Industry Proposals

How to Interact with and use EnPr-EMA

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Mission statement of the European network of paediatric research at the European Medicines Agency (Enpr-EMA)

- Enpr-EMA will facilitate studies in order to increase availability of medicinal products authorised for use in the paediatric population.

This will be achieved by :

- Fostering high quality ethical research on the safety and effectiveness of medicines for children.
- **Establishing a European paediatric research network of national and European specialty networks, investigators and centres with expertise in performing trials in the paediatric population**
- **Efficient inter-network and stakeholder collaboration in order to build up the necessary competences at Community level and to avoid unnecessary duplication of studies.**
- To inform parents, carers, children and young people about clinical trials and encourage their participation.
- Raising awareness among health care professionals of the need for clinical trials in all ages of children and supporting their involvement in such studies.
- Assisting and entering into discussions with ethics committees on issues relevant to research and clinical trials in children.

EnprEMA Coordinating Group

The group is responsible for the network's long- and short-term strategy

Its tasks include:

- **facilitating access of the pharmaceutical industry to paediatric clinical study centres and experts**;
- identifying new networks to include in Enpr-EMA;
- developing common educational tools for children and parents, to increase their willingness to take part in clinical trials.

Where might EU networks help?

- Identify therapeutic and market needs
- Identify partners
- Drug formulation
- Scientific advice and input
- Clinical development programme
- Regulatory requirements, strategy and approvals

We would value

- Improved understanding of how EMA & PDCO utilise network experience in consideration of PIP requests
  - used for review and discussion
  - capability to perform studies being recommended

- How to access advice from Enpr-EMA overall vs reaching out to individual network members
  - If network & members have study delivery capability (with academia and Industry partners) , then potential enhanced value for consultation

We further value

- The generation of standard PIPs for common paediatric diseases and avoidance of duplicative paediatric studies

- Engagement and leverage of insights from network prior to PIP submission
  - Consider impact on timelines

To date

- We have engaged with several national and TA specific networks in relation to Paediatric strategies and PIPs
- Engagement on ‘per PIP basis’ but also on TA specific Portfolio basis
- We would like to do more based on better understanding of EnprEMA

In summary

- We seek to engage with EnprEMA and its networks in the most effective way for advice and consultation on our PIP strategies
- Seeking support to access relevant trial centres and expertise where needed