



# CPME 2011/037 REV 2 FINAL

## Title / Titre

REVISION OF THE « CLINICAL TRIALS DIRECTIVE » 2001/20/EC  
CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION

## Author / Auteur

CPME Board

## CONCERNING / CONCERNE

All delegates

## PURPOSE / OBJET

Adopted by the CPME Board in Brussels, 30/04/2011

## date

20/05/2011

## KEYWORDS / Mots clefs

Clinical Trial, Ethics Committee, Coordinated Assessment Procedure (CAP)



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As the voice of European physicians, the Standing Committee of European Doctors (CPME) would like to thank the European Commission for providing the CPME the opportunity to contribute to this consultation procedure.

In view of the design of the concept paper (“preliminary appraisal approach”) the answers are kept short since further comments could potentially fall outside the scope of the appraisal and the related consultation item.

**Consultation item no. 1:** Do you agree with this appraisal? Please comment.

**CPME Position:** See consultation items No. 4-8 provided the introduction of such submission mechanism is accompanied by an adequately long pilot phase.

**Consultation item no. 2:** Do you agree with this appraisal? Please comment.

**CPME Position:** No, see consultation items No. 4-8 and the support of the optional use of the CAP.

**Consultation item no. 3:** Do you agree with this appraisal? Please comment.

**CPME Position:** Yes, see consultation items no. 4-8 and the support of the optional use of the CAP.

**Consultation item no. 4:** Is the above catalogue complete?

**CPME Position:** Yes.

**Consultation item no. 5:** Do you agree to include the aspects under a), and only these aspects, in the scope of the CAP?

**CPME Position:** No. The following aspects under a) should be transferred to b) which like c) need to be examined by the ethics committees:

“-Risk-benefit assessment: Acceptability of the clinical trial in view of all anticipated benefits, compared to risks and inconvenience for trial subjects (including control groups) taking account of

- the characteristics of and knowledge about the investigational medicinal product;
- the characteristics of the intervention compared to normal clinical practice;



- the design of the trial;
- the relevance of the trial, including the credibility of the results;”

A study that is not scientific is unethical. However, a few parts of the risk-benefit assessment criteria with regard to the characteristics of and knowledge about the investigational medicinal product could remain under a). Furthermore, the listing shouldn't preclude any organizational structure at Member State level i. e. the organisation of the actual assessment is reserved to Member States.

**Consultation item no. 6:** Which of these approaches is preferable? Please give your reasons.

**CPME Position:** The CPME prefers the first - the “opt out” option. This option grants maximum flexibility to Member States.

**Consultation item no. 7:** Which of these three approaches is preferable? Please give your reasons.

**CPME Position:** The CPME prefers the third – the optional option since this option grants maximum flexibility. It should be limited to significant studies (criteria of Voluntary Harmonised Procedure (VHP)).

**Consultation item no. 8:** Do you think such a pre-assessment is workable in practice? Please comment.

**CPME Position:** Yes, provided pre-assessments are optional and provided the characteristics of type-A trials are specified. Also, questions linger who and/or on behalf of whom pre-assessments are carried out. The pre-assessment requirements need to be specified.

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

**CPME Position:** The CPME is of the opinion that there should be one single framework for all clinical trials considering certain variations, e. g. as to non-interventional trials taking into account the protection for patients and the respective workload involved. The non-commercial/academic investigators should receive some financial or other support in order to cope with the administrative workload. However, also in view of the recent pharmacovigilance legislation 2010/84/EU, in any case, a “race to the bottom” needs to be prevented i. e. requirements for clinical trials must not be diminished.

**Consultation item no. 10:** Do you agree with this appraisal? Please comment.

**CPME Position:** The CPME refers to the answer as set out in consultation item no. 9.

**Consultation item no. 11:** Do you agree with this appraisal? Please comment.



**CPME Position:** Yes, for the reasons set out in the appraisal.

**Consultation item no. 12:** Are there other key aspects on which more detailed rules are needed?

**CPME Position:** The CPME suggests specific guidance on the assessments of SUSARs and substantial amendments and suggests these to be assessed by a centralized body.

**Consultation item no. 13:** Do you agree with this appraisal? Please comment.

**CPME Position:** Yes, for the reasons set out in the appraisal.

**Consultation item no. 14:** Which policy option is favourable in view of legal and practical obstacles? What other options could be considered?"

**CPME Position:** The insurance /indemnisation should remain as it is.

**Consultation item no. 15:** Do you agree with this appraisal? Please comment.

**CPME Position:** Yes, for the reasons set out in the appraisal.

**Consultation item no. 16:** Do you agree with this appraisal? Please comment.

**CPME Position:** Yes. Furthermore, the inclusion of incompetent subjects (e. g. minors) in emergency clinical trials without the prior consent from the legal representative/parents requires grounds for expecting a direct benefit to the patient.

The study has been approved by a research ethics committee. However, if temporally feasible, ethics committees could be consulted in these specific urgency situations for a second opinion since they can provide for additional expert assessment and support.

**Consultation item no. 17:** Do you agree with this appraisal? Please comment.

**CPME Position:** Yes, for the reasons set out in the appraisal.

**Consultation item no. 18:** Do you have any comments or additional quantifiable information apart from that set out in the annex to this document? If so, you are invited to submit them as part of this consultation exercise.

**CPME Position:** No.

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