

Dear Madam/Sir,

Please find our response to the Public Consultation Paper on the Assessment of the Functioning of the "Clinical Trials Directive" 2001/20/EC. On behalf of the Lithuanian Bioethics Committee, we would like to support some of the suggestions presented in the document.

We would like to stress the importance of the point 3.4. (Consultation item n°5), because the issues raised under this point would really improve the process of ethical review of clinical drug trials in the countries of the European Union.

In particular, we strongly support:

- The strengthening networks of national Ethics Committees involved in multinational clinical trials (3.4.2.) and
- Clarifying the respective scope of assessment of NCA and Ethics Committees (3.4.3.).

Yours sincerely,

Eugenijus Gefenas, MD, PhD, Chairman

Lithuanian Bioethics Committee  
Didzioji str. 22, LT-01128, Vilnius  
Ph. 370 5 243 0009, 212 4565  
E-mail: lbek@sam.lt