EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on Enpr-EMA activities, achievements and challenges

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Presented by Mark Turner on 16th August 2017

An agency of the European Union

Introduction and background

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."

Introduction and background

- Enpr-EMA is a network of research networks, investigators and centres with recognised expertise in performing clinical trials in the paediatric population

- Members perform research with children (newborns to adolescents), in multiple therapeutic areas, and ranging from pharmacokinetics to pharmacovigilance

Recognition criteria

- Networks to be recognised by quality of paediatric research
- 6 recognition criteria and quality standards for self-assessment
  - ➢ Research experience and ability
  - ➢ Efficiency requirements
  - ➢ Scientific competencies and capacity to provide expert advice
  - ➢ Quality management
  - ➢ Training and educational capacity to build competences
  - ➢ Involvement of patients, parents or their organisations
- Each criterion composed of several sub items
- Set of minimum criteria to be fulfilled
- Self-assessment to updated annually

Mission statement

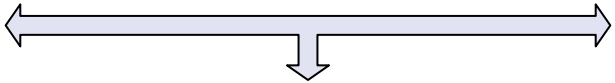
Enpr-EMA will facilitate studies in order to increase availability of medicinal products authorised for use in the paediatric population.

Mission statement

This will be achieved by:

- Fostering high quality ethical research on the safety and effectiveness of medicines for children.
- Efficient inter-network and stakeholder collaboration in order to build up necessary competences at EU level and to avoid unnecessary duplication of studies.
- Informing 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 discussion with ethics committees on issues relevant to research and clinical trials in children.

Facilitate studies in order to increase availability of medicinal products authorized for use in the paediatric population.

Opportunity for medicines  Therapeutic need

Identification of PIP

Development of PIP

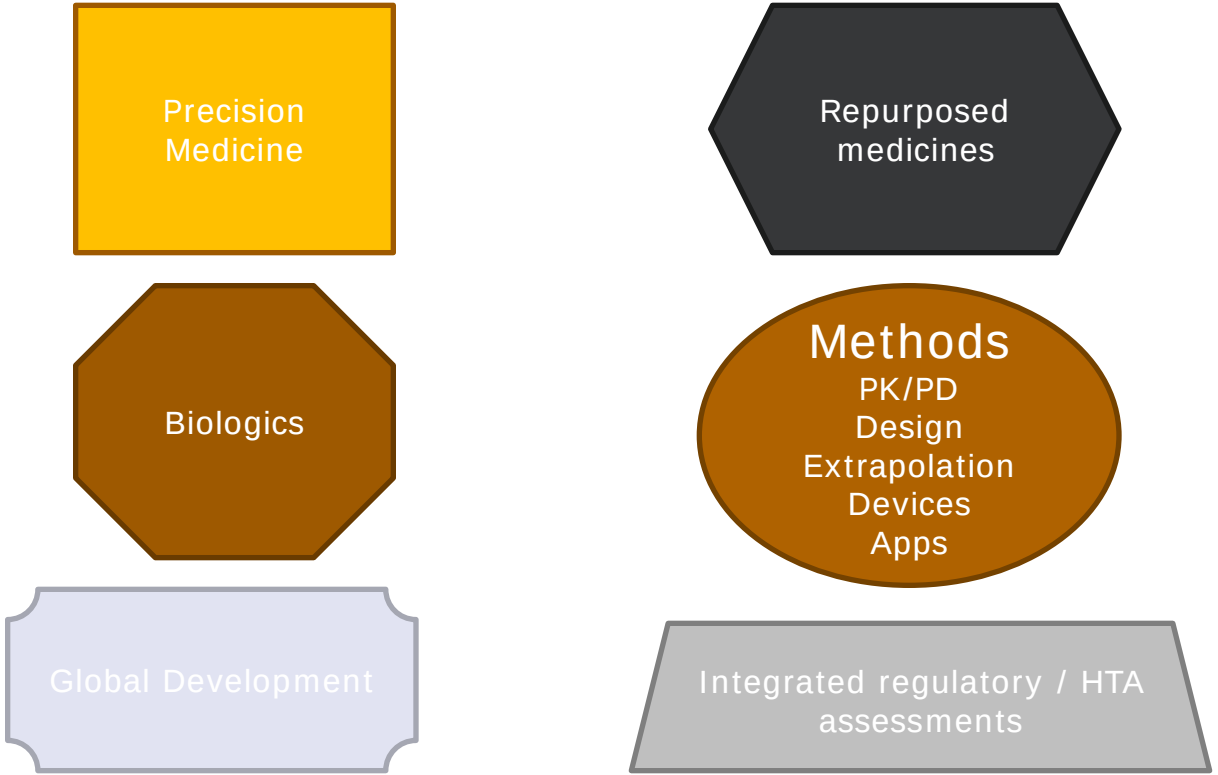
- Writing
- Review

Implementation of PIP

Analysis of PIP

Use of PIP

Opportunities



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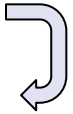

Implementation of PIP

Analysis of PIP

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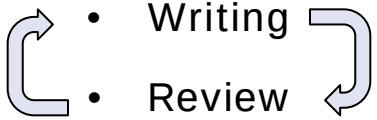
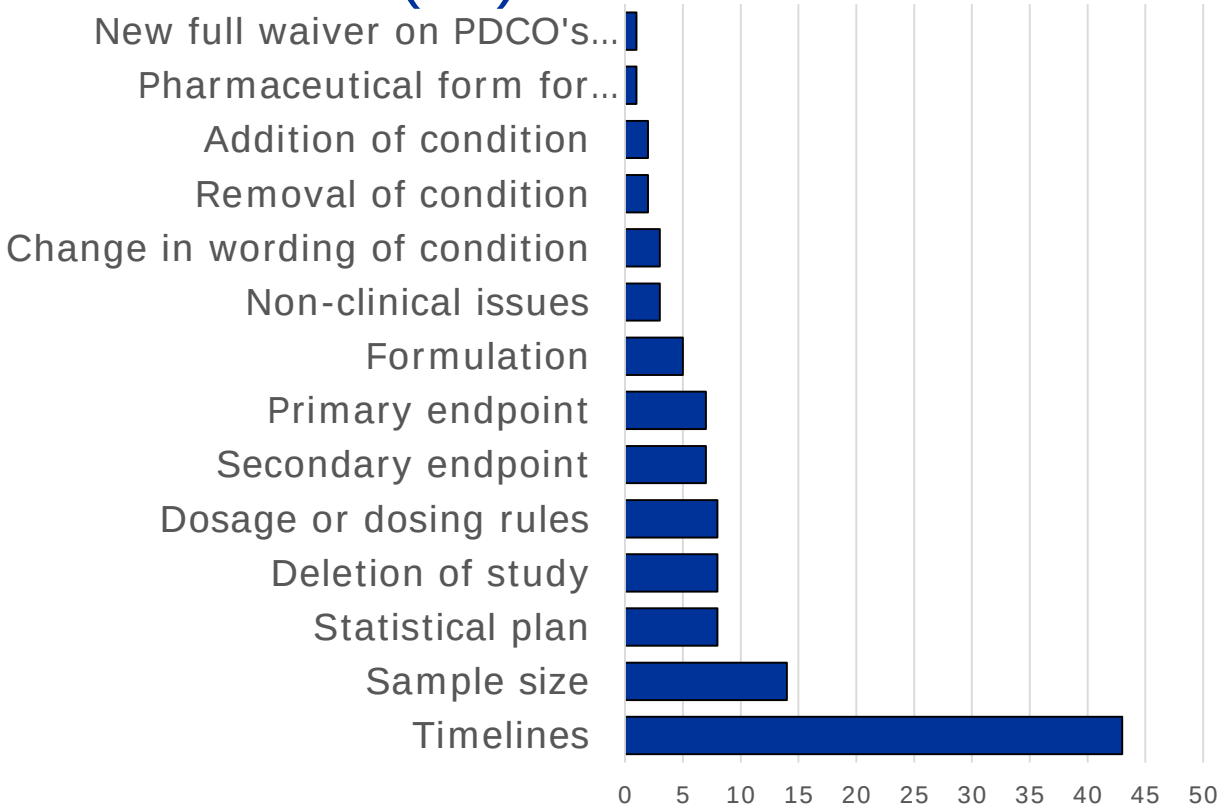


Implementation of PIP

Analysis of PIP

Use of PIP

Modification to PIPs (%)



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Demand for Paediatric Trials Networks

	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Preterm neonates	0	0	0	327	82	2,527	1,552	3,634	4,997	1,979
Term neonates	0	98	5	184	169	1,353	2,283	1,488	2,168	1,749
Infants and toddlers	530	119	20	54,715	2,224	13,318	62,226	17,772	39,095	122,295
Children	2,683	706	270	5783	2,771	21,665	30,831	27,994	65,824	48,358
Adolescents	435	36,458	285	5801	4,869	20,206	22,680	17,628	45,717	36,921
Total	3,648	37,381	580	66,810	10,115	59,069	119,516	68,516	157,261	211,302

Number of children planned to be enrolled in clinical trials, by age by year of authorisation of the trial (or, if not available, by year of protocol upload into EudraCT).

Transnational progress

Share requirements and dialogue with ethics committees

PIP consultation model

CYP involvement

Consultations: 10 year

Enpr-EMA awareness webinar

Trial preparedness

Interactions with PDCO

Challenges

Identifying and attributing value creation

Multiple pathways to success

- Stimulus for network development
- Legacy of previous achievements

Efficiency: time and cost

Predictability

Learning from experience

Global coordination

Topic 4: Creation of a pan-European paediatric clinical trials network

Value of the workshop to all of us

Listen

Learn

Share

Contribute

Influence

** Join our influential working groups **

Thank you for your attention

Further information

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