European Network of Paediatric Research at the European Medicines Agency

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Strategic Aims of Enpr-EMA 2025-2027

Discussion points for the Coordinating Group (confirmed information, updated 3.7.2025*)

11June2025, Pirkko Lepola

# We received several excellent comments regarding the potential future strategic activities. Analysis can be done by reflecting these to EU Ped.Reg. and new regulation objectives informing the Enpr-EMA mandate.

*Article 44*

1. The Agency shall, with the scientific support of the Paediatric Committee, develop a European network of existing national and European networks, investigators and centres with specific expertise in the performance of studies in the paediatric population.

2. The objectives of the European network shall be, inter alia, to coordinate studies relating to paediatric medicinal products, to build up the necessary scientific and administrative competences at European level, and to avoid unnecessary duplication of studies and testing in the paediatric population.

**FOCUS ON MEDICINAL PRODUCTS / MEDICINES**

*Article 95*

*European network*

1. The Agency shall develop a European network of patient representatives, academics, medicines developers, investigators and centres with expertise in the performance of studies in the paediatric population.

2. The objectives of the European network shall be, inter alia, to discuss priorities in the clinical development of medicines for children, in particular in areas of unmet medical need, to coordinate studies relating to paediatric medicinal products, to build up the necessary scientific and administrative competences at European level, and to avoid unnecessary duplication of studies and testing in the paediatric population.

➔ **To coordinate** studies
➔ **To build up** scientific & admin. competences
➔ **To discuss** priorities & unmet medical needs
➔ **To avoid** duplication of trials

# Enpr-EMA Strategic Aims – proposals and comments

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**Regulatory texts leads to the "Clinical Trial Period" and Scientific & admin. activities**

## *Pre-clinical trial period activities*

- Protocol development
- Scientific advice – by PDCO and EMA committees

**Global Activities by the EMA**

- WHO, ICH etc. collaboration
- Reg.Author. collaboration – Pediatric Cluster

## Clinical trial period activities

- Enhance International collaboration
- Provide Enpr-EMA guidance & recommendation
- Increase Enpr-EMA visibility for support
- Enhance / support Medicine CTs
- Enhance / support ATMP CTs
- Enhance / support Combination product CTs
- Share best practices

## Scientific & Administrative activities

- Prepare activities for new EU legislation
- *Provide scientific comments to PDCO for MoA´s / PIPs /s-PIPs per request
- *Inform about EU initiatives
- Collaborate with ACT EU & MedEthics EU
- Publish national trial requirements
- *Inform about EU consultations

## Enpr-EMA governance

- *Review / modify the Enpr-EMA governance documents

- *Respond to EU consultations – **by individual members**

PPI & YPAGs consultation

## *Out of the EMA remit / mandate

- Harmonization of regulatory guidance across the MSs or various jurisdictions
- Medical Devices; development and clinical trials

*Individual networks – can decide own independent activities*