Commission PIP Guideline Public Consultation

Date: 15Oct2013
Commented by: Finnish Investigators Network for Pediatric Medicines, Finland
Enpr-EMA membership: Yes, since 2010.
Network status: Non-profit network without legal status, hosted by CRI HUCH Ltd.
Pages:1.

COMMENTS:
Consultation item No 4: Do you have any comments on the key elements of a paediatric investigation plan?
And
Consultation item No 5: Please feel free to raise any other issues or make any comments which have not been addressed in the consultation items above.

Comment:
This comment relates to the assessed and agreed PIP´s (also modified and deferred), including new paediatric clinical trials (all phases) needed to be conducted and ready to be started in EU member states. It also relates to the Consultation item No 4, about the key elements of a paediatric investigation plan, especially to the Annex, Key Elements, line 685 3. Paediatric clinical studies: line 708 (j) Timelines for completions.

Additional information of planned strategy of completion the studies, is needed to be added to the Key Elements.

1. How the PIP trials will be executed in practice; how the new trial requests (i.e. new study proposals) will be delivered / offered to conducting parties (investigators, hospitals etc.)?

   This information should include the following items:

   a. Will these trials be offered to be conducted to (through) the Enpr-EMA and (to) its member networks within the EU area?
   b. Will these trial requests be followed and up-dated (by collecting the trial request data) in the EU area by the sponsor, OR, in case of transferred responsibility for the request (and feasibility) to the designated CRO, by this responsible contracted research organization? How this data will be collected?
   c. Will the trial request data (b.) be communicated and disseminated to the Enpr-EMA and to the relevant Enpr-EMA member networks?

Behalf of the Executive Committee,
Pirkko Lepola, Executive Secretary of FINPEDMED

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