

Annagrazia ALTAVILLA



Why this Working Group?

Paediatric research peculiarities:

- Ethical challenges
- Limits ⇒ e.g. the lack of harmonisation of ethical /legal frameworks among countries

New provisions:

European Network of Excellence for Paediatric Clinical Research

- Updated ICH Topic E11 guideline
- Updated EC Ethical Recommendations
- New CT Regulation ⇒ new rules, definitions and procedures soon applicable

What has been done so far?

Publications/surveys

- EU survey on ethical and legal framework of clinical trials in paediatrics (*Altavilla et al. J. Int Bioethique, 2008*)
- Impact of the new european paediatric regulatory framework on ethics committees: overview and perspectives (*Altavilla* et al. *Acta Paediatrica*, 2012)
- Clinical Trial Application in Europe: What will change with the new regulation, (Giannuzzi, Altavilla et al. Sci Eng Ethics, 2015)
- Paediatric research under the new EU regulation on clinical trials: old issues new challenges (*Gennet E., Altavilla, EJHL 2016*)
- The ethical framework for performing research with rare inherited neurometabolic disease patients (Giannuzzi et al. EJP, 2017)

> Contribution to EnprEMA WG4 Ethics

- Comments on the revision of EC Ethical Recommendations 2008 (2017)
- Harmonised consent / assent template

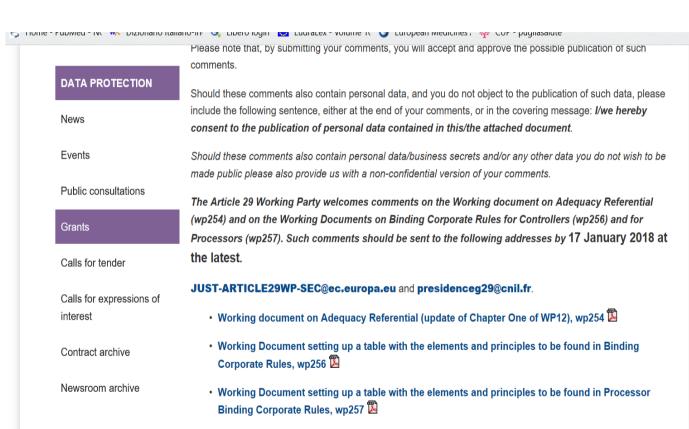
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Risk / benefit assessment in paediatrics

WHAT

- To contribute to the EnprEMA WG4 Ethics task on tarmonised consent / assent templates (to continue)
- Ethical review of TEDDY projects, applications and activities
- To advice on ethical aspects on data handling and sharing
- Participation in public consultations









Please note that, by submitting your comments, you will accept and approve the possible publication of such

comments.

 Operational roles ⇒ to coordinate activities, to draft documents...

HOW

Advisory role
⇒ to review documents,
to provide inputs and suggestions



Interested members

- Annagrazia Altavilla (Espace de Réflexion Ethique PACA-Corse)
- Federico Martinón Torres (H. C. U. de Santiago de Compostela | Fundación Ramón Domínguez)
- Cristina Serén Trasorras (H. C. U. de Santiago de Compostela | Fundación Ramón Domínguez)
- Viviana Giannuzzi (Fondazione per la Ricerca Farmacologica Gianni Benzi onlus)

....others?



New members are welcomed!

Comments and proposals for discussion

Name of the WP: Ethical and legal issues in paediatric research?

