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)

• REC{s 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. \(\rightarrow\) Approval, Opt out

• Clarification that the deliberations and voting of the REC should remain separate 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 tacit 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.