Submission no. 3

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?

No

3 Comments or suggestions

Comments or suggestions for section 1:

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:

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 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?

No

3 Comments or suggestions

Comments or suggestions on section 5:
Section 5.2.1
Approval for protocol changes now required (not notification) may have an impact on study timelines in terms of having amendments approved and implemented at a site level. Also, it is not clear whether there is a difference between an administrative protocol amendment or major protocol amendment that would require approval. This needs to be clarified.

Section 5.3
Not clear on what a product specification file is?
Typically for a clinical trial the reference document is the investigators brochure and not a certificate of analysis. It is not clear why the PI would need to ensure that the product is suitable for release and how is this to be documented? This is not usual for clinical trials. Please clarify further.

Section 6: Records and reporting

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

No

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?

No

4 Comments or suggestions

Comments or suggestions on section 6:
Section 6.6
Approval for protocol changes now required (not notification) may have an impact on study timelines in terms of having amendments approved and implemented at a site level. Also, it is not clear whether there is a difference between an administrative protocol amendment or major protocol amendment that would require approval. This needs to be clarified.

General: Layout and format of the guideline

1 Do you agree with the proposed structure of the guideline?

Yes

2 Do you have suggestions, recommendations or other information that could be included in this guideline?

No

3 Comments or suggestions

Comments or suggestions on layout and format:

Clinical Trial Site Notification Form

1 Does this form capture the appropriate essential information?

Yes

2 Is it obvious who should make the notification?

Yes

3 What information do you think would be useful to be published on Medsafe's list of clinical trial sites?

Comments or suggestions on what would be useful:
Trial site information and qualifications as per form

Re-notification of clinical trial site

1 Since the self-certification process is changing to a notification procedure, would you be amenable to re-notifying your clinical trial site (if applicable) when this revised and updated guideline takes effect, so that the list of clinical trial sites is up-to-date?

Yes

2 Comments or suggestions

Comments or suggestions on re-notification:

Your details

1 Your details

Name and designation:
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

Company/organisation name (if applicable):
Boehringer-Ingelheim

Address:
XXXXXXXXXXXXXX
XXXXXXXXX
XXXXXXX

Phone number:
XXXXXXXXXXXXXXXX

Email address:
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

2 This submission is:

made on behalf of a group or organisation(s)

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

New Zealand, Australia

If you selected other, please specify:

4 I am, or I represent, a:

Sponsor

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

If you selected other, please specify:

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.:

Help us improve our consultations

1 How easy did you find using this website to make a submission?

Easy to use

2 If you have made submissions to Medsafe or the Ministry of Health before, was making today's submission:

I haven't made a submission before

3 If there was one change you could make to the submission process, what would it be?

Top suggested change:

4 Any other comments or suggestions?

Other comments: