FUEHRING Stefan (ENTR)

From: ENTR /F/2 PHARMACEUTICALS
Sent: mardi 8 septembre 2009 14:19
To: FUEHRING Stefan (ENTR)
Cc: SALVADOR ROLDAN Rocio (ENTR)
Subject: FW: Astellas comment on draft update CTA guideline
Attachments: draft CTA 2009 annotated (2).pdf

A/21419

From: Kam, Kwee Lan [mailto:KweeLan.Kam@eu.astellas.com]
Sent: Tuesday, September 08, 2009 1:39 PM
To: ENTR /F/2 PHARMACEUTICALS
Subject: Astellas comment on draft update CTA guideline

Dear Madam, Sir,

Astellas is a drug development Pharmaceutical Company with Headquarters based in the US, Japan and Europe (based in the Netherlands).

We would like to comment on the attached draft guideline "Detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities, notification of substantial amendments and declaration of the end of the trial. Daft Revision 3, […] 2009. ", which was open for comments until 8 September 2009.
As requested, we are forwarding our comment by email.

Our comment is as follows. Please refer to paragraph 2.4 page 11, where is mentioned: "Certain information contained in the application form is going to be made public, following its entry into EudraCT by the national competent authority of the Member State concerned. This publication is done via rendering certain data fields contained in EudraCT public in accordance with the applicable guidelines published by the Commission."

Astellas would like to know which information/EudraCT data fields exactly will be disclosed to the public. It would be helpful if that is clearly mentioned in the updated guideline in order to give the Member States, as well as industry, clear guidance on what is to be made available to the public.

Thank you for consideration, with kind regards,

Kweelan

astellas
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