InSilicoMinds

# Pediatric trial

In silico MD clinical trial in children 12-18 years of age

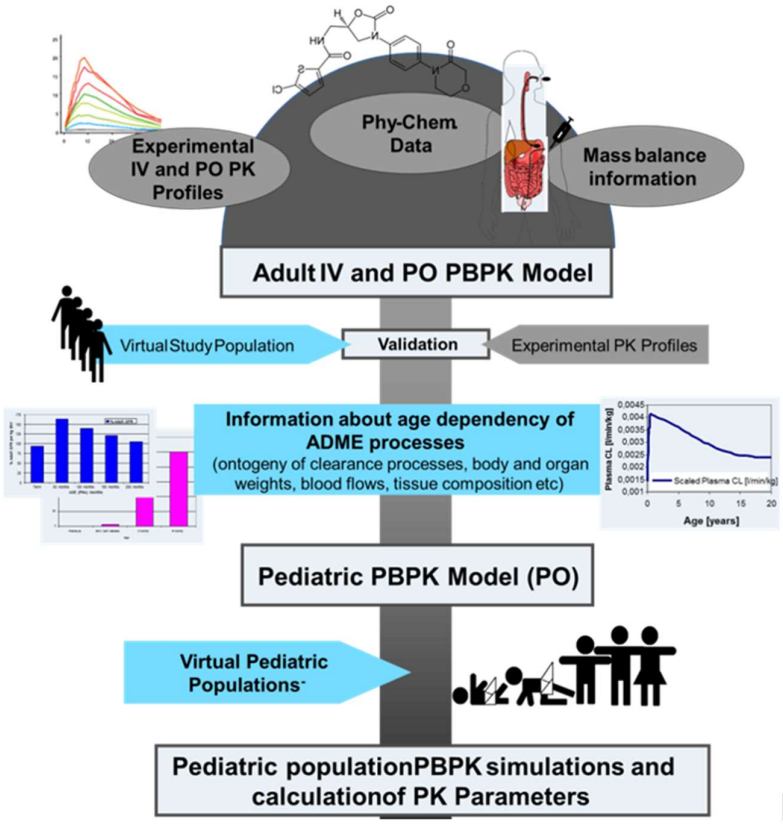
28 August 2021 | Clinical Trails, Pharmacokinetic, Modeling and Simulation, PBPK

**Background:** The Sponsor had performed SD and MD PK, tolerability and safety trials in children 12-18 years of age in acute pain indication. The Sponsor intended to develop a pediatric program in chronic pain indication. Massive amount of PK, tolerability and safety data for the acute and chronic conditions were available in adults.

**Question of Interest:** Could M&S replace the chronic pain SD clinical trial in children 12-18 years of age and predict the optimal PK sampling scheme for the MD trial?

**Methods:** The compound had a "well behaved" pharmacokinetic profile.
PBPK modeling was already successfully applied from adults to children in the acute program.
PBPK modeling was applied in chronic pain as well.

**Results:**
A pediatric PBPK model was developed from the adult model and used to simulated the SD trial.



Impact:

- The Agency accepted the Sponsor's Pediatric Investigational Plan including the in-silico SD PK study in children 12-18 years of age.
- Ethical approach
- The Sponsor reduced costs and timelines of the new generation patch development program