Submission no. 7

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:
None

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?

Yes

4 Comments or suggestions

Comments or suggestions on section 2:
Under Section 2.4
- Placebos used in clinical trials are not considered to be new medicines. Therefore, a clinical trial involving only placebos do not require approval.
* query - How don you define placebo? In a number of vaccine studies, where the placebo is the excipient, detergents and vaccine by-products - are you happy that these are tested head to head without review?

- Clinical trials of medical devices do not require approval, but Medsafe would like to be informed by email of any such trials (via devices@moh.govt.nz).
* Is that aligned with the previous WAND notification scheme? The need for a simple email notification to Medsafe is a surprising result as many in the sector believe the WAND scheme was insufficient; i.e., there should be verification by Medsafe that the devices are manufactured to a high GMP standard and that the medical device evaluation is aligned to clinical evidence (eg a coronary artery stent should not be used for anything other than cardiac revascularisation without additional supporting animal or human data). There needs to be a clear directive otherwise why would anyone bother to inform them.

Topical medicines are excluded from clinical trial provisions as they are surprisingly defined as a "medical device". We argue that these topical medicines are not all the same, and should be considered on a case by case basis. For eg - a topical medicine using an untested active ingredient applied to a burn wound, or to skin donor site. In this instance, the topical medicine is being applied in a manner requiring a sterile and well-tested product. This loophole creates a vulnerability to NZ clinical trial participants. Furthermore, a clinical trial using subdermal botox injections for headaches or spasticity should also be governed by this regulation.

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:
None

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:
None

Section 5: Good clinical practice requirements

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

Yes

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:
5.2.2 There is some confusion in the use of the term Principal Investigator (as you have defined it). We agree with the definition but HDEC name this role as the Coordinating Investigator. We suggest the term should be aligned

The lead investigator (as you have defined it) is termed globally in the sector as the Principal Investigator. We agree with the definition but we suggest the term should be aligned with HDEC and industry.

The investigator is termed globally in the sector as the Sub-Investigator. We agree with the definition but we suggest the term should be aligned with HDEC and industry.

5.3 Phrase:
"The principal investigator must maintain a product specification file. A copy of relevant sections of the current version must be held by any contract manufacturing sites. The product specification file must be consistent with the approved clinical trial documents (for example specifications in the Investigators Brochure, etc.).
The principal investigator should receive a Certificate of Analysis for investigational products, and should verify that the product meets the approved specifications and is suitable for release".

This is the role of the Sponsor and Regulator to ensure the information has been submitted to Medsafe and meets requirements. It is not reasonable to project

these very specific Chemistry, Manufacturing and Controls (CMC) knowledge expectations onto the investigators for verification. We ask that this clause be removed or significantly amended.

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:
6.1
Archiving of trial records.
- Currently it is accepted for trial records to be archived outside of NZ. It is unclear whether this is operating within the parameters of the NZ Privacy Act. We ask that Medsafe take a position on this.

Records must be kept for a minimum of 10 years from date the study ends
- Many paediatric trials require a longer archiving period. We ask that Medsafe take a clear position on this.

General: Layout and format of the guideline

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

Not Answered

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:
None

Clinical Trial Site Notification Form

1 Does this form capture the appropriate essential information?

No

2 Is it obvious who should make the notification?

No

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:
This process is vague and remains very vague for a large hospital, where clinical trials are run through multiple departments that do not overlap. Who is responsible?

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:
None

Your details

1 Your details

Name and designation:
XXXXXXXXXXXXXX

Company/organisation name (if applicable):
Middlemore Clinical Trials

Address:
XXXXXXXXXX
XXXXXXXXX
XXXXXXXXXXX

Phone number:
XXXXXXXXXXXXX

Email address:
XXXXXXXXXXXXXXXXXXXXX

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:

Industry organisation, Institution (eg, university, hospital), Other

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

If you selected other, please specify:
Clinical Trial site

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?

Difficult to use

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

About the same

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

Top suggested change:
It was difficult to see both the change document and questionnaire at the same time. I needed to use two browsers to make it work.

4 Any other comments or suggestions?

Other comments:
None