EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Ethics Guideline – Review of Ethical Considerations

What has changed?

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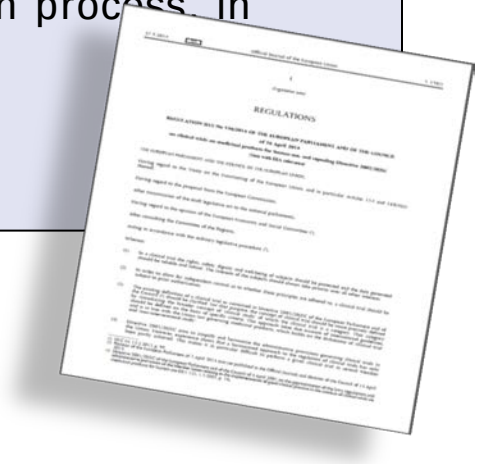
The main points:

1. The Clinical Trials Regulation (EU) No 536/2014
2. Consent, assent and agreement
3. Burden and risks
4. The trials without prospect of benefit
5. Other

Clinical Trials Regulation

Objectives:

- **To protect** the rights, safety, dignity and well-being of subjects and the reliability and robustness of the data generated
- **To foster innovation** and simplify the clinical trial application process, in particular for multistate trials
- **To increase transparency**- balancing varied interest



Some Key Changes from the CT Regulation

- Introducing a **risk-adapted approach:**
  - Less stringent rules to those trials conducted with already authorised medicines
  - Proportionate approach to trial supervision and conduct
- Increasing **transparency** as regards clinical trials and their outcomes.
  - Better patient awareness (engagement) and recruitment
  - Public accountability
  - Avoiding un-necessary trials or harm to patients

Paediatric trials changes (art 32)

Respect for the person

- Minor defined by national legislation
- Assent (refers to national legislation) or agreement
- Trials without prospect of direct benefit:

"*some benefit for the population represented by the minor concerned and such a clinical trial will pose only minimal risk to, and will impose minimal burden on, the minor concerned in comparison with the standard treatment of the minor's condition.*"

- NB: Trials in emergency situations included.

Non-maleficence

Beneficence

Distributive justice

To support these principles

- To involve parents and children in information, design, conduct and evaluation
- To ask assent or agreement from early age (*based on limited available data*). Putting maturity before age.
- To consider burden as subjective load that affects the participant, and also the family (*can only be self-assessed*)
- Inclusion versus exclusion of female adolescents participating in trials (*risk of pregnancy, contraception*)

Next Steps

- Consultation finished in April 2017. Integration of comments
- Adoption by the ad-hoc group after comments by 10 May 2017
- Publication by European Commission
- The rest is for us… to implement

Thank you for your attention

Further information

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Similar concerns globally?

- US wording:
  - Clinical investigations not involving greater than minimal risk;
  - Clinical investigations involving greater than minimal risk but presenting the prospect of direct benefit to individual subjects;
  - Clinical investigations involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subjects' disorder or condition. (…*The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations…)*;
  - Clinical investigations not otherwise approvable that present an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.