REVISION OF THE 'CLINICAL TRIALS DIRECTIVE' 2001/20/EC

Mundipharma Research – Stakeholder Association (Sponsor & IMP Manufacturer)

Deadline for Comments: 13 May 2011

Consultation Topics	**Agree with Appraisal?**
Cooperation in Assessing and Following Up Applications for Clinical Trials	
1.1. Single submission with separate assessment	As a sponsor the single submission is a positive and favoured approach, however due to the potential for national discrepancies in terms of assessment requirements, the separate assessment is currently the best option. This retains flexibility and is logistically favoured in terms of company resources. However we are unsure of the relationship to Voluntary Harmonisation Procedure.
1.2. Single submission with subsequent central assessment	This is currently not a favourable option and would be difficult in practice to achieve – this would require adequate management and a suitable standard of assessment. It is our impression that this could take significantly longer to reach agreement and would therefore delay trial initiation. We would however strive towards this approach after further harmonisation has been achieved.
1.3. Single submission with a subsequent 'coordinated assessment procedure' (CAP)	This is envisaged as being a lengthy procedure with little flexibility, particularly in terms of addition of subsequent member states.
1.3.1 Scope of CAP	Option (a) of only Risk-Benefit is considered to be the most suitable option.
1.3.2 Disagreement with assessment report	Opt out the best to prevent significant delay, but the majority vote is considered to be the best option to prevent the same issues reoccurring from the same MS.

1.3.3 Mandatory / Optional Use	Optional Use is the best approach to allow for flexibility; due to the significant number of proposed changes we would prefer to review the full updated Directive before supporting mandatory use.
1.3.4 Tacit approval and timelines	Tacit approval is not a favourable option; Inspectors and QPs expect a documented approval to proceed and are unwilling to accept a "no-information" approval.
Better Adaptation to Practical Requirements and a more Harmonised, Risk-Adapted Approach to the Procedural Aspects of Clinical Trials	
2.1. Limiting the scope of the Clinical Trials Directive	We agree that the CT Directive scope should not be widened, particularly as this would be excessively resource intensive. However, it would be particularly useful to provide a standardised definition for the Non-Interventional Trials, particularly as the number of trials increases.
2.1.1 Excluding clinical trials by 'academic/non-commercial sponsors' from the scope of the Clinical Trials Directive	As an industrial sponsor we see no logic to removing 'academic/non-commercial sponsors' from the scope of the Clinical Trials Directive. This would be a high-risk strategy. 'Academic/non-commercial sponsors' would also benefit from the fast-track CTA process for approved medicines if included in CT Directive.
2.2. More precise and risk-adapted rules for the content of the application dossier and for safety reporting	No further comments – in agreement with appraisal.
2.3. Clarifying the definition of 'investigational medicinal product' and establishing rules for 'auxiliary medicinal products'	This concept is linked to the definition of non-interventional trials. We would like to further define NIMP labelling for clarity assuming then that "auxiliary medicinal products" would include rescue and escape medication.
2.4. Insurance/indemnisation	As a sponsor we feel that it would be naive not to have insurance for low-risk trials. Our preferred option is Optional Indemnisation by Member States, however we have concerns to Member State cooperation with this option.

2.5. Single sponsor	We are in agreement with Option 1 to maintain the concept of a single sponsor. The discussion of this concept would benefit from incorporating the discussion on non-industrial trials.
2.6. Emergency clinical trials	We are unsure of the purpose of Emergency clinical trials however, we would welcome further clarity and strengthening of the text.
3. Ensuring Compliance with GCP in Clinical Trials Performed in Third Countries	No further comments – in agreement with appraisal.
4. Figures & Data	No further comments on appended Figures & Data.