JETRO
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Guidebook for Clinical Trials in Australia

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1. Introduction

Australia is an attractive location for conducting clinical trials, and several factors contribute to its popularity among researchers and pharmaceutical companies: efficient regulatory approval process, tax incentive offered by the government, population diversity, well-established healthcare system, skilled and experienced clinical investigators contributed to over 50 clinical trial networks with patient recruitment capabilities and establishment of healthcare infrastructure for digital technology development in line with international tendency. The timeline for site start-up can be minimum of three months after dossier preparation and site selection for private site when using Clinical Trial Notification (CTN) scheme which is the fastest ethical and regulatory review process for early phase clinical trials[1]. Australian government is extending its extensive support to tax incentive and improving cost-efficiency compared to clinical trial cost in other developed countries.

2. General Advantages of Conducting Clinical Trials in Australia

2.1 Healthcare System

Australia has a well-established healthcare system with state-of-the-art medical facilities and research infrastructure[2]. According to Commonwealth Fund healthcare report, Australia ranks first for equity and healthcare outcomes among 11 high-income countries belongs to OECD: Australia, Canada, France, Germany, the Netherlands, New Zealand, Norway, Sweden, Switzerland, the United Kingdom, and the United States of America(US), and holds third place for overall healthcare performance, behind Norway and the Netherlands[3]. There are 4.0 practising doctors and 12.8 practising nurses per 1,000 population, and both numbers are higher than OECD average[4]. Over 50 clinical trial networks are in operation in Australia with highly skilled clinicians who can provide access to patients and clinical trial infrastructure and more than 50 independent medical research institutes working closely with hospitals and universities. Australia boasts a skilled and experienced pool of clinical investigators and researchers and has a reputation for producing high-quality clinical research[5]. These are all due to a strong government commitment and national action to ensure an efficient, high-quality and vibrant trial environment[2].

2.2 Geographic and Political Characteristics

Australia's geographic location allows for convenient collaboration with the Asia-Pacific (APAC) region and easy access to a diverse range of patient populations[5, 6]. On the other hand, while there may be variations between states, Australia experiences differences in seasons across the country, and is an ideal location for global patient recruitment for vaccine or respiratory studies[5]. Due to the opposite seasons in the Southern and the Northern Hemisphere, trials requiring specific seasons or climate conditions can be done in the opposite season. Additionally, stable political and economic environment climate in Australia provides a secure environment for conducting long-term clinical trials.

2.3 Diverse Population and Patient Recruitment

Australia is a multicultural country with a diverse population for studies aiming to assess the effects of a treatment across different demographics in variety of trial indications. Among the first-generation who were born overseas and living in Australia, English, Chinese and Indian are the top three ancestries followed by Scottish and Irish[7]. In addition, Australia has an informed and willing population of potential trial participants with a higher level of research participation than one would expect from a population of its size[6]. The Australian treatment process and regimes are also extremely similar to those of other developed populations such

as the US, Canada and a number of European countries. This, coupled with the country's population diversity, enables recruitment of similar patient populations ensuring similar treatment groups.

Australia has several world-class phase 1 centres spread across the nation, with databases of volunteers from different ethnic backgrounds including Japanese and other Asian populations[8]. This database allows early identification of potential participants either for healthy volunteers' studies or for other indications and fast recruitment into those Phase 1 studies. Furthermore, there is a searchable clinical trials registry accessible to the public[9] where patients can search for available trials for their conditions to receive the investigational treatment.

For rare diseases, Australia houses a growing number of national registries[10] which can be accessed for participant identification and rapid enrolment. In addition, there is a great support network called Rare Voices Australia[11] (RVA) to provide a strong, unified voice to advocate for policy as well as health, disability and other systems. The National Strategic Action Plan for Rare Diseases[12] (the Action Plan) was published by the Commonwealth Department of Health and Ageing and was launched on 26th of February 2020[13]. The Action Plan outlines the actions to bring about the best possible health and well-being outcomes.

3. Therapeutic Areas of Strength and Perspective

3.1 Frailty and Central Nervous System (CNS) Studies

With dementia cases projected to triple by 2050 in the country[14], Australia stands out as an optimal destination for clinical trials in dementia research, owing to its aging population similar to other Asian countries. More than 22 percent of Australians will be aged over 65 in 2026[15] and offers a comparable pool of participants for CNS trials. The well-established healthcare infrastructure, coupled with expertise in geriatric medicine, ensures high-quality care during trials. Specifically, Australia's leadership in dementia research is exemplified by the Australian Dementia Trial Network (ADNet)[16], offering a national quality registry and an efficient patient enrolment approach. Additionally, Australia's strong reputation for Parkinson's disease research with leading research institutions and neurology centres[17], contributing to the global understanding of Parkinson's disease make it a strategic choice for its trials, ensuring access to diverse patient cohorts and collaborative networks.

3.2 Cell and Gene Therapies (CGT)

Australia is aiming to become a regional hub in the Asia Pacific region for Cell and Gene (C&G) manufacturing[18]. The Therapeutic Goods Administration (TGA) is the regulatory body responsible for ensuring the safety and efficacy of therapeutic products in Australia[19], and according to a report by AusBiotech[20], the country has several TGA -licensed Good Manufacturing Practice (GMP) sites and five non-TGA licensed sites for regenerative medicine manufacturing sites spread across the country. The report highlights that Australia has nine approved C&G therapies and 153 ongoing clinical trials in 2021 with a rapid clinical trial framework in place[21]. The Cell and Gene Catalyst, national joint venture established and co-led by AusBiotech and Medicines Australia is an initiative that aims to accelerate the development, manufacture, and commercialization of CGT in Australia[22].

Australia also has premier global cancer research hospital pioneering innovative cellular immunotherapy, and 13 clean room GMP facilities to manufacture these life-saving

treatments which holds both commercial supply and clinical trial manufacturing licenses from TGA, ensuring the products from their facility meet global regulatory standards such as for the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA), Japan and other jurisdictions[23].

3.3 Future of the Clinical Trials in Australia: Digital Health and MedTech

The future of clinical trials in Australia is poised for transformation with the integration of digital technologies, including telemedicine and wearable medical devices, expected to enhance data collection and patient monitoring[24]. The adoption of decentralized and hybrid trial models will provide greater flexibility in patient participation. Also, data security and privacy concerns will be heightened, ensuring the protection of sensitive health information in the digital era, and the Privacy Act 1988 which is the principal piece of Australian legislation is protecting the handling of personal information[25].

The Australian Institute of Health and Welfare reports that Australia has an important history with digital technology in the health system, from the pedal-powered radio in 1929 to electronic-prescribing and COVID-19 vaccine passports in 2021[26]. Excellent public and private health systems that are open to trialling and adopting new technologies may interest overseas companies to bring in their business [27].

- **Digital Health**: Australia has invested to build the capabilities and infrastructure to create a world-class platform for the delivery of connected digital healthcare system. The Australian Digital Health Agency and the Digital Health Cooperative Research Centre (DHCRC) were established to strengthen the healthcare infrastructure essential including e-prescriptions and to accelerate the use of data analytics in improving healthcare system[24]. According to the report by Fuji Chimera Research Institution, Japan's telemedicine market will grow by over 60% in 2025 compared to the market size in 2020. IT market for wearable healthcare equipment (smart watches, etc.) and service systems (online monitoring services for the elderly, etc.) are also expected to grow in the next few years[28].
- **Medical Technology (MedTech)**: Even though Australian MedTech companies are typically small-sized start-ups, the country is supported by strong capabilities in areas such as genomic medicine, digital health and precision medicine to lead the sector in the world[29].

4. Efficient and Stringent Regulatory Approval Process and Timeline

4.1 Efficient Regulatory Process

Australia has a streamlined regulatory approval of studies. Category of unapproved therapeutic products covers both medicines and medical devices if the products are not listed in Australian Register of Therapeutic Goods (ARTG). Clinical Trial Notification (CTN) and Clinical Trial Approval (CTA) are two schemes regulated by TGA for clinical trials involving unapproved therapeutic products[30].

CTN scheme for majority clinical trials is basically in place for TGA to have a record of the new trials to be conducted in Australia. TGA has delegated the responsibility of scientific and ethical review of research studies to accredited Human Research Ethics Committees (HREC), hence, it is not involved in reviewing any dossier. TGA only acknowledges the receipt of the notification, and the process is usually settled within one or two weeks. This expedited process

reduces unnecessary duplication of data, reduces costly preparation of extensive applications and ensures research can commence much sooner than in other jurisdictions.

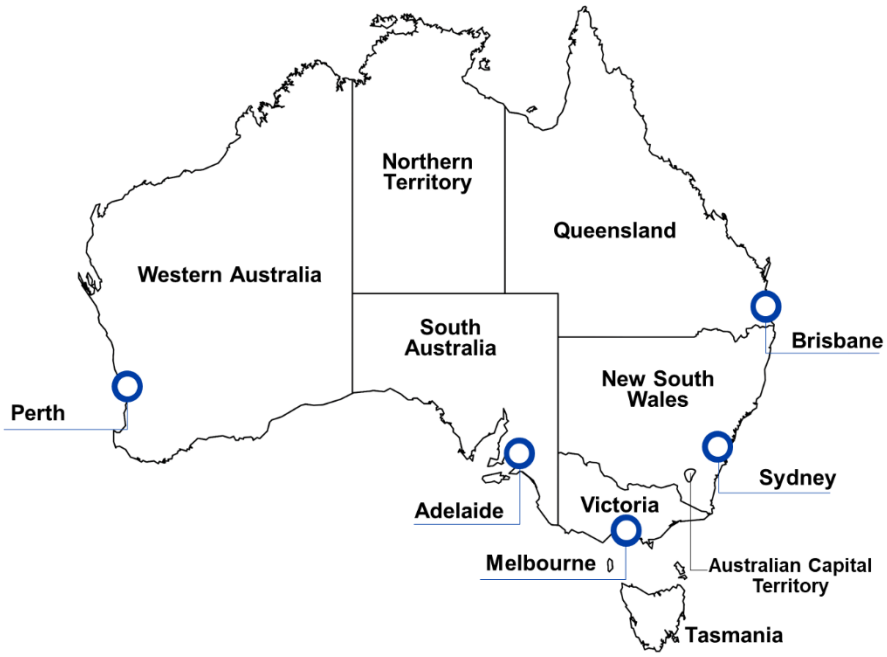
While the CTN scheme may be used for earlier phase studies with adequate preclinical information available, the **CTA scheme** is generally designed for high-risk or novel treatments when there is no or limited knowledge of safety, or for medical device trials when they introduce a new technology which has not been evaluated previously in any country. The CTA scheme will need both TGA and HREC review. The TGA primary responsibility is to review the safety of the product and the HREC is responsible for considering the scientific and ethical issues of the proposed trial protocol[30].

Overall, CTN scheme is to notify TGA via online form only. Whereas CTA scheme requires submission of formal application with scientific data prior to the start of a trial to the TGA after receiving optional pre-submission advice. The other document to submit is the notification form of the commencement of each new trial conducted as per the guidelines approved in the CTA application[30].

The HREC submission is completed via an online platform with minimal required documents. There is one national form for ethics applications across all jurisdictions called Human Research Ethics Application (HREA)[30] to be completed and the online submission will include the protocol, investigator brochure and, if required, the submission of an independent toxicology report etc. The usual review cycle is two to four weeks. National Mutual Acceptance (NMA) is a system for mutual acceptance of scientific and ethical review for multi-centre clinical trials conducted across multiple states in Australia[31]. Under NMA scheme, only one Ethics application is sufficient per regulations for a multi-site clinical trial, result in savings in time and money.

Except for minor dossier requirements, all states have no significant differences in terms of trial quality and processes although large, populated states/territories such as New South Wales, Victoria, South Australia, Western Australia and Queensland have higher competitiveness due to the patient recruitment advantages. Sites and other related companies/facilities can be searched and found on the website by Datapharm Australia Australianclinicaltrials.com/sites[32].

Below is a map of Australia with states/territories and main cities [33]



Research Governance Office (RGO)

RGO at each institution is the responsible party evaluating the risks to the institution and its staff after the HREC approval. The roles and responsibilities of RGO[34]:

Financial management of trials ensuring the budget is appropriately assigned to each department, and the resources allocated for clinical services are not used for research purposes.

Legal compliance

In charge of review and request for revisions to bellow documents and finally facilitation of execution: CDA; Clinical Trial Research Agreement (CTRA); Certificate of Insurance; Form of Indemnity.

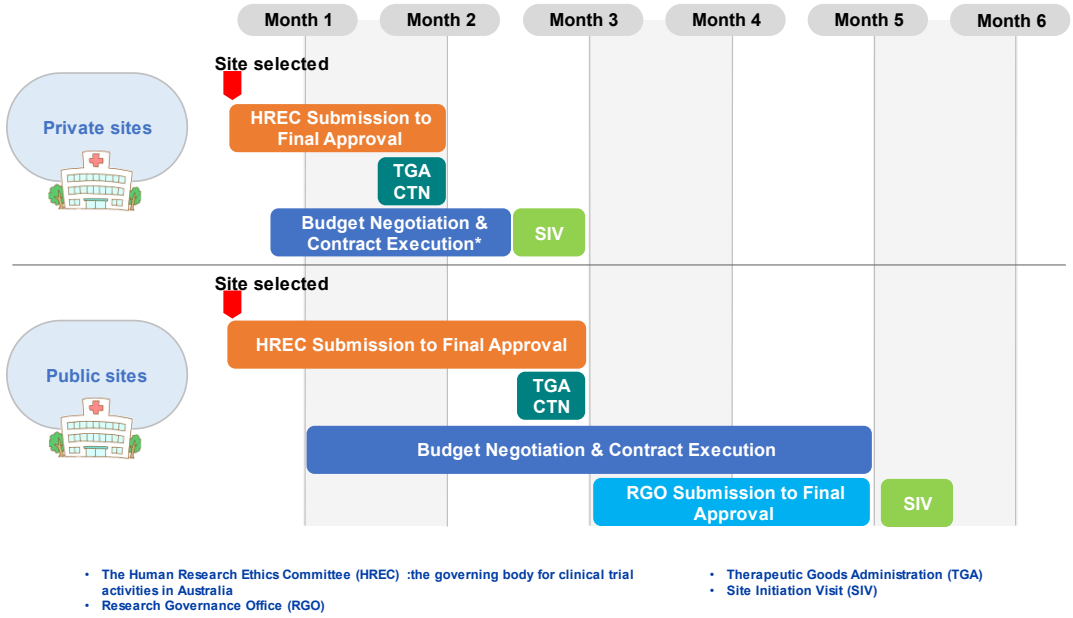
Negotiation and protection of intellectual property for non-sponsored trials

RGO review and approval is an essential review process in public hospitals, however, private sites may not have RGO and there is other review process which is generally much easier and quicker after HREC approval [35].

The below charts demonstrate the overall process and timeline of site start-up in Australia for reference.

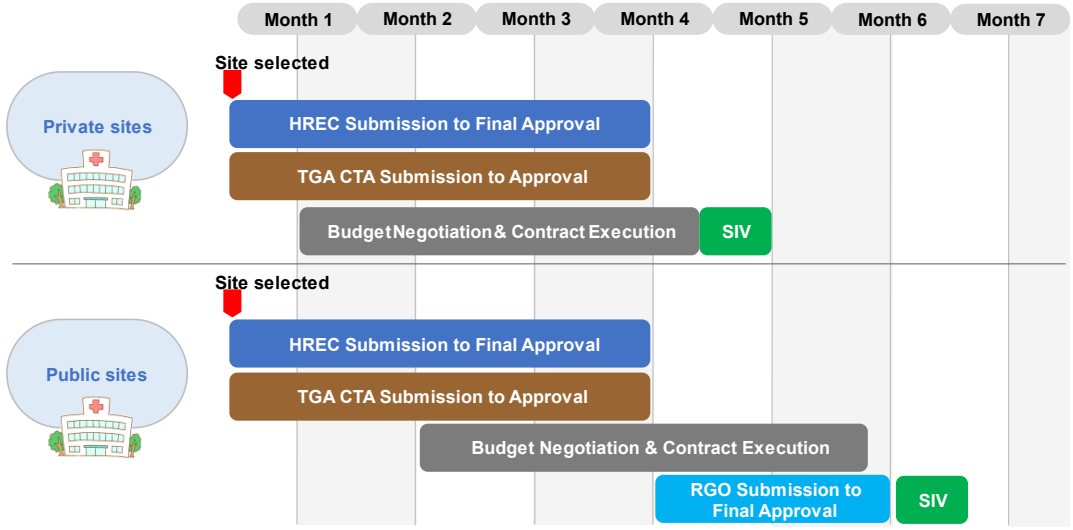
Site Start-up Timelines in Australia

CTN: Clinical Trial Notification scheme for Majority of Applications



- The Human Research Ethics Committee (HREC) :the governing body for clinical trial activities in Australia
- Research Governance Office (RGO)
- Therapeutic Goods Administration (TGA)
- Site Initiation Visit (SIV)

CTA: Clinical Trial Approval scheme for Minority of Applications



- The Human Research Ethics Committee (HREC) :the governing body for clinical trial activities in Australia
- Research Governance Office (RGO)
- Therapeutic Goods Administration (TGA)
- Site Initiation Visit (SIV)

4.2 Stringent Regulatory Framework

Based on the Australian Therapeutical Drugs Act 1989, all trials conducted in Australia must be carried out in accordance with the International Standards of Conduct for clinical trials developed by the International Conference on Healthcare (ICH) and the International

Organization for Standardization (ISO)[36]. As a result of these guidelines, Australian clinical research quality can be wholly relied upon and is viewed with confidence by international regulatory authorities, including the FDA and the EMA and hence Australian clinical trial data can be utilized in other countries, including Japan. Australia's clinical trial data is suitable for both US and European Union (EU) NDA filings. According to FDA data dashboard[37], there were 120 inspections conducted for data from Australia regarding drugs and biologics since fiscal year 2009. Out of all the data, 110 cases were inspected as "No Action Indicated (NAI)" or "Voluntary Action Indicated (VAI)" which means no objectionable conditions or practices were found during the inspection or no administrative/regulatory action is mandatory, and only 10 cases were inspected as "Official Action Indicated (OAI)"[38]. Although adherence to the specific regulatory requirements of the country is essential, there will be an opportunity for marketing authorization without a Japanese local clinical trial if the drug is already approved in Australia, provided there are no major adverse effects reported.

5. Government Support

5.1 Patient Retention and Support

Australia emphasizes a patient-centric approach to clinical development, aiming to enhance patient engagement and recruitment. Initiatives are in place to raise public awareness and involvement in clinical trials through a comprehensive approach by actively promoting among consumers and healthcare providers. Website and informational guides, Australian Clinical Trials[39] have been created to provide a clear understanding of the clinical trial process, enhancing consumer awareness and increasing participation. Additionally, initiatives address cost uncertainties with outlining typical trial costs by the Australian Office of the National Health and the National Health and Medical Research Council (NHMRC)[40]. This authoritative reference assists trial companies and health providers, facilitating negotiations for overseas companies engaging in Australian clinical trials.

5.2 National One Stop Shop

The National One Stop Shop is a national cross-government platform for health-related human research including clinical trials in Australia[41]. The platform provides a coordinated system of approval and reporting processes. It aims to make it easier for patients, researchers, industry representatives, and sponsors to find, conduct, participate, and invest in high-quality and ethical research in the country[42]. The goal is to improve the coordination and harmonization across jurisdictions and offer a single point of access to the sector.

5.3 Government Financial Support and Tax Incentive

The Australian Government is dedicated to fostering the growth of clinical trials in the country and actively addresses barriers through ongoing projects. The Research and Development (R&D) tax incentive scheme offers a globally competitive tax incentive of refundable offset rate of 18.5% above the company's tax rate on eligible expenditure for companies engaging in at least one 'core' R&D activities, including early phase clinical trials[43].

Core R&D activities requirement[44] below:

- The outcome of clinical trial activities must not be known or determined in advance. It can only be determined by applying a systematic progression of work and must be conducted for the purpose of generating new knowledge[45].

- Any supporting R&D activities must directly relate to the core R&D activities, and the activities must be specified

Notably, this incentive allows access for international companies when setting up an entity in Australia (permanent Australian establishment) with the simple process[46] and the R&D entity in its investing phase such as start-up companies are also eligible to the incentive with incurred notional deductions of at least $20,000 AUD on eligible R&D activities. Additionally, companies may obtain expenditure support for R&D activities conducted overseas but scientifically linked to Australian activities.

For the application of the tax rebate, self-assessment for eligibility of entity, activities and expenditure is required[47] as well as registration of R&D activities for every income year to claim the offset followed by lodging forms with the Company tax return to the Australia Taxation Office. Step by step instructions can be found in the Steps for claiming R&D tax offset[48].

Below table shows the incentive and aggregated annual turnover to receive the appropriate tax offset and premium conducted from 1 July 2021[47].

Aggregated Annual Turnover	R&D Intensity	Incentive
Under $20 million AUD	→	Refundable R&D tax offset of Corporate tax rate + 18.5% premium
$20 million AUD or more	All eligible R&D expenditure up to 2% R&D Intensity →	Non-refundable R&D tax offset of corporate tax rate + 8.5% premium.
	Additional eligible R&D expenditure above 2% R&D Intensity →	Non-refundable R&D tax offset of corporate tax rate + 16.5% premium.

In addition, department of Health and Aged Care set the Clinical Trial Initiative which has been funded for Australian researchers and patients to test new treatments through clinical trials. Its focus is on rare diseases and on bringing investigator-led international clinical trials to Australia[49]. Other grants can be found in the R&D grants and incentives[50]. As a result of all government supports and incentives, trials can be 60% less compared to U.S. costs[51] and a publication is showing cost of conducting clinical trial in Japan is greater than that in U.S. for certain analysis[52].

6. Trials Conducted in Australia

BeiGene, Chinese biotech company, has enrolled thousands of patients in clinical trials in Australia since 2014 for Australia's streamlined trials approval system and its diverse patient population and the company has over 2,000 patients at more than 300 research sites across Australia testing products[53]. Earli, US biotech start-up, chose to research and test its cancer detection technology at several sites in Australia with the estimation that at least six months of development timeline will be shorten by speed of the approval process in Australia[54].

Himuka AM Pharma Corp. a multi-asset clinical-stage Japanese biopharmaceutical company, has established Himuka AM Australia Pty Ltd for the development of HM201 in Australia. In April 2023, the entity announced that a Phase 1 clinical trial of HM201[55], a novel adrenomedullin based peptide drug candidate developed for the treatment of Inflammatory bowel disease (IBD), has been completed.

Hiroshi Shinjo, Chief Executive Officer of Himuka AM Australia stated that despite the trial being affected by the COVID-19 pandemic and the severe flooding in Brisbane, the trial overcame the difficulties with the cooperation of the subjects, the clinical site and the CRO.

Another example of a successful conduct of an early phase trial by a Japanese company is Hypertension DNA Vaccine by ANGES[56]. In the ongoing Phase I/IIa clinical trial of a hypertension DNA vaccine in Australia, ANGES evaluated the initial results of the trial after a post-administration follow-up period, which showed no serious adverse events and no safety issues. The DNA vaccine for hypertension is being developed to treat hypertension by producing antibodies (molecules that bind to the target substance through immunological action) against angiotensin II, a substance in the body that raises blood pressure, and suppressing its action in the body. In contrast to many oral drugs currently used in the treatment of hypertension, the injectable DNA vaccine is expected to have a long-lasting effect after a single administration, which will greatly improve convenience for patients, especially the elderly who have difficulty in taking medication.

On the other spectrum of clinical development and looking into success stories of Japanese companies for product registration in Australia, is the example of anticancer agent Halaven® (eribulin mesylate) by Eisai Australia Pty. Ltd. – the Australian subsidiary of Eisai Co., Ltd.- for the treatment of patients with locally advanced or metastatic breast cancer who have progressed after at least two chemotherapeutic regimens for advanced disease. Halaven is the first anticancer agent to be discovered and developed by Eisai in-house and is the only single-agent chemotherapy to demonstrate a statistically significant overall survival (OS) benefit in Phase III studies (EMBRACE study)[57].

7. Things to be Considered by Japanese Companies

Due to attractive features discussed for running trials in Australia, clinical trials and patient recruitment can be very competitive[58]. Australia has been attracting many global sponsors from countries such as from Asia, EU and US, so Principal Investigator (PI) tend to be relatively selective with protocols when they were provided various protocols and to be more interested in advanced therapy/medicines. Competitiveness of patient recruitment can be seen from the fact that many institutions with same therapeutic area and similar indications located in one area, like Cancer Centre of Monash Health and Peter MacCallum Cancer Centre both located in Melbourne[59]. Also, population diversity is limited due to the small overall population compared to other countries with large population. For example, the most populous cities, Melbourne and Sydney have only five million people in each cities[60].

The biggest hurdle for Japanese companies when looking at Australia as clinical trial destination may be the language barrier. Australia's first language is English, so documents preparation and communications with regulatory authorities, clinical investigators, study participants and involved stakeholders will be conducted in English. The professional translator may be hired or assigned in-house English speakers to the projects can result in taking extra time and cost. Additionally, culture and relationship building are different in Australia. The relationship and collaboration are more fluid with PIs and sites because PIs in Australia are generally more approachable and open to communication. In usual case in Japan, Japanese sponsor especially large pharma directly contacts with sites followed by getting touch with PM and CRO whereas in Australia, CRO works as a bridge between sites

and sponsors. Exception might be the time global kick-off meeting is setting up or high level communication including PIs is required between sponsor and sites.

Unlike Japan, Australia is divided into three time zones; Eastern, Central and Western standard time with Daylight Saving Time applicable only to some of the states during October to April[61] which can be a minor obstacle when setting timelines and communicating with stakeholders in different time zones. Difference in public holidays should be considered especially during the yeas-end period. Australia sites and regulatory authorities tend to be closed from the 20th of December until 10 of January[62].

Comparing to Southeast Asia and other developing countries, the cost of conducting clinical trials in Australia can be relatively high due to the difference in quality of trial outcomes and cost of living. Despite its cost efficiency, public sites have limited resources towards clinical trials because they are more patients driven and it can result in delay in expected timelines. Site selection between public and private sites rely heavily on the timeline and funding on the trials.

The foreign exchange risk needs to be considered as we can see from the recent Japanese yen (JPY) depreciation in the second half of 2023. JPY touched the weakest level against the euro since 2008, and fell to the lowest level in four and a half months against the Australian dollar[63]. Currency transfer also can be difficult to manage due to the fluctuating exchange rate of the currencies[64].

8. Conclusion

Regardless of the reason for choosing Australia as a destination for clinical trials, the country's clinical trial process allows flexibility without compromising quality; avoids duplication of processes; and ultimately saves the trial sponsors both time and money. This all combined with the superior scientific talent and excellent medical infrastructure will continue to make Australia a preferred destination for clinical trials. Collaboration is encouraged among academia, industry, and government agencies. Networks and partnerships between different stakeholders enhance the efficiency and success of clinical development effort. Australia actively collaborates with international partners on clinical trials. This collaboration facilitates the sharing of knowledge, resources, and the conduct of global clinical development programs.

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Contact information :

JETRO

Innovation Department

E-mail : IIB@jetro.go.jp

Sydney Office

E-mail : SYD@jetro.go.jp