CLINICAL TRIALS WHITE PAPER

# Enhancing Melbourne's clinical trials reputation

BioMelbourne Network
Progressing BioIndustry

## Unlocking Melbourne's competitive advantage

Melbourne and Victoria is a global destination of choice for clinical trials, and there is great opportunity to leverage this and drive it forward even further, thereby supporting economic and social returns.

Elucidating the key and current challenges and opportunities for Melbourne's clinical trials' sector, BioMelbourne Network partnered with City of Melbourne to convene a focus group of senior clinical trials professionals in May 2025 and identify actionable opportunities that would make a difference to sector support. The session predominantly focused on fostering our reputation as an international leader in clinical trials while considering resources, process, infrastructure and capabilities.

The focus group builds on BioMelbourne Network's partnership with the City of Melbourne, and delivers on elements of their Biotech Roadmap, which identified clinical trials as a key priority moving forward. This focus group is a first step in working with the sector to explore opportunities to strengthen Melbourne's reputation as a leading clinical trial destination.

Concentrating on commercial trials, discussion highlighted Melbourne's strengths across the clinical trials sector and observed that with global landscape changes, now is the time for Melbourne, and Victoria, to showcase its impressive capabilities.

**Actionable opportunities**

1. Address the disconnect between Victorian clinical trial service providers through a Community of Practice with in-person networking events and an online community.
2. Run, or continue, a clinical trials-focused mentoring programme to encourage new workforce.
3. Refresh and promote the Victorian Clinical Trials Gateway.
4. Deliver promotional campaign and storytelling directed towards three target audiences: participants – healthy volunteers and patients; workforce; and inbound sponsors.
5. Attract/coordinate incoming trade missions seeking clinical trial expertise.

## Melbourne as a global destination for clinical trials

BioMelbourne Network brought together leaders from contract research organisations, clinical data management, clinical research services, clinical trials suppliers, clinical trial sites and clinical trials administrators, contract development and manufacturing organisation, and consultants to discuss actionable opportunities to solidify Melbourne's position as the global destination for clinical trials and realise its full potential.

The key points raised during the discussion can be grouped into the following five topics:

1. **Fragmentation of our clinical trials network**
   Melbourne boasts a highly concentrated and well-equipped clinical trials ecosystem, yet its full potential is limited by fragmentation, inconsistent processes, and lack of coordination.
2. **Workforce**
   Significant workforce shortages in Melbourne limits participant recruitment and increases timelines and the costs of clinical trials.
3. **Storytelling**
   Melbourne is already a leading clinical trials destination, but our strengths are under-recognised and under-promoted.
4. **Participant recruitment**
   Recruiting both patients and healthy volunteers remains a critical challenge across Melbourne's clinical trials, driven by a changing population health, public sector-mistrust, a lack of central participant database, and inclusion barriers for regional and culturally diverse participants.
5. **Cost, timeline and regulatory**
   Challenges in start-up timelines, regulatory approvals, workforce and participant recruitment are leading to increased costs and potentially decreased competitiveness.

## Discussion overview

### *Navigating Melbourne's clinical trials networks*

Australia is different from international clinical trial ecosystems: whereas large global companies offer end-to-end services internally, Australia's strength is in its specialised, highly geographically-concentrated and well-equipped clinical trials ecosystem. Each organisation brings niche expertise and unique capabilities. Over the past decade, the ecosystem has evolved significantly. Melbourne is now a collaborative network of specialised organisations, and this collective strength should be celebrated. Success depends on recognising the value of every part of the system.

The central location of the Parkville precinct, as well as key clusters in Bundoora and Clayton precincts, offer exceptional co-location of resources and infrastructure. Melbourne hosts two universities within the global top 50, central laboratories, contract research organisations (CROs), contract development and manufacturing organisations (CDMOs), specialist clinical services, a 24-hour international airport, and a number of active regional players.

The proximity of these assets, within a 'tennis ball throw' of each other, offers immense potential, however this strength is not fully harnessed due to some fragmentation across the sector. Clinical trial sites are actively seeking trials, and CROs are eager to place them, yet fragmentation, unclear points of contact, and inconsistent processes can impede efficiency. Melbourne comprises many accomplished and experienced organisations, but they can operate in silos and fail to adequately promote or refer each other because they're unaware of each other's capabilities. Connecting the clinical trials sector, promoting its collective strength, and enabling cross-promotion would support an increased volume of inbound business.

From a clinical site perspective, operational challenges include uncertainty around sourcing and labelling investigational products. Clinical trial pharmacists and staff are sometimes unsure of where to obtain materials or how to meet compliance requirements. A sector-wide concierge or coordination service could alleviate these issues, though ideally it would be hosted by a neutral and accredited body (such as a dedicated incubator), rather than within a university or medical research institute, which may lack the necessary accreditation, for example NATA (National Association of Testing Authorities).

Parkville has already begun to demonstrate what's possible through effective precinct branding. It's time to build on that momentum and present a united Melbourne clinical trials sector – one that celebrates difference, leverages collaboration, and grows the pie for everyone.

**Opportunities**

To address the disconnect between clinical trials service providers, and unlock even greater collaboration, provide in-person networking events for clinical trials service providers and an online **community of practice**.

Furthermore, refreshing and ensuring ongoing sustainability of the **Victorian Clinical Trials Gateway** will ensure that clinical trials organisations can be showcased to international sponsors as an entire, complete and connected ecosystem made up of over 100 clinical trial service providers.

### *Workforce*

Australia is currently facing a significant workforce shortages in clinical trials, with low staffing levels further contributing to the sector's capacity limitation and leading to higher costs.

Addressing workforce gaps is essential to ensure the sector's long-term sustainability and affordability. Clinical trials are increasingly delivered through national networks; with approximately one-third of Australia's clinical trials taking place in Victoria, ensuring Melbourne companies are backed by a strong and capable workforce will underpin the nation's ability to attract and conduct multi-centre trials across the country. Melbourne and Victoria have the opportunity to solidify their position as the clinical trials gateway to Australia.

Encouraging early career researchers and professionals to enter the clinical trials sector is critical to improving future workforce capacity. Career development of investigators, study managers and coordinators needs to be invested in and pathways into the sector including required qualifications and credentials explained.

It was also acknowledged during the discussion that future workforce efforts should also include doctors involved in medical research. Whilst a 3-6 month clinical trials rotation is included in their training, this exposure is often too brief to build full competency. Structured, apprenticeship-style training programmes are recommended to provide hands-on experience and mentorship. Additionally, structural processes could be considered to address the variation in how clinical trial responsibilities are integrated into clinical workloads – with some health services allocating time during standard working hours, while others expect research activities to be conducted on top of clinical duties. Disparity in structure may cause uncertainty in research responsibilities, resourcing requirements and commitments, and potentially lead to clinician hesitancy to get involved in trials.

**Opportunities**

Development, or extension, of a mentoring programme specifically focused on increasing the interest in and awareness of career pathways into the clinical trials sector. It aims to facilitate matches between students and EMCRs and clinical trials professionals to improve uptake of clinical trials roles early in careers, leading to a highly experienced workforce within just a couple of years.

### Storytelling

Melbourne is already Australia's leading destination for clinical trials, yet this is not widely known or promoted.

Clear storytelling and education are critical to: attract inbound business, retain local innovation, and position Melbourne as a world-class clinical trials hub. There is an opportunity to improve and grow Victoria's story – backed by data – of how local infrastructure and capabilities have enabled successful trials, especially where Australian products are developed, trialled, and retain IP locally, but also of global companies having success in running clinical trials in Australia.

**Campaign elements could include:**

- A shared messaging framework: Five key messages for all stakeholders to use consistently
- Promotional materials: Maps, statistics, success stories, brochures, flags, and digital content
- Public events and activations: Celebrate *International Clinical Trials Day* and leverage major events like the Australian Open or Grand Prix to boost visibility
- Community outreach: Increase awareness in regional and multicultural communities, with multilingual materials
- Education initiatives: Promote understanding of what clinical trials are and the value of participation – including improved access to high-quality care.

Above all, we must lead with pride. Melbourne is more than the sum of its parts: a vibrant, diverse, highly-capable ecosystem with world-class facilities and deep clinical expertise. By clearly telling our story and presenting a unified front, we can grow participation, attract more global trials, and reinforce Melbourne's position as a clinical trials leader.

**Opportunities**

Storytelling should consider three distinct segments, each with their own key messages:

1. Inbound business: While Melbourne is widely recognised for its strength in oncology, this can be expanded. Emerging areas of excellence should be elevated and aligned with future global demand. For example, Melbourne already has strong global research capabilities in childhood allergies, however, this is not widely promoted. This campaign would aim to position Melbourne as the natural "portal of entry" for trials in Australia and highlight Melbourne's capabilities and strengths in clinical trials.

2. Patient recruitment: A city-wide campaign over 6–12 months should showcase Melbourne's capabilities, highlight success stories, and engage key audiences: patients, healthy volunteers, and the wider Victorian public, with the aim of rebuilding confidence in clinical trials and driving participation. Messaging should be unified, data-driven, and highly visible – across social media, print, and physical spaces, such as flags in the City of Melbourne.

3. Workforce building: To increase numbers of both graduates and experienced professionals moving into the clinical trials space, a promotional campaign with collateral should be developed to improve visibility of clinical trials as a career pathway and explain potential roles and trajectories. The campaign could interact with the Careers Hub, launched in July 2025, that showcases the full spectrum of possible roles in clinical trials research.

### *Participant recruitment*

The clinical trials sector is reliant on the recruitment of healthy volunteers and patients. Whilst our hospital system can support an increase in patients, our clinical trials organisations struggle to recruit them.

Four key themes were identified as contributing to these recruitment challenges:

1. The healthiness of our population has changed
2. Culture: There is public fear and apprehension
3. No central database of participants
4. Lacking regional and diverse recruitment.

### *1. Changing healthiness*

Global health is improving, in part due to the growing effectiveness and availability of diagnostics, treatments and therapies. This progress, however, has made it increasingly more difficult to recruit healthy volunteers for clinical trials, as fewer individuals meet the necessary exclusion criteria. For example, the prevalence of antidepressants and stimulants (eg. ADHD medication) now excludes many individuals. Anecdotally, recruiting healthy volunteers in other Australian states is even more challenging than in Melbourne.

### *2. Building trust in clinical trust*

The general public is hesitant to participate in clinical trials and whilst Australia has overall trust in science, a persistent general apprehension in the broader health technologies industry remains, particularly since the Covid-19 pandemic. For example, vaccine hesitancy is widely observed with immunisation rates falling each year since the pandemic, and paediatric clinical trials are proving particularly hard to recruit for.

A culture change needs to happen, as the standard of care in Australia is very high. This is evidenced in the fact that oncology recruitment is relatively easier than for conditions that are non-critical. The appetite to participate depends on the type of medicine/therapy, the phase and the criticality of disease/condition – with the most difficulties observed in trials for products with milder therapeutic benefit where patients often decide to continue with standard treatment instead.

Clinical trials should be a treatment option for all patients, with some trial centres running a trial for just one patient, if the need is there.

Culture change takes time and a story-telling campaign, as detailed above, would support improved public trust in our world-class clinical trials sector.

### *3. No central database of participants*

Clinical trials organisations currently use their own databases to find participants; a national and central registry for participant recruitment does not currently exist. Developing a central database would support recruitment, as well as demonstrate to potential sponsors that Australia does indeed have the critical mass of participants to run the trial here.

A further challenge in delivering a central database is that many of our diseases are not reportable and therefore we simply don't have the data to create a central database of patients. The Australian Institute of Health and Wellbeing holds data on the numbers of people with reportable diseases, however, it would require significant analysis to translate this data into actionable information and would still exclude all non-reportable conditions.

The Federal National One Stop Shop (NOSS)' 'national front door' was raised as a possible answer to this challenge. According to the group, the NOSS was originally intended to overcome the parochiality of ethics and governance across Australian States and Territories, however, the breadth had increased and the general consensus was that NOSS is too far away, and Melbourne and Victoria cannot wait.

*4. Lacking regional and diverse recruitment*

There is an opportunity to extend recruitment efforts into regions, as volunteer recruitment is currently predominantly focussed on metropolitan areas. Regional participants and their families often face travel barriers, or they may be unaware of opportunities to be involved. In a similar vein, recruitment efforts are not reaching diverse communities in metropolitan or regional areas, particularly those where English is not the first language.

**Opportunity**
Deliver a participant recruitment campaign focussing on recruiting both healthy volunteers and patients, as described in storytelling section below.

### *Cost, timeline and regulatory*

Victoria has many clinical trial benefits, including a fast approval process where a first-in-human study can take approximately six weeks to approve. This safe and efficient regulatory system is a strength for the country, with our Human Research Ethics Committees meeting every one to two weeks to review safety data packages. This internationally-competitive strength is one of the reasons that Australia is a destination of choice for clinical trials.

Australia cannot rely on this speed alone though as, with greater global recognition of the value of health technologies – and their clinical trials – international competition remains fierce.
Whilst trial delivery is relatively more expensive than in many parts of Asia, it remains cost-effective relative to the United States and Europe. Additionally, Australia is an attractive 'stepping stone' for Asian companies and markets, with Australia's clinical trial data widely accepted by major global regulators. This position cannot be taken for granted, with winds of change beginning to blow.

International funders and sponsors will continue to require FDA-accepted data, however, shifts in global political and therefore regulatory landscapes offer an opening for Australia and the Therapeutic Goods Administration (TGA) to take on a stronger regional leadership role. There is potential for Australia to drive the development of a coordinated APAC regulatory framework that balances local rigour with international relevance

With the maturation of Victoria's clinical trials sector, the market for more advanced clinical trials is also growing. Trials beyond Phase 1 face lengthier and more unpredictable governance pathways, and therefore their start-up times are not as speedy. Much of this variation is due to inconsistencies across ethics committees, where decision-making can depend heavily on the chairperson's experience and expertise. The growing complexity present in health technologies are challenging some committees, when scientific officers have limited understanding of the specialised areas.

Examples of valuable initiatives that have aimed to improve efficiencies in start-up timelines and regulatory processes include:

1. The St Vincent's Research Valet - provides full HREC submission preparation and liaison through the process - improving support for sponsors, researchers and CROs.
2. IQVIA Investigator Site Portal – brings study start-up, document exchange, learning management, safety notification and site engagement resources into one portal.

Large sponsors typically view Australia primarily through a reimbursement lens, and with the challenges in navigating these processes, it creates an environment where some large sponsors avoid running their clinical trials in Australia altogether. This impacts both Australian patients' access to new therapies and technologies, as well as the Victorian and Australian economy. At the same time, the design of clinical trials is shifting, with inbound sponsors increasingly preferring to conduct both Phase 1 and later-phase studies in a single location to streamline operations.

**Opportunity**
As described in the storytelling section above, the development of communications materials and a campaign detailing the benefits of Melbourne's cost and regulatory landscape would increase incoming sponsors confidence in running their trials in our city.

## About BioMelbourne Network

BioMelbourne Network is Victoria's leading industry association for organisations engaged in biotechnology, medical technology, and health innovation since 2001.

BioMelbourne Network has more than 200 companies and more than 5480 members and focuses on building an engaged and collaborative life sciences community through data and insights, promotes and advocates for sector growth, and provides members with opportunities to accelerate in research, innovation, commercialisation and manufacturing.

## About City of Melbourne's recent support for the life sciences sector

Melbourne City Council is the local government body responsible for the municipality of Melbourne.

Three biotechnology case studies have been published on the Melbourne News website, featuring an industry snapshot, fast facts and case studies for AdAlta, Bionics Institute and 360biolabs.

- Biotech sector boom: wobbegong shark inspires new cancer treatments | City of Melbourne
- East Melbourne institute creates life-changing medtech | City of Melbourne
- Changemaking clinical trials, made in Melbourne | City of Melbourne

The Tianjin office facilitated a Melbourne Clinical Trial Information Session in October 2024. Within the session, four Melbourne based companies attended and two Tianjin companies shared successful Phase 1 trial experiences. 15 Tianjin biotech and pharmaceutical companies participated in the event.

City of Melbourne supported the MedHack AI Hospital Hackathon and Pitch Night in February 2025, an event organised by MLAI (a Machine Learning and Artificial Intelligence entrepreneur group), aimed at uniting the healthcare and AI communities to address significant challenges within Australia's healthcare system.

This paper reflects the discussion that occurred between clinical trials stakeholders who attended the BioMelbourne Network Clinical Trials Focus Group convened in May 2025.

BioMelbourne Network sincerely thanks the participants below for their participation and generous insights and contributions to the discussion.

Attendees (listed alphabetically by company name): Greg Plunkett - Accelagen, Dr Rosalie Cull - Adjutor healthcare, Con Konstantopoulos - Akesa, A. Prof. Tina Soulis - Alithia life sciences, Dr Bev Menner - Cell Therapies, Negin Rahmani - Complete Phase CRO, Claire Gibson - IQVIA, Dr Catherine Osborne - Lab Connect, Anne De Luca - Molecule2Market, Carolyn Stewart - Murdoch Children's Trials Centre, Janet Moore - Nucleus Network, Jeffery Wong - Nucleus Network, Helen Poliviou - Pure CDM, Dr Megan Robertson - St Vincents Hospital, Trang Vo - Syneos Health, Deputy Lord Mayor Roshena Campbell - City of Melbourne, Katie Stewart - City of Melbourne, Yossi Goldfarb - City of Melbourne, Karen Parr - BioMelbourne Network, Jessica Balk - BioMelbourne Network