Submission no. 13

Section 1: Legislation

1 Are the additional guidance documents listed in this section appropriate?

Yes

2 Are there other guidance documents relevant to the conduct of clinical trials of medicines in New Zealand that should be considered for inclusion?

Yes

3 Comments or suggestions

Comments or suggestions for section 1:
no

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

1 Does this section adequately describe the situations when approval is required for clinical trials, and the types of approvals that are required?

Yes

2 Was the information appropriately presented?

Yes

3 Are there any changes you would like to suggest?

No

4 Comments or suggestions

Comments or suggestions on section 2:
None

Section 3: Application for approval of a clinical trial

1 Are the roles and responsibilities of the various parties involved clearly explained?

Yes

2 Is the application process adequately described?

Yes

3 Is the sole circumstance for an abbreviated process for clinical trial approval clearly explained?

Yes

4 Comments or suggestions

Comments or suggestions on section 3:
Section 3.1 - Is there a separate email contact for the Clinical Trial Co-ordinator at Medsafe other then info@medsafe.govt.nz?

Historically we have been writing to XXXXXXXXXXXXXX medsafe email address for clinical trial matters. If there a dedicated general email address for clinical trials matters ?

Section 3.3 "An application for approval for a clinical trial is made by the person responsible for the trail in New Zealand. This person is referred to the Medicines Act as "the applicant"

Can Medsafe explains that the applicant of a clinical trial in New Zealand can be an "individual, company, institution, or organisation in New Zealand ". majority of the time , we are submitting the application as a company / organization in New Zealand and it is the company / organization that is legally responsible .

Is there an option for pre-submission meeting with Medsafe for high risk protocols or products t seek feedback and consultation from Medsafe ?

Section 4: Notification of clinical trial sites

1 A revised (simplified) process has been proposed for notifying clinical trial sites where subjects stay overnight as part of the investigation. Is the explanation of the requirements clear?

Yes

2 Is the revised process adequate to ensure that only trial sites with adequate access to emergency medicine facilities are used in clinical trials?

Yes

3 Are the instructions on the accompanying Clinical Trial Site Notification Form clear and easy to understand?

Yes

4 Is it clear that clinical trial applicants no longer have to notify trial sites where subjects stay overnight, and that this is the responsibility of the site manager?

Yes

5 Do you have changes to suggest that could be considered?

No

6 Comments or suggestions

Comments or suggestions on section 4:

Section 5: Good clinical practice requirements

1 Does the text in this section adequately explain what is required?

No

2 Are there other good clinical practice-related safety issues or safety concerns that you consider should be included in this section?

Yes

3 Comments or suggestions

Comments or suggestions on section 5:
For section 5.3 Investigational product -

It is understood that the investigational product should be labelled in according to GMP Annex 13 labelling requirement, but is it possible to describe the investigational product labeling requirement particularly does the label needs to include the Local New Zealand applicant's name and address or just the global sponsor name and address is adequate ?

Section 6: Records and reporting

1 Are the responsibilities of the sponsor regarding record keeping and reporting clear?

Yes

2 Do you agree that submitting a synopsis of the final report of the clinical trial is sufficient, and that a full report does not need to be submitted unless this is asked for by Medsafe?

Yes

3 Do you have suggestions or recommendations to make that could be included in this section?

Yes

4 Comments or suggestions

Comments or suggestions on section 6:

Your details

1 Your details

Name and designation:
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

Company/organisation name (if applicable):
Covance Inc.

Address:

Phone number:

Email address:
XXXXXXXXXXXXXXXXXXX

2 This submission is:

from an individual or individuals (not on behalf of an organisation or in their professional capacity)

3 I am, or I represent an organisation, based in:

Other

If you selected other, please specify:

4 I am, or I represent, a:

Industry organisation

If you selected health professional, please indicate your type of practice:

If you selected other, please specify:
CRO industry

Publishing submissions and privacy

1 Publishing submissions

You may publish this submission

2 Official Information Act responses

Remove my personal details from responses to Official Information Act requests

3 Commercially sensitive information

This submission does not contain commercially sensitive information

If your submission contains commercially sensitive information, please let us know where.: