



MONASH
University

MONASH UNIVERSITY CLINICAL TRIALS CENTRE

STRATEGIC PLAN 2023 - 2026

monash.edu/medicine/muctc

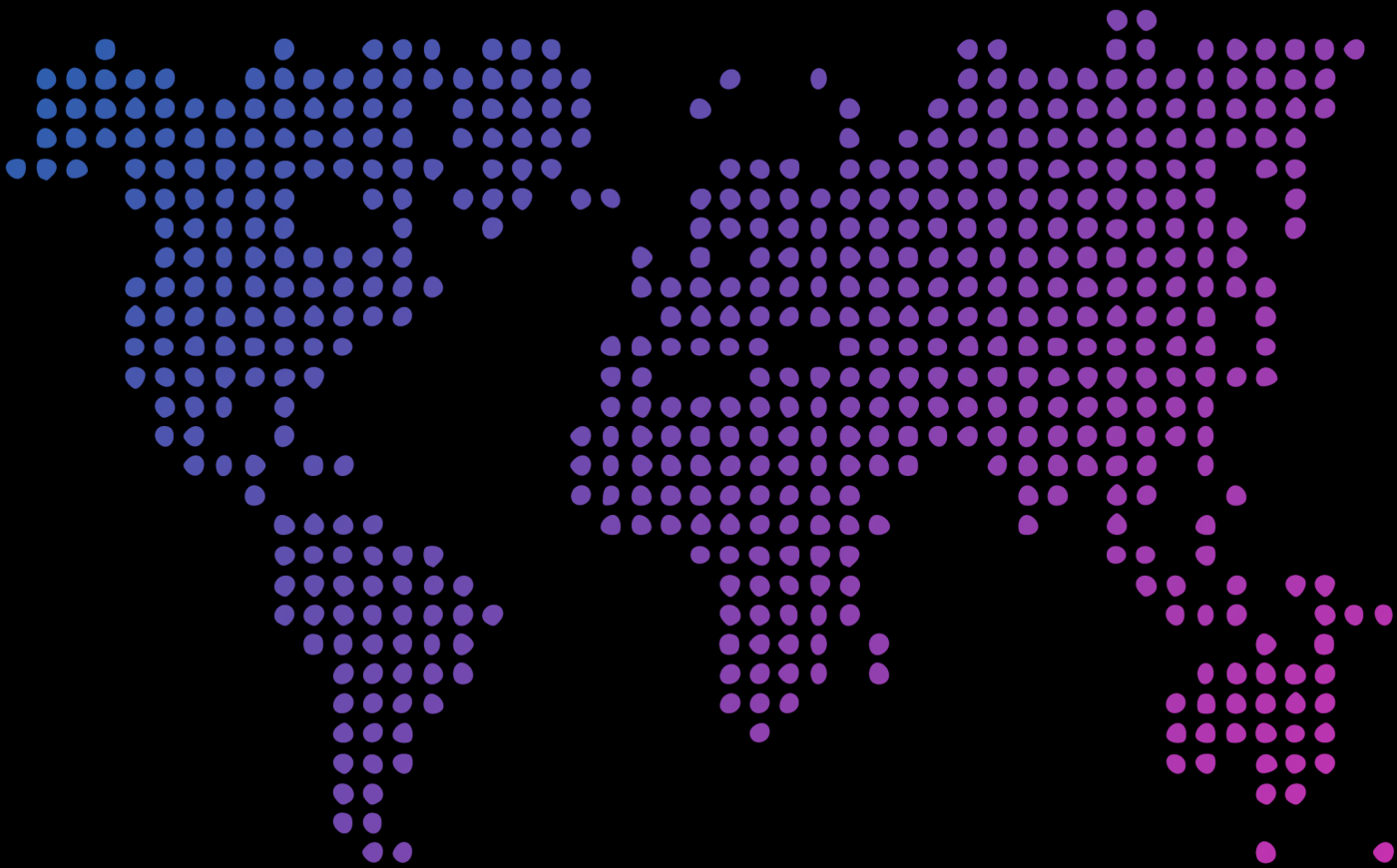
Introduction

Clinical trials are a critical step in the research and development of new drugs, vaccines, medical devices, clinical practices, and diagnostics. They generate evidence on the effectiveness of interventions and provide patient access to new and potentially life-saving interventions, medical treatments and preventive approaches.

Monash University has extensive capabilities in clinical trial design, delivery, analytics, and translation. Together with our vast network of affiliated health service partners, Monash's Faculty of Medicine, Nursing and Health Sciences has completed more than 1000 clinical trials. This leading position in the Australian clinical trial environment affords many opportunities.

To better capture these opportunities and generate greater more efficient and more effective clinical trial activity, the Monash University Clinical Trial Centre (MUCTC) was introduced as a collaborative hub to streamline and accelerate investigator-initiated and industry-sponsored clinical trials.

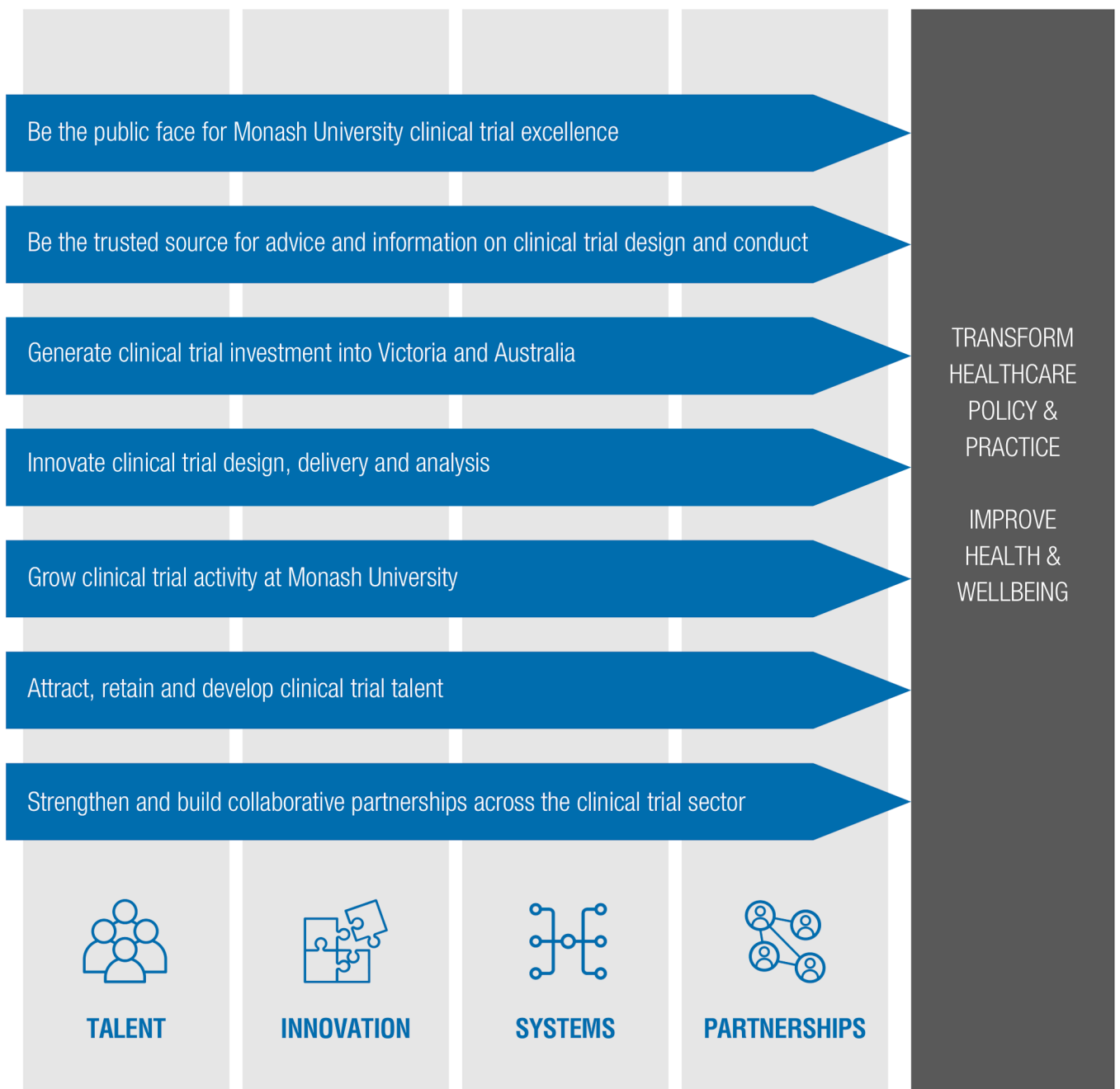
The Monash University Clinical Trials Centre vision is to improve health and wellbeing across the globe through supporting innovative and impactful clinical research.



VISION

Strategic goals

To transform healthcare policy and practice and improve the health and wellbeing of communities, we are focused on seven strategic goals. These goals are aligned with the strategic plans of Monash's Faculty of Medicine, Nursing and Health Sciences, the University's Research Plan and Impact 2030. The achievement of these goals is underpinned by our core capabilities in the areas of talent, innovation, systems and partnerships.



Value proposition

Leveraging the collective expertise and combined capabilities of Monash University and its network, MUCTC will provide value to three main stakeholder groups, (1) principal investigators, (2) health service partners, and (3) industry partners.

PRINCIPAL INVESTIGATORS

- Access to support as needed
- Access to efficient processes and systems for trial management and delivery
- Experienced, qualified clinical trial talent
- Shared resourcing (people, platforms, documentation)
- Networking opportunities with clinicians, health services, industry, regulatory bodies

HEALTH SERVICE PARTNERS

- Access to efficient processes and systems minimising health service administrative burdens
- Reducing risk through access to experienced, qualified clinical trial talent
- Partnership and networking opportunities

INDUSTRY PARTNERS

- Access to Monash University clinical and community networks
- Innovative trial design and delivery opportunities to maximise participant recruitment
- Efficient processes and systems for faster trial startups
- Access to Monash University expertise to improve idea development and R&D performance

Operating model

MUCTC is operating as an Academic Research Organisation (ARO).

AROs are academic, academically affiliated, and/or non-profit institutions that perform one or more functions in the conduct of clinical trials with a focus on developing and sharing knowledge that leads to improvements in patient care.[1]

As an ARO, MUCTC provides scientific rigour and credibility through being embedded within one of Australia's leading teaching and research universities, enabling the Centre to engage a diverse team of academic and clinical experts from multiple institutions and across a variety of agents and sponsors.

This ARO approach allows us to move beyond service provision and add value with academic, clinical, and community and consumer input into research methodologies, analytics, education and training, and innovation. We have a collaborative approach to knowledge generation that includes clinical context and scientific objectivity to advance health knowledge and disseminate the results of research to improve clinical care.

[1] Reist CR, Rorick TL, Berdan LG, & Lopes, RD. 2013. Chapter 3. The Role of Academic Research Organizations in Clinical Research. In Lopes RD, Harrington RA (Editors), *Understanding Clinical Research*. McGraw-Hill Education: United States of America.

Capability framework

Underpinning our value propositions and the services we deliver are MUCTC's core capabilities:



TALENT

MUCTC has experience in building, training and developing cross-disciplinary and multi-site teams of researchers, clinicians, technical and professional support staff to:

- design, deliver, analyse and report on clinical trials
- synthesise evidence from clinical trials
- translate knowledge into clinical practice
- contribute to the education of postgraduate students in relevant scientific/medical fields
- grow our collective capabilities in clinical trial expertise.



INNOVATION

MUCTC has capabilities to develop and test innovative methodological design, conduct, analytical and knowledge translation approaches to:

- increase participant access to clinical trials (e.g. regional/remote participants)
- deliver efficiencies
- increase opportunities for data linkage
- decrease costs
- embed clinically-relevant and consumer co-designed approaches into trials
- decrease the time to conduct and analyse the findings from clinical trials.



SYSTEMS

MUCTC has the capacity to improve clinical trial coordination by streamlining key support services and processes to:

- increase trial resource efficiency and reduce fragmentation and duplication of effort
- reduce reliance on third-party providers
- maximise efficient use of limited trial funding
- improve current approaches to data collection and management
- inform best practice standards for health data governance, aggregation, and use
- embed clinical trials in healthcare safety and quality assurance approaches.



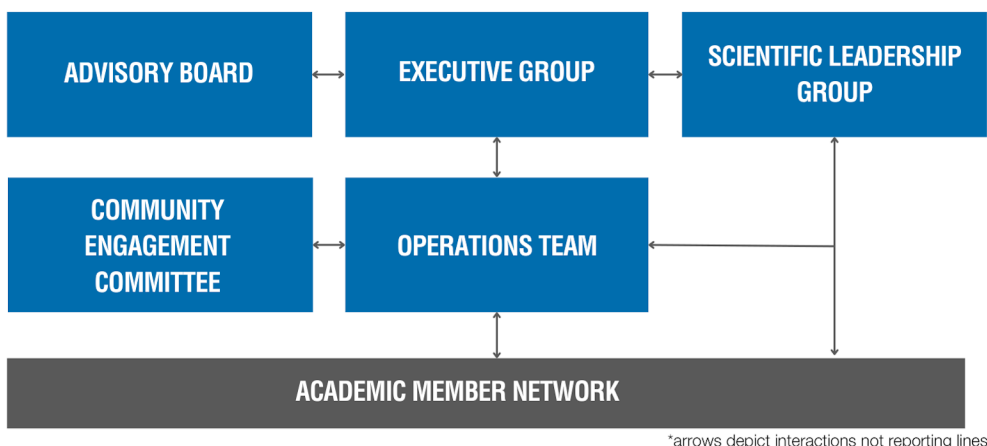
PARTNERSHIPS

MUCTC has extensive relationships which enable us to capture opportunities via partnerships with:

- our clinician researchers across multiple disciplines and therapeutic areas
- communities and consumers through our Community Engagement Committee
- affiliated hospital and research networks including Monash Health and the Victorian Heart Hospital, Alfred Health, Eastern Health, Peninsula Health, Cabrini Health, Epworth Health, Monash Partners and the Alfred Research Alliance
- GP networks across metropolitan and regional centres in all states and territories
- Monash's world-class technology precinct.

Governance

Our governance structure ensures the successful establishment of MUCTC, scientific and operational leadership, and sustainable growth in the long-term.



Our **Advisory Board** is a non-statutory, independent, skills-based board that provides advice to MUCTC on the strategic direction and performance of MUCTC and supports the Centre to achieve its purpose. Membership of the Advisory Board includes representatives from academic, clinical, government, philanthropic and industry organisations.

Our **Executive Group** is the key body within the governance structure which is responsible for the business operations associated with MUCTC that are essential to the attainment of the Centre’s objectives. Membership of this Group includes representatives from central University services and the Faculty of Medicine, Nursing and Health Sciences, Monash University.

Our **Scientific Leadership Group** is responsible for ensuring that the needs and requirements of Monash University and affiliated partners are identified so MUCTC's activities and strategy are fit for internal purposes. This Group includes experts in the scientific and/or clinical landscape from across Monash University.

Our **Community Engagement Committee** provides a mechanism to build and foster partnerships between researchers and the community to ensure clinical research is participant focused, successful and meaningful.

Our **Operations Team** is responsible for the day-to-day operations of MUCTC. This includes all business and administrative functions within the Centre and making certain that activities are aligned with key performance targets.

Our **Academic Member Network** includes the clinicians, researchers and academics that are part of the University and/or our health service partner network that have extensive knowledge, expertise, experience and skills in the design, conduct, analysis and translation of clinical trials.





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FURTHER INFORMATION

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