Clinical Trial Strategic Action Plan for increasing clinical trial activity 2022-2025

Vision

More Queensland patients accessing clinical trials leading to better patient health outcomes.

Goal

Queensland is a first-tier destination for commercially sponsored clinical trials leading to a better health system and supporting a highly skilled clinical workforce.

8 step action plan to attract more commercial clinical trials to Queensland

Action	Reasons why we need to implement	Timeline
Improve operational efficiency		2022-23 
1. Implement the National Clinical Trials Governance Framework (NCTGF)	• Mandatory from mid-2023 for hospital accreditation. • Adopt rapidly to demonstrate commitment to improving governance timelines to increase site selection rate. • Will facilitate standardisation, efficiency and consistency of processes, and reporting of metrics. • Viewed positively by sponsors and sites and is regarded as a positive step to improving governance. • Will improve governance timelines which are a critical factor in determining site selection. • Will drive the education and training for Research Ethics and Governance Officers.	
2. Create a standard schedule of fees for each Hospital and Health Service (HHS)	• Will facilitate more rapid clinical trial budget negotiation, a key source of lost time in project start-up. • Achieves consistent financial advice and a more transparent cost structure. • To be made readily available internally and to Contract Research Organisations (CROs) and sponsors ideally during feasibility and site selection discussions.	
3. Have a single point of contact for clinical trials at each HHS	• Offers significant advantages that translate into increased clinical trial activity. • Means a more rapid response to CRO and sponsor feasibility and can address barriers to start-up. • Central knowledge of investigators, capacity and site capabilities means consistent evaluation of feasibilities. • Builds a strong CRO/sponsor relationship increasing sponsor and CRO confidence in the site and simultaneously addresses actions 7 and 8.	
4. Nominate dedicated clinical trials budget/ contract staff	• Means consistent and more rapid clinical trial budget calculation and negotiation by experienced staff who understand research. • Budget and contract negotiation delays are a key source of lost time and a significant factor influencing site selection. • Committing experienced budget/contract staff ensures a streamlined governance process.	
Improve operational capacity		2022-24 
5. Develop Junior Principal Investigators and Clinical Research Coordinators	• Industry values health services where research is a core pillar of patient care. • Primary investigator capacity can limit clinical trial activity, so this builds clinician capacity. • Embeds a research culture within the hospitals and attracts and retains high calibre clinicians. • Drives career development and ensures knowledge transfer. • Exposes research staff to new and novel therapies and interventions prior to them becoming standard of care.	
Improve research culture		
6. Record and publicly report key metrics for commercially sponsored trials	• Standardised metrics are indicated in the NCTGF and are mandatory. • Critical metrics on site capability and performance inform industry's early clinical trial placement decision making. • Willingness to disclose demonstrates commitment and will attract clinical trials. • Sponsors and CROs (especially overseas CROs) will refer to publication of metrics on respective hospital research websites. • Will inform development and implementation of key performance indicators embedded in the HHS service level agreements. • Increases sponsor and CRO confidence in site. • Engagement with patient advocacy organisations in key therapy areas supports trial participation and recruitment and improves metrics.	
7. Promote to Contract Research Organisations	*NB: Initiate once measures and metrics above have improved, especially start-up times* • In line with action 6, communication of site capabilities and performance increases CRO confidence in site. • Builds relationship with CRO and their trust in the site, leading to increased site selection over time. • CRO (especially overseas CROs) are more likely to consider individual hospitals with published metrics on their own websites.	
8. Engage with large pharmaceutical sponsors	*NB: Initiate once measures and metrics above have improved, especially start-up times* • Pre-existing relationships between sponsors and investigators drive site selection. • Informing sponsor of capabilities, initiatives and performance builds the relationship and drives site selection. • Building linkages with investigators will assist Queensland to be front-of-mind for future trial placement. • Inviting feedback helps to facilitate continued improvement heightening confidence in the site, further driving site selection.	2022-25 

Introduction

Clinical trials are essential for evaluating the effectiveness and safety of medicines, devices, services and interventions to help prevent, detect or treat illness and disease. Through the research done in clinical trials, patients gain access to novel therapies and potentially life-saving treatments. Clinical trials also boost the economy and support a highly skilled workforce. Clinical trials are a critical element of the research and development process bringing benefits to individual patients, health consumers and health systems.

The Clinical Trial Strategic Action Plan 2022-2025 (the Plan) outlines Queensland Health's strategy to ensure a national and global competitive advantage for attracting clinical trials. The Plan includes eight key actions covering areas that industry has indicated are critical when considering where to place their trials, including:

engagement and interaction with industry | development of crucial clinical personnel | standardisation of governance processes | and reporting.

Implementing the Plan will ensure consistency in processes and procedures across the state, enable cross-HHS workforce flow, drive efficiency in starting up and managing clinical trials and ultimately work towards growing Queensland's share of clinical trial activity. The actions set out in the Plan will also increase the economic contribution of clinical trial activities to the state and ensure Queensland maintains its excellent reputation as a tier-one clinical trial destination for commercially sponsored clinical trials, now and into the future.

Background

Queensland Health's clinical trials activity has grown significantly, with an increase of over 80% from 2015 to 2020, outperforming the national growth average. However, Queensland lags behind New South Wales and Victoria in terms of startup times and efficiency. Despite this activity growth, Queensland still only attract 16% of national clinical trial sites compared to the 20% share of the nation's population.

Assessment of Queensland's current clinical trial performance resulted in recommended actions to increase Queensland's competitive position as a location for clinical trials and to maximise the economic impact of clinical trials activities in the state. These actions span:

operational efficiency | operational capacity | and research culture.

There is broad industry support to implement a plan that improves Queensland's attractiveness for clinical trials nationally and internationally. The Plan will enable Queensland Health to approach these challenges and realise associated opportunities strategically. Extensive and widespread collaborative consultation within Queensland Health and with external stakeholders, including valuable input from industry, has contributed to the development of the Plan. The Plan resonated strongly with these stakeholders as a positive and concrete pathway to increase commercial clinical trial activity in Queensland's public hospitals.

The Plan has been developed to:

- align with the principles and directions that underpin the vision of Advancing Health 2026 by delivering and connecting healthcare and pursuing innovation
- align with the objectives of Queensland Advancing Health Research 2026 by building our research leaders and culture, preventing disease and creating the healthcare of the future, translating research into better health outcomes and taking our research and health services expertise to the world
- support the objectives outlined in the Advancing Queensland Biomedical 10-Year Roadmap and Action Plan by being a regionally integrated and globally competitive destination for clinical trials.

It also aligns with the Australian Commission on Safety and Quality in Health Care's initiative and the National Clinical Trials Governance Framework, which is the first step towards the accreditation of health service organisations for the provision of clinical trial services, which is expected to come into effect in mid-2023..

Implementation

The implementation process will begin early in 2022, with the proposed timeline of activities over four years through to 2025. HHSs will implement the Plan in alignment with the relative size and scope of their clinical trial activity, policies and research strategy. The Queensland Clinical Trials Coordination Unit (QCTCU) will provide guidance and coordination across HHSs.

QCTCU will kick off implementation with a series of educational sessions and workshops around the state. The focus will then become local, with working groups at an individual HHS level or across HHS alliances, designing and driving localised implementation plans with collaboration through working groups established around particular action areas.

2022	**2023**	**2024**	**2025**
Initiation	Feedback and track impact	Mid plan review	Assess success
			
Kickstart the implementation plan process in state hospital and health services.	Provide reports on clinical trial activity, conduct reviews and modify the implementation plan accordingly.	Ensure that the implementation plan is optimised.	Success is measured by the increase in commercially sponsored clinical trial activity in Queensland Health over the previous 5 years.

Contact

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