# Revision of the ”Clinical trial Directive” 2001/20/EC

## Concept paper submitted for public consultation

1. Cooperation in assessing and following up application for clinical trials.

| | | **Consultation** | **Comments from the GCP-Unit** |
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| 1.1 | Single submission with separate assessment | | |
| | | Consultation item no. 1 | We agree that a single submission EU portal would be of great benefit to the sponsors as it would reduce the administrative burden related to fulfilling the application forms. The EU portal should preferably be used both for applications to member states as well as applications to the ethics committees (as the IRAS portal in UK). |
| | | Consultation item no. 2 | We agree that the described difficulties related to independent assessment wouldn’t be solved, if the assessment isn’t somehow coordinated. The difference in ideas and views from different authorities is very troublesome, especially to academic researchers who don’t always have the resources to coordinate the views. One may also ask whether these differences should be the problem of the researcher or the authorities themselves. |
| 1.2 | Single submission with subsequent central assessment | | |
| | | Consultation item no. 3 | The idea of a central assessment is appealing, but we agree that a procedure involving all member states in all aspects of each application would cause too much administration. If this – as a consequence – furthermore would lead to an increased fee, it would definitely be a problem for academic researchers in general. |
| 1.3 | Single submission with a subsequent ‘coordinated assessment procedure’ CAP | | |
| | 1.3.1. Scope of the CAP | | |
| | | Consultation item no. 4 | Other items to the catalogue would be<br>- assessment of the planned monitoring of the trial |

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| | | | - assessment of the QA system established for the trial.<br><br>Both bullets should be part of the centralized assessment, as neither the level of monitoring nor the QA system imposed on the study should differ from country to country. |
| | | Consultation item no. 5 | We don't agree completely. The professional content of the subject information should be assessed by the member states as it should balance risk and benefit in a proper way - reflecting the actual risk/benefit ratio, as also assessed by the member states. This should be the same for all patients throughout EU. |
| | 1.3.2 Disagreement with the assessment report | | |
| | | Consultation item no. 6 | As a principle – and if the CAP should really be of benefit – the member states should always come back with only one decision (either decided by voting or by the Agency). It shouldn't be the problem of the researcher to find out how to coordinate the different needs and opinions of each member state.<br>A decision by the Agency would probably be better in terms of appeal opportunities. |
| | 1.3.3 Mandatory/optional use | | |
| | | Consultation item no. 7 | Again – if the CAP should really be of benefit – it should be mandatory for all clinical trials. In this case we would have only one administrative procedure for all applications which would be easier to implement and use. If a study is a single-country study, it will only be assessed by the relevant member state any way – thus it shouldn't lead to extra bureaucracy. |
| | 1.3.4 Tacit approval and timelines | | |
| | | Consultation item no. 8 | It is a very good idea to establish a risk-based approach to the assessment of the clinical trial applications. Shorter time-limits for the A-studies seem reasonable – perhaps only a notification to the authorities are required, if the studies are "True Phase IV-studies"?<br>When introducing a new category of studies (A-studies), it should be defined very clearly who has the mandate to decide whether a study belongs to the category or not. This should not differ from country to country! |

2. Better adaption to practical requirement and a more harmonized, risk adapted approach to the procedural aspects of clinical trials.

| | | Consultation | Comments from the GCP-Unit |
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| 2.1 | Limiting the scope of the Clinical Trial Directive | | |
| | 2.1.1 Enlarging the definition of 'non-interventional' trials | | |
| | | Consultation item no. 9 | It is a good idea to widen the scope of the Directive and in this way harmonise the requirements to clinical studies throughout EU. However one should be very careful to proportionate the requirements in the right way. E.g. Studies of new products should always follow GCP very strict, but GCP should never be a requirement for non-interventional studies. |
| | 2.1.2 Excluding clinical trials by 'academic/non-commercial sponsors' from the scope of the Clinical Trial Directive | | |
| | | Consultation item no. 10 | We completely agree! |
| 2.2 | More precise and risk-adapted rules for the content of the application dossier and safety reporting | | |
| | | Consultation item no. 11 | We agree. |
| | | Consultation item no. 12 | Other areas where a stream-lined and risk-adapted set of rules could be applied would be:<br>- Extent and nature of monitoring<br>- Requirements regarding GCP-training of the study personnel |
| 2.3 | Clarifying the definition of 'Investigational medicinal product' and establishing rules for 'auxillisry medicinal products' | | |
| | | Consultation item no. 13 | It seems like at good idea to combine the rules regarding IMP and auxiliary medicinal products. However we think that there is still a need to make an even more clear definition of an IMP. It is still an open question in many cases, whether the standard |

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| | | | treatment should be regarded as IMP, when an add-on treatment is being tested, and when there is just one effect being measured of the combined treatment. (E.g. reduction of blood pressure, when two drugs against hypertension is being administered – one being standard treatment and the other being a test-product). |
| 2.4 | Insurance/indemnisation | | |
| | 2.4.1 The issue | | |
| | 2.4.2 Policy option | | |
| | | Consultation item no.14 | ---- |
| 2.5 | Single Sponsor | | |
| | | Consultation item no. 15 | We agree that option 1 seems to be preferably given the mentioned prerequisites |
| 2.6 | Emergency Clinical Trial | | |
| | | Consultation item no. 16 | We agree completely. One could add as a fifth bullet, that the requirements regarding quality assurance and quality control should be enforced more strictly in these types of trials. |

3. Ensuring compliance with Good Clinical Practices in Clinical Trials performed in Third Countries

| | | **Consultation** | **Comments from the GCP-Unit** |
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| 3 | Ensuring compliance with Good Clinical Practices in Clinical Trials performed in Third Countries | | |
| | | Consultation item no. 17 | ----- |

4. Figures and Data

| | | **Consultation** | **Comments from the GCP-Unit** |
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| 4 | Figures and Data | | |
| | | Consultation item no. 18 | ------ |