FUEHRING Stefan (ENTR)

From: ENTR /F/2 PHARMACEUTICALS
Sent: vendredi 13 novembre 2009 12:00
To: FUEHRING Stefan (ENTR)
Cc: SALVADOR ROLDAN Rocio (ENTR)
Subject: FW:

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From: Porter, Duncan [mailto:Duncan.Porter@ggc.scot.nhs.uk]
Sent: Friday, November 13, 2009 11:41 AM
To: ENTR /F/2 PHARMACEUTICALS
Subject:

I am very grateful for the opportunity to provide some feedback on the European Commission review of the Clinical Trials Directive. I have worked as a part-time NHS Consultant Rheumatologist in the UK for a number of years and have been involved in investigator initiated clinical trials. In August of this year I moved to a full-time Academic post because it is no longer feasible to continue working in clinical research within an NHS environment. Essentially my change of post has given me 2 days a week to deal with the escalating bureaucracy surrounding the regulation of clinical trials. What I was previously able to do as a part-time NHS Consultant I now need 2 extra days in every week to complete. It is my opinion that the rising tide of bureaucracy surrounding the regulation of clinical trials will inevitably strangle and ultimately kill clinical research amongst the NHS in general and investigator initiated trials in particular.

Paragraph 2.5 states that the ICREL Study found that there had been no decrease in clinical research activity in the EU. It is notable that this Study took place in 2008 and compared activity between 2003 and 2007. Table 1, 3 and 4 all show a sharp decline of activity in 2008 compared to 2007 and the trend appears to be persisting into 2009 even allowing for the fact that the figures only relate to the first ¾ of 2009. In the UK there is little doubt that the number of non-commercial, investigator intiated trials is in steep decline. The study did conclude however that to perform a clinic trial had become considerable more difficult and costly. I would urge the regulatory bodies to take particular note of this with respect to non commercial study and investigator initiated protocols. Industry invests a huge amount of money into the product development which allows them to spend the time and money to make their way through the regulatory processes. NHS Researchers often work alone with very limited secretarial backup. None the less they are faced with requirements that are extremely difficult to meet without significant administrative support. The NHS R&D Departments are universally overworked and under funded and end up adding to the problem rather than solving it. These facts are recognised in paragraph 3.2. The length of time it takes to get a trial through the various processes has also extended greatly (also recognised in paragraph 3.2). As a result many NHS Clinicians are pulling out of clinical research entirely. There are also deleterious impacts on academic departments who seek to collaborate with the industry.

Trials can be brought to full approval much quicker in other parts of the world and in the UK it is not uncommon for recruitment to have finished in other countries before it can start in the UK.

In conclusion it is my believe that the regulations surrounding clinical trials has become too complex and in many cases incomprehensible to the average Clinician. It urgently needs to be

reviewed. A one size fits all approach that deals with commercial phase 1 studies in the same way as non commercial clinical research is clearly inappropriate. The differentiation between these kinds of research has been inadequate and is deleterious to the development and delivery of high quality clinical research in the UK.

Yours sincerely,

Duncan Porter
Senior Lecturer
University of Glasgow

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