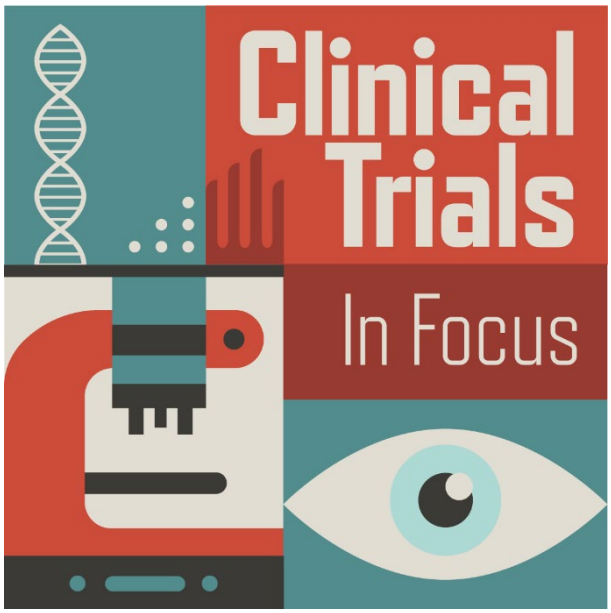
Resources for Effective Monitoring

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

A summary of key policy and implementation documents related to monitoring clinical trials in Australia.



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 GCP, and with any applicable regulatory requirement(s).

The National Statement on Ethical Conduct in Human Research (2007) - Updated 2018 and the Integrated Addendum to ICH E6 R1: Guidelines for Good Clinical Practice (ICH E6 R2) both include monitoring of clinical trials as a quality measure and a responsibility of the sponsoring organisation.

Clinical Trials in Focus, Episode 2: Monitoring Clinical Trials for Quality and Safety.

From 2023 the National Clinical Trials Governance Framework (NCTGF) will also guide 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.

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.

Provider	**Resource**	**Summary information**
Australian Clinical Trials Education Centre and the Victorian Comprehensive Cancer Centre Alliance	Investigator initiated Trials toolkit Subsection: Monitoring	This resource provides an overview of monitoring including monitoring trial conduct and ensuring safety. The resource 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.
Australian Commission on Safety and Quality in Healthcare	National Clinical Trials Governance Framework	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	The Australian Hospital Patient Experience Question Set (AHPEQS) is a survey used by hospitals and healthcare services to ask recent patients about their experiences of treatment and care.

Commonwealth Department of Health	National Standard Operating Procedures for Clinical Trials, including Teletrials in Australia SOP 12: Safety Data Monitoring and Reporting Requirements for Clinical Trials	The National Standard Operating Procedures for Clinical Trials, including Teletrials in Australia include a Standard operating procedure (#12) that describes the procedures and requirements related to the safety data collection, verification and reporting requirements for clinical trials involving Investigational Medicinal Products (IMP) and Investigational Medicinal Devices (IMD). The SOP details sponsor and investigator responsibilities.
National Health and Medical Research Council	NHMRC: National Statement on Ethical Conduct in Human Research	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 5.5 addresses monitoring of approved research by institutions via their research governance arrangements.
National Health and Medical Research Council	NHMRC: Safety monitoring and reporting in clinical trials involving therapeutic goods	The Safety monitoring and reporting in clinical trials 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.
Therapeutic Goods Administration	TGA: ICH Guideline for Good Clinical Practice	The TGA ICH GCP integrated addendum identifies responsibilities of the sponsor (section 5) 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.
Therapeutic Goods Administration	Australian Clinical Trial Handbook V2.4 2021 Guidance on conducting clinical trials in Australia using 'unapproved' therapeutic goods	See the section on Trial sponsor responsibility of trial management and monitoring.
Victorian Comprehensive Cancer Centre Alliance	Different-Ways-Monitor-Clinical-Trials.pdf (vcccalliance.org.au)	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.