

Australia: A Highly Attractive Environment for Drug Development

First in a Three-Part Series

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Australia offers a highly favorable environment for drug research and development, with a mature infrastructure and experienced, capable local resources and expertise. Considering global geopolitical uncertainties, Australia presents a compelling option for sponsors to consider. This first article in a three-part series illustrates the Australian economy, demographics, healthcare investments and expenditures, and the growth of the pharmaceutical market and clinical trials. Ensuing articles will explore the landscape for clinical trials, including the therapeutic areas, the strength of patient centricity and innovation adoption, and the regulatory and reimbursement environment.

Australia is internationally recognized for its highly trained clinical workforce and the high-quality data produced by its research teams. The combination of this scientific and medical expertise means that Australia can provide good value to the clinical development of protocols and trial execution. Australia is especially attractive for Early Phase trials (Phase I and II)

thanks to a diverse participant recruitment pool, sound infrastructure, and fast start-up timelines. First in Human (FIH) Phase I centers – some with ethno-bridging capabilities – are well-established. Further, Australian patients can be recruited into clinical trials in seasonally affected diseases (Southern hemisphere “off season”).

Demographics and Economic Growth

Australia has enjoyed consistent economic growth and one of the highest growth rates among the world's developed economies. In recent years, Australia has established increasingly close relations with other countries in Asia, playing an active role as a facilitator in the economic development of the Asia region. An important component of this role has been Australia's welcoming attitude towards foreign investment. Factors that have helped to attract foreign investors include its abundance of natural resources, a stable and mature financial system, and a safe investment and financing environment.

Population, Medical Resources, and Economy

Australia has a rich mix of cultural backgrounds and heritage, and the number of Australian residents who were born overseas continues to increase. Based on the 2021 census, the top five countries of birth (excluding Australia) are England, India, China (excluding special administrative regions and Taiwan), New Zealand, and The Philippines. Australia's diversity thus enables recruitment of a patient population that reflects the populations of those countries, in addition to other Asian populations. Other than country of birth, ancestry and language are strong indicators of the diversity in Australia. Chinese is the second-most-common ancestry for first-generation Australians.

Population Characteristics and Medical Resources

With the sixth-largest land area in the world, Australia has a population of about 26 million, accounting for only 0.3% of the world's total. Australia's population is expected to grow at a rate of about 0.97% in the next three years. Due to the country's topography, the population is mainly distributed in the eastern and southeast coastal areas of Queensland, New South Wales, and Victoria.

Because of the high net immigration and declining fertility rates, the aging rate of Australia's population is expected to be slower in the forecast period than that of many other countries in the Organization for Economic Cooperation and Development (OECD). Nonetheless, the population aged 65+ is estimated at ~4.3 million in 2022 and is expected to grow by 2.7% annually, driving the healthcare expenditure.

According to the latest available data from the Australian Institute of Health and Welfare (AIHW), cancer accounts for one-fifth of the disease burden in Australia. Because of the aging population, the increase in the diagnosis of cancer has driven the market for oncology clinical trials. In more than 80 oncology projects Parexel has conducted in Australia in the last five years, we have led in the application of emerging modalities including immune checkpoint inhibitors, cell and gene therapy, antibody drug conjugate (ADC), and precision oncology medicines. These modalities represent significant changes in the cancer treatment paradigm.

In terms of medical resource supply, in 2017 and 2018, there were 693 public hospitals with 62,000 beds in total, as well as 657 private hospitals with a total of 34,300 beds in Australia. In 2021, the ratio of doctors to the population was 4.1/1,000, slightly higher than the OECD average of 3.4. Due to hospital construction, better supply in rural areas, and more funds for age-related care, this ratio is expected to rise to 4.4/1,000 by 2025. With regard to the economy, Australia's GDP stagnated in 2019 and 2020 because of factors related to the global pandemic. Economic growth will likely recover gradually in the next three years.¹

The table below shows the population, medical resources, and gross national product of Australia, as well as the expected development data in the past three and the next three years.

Support for Pharmaceutical R&D

The Australian government promotes infrastructure projects nationwide to encourage and provide support to build a highly integrated and innovative R&D ecosystem in the country. An attractive tax-incentive policy and transparent regulatory framework provide a safe investment environment for foreign companies. These factors make Australia an attractive choice for investment in R&D and innovation.

From 2016 to 2019, Australian pharmaceutical enterprises grew from US\$4.9 billion to \$5.2 billion and provided about 60,000 to 70,000 jobs for Australia. In 2021, the medicines imports totaled more than US\$11 billion, compared with exports of US\$2.4 billion.²

Overview of Australia's Population, Healthcare, and Economy¹

E = Estimated	2019	2020	2021	2022	2023E	2024E	2025E
Total Population (million)	25.4	25.7	25.9	26.1	26.3	26.6	26.9
Population Aged 65+ (million)	3.95	4.05	4.17	4.28	NA*	4.52	4.64
Average Number of Doctors/Thousand People	3.9	3.9E	3.9E	4.0E	4.0	4.1	4.1
Average Number of Hospital Beds/Thousand People	3.8	3.8E	3.8E	3.8E	3.8	3.8	3.8
Nominal GDP (US\$ billion)	1,385	1,361	1,646	1,701	1,788	1,825	1,966

*Data not listed in EIU healthcare Australia Q22023

Healthcare and Pharmaceutical Expenditures

Australia’s healthcare system is like that of many developed countries, with high-quality public medical facilities, adequate government medical funds, and sound financing mechanisms. Australia’s healthcare expenditure is predicted to grow at a compound annual growth rate (CAGR) of 4.5% from US\$15 billion in 2019 to \$19 billion in 2026.³ According to OECD data, Australia’s healthcare expenditures accounted for 10.7% of GDP in 2020. This declined to 10.5% in 2021 because of the coronavirus pandemic.⁴ In the future, Australia’s total healthcare expenditure is expected to grow at a CAGR of 4.2% from 2022-26. This is mainly due to the development and use of new technologies, drugs, and diagnostic and therapeutic methods,

in addition to Australia’s aging society and high incidence of non-communicable diseases.⁵

Figure 1 shows Australia’s healthcare and drug expenditures in the past three years and the projection for the next three years. The Prime Minister of Australia allocated AU\$132 billion (US\$91.4 billion) to the healthcare system in the 2022/23 budget, a record high. It is estimated that this figure will increase to AU\$140 billion (US\$83.5 billion) in 2025/26, and the total commitment in the next four years will reach AU\$537 billion (US\$339.8 billion). Australia is also working hard to improve its long-term medical plan, investing AU\$45.5 billion (US\$28.8 billion) in four years to obtain more affordable drugs through the Pharmaceutical Benefits Scheme (PBS), which provides subsidies for most prescription drugs.⁶

Trends in Australia Healthcare and Pharmaceutical Expenditure

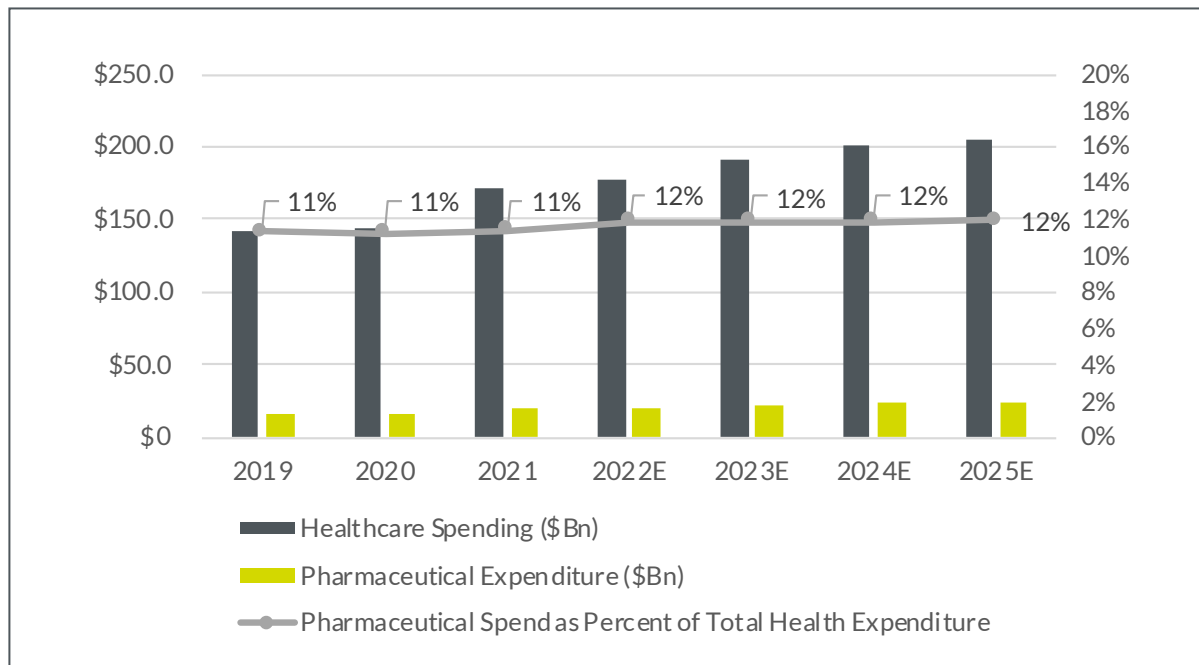


Figure 1: Trends in Australia Healthcare and Pharmaceutical Expenditure

Clinical Trial Activity

In the past five years, the R&D activity in Australia has grown steadily, especially in Early Phase trials (Phase I and Phase II), as shown in Figure 2. It decreased in 2022, mainly due to the challenging environment for raising funds, which has occurred globally. This has led

many companies to adopt a more conservative strategy. Considering the well-established R&D infrastructure in Australia, the support of the Australian government, and the continuous R&D investment of pharmaceutical companies, it is still a preferred destination for conducting clinical trials.

Industry-sponsored clinical trials in Australia 2018-2022

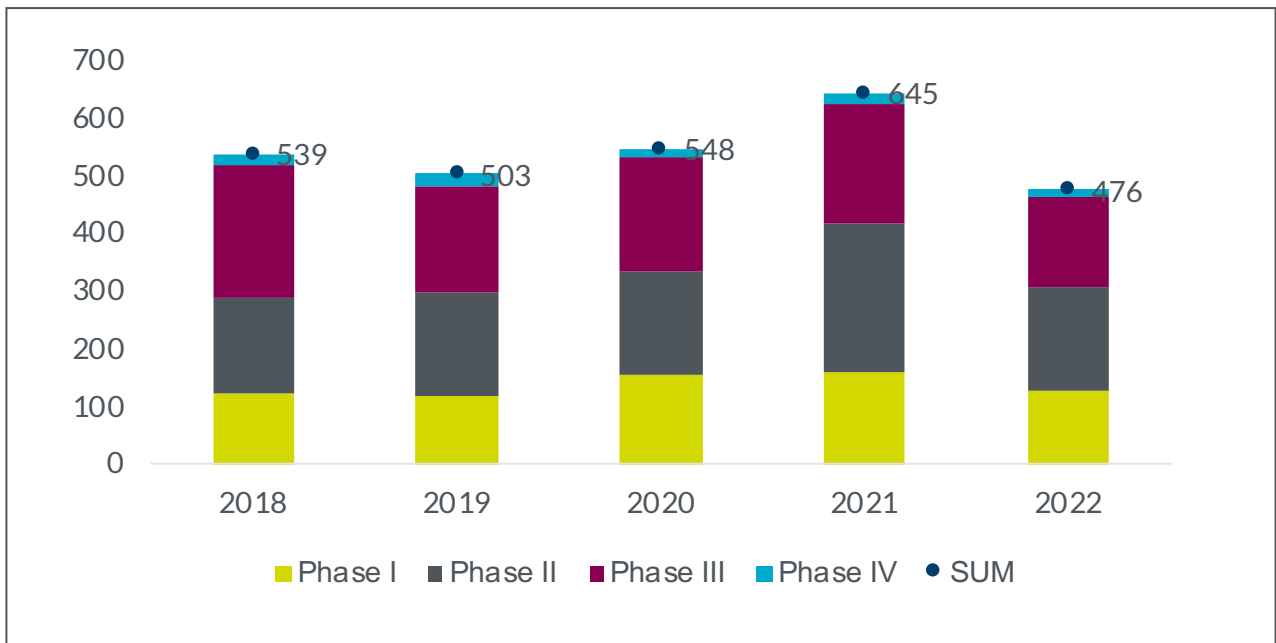


Figure 2: Clinical Trials Trend in Australia Over the Past 5 Years²

Market Opportunities

The 2016 Scientific American Worldview Overall Innovation Scorecard ranked Australia fourth globally for its culture of innovation. In Parexel's experience, Australian clinical research sites have high-quality facilities with state-of-the-art equipment for testing, treatment, and analysis. Data from Australian clinical trials are recognized and accepted by Global Regulatory Authorities including the FDA, EMA, and CFDA.

Under the Therapeutic Goods Act 1989 and associated regulations⁸, ICH-GCP standards are mandatory for all Australian clinical trials. Many Australian researchers have international experience and are familiar with GCP and other guidelines.

Australia offers fast start-up timelines for sites in a private setting.⁹ Research proposals are submitted directly to Australian human research ethics committees (HRECs) which assume the primary review responsibility for ethical and scientific review. Australia has developed the single ethical review approach for multi-center research. This streamlines the approval process.

Further, the Australian government supports the industry with an R&D tax incentive for locally listed companies. This is covered in the second article in this series, which examines in more detail the landscape for clinical research in Australia:

- › The favorable environment for Early Phase trials
- › The strength of government funding support
- › Trials by therapeutic area and the robust infrastructure for oncology trials
- › Patient-centricity and adoption of innovation that fosters patient recruitment and retention

About Parexel: At the Heart of Getting Medicines to Those Who Need Them

Parexel is among the world's largest clinical research organizations (CROs), providing the full range of Phase I to IV clinical development services to help life-saving treatments reach patients faster. Leveraging the breadth of our clinical, regulatory, and therapeutic expertise, our team of more than 20,000 global professionals work in partnership with biopharmaceutical leaders, emerging innovators, and sites to design and deliver clinical trials with patients in mind, increasing access and participation to make clinical research a care option for anyone, anywhere.



Parexel worldwide project experience Region - Australia all projects - past 5 years (as of 13-Apr-2023)

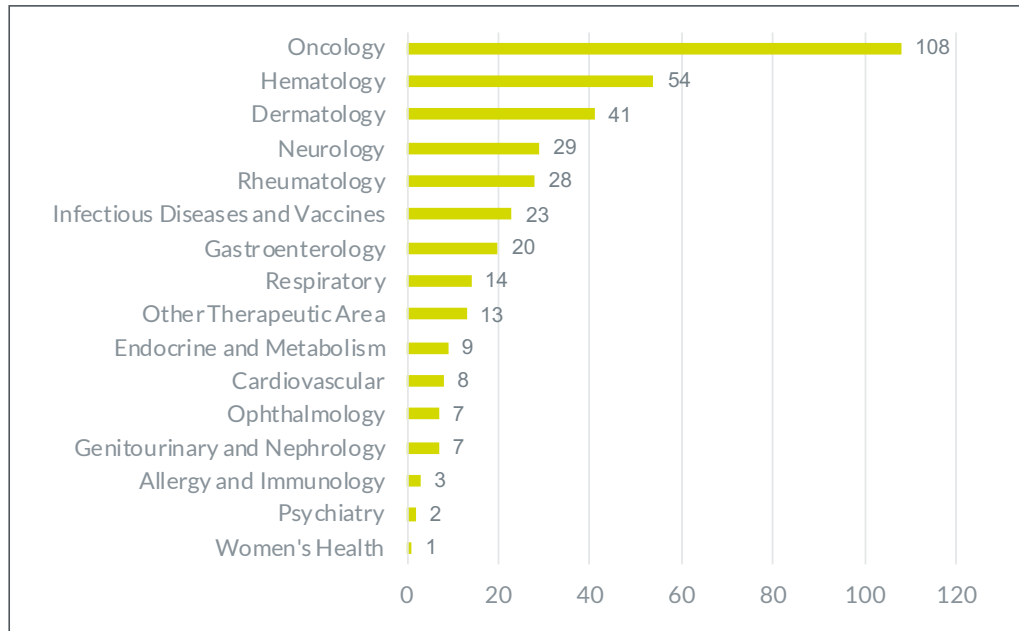


Figure 3: Parexel Clinical Trial Projects in Australia by Indication

In the past five years, our team in Australia has supported more than 300 clinical trial notification (CTN) submissions and nearly 400 clinical projects, offering expertise in regulatory consulting, clinical operations, and market access. These include more than 100 projects in oncology, as well as hematology, dermatology, rheumatology, neurology, and more.

Our depth of industry knowledge and strong track record gained over the past 40 years is moving the industry forward and advancing clinical research in healthcare’s most complex areas, while our innovation ecosystem offers the best solutions to make every phase of the clinical trial process more efficient. With the people, insight, and focus on operational excellence, we work *With Heart™* every day to treat patients with dignity and continuously learn from their experiences, so every trial makes a difference.



1 EIU healthcare-Australia Q22022
 2 EIU healthcare-Australia Q22022
 3 IQVIA MIDAS, Jun 2021; WHO 2021
 Essential Medicines Model list, Jun 2021
 4 Source: EIU healthcare-Australia Q22022

5 EIU healthcare-Australia Q22022
 6 [Biopharma Funding Year in Review \(zymewire.com\)](https://www.zymewire.com)
 7 Citeline Trials | Citeline Trialstrove (informa.com)
 8 [Clinical trials, Therapeutic Goods Administration \(TGA\)](https://www.tga.gov.au)
 9 [The Human Research Ethics Application, NHMRC](https://www.nhmrc.gov.au)

About the Authors



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Natasha is the regional head for Southeast Asia, Pacific, Africa, Australia, and New Zealand, responsible for oversight of clinical deliverables in these regions. She also oversees general administration and legal requirements in Australia and Vietnam. Natasha has more than 20 years of experience in the pharmaceutical field and has spent most of her career at Parexel, covering roles in clinical research, project leadership, and line management. She earned a BSc in Human Physiology and Psychology from the University of Pretoria, South Africa.



Stella Davis

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As regional network manager for the APAC region, Stella plays a key role in delivery of Parexel trials, focusing on site selection – the cornerstone of more predictable recruitment. She has extensive experience in building working relationships with institutions, investigators, and research teams for better data organization that improves efficiency, knowledge sharing, and ultimately brings life-changing treatments to patients. With over 15 years of experience in clinical research at Parexel, Stella has held various roles including clinical research associate (CRA), clinical operations leader, project leader, and CRA line management. Stella holds a BS in Medical Science from Macquarie University in Sydney.