Facilitating Anti-infective Drug Development for Neonates and Young Infants, 9/15/2016

Questions for Panel Discussion:

- Extrapolation:
    - Please discuss if there are clinical conditions in which extrapolating efficacy from adults and older pediatric population is acceptable for neonates.
    - For indications where extrapolation is not feasible, please discuss how clinical efficacy can be demonstrated.
- CSF penetration data
    - Please discuss the role of data from animal models of infection to further our understanding of anti-infective drug development in neonates. Please discuss the pros and cons of currently available models and what some areas of future research might be to facilitate anti-infective drug development.
    - Please discuss the role of in vitro models (such as hollow fiber models) and other tools that can be used to facilitate anti-infective drug development in neonates.
    - Please discuss how CSF penetration data from older children/adults can be used to better inform anti-infective drug development in neonates.
    - Please discuss the potential role of using VP Shunt/other CSF sampling methods to support the limited sampling that might be available in neonates.
- Enrollment and feasibility Issues: Please discuss any potential solutions to overcome the enrollment challenges in neonates
- Pediatric Trial Networks: Please describe how pediatric trial networks can help in obtaining PK/Safety/Efficacy data for the neonatal population and what might be some steps to bring this to fruition
- Labeling:
    - In the absence of CSF penetration data, please discuss the clinical utility of including dosing information in labeling

- Please discuss from a clinical perspective, the pros and cons of classifying the neonatal population by gestational age/post-natal age/post-menstrual age.