

Government of **Western Australia** Department of **Health** 

# WA Clinical Trials Roadmap

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### Minister's foreword

## Translating innovative medical research into immediate patient care

It's the personal stories of heartbreak that motivate us to drive change.

Clinical trials give hope to patients who've exhausted all treatment options, and for those who dream of having improved quality of life; clinical trials elevate quality health care.

As an essential component of high performing health systems, clinical trials enhance health and wellbeing by improving disease prevention, enabling earlier diagnosis, and supporting the development of more effective, kinder treatments with fewer side effects. The WA Clinical Trials Roadmap is a bold plan for the state, a strategy to develop a thriving clinical trials' ecosystem across the largest health jurisdiction in the world.

As global demand for health care services increase, we need brilliant minds to push the boundaries and explore new frontiers. Our Roadmap challenges us to do this.

The Roadmap will encourage global pharmaceutical companies and supporting industries to invest and operate in WA.

Our state is already home to world-leading research. By harnessing the skills of our talented researchers and innovators and empowering clinical trials teams, patients will benefit from new evidence-based methods and interventions that are made in WA.

Building on this foundation with a vision of exporting these opportunities nationally and internationally, WA can continue to drive continuous improvements and more personalised, precision medicine.

Innovative and effective healthcare can only be advanced through clinical trials, resulting in a world of difference for Western Australians now and into the future.

#### Hon Stephen Dawson MLC Minister for Medical Research

#### Acknowledgement of Country and People

WA Health acknowledges the Aboriginal people of the many traditional lands and language groups of Western Australia. It acknowledges the wisdom of Aboriginal Elders both past and present and pays respect to Aboriginal communities of today.

## The WA Clinical Trials Roadmap in context

The WA Clinical Trials Roadmap guides the clinical trials ecosystem across the state.

Developed through widespread consultation with stakeholders, including consumers, the Roadmap aims to expand capacity and improve access to clinical trials in Western Australia.

Driven by the WA clinical trials ecosystem and supported by the Western Australia Department of Health, the Roadmap aligns with the <u>WA Health and</u> <u>Medical Research Strategy 2023-2033</u>.

### **Clinical Trials**

### What are clinical trials?

Clinical trials are studies that allow researchers to investigate and evaluate new and existing treatments, tests, or procedures (including health-related service changes and educational interventions) that may prevent, detect, diagnose, treat, or manage diseases or conditions.



### **Benefits of clinical trials**

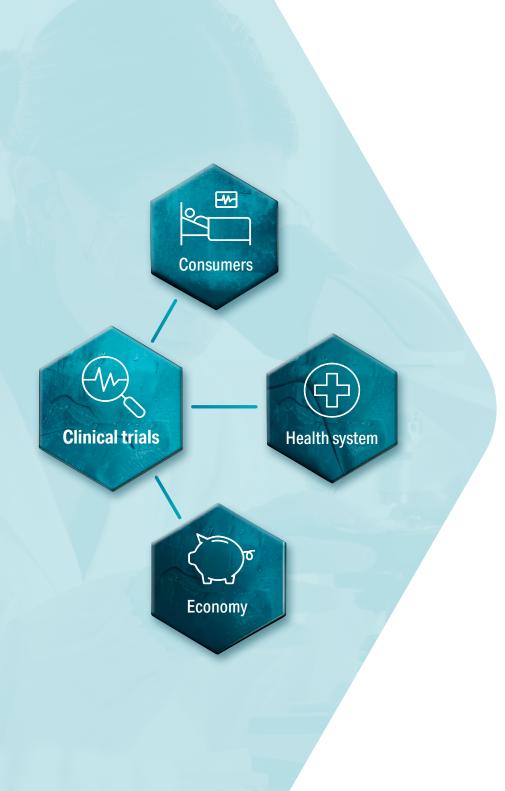
Clinical trials are a key step in translating medical advances into benefits for patients and the community. As an essential component of high-performing health systems, they drive continuous improvement of healthcare delivery, ensuring patients receive the best evidence-based care available.

Clinical trials play a crucial role in improving the health and wellbeing of Western Australians, enabling earlier diagnoses, development of more effective and kinder treatments, and improved disease prevention.

Clinical trials allow researchers to:

- assess the effectiveness and safety of new treatments and interventions
- compare existing treatments and interventions to determine which is better
- find better ways to prevent diseases
- study new tests and procedures to improve diagnoses
- find gentler treatment options with fewer side effects
- understand the causes of diseases.





## The benefits of clinical trials:

#### The benefits of clinical trials for consumers are:

- improved outcomes (higher survival and lower mortality) through access to the latest cutting-edge treatments and interventions before they are more widely available
- increased delivery of evidence-based care
- increased availability of treatment options for advanced diseases such as cancer and rare diseases where there are no standard treatments
- closer clinical surveillance and better clinician adherence in trial-active hospitals which extends benefits to both non-trial and trial-active patients
- increased knowledge of the best treatments and availability of better options to benefit future consumers.

#### The benefits of clinical trials for the health system are:

- improved quality of care, efficiency of care delivery, and health policy and practice
- increased workforce skills including retention of the best clinicians
- enhanced health and medical research infrastructure
- reduced healthcare costs
- increased system capacity to respond to pandemics and health crises.

#### The benefits of clinical trials for the economy are:

- contribution of \$1.6 billion to the Australian economy in 2022 through direct expenditure and investment in clinical trials
- generation of export revenue
- direct employment of 7,700 people in Australia in 2022
- retaining of the evaluation and supply chains of locally developed treatments in Australia through trial infrastructure.

### WA Clinical Trials Roadmap

Vision: Western Australia has a thriving, innovative, networked, competitive, and culturally safe clinical trials ecosystem where every Western Australian has access to world-class clinical trials that are embedded in routine clinical care.

| Strategic theme                                       |  | Goal   | Strategic objectives   |
|---|--|--|--|
| Organisational<br>culture and corporate<br>governance | Drive the embedding<br>of clinical trials in<br>healthcare delivery<br>through organisational<br>culture and corporate<br>governance.  | WA has health system leaders that<br>prioritise, value, and embed clinical<br>trials as a core requirement of<br>healthcare delivery.  | <ol> <li>Build an organisational culture where health leadership at board and executive levels celebrates and engages with clinical trials as a core organisational responsibility.</li> <li>Integrate clinical trials in planning, financial oversight, risk management, and compliance structures for corporate governance.</li> <li>Embed an Aboriginal cultural governance structure.</li> </ol>   |
| People  | Support and enable the<br>clinical trials workforce,<br>investigators, and<br>consumers to actively<br>engage with clinical<br>trials. | WA boasts a sustainable, highly<br>skilled, and collaborative clinical trials<br>workforce and investigators. Consumers<br>are empowered to access clinical trials<br>and be involved in their design.   | <ul> <li>2.1 Boost, retain, and enable a skilled clinical trials workforce through job security, career progression, and career pathways.</li> <li>2.2 Boost, retain, and enable skilled clinical trial investigators through protected time, training, and clear career pathways.</li> <li>2.3 Enhance consumer centricity, promote equity of access to clinical trials, and boost participant involvement, recruitment, and retention.</li> </ul>  |
| Infrastructure and systems                            | Connect and<br>leverage the clinical<br>trials ecosystem<br>through world-class<br>infrastructure and<br>integrated systems.           | A thriving WA clinical trials ecosystem<br>is connected by digital infrastructure<br>and networks, underpinned by core<br>clinical trials physical infrastructure<br>and streamlined through efficient<br>operational systems.   | <ul> <li>3.1 Digitally enable the clinical trials ecosystem to enhance coordination, facilitate patient recruitment, and foster collaboration.</li> <li>3.2 Employ innovative solutions to differentiate and increase collaboration, geographical reach, and accessibility to clinical trials.</li> <li>3.3 Streamline research ethics and governance systems to reduce trial start-up times.</li> <li>3.4 Leverage existing physical clinical trials infrastructure and explore opportunities to foster economies of scale.</li> </ul>        |
| Visibility  | Grow visibility<br>and reputation of<br>WA clinical trials<br>ecosystem.   | WA's renowned clinical trials sector,<br>known for its expert investigators<br>and competitive edge, attracts an<br>increasing number of clinical trials.<br>Growing investment supports long-term<br>sustainability. Visibility and information<br>sharing empower the ecosystem. | <ul> <li>4.1 Grow visibility and reputation of WA's clinical trials sector by encouraging networking at state, national, and international levels to attract more clinical trials.</li> <li>4.2 Increase awareness of clinical trials amongst healthcare workers so information can be shared with consumers at every point of care.</li> <li>4.3 Increase availability and sharing of tailored information about clinical trials to empower consumers and the community to understand, engage, and participate in clinical trials.</li> </ul> |

## **Strategic theme 1:** Drive the embedding of clinical trials in healthcare delivery through organisational culture and corporate governance\*

Goal: WA has health system leaders that prioritise, value, and embed clinical trials as a core requirement of healthcare delivery.

| Strategic objectives   | Sub-objectives  |
|--|---|
| <b>1.1</b> Build an organisational culture<br>where health leadership at<br>board and executive levels<br>celebrate and engage with<br>clinical trials as a core<br>organisational responsibility. | <ul> <li>Support leadership for change that embeds clinical trials as critical to the continuous generation and implementation of improvements for safe and effective health care through: <ul> <li>embedding clinical trials as treatment in clinical pathways and models of care</li> <li>prioritisation of clinical trial activity</li> <li>inclusion of clinical trials delivery in organisational strategic planning</li> <li>clinical trial tracking and monitoring</li> <li>celebrating successes of clinical trials</li> <li>building clinical trials activity into clinical employment arrangements.</li> </ul> </li> <li>Support the ecosystem to implement the National Clinical Trials Governance Framework (NCTGF).</li> </ul> |
| <b>1.2</b> Integrate clinical trials in planning, financial oversight, risk management and compliance structures for corporate governance.   | <ul> <li>Implement agile corporate governance structures that:</li> <li>plan for and embed clinical trials in health care</li> <li>facilitate clinical trial implementation</li> <li>support activities that facilitate dynamic and adaptable best practice health care</li> <li>include key performance indicators to incentivise trial activity and hold leadership members accountable</li> <li>incentivise initiatives that support financial sustainability and the long-term growth of clinical trials in WA.</li> </ul>  |
| <b>1.3</b> Embed an Aboriginal cultural governance structure.  | <ul> <li>Embed formal structures that ensure Aboriginal voices, as subject matter experts, inform decisions that impact on Aboriginal people and Aboriginal communities.</li> <li>Embed cultural safety into clinical trial provision.</li> </ul>   |

\* Corporate governance: For the purposes of this document, corporate governance refers to the structure of rules and practices that prescribe overall strategic planning, financial oversight, risk management, and compliance for a whole organisation. Corporate governance regulates management of an organisation and delegation of responsibility.

## **Strategic theme 2:** Support and enable the clinical trials workforce\*, investigators+, and consumers to actively engage with clinical trials

**Goal:** WA boasts sustainable, highly skilled, and collaborative clinical trials workforce and investigators. Consumers are empowered to access clinical trials and be involved in their design.

| Strategic objectives   | Sub-objectives   |
|--|--|
| 2.1 Boost, retain, and enable<br>a skilled clinical trials<br>workforce* through job<br>security, career progression,<br>and career pathways.            | <ul> <li>Implement solutions to address lack of job security, career progression opportunities, and recognition of roles for clinical trials personnel, in particular clinical trial coordinators, to support retention of a skilled workforce.</li> <li>Attract graduates to the workforce by promoting clinical trials as a career opportunity and increasing availability of clear training pathways.</li> <li>Increase access to quality clinical trials training and mentoring opportunities.</li> <li>Measure and monitor clinical trials workforce metrics.</li> </ul>  |
| 2.2 Boost, retain, and enable<br>skilled clinical trial<br>investigators+ through<br>protected time, training, and<br>clear career pathways.             | <ul> <li>Embed clinical trials as part of routine workflow for trial investigators, including protected time to conduct this work.</li> <li>Improve career pathways for clinicians and other healthcare workers to gain research experience and become clinical trial researchers.</li> <li>Retain and attract additional skilled clinical trials investigators to WA.</li> <li>Increase investigator access to quality clinical trials training and mentoring opportunities.</li> <li>Measure and monitor clinical trials investigator metrics.</li> </ul>  |
| 2.3 Enhance consumer centricity,<br>promote equity of access<br>to clinical trials, and boost<br>participant involvement,<br>recruitment, and retention. | <ul> <li>Partner with consumers in the planning, design, implementation, and evaluation of clinical trials.</li> <li>Ensure consumer and community involvement initiatives engage with under-served communities including Aboriginal people so that trial designs are culturally safe, responsive, and reflect their unique needs.</li> <li>Facilitate equity of access to clinical trials, including people living in regional or remote locations, Aboriginal people, people with rare disease, culturally and linguistically diverse people, and other groups with limited access to clinical trials.</li> <li>Implement tailored engagement strategies to drive recruitment and retention, including for groups with limited access to clinical trials.</li> </ul> |

\* For the purposes of this document, clinical trials workforce includes professionals, other than investigators, who contribute to the successful conduct of clinical trials. This includes clinical trial coordinators, clinical trial nurses, managers, clinicians, liaison officers, pharmacists, research ethics, and governance officers and other supportive staff such as biostatisticians, health economists, psychologists, Aboriginal healthcare workers, and genetic counsellors.

+ Clinical trial investigators refers primarily to coordinating principal investigators and principal investigators who are healthcare workers and researchers responsible for conducting a trial in accordance with an approved protocol. Investigators also include associate investigators, who are senior members of a clinical trials team with varying levels of oversight.

### Strategic theme 3: Connect and leverage the clinical trials ecosystem through world-class infrastructure\* and integrated systems

**Goal:** A thriving WA clinical trials ecosystem is connected by digital infrastructure and networks, underpinned by core clinical trials physical infrastructure and streamlined through efficient operational systems+.

| Strategic objectives  | Sub-objectives  |
|---|---|
| <b>3.1</b> Digitally enable the clinical trials ecosystem to enhance coordination, facilitate patient recruitment, and foster collaboration.  | <ul> <li>Leverage and coordinate digital infrastructure and platforms (such as clinical trial management systems, financial management systems, recruitment software, and pharmacy management systems) to enable trial activity, seamless sector-wide collaboration, and promote cohesion at the public private interface.</li> <li>Use digital solutions and platforms to foster state, national, and international collaboration and harmonisation, including harnessing WA's proximity to the Asia-Pacific region where growth of clinical trials is rapidly accelerating.</li> <li>Consider how clinical trials can be integrated as a function of digital and electronic medical records.</li> </ul> |
| <b>3.2</b> Employ innovative solutions to differentiate and increase collaboration, geographical reach, and accessibility to clinical trials. | <ul> <li>Employ solutions that increase collaboration across the clinical trials ecosystem, including between health service providers, universities, medical research institutes, industry, clinical research organisations, and private health service providers.</li> <li>Foster partnerships with Aboriginal Community Controlled Health Services.</li> <li>Facilitate implementation of trials with decentralised elements to address WA's geographical barriers.</li> <li>Increase WA's capacity to differentiate with innovative trial designs and platforms.</li> </ul>   |
| <b>3.3</b> Streamline research<br>ethics and governance<br>systems to reduce trial<br>start-up times.   | <ul> <li>Streamline research ethics and governance processes.</li> <li>Improve education about research governance for researchers, institutions, governance officers, and research participants.</li> <li>Increase consistency of fees and charges associated with delivering clinical trials across WA.</li> <li>Support the ecosystem to streamline complex organisational processes and improve availability of standard operating procedures, clarity of reporting lines and communication systems.</li> </ul>   |
| <b>3.4</b> Leverage existing physical clinical trials infrastructure and explore opportunities to foster economies of scale.                  | <ul> <li>Grow state-wide clinical trials initiatives such as hubs, coordinating centres, and networks that share resources and foster economies of scale.</li> <li>Increase WA's ability to export clinical trials that recruit nationally and internationally through enabling infrastructure, like coordinating centres.</li> <li>Share and consolidate physical infrastructure that supports trial delivery including space to carry out trials, administrative space, equipment, and facilities (such as imaging and manufacture) to maximise use of existing resources.</li> <li>Explore the needs of regional centres to increase clinical trials activity.</li> </ul>                              |

\* Infrastructure: For the purposes of this roadmap clinical trials infrastructure is defined as any physical and digital infrastructure required to support trial delivery, including downstream clinical trial activity. It does not include workforce.

+ For the purposes of this document, operational systems include policies, guidelines, templates, and ways of working that support the successful conduct of clinical trials in line with approved protocols. This includes research ethics and governance.

### Strategic theme 4: Grow visibility and reputation of the WA clinical trials ecosystem

**Goal:** WA's renowned clinical trials sector, known for its expert investigators and competitive edge, attracts an increasing number of clinical trials. Growing investment supports long-term sustainability. Visibility and information sharing empower the ecosystem.

| Strategic objectives  | Sub-objectives  |
|---|---|
| 4.1 Grow visibility and reputation<br>of WA's clinical trials sector<br>by encouraging networking<br>at state, national, and<br>international levels to attract<br>more clinical trials.                | <ul> <li>Promote the WA clinical trials sector on a state, national, and global level to increase collaboration, investment, and financial sustainability.</li> <li>Improve visibility and connectivity of WA's expert clinical trial investigators at a national and global level to attract more commercial and non-commercial trials to WA.</li> <li>Promote the value that clinical trials add to the economy.</li> </ul> |
| 4.2 Increase awareness of clinical trials amongst healthcare workers so information can be shared with consumers at every point of care.  | <ul> <li>Promote clinical trials to all healthcare workers so trial information can be shared when consumers interact with the health system at<br/>every point of care.</li> </ul>   |
| 4.3 Increase availability<br>and sharing of tailored<br>information about clinical<br>trials to empower consumers<br>and the community to<br>understand, engage, and<br>participate in clinical trials. | <ul> <li>Increase understanding amongst consumers of the benefits of clinical trials, why they are carried out, and the processes in place to minimise risks.</li> <li>Empower consumers to make informed decisions about their participation in clinical trials.</li> <li>Establish systems for feedback from clinical trial participants to ensure information continuously improves and meets consumer needs.</li> </ul>   |

## Appendix A: Guiding resources

- 10-Year Science and Technology Plan, Department of Jobs, Tourism, Science and Innovation, 2023
- ACTA Australian Clinical Trials Alliance Better health through best evidence
- <u>Australian clinical trial handbook, Australian Government, Department of Health and Aged Care, Therapeutic Goods Administration</u>
- <u>Australian Clinical Trials Education Centre</u>
- <u>Australian Medical Research and Innovation Strategy 2021–2026 (health.gov.au)</u>
- CT:IQ Clinical Trials Thinking Smarter (ctiq.com.au)
- <u>Economic value of the health and medical research sector in Western Australia, Association of Australian Medical Research Institutes WA Chapter, Deloitte</u>
   <u>Access Economics, 2023</u>
- In the test tube: Finding WA's formula for health and medical research success. Education and Health Standing Committee, Report No. 9, 2024
- Health and medical life sciences industry: strategy, Department of Jobs, Tourism, Science and Innovation, 2021
- Integrating research in the health system, Australian Academy of Health & Medical Sciences, 2022
- <u>Australia's Clinical Trials Sector, Advancing innovative healthcare and powering economic growth, MTP Connect, 2024</u>
- National Clinical Trials Governance Framework, Clinical Trials in Australia, Australian Commission on Safety and Quality in Health Care
- PARTNER Network
- Strategic Review of Health and Medical Research (McKeon review), 2013
- Sustainable Health Review: Final Report to the Western Australian Government. Department of Health, Western Australia, 2019
- The Australian Teletrial Program
- The National One Stop Shop a national cross government platform for health-related human research, Australian Commission on Safety and Quality in Health Care
- WA Cancer Plan 2020–2025
- WA Health and Medical Research Strategy 2023–2033
- WA Future Health Research and Innovation Fund Strategy (2020–2022)
- Latest update of the clinical trials landscape in Australia 2006–2020. Sydney: Australian New Zealand Clinical Trials Registry, 2022

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