REVISION OF THE 'CLINICAL TRIALS DIRECTIVE' 2001/20/EC
CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION
(SANCO/C/8/PB/SF D(2011) 143488)

Public consultation document

Name of Organisation	Country
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1. Specific comments on text

Consultation item	Do you agree with this appraisal?	Other questions
no. 1	Yes	This would significantly reduce administrative work. However, would we still have to submit country specific documents such as insurance certificates, protocol synopsis in local language, some specific forms set up by local competent authority…? and if so how will the submission of country specific documents be handled?
no. 2	Yes	
no. 3	Yes	*Is the above catalogue complete?* It seems, yes
no. 4	Yes	*Do you agree to include the aspects under a), and only these aspects, in the scope of the CAP?* The "normal clinical practice" may change from a country to another based on which drugs are available and reimbursed in each country. So this may be better to keep the "Acceptability of the clinical trial in view of all anticipated benefits, compared to risks and inconveniences for trial subjects (including control groups), taking account of […] the characteristics of the intervention compared to normal clinical practice" under the scope of each country competent authority.
no. 5	No	*Which of these approaches is preferable?* 1
no. 6	1	*Please give your reasons.* Option 1 would allow to stick to local regulations or specificities, but would avoid to have to many differences between each country *Which of these three approaches is preferable?* 1
no. 7	1	*Please give your reasons.* Option 1 would allow to benefit from a central approval for all studies. Option 2 would be problematic if a study is started in only 1 EU country but then extended to another EU country. Option 3 would lead to disparities between countries. Maybe option 3 could be chosen at the beginning during transition period. *Do you think such a pre-assessment is workable in practice?* Yes *Please comment.* This pre-assessment should not be mantarory for all clincal trials, but optional and applicable only when sponsor thinks this can be the case. Clear timelines for this pre-assessment and list of documents required should be defined and communicated. Clear timelines for clinical trials meeting this definition should be defined and communicated.
no. 8	Yes	Question: would this apply to non-interventional trials?

		Maybe Non-Interventional Studies (NIS) could be included within the scope of the directive, but with less restrictive requirements (submission to EC only, no insurance certificate needed…): this would allow harmonization between EU countries for this kind of study. In addition, a detailed definition of clinical trial and of NIS should be set up for all countries, to avoid the fact that one country may consider a study as a NIS, and another country as a clinical trial.
no. 9	No	
no. 10	Yes	
no. 11	Yes	
		Are there other key aspects on which more detailed rules are needed? First patient inclusion notification, Protocol deviations notifications, Annual study reports or updates
no. 12	Yes	
no. 13	Yes	
no. 14	1	*Which policy option is favourable in view of legal and practical obstacles? What other options could be considered?* Option 1 (Removing insurance/indemnisation requirements for low-risk trials) would allow harmonization between countries. However, this kind of trial should be very well defined to avoid any errors and lack of insurance. A single sponsor can delegate some activities to other co-sponsors or to CROs. So maintaining the concept of a single sponsor does not seem to us to be a problem
no. 15	Yes	
no. 16	Yes	
no. 17	Yes	
		Do you have any comments or additional quantifiable information apart from that set out in the annex to this document? No additional comment
no. 18	No additional comment	*If so, you are invited to submit them as part of this consultation exercise.*

2. General comments

There is no request for general comments in the original concept paper but if you want to add some, please do it here.