Testosterone Session: Discussion Topics

1. The goal of a pediatric development program with testosterone therapy is to obtain evidence to guide the safe and effective use of such therapy in boys with genetic or structural causes of hypogonadism. Therefore, in consideration of the information provided today, please discuss the following:

- Study design and study population (eligibility criteria)
- The appropriate efficacy endpoints
- The appropriate safety endpoints
- Duration of safety follow up
- Estimated trial sample size

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2. Given the information provided today and the study design elements in Question 1 above, please discuss the feasibility issues related to the conduct of such a trial, including:

- Size of a population of boys eligible to be enrolled in the trial
- Recruitment issues

3. Given the known complications of testosterone therapy in pediatric patients (e.g., premature growth plate failure and short stature) what postmarketing safety evaluation(s) do you recommend? Please provide a rationale for your response.