FROST & SULLIVAN

Australia: *Preferred Destination for Early Phase Clinical Trials*

A Frost & Sullivan White Paper

EXECUTIVE SUMMARY

WHAT

The clinical trials process is complex. It requires substantial investment and skilled human re-sources, and involves risks, not least, the navigation of complex regulatory processes. To over-come these challenges, small biotechnology companies outsource their early phase clinical studies to contract research organizations (CROs). This white paper highlights research on why Australia continues to be a hub for early phase clinical trials.

WHY

Reasons to outsource to Australia vary by country. Fast approval times with lower costs and comparable quality appeal to US companies. Chinese companies seek faster and more transparent approval processes, with results that will be acceptable to the US Food and Drug Administration (US FDA).

There are 3 key benefits in outsourcing early phase clinical trials to Australia:

- **Cost-efficiency:** The Australian government offers attractive R&D tax incentives including cash rebates. According to a cost comparison study, Australia is 28% cheaper than the US before tax incentives; and 60% cheaper after tax incentives.
- **Speed:** The Australian clinical trial process allows flexibility without compromising quality. It avoids duplication of processes, saving the sponsors both time and money.
- **Quality:** Australia has a network of universities, independent medical research institutes, clinical trial networks, biobanks, and CROs. Scientific research conducted in Australia ranks the highest in Asia-Pacific in terms of productivity, impact, and one of the most rigorous patent protection systems in the world. Data from studies conducted in Australia can be used to support international regulatory applications, including the US FDA and European Medicines Evaluation Agency (EMEA).

WHO

Key factors to consider when selecting a CRO:

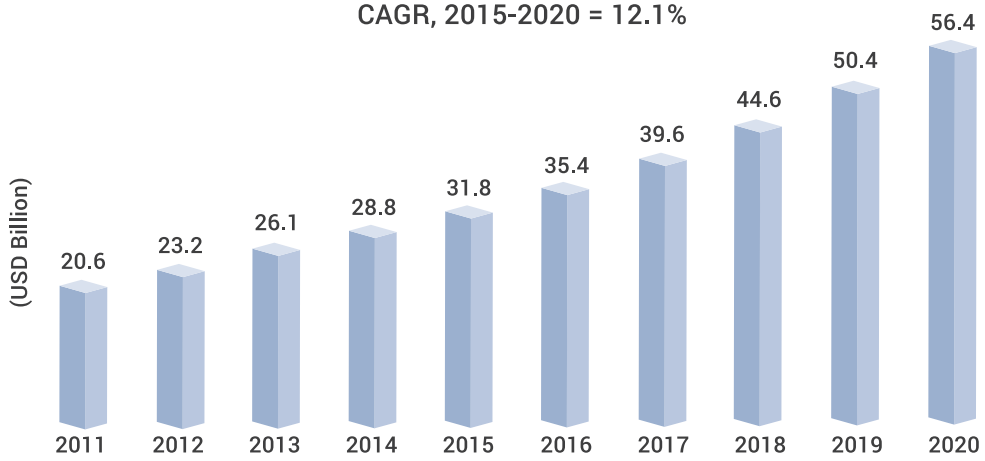
- **Experience:** Expertise in specific therapeutic areas and trial phases; proven track record of trials with biotech and international companies; and thorough understanding of regulatory audits.
- **Capability:** The CRO should have a capable in-house team with strong project management (PM) skills and therapy area experience (Clinical Research Associates or CRAs). Client-centric, flexible and a keen understanding of regulatory requirements in the biotechnology/ pharmaceuticals/devices space are other attributes to look for. The CRO should also offer scalability of IT systems and sophisticated quality systems.
- **Network:** CROs should have international presence and networks, and relationships with the lead investigators, key opinion leaders, and institutions.
- **Cost-competitiveness:** A key consideration for sponsors when choosing between CROs that are similar in quality and capability.

In summary, Australia's superior scientific talent and excellent medical infrastructure makes it a pre-ferred destination for early phase clinical trials.

INTRODUCTION

Pharmaceutical and biotechnology companies are increasingly outsourcing clinical trials to contract research organizations (CROs). In 2015, the global contract CRO market generated USD31.4 billion in revenue, and is forecast to grow at a CAGR of 12.1%, to reach USD56.4 billion by 2020[1].

Total CRO Market: Revenue Forecast, Global, 2011-2020
CAGR, 2015-2020 = 12.1%

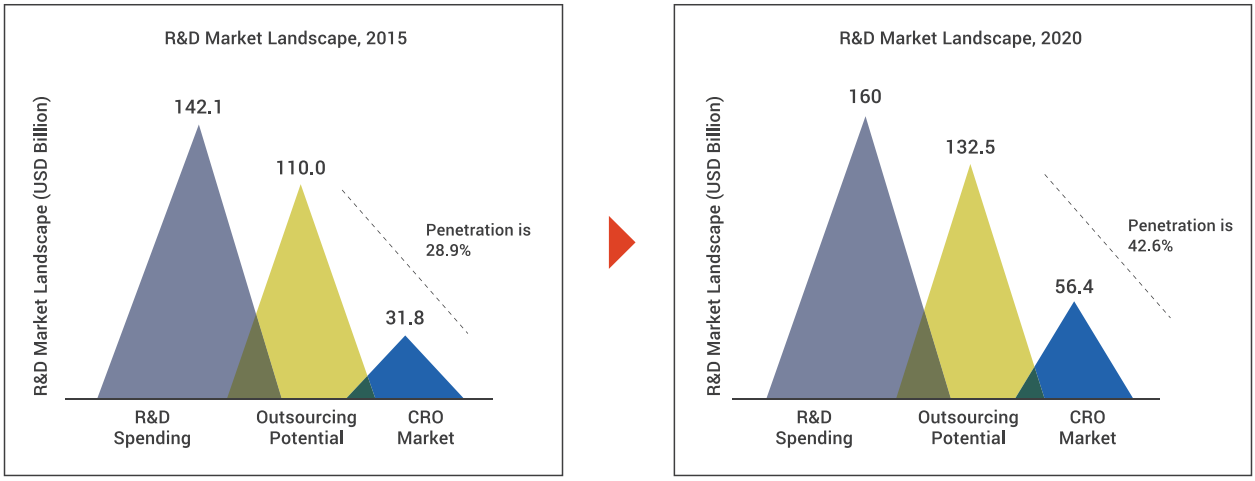


Source: Frost & Sullivan Global CRO report, 2016

The growing demand for CROs underscores the importance of outsourcing in drug research and development. Rising research costs coupled with the loss of revenue due to drugs going off patent are leading large bio/pharmaceutical companies to outsource research and development (R&D) activities in a more cost-effective manner.

More than three-quarters of R&D spending by pharmaceutical and biotechnology companies can be potentially outsourced. To date, CROs penetrate only about 29% of the potentially outsourced R&D budget. Greater penetration of the outsourcing R&D budgets is anticipated to drive the CRO market growth[1].

Total CRO Market: R&D and Clinical Research Outsourcing Landscape, Global, 2015 and 2020



Source: Frost & Sullivan Global CRO report, 2016

While MNCs outsource to CROs to reduce in-house costs and improve scalability, smaller biotechnology companies do it as a faster way to ramp-up. The clinical trials process is complex. It requires substantial investment and skilled human resources, and involves risks, not least, the navigation of complex regulatory processes. To overcome these challenges, small biotechnology companies outsource their early phase clinical studies to CROs[2].

Asia-Pacific is an attractive market for clinical trials. According to a Frost & Sullivan report, in 2015, over 50% of global clinical trials had sites in Asia-Pacific[3]. Sponsors are attracted to Asia-Pacific due to the large availability of patients, many treatment-naïve. Asia-Pacific offers a pool of about 4 billion people, with more than 1.8 billion in easily accessible urban areas[4,5].

Australia is one of the most mature markets in Asia-Pacific for conducting clinical trials. Globally, Australia is recognized as a hub for early phase clinical trials. Each year more than 1,000 research projects are carried out in Australia by pharmaceutical, medical devices, and biotechnology companies, spending more than USD1 billion on clinical trials. Many international biotech companies have also successfully conducted early phase trials in Australia[6].

Reasons to outsource to Australia vary by country. US companies are driven by fast approval times with lower costs and comparable quality, while Chinese companies seek quicker and more transparent approval process, with results that will be acceptable to the US FDA.

This white paper aims to assess the key reasons that position Australia as a preferred destination for biotechnology companies to conduct early stage trials. The report also highlights case studies of foreign companies that have conducted early phase clinical trials in Australia through CROs. The white paper examines the key criteria pharmaceutical and biotechnology companies need to consider when selecting a CRO.

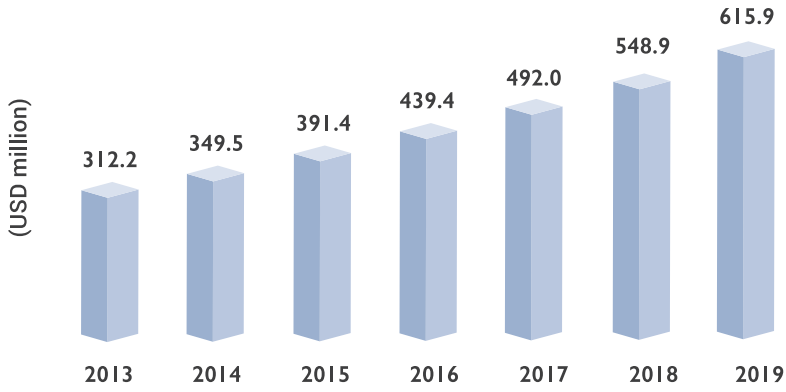
Frost & Sullivan uses a combination of primary and secondary research to understand the merits of conducting early stage clinical trials in Australia. The main areas of focus include the regulatory environment, quality of universities and key opinion leaders, and the cost-efficiency of outsourcing to a CRO in Australia.

The white paper incorporates information obtained from discussions with pharmaceutical and biotechnology companies from the US and China, including their views on the advantages and challenges of conducting clinical research in Australia. Frost & Sullivan also engaged key opinion leaders in clinical trial regulations and tax consultants in Australia to understand the regulatory processes and tax incentives, respectively.

WHY AUSTRALIA IS A DESTINATION OF CHOICE FOR EARLY PHASE CLINICAL TRIALS

Each year more than 1,000 research projects are conducted in Australia by pharmaceutical, medical device, and biotechnology companies, spending more than USD1 billion on clinical trials. Global pharmaceutical companies spend roughly USD200 million in Australia for this purpose. In 2015, the Australian CRO market generated an estimated USD391.4 million in revenue. The market is forecast to reach USD615.9 million by 2019, at a CAGR of 12%[6].

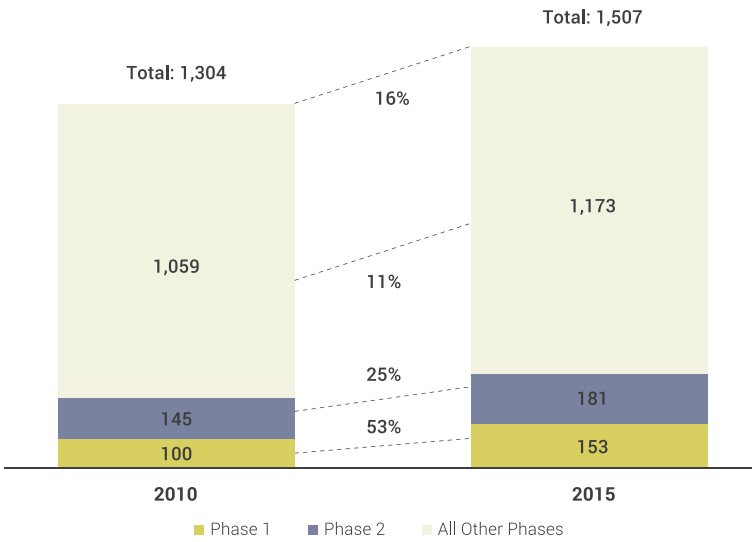
Total CRO Market: Revenue Forecast, Australia, 2013-2019
CAGR, 2014-2019 = 12.0%



Source: Frost & Sullivan, Australia CRO market report: Early Phase Clinical Trials are Set to Drive the Australian CRO Market, 2015.

In 2014, the Phase 1 clinical trials accounted for 6.5% of the total market revenue while 16.3% came from Phase 2 clinical trials[6].

Number Of Clinical Trials Started In A Year In Australia (2010, 2015)



Source: ANZCTR. Australian New Zealand Clinical Trial Registry Website. http://www.anzctr.org.au/ Published 2015. Accessed May 1, 2016.

In the past five years, the numbers of Phase 1 and 2 clinical trials started in a year, have increased at a rate higher than that of the overall trial numbers[7]. Australia is internationally recognized for its superior clinical research and healthcare infrastructure, world-class research capabilities and highly-skilled researchers – all critical pre-requisites for early phase clinical trials. Moreover, early phase trials need only a few treatment-naïve patients. In fact, Australia is fast-becoming the preferred choice for the local biotech and pharmaceutical industry as well as foreign biotech companies that see the benefit of conducting early stage clinical trials in the country.

The three key reasons biotech companies consider Australia as a top choice to conduct early stage clinical trials are:

COST EFFICIENCY

1. The R&D Tax Incentive

The Australian government offers attractive R&D tax incentives to conduct clinical trials in the country. The R&D Tax Incentive, which applies to income years commencing on or after July 1, 2011, is aimed at encouraging smaller firms to engage in R&D[8].

Tax benefits[8,9]

- A 45% cash refund for companies with aggregated annual turnover of less than AUD20 million, and that incur a loss
- A 45% non-refundable R&D tax offset for companies with aggregated annual turnover of less than AUD20 million and that incur a profit
- A 40% non-refundable R&D tax offset for companies with aggregated annual turnover of more than AUD20 million, irrespective of profit or loss

Aggregated annual company turnover	<AUD20million	<AUD20million	>AUD20million
Company Tax Position	**LOSS** 45% cash refund (cheque)	**PROFIT** 45% Tax offset (with any unused offset carried forward)	**PROFIT OR LOSS** 40% Tax offset (with any unused offset carried forward)
	Refundable	Non-refundable*	Non-refundable**
Realized valuer per R&D dollar	45 cents	15 cents	10 cents

Source: R&D Tax incentive. Grant Ready Website. http://www.grantready.com.au/library/scripts/objectifyMedia.aspx?file=pdf/174/06.pdf. Published 2015. Accessed May 1, 2016. Primary interview with Deloitte, Australia.

** Refundable tax offset: Once a company's tax liability is reduced to zero, companies may access a cash refund for any unused offset amount.*

*** Non-refundable tax offset: Companies cannot access a cash refund for any unused offset amount once their liability is reduced to zero. However, the excess offsets may be carried forward into future income years.*

The Australian government wants to encourage innovative companies to set-up and perform R&D in Australia. The current 45% refundable R&D Tax Incentive is lucrative by world standards and assists biotech companies to lower their cost of innovation and R&D. This makes Australia a very cost-effective jurisdiction to carry out clinical trials.

Todd Fielding, Partner, Tax, R&D and Government Incentives at Deloitte Tax Services Pty Ltd, Australia

Eligibility[8]

Applicant eligibility (assessed by the Australian Taxation Office)

- A foreign corporation that conducts R&D activities through a permanent establishment in Australia is eligible. However, it cannot be a tax-exempt entity or majority owned or controlled by a tax-exempt entity or partnership or sole trader or trust other than a public trading trust.
- The R&D must be undertaken on the applicant company's behalf; i.e., the applicant must bear the technical and financial risk, be able to influence or control the conduct and direction of the R&D, and either own or have effective ownership of the R&D results, including the right to exploit the results.
- The R&D Tax Incentive allows foreign corporations to undertake R&D in Australia; irrespective of whether the resulting intellectual property is held in Australia or anywhere else, provided all the eligibility criteria are met.

Activity eligibility (assessed by AusIndustry)

- Under the R&D Tax Incentive, there must be a distinction made between the core and supporting R&D activities. These are to be reported separately.
- Core R&D activities are experimental and whose outcome cannot be known or determined in advance on the basis of current knowledge, information or conducted for the purpose of acquiring new knowledge.
- Supporting R&D activities are activities directly related to the core R&D activities. If these are undertaken for standard operational reasons, the dominant purpose of conducting them must be to support core R&D activities.

Expenditure eligibility (assessed by the Australian Taxation Office)

- Covers most R&D activity expenses including salaries, overheads, contractor costs, feedstock, R&D plant depreciation amounts and materials.
- Applicants must spend a minimum of AUD20,000 on R&D expenditure. The threshold is waived if the R&D is contracted to a registered research provider.
- There is no spending cap for the R&D Tax Incentive. However, for R&D expenditure above AUD100 million, companies can claim a tax offset at the company tax rate, which means there are no additional R&D benefits.

The Australian R&D Tax Incentive is one of the best in the world. What makes it really attractive, especially to small bio-technology companies with low revenues, is the potential cash rebate – most countries offer tax deductions, but not cash refunds. Moreover, the filing process is straightforward and typically refunds come back within a couple of months.

Sukvinder Heyer, Partner at Grant Thornton Australia

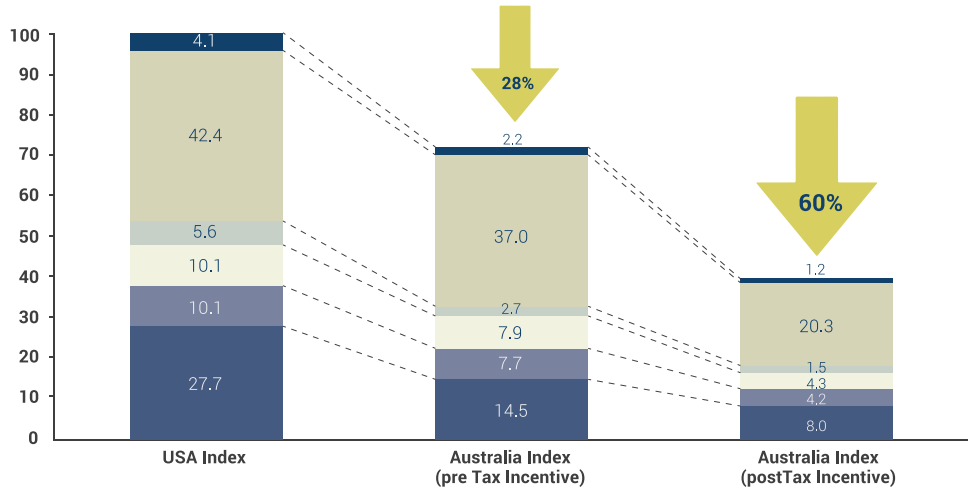
If handled properly, claiming the R&D Tax Incentive is an easy process. Companies can even apply for advance findings on their projects so they gain certainty that their claim is eligible.

Todd Fielding, Partner, Tax, R&D and Government Incentives at Deloitte Tax Services Australia

2. Cost comparison between Australia and the United States[10]

Australia is highly cost-competitive in comparison to the US in the early phase clinical trials. To demonstrate the cost-efficiency between Australia and the US, American CROs were asked to estimate the cost of a standard early phase clinical trial (Phase 1) to be conducted in the US, while an Australian CRO was asked to price the same study using the same specifications and requirements, but to be carried out in Australia. The pricing data was converted to an index with the US study cost indexed to 100. According to the cost comparison study, Australia is 28% cheaper than the US before tax incentives; and 60% cheaper after tax incentives.

Cost Comparison For A Standardized Early-stage Clinical Trial Study Conducted In Australia And The United States



Currency conversion rate: AUD1 = USD0.9

Source: Cost comparison for Phase 1 clinical trial in the US and Australia. Novotech cost comparison case study. 2016.

3.Case study: Cost efficiencies[11,12]

Zafgen, Inc

- Zafgen Inc, a US-based biopharmaceutical company, focuses on obesity or complex metabolic disorders. The company engaged Novotech, a CRO based in Australia, to run a 12-week study with a pool of 150 patients in three different regions of the country, using its new treatment for obesity.
- The biopharmaceutical company selected Australia to run the Phase II study due to the ready availability of potential participants, efficient and fast regulatory environment as well as the favorable tax incentive policies by the government.
- **The tax incentive allowed the project to save up to USD1.8 million.**

The R&D tax incentive is a key benefit to companies conducting clinical trials in Australia, especially small companies with limited resources. It is a substantial incentive.

Alice Chen, Head, Clinical Operations at Zafgen

Conducting trials in Japan and Europe have two challenges: higher cost and language barrier. While in the US, the cost may be higher. Australia clearly has cost and language advantages.

Anita Difrancesco, Vice President, Clinical Development at Samumed

REGULATORY SPEED AND FLEXIBILITY

1. Simplified regulatory framework and process[13]

Most commercially sponsored clinical trials in Australia are conducted under the Clinical Trial Notification (CTN) scheme, which reduces the regulatory burden on clinical trial sponsors. Under this scheme, all clinical trial materials, including the trial protocol, are submitted directly to the institutional ethics committees by researchers at the request of the relevant sponsor. The ethics committee is solely responsible for assessing the scientific validity of the trial design, the safety and efficacy of the medicine or device, the ethical acceptability of the trial process, and the approval of the trial protocol. The institution where the clinical trial is to be conducted gives the final site approval.

The Therapeutic Goods Administration (TGA), the Australian equivalent of the United States Food and Drug Administration (US FDA), is merely notified of a clinical trial after it has received site approval. The TGA does not review any data relating to the trial. However, the TGA has the authority to audit and enquire into the management of a clinical trial.

The CTN scheme eliminates the duplication of processes, enabling sponsors conducting clinical trials in Australia to save both time and money.

Australia has a streamlined regulatory and ethics review process; one can get a clinical trial up and running in a short period of time.

Vice President, Clinical Research, US-based Cancer Therapeutics Pharmaceutical Company

I have been involved in clinical trials in North America and Europe. I have yet to come across a more standardized contract process than what Australia has.

Alice Chen, Head, Clinical Operations at Zafgen

2. Flexibility in the clinical trial process[13]

The Australian clinical trial process allows flexibility without compromising quality. For example, companies conducting clinical trials in Australia do not require the US FDA Investigational New Drug (IND) application approval. Data output from studies carried out in Australia meet global standards and can be used to support international regulatory applications, including the US FDA IND submission. This makes the process more efficient, flexible yet ethical.

3. Government commitment to reduce time and cost[13]

Clinical trial reform is an integral part of the Australian Government's national macroeconomic reform agenda, underlining the country's ambition to remain one of the world's leading destinations for clinical trials. In partnership with the principal stakeholders, the Australian Government is in the process of implementing a series of reforms to further minimize study start-up times, boost patient recruitment, and standardize clinical trial costs.

- **Standardize clinical trial costs to streamline processes and save time:** Plans are underway to publish standard costs for clinical trials to enable sponsors to draw up budgets and reduce individual sites' contract negotiation times.
- **Improve coordination across states:** The National Mutual Acceptance (NMA) program estab-lished in four key states accounts for 90% of clinical trial activity in Australia. The NMA will ensure mutual acceptance of scientific and ethical reviews for multi-center clinical trials.
- **Raise and improve consumer awareness:** The Australian Government website, australianclinicaltrials.gov.au, is easy to use and comprehensive. It has also published the "Consumer Guide to Clinical Trials" to educate consumers about the risks and benefits of participating in clinical trials.
- **Build and enhance capability:** The Australian Government has nationally-accredited education and training courses for investigators and site personnel.

4. Case Study: Regulatory Speed and Flexibility

Case study A[14]:

Samumed Inc

Based in California, Samumed Inc is a pharmaceutical company focusing on advanced regenerative medicine and oncology applications. Samumed worked with an Australian CRO to enroll 29 patients with Androgenetic Alopecia (AGA), or male pattern baldness in two months, for its Phase 1 clinical trial in Australia.

The efficient regulatory pathway ensured that Samumed was able to achieve a rapid start-up. Unlike the US, Australia does not require the Investigational New Drug (IND) application prior to commencing Phase 1 clinical trials. Samumed conducted the trial under the Clinical Trial Notifica-tion (CTN) Scheme, where it submitted research proposals directly to the Australian ethics committees (ECs) that oversee the ethical and scientific review. The EC approved and notified the TGA, preventing unnecessary duplication of processes, saving the sponsor time.

Since the CRO conducted the trial at a private site, a private ethics committee – the Queensland Institute of Medical Research (QIMR) – acted as the central Human Research Ethics Committee (HREC), resulting in quicker start-up compared to a public site. Samumed received the protocol approval in 1.5 weeks from the time of submission.

(Novotech Samumed Case Study, 2016)

Case study B[15]:

OncoMed Pharmaceuticals Inc

OncoMed Pharmaceuticals Inc, a US-based cancer therapeutics pharmaceutical company, conducted three Phase 1 oncology studies in patients with three types of cancers. The company worked with Novotech, an Australian CRO that was able to recruit seven patients from six sites for the metastatic colorectal cancer study, 46 patients from seven sites for non-small cell lung cancer study, and 56 patients from six sites for the pancreatic cancer study.

OncoMed benefited from the flexibility of the clinical trial processes. The company was permitted to revise the dosing schedule. OncoMed submitted revisions to the protocol to the relevant Institutional Review Boards (IRBs) and regulatory agencies and conducted ad-hoc review meetings with the CRO and the DSMB (including investigators) to ensure the immediate implementation of changes. The program underwent further adaptation over the next four years. The CRO promptly implemented protocol changes in the Electronic Data Capture (EDC) database. It also organized training for investigators and site staff on the amended protocol to ensure continued enrollment and data collection. This resulted in high-quality data standards that meet US FDA regulations.

One of the main reasons most Chinese companies opt for other countries to run early phase clinical trials is the time taken to get the China Food and Drug Administration (CFDA) approval which is longer than gaining approvals in other countries.

Head of Regulatory Affairs, RG-Pharma China

CLINICAL TRIAL QUALITY

1. Conducive ecosystem[13]

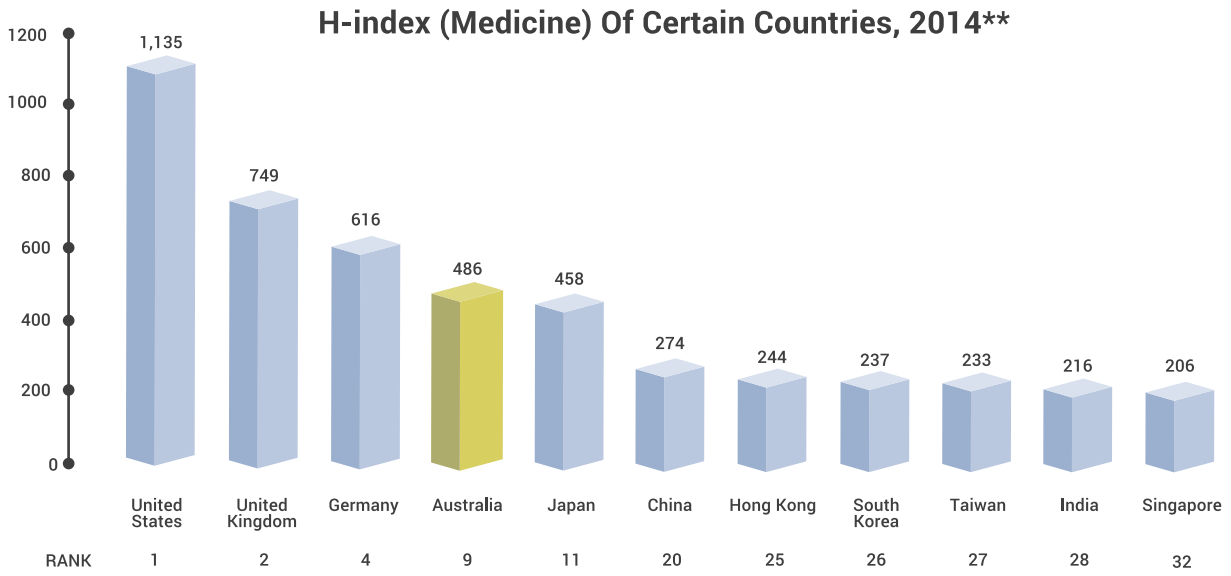
Australia is globally recognized for quality scientific and clinical research. The country offers competitive advantages such as excellent research and healthcare infrastructure, high-quality data capabilities and a network of internationally accredited institutions. With state-of-the-art testing equipment as well as experienced and highly-skilled research teams, Australia has a well-established ecosystem for early phase clinical trials.

The Government reportedly spends more than USD3 billion each year to facilitate medical and clinical research and enhance Australia's medical research infrastructure[16]. The National Health and Medical Research Council (NHMRC), the primary sponsor organization for clinical trials, assists with funding for research and works with key stakeholders to uphold ethical policies within the scientific community. The Australian ecosystem includes:

- **Universities:** Australia has more than 40 universities; some linked to teaching hospitals, while many focus on clinical research.
- **Independent Medical Research Institutes, Biobanks:** Australia has over 50 independent medical research institutes; many operate in close partnership with universities and teaching hospitals, providing a direct interface between laboratory research and clinical practice. Australia has numerous biobanks including cancer and brain banks.
- **Clinical Trial Networks:** Australia has more than 50 clinical trial networks, led by highly-skilled clinicians that can facilitate access to both patients and clinical trial-ready infrastructure.
- **Contract Research Organizations (CROs):** Australia has an experienced and long established CRO market, ranging from independent locally based CROs to affiliates of global firms.

2. Highly-skilled researchers[17,18]

Introduced in 2005, the H-index provides an estimate of the importance, significance, and broad impact of a scientist's cumulative research contributions[16]. Australian scientists in Medicine have the highest H-index in Asia Pacific, reflecting the quality (productivity and impact) of the research in the country[17].



**H-index (an index that attempts to measure both productivity and impact of the publication of the scientist)*

***2014 is the latest data available from the source*

Source: SCIMagoJournal and Country Rank, 2014. Website: www.scimagojr.com. Accessed May 5, 2016.

3. Acceptance by major international organizations[13]

Australia adheres to a well-developed ethical and regulatory framework. Some of the standard codes of conduct are adopted from the International Conference on Harmonisation (ICH) and International Organization for Standardization (ISO). Australia's scientific and clinical community also mandates the standards of good clinical practice (GCP) across all trials, ensuring high-quality results. The Therapeutic Goods Administration (TGA) also closely aligns its prevailing regulatory standards with international counterparts including the relevant European Union guidelines, allowing for easier integration and acceptance by institutions globally.

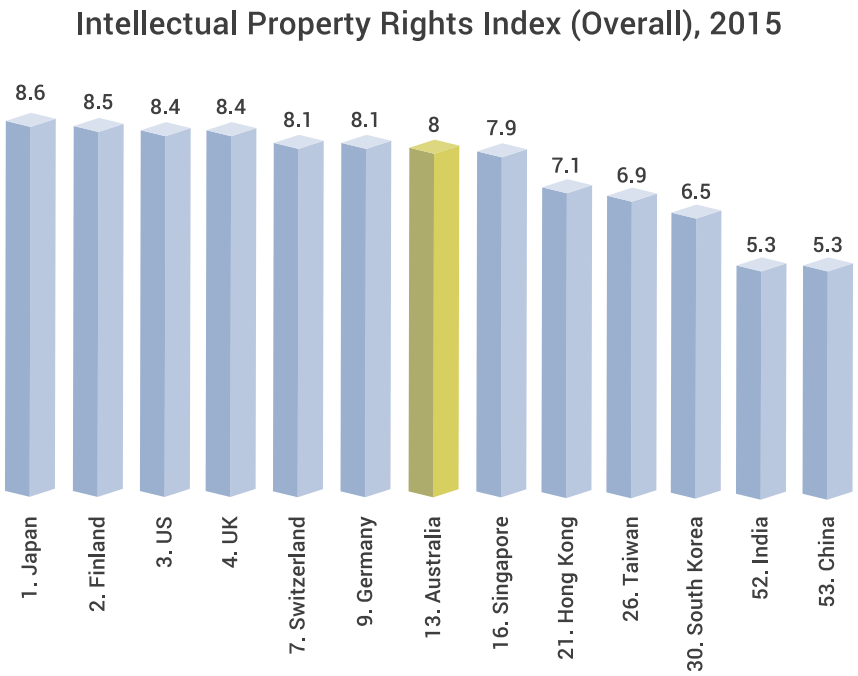
Data output quality from studies conducted in Australia can be used to support international regulatory applications, including the US FDA and European Medicines Evaluation Agency (EMEA).

For Chinese companies that want to market their product internationally, it makes sense to conduct early phase trials in Caucasian population countries, whose clinical trial data would be accepted by the CFDA, US FDA and EMEA. I would recommend US, Europe or Australia, but I would say Australia gives more competitive pricing than the rest.

Head of Regulatory Affairs, RG-Pharma China

4. Strong patent laws[19]

Australia has one of the strongest intellectual property rights protection systems in the world. According to the International Property Rights Index, Australia's intellectual property rights is ranked 13th most secure in the world out of 129 countries.



** Intellectually Property Rights index overall is an index that comprises Protection of Intellectual Property Rights, Patent Protection, and Copyright Protection. This index has compared 129 countries globally.*

Source: The International Property Rights Index 2015. Website: http://internationalpropertyrightsindex.org/countries. Published 2015. Accessed May 5, 2016.

5. Case study: Quality of clinical trials[20]

BAROnova Inc

BAROnova Inc, a clinical-stage medical devices company based in Goleta, California, is focused on developing non-surgical non-pharmacologic devices to induce weight loss. The company developed a novel intra-gastric device using transesophageal delivery for obesity treatment. Its innovative TransPyloric Shuttle® is designed to slow the digestion process and create a sensation of fullness. The device is placed into the stomach endoscopically through the mouth as part of the 15-minute outpatient procedure, and may be removed as needed in a similar fashion and timeframe. BAROnova conducted a pilot clinical trial with Australian CRO, Novotech, at the Gastric Balloon & Lapband Australia Clinic and the Prince of Wales Hospital, Sydney, Australia.

The pilot trial was led by principal investigator, Dr George Marinos, gastroenterologist, and senior lecturer at the University of New South Wales. Dr Marinos' clinical expertise, cutting-edge facilities, and access to the right patient group, contributed to the success of the trial. The six-month study resulted in positive findings validating the efficiency and safety of the product. The human research ethics approved the clinical trial while the TGA approved it as a Clinical Trial Notification (CTN) device trial.

When we decided to look outside to conduct our clinical trials, Australia emerged as our #1 choice. It met all our criteria – a clear regulatory process, clarity on expected timelines, a high standard of care, the same language (English) so no translation was required, and expertise in the medical devices field.

Lian Cunningham, MD, PhD, Vice President,

Clinical Affairs & Regulatory Affairs at BAROnova

KEY FACTORS IN SELECTING A CRO FOR EARLY PHASE CLINICAL TRIALS

EXPERIENCE

Companies intending to conduct clinical trials in Australia look for experience in the specific phase and therapy area. The CRO should have a track record working with smaller biotech firms and multinational companies. This provides sponsors the assurance that the CRO thoroughly understands the challenges working with smaller foreign biotech firms and businesses in a different time zone. The CRO's knowledge of regulatory audit is also important to some companies.

CAPABILITY

Companies evaluate the core competencies of the team especially the project manager and clinical research associate (CRA) and their respective expertise in project management and therapy areas. Companies prefer that CROs have full-time staff rather than contractors. Sponsors expect the CROs to be client-centric and flexible. Companies look for CROs that understand the regulatory requirements in the pharmaceuticals/devices/biotechnology space. Quality and scalability of IT systems and infrastructure, as well as sophistication of quality systems (e.g., standard operating procedures, internal audits, and vendor selection process), are also important criteria.

NETWORK

Companies seek CROs that have an international presence so they can conduct trials simultaneously in multiple countries. Companies also prefer CROs that foster relationships with the lead investigators, key opinion leaders, and institutions.

COST COMPETITIVENESS

One of the key factors companies want from a CRO is cost competitiveness.

EXPERIENCE

- Experience in specific therapeutic area and trial phase
- Experience working with smaller biotech companies
- Experience working with foreign companies
- Experience with regulatory audits

CAPABILITY

- Capable team (PMs CRAs)
- Use of own full time staff vs. vendors
- Flexible client-centric approach
- Understanding of regulatory requirements in the biotechnology/ pharmaceuticals/ devices space
- Quality and scalability of IT systems and infrastructure
- Sophistication of quality system(e.g. SOPs, internal audits, vendor selection process)

NETWORK

- International presence and network
- Local relationships with the lead investigators, key opinion leaders, and institutions

COST COMPETITIVENESS

- Ability to provide high-quality, efficient management of clinical research projects in a cost-effective manner

When selecting a CRO, it is essential that the CRO has relevant experience in the therapeutic area and trial phase. I usually meet the team assigned and it is im-portant that the team has relevant experience in their functional areas.

Alice Chen, Head, Clinical Operations at Zafgen

The only challenge in conducting clinical trials in Australia was the logistics associated with long distance communications across different time zones. Novotech in Australia made sure they conducted all calls at a time suitable to us. The team was capable; they communicated directly with the investigators most of the time in our absence, which prevented unnecessary delays.

Vice President, Clinical Research, US-based Cancer Therapeutics Pharmaceutical Company

We look for the CRO's understanding of the specific medical devices space, experience with medical devices trials, understanding of the regulatory requirement, quality of work, ability to work with small companies, competitiveness on cost, and network with the right principal investigators.

Lian Cunningham, MD, PhD, Vice President, Clinical Affairs & Regulatory Affairs at BAROnova

We wanted to launch the product in a few countries so we wanted a CRO with a presence in multiple countries. The other important factors were cost-competitiveness and reputation of the CRO in the market.

Chief Finance Officer, China-based Pharmaceutical Company that Conducted Phase 1 Clinical Trials for its Oncology Product in Australia

LAST WORD

With a strong research environment, Australia is a vibrant, world-recognized destination for early phase clinical trials. A leader across the key dimensions of speed, quality and cost, Australia has fast, flexible clinical trial approval processes at a competitive global cost. Australian investigators are highly regarded, and data from Australian trials is internationally recognized. The Government also provides attractive incentive schemes to boost R&D.

In summary Australia is a preferred destination for early phase clinical trials.

I would recommend Australia for early phase clinical trials because it has a simplified regulatory process and the data quality complies with the US requirements. Choosing the right CRO is important; I look for experience of the team in the therapeutic area and cost competitiveness. CROs in Australia have met my expectations.

Anita Difrancesco, Vice President, Clinical Development at Samumed

I would recommend Chinese companies that want to expand internationally to conduct their early phase clinical trials in Australia. It produces quality clinical trial data that is less expensive than the US and takes a shorter time to set up. I would advice first setting up an office in Australia to take advantage of the tax incentives Australia offers.

Chief Finance Officer, China-based Pharmaceutical Company

Absolutely, I would recommend incorporating Australia into your clinical trial plans. There are many logistical considerations when working outside the US. Language is one of them. Since Australia is an English-speaking country, there is no need to translate subject-facing documents saving time and money. The R&D tax credit, efficient ethics submission process, standardized contract template are some reasons why I would recommend Australia for conducting clinical trials.

Alice Chen, Head, Clinical Operations at Zafgen Inc

I had a good experience conducting clinical trials in Australia and the CROs in Aus-tralia that we worked with have generally met our expectations.

Lian Cunningham, MD, PhD, Vice President, Clinical Affairs & Regulatory Af-fairs at BAROnova

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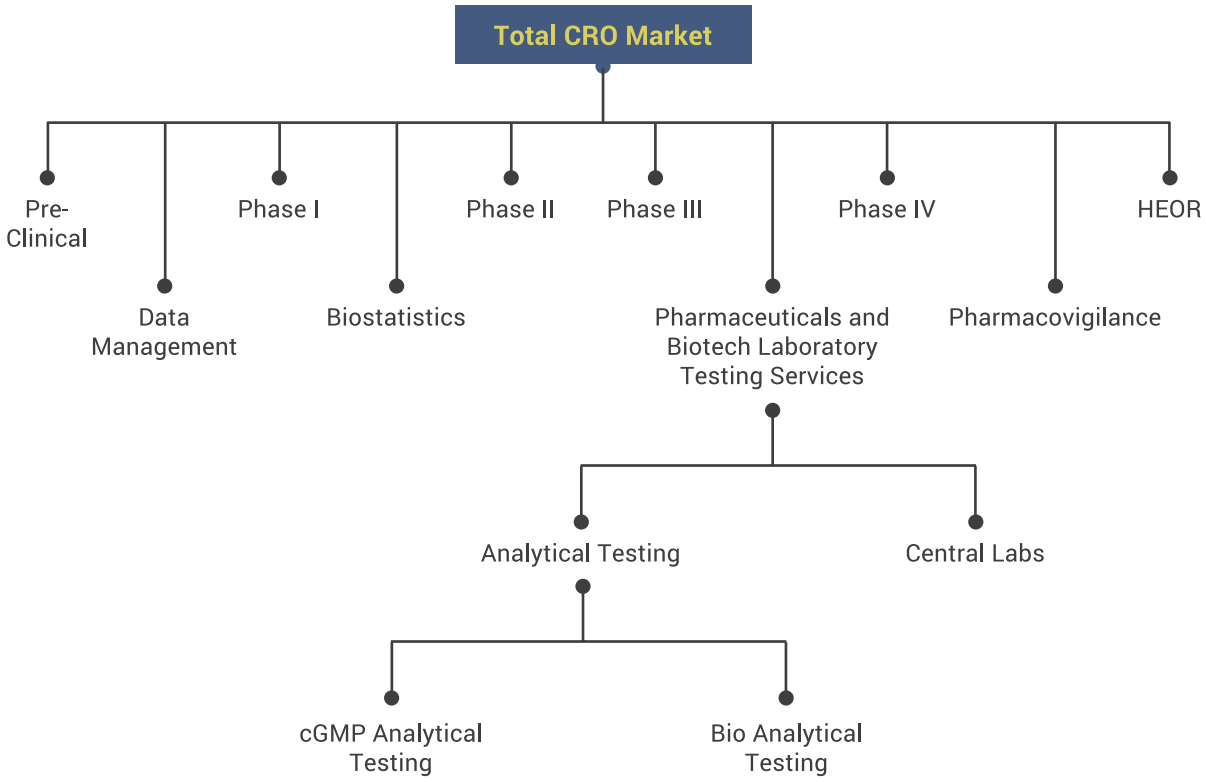
DEFINITIONS



Source: Frost & Sullivan analysis.

Contract Research Organization (CRO): an organization that provides independent development services for pharmaceutical and biotechnology markets. Besides providing basic support services, CROs now offer a broad range of clinical, central lab and analytical services that suit the present demands of the market and the sponsors.

Early phase clinical trials: Early phase clinical trials include Phase 1 and Phase 2 clinical trials.

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