



EUROPEAN MEDICINES AGENCY



# **The European Network of Paediatric Research**

## **Hosted at the European Medicines Agency**





# Introduction and background

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## Legal basis

### European Paediatric Regulation:

“The EMA 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.”

## What is Enpr-EMA?

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- A network of research networks, investigators and centres with recognised expertise in performing clinical trials in children (newborns to adolescents)
- Members research formulations, child friendly methodologies, pharmacokinetics and pharmacovigilance

# Mission statement

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

- Fostering high quality ethical research.
- Promoting competencies and avoiding duplication of studies.
- Informing parents, carers, children and young people about clinical trials and encouraging their participation.
- Raising awareness among health care professionals of the need for clinical trials and supporting their participation.
- Assisting and entering into discussion with ethics committees.



# Main Stakeholders

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- Pharmaceutical Industry
- Patients, parents and patient organisations
- National Competent Authorities
- Ethics Committees
- Medical devices industry
- CRO's
- Hospital pharmacists



# What Enpr-EMA offers industry

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- pool of patients for inclusion
- Speeding up recruitment
- Expert advice
  - treatment options (standard of care)
  - clinical needs
  - feasibility of clinical trials
- Access to academic partners through collaboration with the EMA SME office



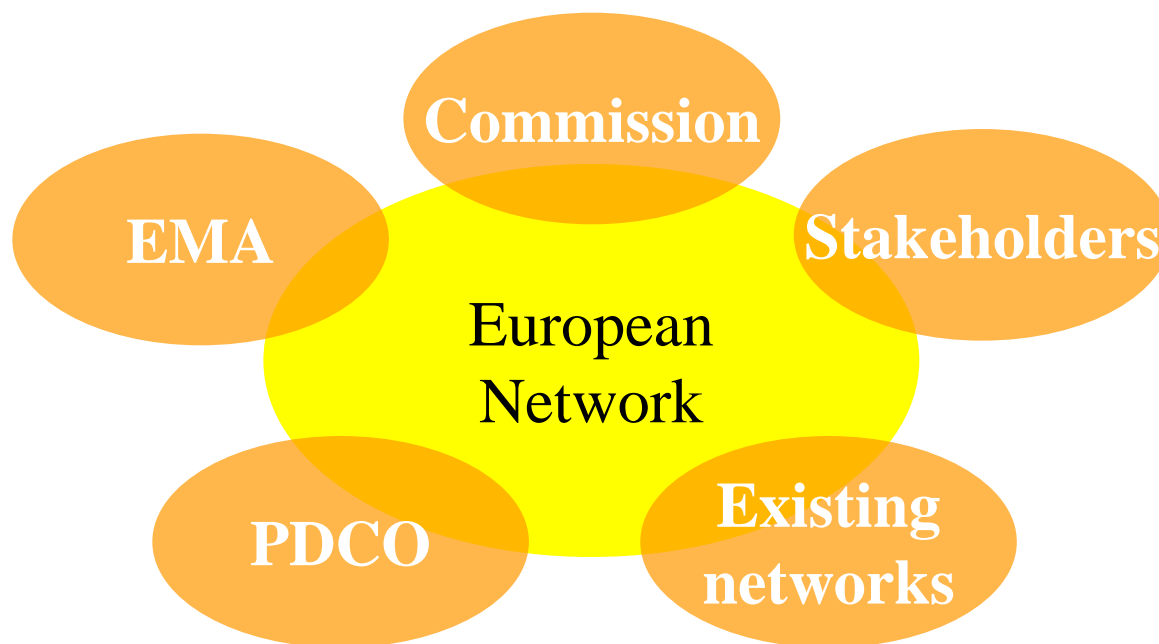
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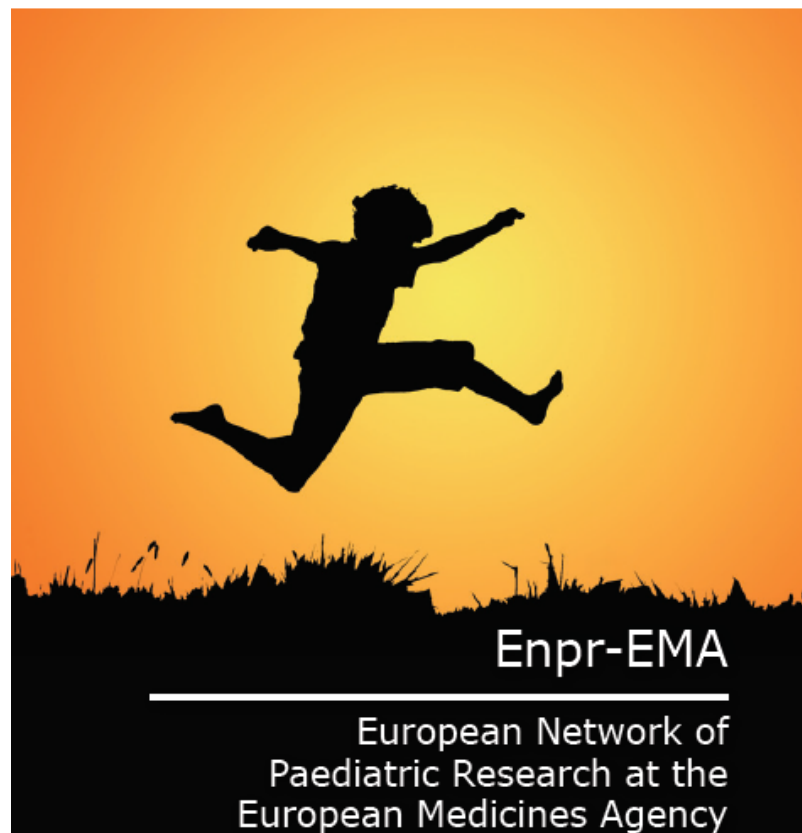
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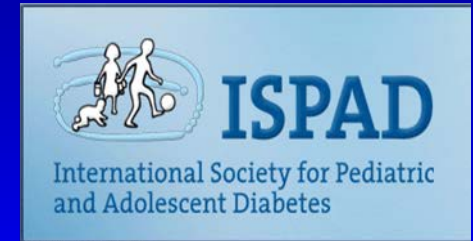
## Organisation and structure





<http://www.ema.europa.eu/ema>





# European Research Network in Diabetes and Endocrinology

EnprEMA meeting  
European Medicines Agency, London  
25<sup>th</sup> February 2013

# **Enpr-EMA European Children and Adolescent Diabetes and Endocrine Network**

## **Aims**

- To develop research infrastructure across the EU within the field of diabetes and endocrinology.
- To work with Industry in the development and implementation of PIPs
- To work with academia to promote drug development in rare paediatric endocrine disorders
- To collaborate with the EMA PDCO in designing strategies for drug development.

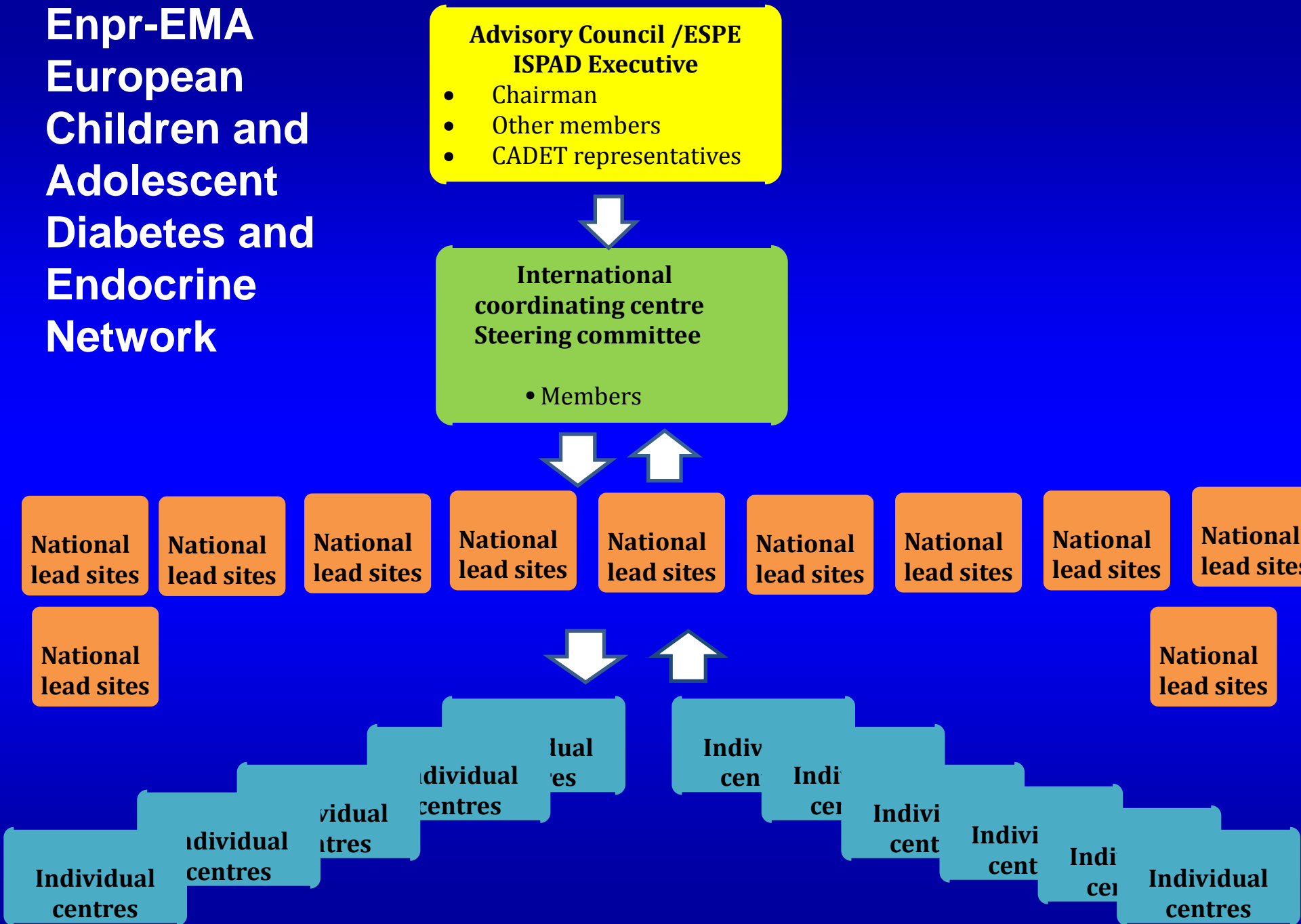
# Stakeholders

- Academic paediatricians
- Industry
- Patient groups
- ESPE
- ISPAD

# Plans

- Establishment of a research network in Diabetes/Endocrinology under the EnprEMA initiative.
- Secure support from relevant academic organisations (ESPE, ISPAD) and relevant European subgroup academic groups (European bone group, European DSD Consortium etc.) patient support groups and national endocrine diabetes associations.
- Establish appropriate organisational structures to enable planning and implementation of research activity with appropriate representation from stakeholders.

# Enpr-EMA European Children and Adolescent Diabetes and Endocrine Network



# Funding

Steering Committee



National administration



Local clinical based

Industry



# Role of EnprEMA networks in type 2 diabetes paediatric drug development

- Collaboration with US investigators  
Multicompany, multi-agency academic led, pharma-funded, CRO managed, trials
- Post-marketing surveillance of all new type 2 diabetes products