

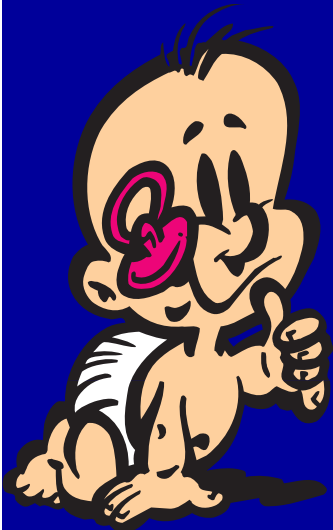
EMEA

Workshop on modelling in paediatric medicines

London

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**EXPECTATIONS FROM PK-PD
MODELLING AND SIMULATION IN THE
EVALUATION OF MEDICINES
IN CHILDREN**



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EUROPEAN REGULATION ON MEDICINAL PRODUCTS IN CHILDREN

- Obligations**
- Incentives**

**for the evaluation of medicinal products
in children**

**➔ expected increased number of performed
clinical trials, number of patients recruited**

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EUROPEAN REGULATION ON MEDICINAL PRODUCTS IN CHILDREN

- **Rationale**

- **PK: influence of maturation**
- **PD: -influence of maturation**
 - **diseases specific to**
children

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CLINICAL TRIALS IN CHILDREN

- more difficult to perform
 - invasiveness: pain, stress
 - recruitment: psychological reluctances
rare patients
- take longer
- take longer

 expected difficulties in performing CTs

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CLINICAL TRIALS IN CHILDREN

- we are lazy
- we want to save money
- we do not want to harm
children

 we need to be smarter than usual !

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FACILITATION OF THE EVALUATION OF MEDICINAL PRODUCTS IN CHILDREN

- **direct extrapolation from adults**
age subsets: - no PK differences
 - no PD differences
- **indirect extrapolation through
modelling** in all / younger age subsets

**→ we badly need the fruit of the present
« think tank »**