European Commission
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Revision of the 'Clinical Trials Directive' 2001/20/EC: Concept Paper Submitted for Public Consultation
GE Healthcare Comments

Below are the comments from GE Healthcare on the Revision of the Clinical Trials Directive 2001/20/EC Concept Paper submitted for public consultation.

B. CONSULTATION TOPICS

1. Cooperation in Assessing and Following up Applications for Clinical Trials.

1.1 Single submission with separate assessment

Consultation item no. 1.

GE Healthcare comment: We assume that 'single submission' means a full CTA package i.e. IMPD plus attachments (protocol, IB etc). We agree that a single submission would reduce the administrative work for sponsors but the application should be harmonised without local additional specific requirements so multinational clinical trials can be managed in one single application.

Consultation item no. 2.

GE Healthcare comment: We agree that separate assessments would not address the issue of independent assessment by each Member State leading to divergent opinions.

1.2 Single submission with subsequent central assessment

Consultation item no 3:

GE Healthcare comment: We agree with this appraisal.

1.3 Single submission with a subsequent 'coordinated assessment procedure'

Consultation item no 4:

GE Healthcare comment: We believe the main categories in the catalogue are complete but there may be instances where local issues should also be discussed in the CAP. We are in favour of a CAP provided applications are completely harmonised and there is a simple way to subsequently add countries as often submissions are staggered e.g. because of delays in set up in different countries. How will annual safety reports, final study reports and end of trial declarations be handled in the CAP? In section 1.3 it states each Member State will divide tasks between the competent national authority and Ethics Committee – it is unclear what this means given there will be a separate Ethics submission and review process in each country?

Consultation item no 5:

GE Healthcare comment: We agree that all the aspects listed under a) should be included in the CAP discussion. There may be local additional issues to be handles in CAP – see item 4.

Consultation item no 6:

GE Healthcare comment: In favour of the 'opt out' with the condition that, as for MAA assessment, the Member State can only opt out if it reaches the level of serious risk. We would like to see a more fully defined process with opportunities for dialogue between the Member State and sponsor to resolve any potential issues. Not in favour of referral to the Commission or the Agency for a decision at EU level as this will most likely increase the administrative burden, cost and timelines.

Consultation item no 7:

GE Healthcare comment: Our preferred option is mandatory for all multinational clinical trials provided the application is totally harmonised. We question how the lead country would be chosen and whether this would result in certain countries doing the majority of the work. Any overloading of countries by such an increased administrative/review burden could potentially lead to a booking-in system such as in the decentralised process and this should be avoided to reduce complexity and timelines.

Consultation item no 8:

GE Healthcare comment: We would support a pre-assessment process if it can be clearly defined so the process is kept fast and simple. The current explanation is not defined well enough e.g. what does 'sufficiently known' mean, how will this be assessed? The process will need to be simple to avoid additional time added to the timeline. Agree that a 'tacit agreement' will not be possible but, as in current practice this is the exception, this is acceptable.

2. 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

Consultation item no. 9.

GE Healthcare comment: We agree but would like to have public consultation on the wider definition. If the goal is to exclude non-interventional trials from the Clinical Trials Directive a clearer definition is required. But if, in fact, they are included in the Directive they will presumably go through an assessment process but with minimal documentation requirements? We have received divergent opinions from Member States on whether a particular clinical trial is non-interventional or not and believe, therefore, there is value in having an assessment process, but would expect it could be reasonably fast-tracked.

Consultation item no. 10.

GE Healthcare comment: We agree – there should be one harmonised set of rules for all types of sponsors.

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

Consultation item no. 11.

GE Healthcare comment: We agree. Using delegated acts is a practical way to increase the detail for a single set of rules, is sufficiently flexible and will greatly improve consistency.

Consultation item no. 12.

GE Healthcare comment: Another key aspect to consider is the classification of substantial versus non-substantial amendments; despite all efforts so far there still seems to be a fair amount of uncertainty and room for interpretation. Could also consider if there could be different set of rules for different stages of study, for example phase 1 versus phase 3 studies.

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

Consultation item no. 13

GE Healthcare comment: We agree. The first and second bullets with the IMP and 'auxiliary medical product' definitions will be very helpful. Agree that setting out the details in the Annex will be a practical way forward to provide the necessary detail.

2.4 **Insurance/indemnification**

Consultation item no. 14

GE Healthcare comment: No comment.

2.5 **Single sponsor**

Consultation item no. 15

GE Healthcare comment: We agree there should be a single sponsor and to allow the sponsor to manage themselves the necessary contracts between other parties.

2.6 **Emergency clinical trials**

Consultation item no. 16

GE Healthcare comment: We agree with the appraisal as this will ensure prioritisation of the health of the patient and also harmonise the process with other countries e.g. United States.

3. Ensuring Compliance with Good Clinical Practice in Clinical Trials Performed in Third Countries

Consultation item no. 17

GE Healthcare comment: The EU Clinical Trials Registry is maintained by regulators so how would there be validation of the information entered for third countries and correction of issues? There will be duplication of effort if trials are added to several country databases e.g. ClinicalTrials.gov – they should be publicly registered in one place.

4. Figures and Data

Consultation item no. 18

GE Healthcare comment: No comment.