Regulatory and Industry: Break-Out 1 - QUESTIONS

- **Regulatory and Industry Lessons Learned**

1. What framework of nonclinical and/or clinical studies should be considered when developing an age-appropriate pediatric formulation? What are the key factors to consider in designing such a framework?
2. What challenges do you see from a regulatory perspective in creating innovative approaches to develop novel formulations, especially novel dosage forms, for pediatric use? How can these challenges be overcome?
3. What are the safety and efficacy concerns associated with different dosage forms that would need to be addressed to enable use in specific pediatric age groups?