

**ASSESSMENT OF THE
CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION
ON THE REVISION OF THE “CLINICAL TRIAL DIRECTIVE”**

Position statement

CEIC – Portuguese Ethical Committee for clinical Research

13-05-2011

We wish to start by congratulating the European Commission on their proposal to maintain academic/non-commercial trials under the scope of the directive as well as not to broaden the definition of “non-interventional trials”. We also appreciate your commitment to “*ensuring that the fundamental ethical rules are applied everywhere*” regarding compliance with good clinical practices in clinical trials in third-world countries.

General Comments

We are concerned with the apparent lack of equilibrium between the efforts to reduce administrative procedures and financial costs on the one hand, and the ethical considerations regarding the safety and the interests of the participants in the clinical trials. There also seems to be an emphasis on decreasing the costs to the promoters while increasing responsibility of Member States. In fact, the reduction in costs seems to be at the expense of:

- classifying some trials as of “low risk” thereby affecting insurance coverage;
- reducing the submission rates to Member States (case of single submission);
- transferring the onus of insurance to Member States.

Specific Comments

Regarding Single submission with separate assessment or Single Submission with “coordinated assessment procedure”

We believe it is unrealistic to separate the scientific from the ethical evaluation – it leads to unbalanced opinions and, in our view, faulty conclusions.

A single submission might be appropriate, but CEIC Portugal would like to analyze the full dossiers.

Issues that require further discussion, include:

- What language should be used? While many of the natural scientists dominate the English language, this may not be the case for the humanities and for some of the lay members of the committees;
- Normative values may vary a great deal between member States;
- Operational concerns regarding conflicting decisions between different ethics committees;
- The danger of too many trials within a single “coordinated assessment procedure” and the question of substantial amendments;
- Significant variation (lack of standard procedures) regarding remuneration of researchers and centers within State Members

Regarding Type-A trials

We believe that with the risk of creating sub-categories of trials, the bureaucracy might increase and there would be little gain, especially since, in practice, the evaluation of these types of trials might take just as long (risk analysis is not the only criterion). The issue of insurance for the participants might also become more tedious and lengthy.

Regarding Insurance

We do not believe it is reasonable to transfer the responsibility to the member States. What about third-world countries? Who decides what low-risk is?

Regarding emergency clinical trials

We need to insure that new medical products can be tested.