Gold Coast Health

National Clinical Trials Governance Framework Action Plan 2025 - 2027

Clinical trial service delivery is now formally evaluated through accreditation against the National Clinical Trials Governance Framework (NCTGF). This action plan outlines the strategies for implementing the NCTGF at GCHHS linked to the 2024 short-notice assessment outcome report.

GOAL Complete 26 actions to ensure GCHHS is fully prepared to meet all NCTGF requirements by the next accreditation cycle

Action	Reasons why we need to implement	NCTGF	Timeframe
Component 1 - Governance Leadership and Culture			
1. Develop a GCHHS Clinical Trial Governance Framework	Define governance structures, roles and responsibilities, systems and processes for delivering safe, high-quality clinical trials.	1.01	Established
2. Implement Clinical Trial Management System (CTMS)	Streamline clinical trial operations and report performance metrics to governing body and stakeholders.	1.01 1.13	2025
3. Develop operational plans for implementation of the NCTGF	Operationalise NCTGF implementation through a safety and quality plan and a partnering with consumers plan.	1.01 2.01	2025
4. Clinical trials workforce census (Survey)	Identify and quantify the clinical trials workforce, review contract arrangements, report FTE to trial ratios, support capacity building.	1.05 1.06	2025
5. Implement quarterly clinical trial performance reporting to Board Research Committee	The NCTGF mandates regular reporting of clinical trial service performance to the governing body.	1.01 1.08	2025
6. Implement strategies to enhance First Nations participation in clinical trials	Enhance Aboriginal and Torres Strait Islander clinical trial participation.	1.04	2026
7. Establish a Pharmacy Clinical Trial Advisory Group (PCTAG)	Support Clinical Trial Pharmacy in reducing clinical incidents and managing risks.	1.05 1.06	Established
8. Clinical trial space and infrastructure audit	Assess capacity (for current and future clinical trials) to plan for necessary renovations or expansions to support clinical trial activities.	1.05	2025
9. Establish a Clinical Trials SharePoint hub	Provide accessible tools and resources that strengthen workforce skills and enhance the safety and quality of clinical trial services.	1.06 1.20	Established
Component 2 - Patient Safety and Quality Systems			
10. Expand monitoring of investigator-led clinical trials	Strengthen oversight, quality assurance, and systematic risk mitigation for investigator-led trials.	1.07 1.08	2026
11. Establish a quality register for clinical trial service delivery improvements and initiatives	Provide an accessible platform for tracking and managing clinical trial service delivery quality issues and improvement initiatives (innovation portal/alternative)	1.08 1.11	2026
12. Produce a GCHHS Annual Research Report	Showcase and communicate research achievements and performance to stakeholders	1.09	2026
13. Enhance and embed clinical trial incident reporting	Systematically capture, analyse, and report clinical trial incidents to drive quality improvement	1.11 1.16	2026

2025
Implementation

2026
Mock Accreditation

2027
NCTGF Accreditation

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Action	Reasons why we need to implement	NCTGF	Timeframe
14. Strengthen and integrate clinical trial complaint management	Ensure all clinical trial complaints are captured, reported, addressed, and analysed for quality improvement.	1.14	2025
15. Implement strategies to enhance recruitment of culturally and linguistically diverse participants.	Align clinical trial participation with local population needs and demographics.	1.15 2.08	2026
Component 3 - Clinical Performance and Effectiveness			
16. Implement a flexible on-line GCP training course	Enhance GCP training and compliance. Provide a flexible option for staff who are unable to attend workshops.	1.20	2025
17. Establish central GCP register	Enhance GCP training and compliance. Provide visibility of GCP adherence and facilitate audits.	1.20	2025
18. Mandate GCP training for clinical trial teams and implement compliance audits	Enhance GCP training and compliance. Ensure clinical trial workforce have received appropriate training. Report compliance rates to governing body.	1.20	2025
Component 5- Partnering with Consumers			
19. Research training package for CAG members	Ensure consumer representatives are adequately trained to participate effectively in research discussions.	2.01 2.02	2026
20. GCHHS Clinical Trial Participant welcome brochure	Customised to GCHHS to ensure participants are informed, supported, welcomed, and understand their rights.	2.02 2.03	2025
21. Implement Participant feedback survey	Obtain participant feedback to inform quality improvement.	1.02 2.02	2025
22. Informed consent audits	Assess the effectiveness of the consent process, identify areas for improvement.	2.04	2026
23. Enhance clinical trials website	Improve clinical trial service visibility, transparency and accessibility for all stake-holders.	2.10	2026
24. Implement one-page summary with PICFs and post-trial participant outcome summary	Support health literacy and improve communication to participants.	2.10	2026
25. Explore external accreditation options from organisations like ACTA and IAOCR	Demonstrate proactive commitment to excellence and support high-quality training and professional development.	N/A	2027
26. Explore activity-based funding and scheduling for clinical trials	Maximise resource utilisation and further support clinical trial service delivery.	N/A	2027