Submission no. 14

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:
the revisions state that all clinical trials need to follow GCP - which is great but that could be made even more clear by saying that 'all clinical trials need to follow GCP, even those that do not qualify for the approval process' (i.e. clinical trials not involving new medicines etc still need to follow GCP). I have heard some people say they don't need to follow GCP if it's an academic trial (i.e. non commercial) but to me a trial is a trial and should always follow GCP regardless

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?

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:
5.1
GCP needs to be added after the third mention of CHMP for consistency
5.2.1
GCP needs to be added after the second mention of CHMP for consistency

There is repetition of the following:-
"Once the trial is approved, the applicant becomes the sponsor, assuming responsibility (including legal liability) for the trial in New Zealand."
within the same section it says
"When the application is approved the applicant becomes the 'sponsor' and is responsible for ensuring that the trial is conducted in accordance with both New Zealand law and Good Research Practice standards"

It says ,
"While the supporting documentation required to be submitted with an application may be prepared by the overseas sponsor of the trial, it is the person responsible for the trial in New Zealand (the applicant) who must make the application to the Director-General for approval of the trial."
But then it says
"it is common for the principal investigator in New Zealand (or a local person or company, such as a clinical research organisation acting in that capacity) to undertake the role of applicant (and subsequently, the sponsor)
Firstly it says the applicant has to be the person responsible for the trial in NZ then it says the applicant can be the PI, local person or company acting for the PI) - can a company be named as an applicant?
This isn't clear.

5.2.2
HDEC have adopted the GCP definitions of Coordinating Investigator (CI) where you have Principal Investigator, then Principal Investigator where you have Lead Investigator, then Sub Investigator where you have Investigator. It would be good to have some consistency here, this can be an area of confusion when you are describing the different roles.

5.2.3
"The monitor (or clinical research associate) is an individual appointed by the sponsor and responsible..." Sponsor = NZ sponsor? NZ sponsor may not do this if they are just the applicant. Maybe you should clarify?

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:
6.4
For clarity
"Within 7 days of the sponsor receiving an investigator's report of a **life threatening or fatal ** SUSAR..."

"Medsafe does not require all other serious, unexpected adverse reactions that
are not fatal or life threatening to be reported within 15 days"
should say:-
"Medsafe does not require all other unexpected serious adverse reactions that
are not fatal or life threatening to be reported within 15 days"

6.6.1
It would be useful t align with HDEC's definitions of what needs submitting and approving as amendments - so substantial or not

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:
I think this revision has been simplified and only has links when they're necessary.

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:
I don't know

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:
XXXXXXXXXXX

Company/organisation name (if applicable):
Cancer Trials New Zealand (University of Auckland)

Address:
XXXXXXXXXXXXXXXX
XXXXXXXX

Phone number:
XXXXXXXXXX

Email address:
XXXXXXXXXXXXXXX

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:

Institution (eg, university, hospital), Other

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

If you selected other, please specify:
clinical trial coordinating centre (akin to a non commercial CRO)

Publishing submissions and privacy

1 Publishing submissions

You may publish this submission

2 Official Information Act responses

Include my personal details in 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:

Easier

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

Top suggested change:
have a back button on each page of questions, I was worried to use the Google Chrome back button in case I lost anything
I liked being able to save for later, it made you not feel pressured to do it in one sitting

4 Any other comments or suggestions?

Other comments:
A very useful thing I used to use in the UK was the clinical trials toolkit http://www.ct-toolkit.ac.uk/
This covers all aspects of clinical trials and is so useful
For SCOTT/Medsafe it would be great if you had an algorithm to help us to work out whether we need to get approval or not. So a series of questions with buttons that drill down and then tell us yes you need to apply for approval or no you don't. The MHRA in the UK have this https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/317952/Algothrim.pdf but it would be great to have something online

One day it would be great to have a NZ version of the full clinical trials toolkit!