IMB Comments on "Revision of the 'Clinical Trials Directive' 2001/20/EC
Concept Paper Submitted for Public Consultation on 09/02/2011

1.1 Single submission with separate assessment

Consultation item no. 1:

We agree that a single submission would greatly reduce the administrative work of sponsors. A single application form could be developed with two parts, the first including the common material, and then a second part for country specific material. The UK Integrated Research Application System (IRAS) is an example of such system.

Consultation item no. 2:

We agree that a single submission with a separate assessment by each Member State would insufficiently address the issue set out above as the difficulties created by independent assessments would remain.

1.2 Single submission with subsequent central assessment

Consultation item no. 3:

We agree that a central assessment performed in the same way as for centrally authorised products would be difficult for clinical trials (due to the reasons highlighted in the concept paper) however a single submission with a subsequent 'coordinated assessment procedure' (CAP) is a good idea.

1.3 Single Submission with subsequent 'coordinated assessment procedure'

Consultation item no. 4 and 5:

A 'single decision' (competent authority and ethics committee) per Member State would be useful, however, the independence of the ethics committee opinion should be maintained. It is not clear how this can be achieved in a 'single decision'.

We agree that ethical issues clearly fall within the ambit of Member States and should remain there. We agree that the aspects under point a) would be suitable for the CAP however the aspects under b) and c) are not suitable for the CAP as they relate to national issues.

1.3.2 Disagreement with the assessment report

Consultation item no. 6

We agree with the following option: "An individual Member State should be allowed to opt out".

The implementation of the second option (MSs vote on the issues) would be difficult as votes may spread equally between the Member States.

The matter could be referred to the Commission or the Agency for a decision at EU level, however this could slow the process significantly, therefore time- efficient procedures would need to be developed.

1.3.3 Mandatory/optional use

Consultation item no. 7:

In order to achieve harmonisation, transparency and to streamline the clinical trials approval process in Europe, the mandatory CAP procedure for all multinational clinical trials is considered the best option.

The advantage the use of the CAP procedure for purely national clinical trials (point a) is not clear to us. Further clarification is required before we can comment on this point.

1.3.4 Tacit approval and timelines

Consultation item no. 8:

We agree that regarding timelines of the CAP, these should not be longer than the timelines provided in the current Clinical Trials Directive. It is noted that the timeline depends on the substance and it is longer for advanced therapy clinical trials.

We consider that an implementation of the pre-assessment stage in order to indentify less 'risky' clinical trials will not shorten the assessment time significantly as this pre-assessment stage will require specific timelines also. In case of disagreement between MS(s) during the pre-assessment phase the whole approval procedure can be prolonged.

The 60-day procedure can be shorter if no issues have been identified during the first phase of an assessment (the procedure can be completed earlier).

2.1 Limiting the scope of the Clinical Trials Directive

Consultation item no. 9:

We agree that rather than limiting the scope of the Clinical Trials Directive through a wider definition of 'non-interventional trial', it would be better to come up with harmonised and proportionate requirements which would apply to *all* clinical trials falling within the scope of the current Directive.

Consultation item no. 10:

We strongly agree with the proposal and disagree with the idea that academic/non-commercial sponsors should be excluded from the scope of the scope of the Clinical Trials Directive.

2.2 More precise and risk-adapted rules for the content of the application dossier and for safety reporting

Consultation item no. 11:

We agree that the inclusion of the guidelines into the Annexes will clarify and streamline the rules for conducting clinical trials in the EU.

Consultation item no. 12:

No additional comments

2.3 Clarifying the definition of 'investigational medicinal product' and establishing rules for 'auxiliary medicinal products'

Consultation item no. 13:

We agree that the combined approach would help to clarify and streamline the rules for medicinal products used in the context of a clinical trial.

2.4 Insurance/indemnisation

Consultation item no. 14:

Concerning insurance, the implications of this for MSs are not fully understood and would need to be discussed and considered further.

2.5 Single sponsor

Consultation item no. 15:

Multiple sponsorship'/'joint sponsorship' is often required for academic multinational clinical trials. We support the idea of multiple sponsorship'/'joint sponsorship' for these types of clinical trials.

2.6 Emergency clinical trials

Consultation item no. 16:

We agree that the rules for an informed consent in emergency clinical trials need to be developed but they need to be in line with the national law. In addition, it is important to highlight that the national ethics committee will need to approve the informed consent form.

3 Ensuring compliance with GCP in clinical trials performed in third countries

Consultation item no. 17:

We agree with the appraisal.

4 Figures and data

Consultation item no. 18:

We have no additional comments.

IMB
May 2011