MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

Guideline on the Regulation of Therapeutic Products in New Zealand

Clinical Trials – Regulatory Approval and Good Clinical Practice Requirements

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Contents

Definitions

Adverse event (AE)	Any unfavourable medical occurrence in a trial participant administered the investigational product. The adverse event does not necessarily have a causal relationship with the treatment.
Adverse reaction/Adverse drug reaction (ADR)	In the pre-approval clinical experience with a new investigational product or its new usages (particularly as the therapeutic dose(s) may not be established): unfavourable and unintended responses, such as a sign (ie, laboratory results), symptom or disease related to any dose of the investigational product where a causal relationship between the investigational product and an adverse event is a reasonable possibility. The level of certainty about the relatedness of the adverse drug reaction (ADR) to an investigational product will vary. If the ADR is suspected to be related with a high level of certainty, it should be included in the reference safety information (RSI) and/or the Investigator's Brochure (IB). For marketed medicinal products: a response to a drug that is noxious and unintended and that occurs at doses normally used in humans for prophylaxis, diagnosis or therapy of diseases or for modification of physiological function.
Agreement	A document or set of documents describing the details of any arrangements on delegation or transfer, distribution and/or sharing of activities and, if appropriate, on financial matters between two or more parties. This could be in the form of a contract. The protocol may serve as the basis of an agreement.
Applicant	According to section 30 of the Medicines Act 1981, an application for clinical trial approval must be made by the importer, manufacturer, or packer, or the intending manufacturer, packer, seller, or supplier of the medicine, in New Zealand (referred to as the applicant). The applicant may be either an individual resident in New Zealand or a New Zealand-registered company. The applicant may also be the trial sponsor.
Approved medicine	A medicine which has been granted consent under section 20 or section 23 (provisional consent) of the Medicines Act 1981 to be sold, supplied, distributed or advertised in New Zealand (sometimes referred to as having marketing authorisation or consent to distribute).
Advanced therapy medicinal product (ATMP)	Medicines for human use that are based on genes, tissues or cells. • Gene therapy medicines: these contain genes that lead to a therapeutic, prophylactic or diagnostic effect. They work by inserting 'recombinant' genes into the body, usually to treat a variety of diseases, including genetic disorders, cancer or long-term diseases. A recombinant gene is a stretch of DNA that is created in the laboratory, bringing together DNA from different sources. • Somatic-cell therapy medicines: these contain cells or tissues that have been manipulated to change their biological characteristics or cells or tissues not intended to be used for the same essential functions in the body. They can be used to cure, diagnose or prevent diseases. • Tissue-engineered medicines: these contain cells or tissues that have been modified so they can be used to repair, regenerate or replace human tissue.

Audit	A systematic and independent examination of trial-related activities and records performed by the sponsor, service provider (including contract research organisation (CRO)) or institution to determine whether the evaluated trial-related activities were conducted and the data were recorded, analysed and accurately reported according to the protocol, applicable standard operating procedures (SOPs), Good Clinical Practice (GCP) and the applicable regulatory requirement(s).
Bioequivalence	When the bioavailability of two different formulations of the same pharmaceutical form and containing the same active ingredient (a test and a reference product) are shown to be comparable after administration of the same dose, the products are said to be bioequivalent. This comparability is determined by a bioequivalence study.
Biosimilar medicine (biosimilar)	A biological medicine that is highly similar (but not identical) to an existing biological medicine (reference product).
Blinding/Masking	A procedure in which one or more parties to the trial are kept unaware of the treatment assignment(s). Single-blinding usually refers to the participant(s) being unaware, and double-blinding usually refers to the participant(s) and investigator(s) and, if appropriate, other investigator site staff or sponsor staff being unaware of the treatment assignment(s).
Certificate of analysis	A certificate issued by the manufacturer of a medicine that provides a summary of testing results on samples of products or materials together with the evaluation for compliance to a stated specification.
Clinical drug development	Clinical drug development, defined as studying a drug in humans, is conducted in a sequence that builds on knowledge accumulated from non-clinical and previous clinical studies. Although clinical drug development is often described as consisting of four temporal phases (phases 1–4), it is important to appreciate that the phase concept is a description and not a requirement, and that the phases of drug development may overlap or be combined.
Clinical trial/Clinical study	Any interventional investigation in human participants intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s); and/or to identify any adverse reactions to an investigational product(s); and/or to study absorption, distribution, metabolism and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy.
Clinical trial site/Investigator site	The location(s) where trial-related activities are conducted or coordinated under the investigator/ institutions oversight (eg, clinical trial units, hospitals).
Clinical trial/study report (CSR)	A documented description of a trial of any investigational product conducted in human participants, in which the clinical and statistical description, presentations and analyses are fully integrated into a single report. A report that presents intermediate results and their evaluation based on analyses performed during a trial is an interim CSR.
Consumer	A consumer is defined as a person who is not a healthcare professional, such as a patient, patient representative, caregiver, friend or relative of a patient.

Coordinating investigator	An investigator assigned the responsibility for the coordination of investigators at different investigator sites participating in a multicentre trial.
Development safety update report (DSUR)	An annual review of safety information during clinical trials of a medicine under investigation – whether or not it is marketed. The main objectives of a DSUR are to: summarise the current understanding and management of identified and potential risks; describe new safety issues that could have an impact on the protection of clinical trial participants; examine whether any new safety information is in line with previous knowledge of the product's safety; provide an update on the status of the clinical investigation/ development programme and study results.
First in human (FIH) trial	A FIH trial evaluates an investigational product in humans for the first time, to study the human pharmacology, tolerability and safety of the investigational product and to compare how effects seen in non-clinical studies translate into humans.
Good Clinical Practice (GCP)	A standard for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of trial participants are protected.
Good Manufacturing Practice (GMP)	The systems that manufacturers of medicines are required to have in place to ensure their products are consistently safe, effective and of acceptable quality.
Gene Technology Advisory Committee (GTAC)	A Committee of the HRC that undertakes scientific assessment of clinical trials that involve the introduction of nucleic acids, genetically manipulated micro-organisms or viruses or cells into human participants. It also makes recommendations to the Director-General of Health on whether or not trials should be approved.
Health and Disability Ethics Committee (HDEC)	HDECs are Ministerial committees (established under section 87 of the Pae Ora (Healthy Futures) Act 2022), whose function is to secure the benefits of health and disability research by checking that it meets or exceeds established ethical standards.
Health Research Council (HRC)	A statutory entity responsible for: • advising the Minister of Health on national health research policy • advising on health research priorities for New Zealand • initiating and supporting health research • fostering the recruitment, training and retention of health researchers in New Zealand.
Independent Data Monitoring Committee (IDMC)	An independent data monitoring committee (eg, Data Safety Monitoring Board [DSMB]) established by the sponsor to assess the progress of a clinical trial, the safety and relevant efficacy data, and to recommend to the sponsor whether to continue, modify or stop a trial.
Individual case safety report (ICSR)	The complete information provided by a reporter at a certain point in time to describe an event or incident of interest. The report can include information about a case involving one participant or a group of participants.

Inspection	The act by a regulatory authority(ies) of conducting an official review of documents, facilities, records and any other resources that the authority(ies) deems to be related to the clinical trial and that may be accessed at the investigator site, at the sponsor's and/or service provider's (including CRO's) facilities, or at other establishments deemed appropriate by the regulatory authority(ies). Some aspects of the inspection may be conducted remotely.
Institution (medical)	Any public or private entity or agency or medical or dental organisation in whose remit clinical trials are conducted. See also clinical trial site/investigator site.
Investigational medical device (IMD)	A medical device being assessed for safety or performance in a clinical investigation.
Investigational product (IP)	A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorisation when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use. Investigational products should be considered synonymous with drugs, medicines, medicinal products, vaccines and biological products. Also referred to as investigational medicinal product (IMP) or investigational medicine.
Investigator	A person responsible for the conduct of the clinical trial, including the trial participants for whom that person has responsibility during the conduct of the trial. If a trial is conducted by a team of individuals, the investigator is the responsible leader of the team and may be called the principal investigator.
Investigator's Brochure (IB)	A compilation of the clinical and non-clinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human participants
Clinical trial monitor / clinical research associate (CRA)	The clinical trial monitor (or clinical research associate) oversees the progress of a clinical trial, and ensures that it is conducted, recorded and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP) and the applicable regulatory requirements.
Medical device	Defined in section 3 of the Medicines Act 1981. Refer to Table 1 in this guideline for the legislation relating to clinical trials.
Medical monitor	Medically qualified individuals who review and evaluate information relevant to the safety of the investigational product throughout the development and implementation of the protocol.
Medicine	Defined in section 3A of the Medicines Act 1981. Refer to Table 1 in this guideline for the legislation relating to clinical trials.
Multicentre trial	A clinical trial conducted according to a single protocol but at more than one investigator site.

New medicine	A medicine for which: • consent for distribution in New Zealand (marketing authorisation) has not previously been granted (unapproved medicines) • approval has been previously granted but the medicine has undergone substantial change(s) which requires referral under section 24(5) of the Medicines Act 1981 • approval has been previously granted but has since lapsed (approval lapsed).
Non-clinical study	Biomedical studies not performed on human participants.
Non-interventional (observational) study	A clinical study where the assignment of the participant to a particular therapeutic strategy is not decided in advance and falls entirely within normal clinical practice. Additionally: • the decision to prescribe the investigational product is separate from the decision to include the participant in the study • no additional diagnostic or monitoring procedures (in addition to normal clinical practice) are applied to the participants.
Participant/trial participant	An individual who participates in a clinical trial who is expected to receive the investigational product(s) or a control product (previously referred to as subject/trial subject).
Pharmacovigilance	Science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem.
Product Specification File	A reference file containing, or referring to files containing, all the information necessary to draft the detailed written instructions on processing, packaging, quality control testing, batch release and shipping of an investigational product.
Protocol	A document that describes the objective(s), design, methodology, statistical considerations and organisation of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents.
Reference Safety Information (RSI)	Contains a cumulative list of ADRs that are expected for the investigational product being administered to participants in a clinical trial. The RSI is included in the Investigator's Brochure or alternative documents according to applicable regulatory requirements.
Rescue medicine	Medicines identified in the protocol as those that may be administered to patients when the efficacy of the investigational product is not satisfactory, the effect of the investigational product is too great and is likely to cause a hazard to the patient, or to manage an emergency situation, for example when washing out pre-medication.
Safety critical adverse events	Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations that should be reported to the sponsor according to the reporting requirements specified in the protocol.
Standing Committee on Therapeutic Trials (SCOTT)	A Committee of the HRC that undertakes scientific assessment of clinical trials of medicines (under section 30 of the Medicines Act 1981) and makes recommendations to the Director-General of Health on whether or not trials should be approved.

Serious adverse event (SAE)	Any unfavourable medical occurrence that is considered serious at any dose if it: • results in death • is life-threatening (this refers to an event/reaction in which the patient was at risk of death at the time of the event/reaction; it does not refer to an event/reaction which hypothetically might have caused death if it were more severe) • requires inpatient hospitalisation or prolongation of existing hospitalisation • results in persistent or significant disability/incapacity • is a congenital anomaly/birth defect. An important medical event that may not be immediately life-threatening or result in death or hospitalisation, that may jeopardise the participant or that may require intervention to prevent serious outcomes should generally be considered as serious.
Serious breaches	Transgressions against the clinical trial protocol or GCP that are likely to significantly affect the safety and rights of a participant, or the reliability and robustness of the data generated in the clinical trial.
Service provider	A person or organisation (commercial, academic or other) providing a service used by either the trial sponsor or the investigator to fulfil trial-related activities.
Signal (in clinical trials)	A report or reports of an event with an unknown causal relationship to treatment that is recognised as worthy of further exploration and continued surveillance.
Significant safety issue (SSI) (in clinical trials)	A safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial.
Standard operating procedures (SOP)	Detailed, documented instructions to achieve uniformity of the performance of a specific activity.
Sub-investigator	Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (eg, associates, residents, research fellows).
Suspected unexpected serious adverse reaction (SUSAR)	An adverse reaction that meets three criteria: suspected, unexpected and serious. • Suspected: There is a reasonable possibility that the drug caused the adverse drug reaction. • Unexpected: An adverse reaction, the nature or severity of which is not consistent with the applicable product information (eg, Investigator's Brochure or alternative documents according to applicable regulatory requirements; see RSI). • Serious: See SAE.
Trial sponsor	An individual, company, institution or organisation that takes responsibility for the initiation, management and/or financing of a clinical trial.

Trial sponsor-investigator	An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to or used by a participant. The term does not include any person other than an individual (eg, the term does not include a corporation or an agency). The obligations of a trial sponsor-investigator include both those of a trial sponsor and those of an investigator.
Unanticipated serious adverse device effect (USADE)	Serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report.
Urgent safety measure (USM)	An urgent measure taken to eliminate an immediate hazard to a trial participant's health or safety.

1 Legislation

Section summary

This section identifies the legislation and other guidance documents to be read in conjunction with this guideline.

1.1 Legislation relating to clinical trials

Table 1 provides the legislation that should be read in conjunction with this part of the guideline.

Table 1: Legislation relating to clinical trials

Legislation	Relevant section(s)
Medicines Act 1981 "Medicines Act"; "the Act"	Section 2 Meaning of 'importer', 'manufacture', 'pack', 'sell' Section 3 Meaning of 'medicine', 'new medicine', 'prescription medicine' and 'restricted medicine' Section 3A Meaning of 'medical device' Section 4 Meaning of 'therapeutic purpose' Section 17 Manufacturers, wholesalers, packers of medicines, and operators of pharmacies to be licensed Section 18 Sale of medicines by retail Section 20 Restrictions on sale or supply of new medicines Section 30 Exemption for clinical trial Section 47 Storage and delivery of medicines Section 88 Refusal of licensing authority to grant licence Part 4 Medical advertisements
Medicines Regulations 1984 "Medicines Regulations"; "the Regulations"	Regulation 39 Conditions under which authorised prescribers and veterinarians may prescribe medicines Part 5 Manufacture, packing, storage and handling
Misuse of Drugs Act 1975	Section 6 Dealing with controlled drugs (including import, supply, administration) Schedules Classes of Controlled Drugs
Misuse of Drugs Regulations 1977	Regulation 31 Restrictions on supply on prescription
Misuse of Drugs (Medicinal Cannabis) Regulations 2019	Regulation 25 Research activity
Public Records Act 2005	Section 18 Disposal of public records and protected records
Privacy Act 2020	
New Zealand Public Health and Disability Act 2000	
Accident Compensation Act 2001	
Hazardous Substances and New Organisms Act 1996	

Continues

Legislation	Relevant section(s)
Health and Disability Commissioner Act 1994	
Health Practitioners Competence Assurance Act 2003	
Health (Retention of Health Information) Regulations 1996	
Health Information Privacy Code 2020	
Human Tissue Act 2008	
Injury Prevention, Rehabilitation and Compensation (Code of ACC Claimants' Rights) Notice 2002	
Radiation Safety Act 2016	

1.2 Additional guidance material relating to clinical trials

In addition to the legislation listed in Table 1 above, the guidance documents in Table 2 may also be helpful.

Table 2: Additional guidance documents relating to clinical trials

Author/Organisation	Guidance documents
Medsafe – Guidelines on the Regulation of Therapeutic Products in New Zealand (GRTPNZ)	GRTPNZ documents are published on the Medsafe website. The following are relevant to clinical trials: • Clinical Trial Safety Monitoring and Reporting • Considerations for First-in-Human (FIH) and Early Phase Clinical Trials • Pharmacovigilance • Bioequivalence of Medicines • Manufacture of Medicines There is also a CV template on the Medsafe website.
Council for International Organizations of Medical Sciences (CIOMS)	• Patient involvement in the development, regulation and safe use of medicines 2022 • International guidelines on good governance practice for research institutions 2023
Ethics Review Manager (Ethics RM)	• Ethics RM User Manual • Ethics RM account login page

Continues

Author/Organisation	Guidance documents
European Commission	• Guidelines on Good Clinical Practice specific to Advanced Therapy Medicinal Products
European Medicines Agency (EMA)	• Strategies to identify and mitigate risks for first in-human and early clinical trials with investigational medicinal products – Scientific guideline (EMEA/CHMP/SWP/28367/07 Rev. 1) • Requirements to the chemical and pharmaceutical quality documentation concerning investigational medicinal products in clinical trials – Scientific guideline (EMA/CHMP/QWP/545525/2017 Rev. 2) • Guideline for the notification of serious breaches of Regulation (EU) No 536/2014 or the clinical trial protocol (EMA/698382/2021)
Health and Disability Ethics Committees (HDECs)	• Standard Operating Procedures for 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 • HRC Research Ethics Guidelines • HRC ethics and regulatory committees
International Atomic Energy Agency (IAEA)	• Good Practice for Introducing Radiopharmaceuticals for Clinical Use
International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)	• ICH E6(R3): Guideline for Good Clinical Practice • ICH E2F: Development Safety Update Report • ICH E2A: Clinical Safety Data Management: Definitions and Standards for Expedited Reporting
Medicines New Zealand	• Medicines New Zealand Guidelines on Clinical Trials Compensation for Injury Resulting from Participation in an Industry-Sponsored Clinical Trial
Ministry of Health	• Code of Practice for Nuclear Medicine • Medicinal Cannabis Scheme guidelines
National Ethics Advisory Committee (NEAC)	• National Ethical Standards for Health and Disability Research and Quality Improvement

2 Overview of Regulation of Clinical Trials in New Zealand

Section summary

Under section 30 of the Medicines Act 1981, medicines that do not otherwise have approval to be distributed in New Zealand may be distributed if the Director-General of Health has approved the clinical trial(s) and the persons conducting it.

Medsafe administers the approval process for clinical trials.

The Health and Disability Ethics Committees administer the separate ethics approval system, which applies to all clinical trials conducted in New Zealand.

Approvals under other legislation may be required for clinical trials using certain types of medicines.

All clinical trials in New Zealand are expected to be conducted in accordance with internationally accepted Good Clinical Practice (GCP) standards.

Approval for a trial may be revoked or suspended, in writing, at any time (eg, if there are significant concerns about patient safety).

2.1 Requirement for approval of a clinical trial under Section 30 of the Medicines Act 1981

Section 30 of the Medicines Act 1981 (the Act) allows the Director-General of Health to approve clinical trials (and the persons conducting them) involving medicines that do not otherwise have approval to be distributed in New Zealand. The Director-General's approval allows for the medicine to be supplied for the sole purpose of being used in a clinical trial. This approval is required for all types of clinical trials of new (unapproved) medicines, including pharmacokinetic, bioequivalence and first-in-human studies. A clinical trial using such medicines must not commence before the Director-General of Health has approved the trial.

The application and approval process for clinical trials is administered by Medsafe, the New Zealand Medicines and Medical Devices Safety Authority. See section 3 of this guideline for the full application and approval procedure, with a summary in Table 3 below.

Table 3: Summary of the application and approval process for clinical trials

1. Submit the application via Ethics Review Manager (Ethics RM).
2. A committee of the Health Research Council (HRC) considers the application.
3. The HRC makes a recommendation to the Director-General of Health on the clinical trial application.
4. Based on the HRC recommendation, Medsafe will issue an approval, a request for further information or a decline letter to the applicant. Medsafe acts under authority delegated from the Director-General of Health.

Medsafe also administers a notification scheme for clinical trial sites that have participants in residence and maintains a list of sites for which it has received notification of compliance with Good Clinical Practice requirements. See section 4 of this guideline for further details about notification of clinical trial sites.

A Health and Disability Ethics Committee must also give ethics approval for a clinical trial. This is a separate process that is not administered by Medsafe. See section 2.6 of this guideline for more information.

Section 30(8) of the Act allows the Director-General to revoke or suspend approval of a clinical trial at any time, in writing (eg, if there are significant concerns about patient safety).

2.2 Good Clinical Practice requirements

All clinical trials conducted in New Zealand are expected to be conducted in accordance with internationally accepted standards for Good Clinical Practice (GCP), as outlined in ICH E6(R3): Guideline for Good Clinical Practice [ICH E6(R3]).

Where there is a conflict between international GCP guidelines and requirements set out in New Zealand legislation, the New Zealand legislation takes precedence. Refer to section 5 and section 6 of this guideline for more information on GCP and New Zealand-specific requirements.

2.3 What is a clinical trial?

The term 'clinical trial' is not clearly defined in New Zealand legislation. For the purposes of this guideline, the ICH E6(R3) definition is used.

Any interventional investigation in human participants intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s); and/or to identify any adverse reactions to an investigational product(s); and/or to study absorption, distribution, metabolism and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy.

2.4 Determining whether a clinical trial requires approval under the Medicines Act 1981

The following points are included to help applicants determine whether a clinical trial requires approval under section 30 of the Medicines Act. Table 4 describes situations where approval is not required, and Table 5 where approval is required.

Table 4 Clinical trials that do not require approval under section 30 of the Medicines Act 1981[a]

A clinical trial involving only **approved medicines**. This applies even if the trial is investigating a new use of an approved medicine (eg, a new indication). However, the medicine used in the trial must be the actual medicine formulation for which consent for distribution in New Zealand has been granted (otherwise approval is required; see Table 5).
Placebos do not contain any active ingredients and do not fall under the definition of medicine in the Medicines Act. Therefore, the use of a placebo in a clinical trial does not automatically mean the trial requires approval.
A **laboratory observational extension or other observational extension** to a clinical trial, where no investigational products are given to participants.
Non-interventional (observational) studies where participants are not assigned to an intervention and the decision to prescribe any medicinal products falls entirely within normal clinical practice.
Medical devices are specifically excluded from the definition of medicine in the Medicines Act. There is no provision under the Medicines Act to require approval of clinical trials of medical devices. Applicants can ask Medsafe to determine the categorisation of the product if they are unsure whether the product is a medical device or a medicine. For more information on clinical trials of medical devices, see section 7 of this guideline.
Radiopharmaceuticals are specifically excluded from the definition of medicine in the Medicines Act. Refer to the Radiation Safety Act 2016 and the Ministry of Health's Code of Practice for Nuclear Medicine. General guidance is also available, such as the International Atomic Energy Agency's Good Practice document.
Xenotransplantation is regulated under Part 7A of the Medicines Act as a specified biotechnical procedure requiring the approval of the Minister of Health.

[a] If a trial meets the criteria in this table but *also* meets any of the criteria in Table 5, approval under section 30 is required.

Table 5: Clinical trials that require approval under section 30 of the Medicines Act 1981

Any clinical trial involving: • **New medicines**, which includes **unapproved medicines** and medicines for which **approval has lapsed**. See the Product/Application Search on Medsafe's website for the approval status of medicines. • **New dose forms or dose strengths or different formulations** of an approved medicine. These are also considered new (ie, unapproved) medicines. This includes the medicine(s) under investigation in the trial and/or any other medicine(s) specified as part of the treatment protocol (including active comparators and rescue medicines).
A substance that is commonly used as an **ingredient in a food, dietary supplement or cosmetic**, being investigated in a clinical trial for a therapeutic purpose. In these cases, the substance is considered to be a new medicine and approval for the trial is required.
Clinical trials involving products that are not medicines in other jurisdictions but are considered to be **new medicines under New Zealand legislation** require approval before they can proceed. The Categorisation of Products page on the Medsafe website has more information. .
An **extension to a clinical trial, where an investigational product is administered**. This includes trials only investigating safety endpoints. If the trial has an open extension phase, submit the protocol for the open extension phase with the initial clinical trial application. However, Medsafe will accept subsequent applications for approval if the applicant can demonstrate that extension of the study will yield scientifically valid results.

2.5 Other legislative requirements relating to clinical trials

Other legislative requirements may apply to clinical trials involving certain substances, including (but not limited to) those listed below.

- A clinical trial involving medicines containing material derived from human tissues or cells (eg, stem cells, blood products) should comply with the Human Tissue Act 2008. For more information, refer to the Human Tissue Act section of the Ministry of Health website.
- A clinical trial involving a new organism or genetically modified organism requires compliance with the Hazardous Substances and New Organisms Act 1996. For more information, refer to the Environmental Protection Authority (EPA) website, or contact EPA by email: info@epa.govt.nz.
- A clinical trial involving the use of a controlled drug requires compliance with the Misuse of Drugs Act 1975 and associated regulations. These set out licensing requirements for importation, possession and supply of controlled drugs, as well as storage, prescribing requirements and requirements for additional approvals (eg, Ministerial approval). For more information, refer to the Medicines Control section of the Ministry of Health website, or contact Medsafe by email: medicinescontrol@health.govt.nz.

2.5.1 Additional approval/licensing requirements

Approval under section 30 of the Medicines Act 1981 provides an exemption that allows new medicines to be distributed for use in a clinical trial. However, it does not negate the need for other regulatory approvals or licenses.

Depending on the proposed activities and the medicines involved, additional licensing and/or issuing of an approval may be required under the Misuse of Drugs Act 1975 and Medicines Act 1981 before the clinical trial can take place. Some examples are listed below.

- Licences are required to manufacture or pack medicines for use in a clinical trial. For more information, refer to the Manufacturing section of the Medsafe website or contact Medsafe by email: GMP@health.govt.nz.
- Where controlled drugs are to be imported for use in a clinical trial, a licence to import controlled drugs is required. In some circumstances, Ministerial approval may be required before a controlled drug can be used in a clinical trial. For more information, refer to Medicines Control section of the Ministry of Health website, or contact Medsafe by email: medicinescontrol@health.govt.nz.
- Appropriate authorisations are required to procure, hold or supply medicines and/or controlled drugs for use in a clinical trial (eg, a licence to sell by wholesale or a licence to deal in controlled drugs). For more information, contact Medsafe by email: medicinescontrol@health.govt.nz.
- Clinical trials involving medicinal cannabis products require a medicinal cannabis licence with a research activity (in addition to any other licensing requirements). The clinical trial must be approved under section 30 of the Medicines Act before making an application for a medicinal cannabis licence. For more information, refer to the Guidance for Applicants for a Medicinal Cannabis Licence or contact the Medicinal Cannabis Agency by email: medicinalcannabis@health.govt.nz.

The timeline for obtaining approval for a relevant licence may differ significantly from Medsafe's timeline for approval of the clinical trial.

2.6 Health and Disability Ethics Committees approval

All clinical trials should comply with the Health and Disability Ethics Committees' (HDEC) requirements, regardless of whether they are trials that require approval under section 30 of the Medicines Act.

HDEC approval is a separate process from the clinical trial approval process under section 30 of the Act and is not administered by Medsafe.

The application for HDEC approval may be made at any time before, during or after consideration of the application for clinical trial approval under section 30 (applications may be submitted concurrently). However, approval under section 30 of the Act is conditional on obtaining ethics approval and the trial must not start until HDEC has granted approval.

Clinical trials should be registered on a clinical trials registry approved by the World Health Organization before commencing in New Zealand.

For more information about HDEC requirements and how to apply for HDEC approval, refer to the HDEC website, or contact the HDEC Secretariat at: hdecs@health.govt.nz.

2.7 Advocacy Services

The Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996 applies to clinical trial participants. For example, consumers should have access to services such as Advocacy Services when they are enrolled in a clinical study. It is desirable but not essential to appoint a patient advocate to a study. If no advocacy service is appointed, patients must be told how and where they can obtain such services if they require them.

3 Application for Approval of a Clinical Trial under Section 30 of the Medicines Act 1981

Section summary

This section describes the application and approval procedure administered by Medsafe for the approval of clinical trials under Section 30 of the Medicines Act 1981.

3.1 Role of Medsafe in the clinical trial approval procedure

Medsafe administers the section 30 application and approval process for clinical trials under an authority delegated from the Director-General of Health. Medsafe receives and processes applications, liaises with the relevant Health Research Council (HRC) committee to obtain their recommendation and issues outcome letters to applicants.

- For general enquiries, email: askmedsafe@health.govt.nz.
- For enquiries relating to a specific clinical trial (once an application has been created), use the NZ Ethics Review Manager (Ethics RM) internal correspondence function.

3.2 Role of the Health Research Council in the clinical trial approval procedure

Section 30 of the Medicines Act 1981 authorises the Director-General of Health to approve a clinical trial on the recommendation of the Health Research Council of New Zealand (HRC).

The HRC maintains two standing committees to undertake scientific assessments of clinical trial applications and make recommendations to the Director-General.

- The Standing Committee on Therapeutic Trials (SCOTT) considers applications for pharmaceutical-type medicines.
- The Gene Technology Advisory Committee (GTAC) considers applications for trials involving gene and other biotechnology therapies.

See the HRC website for further information about the committees, including their terms of reference.

3.3 How to submit an application for approval of a clinical trial

Applicants must use the online NZ Ethics RM system (Ethics RM) to apply for clinical trial approval, as outlined below. Medsafe will not accept paper-based/emailed applications.

In accordance with section 30(3) of the Medicines Act 1981, the application should clearly outline the purpose of the trial and provide information on the trial protocol, investigational product, investigators and trial sites. See Appendix 1 for a list of essential documents to be submitted with the application.

3.3.1 Making an online application for a clinical trial

Use Ethics RM to make an online application for clinical trial approval.

New users will need to create an account for access to Ethics RM. Click on the New User button on the Ethics RM Log-in page and complete the online form. The Help section of the Log-in page has more information about creating an account and how to prepare and submit applications electronically. There is also an Ethics RM User Manual.

In Ethics RM, one applicant 'owns' the project, but they can assign project access to others.

The applicant should use the 'SCOTT / GTAC Application' Online Form in Ethics RM.

3.4 Administrative processing of clinical trial applications

- Within 5 working days of receipt of the online application, Medsafe will send an acknowledgement letter and an invoice to the applicant.
- Applicants should pay the invoice within 5 working days of receipt.

Medsafe will only issue a decision if payment has been received.

3.5 Clinical trial application fee and fee waiver

See the Medsafe Fee Schedule for current clinical trial application fees.

The basic administration fee for the application is non-negotiable and non-refundable. However, under regulation 61A of the Medicines Regulations 1984, the Director-General of Health may waive or refund, in whole or part, the fee in certain circumstances.

Fee waiver applications must be submitted with the initial clinical trial application. Fee waivers will be considered on a case-by-case basis, according to the criteria outlined below.

3.5.1 Criteria for fee waiver

Clinical trials that meet **all** of the criteria shown in Table 6 may be considered for a fee waiver.

To apply for a fee waiver, include a letter with the initial clinical trial application submitted through Ethics RM. The fee waiver application letter should outline how the clinical trial meets the fee waiver criteria.

Table 6: Criteria for fee waiver

The trial is being conducted in the interests of public health in New Zealand, for example: • the trial aims to meet an unmet clinical need (eg, there is currently no treatment available for a condition) • the trial aims to address equity issues • the trial is expected to result in a change to clinical practice; **and**
The trial is not funded or sponsored by the pharmaceutical industry; **and**
The trial is being conducted only in Australia and New Zealand.

Trials conducted by the pharmaceutical industry are not eligible for a fee waiver. However, bioequivalence studies are eligible for an abbreviated approval process with a reduced fee (see section 3.7 of this guideline).

3.6 Consideration of applications for approval of clinical trials

The relevant standing committees of the HRC (SCOTT or GTAC) consider clinical trial applications.

The HRC website has the terms of reference for these standing committees. The applicant should read these documents before submitting an application, as they provide information on the scope of the assessment. For guidance on first-in-human (FIH) and early phase clinicals trials, see *GRTPNZ: Considerations for First-in-Human (FIH) and Early Phase Clinical Trials* (available on the Medsafe website).

The relevant standing committee will consider an application and then convey its recommendation to the Director-General's delegate at Medsafe. The committee may recommend:

- approving the clinical trial
- not approving the trial until the applicant provides further information
- not approving the trial.

Medsafe will liaise with the applicant if further information is required. Applicants will be given the opportunity to address any issues before an application is declined.

Within 32 working days of receiving the application (and providing that the invoice has been paid), Medsafe will notify the applicant of the outcome via Ethics RM.

- If the Director-General's delegate approves the clinical trial application, Medsafe will issue an approval letter.
- If the Director-General's delegate declines an application, Medsafe will provide the reasons for this decision to the applicant.

If the applicant believes that the correct processes were not followed, they have 28 days to lodge an appeal with the Medicines Review Committee. The appeal provisions are set out in section 88 of the Medicines Act 1981.

Trial approval will be revoked if the trial has not commenced within two years of its approval. A new application will need to be submitted before the trial can start.

3.7 Abbreviated clinical trial approval process for bioequivalence studies

Medsafe operates an abbreviated approval process for eligible clinical trial applications for bioequivalence studies. This abbreviated approval process **does not apply to biosimilar products**. To be eligible, **all** of the criteria in Table 7 must be met.

Table 7: Criteria for abbreviated approval process for clinical trial applications for bioequivalence studies[a]

The clinical trial is a bioequivalence study that uses an investigational product that contains the same active pharmaceutical ingredient included in a medicine that is approved in New Zealand (approved medicine); **and**
The proposed route of administration for the investigational product is the same as that for the approved medicine; **and**
The proposed dosage for the investigational product is within the recommended dosage range for the approved medicine.

a. Does not apply to biosimilar products.

A reduced fee applies to clinical trial applications meeting these criteria, and Medsafe aims to issue an outcome within 5 working days of receiving the application. See the Medsafe Fee Schedule for current fee details.

4 Notification of Clinical Trial Sites

Section summary

Clinical trial applications must include information about the clinical trial sites.

Medsafe also administers a Clinical Trial Site Notification scheme covering sites that have study participants in residence (ie, staying overnight or longer). The notification is site-specific and confirms the site's procedures for dealing with medical emergencies arising from a clinical trial. The person responsible for the site completes the notification and updates it whenever the information in the original notification is changed.

4.1 Notification of Clinical Trial sites

Section 30(3)(g) of the Medicines Act 1981 specifies that the clinical trial application must include information about the site(s) at which the trial is to be conducted and the facilities available at those sites. The relevant HRC standing committee reviews this site information when considering the clinical trial application.

If study participants are staying overnight or longer for monitoring purposes as a result of receiving an investigational product, information about the facilities and procedures in place to deal with possible medical emergencies arising from the trial should be provided. Medsafe administers a voluntary Clinical Trial Site Notification scheme to facilitate the collection and processing of this information (see section 4.2 and section 4.3 below).

4.2 Operation of the Clinical Trial Site Notification scheme

Under the Clinical Trial Site Notification scheme, the person responsible for the site (where study participants stay overnight) completes the Clinical Trial Site Notification Form, available for download from the Medsafe website. In most instances, the person responsible for the site will be a site staff member who has responsibility for managing the site, its staff and its procedures (eg, the site manager). By submitting the notification, the person responsible for the site confirms that adequate procedures are in place at the site to manage medical emergencies.

The notification can be made at any time and does not need to coincide with submission of an application for approval of a particular clinical trial.

On receipt of a completed notification, Medsafe will add the site to the Notified Clinical Trial Sites webpage.

If there is a change to any of the information submitted in the original notification form (including changes to contact details), the person responsible for the site should submit a new notification form.

If a notified clinical trial site is no longer operating, the person responsible for the site should inform Medsafe so that it can be removed from the published list of notified clinical trial sites.

4.3 Information for Applicants

Applicants requesting approval of a clinical trial where participants are kept overnight for monitoring purposes as a result of receiving the study medicine should check Medsafe's Notified Clinical Trial Sites webpage to confirm that Medsafe has been notified of the proposed clinical trial site. If Medsafe has not been notified of the site, the applicant should contact the person responsible for the site (eg, the site manager) to submit a notification.

Medsafe recommends that applicants should not commence a clinical trial that requires trial participants to stay at a site overnight (or longer) unless Medsafe has been notified of the site.

5 Good Clinical Practice Requirements

Section summary

This section establishes the expectation for clinical trials to be conducted in accordance with internationally accepted standards for Good Clinical Practice and explains the modifications that are needed to achieve alignment with New Zealand regulatory requirements.

5.1 Compliance with Good Clinical Practice

All clinical trials are expected to be conducted in accordance with internationally accepted standards for Good Clinical Practice (GCP), as outlined in ICH E6(R3): Guideline for Good Clinical Practice (ICH E6(R3)). If applicants need further information that is not covered in this guideline, refer to the EMA's scientific guidelines.

Where there is a conflict between international guidelines and requirements set out in New Zealand legislation, the New Zealand legislation takes precedence. New Zealand-specific requirements relating to the following topics are explained in the corresponding sections of this guideline:

- roles and responsibilities of particular persons defined in the Medicines Act 1981 (see section 5.2)
- manufacture, labelling, storage, distribution and supply of investigational products (see section 5.3)
- preservation of records (see section 6.1)
- patient medical record (see section 6.2)
- safety reporting (see section 6.3)
- reporting of other significant events (see section 6.4)
- reporting changes to a trial (see section 6.5)
- reporting study progress (see section 6.6).

In accordance with the GCP principles, Medsafe encourages inclusion of the patient perspective in clinical trial design and conduct. The CIOMS report on Patient involvement in the development, regulation and safe use of medicines provides additional guidance.

5.2 Roles and Responsibilities of Particular Persons defined in the Medicines Act 1981

Section 30 of the Medicines Act 1981 refers to the *applicant*, the *importer or manufacturer*, and *investigators*. These roles and their legal responsibilities, as defined in the Act, are described below.

In practice, depending on the circumstances of a trial, these roles may not necessarily represent distinct legal entities (eg, where an applicant and importer or manufacturer are same person, or a trial sponsor-investigator where an individual assumes multiple roles).

This section does not provide a comprehensive overview all clinical trial roles and responsibilities.

5.2.1 Applicant

Section 30(2) of the Act states that an application for clinical trial approval must be made by the importer, manufacturer, or packer, or the intending manufacturer, packer, seller, or supplier of the medicine, in New Zealand (referred to as the applicant).

The applicant may be either:

- an individual resident in New Zealand, or
- a New Zealand-registered company.

The applicant is responsible for:

- submitting the clinical trial application and providing the required information and documents (see section 3.3)
- applying for approval of all new investigators (see section 5.2.3 and section 6.5.2)
- supplying any information requested relating to a clinical trial or investigators.

The applicant may delegate the conduct of trial-related activities as necessary and in accordance with ICH E6(R3). However, the applicant retains overall responsibility for the activities specified in Section 30 of the Act.

Some clinical trials may have an overseas trial sponsor (eg, a multinational trial with sites in New Zealand). In these instances, a New Zealand-based applicant (as defined above) is still required.

In some cases, the applicant may also be the trial sponsor.

5.2.2 Importer or manufacturer

Section 30(1) of the Act allows for the distribution of a medicine for a clinical trial, if approved, by the importer or manufacturer, in New Zealand.

The importer or manufacturer is responsible for:

- ensuring the medicine is only supplied to approved investigators
- ensuring that appropriate trial facilities are available for approved investigators to conduct the trial
- keeping complete and accurate records of medicines supplied under section 30 of the Act
- providing 6-monthly clinical trial progress reports (see section 6.6.1)
- supplying a copy of the results of the trial upon its completion (see section 6.6.2).

The importer or manufacturer may delegate the conduct of trial-related activities as necessary and in accordance with ICH E6(R3). However, the importer or manufacturer retains overall responsibility for the activities specified under section 30 of the Act.

5.2.3 Investigators

The Director-General of Health must approve all investigators responsible for conducting the clinical trial in New Zealand.

Investigators should be resident in New Zealand, have competence and experience in a relevant field of study, and hold appropriate qualifications that are recognised within New Zealand. An up-to-date CV that clearly outlines all relevant experience (eg, clinical trial experience, professional experience, employment history), qualifications and training must be provided for each investigator (see Appendix 1). An optional CV template is available on the Medsafe website.

5.3 Quality of Investigational products

ICH E6(R3) provides guidance on the quality requirements for investigational products that should be followed. Investigational products, including active comparators and placebos, are expected to be manufactured in accordance with Good Manufacturing Practice (GMP).

Section 30 of the Medicines Act also places conditions on the labelling, distribution and supply of an investigational medicine.

5.3.1 Manufacture of investigational products

Manufacturers of medicines (including investigational products) in New Zealand must hold a manufacturing licence, as specified in section 17 of the Act. Compliance with the New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods (the Code; Part 1: Manufacture of Pharmaceutical Products) is required. Annex 13 of the Code provides guidance specific to investigational products.

Manufacturers of investigational products in New Zealand should hold a Product Specification File that describes the specifications of the investigational product manufactured for the clinical trial and the manufacturing process, which includes processing, packaging, quality control testing, batch release and shipping. The Product Specification File must be consistent with specifications in the clinical trial documents (eg, the Investigator's Brochure, trial protocol, etc). The manufacturer must issue a Certificate of Analysis (CoA) to the trial sponsor.

The clinical trial application should include information on the quality of the investigational product, such as stability data and evidence of GMP certification.

The trial sponsor should verify that each batch of the investigational product meets the approved specifications and is suitable for use before it is released for use in the trial.

5.3.2 Labelling of investigational products

Section 30(7)(b) of the Act requires that every label on every package of a medicine used in a clinical trial must have the words "***To be used by qualified investigators only***". Medsafe has no objection to words of a similar meaning being used, if these words comply with labelling requirements set out in Annex 13 of the Code.

The investigational product should otherwise be labelled according to Annex 13 of the Code.

5.3.3 Storage requirements for investigational products

Store, handle and ship the investigational products as specified by the trial sponsor or manufacturer and in accordance with section 47 of the Medicines Act 1981 (Storage and delivery of medicines), and Part 5 (regulations 26-37) of the Medicines Regulations 1984.

Some investigational products may require cold storage. Cold storage requirements must be strictly adhered to so that the quality of the product is not compromised in the lead-up to, and during, the clinical trial.

5.3.4 Distribution and supply of investigational products

Section 30(7)(c) of the Act requires that the importer or manufacturer must take reasonable steps to ensure that every person to whom the investigational product is distributed must be approved to conduct the trial (ie, be an approved investigator). The medicine must be used solely by that person or under their direction for the purposes of the trial, and they must have the necessary facilities to conduct the trial.

The clinical trial approval letter will list the approved investigators and trial sites. Customs may not clear delivery of investigational products to any sites or investigators that are not specified on the approval letter. If the delivery site for the investigational product differs from the trial site, this address should be clearly stated in the application form so that it can be included in the approval letter.

Where a clinical trial uses an investigational product containing a substance listed in a schedule to Misuse of Drugs Act 1975, the supply restrictions relevant to that class of controlled drug will apply. The maximum period of supply is 1 month.

Where investigational products are required to be repacked ready for supply to trial participants, this must be undertaken by a person who is the holder of a packing licence or is otherwise authorised to pack medicines (eg, pharmacists operating under a pharmacy licence), as specified in section 17 of the Medicines Act 1981.

6 Records and Reporting

Section summary

This section describes the records and reporting requirements for clinical trials.

6.1 Preservation of records

Complete and accurate study records and data relating to New Zealand trial participants must be retained. Preservation of clinical trial records must comply with New Zealand privacy legislation (Privacy Act 2020) and the Health (Retention of Health Information) Regulations 1996. The following points also apply to clinical trials.

- For all trials, the records may be stored overseas provided they are stored in accordance with New Zealand privacy legislation and Health (Retention of Health Information) regulations and are maintained in an accessible form until they are disposed of in accordance with New Zealand law.
- The timeframes for retention of records will depend on the nature and duration of the trial. Records must be kept for a minimum of 10 years from the date the study ends.

Additionally, the importer or manufacturer of the medicine must keep complete and accurate records of all quantities of the medicine supplied for use in a trial, in accordance with Section 30(7)(d)(i) of the Medicines Act 1981.

Refer to Archives New Zealand for general advice on standards for electronic storage, retention and disposal of public records.

6.2 Patient medical record

Medsafe recommends recording clinical trial participation in an individual's medical record. This is to ensure health professionals who are involved in patient care outside of the trial setting (eg, the emergency department) are aware of the patient's involvement in a clinical trial. The investigator's contact information should also be included.

6.3 Safety reporting

In accordance with *GRTPNZ: Clinical Trial Safety Monitoring and Reporting* (available on the Medsafe website), report adverse events, significant safety issues and urgent safety measures occurring in clinical trials to Medsafe. An annual safety report is also required.

6.4 Other notifiable events

Along with safety reporting requirements outlined in *GRTPNZ: Clinical Trial Safety Monitoring and Reporting*), Medsafe should be notified of any other significant events which may impact the benefit-risk balance of the trial in New Zealand. Examples include:

- suspension or cancellation of ethics approval in New Zealand, for any reason
- serious breaches occurring in the New Zealand clinical trial that are likely to significantly affect the reliability and robustness of the data or the rights, safety or wellbeing of participants (refer to the EMA Guideline for the notification of serious breaches for examples)
- withdrawal of the investigational product from continued development in any jurisdiction, for any reason (relevant to the indication under investigation)
- withdrawal of the investigational product from the market in another jurisdiction, for any reason.

When notifying Medsafe, provide details of the event, including reasons, and proposed actions or mitigations (if required). If there is likely to be no impact on the New Zealand trial, this should be confirmed in the notification.

Medsafe should be notified no later than **15 calendar days** of the trial sponsor's awareness of the event.

Report other notifiable events:

- through Ethics RM (using the SCOTT Post Approval Forms), or
- email at: askmedsafe@health.govt.nz (include the trial name or identifier in the subject line).

6.5 Amendments to the trial

6.5.1 Changes to the trial protocol

Once a clinical trial has been approved, any substantial amendments to the trial protocol should be submitted to Medsafe through Ethics RM for approval (SCOTT Post Approval Form). Medsafe must approve the changes before they can be implemented, except for urgent changes being implemented as a result of serious safety issues (for more information, see *GRTPNZ: Clinical Trial Safety Monitoring and Reporting* on the Medsafe website). To assist Medsafe's evaluation, evidence of acceptance of protocol amendments by overseas regulators may also be submitted, if available .

A substantial amendment is an amendment that is likely to affect to a significant degree any of the following:

- the safety or physical or mental integrity of participants
- the scientific value of the trial
- the conduct or management of the trial
- the quality or safety of any medicine or item used in the trial.

Examples of substantial amendments include (but are not limited to) changes to:

- the design/methodology of the study
- the procedures participants will undertake
- the inclusion or exclusion criteria
- the dosage, frequency, or mode of administration of the investigational product
- safety monitoring procedures.

As the same time, submit consequential changes to other essential trial documents, such as the Investigator's Brochure.

Minor changes, such as administrative updates, typographical corrections and clarifications that do not alter the protocol's intent (including protocol clarification letters and notes to file) do not require prior approval before being implemented. This includes minor changes to other essential trial documents such as the Investigator's Brochure. These may be submitted through Ethics RM for notification at the time of the change, or at the time of submitting the next substantial amendment, or the 6-monthly progress report.

Applications for approval of a new study phase (eg, from Phase 1 to 2) that was not specified in the original clinical trial application must be submitted as a new clinical trial application, not as an amendment. If you are unsure if a new clinical trial application or an amendment is required, email: askmedsafe@health.govt.nz (with 'Clinical trial' in the subject line).

6.5.2 Changes to the trial sites or investigators

Any changes to investigators or trial sites must be approved before they can be implemented (eg, new investigators or new trial sites). Submit these changes to Medsafe via Ethics RM for approval (SCOTT Post Approval Form).

Customs may not release investigational products to trial sites (or delivery sites if different to the trial sites) or investigators if they are not specified on the approval letter. It is the applicant's responsibility to ensure these details are kept up to date by submitting any changes to Medsafe.

6.6 Study progress reporting

6.6.1 6-monthly progress reports

Section 30(7)(d)(ii) of the Medicines Act 1981 requires progress reports to be submitted for approved trials every 6 months.

Submit the first progress report to Medsafe (through Ethics RM) no more than 6 months after the date of approval of the trial, whether or not recruitment of New Zealand trial participants has commenced. Submit subsequent reports at 6-monthly intervals throughout the duration of the trial in New Zealand.

If available, the Development Safety Update Report (DSUR) may serve as the progress report for one of the two 6-month periods (the DSUR executive summary is acceptable, with the full DSUR to be made available on request). A standard progress report is still required for the other 6-month period.

Upon completion of the trial (or the or the New Zealand arm of a multinational trial), submit a notification of conclusion to Medsafe (through Ethics RM). There is no need to continue submitting 6-monthly progress reports once the New Zealand trial has been completed, even if the trial continues elsewhere. If a trial is being terminated early, provide the reasons why.

6.6.2 Final report

Section 30(7)(d)(iii) of the Medicines Act requires a copy of the results of the trial to be submitted on its completion.

Submit the trial results (eg, a synopsis of the final report) to Medsafe when available at the global end of trial. The full report does not need to be submitted to Medsafe but must be held in an accessible form and made available on request.

Medsafe recommends that the outcome of the study be reported to the trial participants.

6.6.3 How to report

Submit post-approval reports (eg, progress reports, trial results) and notification of study conclusion to Medsafe through Ethics RM using the SCOTT Post-Approval Form (PAF).

If you experience difficulties submitting reports via Ethics RM, email Medsafe for advice at: askmedsafe@health.govt.nz (with 'Clinical Trial' in the subject line).

6.7 Health and Disability Ethics Committees reporting requirements

The reporting requirements for HDECs are outlined in the following documents:

- Standard Operating Procedures for HDECs
- Guidance on protocol deviation submissions
- National Ethical Standards for Health and Disability Research and Quality Improvement.

GRTPNZ: Clinical Trial Safety Monitoring and Reporting (available on the Medsafe website) also summarises the HDEC safety monitoring and reporting requirements.

For further information on HDEC reporting requirements, contact the HDECs Secretariat directly at: hdecs@health.govt.nz.

7 Clinical Trials of Medical Devices

There is no provision under the current legislation (the Medicines Act 1981) to require approval of clinical trials of medical devices (medical device trials). However, Medsafe would like to be informed of these trials by email at devices@health.govt.nz. This is so that Medsafe has some knowledge of these trials should any issues later arise. Notifying a medical device trial to Medsafe does not constitute an approval or endorsement of the trial.

Where a medical device is used in the conduct of a clinical trial, but is not a device under investigation (eg, wearables/data collection tools), this does not need to be routinely notified to devices@health.govt.nz.

All devices used in clinical trials must still comply with any other requirements of the Medicines Act 1981 and its associated regulations, and Medsafe should be advised of any post-market action (recall, product correction, alert, etc). Note that medical devices imported for use in a clinical trial are considered exempt medical devices and do not need to be notified to WAND. Refer to the Medical Devices/WAND section of the Medsafe website for more information.

All clinical trials must comply with the Health and Disability Ethics Committees' (HDEC) requirements, regardless of whether they are trials that require approval under section 30 of the Medicines Act.

Medical device trials are expected to be conducted in accordance with international best practice.

For information on safety monitoring and reporting for clinical trials of medical devices, see *GRTPNZ: Clinical Trial Safety Monitoring and Reporting* (available on the Medsafe website).

Appendix 1: Essential documents to be submitted with a Clinical Trial application and to support changes proposed to be made to the trial

A1.1 Documents that must be included with the initial application

- Current CV for coordinating investigator
- Current CVs for investigators
- GMP certification for manufacturer
- GMP certification for packer
- Signed Investigator consent form
- Investigator's Brochure
- Signed Protocol
- Sample labels

Applicants may submit any other documents that they consider are pertinent to the trial.

A1.2 Documents that should be submitted after approval

- CVs for new investigators
- Signed Investigator consent form / Signed protocol for new investigators
- Protocol Amendments
- Adverse Event Reports
- SSIs/USMs and other notifiable events
- Six-monthly progress reports and annual safety reports
- Updated GMP certification for manufacturer
- Updated GMP certification for packer
- Updated Investigator's Brochure
- Updated labels

Applicants may submit any other documents that they consider are pertinent to the trial.

A1.3 Documents that should be submitted after the trial has completed in New Zealand

- Notification of Conclusion of the Study (when trial sites in New Zealand have been closed out and the trial is completed in New Zealand)
- A copy of the results of the trial when this is available (eg, a synopsis of the final clinical study report)

Applicants may submit any other documents that they consider are pertinent to the trial.