FUEHRING Stefan (ENTR)

From: ENTR /F/2 PHARMACEUTICALS
Sent: mardi 1 septembre 2009 10:51
To: FUEHRING Stefan (ENTR)
Cc: SALVADOR ROLDAN Rocio (ENTR)
Subject: FW: 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 Draft Revision 3, [.] June 2009 E

A/20879

From: Wilsher, Colin [mailto:Colin.Wilsher@pfizer.com]
Sent: Tuesday, September 01, 2009 10:35 AM
To: ENTR /F/2 PHARMACEUTICALS
Subject: 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 Draft Revision 3, [.] June 2009 ENTR

The **British Association for Research Quality Assurance (BARQA)** is grateful for the opportunity to comment on EU Commission draft proposals.

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 Draft Revision 3, […] June 2009
ENTR/F/2/SF D(2009) […]
Date of closure of public consultation 8 September 2009

"2.10. Other documents to be submitted
• A list of national competent authorities to which the sponsor has already made the same application with details of their decisions**;"**

Does this mean the exact same submission, i.e. to EU CAs, or does it mean any submission worldwide with those same submission materials? Exactly what information is required with the details of decisions?

"• If available, a copy of the summary of scientific advice from any Member State or the EMEA or peer reviews with regard to the clinical trial;"

What would be a peer review? Would this be official scientific committees or any peer review performed by independent groups or by the sponsor itself?

"3.7. *Ex post* notification of urgent safety measures
Examples for urgent safety measures are as follows:
• There is a need to change immediately the Contract Research Organisation ("CRO") during the conduct of a study or transfer of certain responsibilities towards a different CRO because of hazard risk;
• a trial is halted following the recommendations of a Data Safety Monitoring Board on the grounds of patient safety or a lack of efficacy;"

Lack of efficacy - It should be qualified with:- "lack of efficacy where this is likely to have a significant effect on the safety and/or wellbeing of the subject(s)".

"3.8. Temporary halt of a trial
A temporary halt of a trial is a stop of the trial with the intention to resume it. A temporary halt can be
• a substantial amendment; or
• part of an urgent safety measure as referred to in Article 10(b) of Directive 2001/20/EC. In this case, the notification of the temporary halt of a trial should be done immediately and at the least, in accordance with the deadline set out in Article 10(c) 2nd period of Directive 2001/20/EC, within 15 days from when the trial is temporarily halted."
This is in contradiction to one member state (UK) where a temporary halt to the trial as part of an USM, requires immediate reporting or within 3 days. There is a need for community-wide harmonisation of these requirements so that sponsors can be compliant across the entire EU.

Dr. Colin Wilsher.
BARQA GCP Commiittee