

Implementation of the National Clinical Trial Governance Framework actions and integration of clinical trial services with clinical care at Barwon Health.

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Introduction:

Clinical trials provide early access to innovative treatments and interventions for patients, and improve the overall standard of medical care provided in Australia.¹ Data suggests improved health outcomes for clinical trial participants.² A thriving clinical trials program is fundamental to delivering innovative and evidence based care at Barwon Health (BH), and the Adrian Costa Clinical Trials Centre (ACCTC) is a vital step towards that goal.

The National Clinical Trials Governance Framework (NCTGF) supports the integration of clinical trial services into clinical care for improved patient outcomes. It focuses on two key Standards of the National Safety and Quality Health Service Standards: Clinical Governance, and Partnering with Consumers, across 27 actions.³

Method:

Barwon Health's pilot assessment against the NCTGF was conducted by the Institute for Healthy Communities Australia Ltd (IHCA), and made based on the evidence provided to the assessors. Six clinical trials, from five different departments were sampled during the pilot assessment. A "score" and "rating" against the NCTGF maturity scale was assigned to each "action", which is a guide for progressive improvements in each of the criteria within the framework.

Method:

Barwon Health's initial assessment by the Australian Council on Healthcare Standards to the NCTGF was conducted in July 2023. Commercial, university, collaborative group as well as health service funded clinical trials were sampled. Thirty clinical trials across twenty specialisations, with varying degrees of complexity in trial design from phase 1b/2 to phase 4 were assessed over an entire week. The assessment included review of evidence provided, interviews with clinical staff and trial participants, as well as round table discussions.

Results:

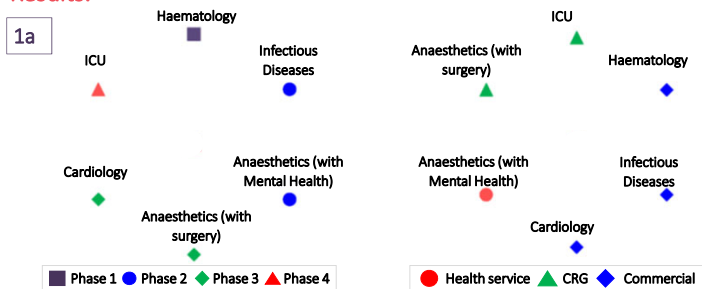


Figure 1a: Radar plots showing the distribution of trials across different departments sampled for the pilot assessment by trial phase (left) and sponsor type (right).

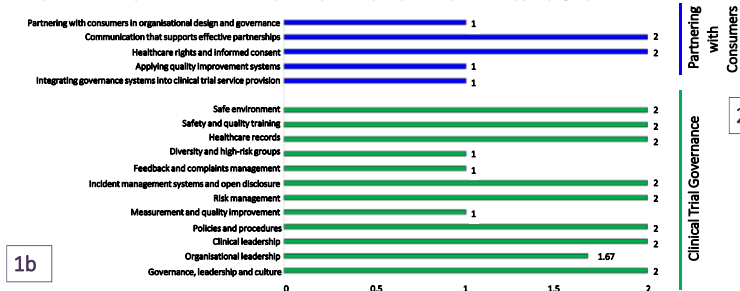


Figure 1b: Bar graph (top) depicts Barwon Health's individual or average maturity scores against actions in relation to clinical trial governance (green) and partnering with consumers standards (blue), during the pilot.

Treemap chart (left) represents the total report of the pilot assessment at Barwon Health, averaged across each standard, number indicates rating received. The maturity scale is defined by the rating, where 1= Initial systems, 2= growing systems & 3 = established systems.

Discussion:

Barwon Health demonstrated a commitment to implement all actions across the NCTGF, and was given an overall "initial systems" rating for the actions in the pilot assessment. The IHCA report set the basis for an action plan that was designed to address the gaps identified in the pilot assessment, and to develop strategies with defined timelines to address these gaps prior to the initial assessment to be held in 2023. With a strategic approach to the 2021 action plan, a small and high-performing team led a targeted implementation of NCTGF standards and actions in 2023. The initial assessment to the NCTGF was conducted in July 2023 by the Australian Council on Healthcare Standards. Although we are still awaiting the final report from the council, pleasingly, Barwon Health showed significant improvement since the pilot in meeting the requirements under the NCTGF Standards. The assessment of the NCTGF implementation resulted in a grading at the upper end of growing, and we aim to score higher in the next assessment.

References:

1. Australian Clinical Trials www.australianclinicaltrials.gov.au/what-clinical-trial/phases-clinical-trials
2. Majumdar S.R et al; Archives of Internal Medicine 24 March 2008, 168, 6, 657–662.
3. The National Clinical Trials Governance Framework and user guide for health service organisations conducting clinical trials, February 2022.
4. Barwon Health Clinical Trials Site Report V2, February 2021

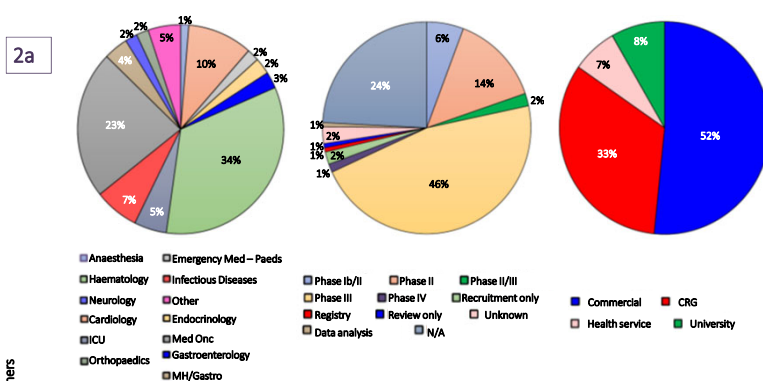


Figure 2a: Pie charts showing the distribution of all active clinical trials at Barwon Health in July 2023, by department (left), phase/complexity (middle) and sponsor type (right).

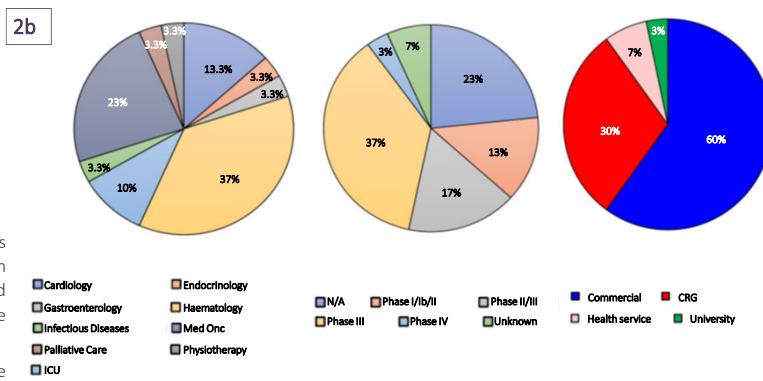


Figure 2b: Pie charts showing the distribution of the thirty clinical trials assessed during the initial assessment at Barwon Health in July 2023, by department (left), phase/complexity (middle) and sponsor type (right).