Please reply to:

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European Commission,
Enterprise and Industry
Directorate-General Consumer Goods
Unit F2 Pharmaceuticals

Consultation on the functioning of the Clinical Trials Directive - 2001/20/EC

In response to the public consultation on the functioning of the clinical trials directive, we wish to leave the detailed comments and practical proposals to the company staff involved with clinical trials management.

However, EIPG would like to emphasise the importance of streamlining approval procedures for clinical programmes in Europe. Our members report that Phase 1 studies are being moved away from Europe to countries with internationally accepted

standards of ICH-GCP. In addition, with multi-country clinical trials that include non-EU countries where patients are allocated centrally, it is often the case that by the time EU countries have approved the study, patient recruitment has finished. This is a most unsatisfactory position for the EU patient population.

Yours sincerely

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