#2 Panel Discussion)
Modeling and Simulation in Neonates and Infants

- **Moderators: Dr.'s Sander Vinks, Tom Dowling**
- **FDA Experience with Neonatal Trials – Dr. Jian Wang (10 minutes)**
- **<u>Panel Discussion (50 minutes): Panelists:</u>**
- Suzie McCune, M.D. (Deputy Director, OTS)
- Jian Wang, Ph.D., Senior Reviewer, Pediatric Clin Pharm Staff
- Yaning Wang, Ph.D., Deputy Director, Division of Pharmacometrics
- Kevin Watt, M.D., Duke University School of Medicine
- Neil Parrott, Ph.D., Roche Pharmaceuticals
- Jeff Barrett, Ph.D., Sanofi
- Ine Skottheim Rusten, Ph.D., Norwegian Medicines Agency

Panel Discussion Question #1

- When considering the situations in which dosing for neonates and infants is to be estimated, what is the add-in value of PBPK versus other modeling and simulation methods? What studies should be conducted that might clarify the value of a particular M&S method?

Panel Discussion Question #2

- Are you satisfied with our present understanding of the ontogeny of drug metabolizing enzymes/ transporters/ receptors? What studies should be conducted to improve our understanding of drug-related ontogeny in neonates and infants?

Panel Discussion Question #3

- ICH E11 specifies “preterm newborn infants” as a separate age group to be addressed. For drugs studied down to birth, should this group be separately addressed? What studies would be needed to clarify this question? What M&S method best addresses a rapidly changing population like the preterm infants?

Panel Discussion Question #4

- How can all models for drug use in neonates and infants be validated? What studies are necessary to establish validation methods in this patient population?