Revision of the Clinical Trials Directive 2001/20/EC

Concept paper submitted for public consultation

LEEM Comments 10 May 2011

Consultation item no. 1:

Leem: YES we agree.

Requirements have to be more concretely specified to avoid any specific national submission requirement
The first step should be to have an harmonisation of requirements.
The portal should be adopted by all Member States, it should be secure and confidential. The submission process should be developed with all stakeholders. The language of submission should be precise (English?)

Consultation item no. 2:

***Leem: YES we agree**. Difficulties will remain for multinational studies, Member States don't have the same way to assess a dossier (lack of clear missions between Competent Authority and Ethics Committee, local conditions)*

Consultation item no. 3:

***Leem: YES we agree**. But a central assessment could be appropriate for multinational studies including many European countries, procedures should have to be worked with stakeholders.*
Central assessment should remain optional, only on request of the sponsor.
A coordinated assessment (like the VHP procedure) including all Member States and supported by European Commission could be a good solution (optional too). Submission to national EC will remain.

Consultation item no. 4:

Leem: YES we agree

Consultation item no. 5:

***Leem: YES we agree**, the CAP can improve assessment and ensure respect of timelines for multinational studies. The CAP should be optional, applicable for amendments, and the decision should be binding for all Member States.*

Consultation item no. 6:

Leem: the first approach is preferable.

The CAP will be chosen for multinational studies. So, it is important to have an assessment within the directive timelines to be able to start the study in all the countries quickly.

Consultation item no. 7:

Leem: the third approach is preferable *. It seems to be a good approach to an harmonized system ant to have similar assessment across the European Union. Approach number 1 can't be an option for single country studies.*

Consultation item no. 8:

Leem: YES we agree*. A pre-assessment by the sponsor is a good idea. But we need more information on it, because interpretation of each item could be different from a sponsor to another. So, it is difficult to evaluate if it is workable or not.*

Consultation item no. 9:

Leem : *The acceptance of this proposal will depend of what is "harmonised and proportionate requirements". Coordination with others directives (pharmacovigilance) and the PASS studies should be done.*

Consultation item no. 10:

Leem: YES we agree*.*

Consultation item no. 11:

Leem: YES we agre*e. To clarify and to harmonise the content of the application dossier and safety reporting rules among member States would improve the process and the conduct of the studies. But in this paragraph, a reference to "a basic legal act" is done. Which kind of framework is it ? More details on the kind of legal framework which will be chosen is important for a better answer on this consultation item.*

Consultation item no. 12:

Leem: /

Consultation item no. 13:

Leem: YES we agree, *particularly for a narrowed definition of IMP.*
We need more details on what should be considered a "reference" in a clinical trials and on the new term "auxiliary products": are non-IMP and ancillary materials (like infusion products, diagnostic products…) included ?. A special attention to avoid the set up of a new category of products used in clinical trials should be taken, so, definition have to be very clear. Of course, such a proposal should be applied in all Member States.

14. Consultation item no. 14:

Leem: *Further discussion on this consultation item is required. An harmonised system is important. If an optional system is chosen, there is a risk for non application in a country, and a risk of discrepancy in competitiveness.*

15. Consultation item no. 15:

Leem: *Further discussion on this consultation item is required. In adopting a single sponsor approach, it is important to take into account the possibility of shared or delegated responsibility.*

16. Consultation item no. 16:

Leem: YES, we agree.

17.Consultation item no. 17:

Leem: YES we agree*. It must be acceptable to register clinical trials conducted exclusively outside EEA in public registers others than EudraCT, for example clinicaltrials.gov. Registering clinical trials conducted outside EEA in EudraCT doesn't provide help to European patients.*

18 Consultation item no. 18:

Leem: /