

FUEHRING Stefan (ENTR)

From: ENTR /F/2 PHARMACEUTICALS
Sent: lundi 7 septembre 2009 10:23
To: FUEHRING Stefan (ENTR)
Cc: SALVADOR ROLDAN Rocio (ENTR)
Subject: FW: Comments on ENTR/F/2/SF D(2009) [.] Detailed guidance.... Revision 3

[A/21248](#)

From: Fred Lackenby [mailto:f-lackenby@ono-uk.co.uk]
Sent: Monday, September 07, 2009 10:15 AM
To: ENTR /F/2 PHARMACEUTICALS
Cc: 'Steve Deacon'; 'Tomohiro Kuwayama'
Subject: Comments on ENTR/F/2/SF D(2009) [.] Detailed guidance.... Revision 3

Dear Sirs,

Firstly we would like to say how much we appreciate the opportunity to comment on the revision to the new guidance because as the Clinical Trials Directive has developed so it has become clear many of the undocumented interpretations of the directive were increasing with time.

We have several comments for which we would appreciate your consideration:

It would be beneficial to Sponsors for some guidance about re-use of Eudract numbers. It is indicated in the section on resubmissions that the same EudaraCT number can be used with a letter suffix. But in the case where a EudraCT number was obtained and the study not carried out beyond applying for a EudraCT number, we feel there should be a mechanism laid out to recycle the unused EudraCT number.

The new guidance does not mention recognition of the FDA form 1572. Considering the truly global scope of phase II and III clinical trials and the increase in US centric study management, we would respectfully suggest a row in the "Who assesses what" table to indicate if Form 1572 is recognised by which of the Competent Authorities.

ONO appreciates the additional guidance in the proposed guidance in relation to protocol amendments.

Once again, thank you for this opportunity to comment on the guidance.

Best wishes

Fred Lackenby

Regulatory Affairs Manager
ONO Pharmaceuticals UK Ltd
11th Floor, Marble Arch Tower
55 Bryanston Street
London W1H 7AA
Tel. 0207 258 5300 Ext 323
Fax. 0207 723 5812