MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

Guideline on the Regulation of Therapeutic Products in New Zealand

Considerations for first-in-human (FIH) and early phase clinical trials

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Definitions

For a table of definitions, see Medsafe's *Guideline on the Regulation of Therapeutic Products in New Zealand*: *Clinical trials – Regulatory Approval and Good Clinical Practice Requirements* (abbreviated as *GRTPNZ: Clinical Trials*.) This document is published on the Medsafe website

1 Purpose

This guidance document is for trial sponsors and other individuals or organisations involved in the conduct of first-in-human (FIH) or early phase clinical trials in New Zealand. It provides guidance aimed at ensuring that a high standard for participant safety is met and can be clearly demonstrated.

The full regulatory requirements for clinical trials in New Zealand are outlined in Medsafe's *GRTPNZ: Clinical Trials* (available on the Medsafe website).

2 Overview of FIH and Early Phase Clinical Trials

Early phase clinical trials can be broadly defined as non-therapeutic, exploratory trials in human participants. They study the human pharmacology, tolerability and safety of an investigational product and compare how effects seen in non-clinical studies translate into humans.

A FIH trial evaluates an investigational product in humans for the first time. These studies are often undertaken in healthy volunteers but can also include patients with a specific disease.

3 General Considerations

FIH and early phase clinical trials are a key step in medicines development. However they are associated with a greater level of uncertainty (and therefore risk) compared to later phase clinical trials due to the lack of experience with the use of an investigational product in humans.

A risk assessment should be conducted and documented (eg, in the clinical trial protocol and/or other relevant documents included in the clinical trial application) for all FIH and early phase clinical trials. This should clearly outline potential risks and how these will be mitigated. Aspects that should be considered as part of the risk assessment include (but are not limited to):

- the quality of the investigational product and active pharmaceutical ingredient
- interpretation and relevance of the non-clinical data
- dosing selection and dose escalation decisions
- clinical trial design and conduct
- trial site facilities, procedures, and staff expertise.

Sponsors and investigators wishing to conduct FIH and early phase clinical trials in New Zealand should refer to the European Medicines Agency (EMA) Guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products (EMEA/CHMP/SWP/28367/07).

4 Clinical Trial Sites

FIH and early phase clinical trials should take place at clinical trial sites with appropriate facilities, procedures and staff expertise to mitigate and manage the increased level of risk to study participants.

Medsafe expects that early phase clinical trials will have previously been conducted at a trial site before FIH trials are conducted at the site. The site should also be notified to Medsafe (via the Clinical Trial Site Notification Form) before a clinical trial application is made.

Further considerations for clinical trial sites are discussed below.

4.1 Facilities

4.1.1 Monitoring and supervision

FIH and early phase clinical trials should take place under controlled conditions (such as inpatient units). Clinical trial sites should be set up in a way that allows for close supervision and monitoring of study participants.

All areas of the site accessible by participants (including wards, bathrooms, recreation areas, etc) should have alarms to alert staff to an emergency. These alarms should be regularly tested.

4.1.2 Emergency trolley

Clinical trial sites should have access to emergency medicines and equipment for resuscitating and stabilising individuals in an acute medical emergency (such as cardiac or respiratory arrest, anaphylaxis, cytokine release syndrome, convulsions and hypotension).

An emergency trolley should be easily and rapidly accessible in all areas occupied by study participants. At a minimum, emergency trolley(s) should be stocked according to current clinical guidelines. The contents should be regularly checked to ensure they remain appropriate and in date.

Continuous monitoring equipment to monitor vital signs such as heart rate and rhythm, blood pressure, oxygen saturation and temperature should also be available.

4.1.3 Emergency hospital facilities

Clinical trial sites not located within a hospital should have procedures in place to transfer participants to hospital with minimal delay in case of a medical emergency. The site should be able to transfer participants to a hospital that can provide an appropriate level of care in an emergency, with journey time of less than 15 minutes. A procedure for transferring participants to the hospital should be documented.

For clinical trial sites located within a hospital, the unit should have access to hospital emergency response staff who are able to rapidly respond in case of a medical emergency. A procedure for alerting hospital staff should be documented.

4.1.4 Handling and storage of the investigational product

Handling and storage of the investigational product should be in accordance with the trial protocol and manufacturer requirements.

The facilities, equipment and procedures required for handling and storage of the investigational product will vary depending on the type of trials being conducted at the unit and the nature of the investigational product(s).

At a minimum, clinical trial units will need basic facilities, equipment and procedures for the safe storage and handling of the investigational product and maintaining records of its receipt, storage, use and disposal (for example for trials where the investigational product is pre-packed and labelled by the sponsor ready for administration to individual participants). There should be a designated storage area for the investigational product that is secure and accessible only to authorised staff.

Additional requirements will depend on specific activities that need to be carried out at the trial site. For example, investigational products used in FIH and early clinical trials often require specific preparation at the trial site (or another offsite facility), for example, oral powder for constitution as a suspension or intravenous formulations requiring dilution steps. There may be a need for flexibility to allow for adjustment of doses as the safety and pharmacokinetic data becomes available during the trial.

Where manufacturing or packing activities are required, it will be necessary to obtain the relevant licence(s). For more information, refer to *GRTPNZ: Clinical Trials* (available on the Medsafe website).

4.2 Staff expertise

4.2.1 Investigator

The investigator should have relevant medical qualifications, training and clinical experience. Those wishing to undertake FIH trials should already have experience running Phase I trials. A relevant post-graduate qualification (eg, post-graduate qualifications in clinical pharmacology or pharmaceutical medicine) is highly desirable.

There should be procedures in place at the clinical trial unit to assess the suitability of the investigator. Where gaps in expertise are identified there should be appropriate mitigations in place (eg, oversight of an expert advisor).

4.2.2 Sub-investigators and other medical staff

Consideration should be given to the early phase clinical trial experience of sub-investigators and their ability to safely provide medical cover in the absence of the investigator.

Medical staff trained in advanced life support (ALS) and with experience managing medical emergencies should be present on all dosing days.

4.2.3 Nursing and support staff

The non-medical members of the research team should have appropriate training that allows them to safely execute protocol mandated activities. It is expected that the nursing staff involved in FIH studies have experience in early phase clinical research. All clinical staff should have formal training for managing medical emergencies.

4.3 Procedures

4.3.1 Quality system

Clinical trial sites should have procedures in place to cover the full range of activities undertaken at the site. Procedures should be formally documented as Standard Operating Procedures (SOPs). These SOPs should include procedures for (but not limited to):

- handling common medical emergencies
- handling immediate maintenance of life support in an acute medical emergency including resuscitation and stabilisation of participants
- transferring participants to hospital including handover of relevant medical information
- unblinding in an emergency
- out-of-hours medical cover and contact with the sponsor or investigator
- required qualifications, training and experience for key roles and responsibilities
- staff training and refresher training to maintain competencies for all key activities
- practical training (including simulation-based training) for handling medical emergencies, to ensure all clinical staff know what to do in such situations
- staffing levels and resourcing requirements
- participant recruitment, including identification, verification of medical history and monitoring for over-volunteering
- study protocol implementation including dose escalation and stopping rules
- management of the investigational product
- risk assessment and mitigation (to ensure the site is appropriately resourced for trials conducted at the site).

Quality control (QC) activities should be built into all key procedures to ensure standards are maintained, and quality assurance (QA) procedures should detail how these activities are audited.