Submission no. 19

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?

Yes

3 Comments or suggestions

Comments or suggestions on section 5:
There is a requirement that the principal investigator must maintain the product specification file and needs to verify that the investigative product meets specifications and is suitable for release. The role of the principal investigator in this regard needs to be further explained or clarified as the manufacturer and clinical trial sponsor is responsible for the checking of specifications and release of the product. We do not believe that the Investigator has the best background with regard to the technical release specifications of the product.

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:
In section 6.7 ‘How to submit changes to clinical trials, adverse reaction reports and study reports to Medsafe’, it is advised that all reports and applications related to clinical trials should be submitted using the online clinical trial application system, or by email to info@medsafe.govt.nz . There is also a reference made in section 6.3 ‘Reporting other adverse events’ that sponsors should follow the process in the Part 8 Pharmacovigilance Guideline for reporting adverse reactions. We believe some clarity is needed on the process to follow for reporting.
For instance should a Significant Safety Issue or DLT SUSAR report be submitted as outlined in section 6.7 of the proposed Clinical Trial Guideline, or to medsafeadrquery@moh.govt.nz which is provided in the Part 8 Pharmacovigilance Guideline, or to both? Further clarity could be achieved by bringing all the information on clinical trial adverse reaction reporting together in the proposed guideline.

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:
The revised guideline is of good quality with only a few specific points of concern mentioned in the specific sections

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:

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:
XXXXXXXXXXXXXXXXXXXXX

Company/organisation name (if applicable):
AbbVie Limited

Address:
XXXXXXXXXXXXXX
XXXXXXXXXX
XXXXXXXXXXXX

Phone number:
XXXXXXXXXXXXXXXX

Email address:
XXXXXXXXXXXXXXXXXX

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

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?

Adequate

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

Harder

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

Top suggested change:
Not having to go back to the main screen after completing each section. It would be preferable for the questionnaire to move onto the next section as each one is completed

4 Any other comments or suggestions?

Other comments:
It would be good if information regarding new consultations could be emailed to sponsors as there is sometimes a delay in finding out about the consultation.