

Strategies to support neonatal development in Europe

Problem statement

- Highest proportion of Off-label use in neonates
- Lack of age adapted formulations
- Delayed/ lack of access to innovative medicines
- Knowledge gaps in developmental pharmacology
- Limited number of clinical trials in children
- Lack of suitable clinical trial methodology
- Lack of infrastructure for clinical trials in neonates
- Limited funding for research on paediatric medicine development in special populations
- **failure of market forces**

Strategies to support neonatal development in Europe

Clinical Trial Sponsors/ Marketing authorisation holder

- **increase feasibility of CT** (multi-company-multi-drug trials)
- **prioritisation strategies for CT** (favourable development)
- **innovative CT methodologies** (microsampling, microdosing, modeling/simulation => Extrapolation)

Neonatal Networks/ Academia/ Physician

- **Increase public awareness regarding** added value of authorised medicinal products for neonates and age appropriate formulation
- Inform patients about opportunities for **participation in clinical trials**
- Design studies with a **system approach**, adding endpoints in order to increase basal knowledge
- Apply for **Qualification opinions** for relevant methodologies (microsampling, microdosing, PBPK)

Parents/ Public/ EU Commission

- advocate for **public funding** for children`s health research
- advocate a **system approach**

Regulators, EU Commission

- **Scientific and regulatory support** for CTA and MAA