



14<sup>th</sup> October 2007

By email: CTCONF@emea.europa.eu

Arielle North and Fergus Sweeney  
EMEA, 7 Westferry Circus  
Canary Wharf, London, E14 4HB

Dear Dr North and Dr Sweeney,

Thank you for giving us the opportunity to attend the joint meeting between Regulators, clinical trialists and the European Commission held on October 3<sup>rd</sup>, 2007 at the EMEA, to represent the point of view of academic clinical researchers in the field of childhood cancer working in Europe.

Please find below a brief summary of the key issues we would like to be included in the report from SIOP Europe.

*There was a clear mismatch between the perceptions of the Regulators in contrast to the experience of the clinical trial groups as where the block to clinical research lies. We do not believe that the problems can be solved by simple "fine-tuning" of the existing legislation. The process of launching a multinational trial remains incredibly bureaucratic and has a disproportionately negative effect on trials for rare tumours, which need participation from many centres and countries. A single CTA application process with mutual recognition in all participating European countries would be helpful, as would a process to support academic institutions to accept the role of 'pan-European' sponsor with national co-sponsors.*

*A particular issue for clinical trials in children is the bureaucracy of pharmacovigilance in phase III trials due to the definition of IMPs. We did submit detailed comments on this point to the European Commission's Consultation on IMPs in Non-commercial Trials, in 2006. We were therefore disappointed to see that the recent guidance on IMPs, issued May 2007, made no mention of any special consideration for off-label use of out of patent drugs in children, when they have a long established safety and efficacy profile. (please see our letters of Nov 2006 to Dr Birka Lehman, Dec 2006 to Dr Rui Santos-Ivo and of Oct 12<sup>th</sup> 2007 to CTCONF for further details).*

Thank you once again for giving us this opportunity to provide you with the experience of the clinical trialist working in the field of childhood cancer across Europe. We trust you find our comments valuable and that they can be taken into account in revising the Directive.

Yours sincerely

Kathy Pritchard-Jones  
President, SIOP Europe and  
Chairman of the SIOP Europe Clinical Trials Committee

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