vfa. Die forschenden Pharma-Unternehmen

vfa Comments on the European Commission's Draft Concept Paper

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

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1. COOPERATION IN ASSESSING AND FOLLOWING UP APPLICATIONS FOR CLINICAL TRIALS

Consultation item no. 1: SUBMISSION route:
We agree that *"a single submission would greatly reduce the administrative work of sponsors for submission of documentation to the Member States concerned?"*

Consultation item no. 2: ASSESSMENT of the information:
We agree that *"A separate assessment would insufficiently address the issue set above: The difficulties created by independent assessments would remain."*

Consultation item no 3: single submission with subsequent central assessment
We agree that *"a central assessment is not appropriate…"*

Comment: vfa shares the commission's preliminary appraisal that the centralized option is not viable. The TGN 1412 case has clearly shown that the responsibility for a clinical trial is always seen on the national level and therefore in the end the authorization of a trial has to be defended on a national level.

Therefore the concerned national authorities in the member states must be involved in the authorization process of a clinical trial which is to be conducted on their territory.

We think it is better to pursue and design a more realistic option instead of consisting on an option which is rejected both by the Commission and the member states.

Consultation item no 4: Is the "catalogue" complete?
Yes.

Comments: vfa strongly supports the proposed CAP-procedure as an optional procedure for multi-national trials.

Consultation item no 5: include aspects concerning the risk benefit assessment as well as aspects related to quality of the medicines and their labeling and only these aspects in the scope of the CAP?
Yes

Consultation item no 6: which of the approaches is preferable?
We prefer the following approach

> *- an individual Member State could be allowed an 'opt out', if justified on the basis of a 'serious risk to the safety of the participants'*

for the following reasons:

The options 2 and 3 would again not ensure an early and sufficient involvement of the national authorities. The national authorities need an involvement in the authorization decision to ensure their later regulatory responsibility during the conduct of the trial in the member state. Based on this it would not be justifiable if a member state would be overruled and forced to take over responsibilities for a trial that would not have been authorized in that member state.

Consultation item no 7: Which of the approaches is preferable?

We prefer the following approach:

> *Coordinated assessment procedure completely optional – and only for multi-national trials*

for the following reasons:

vfa supports option 3 yet the CAP should be limited to multi-national clinical trials. It would not make sense to apply the CAT on clinical trials conducted in one single MS.

Consultation item no 8: pre-assessment
We think pre-assessment would be workable in practice. Nevertheless the current voluntary harmonization procedure (VHP) shows that a shorter timeline is possible.

2. BETTER ADAPTATION TO PRACTICAL REQUIREMENTS AND A MORE HARMONISED, RISK-ADAPTED APPROACH TO

Consultation item no 9: proportionate requirements for *all* clinical trials
We do not agree.

Consultation item no 10: proportionate requirements apply to all sponsors
We do agree.

Comments: A distinction based on the nature of the sponsor is not justified. A clinical trial with an academic sponsor is per se not less risky than a clinical trial conducted by a "commercial sponsor". A risk-based approach would be better.

Consultation item no. 11: more precise and risk-adapted rules for contents of the application dossier and for safety reporting
We agree.

Consultation item no. 12: Are there other key aspects on which more detailed rules are needed?
No, we don't see others.

Consultation item no 13: combined approach regarding the definition of 'investigational medicinal product'
We agree; add–on therapies and background therapies given to all patients as well as ancillary materials such as infusion/saline solutions etc. should explicitly be categorised as 'auxiliary medicinal products'. PET tracers used as a diagnostic agents and other diagnostics should also be included in the list of auxiliary medicinal products.

Consultation item no 14 : policy options in view of legal and practical obstacles regarding insurance/indemnisation
vfa supports the idea of having an "o*ptional indemnisation by member state".*

Consultation item no 15: single sponsor
We agree.

Comments: The argument of the commission should be clearly supported as a clear responsibility is needed in clinical trials. A "multi-sponsor" concept would raise the question of the responsibility within the trial as the risk that none of the involved sponsors would be approachable for the authorities in case of adverse events, quality obligations etc.

Consultation item no 16: Emergency clinical trials
vfa supports this appraisal.

3. ENSURING COMPLIANCE WITH GOOD CLINICAL PRACTICES IN CLINICAL TRIALS PERFORMED IN THIRD COUNTRIES

Consultation item 17: Criteria

We agree that

1) "*codifying in the revised legislative framework, the provision in point 2.7.2.4* of the detailed guidance CT-1

2) *"further supporting capacity building in third countries where the regulatory framework for clinical trials, including its enforcement is weak"*

could further support and supplement the implementation. But clinical trials performed in third countries should not be obligatory registered in the EU clinical trials database EudraCT and thus be published via the public EU-database EudraPharm. Internationally the database www.clinicaltrial.gov is supported and used by the research-based companies. So where a clinical trial referred to has been performed in third countries, a reference to the entry of this clinical trial in a public register (e. g. www.clinicaltrial.gov) should be sufficient. This would also be in line with the "Joint position on the disclosure of clinical trial information via clinical trial registries and databases" which is unanimously supported by the vfa.

4. FIGURES AND DATA

Consultation item No 18: additional data
vfa has no additional data to provide.