FUEHRING Stefan (ENTR)

From: ENTR /F/2 PHARMACEUTICALS
Sent: mardi 8 décembre 2009 14:54
To: FUEHRING Stefan (ENTR)
Subject: FW: Consultation of the EU trials directive

Attachments: gcp_plos.pdf

gcp_plos.pdf (86 KB)

A/29843

-----Original Message-----
From: Alex McMahon [mailto:a.mcmahon@dental.gla.ac.uk]
Sent: Tuesday, December 08, 2009 2:50 PM
To: ENTR /F/2 PHARMACEUTICALS
Subject: Consultation of the EU trials directive

Dear Sir/Madam,
I wish to contribute my newly publised paper in PLoS Medicine to this public consultation. I have attached a pdf. My main concern is that the current trials regulations are inapplicable to most noncommercial research. These type of trials should be exempt from the Directive and it's progeny. Perhaps a new version can be worked up but the current regulations need to be scrapped in the meantime. Academics working on single centre trials were doing okay with the Declaration of Helsinki and Ethics Committees before these new regulations (copied from the system for licensing new medicinal products and novel compounds).

http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000131

Summary Points
Trial regulations are damaging noncommercial research and patients.
The International Conference on Harmonisation (ICH) version of Good Clinical
Practice (GCP) is inapplicable to most noncommercial research.
ICH GCP is not usually legally binding (as conceded by the regulatory authorities in the UK).
Other parts of the world should learn a lesson from the misguided trial regulations that have been created in Europe.

Kind Regards,
Dr Alex McMahon,
Reader in Epidemiology,
Community Oral Health, Level 8,
Glasgow University Dental School,
378 Sauchiehall Street,
Glasgow, G2 3JZ