FUEHRING Stefan (ENTR)

From: ENTR /F/2 PHARMACEUTICALS
Sent: mardi 8 septembre 2009 15:09
To: FUEHRING Stefan (ENTR)
Cc: SALVADOR ROLDAN Rocio (ENTR)
Subject: FW: Detailed Guidance for the Request for Authorisation of a Clinical Trial on a Medical Product for Human Use to the Competent Authorities, Notification of Substantial Amendments and Declaration of the End of the Trial (Draft Revision 3)

A/21432

From: Karen Real [mailto:kreal@realregulatory.ie]
Sent: Tuesday, September 08, 2009 3:08 PM
To: ENTR /F/2 PHARMACEUTICALS
Subject: Re: Detailed Guidance for the Request for Authorisation of a Clinical Trial on a Medical Product for Human Use to the Competent Authorities, Notification of Substantial Amendments and Declaration of the End of the Trial (Draft Revision 3)

Dear Sir/Madam,

We, at Real Regulatory Ltd, have read with great interest the draft revised guidance for the conduct of clinical trials. We feel that this revised guidance will help clarify and create greater harmony for clinical trials among member states. We note the emphasis placed on the fact that the guidance is not the bare minimum and that countries cannot 'add-on' to these with their own, additional requirements. The re-structured guidance, along with specified references to more in-depth guidance is far more directed than the current version of the document, and overall is much more useable.

We have also read with interest the revised end of trial procedure and note the acknowledgement that it is not always possible to provide the clinical summary report within one year. This is in line with our own experience and we feel that this will reduce the pressure on industry to try and rush out these reports in order to maintain compliance.

One query we have was that whilst reading the consultation document, we noticed that the revised guidance no longer lists the inclusion of the labels for the IMP among the documents required for the initial CTA application submission. However, further on in this guidance document, (section 3.3.2) there is reference to the fact that minor changes to the labeling aren't necessary considered substantial. This later reference implies that perhaps the requirement for labels to be included in the initial CTA application has been omitted rather than consciously removed? We would recommend further clarification here. Furthermore, as the labeling requirements throughout Europe vary, we would request that more detailed clarification for clinical trial labels be provided.

We eagerly await finalisation of this guidance document.

Kind regards

Karen Real
Director
Real Regulatory

Tel +353 (0)1 885 1710 (Dublin)
Tel +44 (0) 203 178 7140 (London)

Fax +353 (0)1 882 9823
Mob +353 (0)87 679 8791