FUEHRING Stefan (ENTR)

From: ENTR /F/2 PHARMACEUTICALS
Sent: jeudi 14 janvier 2010 11:17
To: FUEHRING Stefan (ENTR)
Subject: FW: Consultation on the Clinical Trials Directive

A/957

From: Mike Clarke [mailto:mclarke@cochrane.ac.uk]
Sent: Wednesday, January 13, 2010 12:29 AM
To: ENTR /F/2 PHARMACEUTICALS
Subject: Consultation on the Clinical Trials Directive

Please consider the following input to the Consultation on the Clinical Trials Directive. It is from the UK Cochrane Centre (www.cochrane.ac.uk), part of the international Cochrane Collaboration (www.cochrane.org).

We hope that any revision to the Directive or its implementation will place increased emphasis on the importance of systematic reviews for the design, analysis and interpretation of clinical trials.

We urge that all clinical trials should be justified, ethically and scientifically, by a systematic review of the pre-existing evidence. (Clarke M. Doing new research? Don't forget the old: nobody should do a trial without reviewing what is known. PLoS Medicine 2004;1:100-102)

We urge that the findings of all clinical trials should be made publicly available. (Ghersi D, Clarke M, Berlin J, Gulmezoglu M, Kush R, Lumbiganon P, Moher D, Rockhold F, Sim I, Wager E. Reporting the findings of clinical trials: a discussion paper. Bulletin of the World Health Organisation 2008;86:492-493)

We urge that the reporting of all clinical trials should include an updated systematic review of the evidence, into which the trial's results have been incorporated. (Clarke M, Hopewell S, Chalmers I. Reports of clinical trials should begin and end with up-to-date systematic reviews of other relevant evidence: a status report. Journal of the Royal Society of Medicine 2007;100:187-190)

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