technology readiness levels framework is proposed to accurately track progress of vaccine innovations along the vaccine innovation cycle.

1. Introduction

Despite remarkable achievements of vaccines in saving millions of lives and contributing significantly to global health and economic prosperity [1,2], numerous infectious diseases remain prevalent, posing significant challenges to public health systems [3]. Infectious diseases disproportionately affect populations in low- and middle-income countries, as well as certain indigenous populations in some high-income countries [4,5]. Persistent inequities underscore the critical need for continuous vaccine development and innovation [6].

International alignment is crucial to address global health challenges

through vaccine innovation [7,8]. Different national and international actors contribute to various stages of development [9], as described in the Vaccine Innovation Cycle [10]. However, conventional “push” mechanisms that fund research and development, and “pull” mechanisms that reward successful product development are frequently misaligned in scale, timing and predictability with the cost and risk of vaccine R&D. This can limit sustained private sector engagement in fragile markets [3,11]. International alignment of innovation policies and resource pooling are essential for ensuring the efficacy and efficiency of national innovation systems [12]. The COVID-19 vaccine response is a case in point, reducing development timelines from 14 [13]

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<https://doi.org/10.1016/j.vaccine.2026.128525>

Received 22 December 2025; Received in revised form 5 March 2026; Accepted 23 March 2026

Available online 30 March 2026

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to just 1–2 years through urgent, multi-level, and cross-institutional policy actions [14].

This characterizes the vaccine innovation system as a global innovation system, with structural coupling at various geographical levels [14,15]. Within this global context, the national Vaccine Innovation Systems – defined as networks of actors involved in researching and developing new products and services, influenced by various laws, policies, regulation, and social norms [16] – play a crucial role. While these systems are increasingly called upon to pursue international collaboration and complementarity [17,18], concerns over vaccine equity and vaccine nationalism [19] have prompted many countries to invest in sovereignty domestic vaccine capabilities [20,21].

In this context, it remains unclear how national vaccine innovation systems evolve and how effective national push and pull mechanisms are in shaping these systems, particularly in the context of global vaccine development challenges. This study aims to contribute to an understanding of how one national innovation system – Australia's – can be empirically mapped, while acknowledging the broader global context. Foundational work by [22–24] established how national innovation systems evolve in historical and international contexts, including applications to the U.S. vaccine supply system. This study does not seek to reopen foundational debates on the evolution of national innovation systems. Instead, it builds on this literature by presenting an empirical mapping of Australia's vaccine innovation system, focusing on how public datasets illuminate both the scope and the limits of tracing vaccine assets across patent filings, grant funding, and clinical trials. Australia, with its robust healthcare system and strong biomedical research capabilities, is the case study to understand how countries can contribute to global vaccine innovation. By examining Australia's vaccine legacy, strengths, gaps, and opportunities within its national vaccine innovation system are identified, informing future strategies and collaborations to address unmet medical needs and contribute to global vaccine innovation efforts.

2. Methodology

This study mapped the Australian vaccine landscape as a case study to empirically map its national vaccine innovation system. Australia's robust healthcare system and strong biomedical research capabilities allow for a clear analysis of how public funding translates along the vaccine value chain, while simultaneously understanding how certain research capacities might attract international collaborators. Moreover, Australia's geographical location enables specific expertise in tropical infectious diseases and regionally relevant Southern Hemisphere infection patterns.

First, a nationwide conference with key opinion leaders and document analysis informed a narrative description of Australia's vaccine innovation system. Subsequently, a multi-database approach to query patent, grant, and clinical trial databases for vaccine value chain activities from 2000 to 2023 empirically mapped data on Australia's innovation activities (Fig. 1). Patent analysis serves as a proxy for assessing inventive activity and early-stage innovation [25]. Grant funding analysis helps understand how research efforts, particularly for institutes and small-to-medium-sized enterprises are tailored towards specific disease areas. Clinical trial analysis reveals short-term market entry prospects and ongoing innovation efforts [26,27]. This resulted in three distinct datasets that collectively offer insights into the evolution of vaccine technologies from conception to human testing.

2.1. Structural analysis

Building on the Vaccine Innovation Cycle [10], a structural analysis of the vaccine innovation system requires insights into (1) funding and business development; (2) research and development; (3) GMP production and manufacturing. Initial insights were distilled from a first nationwide conference on Australia's vaccine innovation ecosystem. This conference, organized in May 2024, gathered key opinion leaders from across Australia to identify bottlenecks and recommendations to

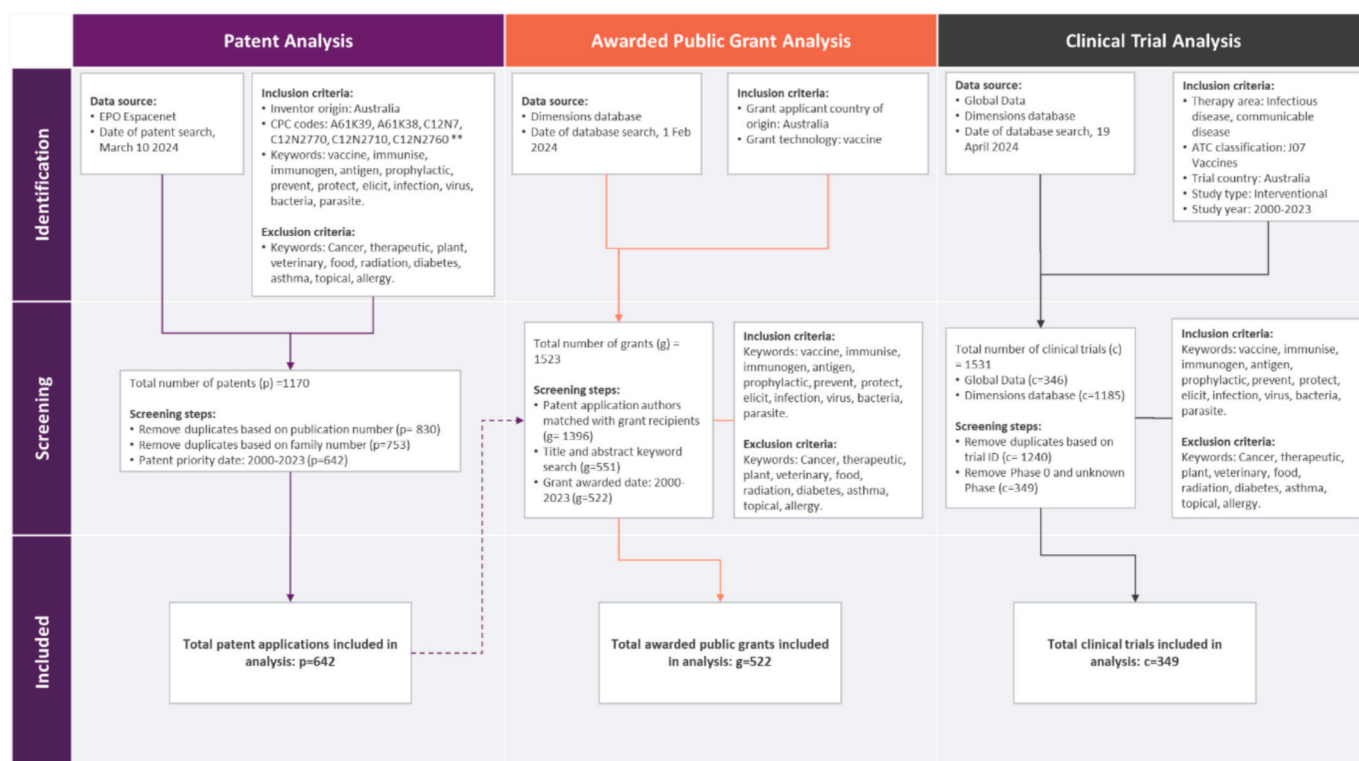


Fig. 1. PRISMA flowchart of research methodology. EPO = European Patent Office, CPC codes = Cooperative Patent Classification, ATC = Anatomical Therapeutic Chemical classification system.

streamline Australia's vaccine value chain [28].

A non-systemic review of publicly available reports was used to construct a description of core structural elements of the Australian vaccine innovation system. The search for newspaper articles, press releases and reports by major organisations like MTP Connect and the Australian Government was performed using Google and Google Scholar. Keywords included public funding, investments, infrastructure, innovation, and manufacturing combined with Australia and vaccine.

2.2. Patent landscape

2.2.1. Data collection

Patent data were drawn from the European Patent Office (EPO) Espacenet search engine, which provides authoritative worldwide coverage of publication metadata with Cooperative Patent Classification (CPC) and Cooperative Patent Classification (IPC) codes to ensure completeness and consistency across patent families. The search strategy included Boolean operators to combine vaccine-specific CPC codes, targeted keywords, Australian inventorship, and patent applications filed between 2000 and 2023. CPC codes and keywords are based on previous studies [29–31]. The focus was specifically on prophylactic vaccines targeting human infectious diseases, excluding therapeutic vaccines and other vaccine applications. Data collection was conducted on March 10th, 2024. Due to the 18-month publication delay, the dataset includes applications published on or before September 10, 2023. The resulting dataset underwent deduplication and manual screening to ensure relevance. For all patents applicant names were categorized as either academic institute, private organisation, public organisation or individual innovator.

2.2.2. Data analysis IPC

The 883 uniquely occurring IPC codes in the patent dataset were listed in an Excel sheet. All IPC code descriptions were retrieved from the World Intellectual Property Organisation (WIPO) IPC Publication. Codes referring to either the type of invention (e.g. Medicinal Preparation with antigens or peptides), the use of antigens or proteins from, or the use of products against certain pathogens (e.g. specific viruses, bacteria or protozoa), and codes referring to specific therapeutic activities were defined and categorized for analysis. These IPC characterizations were linked to all patents in the dataset with the respective IPC codes mentioned.

2.3. Grant funding landscape analysis

Dimensions AI database was consulted to identify awarded grant funding related to prophylactic vaccine development programs in Australia. Only Australia-based applicants are eligible for funding programs captured within this database. The search strategy employed a multi-tiered screening process to ensure both relevance and accuracy. This dataset was further refined through a keyword search of titles and abstracts. Keywords for inclusion and exclusion criteria mirrored those used in the patent analysis. The date of awarded grants was limited to 2000 and 2023.

2.4. Clinical trial analysis

The clinical trial landscape analysis combined both the Dimensions AI database and Global Data. The initial query returned 1531 trials (1185 from Dimensions AI and 346 from Global Data). Inclusion criteria included: trials conducted in Australia, focused on interventions for infectious or communicable diseases, registered between 2000 and 2023, and classified under the Anatomical Therapeutic Chemical (ATC) code J07 (Vaccines). The dataset underwent deduplication based on trial identification numbers, followed by a targeted keyword search. This methodology ensured the development of a dataset including only relevant human infection vaccine-related clinical trials in Australia,

providing an overview of the country's later-stage vaccine landscape.

2.5. Dataset linkage feasibility

We attempted to trace vaccine innovations across patents, research grants, and clinical trials to assess how assets move through the value chain. One such attempt included the matching of patent application authors with grant recipients to establish a direct link between early-stage innovations and research funding, providing insight into the continuity of vaccine development efforts. However, this proved infeasible due to the absence of consistent unique identifiers across datasets and inconsistent naming conventions. Publication lags and confidentiality restrictions further complicate linkage. Moreover, vaccine development often involves multiple overlapping technologies and approaches, complicating efforts to trace progression along the value chain. As a result, deterministic one-to-one mapping of individual vaccine assets was not possible. Our approach instead provides a descriptive overview of each dataset, highlighting where data gaps prevent more integrated system-level mapping. This methodological limitation is itself an important finding, as it demonstrates why institutional linkage in vaccine innovation remains difficult without enhanced data infrastructure.

3. Results

3.1. Structural analysis

3.1.1. Funding and business development

From 2016 to 2019, Australia's academic performance ranked 7th for medical biotechnology, and Australia ranked in the top 5 globally for biotechnology innovation [32]. This strong performance extends to various sub-disciplines within the field. Australia's R&D expenditure relative to its Gross Domestic Product (GDP) is considered low at 1.8% (OECD average is 3%), and these expenditures include biomedical research, as well as epidemiological and operational research [33]. Over the past two decades, investments have increasingly focused on applied and translational research, with the share of basic research funding decreasing from 60% in 1996 to 40% in 2019 [34]. In October 2022, the Australian government announced a National Reconstruction Fund (NRF), investing AUD 15 Bn in 7 priority areas through loans, guarantees and equity, for medical science manufacturing projects among others (Department of Industry Science and Resources, 2022) [35]. This shift towards later stage R&D has coincided with an increase in the Australian venture capital sector [34]. Yet, the capital raised in medical projects has fallen back to 2018 levels of AUS 0.4 billion after peaks of AUS 1.7 billion in 2020, and even AUS 7.7 billion in 2021. Nevertheless, private R&D investments far exceed public resources from the three main state funders (Biomedical Translation Fund (BTF), Medical Research Future Fund (MRFF) and The National Health and Medical Research Council (NHMRC), representing 70% of total R&D expenditure (MTP [36]).

3.1.2. Research and development

Australia's public innovation system is relatively closed, with public funding distributed to Australian partners, primarily via the NHMRC, MRFF and the Australian Research Council (ARC) [34]. These public grants are mostly investigator-led, with a limited number of translational projects, limiting a product-development approach [28]. Notable international examples of contrasting approaches where partnerships are at the core of project funding include CARB-X for development of novel antibiotics [37], and CEPI for epidemic preparedness innovations [38].

Australia has a low population density yet is organized through distinct state-level governments, each with their own mandates, priorities and ambitions [39]. Through this system, distinct grants for research and innovation are made available at the state level, for

example the South Australia's Research and Innovation Fund [40], and the Western Australia's Collaborative Research Grant [41]. This results in redundant and overlapping activities as a result of competition between states [28].

3.1.3. GMP production and manufacturing

Manufacturing of biologicals is known to be technically demanding, lengthy and complex [42], limiting the potential for agility as well as upscaling during times of crisis [43,44]. Pre-COVID-19, there was little economic pressure on supply chains in the pharmaceutical industry, leading to a low diversification of suppliers and off-shoring to highly specialized suppliers [45]. While the complete pharmaceutical manufacturing industry in Australia equalled \$12 billion with ~16,000 people employed – including small molecules manufacturing – there is a lack of skilled personnel for the highly specialized bioprocessing required to manufacture vaccines [46]. As a result, production is already off-shored during early clinical development [28] which limits the development of a vibrant innovation ecosystem with sufficient medium-sized companies that can scale innovation and reap commercial benefits [45]. These constraints also reduce the likelihood that promising Australian-origin candidates progress through later-stage trials and commercial launch while retaining a substantial domestic manufacturing footprint.

3.2. Patent application landscape analysis

The patent analysis revealed a dynamic trend in vaccine-related applications in Australia between 2000 and 2022. Over this period, the cumulative count increased more than twenty-fold, from 29 applications in 2000 to 642 in 2022 – an average annual growth rate of around 14% (Fig. 2). Patent activity in Australia displayed several notable peaks and troughs between 2000 and 2021; with pronounced peaks visible in 2006 and 2017 and the lowest count occurring in 2013. The largest annual surge was observed in 2020 during the COVID-19 pandemic, when applications jumped to 49 – double the 25 filed in 2019, representing a 96% year-on-year increase. The rapid mobilization in response to COVID-19, evidenced by the unprecedented numbers of patent applications, demonstrates the field's responsiveness to emerging

diseases, technological advancements, global health priorities and showcases the adaptability of the Australian vaccine innovation system.

3.2.1. Patent applicants

11 applicants (5.5% out of 202 individual applicants) account for the majority ($n = 323$, 42%) of all 642 patent filings (Fig. 3). Most applicants were academic institutions, with the University of Queensland filing the largest number of patent applications ($n = 49$, 7.6%). The most prolific public organisation Commonwealth Scientific and Industrial Research Organisation (CSIRO) ranked ninth with 17 (2.6%) patent applications. There is a joint 10th place for private entity CSL Innovation Pty Ltd. and the MacFarlan Burnet Centre, each with 17 (2.6%) patent applications.

3.2.2. Patent content: IPC code analysis

577 out of 642 patents were characterized as a medicinal preparation by one or multiple IPC codes. 350 patents were characterized as a medicinal preparation with antigens or antibodies, 278 patents as a medicinal preparation containing peptides, and 43 patents were described as medicinal preparations for gene therapy. These categories were not mutually exclusive. Of the 65 patents that were not described as medicinal preparations, 34 patents described viruses or compositions thereof, 13 described vectors, and 10 described cells or cell lines.

A subsequent in-depth analysis of IPC codes that refer to specific micro-organisms (viruses, bacteria, protozoa, etc.) is provided in Fig. 4. 231 patents referred to IPC codes related to viruses, with specific mentioning of hepatitis virus (35), herpesviridae (29), and lentiviridae (24) being most prominent. Several respiratory viruses were also mentioned frequently: coronaviridae (24) orthomyxoviridae (23), and influenza / rhinovirus (23). 157 patents referred to IPC codes related to bacteria, in this group mycobacterium (19) and streptococcus (15) were most prominent. Within the group of patents referring to parasites and protozoa (39), malaria (17) and hemsporidia (17) were most prominent.

3.3. Grant funding landscape analysis

3.3.1. Beneficiaries

Analysis of Australia's vaccine development grant funding between

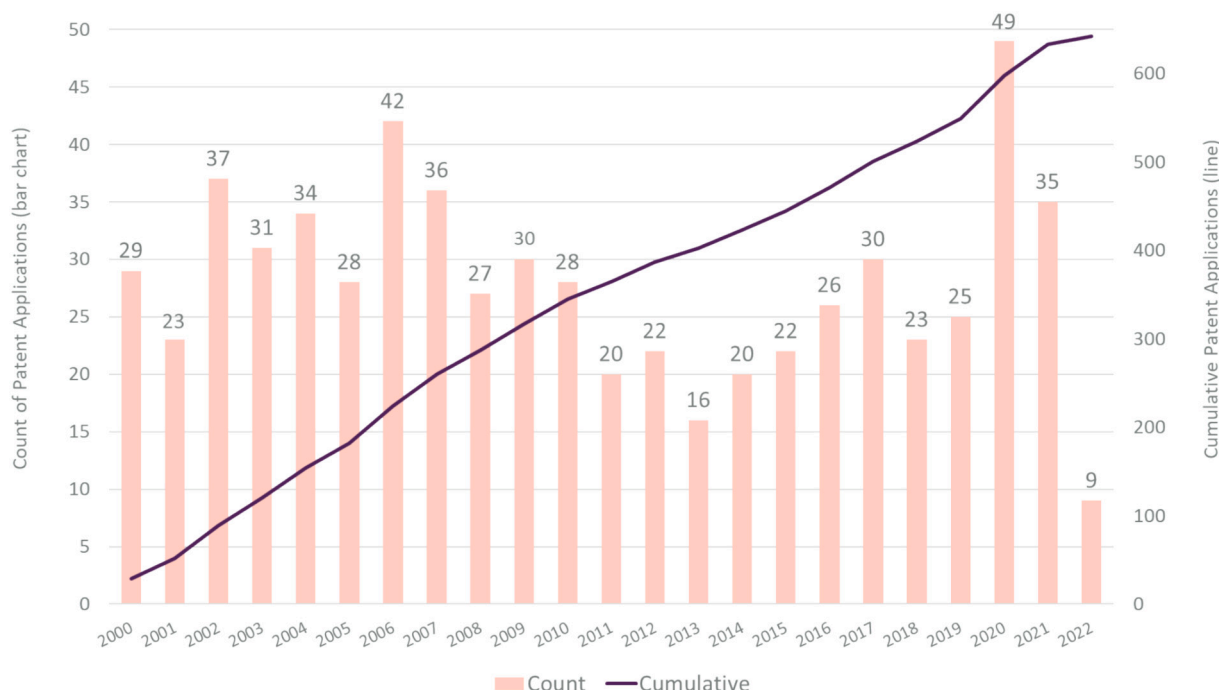


Fig. 2. Graph showing the count of patent applications (bar chart) and the cumulative patent applications (line graph) for all patent applications in the dataset.

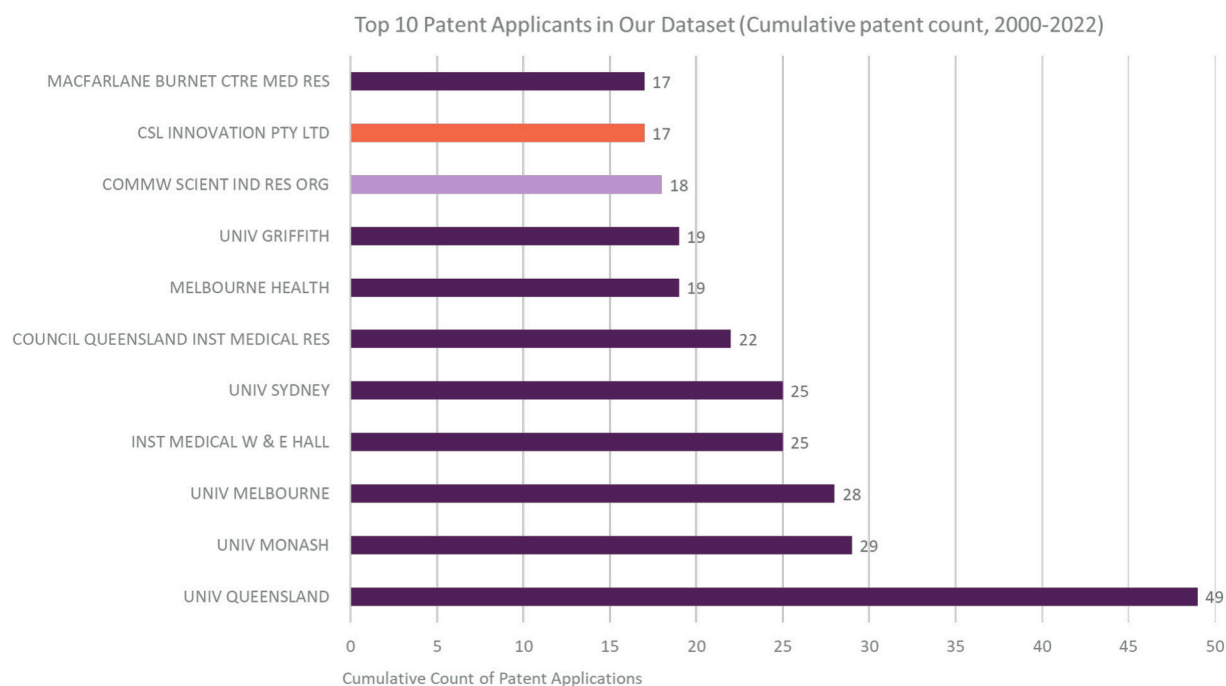


Fig. 3. Number of patent applications filed per organisation type. Academic institutes are highlighted in purple, private organisations in orange, public organisations in light purple. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

2000 and 2023 revealed 522 projects awarded a cumulative AUD\$670 Million (USD\$541 M) to 38 primary applicants (see Fig. 5). These projects were not necessarily a subset of the 642 patent applications. 93% of awarded funding was received by 15 institutions, predominantly academic, with the University of Melbourne receiving AUD\$131 M / USD \$87 M. Two notable private beneficiaries are Vaxine (AUD\$30.5 M / USD\$20 M) and Aviragen Therapeutics (AUD\$18.9 M / USD\$12.6 M). Discrepancies between grant beneficiaries and patent applicants arise from search scope differences and mergers/acquisitions (e.g. Vaxine Pty Ltd. patenting on vaccine adjuvant technologies but engaging in vaccine co-development with National Institutes of Health (NIH) and Aviragen Therapeutics acquiring Biota Australia).

3.3.2. Target infectious diseases

Fig. 6 shows the top 15 primary target pathogens for human vaccine development between 2000 and 2023 that collectively account for 52% (273 projects) of funded projects and cumulatively received 47% (AUD \$312.7 M / USD\$242.5 M) of the funding. 28% of projects representing 45% of funding (AUD\$300.6 M / USD\$253 M) were directed towards unspecified infectious diseases. This pattern aligns with early-stage research practices and intellectual property considerations, where targets are often undisclosed. The results should be read not as evidence of rational optimisation, but as a descriptive picture of how public funding has historically been distributed.

The top 15 funded primary target pathogens can be categorized into three distinct tiers based on target infectious disease, reflecting Australia's multifaceted approach to vaccine research and development. Tier 1 (Group A) includes three high-priority pathogens: Influenza (AUD \$58.6 M / USD\$46 M, 32 grants, 8.7% of the total funding awarded), Malaria (AUD\$49 M / USD\$41.3 M, 66 grants, 8%), and HIV (AUD \$46.3 M / USD\$34.4 M, 29 grants, 6.9%), collectively accounting for 23.7% of total funding awarded. In this dataset, “influenza” encompasses seasonal influenza as well as projects describing broadly protective, zoonotic or next-generation influenza vaccines. The prioritization found here aligns with domestic public health concerns (influenza), regional health security issues (malaria), and global health commitments (HIV). Notably, while malaria is not endemic in Australia, its high

funding reflects Australia's commitment to the significant disease burden in neighbouring Southeast Asian and Pacific Island countries.

Tier 2 (Group B) consists of the following four pathogens: Pneumococcal disease (AUD\$28.6 M / USD\$22.9 M, 4.3%), Tuberculosis (AUD \$26.9 M / USD\$20.3 M, 4%), Group A Streptococcus (GAS; AUD\$21.5 M / USD\$16.8 M, 3.2%), and Hepatitis C (AUD\$20.6 M / USD\$17 M, 3.1%), representing 14.6% of total funding. This tier addresses both domestic health priorities (pneumococcal disease, hepatitis C) and regional concerns (tuberculosis). The focus on GAS notably targets health disparities in Indigenous Australian communities.

Tier 3 (Group C) encompasses nine pathogens collectively accounting for 8.4% of total awarded funding. This tier includes emerging threats (COVID-19, AUD\$7.7 M / USD\$5.7 M, 1.15%), regionally relevant pathogens (Flavivirus, AUD\$7.7 M / USD\$5.8 M, 1.15%), and ongoing public health concerns such as sexually transmitted infections (Chlamydia, AUD\$5.5 M / USD\$4.6 M, 0.83%). The relatively low funding for COVID-19 in comparison to other diseases likely reflects the dataset's longer timeframe (2000–2023), with COVID-19 research primarily occurring from 2020 onwards, and possibly also indicative of the lower dependency on Australian public funding due to the availability of international public and private funding for vaccine development [47].

3.4. Clinical trial landscape analysis

3.4.1. Timeline

Fig. 7 shows the temporal distribution of 349 infectious disease vaccine clinical trials conducted in Australia from 2000 to 2023, categorized by trial phase and sponsor location. The trials were stratified into two primary categories: those sponsored by Australian entities (purple shades, 130 trials, 37% of the data set) and those with international sponsorship (red shades, 219 trials, 63%). These trials were not necessarily linked to the patent applications or grant-funded projects, nor do Australian trials necessarily include novel Australian innovations.

The data reveals a gradual upward trend in Australia-based clinical trial activities over the study period. This trend is punctuated by a significant spike in trial numbers coinciding with the SARS-CoV-2

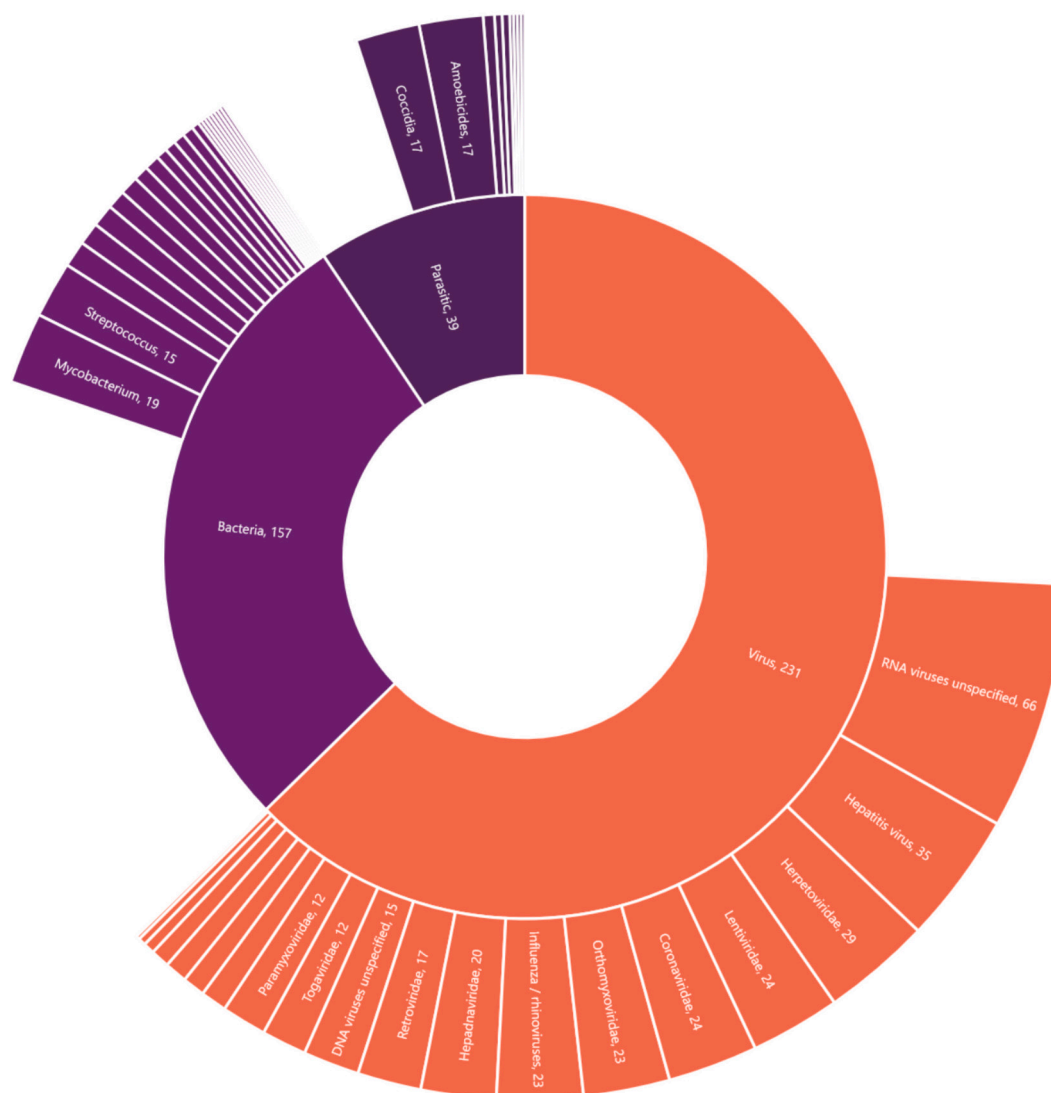


Fig. 4. Frequency of pathogen types mentioned in IPC codes of unique patents.

pandemic (2020–2022). This surge is best interpreted as a transient stress-test of Australia's clinical trial capacity rather than a new baseline of activity.

This analysis underscores Australia's growing role in global vaccine development, and highlights the country's capacity to rapidly scale up clinical trial activities in times of global health crises, demonstrating the flexibility of Australia's clinical trial infrastructure in adapting to changing global health priorities.

3.4.2. Target infectious diseases

Analysis of clinical trial sponsorship and infectious disease targets in Australia revealed distinct patterns between domestic and international sponsors (Fig. 8). The top five infectious disease targets, accounting for 50% of all clinical trial activity regardless of sponsor, include COVID-19 (19%), Seasonal influenza (10%), Respiratory Syncytial Virus (RSV; 9%), Pneumococcal infections (7%), and *Neisseria meningitidis* (5%).

COVID-19 emerged as the predominant focus for Australian-sponsored clinical trials, reflecting the nation's rapid response to the global pandemic. In contrast, seasonal influenza, RSV, and *N. meningitidis* vaccine trials were primarily driven by international sponsors, with a notable emphasis on later-phase studies where seasonal recruitment is an advantage. Pneumococcal infection trials exhibited a more balanced distribution, with Australian sponsors active across all

clinical trial phases, while international sponsors conduct Phase 3 trials.

Beyond the top five, malaria, herpes zoster, and human papilloma-virus (HPV) trials were predominantly sponsored by international entities. Conversely, clinical trials for pertussis, rotavirus and streptococcal infection are primarily conducted under Australian clinical trial sponsorship. This distribution underscores Australia's dual role in nurturing domestic vaccine innovation while simultaneously serving as a strategic hub for international vaccine development efforts.

4. Discussion

This analysis of Australia's vaccine value chain over the past 2 decades reveals a complex and dynamic landscape, while demonstrating both the potential and the limitations of mapping a national vaccine innovation system.

4.1. Key messages

4.1.1. Responsive innovation system with cross-disease spillover effects

The relatively large amounts of public funding rewarded to malaria, influenza, hepatitis and streptococcus translate into more patent applications and clinical trial activity. While not all patents are necessarily of the same quality [27], the data show translational efforts, indicative of a

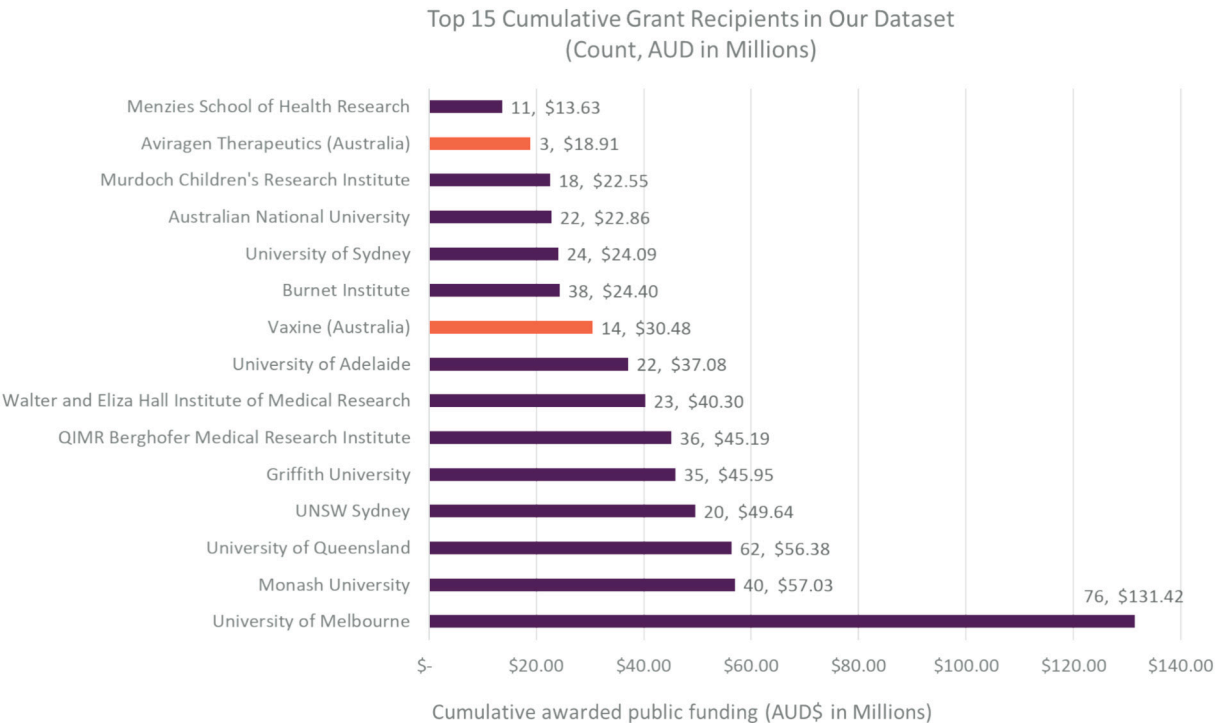


Fig. 5. Top 15 cumulative grant recipients (period 2000–2023). Academic organisations are highlighted in purple, private organisations in orange. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

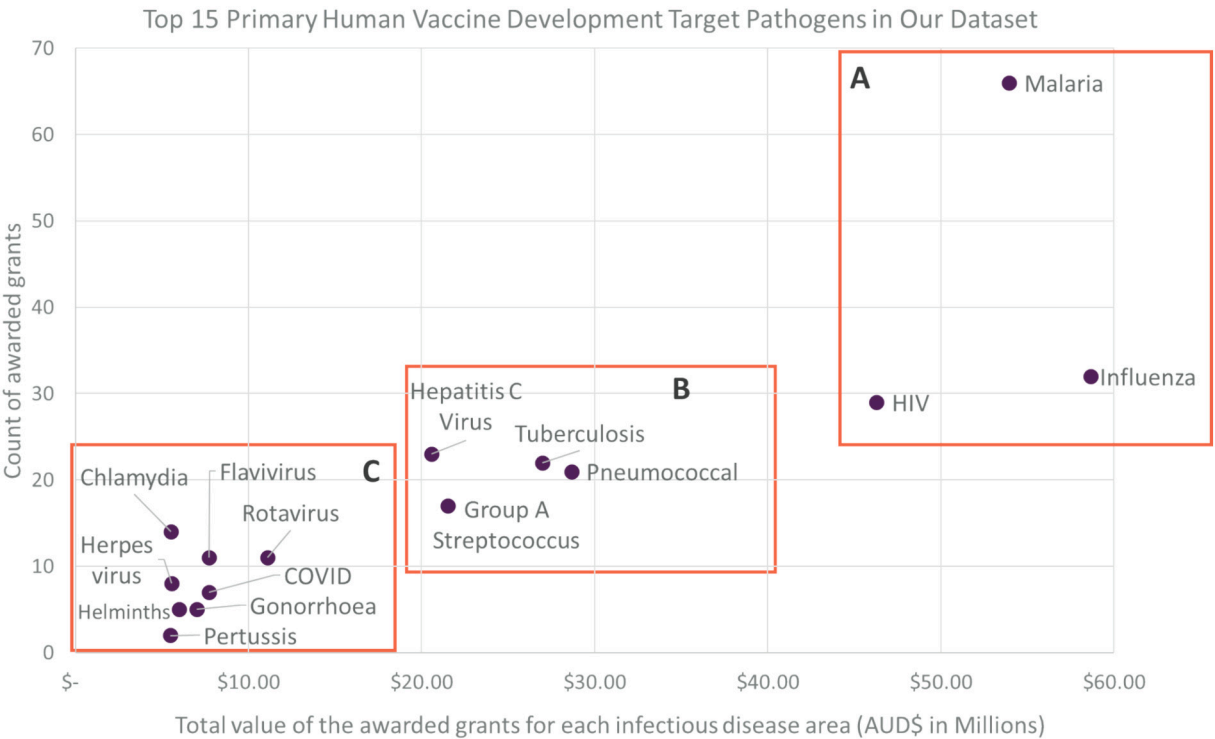


Fig. 6. Top 15 cumulative grant funded primary human vaccine development target pathogens in Australia between 2000 and 2023.

supportive innovation climate [48]. Moreover, the extensive number of potential target applications in the patent literature underscores findings of cross-disease innovation spillover effects from research funding [49,50]. When viewed against WHO's R&D Blueprint priority disease families, Australia's vaccine-related patents, grants and trials are concentrated in areas where vaccine platforms are more advanced and

regionally relevant [51].

The patent and clinical trial analyses also demonstrate the responsiveness of vaccine-related innovation in Australia to emerging health threats and technological breakthroughs. The rapid mobilization observed during the COVID-19 pandemic highlights the adaptability of Australia's vaccine innovation system. Such responsiveness is a

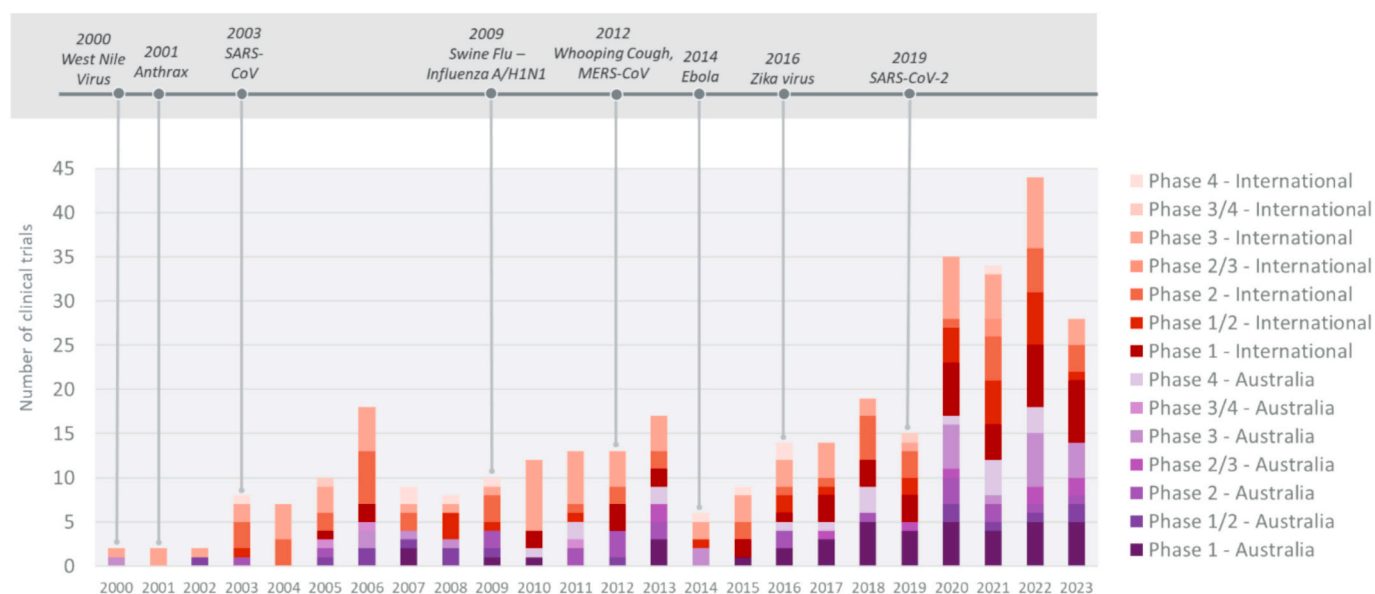


Fig. 7. Clinical trials for infectious disease vaccines in Australia by trial phase and origin of the clinical trial sponsor. Large outbreaks of infectious diseases with pandemic potential are indicated above. Note: Australian subsidiaries of global pharmaceutical companies are categorized as international sponsors.

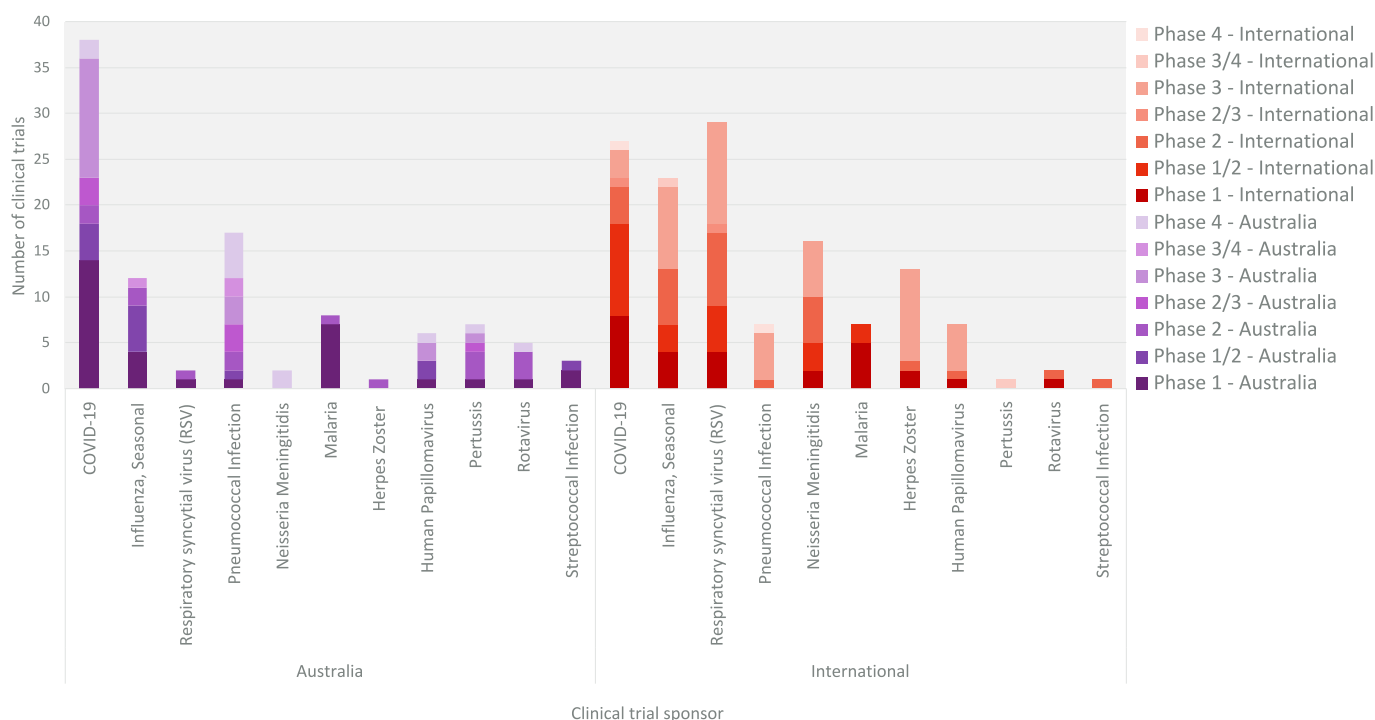


Fig. 8. Clinical trials for infectious disease vaccines in Australia by infectious disease target and origin of the clinical trial sponsor. Note: Australian subsidiaries of global pharmaceutical companies are categorized as international sponsors.

significant asset in addressing emerging infectious diseases and potential pandemics [50]. It underscores the importance of a national research strategy that both aligns with identified research priorities and maintains surge capacity for global, regional, and local emerging infectious disease events [17].

4.1.2. National innovation system in global context

The tiered distribution of grant funding reflects Australia's strategic balancing of domestic public health needs, regional health security, and global health commitments [52]. Varying funding levels may indicate differences in disease burden, existing intervention efficacy, or potential

public health impact of increased investment [53]. Allocations are also shaped by political economy factors: institutional lobbying, program mandates, and demand pressures [54]. These results should therefore be read not as evidence of rational optimisation, but as a descriptive picture of how public funding has historically been distributed.

Public investments in infectious disease research did not necessarily translate into clinical trial activity by Australian sponsors, with HIV as a notable example. This pattern is consistent with a funding structure that favours early-stage, investigator-initiated research over the substantially higher capital requirements of Phase 2 or Phase 3 vaccine trials. This discrepancy can be attributed to several factors, including limited

translation of academic research [55,56], geographical spread of infections and the global nature of clinical trial infrastructure [57].

Vice versa, diseases like RSV and *Neisseria meningitis* received limited public funding and had limited patent output, but were over-represented in clinical trials, especially by international sponsors. The Australian R&D Tax Incentive (RDTI) encourages US companies to conduct Phase 1 trials in Australia, but the subsequent phases often move offshore, likely due to the need for larger study populations and international funding sources [58]. In these cases, the called-upon international collaboration and complementarity [18] are thus mainly driven by economic reasons.

4.1.3. Niche focus

Australia has been an attractive location for certain internationally sponsored clinical trials, particularly in areas such as influenza, RSV, and meningococcal disease. Australia's position in the Southern Hemisphere offers a unique advantage for diseases with marked seasonality [59,60], allowing organisations to conduct trials year-round by alternating between Hemispheres [61]. Particularly for respiratory infectious diseases this accelerates vaccine development by reducing timelines and providing a more comprehensive understanding of vaccine efficacy across diverse global populations.

4.2. Implications

Australia's attractiveness for internationally sponsored clinical trials, particularly for seasonally influenced diseases, presents an opportunity to strengthen global research collaborations. Manufacturing capabilities form a critical link between early-stage R&D and realised vaccine products [43]. This could lead to faster vaccine development timelines and more robust efficacy data across diverse populations. Limited domestic capacity for GMP-grade production and scale-up has historically led to early off-shoring of manufacture, even for candidates with substantial Australian scientific input. Retaining more components of the vaccine value chain domestically presents significant economic opportunities, including job creation and increased investment in the biotechnology sector.

To further enhance Australia's role in the global vaccine innovation system, several areas for improvement can be identified. In the early phases of the Vaccine Innovation Cycle [10], efforts should focus on IND enabling studies and at-scale GMP manufacturing capacity ([43]; MTP [58]). Furthermore, given Australia's low population density and distinct state-level governments, the innovation system should prioritize improving and streamlining regulatory approval processes and ensuring timely access to target populations [62,63]. Efforts to improve the innovation system include economic and healthcare development to support access to at-risk patient groups [64]. Refinement of regulatory frameworks like the ACCESS consortium [65], will fortify Australia's positioning as a 'first wave' launch country [66]. This will facilitate the presence of high-growth firms – a hallmark of high-quality entrepreneurial innovation systems [67] – and correspondingly will strengthen its role in the global clinical trial innovation system.

Significant reform is already underway in Australia. In 2024, the federal government announced funding for the development a National One Stop Shop for Clinical Trials and Human Research [68]. A 2024 review of Australia's health technology assessment policies and methods called for reforms to improve equitable and timely access to new vaccines [69]. In August 2025, Australia released a draft National Health and Medical Research Strategy to strengthen coordination and impact [70]. The new National Immunisation Strategy for Australia 2025–2030 has 6 priorities which include harnessing new technologies through program strengthening, horizon scanning, championing vaccine R&D and maintaining onshore manufacturing [71]. In November 2025 new legislation was passed in both Houses of Parliament to establish an independent Australian Centre for Disease Control agency in 2026 [72]. A strategic examination of the R&D system with the aim to strengthen

science and innovation capabilities is ongoing [73]. In November 2025 Australia launched a national vaccine incubator backed by AUD\$33 M in funding (BioMelbourne [74]).

The success of these combined efforts will be contingent on available resources, collaboration, learning effects and organizational capabilities among members of the innovation community [67,75]. This requires a sustained and aligned focus on national research priorities. Historically, such focused research strategies have paid off; the development of HPV vaccine Gardasil drew on two decades of consistent research funding by the NHMRC, even when the final product is commercialised through multinational pathways [76].

Recent shifts in international health governance and funding priorities present a critical juncture for the global vaccine innovation systems [77,78]. Countries such as the United States are re-evaluating their commitments to vaccine R&D [78,79], while CEPI is calling for a health security partnership for the IndoPacific region to strengthen vaccine research, manufacturing and delivery systems in Southeast Asia and the Pacific as a core global risk-reduction measure with a focus on epidemic and pandemic prone pathogens [80]. Australia can leverage its existing strengths and strategic investments, including the new national virtual infectious disease incubator, Biointellect Venturer, to assert its position as a key player in the global vaccine innovation ecosystem.

4.3. Limitations

The current study comes with a number of limitations. In some cases, CPC and/or IPC codes were incomplete or did not correspond. A significant portion of the grant dataset (28%, 147 awarded grant programs) lacked identifiable infectious disease targets, despite receiving 46% (AUD\$300.6 M / USD\$253 M) of funding. This pattern aligns with early-stage research practices and intellectual property considerations, where targets are often undisclosed or the focus is on broader platform technologies. And finally, the study period (2000–2023) may not capture the full trajectory of some vaccine developments.

Limitations also arose from the fragmentation of data across datasets. The lack of consistent unique identifiers across datasets made it unfeasible to reliably match patents, grants and clinical trials for the same assets (see section 2.4). This same fragmentation prevents a robust assessment of how many vaccine-related patent families progressed into clinical development, and how many TGA-approved (Therapeutic Goods Administration) vaccines can be attributed to Australian public funding streams. While aggregate patterns in patents, grants, and clinical trials provide insight into Australia's positioning, the inability to link individual assets underscores a key structural barrier in vaccine innovation research. This fragmentation reflects a broader challenge in innovation system studies: the complexity of tracing flows across institutional and technological boundaries [22–24]. This analysis thus demonstrates the need to implement a suitable framework to measure translation and impact of public funded research.

4.3.1. Future research

Critically, fragmented public datasets prevent one-to-one tracing of vaccine assets across the innovation pipeline, demonstrating the structural need for better integrated data systems. This limitation must be acknowledged in national and global analyses of vaccine innovation. The technology readiness level (TRL) framework is a globally accepted benchmarking tool for assessing the maturity of different technologies on a nine-point scale [81]. This framework has been adapted for vaccine products and is already used by organisations such as NIH in 2019 [82,83]. In Australia, implementing a national standard TRL framework could provide a consistent approach for all stakeholders in the vaccine value chain, facilitating the measurement of translation and commercialization. Future work could build on this foundation by quantifying the vaccine development pathway, tracking funding and resources, pursuing deeper institutional linkage, cross-disease analyses and comparative international studies – directions that fall outside the scope

of this article but remain vital for advancing understanding of vaccine innovation systems. This is essential to evaluate the impact of public funded vaccine research.

CRedit authorship contribution statement

Linda H.M. van de Burgwal: Writing – review & editing, Writing – original draft, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Esther S. Pronker:** Writing – review & editing, Writing – original draft, Visualization, Investigation, Formal analysis, Data curation, Conceptualization. **Jennifer Herz:** Writing – review & editing, Validation, Conceptualization.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: The authors declare that they have no conflict of interest. Jenny Herz is also founder and director of Biointellect, an Australian-based life sciences consultancy firm, and the Australian national vaccine incubator Biointellect Venturer. The contribution of LvdB was funded by the Veni SGW program (project number VI.Veni.2015.044) of the Dutch Research Council (NWO). The funder had no involvement in study design, collection, analysis and interpretation of data, or writing and deciding to submit the article.

Acknowledgements

The authors would like to acknowledge the contribution of participants and speakers at the first Australian Vaccine Value Chain Conference, held May 2024 in Sydney, NSW for feedback and responses to initial results presented here.

The contribution of LvdB was funded by the Veni SGW program (project number VI.Veni.2015.044) of the Dutch Research Council (NWO). The funder had no involvement in study design, collection, analysis and interpretation of data, or writing and deciding to submit the article.

Data availability

Data will be made available on request.

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