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?