14Oct2019

WORKING GROUP 4:

DIALOGUE AND INTERACTION WITH ETHICS COMMITTEES

Pirkko Lepola

EnprEMA WG 4 – Ethics - Composition

WG4 since 01Nov2017:

Primary members -> drafting documents

- Pirkko Lepola, Chair (Finnish Investigators Network for Pediatric Medicines, Helsinki, Finland)
- Maxine Kindred, (Janssen Research & Development, Buckinghamshire, UK)
- Viviana Giannuzzi (Fondazione per la Ricerca Farmacologica Gianni Benzi, Valenzano, Italy)
- Heidi Glosli (Oslo University Hospital, NorPedMed, Oslo, Norway)
- Martine Dehlinger-Kremer (SynteractHCR Deutschland GmbH, Munich, Germany)
- Harris Dalrymple (PRA HealthSciences, Reading, UK
- Peter Sallabank (RegulinX, Surbiton, UK)
- David Neubauer (University Children's Hospital, Ljubljana, Slovenia)
- Geraldine Boylan (Irish Centre for Fetal & Neonatal Translational Research, University College Cork, Ireland)
- Jean Conway (Irish Centre for Fetal & Neonatal Translational Research, Paediatric Unit, Cork University Hospital, Cork, Ireland)

Co-members -> reviewing documents

- Christina Manfredi (CVBF-Consorzio per Valutazioni Biologiche e Farmacologiche, Pavia, Italy)
- Jo Dewhurst (PRA HealthSciences, Reading, UK
- Diane Hoffman (prev. Janssen Research & Development, US – Retired)

EnprEMA WG 4 – Ethics - Role

Role:

Develop pragmatic responses to be implemented within six months (approx.!);

- **Examples of good practice when ECs consider trials relating to children and young people**
- **Develop proposals to disseminate examples of good practice to ECs**

EnprEMA WG 4 – Ethics – Tasks 1 and 2

- **First Report**: Plan Report - Recommendations (12), published in December **2013** for Enpr-EMA (only)
- **1 Task: Deliverable**: "Tool Kit" - Informed Consent and Assent for Paediatric Clinical Trials in Europe
  - **Published on Enpr-EMA web-site on 18 December 2015**
  - **1. Article:** *"Informed Consent and Assent Tool Kit for Paediatric Clinical Trials in Europe";* Published 25May2016, Archives of Disease in Childhood
    - **Authors: Pirkko Lepola, Allison Needham, Jo Mendum, Peter Sallabank, David Neubauer, Saskia de Wildt**
- **Additional WG activities in 2016:**
  - **Contribution to PROPOSED CHANGES TO THE U.S. COMMON RULE Implications for Pediatric Research (Federal Policy for the Protection of Human Subjects)**
    - **Comments submitted on January 2016 by Mark Turner, the behalf of the Enpr-EMA**
- **Task 2: Consultation:** Take part to Public Consultation of the *"Ethical considerations for clinical trials on medicinal products conducted with the paediatric population" (2008),* open June-September **2016**
  - **Contributed by EFGCP CMWP (European Forum for Good Clinical Practice, Children's Medicines Working Party; WP 1**
  - **In collaborating with a small group of PDCO members**

Enpr-EMA WG4 – Ethics - Task 3

Task 3: 2016-2017: Background facts:

1. New EU CT Reg. (impl.approx.10/2018) will harmonise the clinical trial application (CTA) process, but IC/Assent issues remain with each Member State.
2. There are noticeable differences between national IC and assent requirements in Europe due to national laws and regulations (See: Tool Kit data)
3. These discrepancies can present challenges for multicentre paediatric CTs

Plan for the deliverable: "Partly harmonized of IC / Assent templates"

- **Identify of all similar elements across assents -> Prepare to include all elements**
- **Add Items included in the WHO template guidance as they were deemed important to the assent**
- **Isolate and collect the issues repeatedly comes to be solved with ICs and Assents**
- **Compile standard sections, reflecting the revised "EU Guideline" age categories**
- **Review all existing templates and verify those also with the "Tool Kit" data**
- **Draft partly harmonized (as much as possible) core templates (3 ?) with standard language (English)**
- **Make recommendations, what type of visual aid could be used, and what is publicly available.**

Enpr-EMA WG4 –Ethics - update – Task 4

4. Task & Deliverable – Modified from the orginal Task 3 plan:

The Consent / Assent information as a Guidance Document for all Enpr-EMA stakeholders and public to be placed publicly available on Enpr-EMA web-site -> NO TEMPLATES (Decision 1/2018)

Process:

- Comparison of the review responses with the EU Ethics Guideline (Revision 1); published in October 2017.
- Correcting the guidance according to Ethics guideline (R1), CTR and GDPR
- Preparing to include all important elements from eYPAGnet Report + review I and II
- Asking review comments from EAP Ethics Working Group -> No comments received
- Finalize the format

Task 4: The Guidance Document - Process

- **Drafting process between; April 2017 – October 2019**
- **Versions 1.0-7.0 including comments /documents from:**

  - **European Academy of Pediatrics> EAP Ethics Working Group**
    - **1. Feedback; 29June2017**
    - **2. Feedback 18 October 2018**
    - **3. No final comments received (01-09/2019)**

  - **Inclusion of eYPAGnet Feedback;**
    - **1. 25November2018 - Report**
    - **2. August-September 2019 – Reviews I + II by e-mails**

  > Children´s Voice

  - **Revised EU Ethics Guideline (R1); September 2017**

  > Ethical Proof

  - **Legal EU documents: EU CTR (2014), EU GDPR (2018)**

  > Legal Proof

  + Language Proof (English)

Task 4: The Guidance Document

- **Forewords**
- **Recommendation symbols per age groups**
- **Table 1: General Information for Informed Consents & Assents**
- **Table 2: Trial Specific Information for Informed Consents & Assents (Agreements)** – 25 Subject Element sections
- **References & links to legal and ethical documents**

- **Total of 12 pages (version 7.0) -> Finalization**

- 10-11/19

Task 4: Next steps - Publication

- **Manuscript under creation**
- **Following the same procedure as with the ToolKit**
  - **First placed to Enpr-EMA website**
  - **Into the article with the copyright mark; © European Medicines Agency, 2018. Reproduced with permission.**
- **Selection of suitable paper and submitting**

->Approx. 11-12/2019

THANK YOU!