## FUEHRING Stefan (ENTR)

**From:** LENE GREJS PETERSEN - 9305 [LGP@dkma.dk]
**Sent:** lundi 7 septembre 2009 13:35
**To:** FUEHRING Stefan (ENTR)
**Cc:** KARINA MARKERSEN - 9671; LENE GREJS PETERSEN - 9305
**Subject:** SV: COM-publications on clinical trials - response public consultation

Dear Stefan Führing,

The Danish Medicines Agency has some comment to the draft revision of the guideline on application for clinical trials, substantial amendment, and declaration of end of trial in public consultation.

In section 3.6 it is stated that: If the national competent authority raises no grounds of non-acceptance the sponsor may implement the amendment.

In the Danish legislation the sponsor have to await an approval for the submitted substantial amendment. This should be possible due to the fact that the directive 2001/20/EC is a so called 'minimum' directive and the MS can implement stronger rules than stated in the directive.

Therefore we would like to have the text changed so it not stated that the sponsors can implement the amendment if the NCA raises no ground of non-acceptance, as this is not the case in Denmark.

Kind Regards

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Emne: COM-publications on clinical trials - update

Dear participants to the "Ad-hoc group on the implementation of the 'Clinical Trials Directive' 2001/20/EC" ("Brussels group")!
Pl. note that we have posted, today, the following documents on our website:
- CT application form applicable as of autumn 2009;
- Q&A document version 3.0.
Moreover, we have launched today the public consultation of the draft revision of the guideline on application for clinical trials, substantial amendment, and declaration of end of trial. Deadline for submission of comments is 8 September 2009.

All documents can be accessed via our clinical trials website:
http://ec.europa.eu/enterprise/pharmaceuticals/clinicaltrials/clinicaltrials_key.htm

Best regards,
Stefan Führing
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