PopSim meeting:

Paediatric Extrapolation in Drug Development: Has the Paradigm Shift started?

24 August 2021, 13.00-16.45

@ University of Copenhagen, Dept Drug Design and Pharmacology.

Auditorium 3, Universitetsparken 2, 2100 Copenhagen Ø.

The importance of evidence based medicine in children has received increasing attention after a history of neglecting children as part of drug development. Drug development present a complex dilemma where the need to gather evidence is balanced with the ethical considerations associated with the burden of conducting clinical trials in children. Paediatric extrapolation is an approach where clinical data in children is partially or fully generated by extrapolating data from relevant sources in adults. In many ways the technical framework for paediatric extrapolation is well established in the field of pharmacometrics and methods are generally encouraged by regulatory authorities. Thus, the use of paediatric extrapolation represents a paradigm shift from traditional drug development in children. But is paediatric extrapolation currently being used optimally? Has the paediatric extrapolation paradigm shift really started? And what is blocking the road for better drug development in children? These are questions we will discuss at this PopSim meeting with an exciting line of presenters and panellists from regulatory authorities and industry.

Programme

13.00-13.15 Welcome (Rasmus Juul Kildemoes, PopSim, Novo Nordisk)

13.15-13.45 (30 min) Perspectives from the Danish Medicines Agency (Anne-Mette Hoberg, Danish Medicines Agency)

13.45-14.30 (45 min). Paediatric Extrapolation: Has the Paradigm Shift started? (Cécile Ollivier, Critical Path Institute)

14.30-15.00 Break & Network

15.00-15.30 (30 min) Paediatric drug development of GLP-1 agonists in treatment of type 2 diabetes (Kristin Cecilie Carlsson Petri, Ascendis Pharma)

15.30-16.00 (30 min) Dose selection during paediatric development of Tapentadol – a novel opioid analgesic (Estelle Watson, Lundbeck)

16.00-16.30 (30 min) Panel discussion: How can the regulations for paediatric drug development be further improved, for the benefit of paediatric patients?

16.30-16.45 Wrap-up and concluding remarks (Rasmus Juul Kildemoes, PopSim, Novo Nordisk)

Practicalities:

The meeting will be a semi-virtual meeting, and will be free of charge for both members and non-members. Please sign up to join the meeting in person (Auditorium 3, Universitsparken 2) or to receive login details to the join the virtual meeting (link will be forwarded).