Resources for Effective Monitoring

Appendix to the Podcast: Monitoring Clinical Trials for Quality and Safety



NSW Regional Health Partners, Maridulu Budyari Gumal (SPHERE) and Sydney Health Partners have identified resources to support clinical trials sites in their monitoring activities. This resource is an appendix to the Clinical Trials in Focus podcast, Episode 2 Monitoring Clinical Trials for Quality and Safety.

Monitoring clinical trials when the sponsor of the trial is a Local Health District, Medical Research Institute or University, and the trial is investigator-initiated, is an important sponsor responsibility.

Monitoring clinical trials verifies that:

- The rights and well-being of participants are protected;
- The reported trial data are accurate, complete and verifiable from source documents;
- The conduct of the trial is compliant with the approved protocol/amendment(s), with Good Clinical Practice (GCP), and with any applicable regulatory requirement(s).

The National Statement on Ethical Conduct in Human Research and the ICH Guidelines for Good Clinical Practice, both include monitoring of clinical trials as a quality measure and responsibility of the sponsoring organisation. The National Statement states that each institution has ultimate responsibility for ensuring, via its research governance arrangements, that all its authorised research is monitored. Monitoring should be commensurate with the risk, size and complexity of the research.

From 2023 the National Clinical Trials Governance Framework (NCTGF) also guides the provision of clinical services including trials and notes the need to monitor the conduct of the trial when the site and/or organisation is the sponsor. The NCTGF requires organisations to monitor adherence to the approved clinical trial protocol to minimise the number of trial protocol deviations and violations.

This means that having a monitoring process for trials your organisation sponsors is more important than ever.

Below is a summary of the key policy and implementation documents related to monitoring clinical trials in Australia.

Provider	Resource	Summary information
Australian Commission on Safety and Quality in Healthcare	National Clinical Trials Governance Framework (NCTGF)	See Actions 1.11 Incident management systems and open disclosure and 1.12 Suggested strategies to meet this action.
Australian Commission on Safety and Quality in Healthcare	Australian Hospital Patient Experience Question Set (AHPEQS)	The AHPEQS is a survey used by hospitals and healthcare services to ask recent patients about their experiences of treatment and care.
National Health and Medical Research Council	Safety monitoring and reporting in clinical trials involving therapeutic goods	The Guidance provides advice on how risk-based quality management may be applied in a non-commercial trial setting. It identifies commonly used monitoring techniques for both remote and on-site monitoring.
National Health and Medical Research Council	National Statement on Ethical Conduct Human Research 2025	The National Statement defines monitoring as the process of verifying that the conduct of research conforms to the approved proposal. • Chapter 5.1. defines institutional responsibilities (research Governance). Institutions are responsible for human research they conduct this includes monitoring in accordance with the national statement. • Chapter 5.4 addresses monitoring of approved research by institutions via their research governance arrangements.
Therapeutic Goods Administration	TGA Annotations to ICH Guideline for Good Clinical Practice	The TGA ICH GCP integrated addendum identifies responsibilities of the sponsor for trials involving therapeutic goods. It notes: • The sponsor should implement a system to monitor quality throughout all stages of the trial process. • Sponsors should use a risk-based approach to quality management and when identifying risks decide which should be reduced or accepted.

Provider	Resource	Summary information
Therapeutic Goods Administration	Australian Clinical Trial Handbook	The handbook provides guidance on conducting clinical trials in Australia using 'unapproved' therapeutic goods. See the section on Trial sponsor responsibility of trial management and monitoring.
Australian Clinical Trials Education Centre (A-CTEC) and the Victorian Comprehensive Cancer Centre (VCCC) Alliance	Investigator Initiated Trials Toolkit: Monitoring Section	This resource provides an overview of monitoring including monitoring trial conduct and ensuring safety. It provides information on: • who is responsible • links to national guidelines • different models of monitoring • what activities should be included when monitoring • documentation following the monitoring visit • managing non-compliance corrective and preventative actions
Victorian Comprehensive Cancer Centre (VCCC) Alliance	Different Ways to Monitor Clinical Trials	This document identifies: • The benefits of monitoring • What is source data verification monitoring • What should be monitored • Different types of monitoring Top tips to choose the right monitoring strategy

Other audit resources

Please see the other audit resources available on your partner organisation's website:

NSW Regional Health Partners (NSWRHP)

Sydney Health Partners (SHP)

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