FUEHRING Stefan (ENTR)

From: ENTR /F/2 PHARMACEUTICALS
Sent: mardi 8 septembre 2009 8:58
To: FUEHRING Stefan (ENTR)
Cc: SALVADOR ROLDAN Rocio (ENTR)
Subject: FW: Comments on proposed changes to Detailed Guidance for the request for authorisation of a clinical trial ....
Follow Up Flag: Follow up
Flag Status: Red

A/21373

From: Brookwood Academy [mailto:profgcp@brookwoodacademy.org]
Sent: Monday, September 07, 2009 7:21 PM
To: ENTR /F/2 PHARMACEUTICALS
Subject: Comments on proposed changes to Detailed Guidance for the request for authorisation of a clinical trial ....

Re: Comments on proposed changes to Detailed Guidance for the request for authorisation of a clinical trial.. Draft Revision 3 (2009)

Dear Sirs
I would like to make the following comments and observations regarding the above mentioned proposed draft guidance:

Section 2.6, paragraph 4, line 2
It appears that if the medicinal product is marketed in an ICH country (eg. the USA) then the SmPC can substitute the IB. However, an SmPC for a product in the USA and in particular Japan may not be suitable.
Is it wise to include "ICH Country" in addition to any Member State?

Section 3.3.1
The examples given are very useful. I used these in a group exercise at a recent training workshop in Copenhagen attended by clinical research delegates of the major Danish pharmaceutical companies. Participants commented that some of the terminology used in the examples was vague. For example in the last example of this section "Limited lengthening of the trial time" is too open for interpretation. A more definitive example should specify what limited lengthening is and when it becomes a substantial amendment. Minor changes in the recruitment procedure -- perhaps give an example;

Sections 3.3.1, 3.3.2 and 3.3.3
The examples define what is and what is not considered to be a substantial amendment. It would be helpful here to also include the notification requirement -- to the competent authority (CA) only, to the ethics committee (IEC) only or to both CA and IEC. Based on my workshop experience, those having to notify still have difficulty deciding which amendments are notifiable to only CA or IEC. Perhaps more examples can be given and/or the notification requirements added to each of the examples provided in each section. I believe all of those listed would be notified to both CA and IEC.

Section 3.7
The terminology *Ex Post* is vague. The dictionary definition of *Ex Post* is "based on analysis of past performance". I think some more definitive advice is required about the timescale (eg. within 3 days).

Typographical errors have also been noted:

Section 2.7.1, bullet point 2, subsection 3
CMP compliance should be GMP compliance

Section 2.8.3, duplication in subheading

Yours faithfully
Professor Dr David Hutchinson

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