The draft Proposal of a Regulation for Clinical Trials by the European Commission

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Background

- **Proposal published 17 July 2012**
- **Ethics Committees (RECs) neither mentioned nor involved in the assessment of clinical trial applications.**
- **Drift to social ethics, wordings like ‚individual therapeutic benefit‘, ‚well-being‘ etc largely missing, instead:‘ public health benefit‘ and ‚relevance‘ frequently used.**
- **Ethics limited to Informed Consent issues.**

Background

- **Co-determination rights of the Member States concerned extremely limited, decisive role of the reporting MS.**
- **Extremely short time-lines which do not allow for a sound assessment.**
- **Vulnerable people like minors, incapacitated and persons deprived of liberty were not properly protected.**

Results of the 1st Reading of the EP: Achievements (29 May 2013)

- **RECs are an essential part of the regulation (definition, tasks, etc.) and participate in the assessment of the clinical trial applications.**
- **The level of protection for minors, incapacitated persons, persons deprived of liberty and people with special needs were noticeably and rather satisfactorily raised.**
- **The wording is now much more in agreement with the DoH and emphasizes individual ethics.**

Result of the 1st Reading of the EP: Achievements (29 May 2013)

- **Co-determination rights of the MS have been strengthened. Disregarded comments have to be notified, the rationale for disregarding explained.**
- **Transparency of trials results is addressed.**

Critical Points

- **Clarification of the role of the RECs of the MS concerned regarding the assessment of part I of the application (trial protocol, risk-benefit assessment)**
- **Clarification of the impact of the assessment of the competent REC. → Approval, Opt out**
- **Clarification that the deliberations and voting of the REC should remain seperate and independent of the decision-making of the NCAs.**

Critical Points

- **Article 29, 3a (new) considers trials were subjects are informed only, no Informed Consent is asked for. Subjects are expected to proactively reject participation if they want. → should be deleted.**
- **Clinical Trials with pregnant or lactating women shall be widely permitted even if not providing the potential for direct benefit (Art. 31a (a))**
- **Clinical trials in emergency situations allow proportionate risks and burdens even if there is no potential for direct benefit (Art. 32 (e) and (ea)).**

Critical Points

- **Still much too short time-lines linked with the concept of tacid approval. → lack of responsible decision-making and responsibility.**
- **Definition of ‚low risk trial' too wide, covering treatments recommended by standard guidelines or supported by sufficient published evidence.**
- **It needs to be stressed that the Informed Consent interview should be done by physicians only.**

Further proceedings

- **The EP and the European Council start now negotiations to prepare a final und mutually acceptable text.**
- **The final reading in the EP is currently planned for early October 2013.**
- **The RECSs in Europe have to work hard to get their voices heard by the law makers.**