Optimisation of first clinical studies in special populations : towards semi-physiological pharmacokinetic models

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Propositions to the thesis:

"Optimisation of first clinical studies in special populations: towards semi-physiological pharmacokinetic models"

1. Commonly used approaches for prediction of the pharmacokinetics in children lead to substantially different dose recommendations.
   This thesis

2. Prediction of the pharmacokinetics in young children by allometric scaling in combination with a maturation function is not supported by scientific evidence.
   This thesis

3. Semi-physiological frameworks combine the best of two worlds: they "do not shy for complexity and strive for simplicity" (Sheiner).
   This thesis

4. The challenge of developing a semi-physiological pharmacokinetic model is not to miss important mechanistic insights and to be parsimonious at the same time.
   This thesis

5. Restrictions with regard to the collection of samples dictate the use of optimised study designs and dedicated data analysis techniques

6. "Perfect storm simulations" to assess extreme cases have become common practice but require predictive models.

7. Sharing of knowledge and data yields predictive models that enable estimation of the right dose for every patient

8. Non-governmental organizations are essential partners in the development of medicines for orphan diseases and special patients

9. "There is a difference between being convinced and being stubborn"
   Maya Angelou

10. "Bad times have a scientific value"
    Ralf Waldo Emerson, Considerations by the Way

11. "Universal compassion is the only guarantee of morality"
    Arthur Schopenhauer, The Basis of Morality