Revision of the 'Clinical Trials Directive' 2001/20/EC, concept paper submitted for public consultation 9 February 2011.

Feedback from Hammersmith Medicines Research (HMR): a contract research organisation, specialising in early phase studies of potential new medicines for sponsors in the pharmaceutical industry in the UK and abroad. HMR falls within the EU definition of a small and medium-sized enterprise.

Consultation item 1 (single submission with separate assessments)

Not applicable to our early phase studies, which are almost universally single-centre studies.

Consultation item 2 (single submission with separate assessments)

Not applicable to our early phase studies, which are almost universally single-centre studies.

Consultation item 3 (single submission with central assessment)

Yes. The procedure would be far too slow, unwieldy and costly for early phase studies, and would be completely unnecessary and of no benefit, since virtually all of our studies are single-centre studies.

Consultation item 4 (single submission with coordinated assessment procedure)

Yes

Consultation item 5 (single submission with coordinated assessment procedure)

Yes

Consultation item 6 (disagreement with the assessment report)

Preferred option: opting out. If a Member State is concerned about serious risk, it should be allowed to opt out. Voting by majority won't work if there is an even split among Member States. Deferral to the Commission or Agency would take far too long.

Consultation item 7 (mandatory/optional CAP)

Preferred option: CAP is optional. We do not consider it appropriate that CAP be mandatory for all clinical trials. Submission of single-centre studies to a CAP would be far too slow, cumbersome and costly. Furthermore, the current system works well in our Member State, and further change and disruption would increase our costs, cause needless delays and discourage sponsors from placing early phase studies in Europe. We don't consider that the regulatory burden of making 2 or 3 separate submissions to be significantly greater than that of making one submission, so would prefer, if CAP were introduced, to have the option of making separate submissions for studies in 2 or 3 Member States.

Consultation item 8 (pre-assessment of applications)

Yes, it's theoretically workable in practice. But an additional pre-assessment step could increase timelines for review of all applications.

Consultation item 9 (limiting scope of CTD)

Not applicable to our early phase studies – all are interventional.

Consultation item 10 (inclusion of academic trials)

Yes. Academic sponsors should not be exempt from the Directive: standards of protection of trial subjects should be the same across all trials.

Consultation item 11 (risk-adapted rules for application and safety reporting)

Yes. It's helpful that the contents of the application are now common to all Member States (however, the format of the detailed guidance (CT-1, Mar 2010) is unhelpful as it does not contain a single complete list of required documents). A unified, risk-based approach would be useful; however, the requirements must be proportionate.

Consultation item 12 (risk-adapted rules for application and safety reporting)

No.

Consultation item 13 (non-IMPs)

No. Licensed medicinal products and other products used, for example, as rescue medication, challenge agents or diagnostic agents are clearly not IMPs because they are not used as test or reference treatment in a clinical trial. So, they are not subject to the rules on manufacturing and labelling of IMPs. Regulation of non-IMPs would be burdensome and costly, as the current non-mandatory guidance on non-IMPs suggests that some Member States have disproportionate requirements concerning those agents. Any new requirements might preclude use of research methods that are established clinical practice or stifle innovation in methodology.

Consultation item 14 (insurance/indemnity)

Both policy options should be adopted. Currently, there are no clear guidelines on the level of insurance that should be available for a given trial, and that causes confusion. So, for our early phase studies, availability of indemnity from the Member State would be attractive to our international sponsors. A national indemnity scheme would also make it easier for ethics committees to review the insurance/indemnity arrangements.

Consultation item 15 (single sponsor)

Not applicable to our early phase studies.

Consultation item 16 (emergency clinical trials)

Not applicable to our early phase studies.

Consultation item 17 (trials in third countries)

Not applicable to our early phase studies. However, in the interest of harmonisation, shouldn't trials done in ICH countries be accepted if they are not registered in EudraCT?

Consultation item 18 (additional comments)

No.