EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on EC Consultation on Revision of the Clinical Trials Directive 2001/20/EC

ENCePP Response to Public Consultation on Concept Paper on revision of the Clinical Trials Directive

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An agency of the European Union

Concept Paper revision of Directive 2001/20/EC

- EC planning to put forward in 2012 a legislative proposal to revise the Clinical Trials Directive.

- To assess the impact of this revision a public consultation was held 09 October 2009 to 08 January 2010.

- Concept paper submitted for public consultation 09 February 2011. Purpose:

  - To seek views on more concrete ideas on the issues that have been presented in a rather general way during the 2009/10 public consultation.
  - To verify with stakeholders the core data which forms the basis of the impact assessment.

Consultation Topics

1. **COOPERATION IN ASSESSING AND FOLLOWING UP APPLICATIONS FOR CLINICAL TRIALS (Items 1-8).**
2. **BETTER ADAPTATION TO PRACTICAL REQUIREMENTS AND A MORE HARMONISED, RISK-ADAPTED APPROACH TO THE PROCEDURAL ASPECTS OF CLINICAL TRIALS (Items 9-16).**
3. **ENSURING COMPLIANCE WITH GOOD CLINICAL PRACTICES IN CLINICAL TRIALS PERFORMED IN THIRD COUNTRIES (Item 17).**
4. **FIGURES AND DATA (Item 18).**

Streamlining rules for conduct of CT

Items no 11 and 12: providing one single, EU-wide, risk-adapted set of rules. ENCePP:

- Supports the proposal for more precise and risk-adapted rules for the content of the application dossier and for safety reporting by means of sufficiently detailed provisions on these topics being included in Annexes to the basic legal act.

- Suggests EC takes account of implementing measures for new PV legislation and considers principles underlying ENCePP Code of Conduct and work on methodological standards.

Single sponsor for clinical trials (Item no.15)

- EC Appraisal: concept of single sponsor maintained provided:
  - clarified that 'responsibility' of the sponsor is without prejudice to the (national) rules for liability; and
  - ensured that the regulatory framework for clinical trials in the EU is truly harmonised
- Response: While ENCePP seeks to facilitate research by consortia or networks, it is hard to argue against the requirement for a person who can ultimately and authoritatively inform the national competent authority about the clinical trial and ENCePP agrees with the appraisal laid out in the concept paper.

Definition of non-interventional trials

2.1. Limiting the scope of the Clinical Trials Directive

2.1.1. Enlarging the definition of 'non-interventional' trials

Preliminary appraisal: Rather than limiting the scope of the Clinical Trials Directive through a wider definition of 'non-interventional trial', it would be better to come up with harmonised and proportionate requirements which would apply to *all* clinical trials falling within the scope of the present Clinical Trials Directive.

Consultation item no. 9: Do you agree with this appraisal? Please comment.

ENCePP response on concept of low-risk trials

In response to item no. 8 i.e. concept of 'Type-A trials':

- '*..it is paramount that the introduction of a sub-categorisation within clinical trials per se should not have any implications for 'non-interventional trials' and should not lead to any blurring of the boundaries between the two entities or enlargement of the scope of the Clinical Trials Directive*.'

- '*This requires that particular attention should be paid to clearly defining what constitutes a 'non-interventional trial' falling outside the scope of the Directive as distinct from an interventional clinical trial falling within the scope*.'

ENCePP proposed new recital text

- *The classification of a study as a non-interventional trial should be scientifically-based and determined by the methodological instruments involved.*
- *This will readily determine whether a study is a systematic assessment of events that unfold without interference in their course.*
- *Such an observational study is clearly distinct from a trial, which implies an element of intervention either in terms of treatment with a medicinal product itself or in terms of the diagnostic and monitoring procedures applied in the context of the overall therapeutic strategy being followed.*

Recital text continued

➢ If the methodologies involved require prospective data collection or suggest intervention, further consideration should be given as to whether a trial should be classified as falling within the scope of the Clinical Trials Directive. In this case,

- *if treatment with the medicine has already commenced, or*
- *if treatment that will happen is not assigned a priori in a protocol, &*
- *the therapeutic strategy within which the treatment is prescribed, including the related diagnostic or monitoring procedures applied, can be considered as current clinical practice,*

⇒ classified as non-interventional.

Revised Definition of non interventional trial

"A trial with monitoring of patients and/or prospective data collection, where the medicinal product(s) is (are) prescribed independently to the inclusion of the patient in the trial and as part of a therapeutic strategy which is applied according to the current clinical practice. The therapeutic strategy, including related diagnostic and/or monitoring procedures, shall not be influenced by inclusion of the patient in the trial."

Submission of response

- ✓ Response first draft by TF 19 April 2011,
- ✓ Circulated to ENCePP Plenary 04 May 2011
- ✓ Adopted by ENCePP SG 11-12 May 2011
- ✓ Submitted on deadline of 13 May 2011
- ✓ Published on ENCePP website 01 June 2011 www.encepp.eu
- ✓ Published on EC website 24 June 2011

http://ec.europa.eu/health/human-use/clinical-trials/developments/ct_public-consultation_2011_en.htm