#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)
- **Panel Discussion (50 minutes): Panelists:**
  - 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?