

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

Panel discussion questions

Session 2

In age cohorts where substantial differences in response are expected, please discuss trial design considerations and any drug class specific considerations:

- a. What are potential objective parameters that can be used as a primary efficacy measures?
- b. What are considerations about the treatment effect on the endpoint in order to design the trial?
- c. What are some strategies to derive the dosing in this age group?
- d. What are the considerations for safety assessment including sample size and duration of study?
- e. What are some considerations for including or not including a control/comparator group?
- f. What are specific considerations for premature neonates, if any?