

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

*Pediatric Oncology Subcommittee of the
Oncologic Drugs Advisory Committee (pedsODAC) Meeting*

June 16, 2023

DRAFT QUESTIONS

Discussion Topics Related to Dosage Optimization of New Drug and Biological Products for Pediatric Patients with Cancer

1. **DISCUSSION:** Discuss the unique considerations associated with dosage optimization in pediatric oncology.
2. **DISCUSSION:** Discuss the potential challenges to identifying an optimized dosage for new drugs and biological products for pediatric cancers and potential strategies to address these challenges.
3. **DISCUSSION:** For drugs and biological products being developed in both adult and pediatric patients with cancer, consider how the timing of dosage selection in adults impacts the timing of trial initiation and dosage optimization in pediatric patients with cancer.
4. **DISCUSSION:** Discuss the considerations for dosage optimization in pediatric oncology clinical trials investigating combination therapies.