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
CCRA Clinical Contract Research Association **Address** PO Box 1055 Oadby Leicester LE2 4XZ Tel: +44 (0)116 2719727 Email : mail@ccra.org.uk Representative on this matter: **Ms. Susan N Dilks** Director of Operations	**UK** **CCRA is the government Accredited Trade Organisation (ATO) for the CRO sector in the UK**

Specific comments on text

Consultation Item	Do you agree with this appraisal?	Other questions
no. 1	Yes	CCRA agrees that this would reduce administrative cost and save time
no. 2	Yes	CCRA agrees. This would only reduce the administrative burden and would not address the issue of conflicting points of view in different member states.
no. 3	Yes	CCRA agrees that a central assessment is not appropriate for clinical trials approval as this would lead to time delays
no. 4	Yes	CCRA believes the above catalogue is complete
no. 5	Yes	CCRA agrees that it makes more sense to have ethical and local issues assessed locally.
no. 6 no. 7		Option 1, MS 'opt out' is preferable. CCRA believes that in a case where a member state does opt out it's reasons for doing so should be immediately reported to the others as a safe-guard CCRA believes that CAP should not apply to single state studies. Although we agree that CAP should become mandatory for multinational studies this should not be implemented until there has been a 'bedding in' period i.e optional to begin with moving toward mandatory implementation.
no. 8	No	Pre-assessment may be welcomed but should be optional as mandatory legislation may add another layer of delay
no. 9	Yes	CCRA agrees and has no comment to make.
no. 10	Yes	The same rules and regulations should apply to all studies irrespective of the nature of the Sponsor. There is no reason why non-commercial studies should be run more relaxed standards.

no. 11	Yes	However, we feel that it will be difficult to agree a risk structure EU-wide.
no. 12		No comments
No. 13		CCRA agrees. Clarification and EU standardisation will simplify IMP production and possibly reduce IMP costs for multinational studies. CCRA would however wish for the current requirements for comparators and challenge agents not to be relaxed in cases where they have been modified (e.g. packaging/labelling/over-encapsulation) from the standard commercially available form. In which case the current GMP procedures should still be adhered to.
no. 14		Re 2.4: CCRA would dispute that the Directive not discriminating between degrees of risk leads to additional insurance costs. Insurers make their own assessments of trial/protocol risks. Trial insurance is underwritten across Europe on either individual trials or programmes of studies on their individual risk profiles. Costs for finding out what coverage is needed in individual member states is minimal in the scale of what trials cost to run. There is a wealth of information as to what insurance requirements are with local regulatory bodies, data collected by CROs and of course available from specialist insurance brokers. Re 2.42: How will “low risk” be defined? Optional indemnification by Member State: How many states would buy in to this concept in the current economic climate (despite the very low loss record)? Is this proposal for unlimited amount of indemnity? The UK does not legislate mandatory insurance and made it clear nothing is planned in this regard. Providing market economy insurance is viable risk transfer for the vast majority of trial sponsors. Assessment of protocols, patient/volunteer information and risk by insurers is an excellent “independent” check on trial safety issues, procedures and regulatory compliance. A state funded system could of course be reinsured in to the commercial arena but this would be a huge seed change for national governments especially we would suggest for the UK.
no. 15	Yes	CCRA agrees that the concept of a single sponsor is preferable as responsibility is clearly defined

no. 16	Yes/No	It is important for Investigators to act quickly in these situations, but additional power to act independent of any sort of pre-procedure consent should be restricted to wholly life/death situations.
no. 17	Yes	CCRA agrees. The data must be to a unified standard..
no. 18		CCRA has no further comments to add.

1. 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.