MTPConnect

Australia's Life Sciences
**Innovation Accelerator**

# Australia's Clinical Trials Sector

## Advancing innovative healthcare and powering economic growth

**JUNE 2024**

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# Foreword by Stuart Dignam, CEO of MTPConnect

Clinical trials are an integral part of the research and development pipeline for new treatments and refinement and repurposing of existing treatments. They play a vital role in ensuring that all Australian patients continue to receive the best, safest and most effective treatments.

MTPConnect's clinical trials report, which was first published in 2017 and then updated in 2021 has been a valued resource for State and Federal governments, local and international sector participants and financial investors alike as it provides a holistic and comprehensive overview of the current state of the environment in Australia. It provides vital metrics around the economic and health impacts of clinical trials, a detailed analysis of clinical trial activity and outlines Australia's position in the global market and priority focus areas to support sector growth.

In this edition of the report, we build on our previous reports to highlight how the sector and the broad set of economic and activity metrics have evolved since 2019.

As COVID-19 pandemic restrictions were eased, we saw a surge in clinical trial activity in Australia in 2021. But we have also seen those gains fall away, with trial numbers dropping back to pre-pandemic levels, letting slip the opportunity to entrench a greater share of global industry-sponsored trials in Australia.

Although Australia has maintained its reputation as an attractive clinical trials destination from 2015-22, our conversations with sector stakeholders reinforce the need for urgent action across four key priorities: improving efficiency in trial start up, enhancing data transparency, increasing patient awareness and access to support recruitment, improving visibility and access to trials for patients and clinicians and expanding the workforce to support clinical trials growth.

It is worth noting that these priorities have not changed much since our 2021 report, underscoring the need for urgent action. The National One Stop Shop initiative, which supports three of the four priorities, is a step in the right direction. It presents an opportunity for Australia to leverage its reputation for excellence in early phase trials to become more competitive in attracting late phase trials and deliver more life-saving innovations to Australian patients.

Despite ongoing challenges across the sector, Australia is at an exciting juncture, with emerging innovation and trends that create significant new opportunities. Patient-centricity in trials is on the rise, enhancing patient engagement and outcomes. Digital health solutions are improving access to trials for our underserved regional and rural populations, while the emergence of precision medicine and innovative trial designs are revolutionising the clinical trial process and attracting greater investment into the clinical trials economy. Additionally, with regulatory change and uncertainty in the European Union and United States, Australia is well-positioned to leverage its faster trial environment to capture a greater share of the global market for medical device trials.

As the world moves beyond the pandemic, it is imperative for Australia to ramp up investment in clinical trials to uphold its global competitiveness and continue delivering world-class healthcare to its people.

**Stuart Dignam**

# Foreword by the Expert Advisory Group

MTPConnect's clinical trials report plays a crucial role in the sector, and it has been doing so since its initial publication in 2017. By consistently tracking the sector's performance across key metrics related to economic impact and patient health benefits, as well as analysing clinical trials activity throughout Australia, this report fosters a shared understanding of the sector's broader impact on the economy. It also provides an opportunity for sector participants and stakeholders to reflect on progress achieved thus far and focus on addressing key priorities for continued growth. We take pride in contributing to its development, ensuring that it represents a diverse range of perspectives from across the sector.

| EAG member name | Organisation | Position |
|---|---|---|
| **Ana Svensson** | Novo Nordisk | Senior Director, Clinical, Medical and Regulatory, Novo Nordisk Oceania |
| **David Lloyd** | Southern Star Research | CEO |
| **David Wilks** | Bristol Myers Squibb | Executive Director, Regional Head of RCO Pacific at Bristol Myers Squibb |
| **Janelle Bowden** | AccessCR | Managing Director |
| **Kylie Sproston** | Bellberry | CEO |
| **Melanie Gentgall** | Sanofi | Head of Clinical Operations, Sanofi Translational Science Hub |
| **Steve Webb** | Australian Clinical Trials Alliance (ACTA) | Board Director |

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# Contents

# Executive summary

This report, **Australia's Clinical Trials Sector: Advancing innovative healthcare and powering economic growth**, is the result of extensive and comprehensive stakeholder engagement. It serves as an update to our previous 2021 and 2017 reviews, by providing a current snapshot of the size and scope of Australia's clinical trials sector, highlighting areas of success and imperatives for improvement.

The 2024 review examines how the value derived from clinical trials in Australia, and how the level of clinical trial activity has evolved over the past three years (2019-22). It also provides an update on the emerging opportunities and priorities that were foreshadowed in the 2021 report, considers how these have unfolded in recent years, and discusses in detail the future opportunities and areas for improvement facing the sector today.

Australia has maintained its reputation as an attractive destination for clinical trials underpinned by the following factors:

- A strong reputation for the quality and global standing of its investigators and the networks that support them.
- Highly developed research infrastructure and systems that have enabled Australia to continue conducting clinical trials through disruptive global events such as the COVID-19 pandemic.
- High-quality data collection and overall compliance with Good Clinical Practice (GCP) guidelines, which ensures that data collected in Australian trials can support submissions to international regulators, including the United States' Federal Drug Administration (FDA) and the European Union's European Medicine Agency (EMA).
- Specialised and dedicated early-phase infrastructure that enables the delivery of timely, high-quality trials, supported by streamlined processes and private ethics committees.
- The convenience and speed of the Therapeutic Good Administration's Clinical Trial Notification (CTN) scheme, which enables the faster start-up times that are particularly crucial for early phase trials.
- The financial support provided by the Australian government's extension of its research and development (R&D) tax incentives, improving Australia's cost competitiveness.

In 2022, the clinical trials sector in Australia employed c.7,700 Australians. Around 90,000 Australians participated in trials and there were 1,850 trials started. This activity saw c.$1.6 billion spent on clinical trials in 2022, up from c.$1.4 billion in 2019, which is largely attributable to increasing spend on trials, with the number of clinical trials declining slightly over the period. The exhibit below shows how these key metrics have trended over the past seven years.

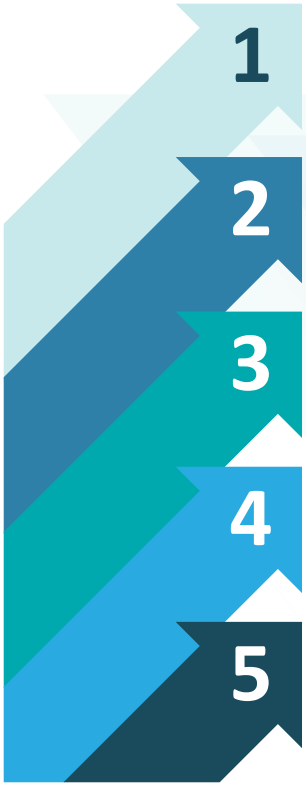
| Metric | 2015 | 2019 | 2022 | CAGR % (2019-22) |
|---|---|---|---|---|
| Expenditure | $1.1 billion | $1.4 billion | $1.6 billion | 4.1 |
| Employment | 6,900 employees | 8,000 employees | 7,700 employees | (1.5) |
| Patient participation | Not reported | 95,000 | 90,000 | (1.8) |
| Number of trials started | 1,460 | 1,877 | 1,850 | (0.5) |
| Share of global industry-sponsored trials | c.5% | c.5% | c.5% | N/A |

Source: ANZCTR; Clinicaltrials.gov; L.E.K. research and analysis

As our exhibit above highlights, the growth of the clinical trials sector since 2019 has been stagnant or declining across several metrics. While there was a robust rebound in 2021 following falls in key metrics in 2020 due to COVID-19, Australia has not maintained its post-COVID gains into 2022. Nonetheless, there are emerging opportunities that need to be capitalised on, and key priorities that need to be addressed urgently in order to ensure the sector continues to grow strongly.

## Emerging opportunities in clinical trials

The five most significant emerging opportunities in the Australian clinical trials sector are focussed on patient engagement, digital health solutions, precision healthcare, innovative trial designs, and medical device trials:




1. There is growing awareness of a need for more patient centricity and diversity in clinical trials. Australia has a significant opportunity to capitalise on its diverse and multicultural population to attract more trials, recruit more participants, and ultimately serve and improve the health outcomes for more of Australia's population, if it can effectively engage and support their participation and involvement in trials.
2. Digital health solutions, such as teletrials offer promise in improving access to all Australians, particularly those in regional and remote areas. These communities have historically lacked the opportunity to participate in, and benefit from clinical trials due to their distance from research institutions.
3. Precision medicine offers a significant opportunity to improve patient outcomes. Clinical trials for the development of precision medicines are gaining momentum globally and locally with rapidly growing usage of biomarkers in trials, which is attracting significant government, non-industry, and industry investment.
4. Innovative trial designs, such as platform/umbrella/basket trials designs using strata or multi-factorial (multi-domain) designs, that can be used with or without adaptive methods, are growing and revolutionising trial processes with the support of government funding. These trials can enhance trial efficiency, providing patients with access to novel therapies sooner.
5. The tightening of medical device regulations in the European Union and United States is increasing the burden of proof and timelines for medical device trials. With Australian centres of excellence housing large, national medical device registries which can streamline patient recruitment and trial start-up times, Australia is well positioned as an increasingly attractive destination for medical device trials.

## Key priorities for the sector's future

In order for Australia to defend and build a strong competitive position in the global clinical trials market and continue to deliver benefits for patients, four key priority recommendations have been identified.

> **Priority 1:** Continue to improve the efficiency of the sector's clinical trial start-up processes, such as ethics and governance approvals.

Australia has a strong global reputation in supporting early phase (Phase I and II) trials, but we have not had similar success in attracting the larger, more complex Phase III and IV trials. In order to grow Australia's global share of Phase III and IV trials, it is critical to:

- Continue to streamline our ethics processes towards a true, single ethical review across all jurisdictions.
- Streamline site governance approval processes to improve consistency from site to site and study to study.
- Improve patient recruitment at each site (addressed in Priority 2 below)

Since these later phase trials typically involve larger patient cohorts across multiple sites, they present an opportunity to further grow the economic benefits as well as patient health benefits from clinical trials.

> **Priority 2:** Enhance patient awareness and the ability to efficiently recruit patients at each clinical trial site, to improve site economics for these trials.

Patient awareness and participation in clinical trials in Australia still lags countries such as the UK by a significant level. Australia has a diverse, multicultural population that could be further leveraged to attract more global clinical trials as companies are looking to demonstrate the efficacy of their novel medicines and devices in diverse populations. In order to do this, significant investment in patient awareness and engagement is required. Particularly, we need to engage with our culturally and linguistically diverse (CALD) populations and Aboriginal and Torres Strait Islander communities to improve awareness and understand and address their barriers to participation.

> **Priority 3:** Grow the size and capabilities of Australia's clinical trials workforce.

As highlighted by our metrics above, Australia's clinical trials workforce has not grown since 2019. Stakeholders have continued to highlight the ongoing shortages of experienced Clinical Research Associates (CRAs) and Clinical Trials Coordinators (CTCs), which were also mentioned in the previous editions of this report and in the October 2021 MTPConnect REDI Initiative Skills Gap Analysis report. In order to grow the size and capabilities of the workforce, there needs to be greater awareness of career pathways and opportunities in the clinical trials sector among graduates, and better training and workforce development programs, such as those developed in recent years by the MTPConnect Researcher Exchange and Development within Industry (REDI) program and PRAXIS Australia. Investing in these areas will enable the growth of highly skilled jobs in the sector, and in turn, support further growth in clinical trial activity in Australia. Furthermore, Australia still lacks a reliable method of capturing clinical trials workforce metrics, an opportunity that that could greatly assist in addressing current workforce limitations.

> **Priority 4:** Enhance the sector's overall transparency, with better data collection, data tracking and data registries, particularly to track patient recruitment, participation and metrics related to medical device trials in addition to drug trials.

Although the Australia New Zealand Clinical Trials Register (ANZCTR), Australia's national registry for tracking clinical trial activity, collects, curates and maintains extensive clinical trials data, the current system relies on self-reporting. Consequently, there are gaps in the quantity and granularity of information supplied to ANZCTR by sponsors, and the currency of information. Particularly, we noted that there is a significant dearth of information recorded for medical device trials (where even the phase of trial is not commonly reported or recorded). This gap is not unique to Australia and is also seen in international databases such as ClinicalTrials.gov. Increasing the granularity of information would provide richer insights into Australia's competitive position for trials by type, growth rates of certain types of trials and help inform workforce planning and policy development.

Australia has an opportunity to play a global leadership role in reviewing the clinical trials data that would be strategically useful to collect (e.g., clinical trial start-up timelines, phase and therapeutic area information for medical device trials) and implement processes to collect this information efficiently.

Progressing these recommendations will require commitment from the entire sector. All these stakeholders will need to increase their efforts around each of the four recommendations, to accelerate the pace of progress and position Australia as a more desirable destination than currently for global trial sponsors.

Other competing countries and regions such as Singapore, UK, and South Korea are implementing measures to improve the attractiveness of their respective clinical trials sectors. Australia risks falling behind such countries if it does not take significant steps to address the priorities outlined above.

# 1. Introduction and context

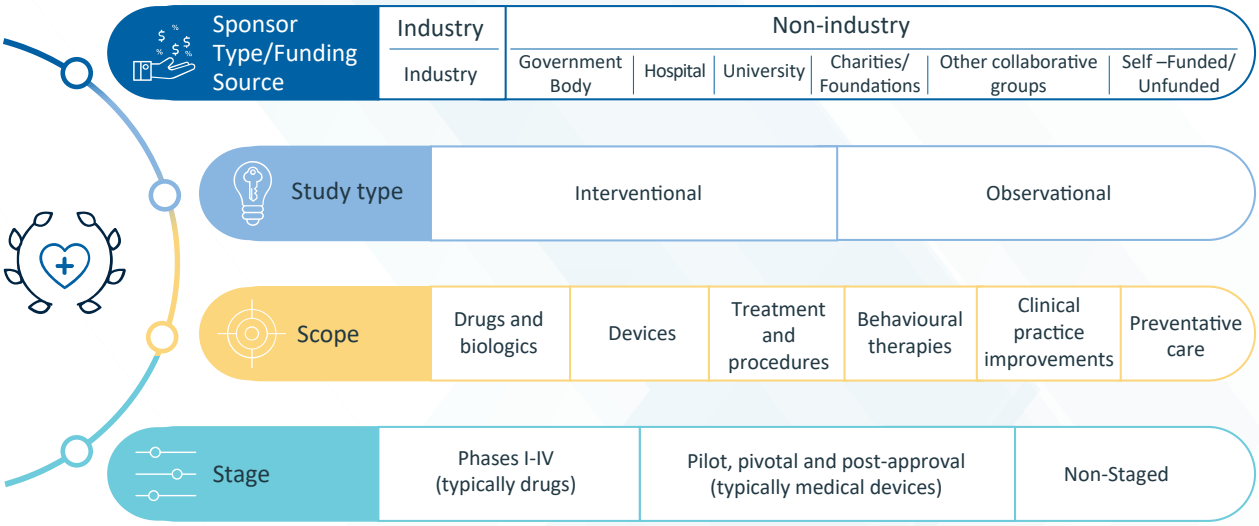
## Introduction to clinical trials

Clinical trials are a critical link in the value chain for developing new therapies and technologies, to ultimately improve health outcomes across the world. Their primary purpose is to assess the safety and efficacy of new medical therapies, but also provide a pathway for patients who have failed other forms of treatment to access novel therapies that have yet to be brought to the broader market.

Clinical trials can take many forms, with features and characteristics that can vary widely, depending on the unique circumstance of each study. The clinical trials defined in this report are segmented based on the four key parameters illustrated in Figure 1 below.

**Figure 1**

**Four key parameters of clinical trial**

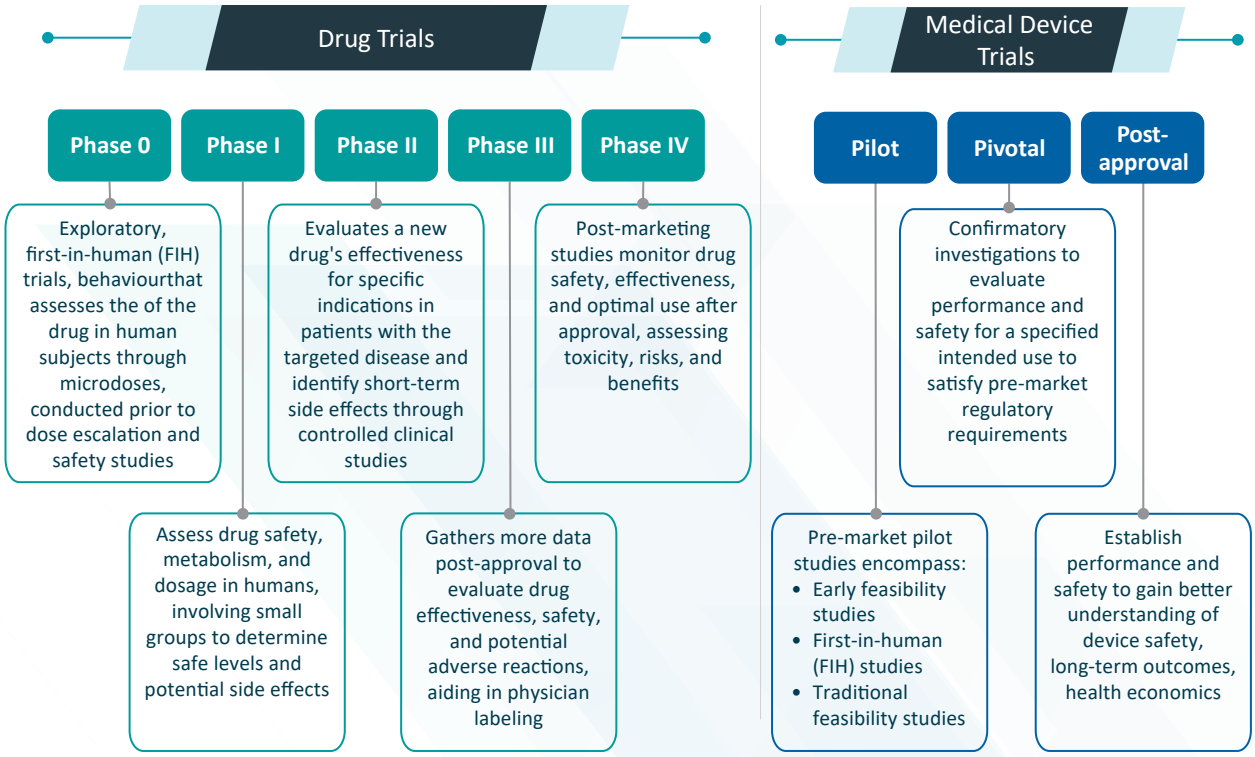



Trials are sponsored and funded by a wide range of industry and non-industry stakeholders, including healthcare professionals and other industry sources, government sources, philanthropic donors, hospitals and universities, and patients. They span a wide range of interventions, methodological designs and scope of treatment strategies, from medical devices to drugs to behavioural therapy.

Further background on the various sector participants and an overview of the clinical trial start-up process and its key parameters can be found in Appendix 3.

Clinical trials involving therapeutic goods are typically categorised into phases that occur across the development lifecycle continuum. Most trials are classified into one of five phases (0-IV) that indicate the stage of development. Medical device trials sometimes fall within one of the four trial phases, but often go through 'stages' instead. These stages might include a Pilot study, which include Early Feasibility studies, First In Human (FIH) studies or a Traditional Feasibility study (similar to combined Phase I and II trials); a Pivotal study (to confirm clinical efficacy and risks, similar to traditional Phase III trials); and Post-approval studies (to determine long term effectiveness and risks, similar to traditional Phase IV trials).

**Figure 2**
**Clinical trial stages, drugs and medical devices**[1,2]




Source: ANZCTR – Data field definitions; MTAA – Clinical Trials Regulatory Framework

## Context for this report

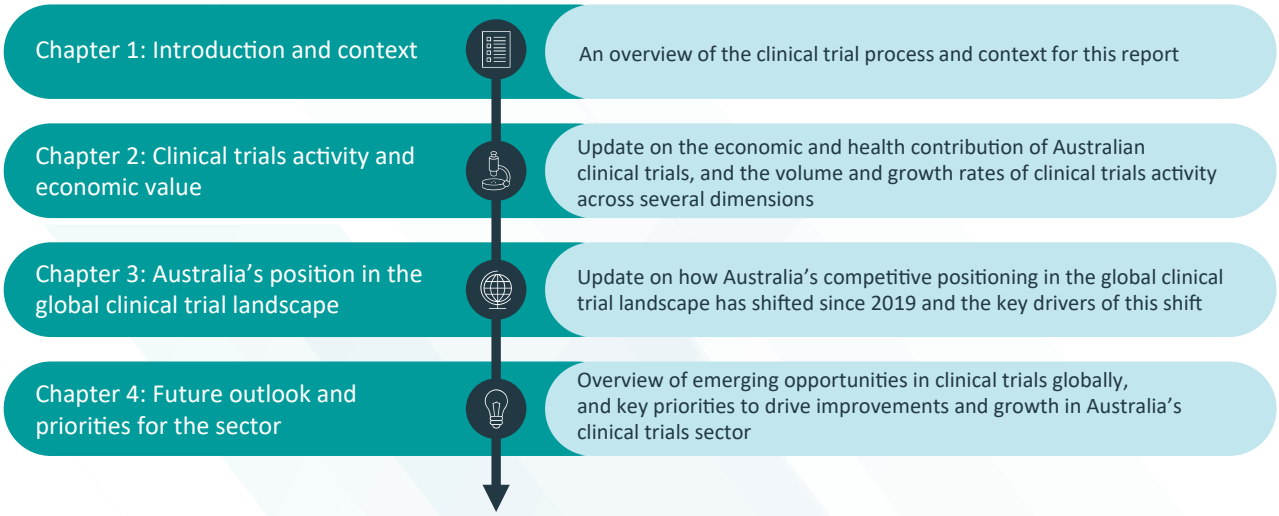
In 2017 and 2021, MTPConnect carried out holistic and comprehensive reviews of the state of the clinical trials market in Australia, with summary reports produced in both those years and with the 2021 report also containing data from the pre-pandemic period, up to the end of 2019. This 2024 report builds on the detail from those reviews and incorporates new data from 2020 - 2022, as an update to these previous reports.

It examines how the value derived from clinical trials in Australia, and the volume and growth rates of Australian trials activity have evolved over the past three years (2019-22). It also provides a review and update of the emerging opportunities and priorities that were outlined in the 2021 report, considering these developments as Australia and the rest of the world recovers from the COVID pandemic.

The report is structured as shown in Figure 3 below:

[1] ANZCTR, Data field definitions, accessed February 2024.
[2] MTAA, Clinical Trials Regulatory Framework, accessed February 2024.

**Figure 3**
**How this report is structured**




## Methodology in brief

This report has drawn on a wide range of information sources, both quantitative and qualitative, to update on recent developments in the sector. It includes information sourced from the MTPConnect industry survey, consultations with industry stakeholders, as well as clinical trials activity data from the ANZCTR and ClinicalTrials.gov.

| Topic | Source |
|---|---|
| Clinical trials activity and economic value | • ANZCTR<br>• ClinicalTrials.gov<br>• MTPConnect industry survey<br>• Desktop research and analysis |
| Australia's position in the global clinical trial landscape | • ClinicalTrials.gov |
| Future outlook and priorities for the sector | • Stakeholder consultations<br>• Desktop research |

The value derived from the clinical trial sector, including economic contribution, jobs and patient participation, are primarily drawn from a MTPConnect industry survey that was conducted in conjunction with Medicines Australia (MA), Medical Technology Association of Australia (MTAA) and AusBiotech. The survey respondents include medical technology, biotechnology and pharmaceutical (MTP) companies, contract research organisations (CROs) and clinical trial sites. In total, survey respondents contributed clinical trials data on approximately 400 clinical trials commenced in Australia, involving approximately 15,000 participants in 2022.

Detailed information on the methodology used to calculate the appropriate economic and activity metrics shown in this report can be found in Appendix 4-7.

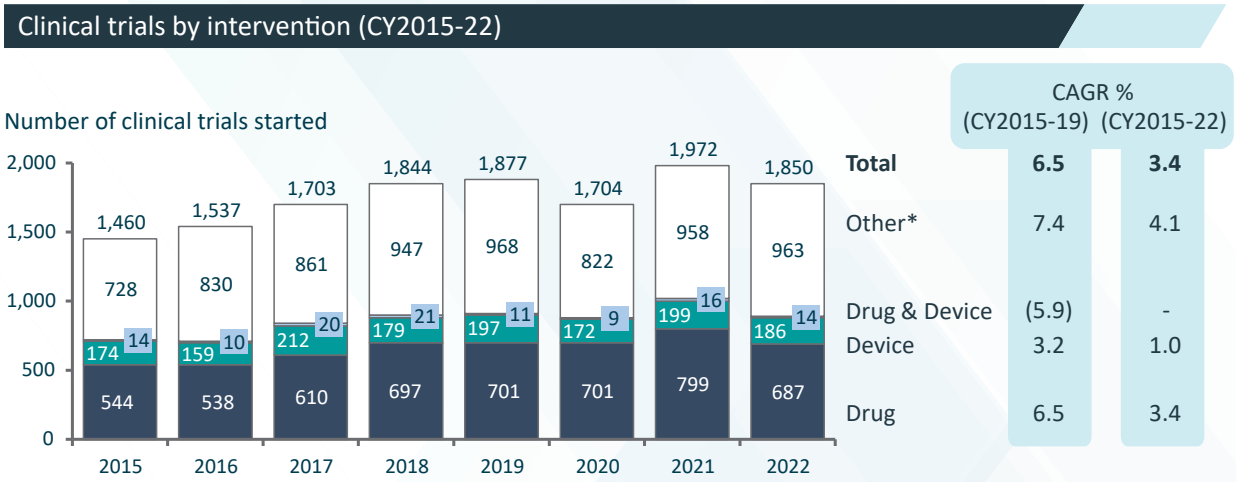
# 2. Clinical trials activity and economic value

## Clinical trials activity in Australia

*Overview of clinical trials activity (2015-22)*

As Figure 4 shows, there were 1,850 clinical trials in Australia in 2022, according to data recorded by ANZCTR, which reflects an average (although inconsistent) annual growth rate of 3.4% since 2015. On average, drug trials grew by 3.4% per annum, device trials grew by 1.0% per annum, and 'Other' trials grew by 4.1% per annum over this period, as shown in Figure 4 below. Clinical trial starts have returned to the pre-pandemic levels observed in 2019, after two years of volatility in 2020 and 2021.

**Figure 4**
**Clinical trials by intervention**




Note: *'Other' trials includes observational studies and interventional trials listed as 'Behaviour', 'Lifestyle', 'Prevention' research, as well as other treatments that do not involve a drug or medical device
Source: ANZCTR Data (14 Nov 2023); L.E.K. analysis

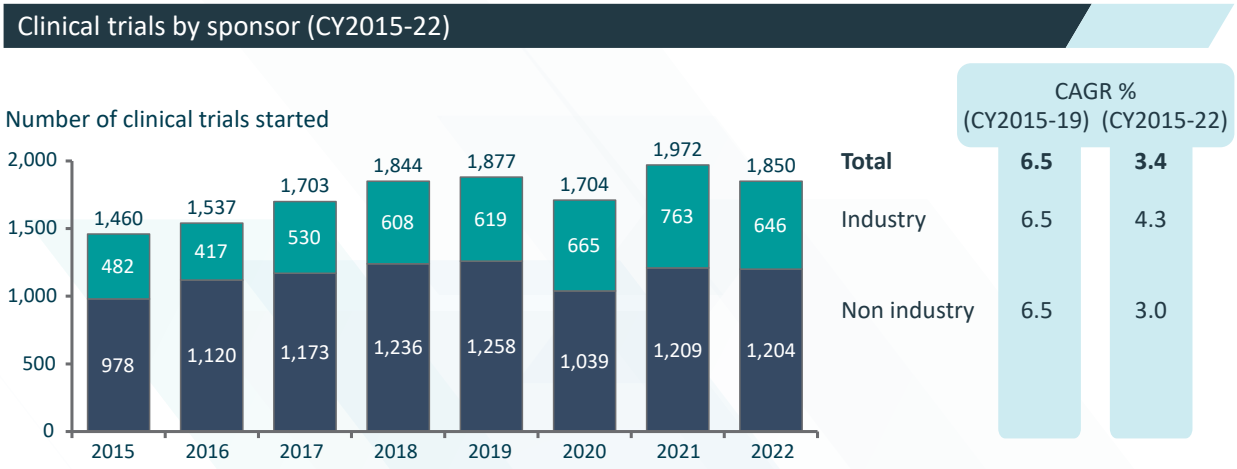
Industry-sponsored trials, which aim to commercialise underlying intellectual property such as drugs and/or devices, accounted for almost a third of all clinical trials commenced throughout the period from 2015 to 2022, as shown in Figure 5 below. In the pandemic-affected years (2020 and 2021), the proportion was higher at 39%.

Overall, industry-sponsored trials have been more resilient than non-industry sponsored trials through COVID-19, growing by 4.3% per annum from 2015-22. This compares to non-industry-sponsored trials, which have grown more slowly, at 3.0% per annum over the same period.

A large proportion of industry-sponsored trials are funded by multinational companies, with only 9% of industry drug trial sponsors headquartered in Australia.[3] This foreign investment makes a valuable contribution to patients and the broader economy in Australia, as highlighted earlier in this report.

[3] Trialtrove, total number of sponsors of Australian trials in 2022 with Australian headquarters, accessed February 2024

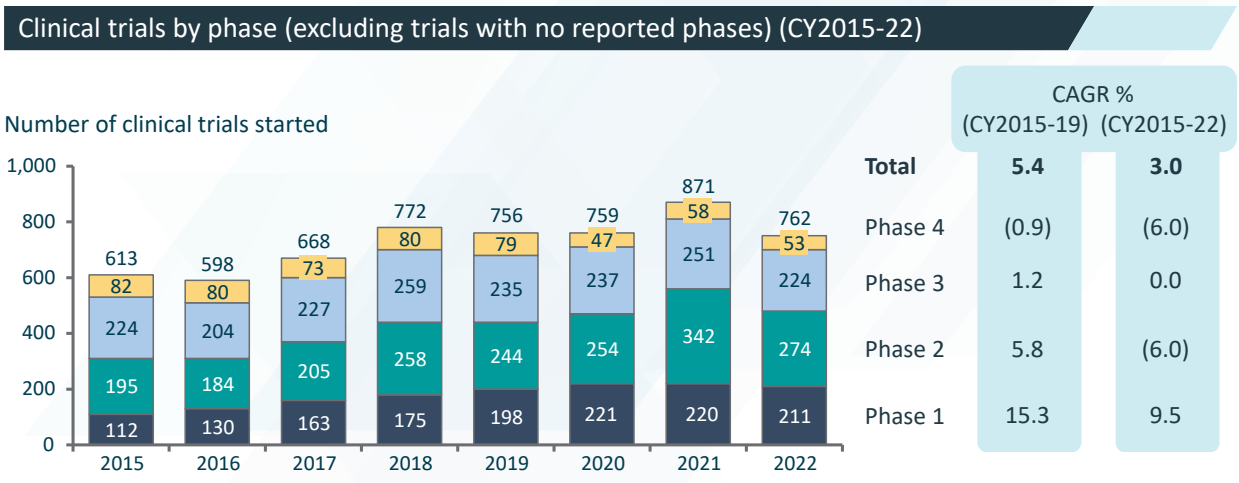
**Figure 5**
**Clinical trials by sponsor**




Source: ANZCTR Data (14 Nov 2023); L.E.K. analysis

Non-industry sponsored trials or Investigator Initiated Trials (IITs) encompass a wide range, including both academic and collaborative group trials. While these trials do not typically deliver the foreign investment of many industry-sponsored ones, they still bring considerable benefits to the sector by supporting local research, improving clinical outcomes for patients, developing both the clinical trials workforce and infrastructure, and improving clinical practices through evidence-based guidelines.

**Figure 6**
**Clinical trial activity by phase**




Source: ANZCTR Data (14 Nov 2023); L.E.K. analysis

As described in Chapter 1 of this report, clinical trials can be classified into four phases (indicating the stage of development of a drug), while medical device trials can be classified into three 'stages' or phases. Medical device trial phases are not captured by ANZCTR or ClinicalTrials.gov and are instead

classified as 'Not applicable' on these databases, an issue that is discussed in greater detail in Chapter 4 of this report. A large proportion of clinical trials do not need to go through all four phases and therefore might not have a phase nomenclature to report.

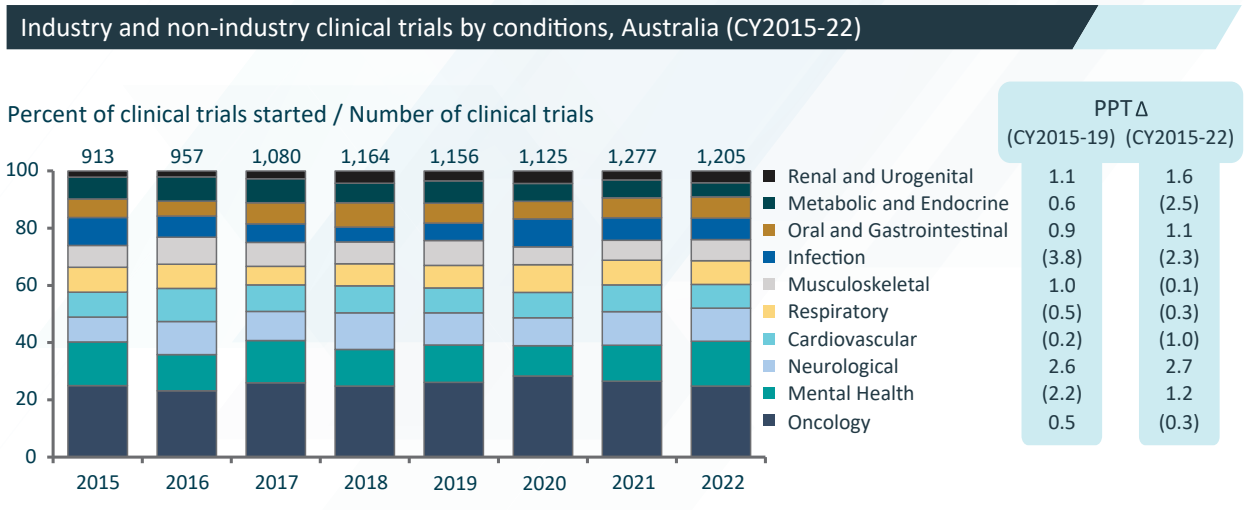
As illustrated by Figure 6 above, Phase I trials have grown the fastest since 2015 (9.5% per annum). Phase II trials have grown at 5.0% per annum. The number of Phase III trials have remained flat since 2015, and Phase IV trials have declined during this period by 6% per annum.

Phase III and IV studies typically require larger patient numbers and multiple sites globally. Countries that can provide many sites with effective enrolment processes and efficient start-up timelines will be more attractive to sponsors looking to streamline trial operations and costs. Australia's relatively small population and geographic spread, as well as the known need to streamline ethics and site governance processes, can hamper Australia's ability to bid for these studies. As we increase our ability to engage and recruit our diverse population to clinical trials, improve our start-up processes, as well as improve the infrastructure to run trials outside metro centres, there is a real opportunity to increase the number of later phase trials we can attract to Australia. These trials are more likely to lead to regulatory approvals, as well as the direct economic benefits of the trial investment. Conduct of these trials in Australia also has the potential benefit of giving patients and clinicians early access and experience with these interventions, as well as information on their use in the Australian context for regulatory applications and health technology assessments which may help reduce uncertainty.

## Clinical trials activity by therapeutic area

The level of clinical trials activity varies significantly by therapeutic area, reflecting areas of unmet need and R&D intensity, as well as Australia's relative strengths versus other countries. Figure 7 below shows how clinical trials activity in ten leading therapeutic areas has grown since 2015.

**Figure 7**
**Industry and non-industry clinical trials by conditions**




Source: ANZCTR; ClinicalTrials.gov; L.E.K. analysis

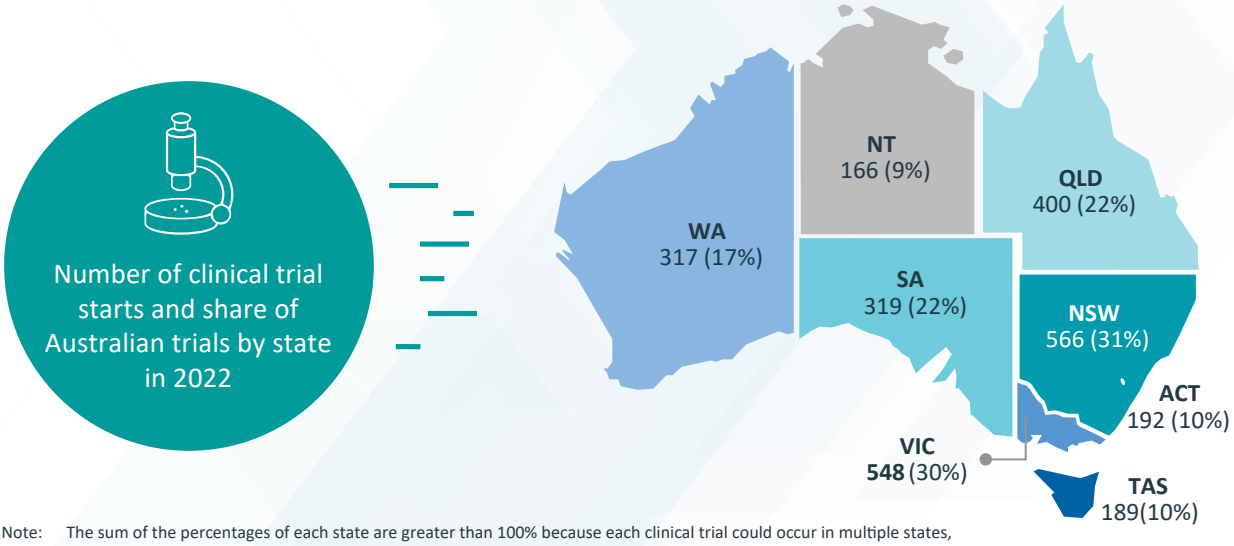
Oncology is the most frequently studied therapeutic area in Australian clinical trials. According to the Australian Institute of Health and Welfare (AIHW), it also forms the largest burden of disease in Australia.[4] However, the number of oncology clinical trials commenced annually has been consistent, at around 300 trial starts per year since 2018.

The fastest growing of the five leading therapeutic areas in Australia is neurology, which has grown at 8% per annum since 2015. With an ageing global population, and an increased burden of dementia, strokes and other neurological diseases in people over the age of 65, there is a need to address care of these conditions, which could explain this increased activity.[5] The adjacent therapeutic area of mental health has also displayed strong growth over the period. Both therapeutic areas have, and will continue to benefit from dedicated Medical Research Future Fund (MRFF) Missions, i.e. the Dementia, Ageing and Aged Care Mission, and the Million Minds Mental Health Research Mission, driving greater volumes of non-industry sponsored trials.[6]

## *Clinical trial activity by state*

The relative intensity of clinical trial activity across states has remained constant since 2019. Of the clinical trials commenced in Australia in 2022, 30% have sites in each of Victoria and NSW, in line with what was reported in 2021. Other locations - Western Australia, South Australia, the Northern Territory, Tasmania and Queensland – have comparatively lesser activity, given their size and resources.

**Figure 8**
**Number of clinical trial starts by state in 2022**




Note: The sum of the percentages of each state are greater than 100% because each clinical trial could occur in multiple states, in which case it would be counted more than once in the figure above
Source: ANZCTR Data (14 Nov 2023); L.E.K. analysis

This distribution is due to Victoria and NSW having the largest proportions of Australia's population and the most developed clinical trials infrastructure. Both states host some of Australia's largest teaching

[4] AIHW, Australian Burden of Disease Study 2022
[5] AIHW, Australian Burden of Disease Study 2022
[6] Department of Health and Aged Care, All MRFF Initiatives, accessed February 2024.

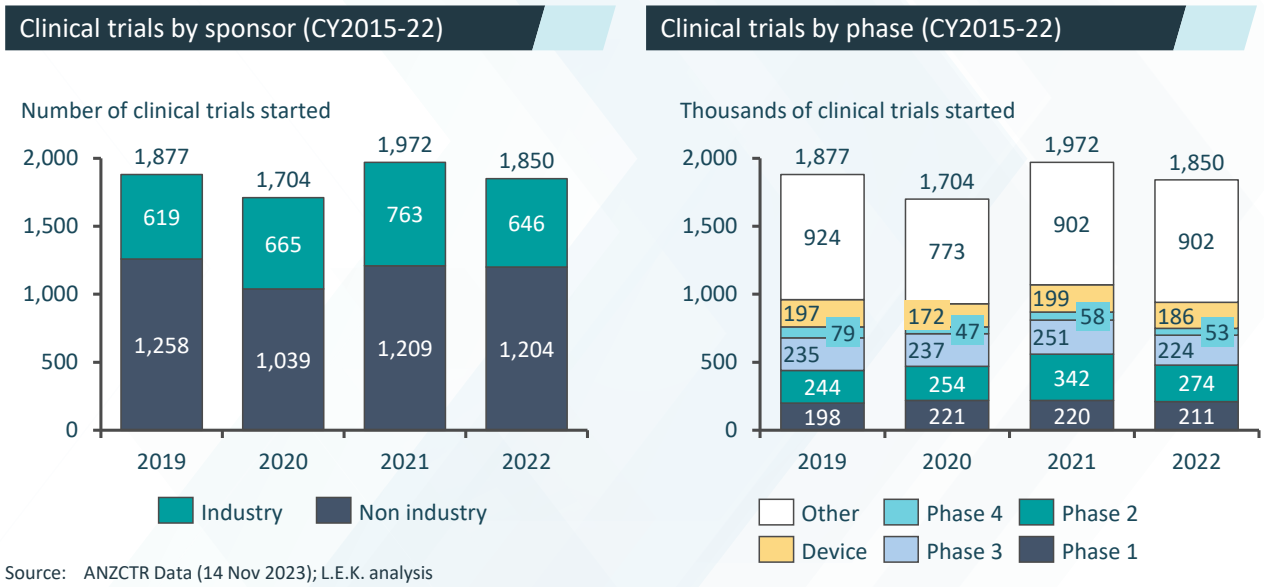
hospitals and cancer treatment centres, and of the 58 members of Association of Australian Medical Research Institutes (AAMRI), Victoria and NSW represent 18 and 19 members respectively.[7]

Despite the higher concentration of MRIs in Victoria and NSW, the presence of large MRIs in other states, such as the South Australian Health and Medical Research Institute (SAHMRI) in South Australia and the QIMR Berghofer Medical Research Institute in Queensland ensures that clinical trials activity is well distributed across states, with South Australia and Queensland holding 22% share of clinical trials activity each.

### *Impact of COVID-19 on clinical trials activity*

COVID-19 significantly disrupted clinical trials in Australia and around the world. Many clinical trials were paused or postponed due to concerns regarding patient safety, or because of the diversion of healthcare infrastructure to treat COVID-19. The number of clinical trials commenced in Australia in 2020 fell by approximately 10% when compared to 2019. This decline was seen most in non-industry sponsored trials, which decreased from 1,258 in 2019 to 1,039 in 2020. By comparison, the number of industry-sponsored trials rose over the same period, from 619 trials in 2019 to 665 in 2020.

**Figure 9**
**Clinical trials by sponsor and phase**




Source: ANZCTR Data (14 Nov 2023); L.E.K. analysis

The total number of clinical trials bounced back strongly in 2021 as most of Australia came out of COVID-19 lockdowns and pandemic restrictions were eased, compared to many other parts of the world. This was largely driven by industry-sponsored clinical trial starts, with 763 trials commenced in 2021 compared to 665 in 2020. Non-industry sponsored trials increased by c.20% between 2020-21 from 1,039 trials in 2020 to 1,209 in 2021 but have yet to completely recover to pre-pandemic levels. This was likely driven by a combination of the following factors:

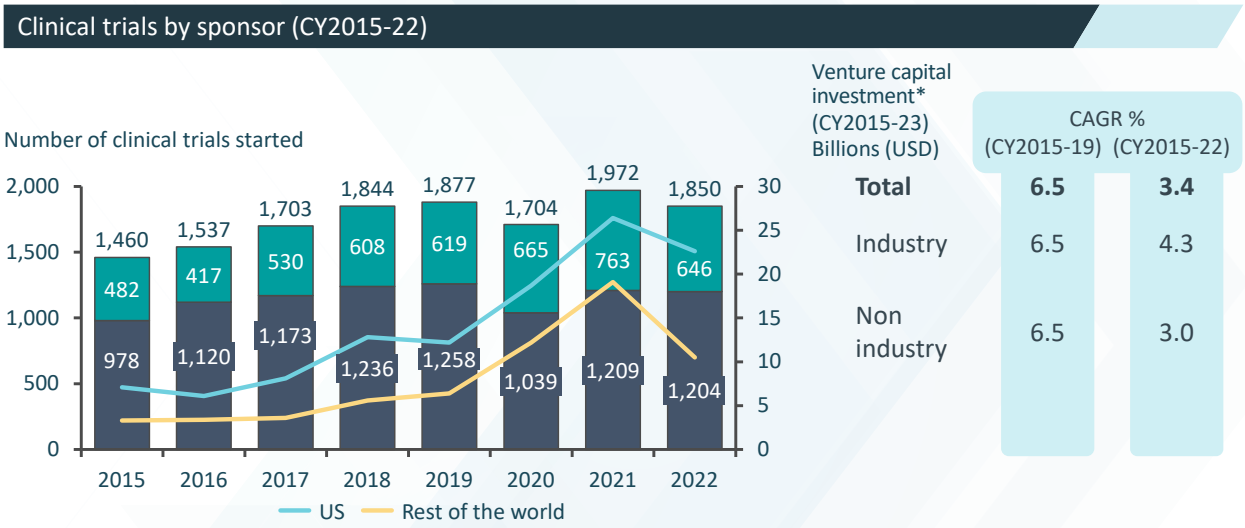
- Investigators and industry sponsors began trials in 2021 that were held back or paused in 2020, due to the impact of COVID-19.

[7] AAMRI website, List of members, accessed February 2024.

- Many other parts of the world with similar high quality healthcare systems like Australia continued to be impacted by COVID-19 in 2021 (e.g., through the Omicron strain).[8,9]
- There was a rapid growth in infectious disease and/or respiratory trials related to the development of various COVID-19 vaccines and therapeutics. The urgency created by higher COVID-19 numbers also created more pressure on clinical trials, leading these to be carried out more quickly than usual.

The volatility suffered by capital markets providing funding to MTP companies to conduct clinical trials has also likely affected the number of clinical trials observed in 2022, as shown in the following figure. Global venture capital investment in MTP companies began to decline from the latter half of 2021, a factor supported both by independent evidence and feedback from stakeholder conversations.[10] Investors sought to preserve their cash in the face of macroeconomic uncertainties (such as the war in Ukraine and generally high global inflation rates).[11] The collapse of the Silicon Valley Bank in 2023 was an additional shock to the system.[12]

**Figure 10**
**Clinical trials by sponsor**




Note: *Investment into emerging therapeutic companies, that represent 95% of drug development companies
Source: ANZCTR Data (14 Nov 2023); Biotechnology Innovation Organisation; L.E.K. analysis

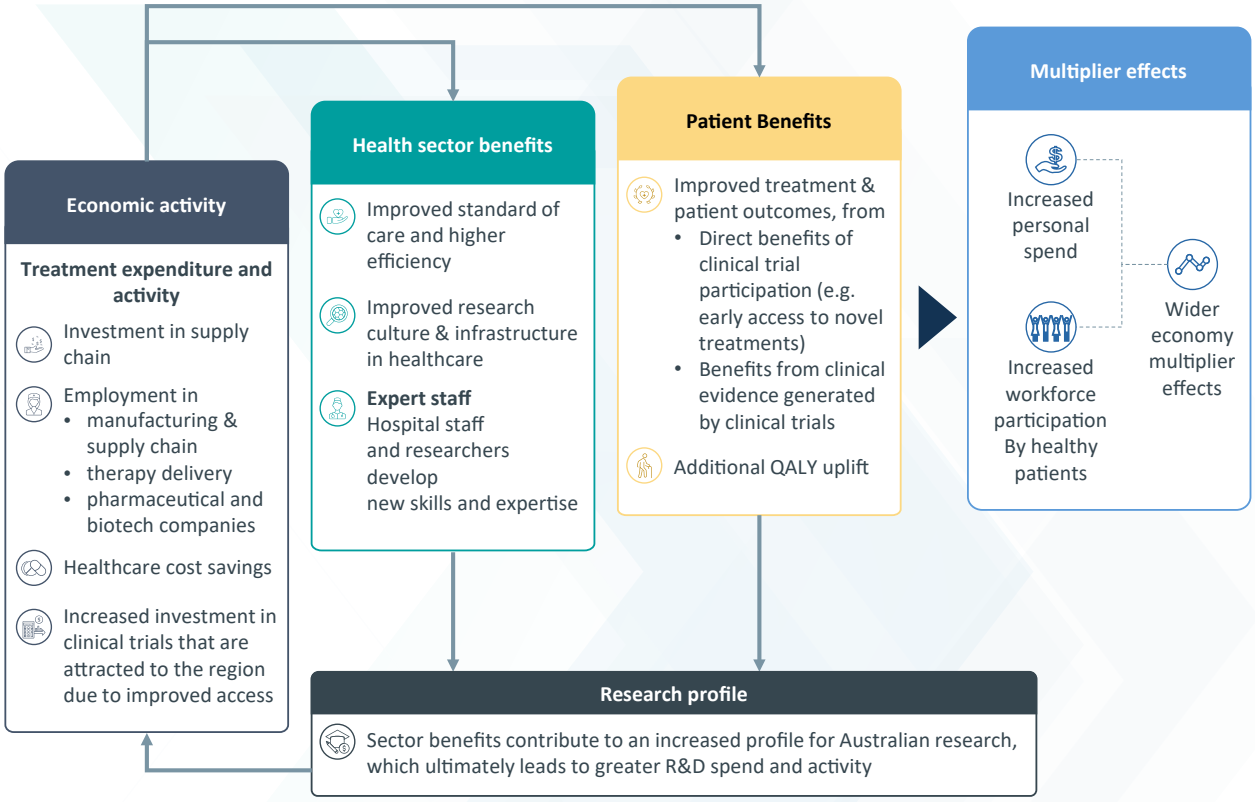
All these factors have resulted in tighter R&D budgets for MTP companies and have dampened growth in clinical trial starts in Australia and globally.

[8] American Hospital Association, New Analysis Shows Continued Negative Impact of COVID-19 on Hospital & Health System Financial Health in 2021, March 2021.
[9] WHO, COVID-19 continues to disrupt essential health services in 90% of countries, April 2021.
[10] L.E.K./MTPConnect interviews with sector participants, 2023.
[11] J.P.Morgan, Biopharma Licensing and Venture Report, 2023.
[12] Harvard Business Review, Silicon Valley Bank's Focus on Startups Was a Double-Edged Sword, March 2023.

## Overview of value derived from clinical trials

Clinical trials make a significant, beneficial contribution to Australia's health, wellbeing and economy. They deliver an array of direct and indirect health and economic benefits, including job creation, patient health benefits and sector skills development as highlighted in Figure 11 below.

**Figure 11**
**Benefits across the broader sector**




Source: MTPConnect's 2022 Sector Competitiveness Plan Report; Medicines Matter 2022 report; L.E.K. research and analysis

These benefits do not just apply to those patients who directly participate in clinical trials: their impacts resonate across the broader healthcare sector, through stronger research and health ecosystems and culture, improved standards of care and a more highly skilled workforce. Patients involved in clinical trials (even in placebo treatments) typically have better health outcomes, as do patients treated in hospitals conducting clinical trials, even if the latter are not involved in a clinical trial.

The wider Australian economy also benefits, through increased workforce participation (from healthier patients), increased personal spending (by patients and sector employees) and increased tax revenues to support further government expenditure in the sector.

All these benefits reinforce each other in turn. They are covered in more detail in Appendix 8, which focuses on the various components of value derived from clinical trials, a topic also addressed in the two previous reports.

This chapter analyses the economic and health benefits of clinical trials derived by Australia in 2022 and highlights how these have evolved as the sector has emerged from the impacts of the COVID-19 pandemic.

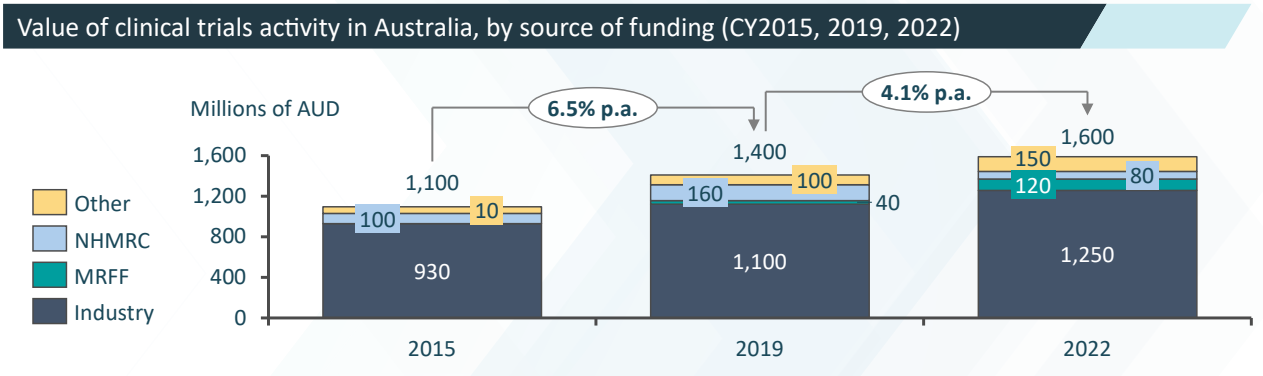
## Economic activity

### *Clinical trials expenditure and funding*

Clinical trials contributed approximately $1.6 billion to the Australian economy through direct expenditure or investment in 2022, up by 13% from $1.4 billion in 2019. This represents a compound annual growth rate (CAGR) of 4.1% per annum between 2019-22. In comparison, the 2021 report showed that total clinical trials expenditure grew by 6.5% per annum between 2015-19.

The slowing growth in expenditure between 2019-22 is largely attributed to the number of trials remaining flat over the period, due to the disruption caused by the COVID-19 pandemic. Overall, the total expenditure of $1.6 billion on clinical trials represents approximately 22% of total spending on health research in Australia in 2022, which is at the same level as in 2019.[13]

**Figure 12**
**Value of clinical trials activity in Australia, by source of funding[14,15,16,17]**




| | 2015 | 2019 | 2022 |
|---|---|---|---|
| Number of industry sponsored trials | 482 | 619 | 646 |
| Number of non-industry sponsored trials | 978 | 1258 | 1204 |

Source: MRFF; AAMRI; NHMRC; PBS; ANZCTR; Clinicaltrials.gov; L.E.K. research and analysis

The expenditure on industry-sponsored trials increased by 4% per annum, from $1.1 billion in 2019 to $1.3 billion in 2022. This growth in economic value can be explained by two key factors:

- Growth in the number of industry-sponsored trials, which grew by 2.4% per annum from 619 trials in 2019 to 646 trials in 2022. This is discussed further in the following section of this report, 'Clinical trials activity in Australia'.

[13] AIHW estimates of total spending on health research in Australia was $6.3 billion in 2019 and $7.3 billion in 2022.
[14] 'Industry' refers to all trial expenditure sponsored by MTP companies.
[15] 'MRFF' refers to all trial expenditure sponsored by the MRFF.
[16] 'NHMRC refers to all trial expenditure sponsored by the National Health and Medical Research Council (NHMRC).
[17] 'Other' refers to all trial expenditure funded by non-government or other government sources, and university, hospital and MRI investment income.

- An increase in underlying operational costs for these trials, driven by the increase in the number of complex trials (including areas such as precision oncology), and rising costs of equipment, drugs and services as a result of inflation.

Approximately 9% of industry-sponsored trial expenditure is related to medical device trials, with the remaining 91% related to drug trials. This mix reflects the relative proportion of total trial starts for medical device and drug trials in Australia in 2022.[18]

Expenditure by non-industry organisations (MRFF, NHMRC and 'Other' in the figure above) such as universities, hospitals and MRIs on clinical trials was estimated at $350 million, an increase of 17% from $300 million from 2019.

The MRFF funded $120 million of clinical trials expenditure in 2022. This included expenditure directly through its 'Clinical Trials Activity' initiative, as well as expenditure through any MRFF 'Missions' that included plans for clinical trials. The approach used by this report to calculate the total MRFF expenditure has been refined from the methodology used in the 2021 report, which only included the 'Clinical Trials Activity' initiative. The revised approach provides a closer estimate of MRFF clinical trials expenditure. The $120 million estimate represents the probable minimum MRFF funding supporting clinical trials, as the MRFF also funds clinical research through other initiatives such as the 'Medical Research Commercialisation' initiative, where clinical trial expenditure cannot be easily apportioned.

The NHMRC funded $80 million of clinical trials expenditure in 2022 in the form of competitive grants. It should be noted that, like MRFF expenditure, this report's approach used to estimate the NHMRC contribution has been refined from that used in the 2021 report, based on insights from industry stakeholders. It now only includes expenditure through the Clinical Trials and Cohort Studies (CTCS) Grants scheme and excludes all other NHMRC grants.[19]

Expenditure by 'Others' (such as universities, hospitals and MRIs) on clinical trials grew from $100 million in 2019 to $150 million in 2022 (up 16% per annum). This income is derived from non-government sources (non-government grants from Trusts and Foundations, commercial income, philanthropy), other government sources (e.g., state governments), and other sources (investment income, one-off income such as the sale of a large asset or one-off schemes). This growth continues an eight-year trend, where non-government sourced income has grown from 50% of total independent MRI revenue in 2014 to 64% in 2020. The largest drivers of the growth in 'Other' expenditure are growing commercial incomes and other incomes, the latter benefitting most from one-off schemes started during the COVID-19 period.[20,21]

For context, non-industry sponsored trials in the United Kingdom account for a larger portion of the economic value generated by clinical research. In 2020, they contributed 33% ($1.7 billion) of the total gross value added (GVA) by clinical research.[22] In contrast, non-industry sponsored trials in Australia

[18] See section 'Clinical trials activity in Australia' for more detail.
[19] L.E.K./MTPConnect interviews with sector participants, 2023.
[20] AAMRI, The AAMRI Report 2022.
[21] 'Commercial income' reported by MRIs refers to income from licencing, royalties and other returns from commercialising their research intellectual property (IP) or collaboration with industry on research projects.
[22] United Kingdom, Department for Science, Innovation & Technology, Independent report: Commercial clinical trials in the UK: the Lord O'Shaughnessy review - final report, May 2023.

during the same period only accounted for 22% ($300 million) of the total value of clinical trials. These findings underscore the necessity for greater government funding of clinical trials in Australia, particularly to support an increase in non-industry sponsored trial activity, in order to align with leading research nations internationally.

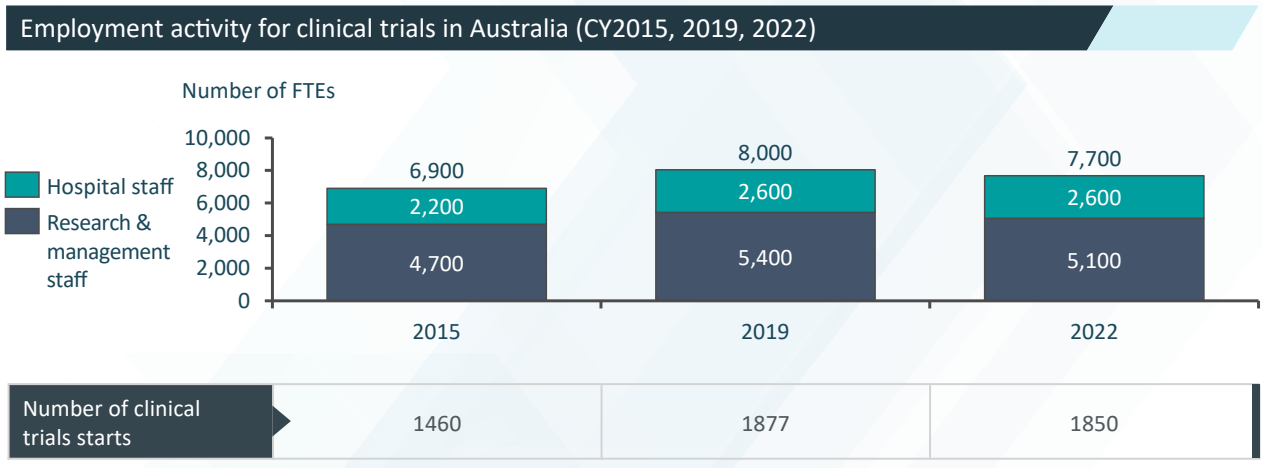
It is worth noting that the overall expenditure on clinical trials includes the cost of investigational drugs and devices provided by sponsors in clinical trials. It does not include 'avoided healthcare costs', which are sometimes covered by trial sponsors. These include the cost of pathology testing, diagnostic imaging, in person clinical examinations and other incidental costs.

### *Clinical trials employment*

As can be seen in Figure 13, approximately 7,700 people were directly employed by the clinical trials sector in 2022, a decrease of 3.8% relative to 2019 levels. Employees are comprised of two main categories:

- Clinical, research and management staff employed at MTP companies and service providers such as CROs, MRIs and academic trial centres.
- Clinical staff employed within hospitals, clinics and other trial sites.

**Figure 13**
**Employment activity for clinical trials in Australia**




Source: ANZCTR; Clinicaltrials.gov; L.E.K. research and analysis

The lack of growth in employment figures is supported by the overall number of clinical trial starts in Australia, which was 1,877 in 2019 and 1,850 in 2022.

Sector participants have also cited a lack of growth in workforce over this period and noted several challenges, including:

- The research workforce, which has become increasingly casualised over this period as clinical trial sites in particular have faced increasing budgetary pressures.[23]

[23] L.E.K./MTPConnect interviews with sector participants, 2023.

- The lack of a clear pathway to recruit and develop new clinical research staff from universities and related professions. Individual companies are developing their own approaches to recruiting new staff (for example, from PhD programs).

The 4% decline in the clinical trials workforce between 2019-22 in the setting of a 1% decline in clinical trials means research organisations are having to run more clinical trials with fewer staff. An over-burdened workforce increases risks of staff burnout, perpetuating even greater loss of staff from the sector, in addition to increased risk of reduced efficiency and quality of work.

Developing a sustainable and skilled clinical trial workforce is a key priority for the sector, in order to ensure continued growth. This has been an ongoing issue across the sector, with this analysis showing that the size of clinical trial workforce has likely declined over the period. More needs to be done by industry and government sources to address this. This is discussed further in Chapter 4 of this report, 'Future Outlook and Priorities for the Sector'.

It should be noted that the total employment figure is likely to be higher because the employment estimate only considers full-time equivalent (FTE) employees who directly contribute to the trial process. It does not consider independent/sole contractors or clinical staff employed within hospitals, clinics and other trial sites, who may have indirect roles in clinical trials (for example, staff employed in pharmacy, pathology and imaging facilities).

## Patient and sector benefits

### *Participant / patient benefits*

Patients are the main beneficiaries of clinical trials, and they derive benefit in a number of ways:

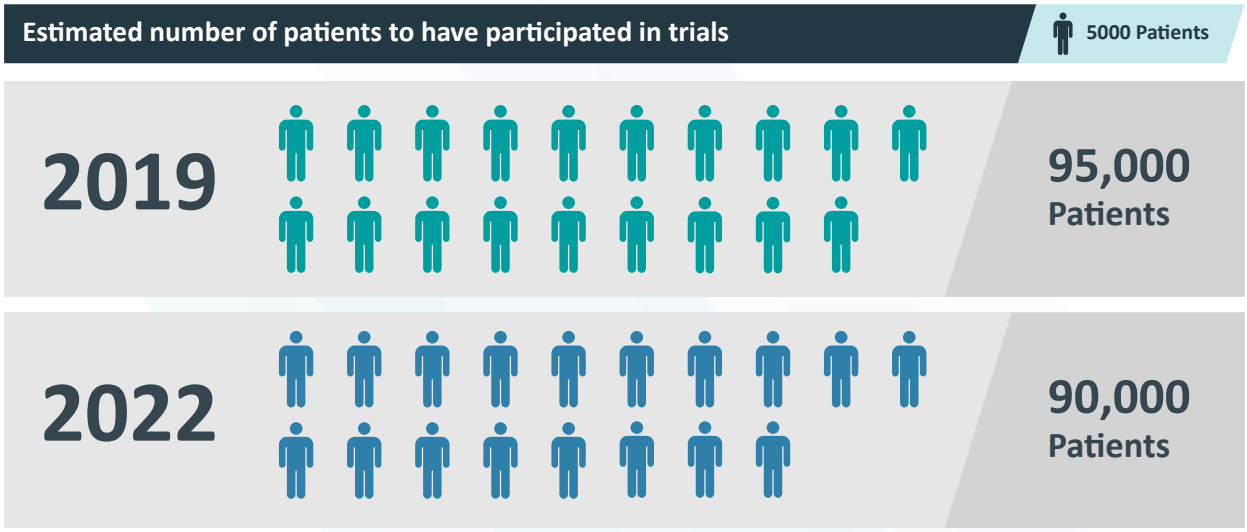
- Through early access to new medical/health interventions, that can result in better clinical outcomes such as higher survival or lower mortality rates.[24]
- Through receiving closer clinical surveillance and better clinician adherence with evidence-based care, which ultimately leads to better health outcomes. This benefit extends not only to patients within trials, but also non-trial patients within trial-active hospitals.[25,26]
- Trial participants can become more interested in their health and become more 'Activated' – empowered with the knowledge, skills and confidence to better manage their health, which often leads have better health outcomes.[27]
- Evidence generated from the clinical trials supports improved clinical practice and the provision of new safe and effective treatments.

Since publicly available data on the number of Australians who participate in clinical trials each year is limited, the 2021 edition of this report developed an estimate using MTPConnect industry survey results and an analysis of patient numbers by trial phase and therapy area. This report has further refined this

[24] Bouzalmate-Hajjaj, Amira et al., Benefits of Participation in Clinical Trials: An Umbrella Review. International Journal of Environmental Research and Public Health, November 2022.
[25] National Institutes of Health (NIH), Clinical Trials, Benefits, Risks and Safety Measures, accessed February 2024.
[26] Krzyzanowska, Kaplan, Sullivan, How may clinical research improve healthcare outcomes?, Annals of Oncology, November 2011.
[27] Greene, J., Hibbard, J.H., Why Does Patient Activation Matter? An Examination of the Relationships Between Patient Activation and Health-Related Outcomes., Journal of General Internal Medicine, November 2011.

methodology to consider patient participation in industry-sponsored and non-industry sponsored trials separately. Details of the methodology can be found in Appendix 7.

**Figure 14**
**Patient participation in clinical trials 2019, 2022**




Source: ANZCTR; Clinicaltrials.gov; L.E.K. research and analysis

Based on this updated methodology, an estimated 90,000 patients participated in clinical trials in Australia in 2022, representing a decline of approximately 5% from 95,000 patients in 2019. This difference is attributed to the following three factors:

- The change of methodology between calculating the 2019 and 2022 patient participation figures for non-industry sponsored trials.
- The overall volume of trials in 2022 has declined slightly compared to 2019, as mentioned earlier in this report.
- A continued shift in the phase mix of trials towards early phase trials (Phases I and II), as compared to later phase trials (Phases III and IV). These details are covered in Chapter 3 and 4 of this report. Early phase trials tend to have smaller patient cohorts compared to later phase trials, so the change in phase mix of trials drives a slight decline in overall patient participation.

Approximately four out of every 1,000 Australians participate in clinical trials per year. While it is difficult to directly compare Australian patient participation with global benchmarks, there appears to be potential for even greater participation rates in Australia. When compared with clinical trial recruitment rates in the United Kingdom, where at least 19 out of every 1,000 British people participated in clinical trials in 2022, there is the potential to increase longer term participation by four to five times more than the current levels in Australia.[28] A likely driver of this difference is the United Kingdom's higher rate of later-phase trials, which typically have greater participation rates than early-phase trials, as discussed above. In 2020, industry-sponsored trials in the United Kingdom had c.3x the number of Phase III trials

[28] NIHR, NIHR Annual Report 2022/23, based on 1,289,937 trial participants in the U.K. between April 2021 and March 2022 across the NIHR CRN portfolio of trials, which represents only a subset of all trials. The U.K. population was approximately 67,500,000 in 2022.

to Phase I trials.[29] By comparison, ANZCTR data shows that industry-sponsored Phase I and III trials in Australia were roughly equal over the same period.

### *Sector benefits*

A strong and globally competitive clinical trials sector generates broader benefits for the healthcare ecosystem, including:

- **Enhancing clinical capability and clinical practice development:** clinical trials provide evidence of efficacy for new treatments and improvements to standards of care that deliver enduring benefits to Australia's healthcare system, and also help identify unnecessary and ineffective interventions. The clinical staff involved in trials gain experience with innovative therapies that will become the future standards of care. This could lead to faster adoption and application of the latest R&D practices in clinical medicine, as well as the implementation of these into broader policy and practice in the sector.
- **Attracting the best global clinical talent**
  - Clinicians and researchers want to work at the cutting edge of their field.
  - This improves the sector in two ways:
    - More skilled/knowledgeable clinicians/researchers help to improve Australia's capabilities and reputation, attracting and enabling more complex and higher value clinical trials.
    - More clinicians/researchers help to resolve the current lack of clinician/researcher capacity, which has been a longstanding issue, and growing more since COVID.
- **Elevating translational research capability:** the funding of trials contributes to infrastructure availability at clinical sites and supports further R&D in healthcare. In parallel, Investigator Initiated Trials (IITs) and high-quality academic research build further capability and capacity, elevate care standards in Australia and contribute to the international reputation of Australian medical experts, investigators and research staff. This further enhances Australia's position as an attractive market for clinical trials and eventually, for the market entry of new and novel products.
- **Supporting manufacturing of medical products:** Australia is growing the medical product manufacturing industry, committing at least $1.5 billion to a Medical Manufacturing Fund, as one of the National Reconstruction Fund's seven priority areas.[30] Clinical trials are an important part of the commercialisation pathway for medical products. They also provide an avenue to test and validate Australia's competitiveness in scaling up manufacturing capabilities in areas of research such as vaccine production, stem cell and gene therapies. Large-scale production can be anchored to the location where clinical trials take place. Providing products to local clinical trials can also be an important source of income for Australian medical manufacturers.

The significance of these broader sector benefits was amplified throughout COVID-19. Australia's clinical trials sector drove translational research and the development of several COVID-19 vaccine candidates, including homegrown and international candidates, rapidly skilled up thousands of healthcare practitioners in vaccine administration, provided trial participants with early access to protection against

[29] Association of the British Pharmaceutical Industry, Clinical research in the UK: an opportunity for growth, 2021.
[30] Department of Industry, Science, and Resources, October 2020.

severe COVID-19, and developed new manufacturing capabilities, such as the Moderna mRNA and CSL facilities in Victoria and the Sanofi Translational Science Hub in Queensland.

The increase in economic activity and the flow-on benefits of conducting clinical trials contribute to the broader economy, multiplying the direct economic impact of these trials. These multiplier effects are difficult to determine accurately and as such, are excluded from the overall estimate of the economic impact of clinical trials in Australia.

# 3. Australia's position in the global clinical trial landscape

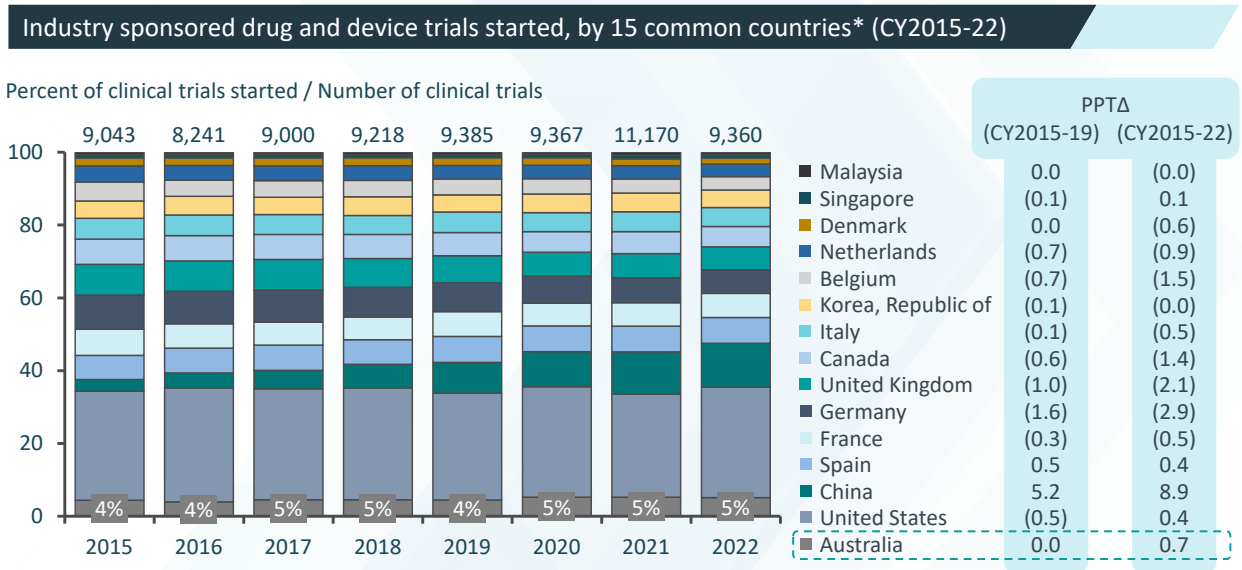
## Australia's global position in clinical trials

Overall, Australia has maintained its share of industry-sponsored trials over the 2015-2022 period, sitting at a 5% market share across the 15 comparison countries studied in the 2021 and 2017 reports. This list has been maintained to allow for direct comparison between reports.

As Figure 15 demonstrates, growth in global trials across these 15 countries has been flat since 2015, with between 9,000 and 10,000 trials commenced per year during 2015-2022.

The research behind this report has also reviewed the material growth in countries outside the comparison set of 15, to identify up-and-coming markets. Poland and Brazil are two countries that have, in recent years, increased their activity in clinical trials. Poland has surpassed Denmark, the Netherlands, and Belgium in its share of global trials, with 2.5% of global trials in 2022. Brazil has demonstrated the greatest increase in share of trials across all countries in the top-20 countries globally, growing from 1.0% in 2019 to 1.4% in 2022.

**Figure 15**
**Industry-sponsored drug and device trials across 15 common countries, 2015 - 2022**




Note: *Includes Drug, Device, and Drug & Device intervention types only. Includes Industry sponsored trials only. 'Withdrawn' trials are excluded. Trial counts are based on planned recruitment within each country – the same trial may be counted in multiple countries
Source: ClinicalTrials.gov (as at 14/01/2024); L.E.K. analysis

On a per capita basis, Australia attracts approximately 19 industry-sponsored trials per one million people, and as such it leads the top 10 countries by industry-sponsored clinical trial share, as illustrated in Figure 16 below. Growth in the number of clinical trials in Australia across 2015 – 2022 sits second only to China, which has had explosive growth over this period, increasing its share of trials by 9%. Importantly, China's growth appears to stem from trials conducted by Chinese companies who are responsible for c.75% of all Chinese industry-sponsored trials.[31]

This serves as further evidence that Australia is a very attractive destination for industry-sponsored

[31] Clinical Trials Arena, The great wall: why overseas sponsors are yet to fully tap into China's clinical trial resources, May 2022.

clinical trials. However, as examined earlier in Chapter 2 under 'Participation/patient benefits', Australia still lags behind other countries such as the United Kingdom on overall (non-industry and industry-sponsored trial) patient participation rates, indicating fewer patients per trial than in other countries.

**Figure 16**
**Industry-sponsored drug and device trials per capita, top 10 countries by share**

Industry-sponsored drug and device trials per capita, top-10 countries by share*

| | Trials per million of population, 2022 | Share of global trials |
|---|---|---|
| **United States** | 8.5 | 20.0% |
| **China** | 0.8 | 8.0% |
| **Spain** | 13.9 | 4.7% |
| **France** | 9.1 | 4.4% |
| **Germany** | 7.3 | 4.3% |
| **United Kingdom** | 8.8 | 4.2% |
| **Canada** | 13.4 | 3.7% |
| **Italy** | 8.4 | 3.5% |
| **Australia** | 18.5 | 3.4% |
| **Korea, Republic of** | 17.1 | 3.1% |

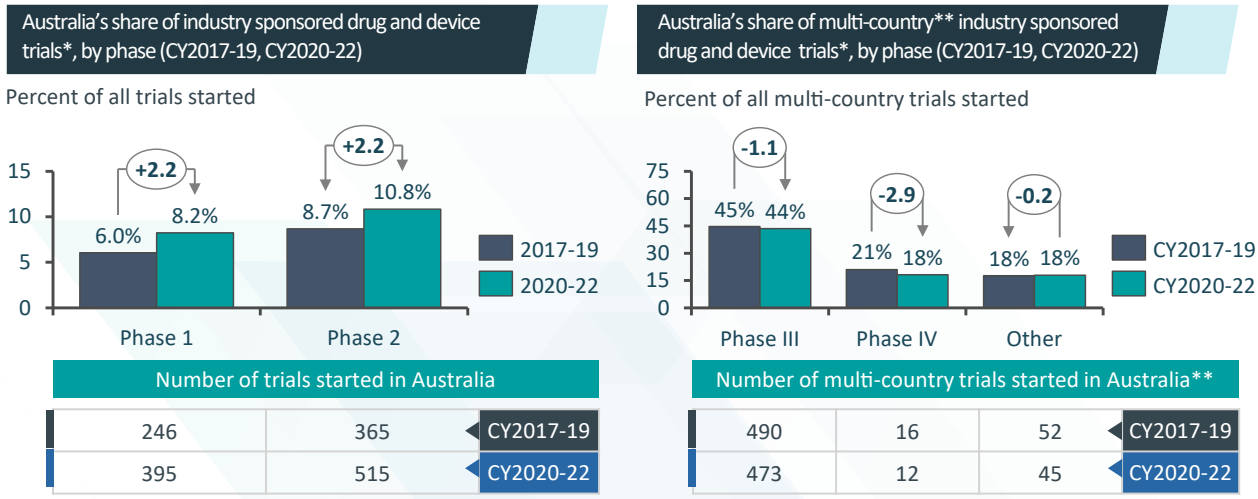
Note: *Data represents only trials registered on ClinicalTrials.gov, which is a subset of all clinical trials and underestimates the number of trials per capita
Source: ClinicalTrials.gov (as at 14/01/2024)

As illustrated by Figure 17 below, Australia has continued its strong performance in global industry-sponsored early phase trials. In the 2020-22 period, its share of global, industry-sponsored Phase I and II trials increased by two percentage points over the previous period (2017-19).

Australia has also held its share of multi-country, industry-sponsored Phase III trials at a steady 44% over 2020-22, similar to the 45% figure observed for 2017-19. However, its share of Phase IV trials has continued the downward trend seen in 2021, with 18% of multi-country, Phase IV trials having an Australian site in 2020-22, as compared to 21% in 2017-19.

## Figure 17

**Australia's share of industry-sponsored drug and device trials, vs its share of multi-country trials**




Note: *Includes Drug, Device, and Drug & Device intervention types only. Includes Industry sponsored trials only. 'Withdrawn' trials are excluded; ** Multi-country trials defined as trials with enrolment in more than three countries
Source: ClinicalTrials.gov (as at 14/01/2024); L.E.K. analysis

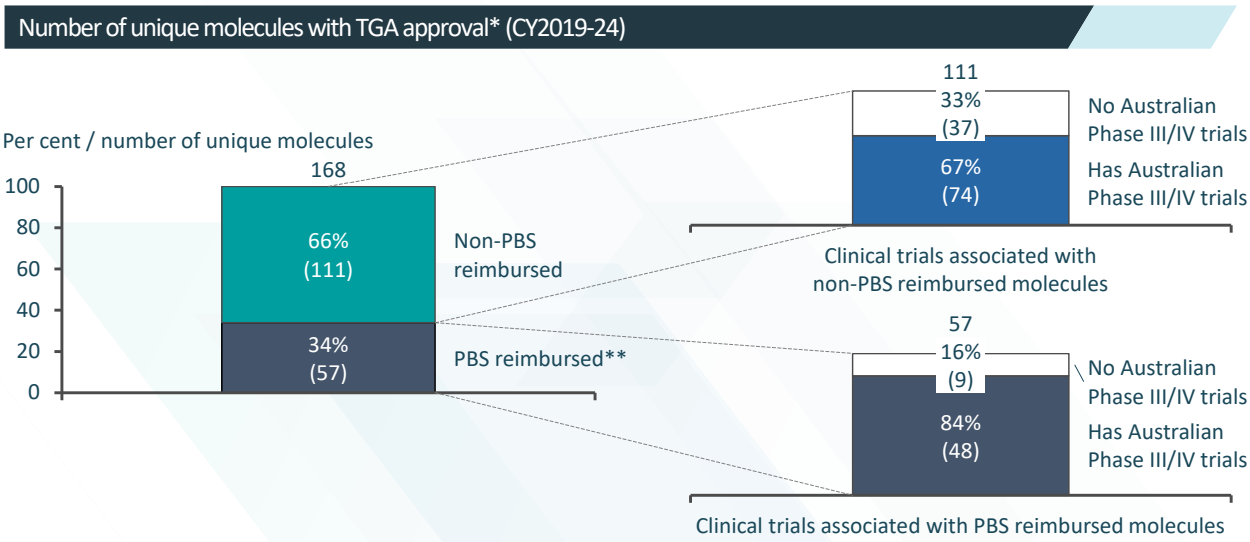
This decline in later-phase trials presents an opportunity for growth if Australia can implement appropriate mechanisms to incentivise industry investment in such trials. Stakeholder consultations have highlighted that multinational pharmaceutical and medical device companies are increasingly considering the ethical and economic implications of running late-stage trials in countries where they do not plan a commercial launch. This could particularly be the case for new modalities with no clear commercial pathways, such as cell and gene therapies and radiopharmaceuticals.

Lowering the barrier to reimbursement for innovative therapies through improvements to the health technology assessment process may be a mechanism to help incentivise sponsors to initiate late-phase trials in Australia. This offers two key benefits; earlier (and ongoing) access to novel and typically expensive therapies for patients who might not otherwise have access to these medicines; and the possibility of attracting additional investment into late-stage trials, research and manufacturing infrastructure and new jobs.[32] The ongoing Health Technology Assessment Policy and Methods Review provides an opportunity to ensure the reimbursement approval processes address this need.

Figure 18 below shows supportive evidence that lower barriers to reimbursement incentivises companies to initiate late-phase trials in Australia. Analysis of unique, non-biosimilar molecules approved by the Therapeutic Good Administration (TGA) since 2019 shows that 84% of the molecules that successfully received Pharmaceutical Benefits Scheme (PBS) reimbursement approval had associated Phase III or IV trials in Australia. Conversely, only 64% of molecules that were not PBS reimbursed had associated Phase III or IV trials in Australia. This suggests either that therapies with a higher likelihood of PBS reimbursement are more likely to be trialled in Australia, or that evidence obtained in the Australian context is viewed more favourably by health technology assessment (HTA) review bodies. The causal relationship between these two outcomes is not clear, but the analysis suggests a link.

[32] L.E.K./MTPConnect interviews with sector participants, 2023.

**Figure 18**
**Number of unique TGA-approved molecules**




Note: *The 168 molecules described in the chart exclude biosimilars; **There is a time-lag between TGA approval and PBS reimbursement, with 57% of TGA approved drugs in 2019 approved for reimbursement, compared to 11% in 2023, and 0% in 2024
Source: Trialtrove; PBS; TGA; National Immunisation Program; L.E.K. research and analysis

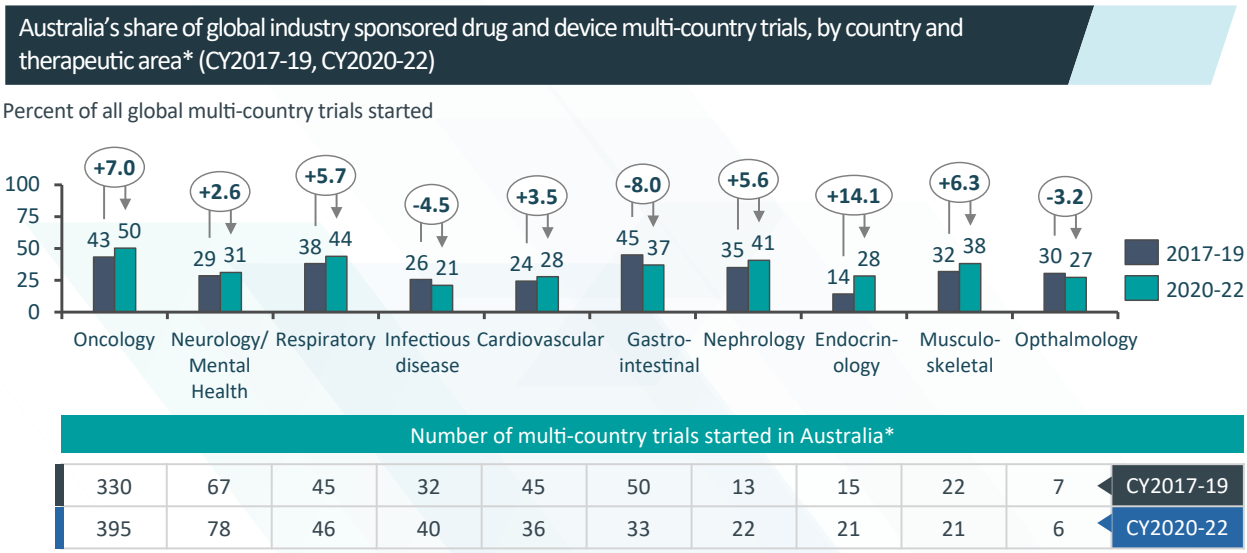
## Australia's competitiveness by therapeutic area

Australia has also maintained its competitiveness in the large oncology trials sector, with its share of global, multi-country oncology trials growing by 7% in 2020-22, as compared to 2017-19. Oncology trials represent the large majority of trial activity with 32% of all industry-sponsored trial starts globally over the period of 2020-22.[33] Other key therapeutic areas where Australia has gained share over the last three-year period are respiratory (likely related to COVID-19), cardiovascular and nephrology.

[33] Trialtrove, calculated as the proportion of all industry trials within the oncology therapeutic area between the period of Jan 2020 – Dec 2022.

**Figure 19**

**Australia's share of global industry-sponsored drug and device multi-country trials, by country and therapeutic area**




| Number of multi-country trials started in Australia* | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 330 | 67 | 45 | 32 | 45 | 50 | 13 | 15 | 22 | 7 | CY2017-19 |
| 395 | 78 | 46 | 40 | 36 | 33 | 22 | 21 | 21 | 6 | CY2020-22 |

Note: *Includes Drug, Device, and Drug & Device intervention types only. Includes Industry and Industry & Other sponsored trials only. 'Withdrawn' trials are excluded. Multi-country trials are defined as having planned recruitment in more than three countries. Therapeutic areas were determined using a search of key words within the 'conditions' field in the clinical trial database – excludes trials where multiple therapeutic areas were found
Source: ClinicalTrials.gov (as at 14/01/2024); L.E.K. analysis

## Sources of competitive advantage

As Figure 19 shows, Australia has managed to maintain its overall share of global trials and it continues to strengthen its global share of early phase trials and oncology trials. These successes indicate that Australia's traditional competitive advantages in hosting clinical trials still help Australia to differentiate itself in this market. Its key sources of competitive advantage are:

- A strong reputation for the quality and global standing of its investigators and the networks that support them.
- Robust research infrastructure and systems that enabled Australia to continue conducting clinical trials through disruptive global events such as the COVID-19 pandemic.
- High-quality data collection systems and overall compliance with Good Clinical Practice (GCP) guidelines, which ensures that data collected in Australian trials can support submissions to international regulators, including the United States' Federal Drug Administration (FDA) and the European Union's European Medicine Agency (EMA).
- Specialised and dedicated early-phase infrastructure that enables the delivery of timely, high-quality trials, supported by streamlined processes and private ethics committees.
- The convenience and speed of the Therapeutic Good Administration's Clinical Trial Notification (CTN) scheme, which enables the faster start-up times that are particularly crucial for early phase trials.
- The tax relief provided by the Australian government's extension of its R&D tax incentives, improving Australia's cost competitiveness.

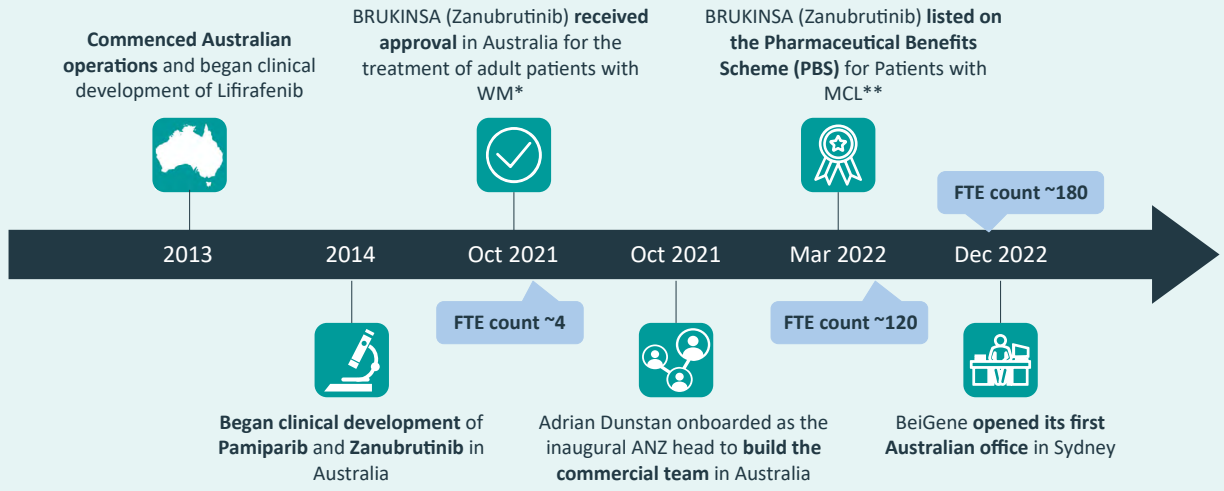
The combination of these factors has not only continued to position Australia as an attractive clinical trials destination globally but has also served to grow the economic footprint of the sector. The case of BeiGene's rapid growth of its Australian operations (see below) is illustrative in this respect.

## Case study – BeiGene

BeiGene is a global biotechnology company specialising in the development of cancer treatment drugs. Founded in 2010 in Beijing, it has grown significantly throughout the world, with a particularly strong presence in both Beijing and the US. Between 2018 and 2023, it has rapidly grown outside of these two locations, with a 34% year on year growth rate across these five years.

Since starting its first Australian clinical trial in 2013 for Lifirafenib, BeiGene has enrolled 2,200+ patients in 40+ trials in Australia. BeiGene's growth in Australia has also augmented the broader economy, adding over 180 jobs across six states in Australia, with approximately 75% of these employees working in clinical operations. Furthermore, BeiGene's product testing is deeply integrated into the healthcare system, with its treatments tested at over 300 sites and over 90 hospitals and clinics across Australia.

**Figure 20**
**BeiGene timeline in Australia**




Notes: *Waldenström's macroglobulinemia; **Mantle Cell Lymphoma
Source: Company website; L.E.K. research and analysis

BeiGene's leadership attributes its increasing investment in Australia to the country's strong clinical research ecosystem. In particular:

**1. A strong clinical trials network**

Australia hosts over 50 clinical trial networks providing Phase I to IV clinical trials. The industry's 7,700 strong workforce includes individuals with expertise spanning all aspects of life sciences.

> *"… BeiGene's leadership identified Australia as a country with strong commitment to clinical trials and the capabilities to successfully conduct complex and critical first-in-human studies …"*
>
> Dr Arthur Alston, BeiGene Head of Medical Affairs, APAC

**2. An efficient and globally recognised regulatory system**

Australia has a globally recognised regulatory system (accepted by the United States Food and Drug Administration, and similar bodies within Europe, the Middle East and Africa, among others) that leverages systems such as the Clinical Trials Notification (CTN) scheme to promote quicker regulatory approval.

> *"… On average in Australia, the first patient into a clinical trial [after approvals] is about three months, whereas in the US or the EU, it's six to nine months — it's efficient …"*
>
> Adam Roach, BeiGene Head of APAC

**3. Attractive R&D grants and incentives**

Australia offers many grants and incentives to promote medical research and development. The NHMRC provides over $100 million in funding annually through various programs.

Tax benefits are available under the R&D Tax Incentive scheme which BeiGene has been able to leverage to increase its investment in clinical trials.[34] Other funds include the Medical Research Future Fund ($750 million over 2022-32), the mRNA Clinical Trials Enabling Infrastructure Grant Opportunity and the Biomedical Translation Fund ($500 million).

[34] Cancer Trials Australia, BeiGene works with Cancer Trials Australia for its Australian clinical trials, August 2019.

# 4. Future outlook and priorities for the sector

This final chapter identifies the themes and trends that will shape the future dynamics of clinical trials and determine the scope and nature of the opportunities for the Australian clinical trial sector. It outlines current impediments and areas for further development and highlights the key priorities for the future that will enable Australia's clinical trials sector to continue to grow. Overall, these issues are consistent with and build on the opportunities and priorities identified in MTPConnect's previous two reports. This reflects the growing need to address these challenges, in order to prevent the sector from stagnation or worse, decline. This chapter highlights some (but not all) of the last three years' developments – most notably, the National One Stop Shop (NOSS) reform and its potential for broad-based positive impacts on the sector.

## Emerging opportunities in clinical trials

Our 2021 report identified four emerging healthcare trends that could create new opportunities for Australia's clinical trials stakeholders. These are still relevant today and our 2024 report has identified an additional fifth priority around medical device trials. The five priorities are:

**1. Patient awareness, engagement and centricity:** Patient advocacy groups have played a significant role in increasing patient awareness and engagement in clinical trials, an important factor behind the successful growth of clinical trials. These groups are striving to heighten patient awareness, yet they continue to face challenges due to disparities in funding among advocacy organisations and suffer from the innate challenges of conveying information that requires technical proficiency to comprehend effectively.

Consumer engagement and involvement is increasing, especially within academic trials. However, Australia still has significant headroom to grow patient participation in clinical trials. This can only be achieved by educating patients about clinical trials, the value they provide, and designing trials in such a way that engages patients and reduces barriers to participation.[35]

There is a need to further understand the experience of trial participants in the Australian context, to identify strategies for enhancing enrolment and retention in clinical trials, for example, cultural and language barriers, health and research literacy, and time and financial impacts. In particular, there is very limited engagement of Aboriginal and Torres Strait Islander and CALD communities in clinical trials, and no tracking of their participation in clinical trials. The awareness of the importance of engaging diverse populations is growing, highlighted by recommendations from the United States FDA which sets out guidance for sponsors to increase enrolment of underrepresented populations in clinical trials.[36]

There is also a growing understanding of how important patient centricity is to trial design. This includes trials that prioritise the needs of the patient from design to delivery, with the number of PubMed publications mentioning patient centricity in the context of clinical trials increasing by 78% between 2019 to 2022. Government support for patient centricity is also growing, with the Co-design of an Enhanced Consumer Engagement Process for HTA consultation that was delivered by the Australian Government Department of Health and Aged Care (DoHAC) in April 2024 proposing recommendations to enhance consumer engagement in relation to HTA processes undertaken by the TGA, Pharmaceutical

[35] L.E.K./MTPConnect interviews with sector participants, 2023.
[36] United States FDA, Enhancing the Diversity of Clinical Trial Populations – Eligibility Criteria, Enrolment Practices, and Trial Designs Guidance for Industry, November 2020.

Benefits Advisory Committee (PBAC), and other HTA committees, and onwards to subsidised listing and post-market reviews.[37]

The emergence of decentralised clinical trials (DCT) is one of several solutions helping the shift towards patient centricity, by improving access for patients, especially those in rural and regional areas, and allowing trial designers to improve their understanding of patient perspectives from a broader demographic. As for patient centricity in trials, there has been a significant (300%) increase in clinical trials mentioning decentralisation between 2019 to 2022; however, the sample size for this remains small, with only 10 trials on Trialtrove reporting decentralisation in 2019, and wide variation in what decentralisation means.[38]

**Opportunity**

There is a further need for flexible trial designs that involve and engage the diversity of patients, carers and communities (including Aboriginal and Torres Strait Islander peoples and other culturally and linguistically diverse communities).

Improving access will allow Australia to better leverage its highly diverse population.[39] Not only will this ensure that clinical trial study populations will more accurately reflect the patients likely to receive the therapy after approval, but will increase the attractiveness of Australia to trial sponsors seeking to meet diversity requirements.[40]

At the same time, there is more scope for advocacy group activity and other measures (including Government support of these groups) to continue raising patient awareness and engagement in trials. Allowing feedback from these broad and diverse patient groups to be integrated into trial design and management. Increasing patient awareness, engagement and understanding in clinical trials is also a key part of the NOSS mandate, and this could represent a key avenue for driving education and awareness campaigns to improve patient participation. Efforts to increase awareness will need to be matched with efforts to improve access, including improving the ability for patients to identify relevant trials, and working to support sites and sponsors in improving the dissemination of information on clinical trials. These measures will help Australia's clinical trials sector achieve a broader patient reach and better clinical outcomes for all Australians and increase patient access, recruitment and retention in under-represented populations. Improving access to these populations will allow Australia to better leverage our population diversity and further increase Australia's attractiveness in clinical trials, as awareness of the need for diversity in clinical trials participation globally continues to grow.[41][42] This will also help the Australian clinical trial sector attract more local and international clinical trials sponsors.

[37] Australian Government Department of Health and Aged Care: Co-design of an Enhanced Consumer Engagement Process for health technology assessment, 2024
[38] Symons, T, A mapping exercise to identify initiatives to support the implementation of decentralised clinical trials including teletrials in Australia, CT:IQ, December 2023
[39] Australian Human Rights Commission, Face the facts: Cultural Diversity, accessed February 2024.
[40] L.E.K./MTPConnect interviews with sector participants, 2023.
[41] L.E.K./MTPConnect interviews with sector participants, 2023.
[42] Schwartz et al., Why Diverse Clinical Trial Participation Matters, The New England Journal of Medicine, April 2023.

**2. Digital health solutions:** The adoption of telehealth and other digital health solutions across the healthcare sector grew considerably during COVID-19. In clinical trial settings, digital health solutions have supported patient recruitment with online portals, e-consent, AI matching and patient engagement, and remote monitoring solutions. These solutions have been adopted and applied more recently and more often to healthy volunteer trials (for example, vaccine trials), which have less clinical complexity compared to patient-focused trials (for example, oncology trials). The creation and expansion of centralised, national patient registries is a digital health solution that has been highlighted by industry stakeholders as a useful tool for accelerating the trial patient recruitment process, especially for patients with rare and chronic diseases.

Since the last iteration of this report, there has been some notable growth and development in this space. One example is the introduction of the $75 million Australian Teletrial Program, supported by government investment under the MRFF from 2021 onwards. The program aims to improve access to and participation in clinical trials for rural, regional, and remote Australians by using telehealth to connect clinical trial site clusters in these areas.[43]

**Opportunity**

Significant potential exists for Australia's clinical trials sector to increase and harmonise the adoption of digital health and AI in relevant clinical trials. Policies such as those relating to remote access to electronic medical records and patient data (in line with the Government's new digital health strategy) can be made simpler. There also needs to be appropriate digital literacy training provided to various parts of the community, to further minimise barriers to access.

Remote monitoring and e-consent can reduce the need for travel that might otherwise make participation for those in rural and remote areas impossible. Increasing access increases the patient pool and reduces the financial and time burden on the patient. This will improve equitable access to clinical trials, as well as support improved patient recruitment and improved efficiencies in trial conduct.

**3. Precision healthcare:** Precision medicine trials are expanding in number and scope, with over 63% of oncology trials in 2022 utilising biomarkers, up from 56% in 2015.[44] The growth in these trials is further supported by innovative services such as PrOSPeCT, which has secured $185m of funding from government and industry for Comprehensive Genomic Profiling (CGP)-driven trials matching.

## PrOSPeCT

PrOSPeCT (Precision Oncology Screening Platform Enabling Clinical Trials) is Australia's largest cancer genomics initiative. It brings precision oncology trials to the Australian community by linking genomic technology to trials of new therapeutic products. Led by Omico and officially launched in July 2023[45], PrOSPeCT seeks to screen 20,000 late-stage cancer patients and place an additional 3,000 patients onto clinical trials within the next two years.

[43] Australian Teletrial Program website, accessed February 2024.
[44] Trialtrove, accessed February 2024.
[45] Omico website, accessed February 2024.

The $185 million program investment comprises $61.2 million from the Australian Government's Medical Products stream of the National Manufacturing Priority, $25 million from the NSW government, up to $20 million from Roche Australia, and a commercial collaboration between Omico, the National Computational Infrastructure at Australian National University, and the Children' Cancer Institute.

PrOSPeCT's key aims over the next two years are to:

- Undertake comprehensive genomic profiling of 20,000 cancer patients or people with unmet clinical needs.
- Empower $525 million in new direct investment in locally based clinical trials.
- Deliver 650+ new jobs for research scientists involved in genomics, clinical trials and diagnostics

The Government's commitment to precision healthcare in PrOSPeCT is mirrored in other organisations such as Zero Childhood Cancer project, which drew $67 million of joint funding from the MRFF and the Minderoo Foundation.[46] The program provides in-depth genomic analysis to support cancer treatment for all Australian children. This creates opportunities to drive growth in the adjacent research area of paediatric trials, where stakeholders have been calling out for greater investment and there is evidence of sector evolution internationally, with the United States FDA now requiring companies to have a strategy for developing drugs for paediatric populations.[47] The paediatric trial opportunity in Australia is small, but the benefit to patients and families, and the healthcare system could be large.[48]

**Opportunity**

The Australian clinical trials sector can further develop the infrastructure, capabilities and skills required to support precision medicine trials. One approach involves expanding the reach of CGP services offered to patients, through innovative programs like PrOSPeCT and by establishing digital technologies to streamline how patients are matched onto trials. Improvements like these will continue to position Australia as an attractive destination for cancer trials and the next generation of biomarker enabled trials for conditions involving neurological disorders, rare diseases and the like.

**4. Innovative trial designs:** There has been an increase in the number of platform/umbrella/basket trials designs using adaptive methods since 2020, as companies and academic sponsors look to develop new treatment combinations and pathways.[49] These trial designs offer enhanced efficiency with the capacity to answer questions faster and at lower cost. Innovative trials are further encouraged through government funding such as the $23.7 million grant provided by the 2023 Innovative Trials and delivered through the MRFF.

[46] Zero Childhood Cancer website, accessed February 2024.
[47] United States FDA, Paediatric Research Equity Act.
[48] Lorentzos, M.S. et al., Providing Australian children and adolescents with equitable access to new and emerging therapies through clinical trials: a call to action, The Medical Journal of Australia, January 2024.
[49] When comparing search results of terms 'basket study', 'umbrella study' and 'adaptive clinical trial' on clinicaltrials.gov (filtered for Australian results), 2.3 times as many trials appeared in the 2020-22 period compared to 2017-19 period.

**Opportunity**

Adopting innovative trial designs will help the Australia clinical trials sector remain at the forefront of medical research in these complex and rapidly changing disease areas. To continue to be a country of choice for innovative trials, Australia needs to develop its ethics and governance capabilities to holistically encompass platform/umbrella/basket, N-of-1 and adaptive trials.

**5. Medical device trials:** Global regulatory changes like medical device regulation (MDR) and in vitro diagnostic regulation (IVDR) in the European Union,[50] and the FDA's proposed changes to in vitro diagnostic products (IVDs) in the United States, increases the burden of proof and timelines for medical device trials.[51]

The importance of clinical evidence of efficacy to drive medical device adoption by clinicians and patients is also growing, with the FDA releasing guidance for using real-world evidence (RWE) in medical device regulatory decision making in December 2023, and the TGA revising the clinical evidence guidelines for medical devices to improve the usage of RWE in medical device applications in February 2023.

These changes present an opportunity for Australia to grow its share of device trials, which have been flat at approximately 10% of total trials over the last five years.

**Opportunity**

Australia can leverage its sources of competitive advantage to grow the number of medical device trials conducted. This will require enhanced communication and promotion of Australia's attractiveness as a clinical trials destination to medical device companies, to promote the same competitive advantages as those underpinning the far greater numbers of clinical trials held to test new and emerging drug therapies.

Australia also houses numerous centres of excellence in medical device R&D, such as SAHMRI and Monash University, which house multiple national medical device registries. These registries can be leveraged to improve ease of medical device patient recruitment, especially in later-phase, post-market studies.

[50] European Commission, The European Union Medical Device Regulation, May 2021.
[51] United States FDA, Proposed rule regarding laboratory developed tests, September 2023.

## Case study – Transcatheter Aortic Valve Implantation (TAVI), Medtronic

Medtronic has been conducting first in human clinical trials in Australia for over a decade. Medtronic considers Australia an important destination for sites for global studies due to the quality ethics review process, short timeframes to commence studies, and the high-quality health workforce supporting trial activity.

Both Medtronic and Edwards Lifesciences have conducted clinical studies in Australia for Transcatheter Aortic Valve Implantation (TAVI).

Heart valve disease (HVD) affects more than half a million Australians, yet an estimated 250,000 Australians are unaware that they are living with the condition. If left untreated, HVD can damage the heart's valves, leading to heart failure, stroke, and arrhythmia (an irregular heartbeat), or death.

Aortic Stenosis (AS) is the most prevalent type of acquired heart valve disease in Australia. Aortic stenosis occurs when the heart's aortic valve does not open properly, reducing the flow of blood as it exits the heart and is pumped to the rest of the body. Left untreated, aortic stenosis can result in heart failure and possibly death.

Transcatheter Aortic Valve Implantation (TAVI) is a minimally invasive procedure to replace the aortic valve via a catheter inserted into the leg or chest. The alternative to TAVI is open-heart surgery to remove the damaged valve and replace it with an artificial valve.

Today, over 700 Australian patients are able to benefit from TAVI thanks to some of Medtronic's first in human TAVI clinical studies for those with severe AS at high, intermediate and low risk of surgery. This enabled them to avoid an open-heart surgery and received the minimally invasive TAVI valve replacement, whilst supporting evidence generation to enable broader access to the therapy in Australia.

Australia had a number of leading clinicians and sites involved in TAVI first in human trials. From these first in human studies, Australian clinicians have become global proctors for this therapy, advisors to boards and committees to support product design and therapy development in clinical settings and leading experts and speakers and fellows sought after around the globe.

## Key priorities for the sector's future

This report has reviewed the progress and achievements of the clinical trials sector in Australia over the past three years. As we have noted in the clinical trials activity metrics, this is a critical time for the sector as the global clinical trials landscape returns to post-pandemic trends.

Australia has proven an attractive clinical trials destination, particularly for early phase trials, evidenced by its continued capture of share of the global market. As one of the only fully functioning countries for trials during the pandemic, it has demonstrated the well-known strength and capability of its healthcare and research systems. For global medical device and pharma companies holding clinical trials, Australia can be an attractive option: trials can commence quickly, patients can be easily recruited, and key opinion leaders, whose expertise is vital for enhancing the quality of clinical trials, are readily accessible.

However, the global clinical trials sector is becoming increasingly competitive, and Australia must continue to take action to maintain and enhance sources of competitive advantage in the global market.

There are four key priorities for promoting future growth in clinical trials activity in Australia, consistent with the priorities identified in the 2021 report. These priorities each relate to an existing problem/ weakness in the Australian clinical trials landscape.

### 1. Continue to improve the efficiency in clinical trial start-up processes, such as ethics and governance approvals

Sector participants continue to praise Australia's advantages in efficiency created by the Clinical Trials Notification (CTN) scheme, which offers quicker trial start-up timelines than other countries, particularly for early-phase (Phase I and II) trials, and the National Clinical Trials Governance Framework, introduced in 2023, which is being implemented progressively and helping to improve consistency in clinical trials delivery.[52,53] However, ethics and governance approval processes across Australia remain highly individualised and vary between institutions and states. This complicates these processes and increases trial start-up times, which may deter trial sponsors from conducting trials in Australia. The impact is felt most often in later-phase trials (Phase III and IV), which tend to involve larger patient cohorts and multiple trial sites. Australia's weakness in Phase III and IV trials, as demonstrated by the ongoing loss of global share of later-phase trials described in Chapter 3, represents an opportunity for growth.

The solution involves two separate elements:

- The CTN scheme, which has been a significant source of competitive advantage for Australia, particularly in early phase trials, should be maintained for both device and drug trials.
- Cross-jurisdictional ethics and governance processes should continue to be streamlined. Australia has already harmonised drug and device registrations with other jurisdictions and should therefore be able to harmonise ethics and governance processes across Human Research Ethics Committees (HRECs) for large Phase 3 clinical trials in particular. Australia's relatively smaller population with large geographical dispersion means that a unified national approach to attracting clinical trials is critical. The National One Stop Shop (NOSS), announced by the Federal Government in 2023 (and outlined in the case study below), is aimed at addressing this issue and more broadly, improving the efficiency and interconnectedness of clinical trial start-up process in Australia.

#### Case study – the National One Stop Shop (NOSS)

The National One Stop Shop aims to improve the efficiency and interconnectedness of the clinical trials start-up process in Australia through:

- Providing streamlined, cross-jurisdictional ethics and governance approvals that incorporates key application, notification, and approval systems.
- Aligning with the CTN and CTA schemes administered by the TGA.
- Creating an embedded and automated next-generation national clinical trials and research registry.

[52] L.E.K./MTPConnect interviews with sector participants, 2023.
[53] Australian Commission On Safety And Quality In Health Care, The National Clinical Trials Governance Framework, 2022

- Providing research management capability and sophisticated monitoring and reporting functionality for different users, including calculated data to support the accreditation of trial services.
- Creating a public website for Australians in the community to search for and access a clinical trial and enable sponsors to access accredited trial sites.

These reforms have been developed through extensive stakeholder consultations involving more than 1,400 people throughout 2021-22. If implemented appropriately, the NOSS will build on the existing advantages to trial start-up times that Australia offers. These include the lack of a requirement for an active Investigational Drug (IND) or Identification of Medicinal Products (IDMP) in place, prior to initiating trials; and the speed of the TGA CTN scheme, which is a particular advantage for Phase I trials.

The implementation of these reforms will be led by Emeritus Professor Ian Chubb, AC, FAA, FTSE, who will Chair the Inter-Governmental Policy Reform Group announced by The Hon Mark Butler MP, Minister for Health and Aged Care, at the Medtech23 conference organised by the Medical Technology Association of Australia (MTAA) in November 2023.

The Inter-Governmental Policy Reform Group (IGPRG) will also have a key role in implementing and regulating the National Clinical Trials Governance Framework, which will ensure a nationally consistent approach to clinical trials at a site level.

### 2. Enhance patient awareness and the ability to efficiently recruit patients at each clinical trial site, to improve site economics for these trials

Patient recruitment is one of the greatest challenges in successfully operating and delivering clinical trials. Inefficient patient recruitment can result in longer trial durations and increasing trial costs. This issue is particularly relevant for sites in smaller Australian cities or regional areas, which are harder to recruit for and which become less attractive locations for the sponsors who conduct these trials. What results is a reduced access to clinical trials and healthcare for patients in these regions.

There are five elements that contribute to a solution:

- Increase promotion and awareness campaigns to improve community awareness and diversity of clinical trials, especially in CALD and Aboriginal and Torres Strait Islander people, as well as improving infrastructure to support non-English speaking participants, and culturally/diversity sensitive trial practices.
- Increase patient centricity, through greater consumer involvement in clinical trial design and conduct, and the appropriate use of technology and decentralisation to improve trial design/access and improve patient recruitment per site. Patients may be recruited through primary care or directly through social media campaigns or teletrials.
- Embed clinical trials into the routine practices of hospitals through the National Clinical Trials Governance Framework.
- Fund clinical trials networks to continue to boost clinician awareness.

- Build national, centralised patient registries and matching services to streamline patient recruitment through improving access to diverse participant pools.

### 3. Grow the size and capabilities of the clinical trials workforce

Stakeholders have continued to highlight the ongoing shortages of experienced CRAs and CTCs, which were also mentioned in the previous editions of this report and in the October 2021 MTPConnect REDI Initiative Skills Gap Analysis report. Some companies have begun hiring junior clinical research staff members from various science and nursing graduate courses to address their internal shortages.

There are two key issues exacerbating this shortage. The first is the lack of employment protection for research staff. Research staff, especially CTCs, are typically contracted through project-based contracts. Other healthcare career pathways tend to have longer-term contract or full-time employment, which makes the CTC pathway less attractive in comparison. The second is that there is no clear, direct career path for employees that come straight from university courses, especially for those who complete undergraduate degrees (most CRAs and CTCs come from PhD pathways).[54]

There are several possible solutions to this problem:

- More must be done to improve the visibility and awareness of clinical trials as a viable career pathway for high school and university students, as well as for nurses across the healthcare sector.
- Additionally, there needs to be more development of subsidised internships/work placements for science and nursing graduates, to provide them with entry-level experience with clinical trials.
- Finally, the sector needs to expand existing mentorship programs and apprenticeship models to grow the cohort of experienced and expert staff outside of the major clinical research centres.

There are already existing, successful programs providing mentorship and apprenticeship opportunities, and entry-level work placements for would-be clinical trial staff. These include the various programs conducted by MTPConnect's REDI program, PRAXIS Australia's PROgress Program, The Victorian Comprehensive Cancer Centre (VCCC) Alliance's Clinical Trials Mentoring Program, and the ARCS Mentoring Program. However, even greater investment is needed to match the scale of this problem, evidenced by persisting clinical trials workforce shortages.

### Case Study – Tackling clinical trials workforce issues, the MTPConnect REDI Initiative

MTPConnect's REDI Initiative, a $32 million program funded by the MRFF, is designed to align workforce skills with the current and future needs of the MTP sector. The REDI Initiative began by assessing skills gaps and providing support for interventions to address them. One of the seven themes identified by the initiative was 'Clinical Trials,' which highlighted seven specific skills gaps.

One of these gaps was the need to design strategic clinical trials to address regulatory and funding needs. This gap significantly hampered the SME sector's ability to work with CROs and clinical trial sites. Poor trial design led to a slowdown in data generation and registrations, costing millions of dollars. REDI supported the development and delivery of two courses—one for therapeutics and one for medical devices—to assist SMEs in enhancing their clinical trial designs.

[54] L.E.K./MTPConnect interviews with sector participants, 2023.

REDI also spotlighted a shortage of CTCs, who oversee the day-to-day running of clinical trials at sites, where they predominantly liaise with and monitor patients. There were three main factors behind this shortage. Firstly, staff training and development happened in-house, with no specific graduate program; secondly, staff job security was an issue where sites had a contractual approach to clinical trials and staffing them; and the third factor was the movement of CTCs into other industry roles.

REDI's approach has been to support a competency-based internship program, where science and nursing graduates are placed within clinical trial units and formal training delivered centrally to them over a six month – one year timeframe. Overall, 83 new CTCs (including study coordinators) have entered this workforce after training delivered by the VCCC Alliance and PRAXIS. Data from the 2020-22 cohorts shows that over 90% of these have been retained within the clinical trials sector. Another beneficial outcome has been the extension of longer employment contracts to graduates and their colleagues by the sites, thereby aiding in alleviating the shortage further.

REDI has also identified a shortage of CRAs who serve as liaisons between study sponsors and clinical trial sites; however, experienced CRAs are highly employable, making retention an issue for their employer and for the clinical trials environment generally. Developing new staff is both costly and time consuming and is a key reason why small to medium sized CROs only hire a few new CRAs per year.

There was no consistent feedback on how REDI could best address this problem, so REDI took a 'bottom up' approach, by encouraging the hire of new CRAs into the ecosystem and supporting companies to develop these employees. A "traineeship" approach was taken, where CROs hired staff and ARCS Australia was contracted to train them. 75 fresh CRAs have now been through this program, with very high retention of the first cohort of 35. This additional training has seen companies increase their hiring of CRAs, and more CRAs enter the workforce overall.

REDI has made huge progress in closing skills gaps in clinical trials. It has helped innovators work better with CROs to better design trials, and therefore decrease the time and cost of advancing their therapeutics, devices and diagnostics. By bringing on new workers to undertake clinical trials, REDI has supported revolutionary programs that have changed clinical trials in Australia. It has moved employers from relying on competent workers to be ready for work straight from university, to instead be more engaged in developing a competent workforce. It has impacted the way CROs hire fresh CRAs, and also the way sites (hospitals especially) hire and retain their clinical trial staff. Much has been achieved, but it must also be noted that these programs require ongoing support from industry and government to close the skills gap highlighted by the REDI Skills Gap report.

### 4. Enhance the sector's overall transparency

The ANZCTR is Australia's national registry for tracking clinical trial activity. However, it currently only accounts for around 60% of all trials commenced in Australia. Its scope of data collection could be further expanded across the metrics it collects and the protocols it sets for data input. The current system relies on self-reporting, which often means more granular details (such as information on phases for medical device clinical trials) are not always captured. This gap is also seen in international databases such as ClinicalTrials.gov, where phase data for medical device trials is also not collected. The lack of data on device trials by phase hinders the sector's ability to better monitor and grow the number of device trials in Australia.[55] Increasing the granularity of information would provide richer insights into Australia's competitive position for trials by type, growth rates of certain types of trials and help inform workforce planning, policy development and sponsor investment in trials.

[55] L.E.K./MTPConnect interviews with sector participants, 2023.

Australia has a chance to a play a global leadership role in addressing this information gap. Specifically, three areas for improvement include:

- Review and improve the data collection and processing of the start-up timelines for clinical trials, nationally and in each state.
- Establish regular tracking and monitoring of patient participation in clinical trials, including participation of Aboriginal and Torres Strait Islander peoples and culturally and linguistically diverse communities.
- Expand the reporting of clinical trials metrics tracked by the ANZCTR to include reporting of medical device trials by phase and therapeutic area, as is done for drug trials in this country.

## Conclusion

The Australian clinical trials industry is at a crossroads – it has delivered significant economic and patient health benefits to date but needs urgent action to ensure continued growth. In 2022, the clinical trials sector in Australia employed c.7,700 Australians. Around 90,000 Australians participated in trials and there were 1,850 trials started. This activity saw c.$1.6 billion spent on clinical trials in 2022.

However, there is a need to significantly invest in the sector to address the four key priorities identified in this report to ensure Australia maintains its attractiveness as a clinical trial destination. Addressing these priorities will require commitment from government and industry alike. MTPConnect looks forward to working with all stakeholders collaboratively to address these important priorities.

# Appendices

## Appendix 1 – List of senior sector stakeholders consulted

This report has been developed with input from 52 senior sector experts through targeted stakeholder consultations. Many of these executives are also representatives of AusBiotech, Medicines Australia (MA), the Medical Technology Association of Australia (MTAA) and the Research & Development Taskforce (RDTF). The perspectives shared by these senior stakeholders from industry associations, companies, regulatory bodies, research organisations, government representatives and funders have informed the positive and negative elements behind Australia's competitive advantage in this sector, as well as the emerging opportunities and priorities for the future. MTPConnect would like to thank all those who shared their time and insights through these stakeholder consultations. The list of stakeholders is shown in the table below.

| Name | Organisation | Name | Organisation |
|---|---|---|---|
| Andrew Davidson | Melbourne Children's Trials Centre (MCTC), Murdoch Childrens Research Institute | Tina Soulis | Alithia Life Sciences |
| Andrew Batty | VividWhite | Falko Thiele | BIOTRONIK |
| Angie Barba | ANZCTR | Gemma Eldridge | Medpace |
| Caitlyn Aherne | Life Healthcare | Christina Haskis | AbbVie |
| Caroline Pile | Norgine | Helen Aunedi | Roche Australia |
| Carrie Bloomfield | GSK | Ian Burgess | MTAA |
| Christopher Smith | VividWhite | Louise Imray | Novartis |
| David Cain | Astellas | Jane Kelly | CMAX |
| David Henderson | Biogen | Jasjit Baveja | MTAA |
| Deborah Bell | Avania Clinical | Jo Briffa | Eisai EMEA |
| Deidre Mackechnie | APAA | Katherine Davies | Norgine |
| Deama Amr | Medtronic Australasia | Kerstin Schuetz | Medical Device Partnering Program |
| Kurt Lackovic | Cancer Trials Australia | Lauren Macnaughton | Eli Lilly |
| Megan Campbell | NACCHO | Leanne Weekes | Bellberry |
| Megan Robertson | St Vincent's Hospital, Melbourne | Lisa Nelson | Scientia |
| Melina Willson | ANZCTR | Monique Alves | Biogen |
| Simon Cook | Eudaemon Technologies | Nicole Gaupset | Alexion |
| Tim O'Meara | 4DMedical | Nikhil Jayaram | PTC Therapeutics |

| Name | Organisation | Name | Organisation |
|---|---|---|---|
| Lynda Paton | Amgen | Sharon Charles | ProPharma Group |
| Penny Lovell | UCB | Simon Dawson | Kyowa Kirin |
| Peter Astles | Besins Healthcare | Simon Singer | TGA |
| Robert Kent | ARCS; The Kinghorn Cancer Centre | Stefan Czyniewski | Mobius Medical |
| Rosina Velona | Navi Medical Technologies | Sue Mason | ARCS, The Kinghorn Cancer Centre |
| Saraid Billiards | AAMRI | Tahli Fenner | TGA |
| Serena King | Biogen | Trina O'Donnell | Bellberry |

## Appendix 2 – List of survey respondents

MTPConnect would like to thank Stuart Anderson (MTAA), Deborah Bell (MTAA), Constantine Tablan (MA) and Karen Parr (AusBiotech) for assisting with distributing and canvassing responses to the industry survey. The following businesses submitted responses to the MTPConnect industry survey. Respondent companies reported starting 406 trials in 2022, a number that represents 63 percent of the total 646 industry-sponsored trials started in that year.

| Company | Company |
|---|---|
| 4D Medical | CMAX Clinical Research |
| AbbVie | Edwards Lifesciences |
| Alexion | Johnson & Johnson Medical |
| Astellas | IQVIA |
| AstraZeneca | Medtronic |
| B.Braun | Mobius |
| Biogen | Novotech CRO |
| BIOTRONIK | Roche |
| Boehringer Ingelheim | Southern Oncology Clinical Research Unit |
| Bristol Myers Squibb | Stryker |

MTPConnect would also like to specifically acknowledge the assistance of Angela Magira (RMH) and Marian Lieschke (PMCC) for completing the survey on behalf of their respective institutions.

## Appendix 3 – Sector participants and overview of clinical trial start-up process

### Sector participants

Several sector participants play key roles in the conduct of clinical trials in Australia. These include medical technology, biotechnology and pharmaceutical (MTP) companies, contract research organisations (CROs), medical research institutes (MRIs), trial sites/units, universities and clinical trial networks, as illustrated in the figure below. Representatives from each of these organisations have contributed to this report, through sector consultations and by providing data not available in the public domain. Their input has provided a broad and representative range of perspectives on key issues and opportunities for Australia to strengthen and grow the clinical trials sector. These issues and opportunities are outlined in the body of this report.

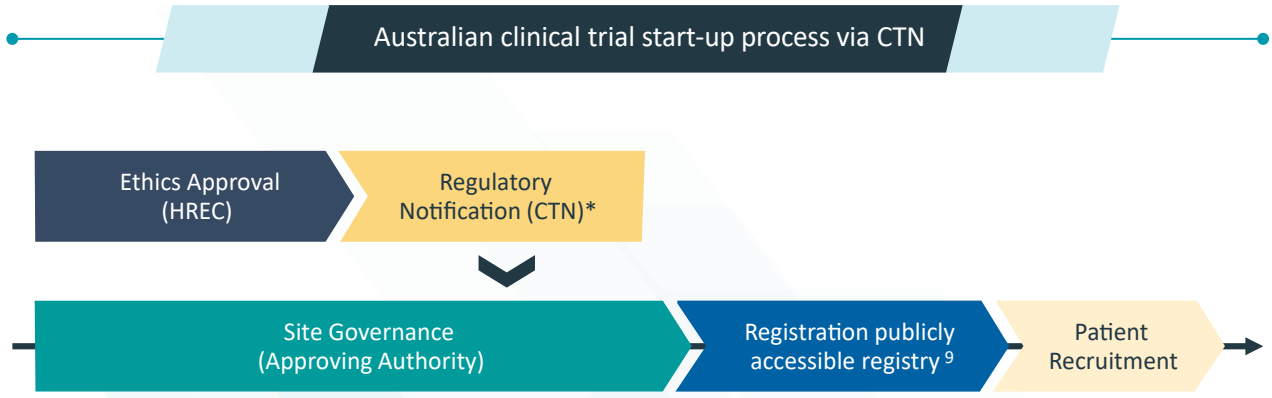
| Sector organisation | Description of Role |
|---|---|
| MTP companies (industry) | MTP companies are the main sponsors of clinical trials in Australia in value terms. While most medical technology companies tend to manage clinical trials inhouse, biotechnology and pharmaceutical companies typically use a combination of in-house and outsourced CROs to manage trials. Collectively, MTP companies and CROs spend the most on clinical trials. |
| Contract Research Organisations (CROs) | CROs are service providers that design, plan and manage clinical trials on behalf of sponsors (typically MTP companies). They can range from small, niche local providers to large, full service multinational companies. |
| Medical Research Institutes (MRIs) | MRIs undertake medical research (including the conduct of clinical trials) focused on one or more therapeutic or research areas. MRIs are often intertwined with hospitals, universities and clinical trial networks. |
| Trial sites/units (public/private hospitals, clinics, specialised units, GP practices) | The main role of a trial site is to host trials and provide clinical staff for the conduct of trials on site. Hospitals are involved in clinical trials both as sponsors and in recruiting, treating and monitoring patients in trials on behalf of other sponsors. Private clinics are less likely to sponsor trials. However, they are involved in recruiting patients and conducting trials. |

| | |
|---|---|
| Universities | While not usually trial sites for commercial studies, universities are typically involved in early-stage trials, where the financial trade-offs are too great for MTP companies or the level of investment is not prohibitive, or in trials relating to clinical practice, behavioural therapies and preventative care (rather than new drugs/devices or discoveries). |
| Clinical trials networks | A clinical trial network is a group of researchers, clinicians and academics who share infrastructure to conduct multi-centre clinical trials and facilitate knowledge-sharing between researchers in a field. They are typically virtual and do not have any physical infrastructure. |

## Overview of Clinical Trial Start-Up Process

In Australia, a series of steps and procedures are required before a clinical trial can be initiated. There are two TGA schemes under which clinical trials involving unapproved therapeutic goods may be conducted: the Clinical Trial Notification (CTN) Scheme and the Clinical Trial Approval (CTA) Scheme. The CTA Scheme is an approval process; however, almost all clinical trial sponsors that supply unapproved drugs and devices for human use go through the CTN scheme (see figure below).[56] The scheme defers the review of each clinical trial to the relevant Human Research Ethics Committee (HREC).[57] With advice from the HREC, and after regulatory notification of the intent to sponsor a clinical trial is submitted to the TGA, the institute or organisation responsible for the conduct of the trial becomes the ultimate approving authority. In public health organisations, a site governance review occurs through the Site Specific Assessment (SSA) process. While the Therapeutic Goods Administration (TGA) will accept the CTN form submission as the sponsor is obtaining the necessary endorsements, typically the CTN is submitted after HREC approval and before governance approval. The sponsor must ensure that all relevant approvals are in place before commencement of the trial.[58]

[56] The remaining unapproved drugs and devices must pass through the CTA scheme which requires TGA to evaluate summary information about the product including relevant scientific data. For this reason, the CTA scheme is a slower than the CTN scheme. This CTA scheme is relevant for certain Class 4 biologicals, which typically contribute fewer than five trials annually. For this reason, it is not discussed at length in this report.
[57] NHMRC, National Statement on Ethical Conduct in Human Research, 2023 – National Statement on Ethical Conduct in Human Research (2023) requires clinical trials are registered on a publicly available registry (e.g. Australia and New Zealand Clinical Trials Registry [ANZCTR], ClinicalTrials.gov) before the recruitment of the first participant.
[58] Department of Health, Therapeutic Goods Administration, Clinical Trials website, May 2022




Note: * The TGA encourages all parties to be in agreement as to when the CTN form should be submitted. Clinical trials that do not involve 'unapproved' therapeutic goods are not subject to requirements of the CTN or CTA schemes

## Appendix 4 – Methodology for analysing clinical trials activity

Two main clinical trials registries have been used in analysing data in this report – ANZCTR and ClinicalTrials.gov. Background information regarding each registry and their data limitations are provided below.

### ANZCTR

Clinical trial activity in Australia has been measured in this report using ANZCTR data, which was received on 14 November 2023. ANZCTR is a voluntary registry of clinical trials. ANZCTR supplements the data relating to clinical trials on its registry with information from clinical trials registered on ClinicalTrials.gov, which is mandated by the US government for studies initiated after January 2017 and conducted wholly or partly in the United States.[59]

As the number of trials that are never registered is unknown, we have not provided an estimate for 2023 trials. However, for trials that have been registered, the ANZCTR captures around 62% of studies recruiting in Australia according to ANZCTR.[60] This is broadly in line with the coverage of data reported in the Clinical Trials in Australia (2021) report.

The clinical trial activity analysed in this report leverages the number of clinical trials started, rather than the total number ongoing. These two metrics differ, as many trials run longer than one year. However, since sponsors are not required to update their trial status and trial data in ANZCTR, the data quality for ongoing trials is somewhat limited. Therefore, the number of clinical trials started remains a proxy for the level of clinical trial activity in Australia and has been used to analyse trends since 2015.

The data has been segmented in this report in the following ways, to analyse drivers of clinical trial activity:

- Sponsor type – which indicates the individual or organisation responsible for the trial. In this report sponsors have been classified into either industry (capturing 'industry' and 'commercial sector/industry' ANZCTR sponsor types), university, individual, government and hospital (including 'government body', 'NIH', 'US Fed' and 'hospital' ANZCTR sponsor types) and other (including 'other', 'charities/societies/foundations' and where no other sponsor was indicated).
- Study type – which indicates whether a clinical trial was conducted on an interventional or observational basis.
- Intervention type – which may or may not include a drug (including 'medicine' or 'biological'), a device and/or other studies (including 'dietary supplements', 'behavioural' and 'procedural' interventions, etc.).
- Trial phase – which includes phases I to IV of the drug development life cycle. Where combined phase trial designs are used in a registered trial, the higher phase is presented in this report. For example, a combined Phase I and II trial is presented in this report as a Phase II trial. Device trials are not registered by phase and are classified under 'Other' for both ANZCTR and ClinicalTrials.gov.[61]

[59] US National Institute of Health, FDAAA 801 and the Final Rule, accessed January 2024
[60] ANZCTR, Latest Updated of the Clinical Trials Landscape in Australia (2006-2020).
[61] ClinicalTrials.gov, Protocol Registration Data Element Definitions for Interventional and Observational Studies, accessed February 2024.

- Therapeutic area – the largest of which include oncology, mental health, neurology, musculoskeletal and cardiovascular. ANZCTR and ClinicalTrials.gov users can select multiple therapeutic areas when registering a clinical trial. As a result, it is impossible to sum the number of clinical trials by each therapeutic area. For example, clinical trial relating to the treatment of COVID-19 may be classified under both 'Infectious Disease' and 'Respiratory' therapeutic areas.
- State – which refers to each of Australia's eight states and territories. A clinical trial is defined as existing within a state when it has at least one trial site within that state. Most clinical trials occur across multiple sites and often in multiple states. In those cases, the clinical trial is counted more than once in the data presented in this report.

Participation statistics in clinical trials are available on ANZCTR. However, these statistics have not been considered in this report because of the infrequent updating by sponsors, as described above. In addition, the numbers reported are often global patient recruitment/participation numbers rather than Australia-specific.

### ClinicalTrials.gov

For global comparisons, this report exclusively uses industry-sponsored trials on ClinicalTrials.gov, extracted on 14 January 2024. ClinicalTrials.gov is widely considered to be the most comprehensive registry, with information for approximately 400,000 studies in over 200 countries. Despite this, the registry relies on sponsors reporting appropriate information regarding their trials, so there remain limitations around the accuracy, completeness and timeliness of information in the registry.[62] This timeliness issue extends to more than half of the trials and, for this reason, the data originally presented in the Clinical Trials in Australia (2021) report has been updated to reflect changes in the source registries.[63]

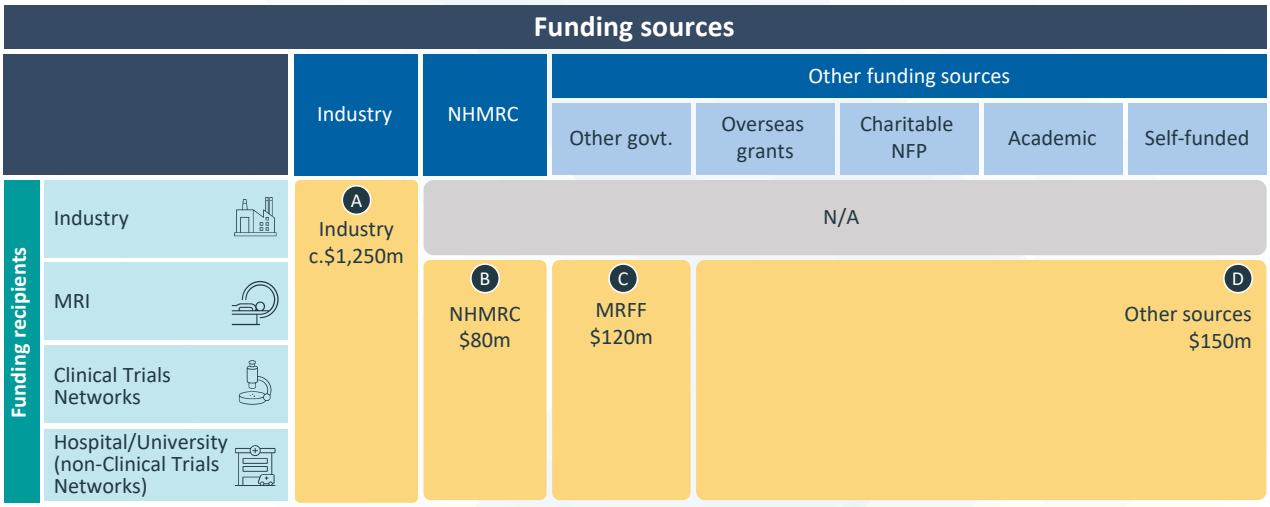
[62] Tony Tse, et al., How to avoid common problems when using ClinicalTrials.gov in research: 10 issues to consider, British Medical Journal, March 2018
[63] The Lancet, Fewer than half of US clinical trials have complied with the law on reporting results, despite new regulations, EurekAlert, January 2020

## Appendix 5 – Methodology for calculating the economic value of clinical trials

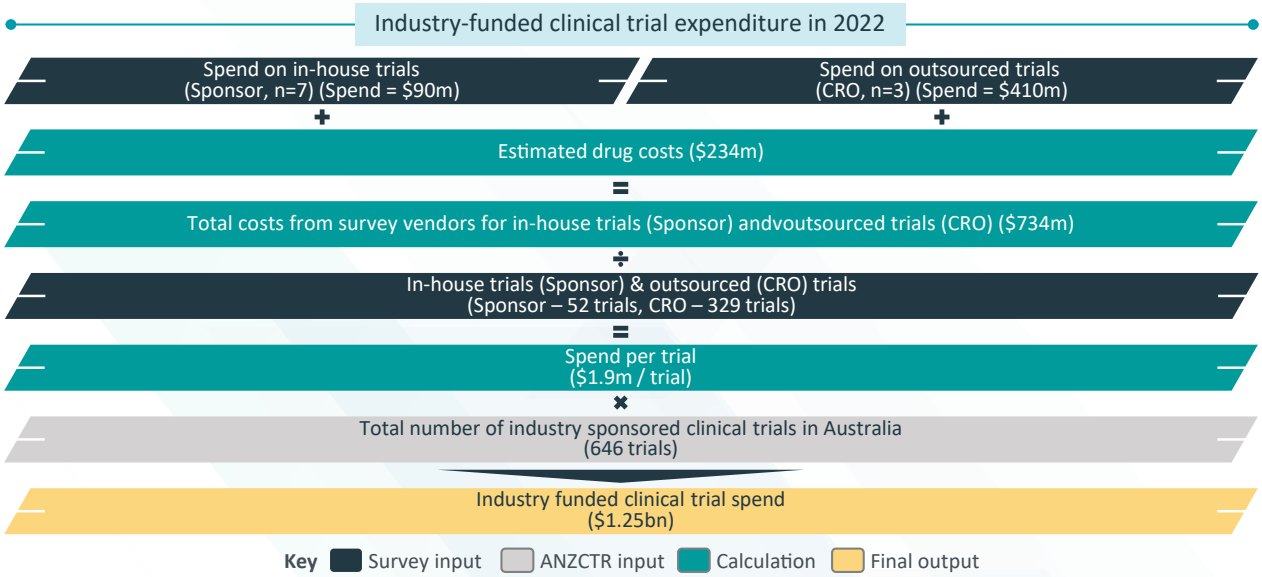
The availability of economic data relating to clinical trials is widely acknowledged to be limited. Therefore, we have modelled this data using a combination of the MTPConnect industry survey, as well as secondary data sourced from industry and sector reports, and the application of scale factors.

The total clinical trials expenditure comprises the estimate of total spend on clinical trials in Australia by public and private entities on all forms of clinical trials. The methodology is based on a bottom-up approach for the primary sources of funding for the sector, with the residual balance based on expenditure within universities, hospitals and independent MRIs.

The estimated total represents the minimum expenditure, with several areas being difficult to quantify. These include additional clinical trials expenditure within clinical trials networks; additional NHMRC funding of R&D initiatives outside of the CTCS, which may include clinical trials; and additional MRFF funding of R&D and commercialisation initiatives. Some, but not all of this may be captured within C) MRFF spend (see the following figure for an explanation of this calculation).



## Appendix 5a – Industry expenditure




Source: MRFF; AAMRI; NHMRC; PBS; ANZCTR; Clinicaltrials.gov; L.E.K. research and analysis

This report's calculation of industry expenditure has been based on primary research data from the MTPConnect industry survey of MTP companies. Not all survey responses included matching spend data for trials started in 2022; therefore, only 381 of the 406 trials are included in the spend analysis, as shown in the diagram above. Most respondents were members of AusBiotech, MTAA, MA and the RDTF, and were made up of larger corporates, including several multinational corporations.

To ensure total expenditure was captured within the report, an analysis was undertaken to determine whether the costs of drugs and devices provided in clinical trials were provided accurately in survey responses. Where there were gaps, this report's analysis has leveraged the PBS to determine market estimates for trials that did not report on drug costs. Where available, the costs of devices used in clinical trials has also been included.

Sample bias is possible, due to the nature of distribution which favours larger MTP companies. However, given the large (63%) proportion of all industry-sponsored trials represented here in the survey, it is likely that the calculations represented here are close to those of the industry average.

## Appendix 5b – NHMRC expenditure

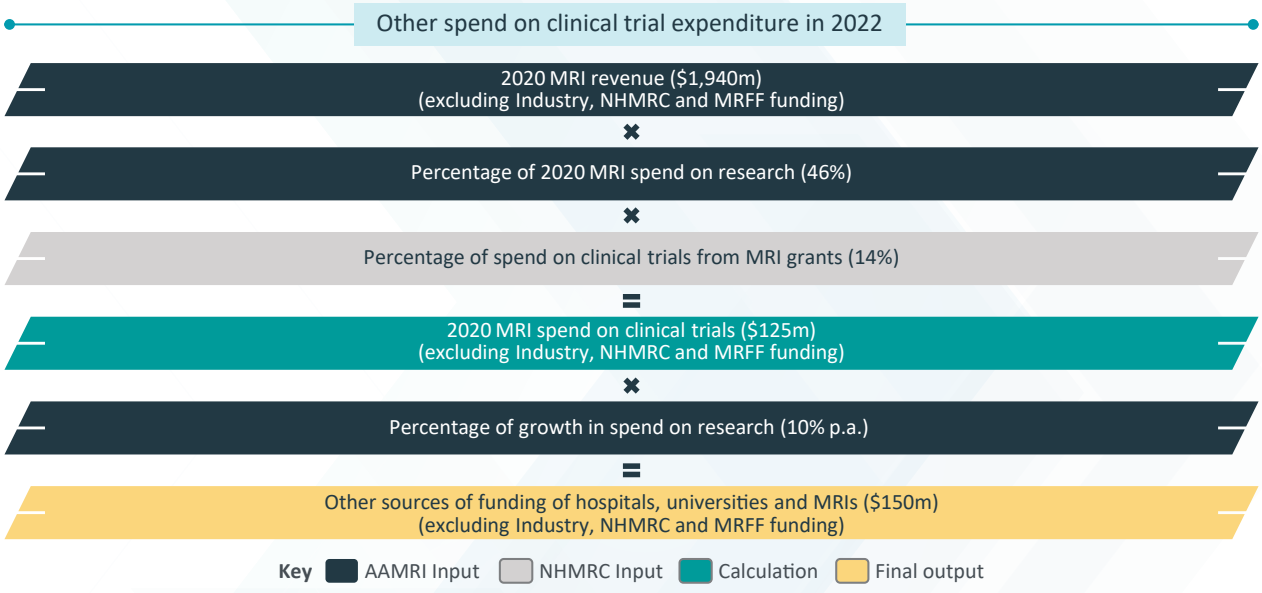
NHMRC expenditure on clinical trials have been taken as the total amount funded through the CTCS Grants scheme in 2022, which was approximately $80 million. NHMRC funds are typically awarded to universities, MRIs or investigators using clinical trial networks; they are not awarded to commercial companies. The adjustments made to this methodology from those in the 2021 report reflect insights from industry stakeholders. Specifically, any expenditure attributable to non-CTCS NHMRC grants have now been excluded, as the indirect funding of clinical trials through these grants is now believed to be negligible.

## Appendix 5c - MRFF spend

The MRFF data reflects the combined spend of projects funded under the 'Clinical Trial Activity' initiative, which started in 2022 (at approximately $100 million). It also reflects any other MRFF 'Missions' initiatives starting in 2022 and which described any association or intent to support clinical trials activities (at approximately $20 million). By comparison, the 2021 report only included the 'Clinical Trial Activity' initiative.

This adjustment, like the one above in Appendix 5b, is based on inputs from those industry stakeholders who have advised that 'Missions' initiatives are involved in supporting clinical trials. This number is still likely an underestimate, as the MRFF also funds health research through other activities such as the 'Medical Research Commercialisation' initiative, where clinical trial expenditure cannot be easily apportioned.

## Appendix 5d – Other spend




Source: AAMRI Member Report 2022; L.E.K. Research and Analysis

Neither the AAMRI, nor the individual MRIs, publish clinical trial expenditure. MRI expenditure on clinical trials is calculated using a proxy indicator for the average percentage of MRI expenditure specifically for clinical trials (i.e. excluding revenue from industry, NHMRC or MRFF that is captured elsewhere in appendix 5a, 5b or 5c above). The proxy used is the proportion of NHMRC funding provided to MRIs for the purpose of clinical trials. This proxy has been tested and validated by senior industry stakeholders and is broadly unchanged since the 2017 and 2021 iterations of this report.

Total revenue and expenditure figures are available in AAMRI's 2022 Member Report. This is the latest report available, and its figures are available for 2020. AAMRI is the industry association representing MRIs in Australia. It includes data that represents most MRIs in Australia (data has been gathered from 50 of 58 AAMRI members).

## Appendix 6 – Methodology for clinical trials employment

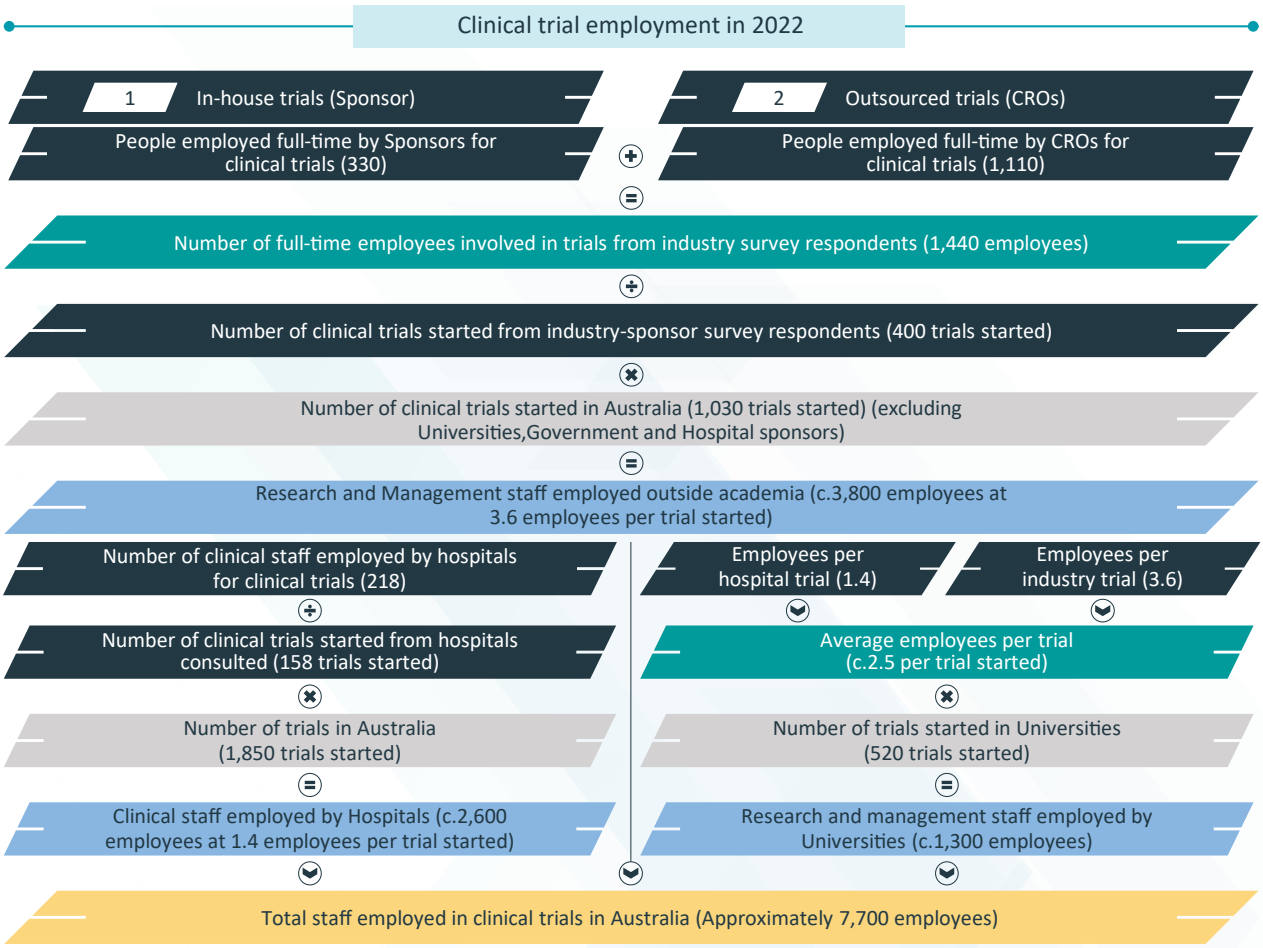
Employment in the clinical trial sector has two separate components: research and management jobs at MTP companies and comparable roles in MRIs and universities, which is estimated to be 5,100 persons (1,300 in academia, 3,800 outside academia); and clinical staff in hospitals, clinics or other trial sites, estimated at 2,600 persons.

Research and management employment estimates have been sourced from survey data. MTPConnect industry survey respondents have indicated they have 1,435 full-time employees who were directly involved in clinical trials in Australia. By scaling these numbers up to the whole industry, as shown in the figure below, it has been estimated that there are a total of 3,800 employees in research and management (excluding academia). This estimate is based upon a scale-up of clinical trials started, rather than ongoing, which exposes the calculation to possible sample bias.

The number of clinical staff supported by trials is difficult to estimate, due to the part-time nature of many clinical trial roles and incomplete employment data for Australia's healthcare system. The number of full-time employed clinical staff supporting trials has been estimated at approximately 2,600, using inputs from clinical trial units at several hospitals and MRIs.

The number of academic staff has not been directly obtained through primary research. It is estimated there are 1,300 clinical trial research and management staff employed by universities. This has been calculated on a per trial basis on the assumption that the number of academic staff involved per university sponsored trial is the average of the number of staff employed to support government and hospital sponsored trials, and the rest of the sector (excluding universities, government and hospital).

In total, our estimates suggest there are at least 7,700 employees in the clinical trial sector. This includes 2,600 in hospitals, 1,300 in universities and 3,800 in other research and management positions across the sector. However, there could very well be many more people employed in the sector, given the many people employed either as independent/solo contractors or within roles that partially support clinical trials in an indirect capacity (for example, clinical staff at imaging facilities).



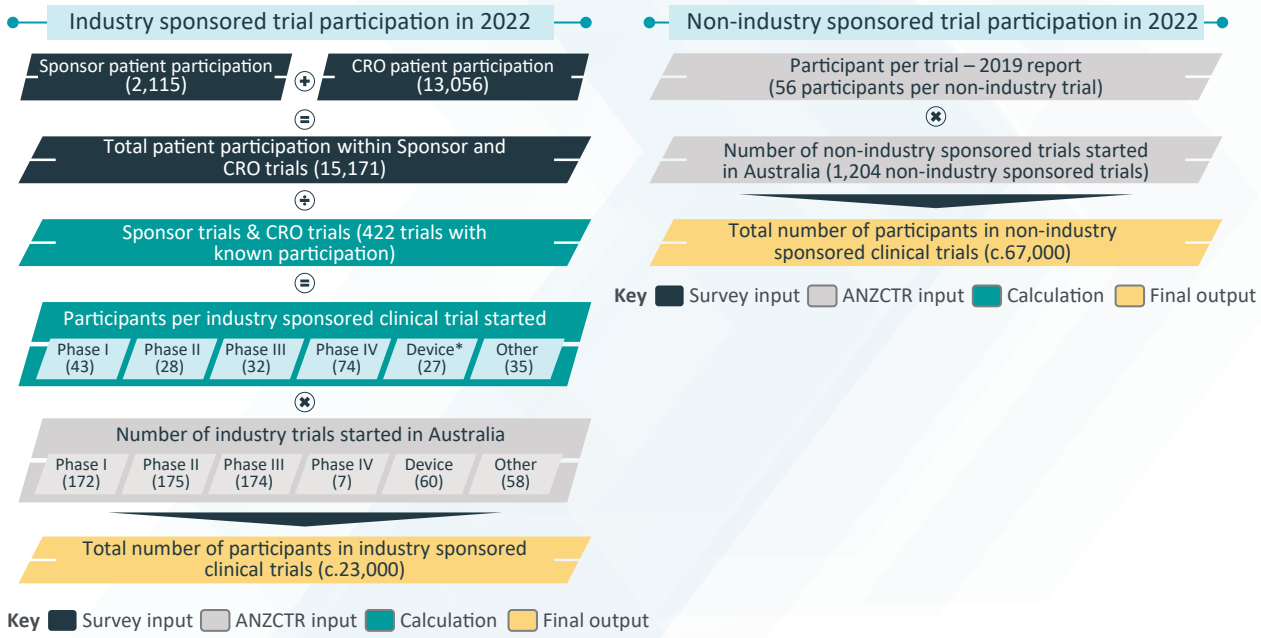

Source: ANZCTR; L.E.K. Analysis

## Appendix 7 – Methodology for clinical trials participation

Publicly available data on the number of Australians who participate in clinical trials is limited, with reported numbers typically including global participation in global trials with Australian sites. Therefore, we have estimated their participation as follows:

- **Industry sponsored trial participation:** patient participation within industry-sponsored clinical trials was calculated based on primary research data collected in a survey of MTP companies. The industry survey respondents indicated their clinical trials supported 15,171 patients, with the total number of clinical trial participants estimated by calculating the average number of participants per phase, multiplied by the number of industry-sponsored clinical trials started in each phase in 2022.
- **Non-industry sponsored trial participation:** in this report, non-industry participation has been estimated separately from industry sponsored participation, unlike the previous report where the non-industry estimate was based on industry survey results. We have now applied the 2021 non-industry participation rate of 56 participants per non-industry trial to 1,204 non-industry trials in 2022. In total, this represents approximately 90,000 participants in Australia in 2022.

These numbers and the methodology behind their calculation are summarised in the following figures:




Note: *Device trials calculated as the average of device trial participation across all device trial phases from survey responses
Source: MRFF; AAMRI; NHMRC; PBS; ANZCTR; Clinicaltrials.gov; L.E.K. research and analysis

## Appendix 8 – Economic and health benefits of clinical trials

The economic activity generated by clinical trials includes investment (expenditure on clinical trials), jobs created and reduced costs to the healthcare system. The latter comes in the form of treatment costs that are typically borne by the trial sponsor, rather than Australia's healthcare system or patients, had they not participated in a clinical trial.

Trial activity triggers a range of flow-on benefits. Patients benefit through early access to new treatments and better care outcomes. The sector benefits through a strengthened research ecosystem and culture, improved standards of care and a more highly skilled workforce.

The wider economy experiences a variety of multiplier effects, including increased personal spending by healthier trial patients and those employed in the many jobs supported by the sector. Increased personal spending is funded in part by increased workforce participation rates of healthier clinical trial patients. This in turn supports government expenditure through the tax revenue associated with personal income.

The sector also benefits through more growth and investment: because Australia already has a reputation for high standards of care, high efficiency, a strong research culture and advanced healthcare infrastructure, it is seen as a more attractive market for trial sponsors to run more clinical trials. This boost of activity creates a 'positive feedback loop', where more clinical trials activity in turn makes Australia more attractive as a clinical trials market.

## Appendix 9 – References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## Appendix 10 – Glossary of terms

| Acronym | Definition | Acronym | Definition |
|---|---|---|---|
| AAMRI | Association of Australian Medical Research Institutes | IGPRG | Inter-Governmental Policy Reform Group |
| ACTA | Australian Clinical Trial Alliance | IIT | Investigator Initiated Trial |
| AIHW | Australian Institute of Health and Welfare | IND | Investigational Drug |
| ANZCTR | Australia and New Zealand Clinical Trials Registry | IVD | In-Vitro Diagnostic Products |
| CGP | Comprehensive Genomic Profiling | IVDR | In-Vitro Diagnostic Regulation |
| CRA | Clinical Research Associate | MDR | Medical Device Regulation |
| CRO | Contract Research Organisation | MRI | Medical Research Institute |
| CTA | Clinical Trial Approval | MMS | Modern Manufacturing Scheme |
| CTC | Clinical Trial Coordinator | MRFF | Medical Research Future Fund |
| CTCS | Clinical Trials and Cohort Studies | MTAA | Medical Technology Association of Australia |
| CTGF | Clinical Governance Trials Framework | MTP | Medical Technology, Biotechnology, Pharmaceutical and Digital Health |
| CTN | Clinical Trial Notification | NHMRC | National Health and Medical Research Council |
| DCT | Decentralised Clinical Trials | NOSS | National One Stop Shop |
| DoHAC | Department of Health and Aged Care | NSW | New South Wales |
| EMA | European Medicine Agency | PBAC | Pharmaceutical Benefits Advisory Committee |
| FDA | Federal Drug Administration | PBS | Pharmaceutical Benefits Scheme |
| FIH | First In Human | PPP | Public Private Partnership |
| FTE | Full Time Equivalent | PrOSPeCT | Precision Oncology Screening Platform Enabling Clinical Trials |
| GCP | Good Clinical Practice | RDTF | Research & Development Taskforce |
| HREC | Human Research Ethics Committee | RWE | Real-World Evidence |
| HTA | Health Technology Assessment | SSA | Site Specific Assessment |
| IDMP | Identification of Medicinal Products | TGA | Therapeutic Goods Administration |