Revision of the 'Clinical Trials Directive' 2001/20/EC
Concept paper submitted for public consultation

Medical Schools Council response

May 2011

The Medical Schools Council represents the interests and ambitions of UK medical schools as they relate to the generation of national health, wealth and knowledge through biomedical research and the profession of medicine. The membership of the Medical Schools Council is made up of the Heads or Deans of the 31 UK undergraduate medical schools, plus the London School of Hygiene and Tropical Medicine (postgraduate).

The Medical Schools Council welcomes the opportunity to respond to the 'Revision of the 'Clinical Trials Directive' 2001/20/EC concept paper'. The importance of multinational clinical trials is clear, yet the Clinical Trials Directive has caused significant barriers in establishing this type of study.

Our members have encountered significant challenges resulting from the single sponsorship model. Current issues include concerns that:

- Different interpretation of the directive by Member States makes the management of trials overly complicated
- Excessive insurance bills mean that the risks outweigh the benefits of sponsorship
- High costs to cover staffing and support for the trial are not shared
- Establishing trials under this model is time consuming

To address these problems we believe that a co-sponsorship model should be adopted. We support a co-sponsorship model for the following reasons.

- Academic led multinational clinical trials could benefit in particular as these are the trials that are currently most likely to be put off by the excessive burden of single sponsorship
- Resource burden is shared
- Responsibilities can be clearly defined at the appropriate level and allow local oversight of trials
- Provided clear, transparent and robust systems are in place, auditing and inspection of trials by regulators can still be effective

Please see below for our responses to the individual consultation items:

Consultation item no. 1: Do you agree with this appraisal?
We agree

Consultation item no. 2: Do you agree with this appraisal?
We agree

Consultation item no. 3: Do you agree with this appraisal?
We agree

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

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

Consultation item no. 6: Which of these approaches is preferable?
We prefer the option that "an individual Member State could be allowed to 'opt-out', if justified on the basis of 'serious risk to public health or safety of the participant". Both a vote and referring to the Commission or the Agency would be time consuming and are less practical than this option.

Consultation item no. 7: Which of these three approaches is preferable?
We believe the CAP should be mandatory for all multinational clinical trials. As a mandatory CAP for all trials would not be appropriate for single Member State trials, a multinational level is most appropriate for coordination and should be introduced to facilitate collective responsibility.

Consultation item no. 8: Do you think such a pre-assessment is workable in practice?
We agree that this could be workable in practice. We welcome the potential to speed up the process, though believe it is essential that proper systems are in place to support pre-assessment. It is important to ascertain how each Member State would carry out its pre-assessment. There should be consistency in approach to ensure that this is an efficient and effective process and it should be clear what would happen in the case of disagreement between Member States on a pre-assessment.

Consultation item no. 9: Do you agree with this appraisal?
We agree that harmonisation and proportionate requirements should apply to all clinical trials falling under the scope of the current Clinical Trials Directive. Excluding more trials from the directive would create difficulty in coordinating effort. 'Non-interventional trials' should be subject to the pre-assessment process outlined under consultation item number 8.

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

We agree that the principle of harmonisation could be damaged by excluding 'academic/non-commercial sponsors' from the scope of the Clinical Trials Directive. However, it is important that there is a risk proportionate approach for these trials.

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

We agree that this will be helpful.

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

There are no other key aspects requiring more detailed rules.

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

We agree with the appraisal. Current rules for IMPs are burdensome and therefore we welcome this simplification. Auxiliary medical products should be regulated proportionately to ensure that compliance with regulation is not overly resource intensive.

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

We are keen to see greater alignment of risk and insurance requirements. Options would need to be referred to our members' insurers to assess the legal and practical obstacles.

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

We strongly disagree. As outlined in our introduction the concept of 'single sponsorship' has caused significant difficulties for UK medical schools. Co-sponsorship is essential to reduce the burden on institutions keen to engage in multinational trials, which are put off by the excessive risk and cost of single sponsorship. Whilst not allowing evasion of liability in terms of civil/common law, co-sponsorship would provide collective responsibility for the management and financing of the study instead of placing the burden for this on one sponsor in one country. Devolving certain responsibilities to other sites can be successful as long as these responsibilities are clearly defined and assigned. Provided that those responsible for collecting and collating trial data have transparent, clear and robust systems in place to manage the study, regulators will be able to effectively inspect and audit trials. The success of multinational cancer studies shows how co-sponsorship models can work to provide accountability and reduce burden. We believe that co-sponsorship does not damage the potential for harmonisation but instead could facilitate co-ordination as co-sponsors' agreements can work to minimise regulatory variance.

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

We agree that this is a viable option.

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

We agree that this is important for patient safety and for securing valid data.

Consultation item no. 18: Do you have any comments or additional quantifiable information apart from that set out in the annex to this document?