It is essential to consider the opinions and attitudes of ethics committes towards the proposed changes to the procedure of assessment of clinical trials. They can provide many practical advices and different points of view than other regulators. This document represents the opinion of a member of an ethics committee and member of the Forum of Ethics Committees of the Czech Republic. It keeps the structure of the original document published by European Comission and mentions the most important points to consider before making changes to the procedures in assessment of CTs.

3.1 – It is necessary to take into account the pecularities of each country´s national laws that have to be respected and that reflect the historical development of the country.

3.2 - It is not an accurate description of the situation. It seems that the weaknesses mentioned in the document arise form the disparity between the amount of facts, which the sponsors want to get from the trial, and the time they want to invest in the preparation and realisation of the trial according to the moto: „Time is money!“. If sponsors complain about the regional requirements, which usually do not mean big changes of the design or protocol of the trial, they may do the changes by the means of amendment which fastens the process of preparation of the trial´s documentation. The companies overestimate data about costs and number of employees. It can be partially caused by bad logistics and organisation in the company and not by the implementation of the Directive 20.
It is not possible to apply the Directive entirely to the academic trials. We propose to specify clearly the conditions for academic trials and so minimise the administrative work. We share the opinion that requirements should be differenciated according to the risk in phases I to IV
Unequal standard of the assessment in different countries should not be solved by centralisation of the procedures and restriction of individua country´ s assesssment. It should be done by a systematic education and training – common workshops – harmonisation resulting from mutual discussions.

3.3.1 – VHP process seems to be an acceptable solution for some types of the studies
3.3.2 – It might be acceptable to have for example centralised assessment of pharmaceutical documentation or clinical scales by a group of experts from european regulatory authorities. They could give a standpoint/recommendation for all concerned countries which would later decide to accept or refuse it.

3.4.1 – We don´t agree. It would require institucionalisation of the ethics committees. Voluntary ethics assessment cannot be presumed.
3.4.2 – It is a potentially possible solution that would lead to progressive harmonisation but there are no existing conditions to assure such international collaboration. It would need professional involvement of members of ethics committees.
3.4.3 – We agree. It would be beneficial to clarify as well the extent of responsibilities and roles in assessing various documents by ethics committees (especially insurance treaty). We encourage the division of competences between ethics committees and regulatory authority.

4.1.1 – It is necessary to unify the interpretation of amendments. The term „Substantial amendment“ should be reserved for essential changes that would remarkably affect the assessment of efficiency and safety (exact list). All other changes should figure as „Non-substantial“. The sponsor should have more responsibility and should be penalised for each redundant SA if the concrete SA doesn´t concern the country where it is submitted.
4.1.2 – We propose to charge sponsors for each SUSAR report or penalise him for over-reporting which leads to excessive administrative work and in consequence to ignoring of the

content by both ethics committees and investigators. We want to promote 6 months line listings and submitting to each ethics committee safety reports only from sites under its supervision.
4.1.3 – Exact definition of non - interventional studies is necessary. We require concrete risk assessment (high/low) from the sponsor in the CTA.
4.2 – It should be obligatory for the sponsor to deal with SUSAR. The increase in pharmacovigilance staff of big investigating companies is logical. Investigators and ethics committees should get assessed reviews with clear description of SADR/SUSAR.
4.3.1 – We agree with the necessity of revising and amending the Directive (conditions for academic research, clear division of competences between regulatory authorities and ethics committees, sponsors and investigators). Regulatory authorities and ethics committees shouldn´t assure responsibility but control of respecting GCP and legal aspects.
4.3.2 – We don´t agree because the conditions are not favorable (legislation, capacity of EC work) and the change would lead to going round the rules.

5.1 and 5.2 – It is necessary to distinguish the requirements for single phases I-IV. The sponsor should categorize trials according to the level of risk for participants and eventually adapt the insurance to it as well.

5.3 – We don´t agree. We have the same attitude only about establishing more moderate rules for academic research. Therefore it must be clearly determined which trial is purely academic.

5.4.1 – We agree with the review.
5.4.2 – We find it essential to define the competencies of NCA and EC in assessing the documents . We want to point out that ethics committee is not a controlling institution but a group of volunteers, who don´t have qualification for assessing specialised documents like contracts with sites and insurance companies. If this is anticipated, each EC should be completed with a lawyer specialised on commercial law and insurance. We would prefer the EC to check only whether the trial is insured and how can the participant ask for indemnification.Other aspects should be settled in the site contract.
5.4.3 – We agree with the review of the requirements for academic trials. Data from those trials cannot be used for drug authorisation.

6.1 – We agree about the rigidity of the rules in paediatric trials.
6.2 – We agree that the paediatric trials should be more transparent and shouldn´t be duplicated. We don´t agree with the creation of the network of sites and investigators – can be easily misused. Concerning emergency trials – The situation in CR is satisfactory and may be used as a model for other countries. The responsibility of EC and NCA should be underlined.

7.3.3 – We agree with the international cooperation in inspections. When non-compliance with GCP is proved, the mecicinal product should not be authorised.
7.3.4 - We agree with optional assessment by EMEA, especially if the data are to be used for marketing authorisation.
7.3.5 - We agree with strengthening the transparency and especially with publishing cases of non-compliance with GCP (inspections)
7.3.6 – We don´t agree with financing of the trials by EU.