MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

Proposed updates to the Guideline on the Regulation of Therapeutic Products in New Zealand: Clinical Trials

A summary of the major changes and rationale

August 2024

Contents

Summary of major changes and rationale

Title

Proposed changes	Rationale
Removed part number ('Part 11') from guideline title. The new title is 'Guideline on the Regulation of Therapeutic Products in New Zealand: Clinical trials – regulatory approval and good clinical practice requirements'	For consistency with other updated Medsafe guidelines.

Definitions

Proposed changes	Rationale
Added a list of terms commonly used in the guideline with definitions.	To provide clarity to readers regarding terms used in the guideline.

Section 1: Legislation

Proposed changes	Rationale
Updated/added to list of relevant legislation and reformatted into table. Changes include: • Health Information Privacy Code 2020 • Misuse of Drugs (Medicinal Cannabis) Regulations 2019 • Privacy Act 2020 • Radiation Safety Act 2016	Some legislation has changed and/or has been identified as relevant since the last guideline update.

Updated/added to list of relevant guidance and reformatted into table. Changes include:
• Council for International Organizations of Medical Sciences (CIOMS)
  ○ Patient involvement in the development, regulation and safe use of medicines
  ○ International guidelines on good governance practice for research institutions
• Ethics Review Manager (Ethics RM)
  ○ Account login page
• European Medicines Agency (EMA)
  ○ Requirements to the chemical and pharmaceutical quality documentation concerning investigational medicinal products in clinical trials – Scientific guideline (EMA/CHMP/QWP/545525/2017 Rev. 2)
  ○ ICH E2A Clinical safety data management: definitions and standards for expedited reporting – Scientific guideline (CPMP/ICH/377/95)
	Some guidance materials have changed and/or have been identified as relevant since the last guideline update.

○ ICH E2F Development safety update report – Scientific guideline (EMA/CHMP/ICH/309348/2008) • Health and Disability Ethics Committees (HDECs) ○ Guidance on protocol deviation submissions • Health Research Council of New Zealand (HRC) ○ Guidelines for Researchers on Health Research involving Māori ○ Pacific Health Research Guidelines • International Atomic Energy Agency (IAEA) ○ Good Practice Guideline • International Conference on Harmonisation (ICH) ○ Integrated Addendum to ICH E6(R1): Guideline for good clinical practice E6(R2) • Medicines and Healthcare products Regulatory Agency (MHRA)/Health Canada ○ Guideline on how to increase transparency when presenting safety information in the Development Safety Update Report (DSUR): region-specific requirements for Canada and the United Kingdom • Ministry of Health ○ National Standards for Vaccine Storage; Transportation for Immunisation Providers 2017 (2nd edition) ○ Code of Practice for Nuclear Medicine • National Ethics Advisory Committee (NEAC) National Ethical Standards for Health and Disability Research and Quality Improvement	

Section 2: Overview of Regulation of Clinical Trials in New Zealand

Proposed changes	**Rationale**
Expanded the definition of clinical trial to include additional criteria that distinguish clinical trials from usual clinical practice.	To provide more clarity on the scope of this guideline and to better align with international definitions. The Medicines Act does not define a clinical trial.
Added radiopharmaceuticals to the list of clinical trials not requiring approval under section 30 of the Medicines Act.	Radiopharmaceuticals are not regulated under the Medicines Act.
Added a new subsection with information on additional approval/licensing requirements (eg, to pack, import or manufacture medicines or conduct clinical trials involving medicinal cannabis).	To provide more information on other legal obligations outside of the clinical trial approval process.

Section 3: Application for Approval of a Clinical Trial under Section 30 of the Medicines Act

Proposed changes	Rationale
Updated to indicate that primary method of communication for clinical trial applications should be via Ethics RM.	Ethics RM preferred over email for administrative purposes.
Updated the criteria for fee waivers and added information on how to apply.	To provide more clarity on which clinical trials are eligible for a fee waiver and the process for requesting one.
Added a link to the new proposed guideline for first in human/early phase trials (this document is also being consulted on – see below).	To direct readers to additional guidance on the conduct of first in human/early phase trials.

Section 4: Notification of Clinical Trial Sites

No major changes.

Section 5: Good Clinical Practice Requirements

Proposed changes	Rationale
Added a recommendation for patient-centric clinical trial design/conduct with reference to relevant CIOMS guidance.	This is consistent with Good Clinical Practice (GCP) principles, existing ethical standards and values outlined in the New Zealand Health Strategy.
Clarified the terminology used for those involved in the running of clinical trials, and aligned with international naming conventions where the Act allows (ie, applicant, sponsor, investigators and monitor).	The previous terms were not clear and in some cases conflicted with international naming conventions.
Included more information on requirements for labelling of investigational medicines.	To provide further clarity on requirements as specified in section 30 of the Medicines Act and Annex 13 of the New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods.
Included more information on the requirements for the supply and distribution of investigational products.	To provide further clarity on requirements as specified in section 30 of the Medicines Act.
Updated information on supply restrictions for controlled drugs.	To align with the latest amendments to the Misuse of Drugs Regulations.

Added a new subsection with information on cold chain requirements for medicines requiring cold storage, including reference to Ministry of Health guidelines for vaccine storage and transportation.	To address additional considerations for investigational products requiring cold storage.

Section 6: Records and Reporting

Proposed changes	**Rationale**
Updated requirements for adverse event reporting so that sponsors with a pharmacovigilance system in place are not required to report SUSARs to Medsafe (details of the pharmacovigilance system must be submitted with the clinical trial application).	To simplify reporting requirements for sponsors who have appropriate systems in place to analyse these reports and identify potential safety issues.
Clarified reporting requirements for non-fatal or life-threatening SUSARs and other adverse reactions (must be held in accessible form and made available on request).	To provide clarity on requirements for non-fatal or life-threatening SUSARs and other adverse reactions
Added the option of reporting adverse reactions via the CARM reporting webform online or the CIOMS form on Ethics RM.	To provide sponsors with another option for adverse reaction reporting.
Added additional examples of significant actions/issues that must be reported to Medsafe including serious safety issues, urgent safety measures, and serious breaches.	To provide more clarity to sponsors about what needs to be reported to Medsafe.
Updated reporting timeframes for fatal and life threatening SUSARs and significant actions/issues to 15 calendar days (urgent safety measures must still be reported within 7 days).	To allow more time for sponsors to report significant events that do not require urgent safety measures to be taken.
Clarified requirements for periodic safety reports to be submitted annually and that DSUR may serve as the safety report (this is additional to 6 monthly progress reports).	To provide more clarity to sponsors about how frequently periodic safety reports need to be submitted and to reduce duplication by allowing DSUR to serve as the safety report.
Clarified requirements for reporting trial amendments and other trial changes after a clinical trial is approved.	To provide more clarity to sponsors about when submission of an amendment or other action is required for trial changes.
Added wording to indicate that if the trial has not commenced within two years of the approval, the application will be revoked.	To ensure that clinical trials that are commencing meet current requirements.

Added a link to the new proposed guideline for safety monitoring and reporting requirements (this document is also being consulted on – see below).	To direct readers to additional guidance on safety monitoring and reporting requirements for clinical trials.
Added new subsection which links to relevant guidance materials for HDEC reporting requirements.	To ensure sponsors are aware of HDEC reporting requirements.

Section 7: Clinical Trials Involving Medical Devices

Proposed changes	Rationale
This is a new section which outlines expectations and requirements for trials involving medical devices which are not regulated under Section 30 of the Medicines Act.	To ensure that relevant information on clinical trials involving medical devices can be easily found by readers.

Considerations for First-In-Human (FIH) and Early Phase Clinical Trials

Proposed changes	Rationale
This is a new document.	This document has been produced following a request from the HRC Standing Committee on Therapeutic Trials (SCOTT) that Medsafe provides more guidance to entities wishing to conduct first in human and early phase trials as there are specific considerations for these types of trials that will be taken into account in the clinical trial review/approval process.

Clinical Trial Safety Monitoring and Reporting for Investigational Products (Medicines and Medical Devices)

Proposed changes	Rationale
This is a new document.	This document has been produced following a request from (and in collaboration with) the New Zealand Association of Clinical Research (NZACRes) that Medsafe provides more guidance on safety monitoring and reporting in clinical trials as there is currently lack of consistency in approach.