

Analgesic Clinical Trial Designs, Extrapolation, and Endpoints in Patients from Birth to Less Than Two Years of Age

Panel discussion questions

Session 1

Based on the evidence that has been presented, what type of efficacy extrapolation approach, if any, would be acceptable to any age group below 2 years? For each drug class, how does age impact the recommendation?

- NSAIDs
- Acetaminophen
- Opioids
- Local anesthetics

Session 1

If an extrapolation approach is acceptable,

1. What safety data are needed in these age groups? For each drug class, please comment on:
 - a. Specific safety concerns that need to be addressed
 - b. Sample size considerations for safety assessment
 - c. The need for a sequential design starting with older age cohorts and moving lower in age, if any
 - d. Duration of safety assessment understanding this may vary depending on the drug class
2. What are the design considerations for the PK study (Developmental immaturity of drug metabolizing enzymes are expected, and PK assessment will be required as part of the pediatric program)
 - a. Single versus repeated dose
 - b. Real-time assessment of PK