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Pediatric Ontogeny: Ready for Incorporation into Modeling in Pediatric Drug Development?

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Pediatric Ontogeny

- **Ontogeny**: the development of an individual organism or anatomical or behavioral feature from the earliest stage to maturity
  - Critical to the discussion today is the full extent of developmental changes that affect drug therapy;
    - Drug disposition and effect during every phase of pediatrics, neonates through adolescence
- The goal today is to identify those ontological processes which have sufficient quantitative information to be used for modeling in pediatric drug development.

Pediatric Ontogeny

The objectives of this workshop are to:

- **Review the present state of knowledge of the ontogeny** of systems critical to drug dosing and effect in pediatric patients.
- **Discuss whether our knowledge of ontogeny of specific systems is adequate** at the present time to make pediatric dosing and effect predictions through modeling and simulation.
- **Identify pathways forward for acquiring the additional information** needed for incorporating ontogeny into modeling and simulation predictions for pediatric new drug development.

Questions to be addressed in the panel discussions - 1

- How should validity of a parameter for use in pediatric drug development modeling that displays a developmental change be established?
- Which specific aspects of those developmental systems reviewed have validity for use in modeling in pediatric drug disposition?
- Which specific aspects of those developmental systems reviewed should be targeted for future research necessary for use in pediatric drug development?

Questions to be addressed in the panel discussions - 2

- What establishes the validity of a PBPK model that incorporates pediatric ontogeny for one or more systems affecting drug disposition or effect?
- What are the optimal methods for establishing quantitative estimates of a system affecting pediatric ontogeny, and drug disposition and effect?

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Moderators of Today's Sessions

- Jill Morgan, Pharm.D., BCPS, BCPPS
  - Associate Professor and Chair
  - Department of Pharmacy Practice and Science
  - Un. of Maryland School of Pharmacy

- Jian Wang, Ph.D.
  - Associate Director for Regulatory Science
  - Office of Drug Evaluation IV, Office of New Drugs
  - Center for Drug Evaluation and Research, U.S. Food and Drug Administration


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