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

Consultation questions

August 2024

Contents

Consultation Questions

Your details

This section asks for information about yourself. The information will help in the analysis of stakeholder comments. You are encouraged to fill in this section, however your submission will still be accepted if you do not provide these details.

1.	What is your name?	
2.	What is your email address?	
3.	Are you providing feedback as an individual or on behalf of an organisation or group?	• As an individual • On behalf of an organisation or group If applicable, please provide your organisation or group name:
4.	Which country are you or your organisation based in?	• New Zealand • Australia • Other If you selected other, please specify:
5.	Which of the below options best describes you in the context of this consultation?	• Member of the public/Participant in a clinical trial • Clinical trial sponsor • Clinical trial investigator • Other clinical trial staff • Healthcare professional • Institution (eg, university, hospital) • Industry organisation • Manufacturer • Supplier • Importer • Government • Professional body • Consumer organisation • Regulatory affairs consultant • Other If you selected other, please specify:

Publishing submissions and Official Information Act requests

Publishing submissions		
6.	We intend to publish the submissions from this consultation, but **we will only publish your submission if you give permission**. We will remove personal details such as email addresses and the names of individuals. If you do not want your submission published, please let us know below. (Required)	• You may publish this submission • Do not publish this submission
Official Information Act responses		
7.	Your submission will be subject to requests made under the Official Information Act (even if it hasn't been published). If you want your personal details removed from your submission, please let us know below. You can also tell us if you would like us to withhold other information from your submission (for example, because it's commercially sensitive). Any decision Medsafe makes to withhold information can be reviewed by the Ombudsman, who may tell us to release it. (Required)	• Include my personal details in responses to Official Information Act requests • Remove my personal details from responses to Official Information Act requests If there is other information you would like us to withhold, please specify:

Guideline on the Regulation of Therapeutic Products in New Zealand: Clinical trials – regulatory approval and good clinical practice requirements

The following questions relate to the proposed major changes in the Guideline on the Regulation of Therapeutic Products in New Zealand: Clinical trials – regulatory approval and good clinical practice requirements.

Notes:

1. The part number (Part 11) has been removed from the title of the guideline. In future, other Medsafe guidance documents will no longer include a part number.

2. No major changes are proposed in Section 4: Notification of Clinical Trial Sites.

Definitions

8.	Do you have any comments on the proposed definitions?	• Yes • No Provide comments:

Section 1: Legislation

9.	Is there additional legislation or guidance materials that are relevant and should be added?	• Yes • No If yes, please specify:
10.	Is there legislation or guidance materials that are not relevant and should be removed?	• Yes • No If yes, please specify:

Section 2: Overview of regulation of clinical trials in New Zealand

11.	Do you agree with the updated definition of clinical trials?	• Yes • No Provide comments:
12.	Do you have any other comments on this section?	• Yes • No Provide comments:

Section 3: Application for approval of a clinical trial under section 30 of the Medicines Act

13.	Do you agree with the updated criteria for fee waivers?	• Yes • No Provide comments:
14.	Do you have any other comments on this section?	• Yes • No Provide comments:

Section 5: Good Clinical Practice Requirements

15.	Do you agree with the recommendation for patient-centric clinical trial design and conduct?	• Yes • No Provide comments:

16.	Do you agree with the way the applicant, sponsor, investigator and monitor have been defined?	• Yes • No Provide comments:
17.	Do you agree with the updated requirements for labelling, supplying and distributing investigational products?	• Yes • No Provide comments:
18.	Do you have any other comments on this section?	• Yes • No Provide comments:

Section 6: Records and Reporting

19.	Do you agree with waiving the requirement for reporting suspected unexpected serious adverse reactions (SUSARs) for sponsors with a pharmacovigilance system?	• Yes • No Provide comments:
20.	Do you agree with the updated list of reportable actions/issues?	• Yes • No Provide comments:
21.	Do you agree with the updated reporting timelines?	• Yes • No Provide comments:
22.	Do you agree with the requirements for periodic safety reporting/Development Safety Update Report (DSURs)?	• Yes • No Provide comments:
23.	Do you agree with the requirements for notifying trial protocol amendments or other changes to a trial?	• Yes • No Provide comments:
24.	Do you have any other comments on this section?	• Yes • No Provide comments:

Section 7: Clinical trials involving medical devices

25.	Do you agree with the inclusion of this new section?	• Yes • No Provide comments:

General comments

26.	Do you have any further comments on this guideline?	• Yes • No Provide comments:

New guidance documents

The following questions relate to the two new guidance documents:

- Considerations for First in Human (FIH) and Early Phase Clinical Trials; and
- Clinical Trial Safety Monitoring and Reporting for Investigational Products (Medicines and Medical Devices).

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

27.	Do you agree that additional guidance for FIH and early phase clinical trials is needed?	Yes No Provide comments:
28.	Do you consider the guidance in this document to be broadly applicable to all types of FIH and early phase trials?	Yes No Provide comments:
29.	Do you agree with the requirement for a risk assessment as described in 'general considerations'?	Yes No Provide comments:
30.	Do you agree with the level of experience required for clinical trial sites and investigators wishing to conduct FIH trials?	Yes No Provide comments:
31.	Do you have any other comments on the contents of this document?	• Yes • No Provide comments:

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

32.	Do you agree that additional guidance on safety monitoring and reporting in clinical trials is needed?	• Yes • No Provide comments:
33.	Do you agree with the roles and responsibilities of entities involved in clinical trials in New Zealand outlined in the guideline?	• Yes • No Provide comments:
34.	Do you have any comments on the reporting requirements for clinical trials involving medicines?	• Yes • No Provide comments :
35.	Do you have any comments on the reporting requirements for clinical trials involving medical devices?	• Yes • No Provide comments :
36.	Do you have any other comments on the contents of this document?	• Yes • No Provide comments :

Final comments

37.	If you have any further comments that have not been covered in the previous questions, please provide them here.	Provide comments: