



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EnprEMA/PDCO interactions

Marek Migdał, Angeliki Siapkara

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Interactions between PDCO and EnprEMA members

- Since 2017 a timeslot during the PDCO plenary meeting reserved for the EnprEMA members (currently every other month)
- Presentation of the network – by representative/s either in person or by phone
- During the meeting: description of the network activities
- Discussion how the PDCO could best solicit network input on general scientific questions during the PIP assessment



Interactions between PDCO and EnprEMA members

Already done meetings with:

- RIPPS,
- FINPEDMED
- NIHR-CRN
- PRINTO
- EUCROF
- ECFS-CTN
- ECAPN
- GNN
- eYPAGnet



Interactions between PDCO and EnprEMA members

Some thoughts:

- *„need for early interaction of academia with applicants to provide input to the PIP preparation, study protocol and eventually identification of sites and conduct of the clinical studies“*
- *„need to improve and increase dialogue with PDCO to discuss paediatric needs, study design, standard of care“*
- *„possibility to provide a consolidated network expert opinion on general scientific questions (as opposed to individual expert opinion) within a 2-3 week timeframe“*
- *„need for training in regulatory science and procedures for members of the network“*