ENPR-EMA WORK SHOP 26JUNE2014

WORKING GROUP 4:

DIALOGUE AND INTERACTION WITH ETHICS COMMITTEES

Allison Needham / Pirkko Lepola

EnprEMA WG 4 - Ethics

Mandate:

- **Enpr-EMA Annual workshop 06/2013 agreed to set up several ad hoc Working Groups (WG1-6) tasked with addressing the most important of the needs identified during the meeting**

- **Between the August and October 2013, the Enpr-EMA identified and confirmed all working group members and published the mandate for the WGs with the purpose to develop pragmatic responses to some of the needs that can be implemented *within six months***

- **The focus was on stating what networks can do, or what networks need to do, rather than developing comprehensive guidance**

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Task:

Dialogue and interaction with Ethics Committees, including specifications to:

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

Timeline:

- **All WGs were expected to send an update of the plan to the Secretariat by 15th December 2013 for discussion by the Coordinating Group in January 2014**
- **Final proposals to be introduced at next Enpr-EMA work Shop June 2014**

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Participants:

- Allison Needham (GRIP) – Chair
- Pirkko Lepola (FINPEDMED)
- Peter Sallabank (Regulinx)
- Jo Mendum (PRA Health Sciences)
- David Neubauer (European Academy of Pediatrics/Ljubljana University)
- Ivana Silva (EMA)
- Richard Trompeter (GOSH/ IPTA)
- Alan Boddy (Newcastle University)

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Results and deliverable:

- The group organized 3 WEB-meetings (29-Aug-2013, 03-Oct-2013 and 08-Nov-2013). Further discussion and development of the deliverable was conducted by email

- Final Report with Short term – and Long Term Recommendations was published in December 2013 to be discussed in CG meeting on January 2014

- Report did not include one specified deliverable to be implemented within 6 months – instead, it included 7 Short Term – and 5 Long Term Recommendations, i.e. specified deliverables, what could be done. Each of the recommend deliverables (12) was considered as a good example to be disseminated within ECs and Enpr-EMA

- After CG meeting, it was decided to choose one of the recommendations to be developed as a practical deliverable. There was consensus within the group that consent and assent presented the greatest challenge in achieving ethical approvals across Member States. This informed our decision to select the deliverable "A table that shows requirements/regulations regarding consent of children in Member States", because it was already included in the WG Report as an example

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Final deliverable:
Table of EU EC details for informed consent for paediatric trials

Table form:

- **Word document**

- **Data including legislative surroundings of the informed consent requirements for pediatric clinical trials, listed by country – 26 EU Member States and EEA States**

	Consent/assent from child		Consent from parent(s)/guardian(s)	General informed consent information	
Country	Legal age of consent	Mandatory /suggested age ranges defined for consent and assent	Number of required signatures	Official language requirements	IC template(s) / guidelines

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Summary and next steps - responsibilities:

- Complete the table with more accurate details (some country-specific data need to be defined in more detailed form) - WG
- Add country-specific additional information, if any existing (i.e. templates or direct web-links to regulations and guidelines) – WG and Enpr-EMA
- Publish the Table on Enpr-EMA web-site for comments (if any non-valid information exists in the table, it will need to be corrected) – Enpr-EMA
- Notify all partners (networks, companies etc.) about the table, which can be used by all partners – Enpr-EMA
- Create follow-up system to keep the table up-to-date – Enpr-EMA