

Oncologic Drugs Advisory Committee
Pediatric Subcommittee

Agenda

8:00	Call to order and Introduction	Victor M. Santana, M.D.
	Welcome	Richard Pazdur, M.D.
	Conflict of Interest	Kimberly L. Topper, MS
8:15	Charge to Committee	Steven Hirschfeld, M.D.
8:20	Open public hearing	
8:50	Review of ethical principles as applied to research in children with cancer	Eric Kodish, MD. Ph.D.
9:15	Committee Discussion	
9:40	Review of developmental pharmacology	J. Steven Leeder, Pharm.D., Ph.D.
10:05	Break	
10:20	Challenges of pharmacokinetic/ pharmacodynamic assessments in pediatric oncology	Clinton F. Stewart, Pharm.D.
10:45	Pharmacogenomic considerations and opportunities in trial design	Mary V. Relling,
11:10	Committee Discussion	
11:45	Lunch	
12:45	Open Public Hearing	
1:15	Approaches to endpoint validation with small numbers of patients-challenges, constraints, and methods	Steven Goodman, M.D., MHS, Ph.D. and Edward L. Korn, Ph.D.
2:00	Summary of experience with Phase II window studies	Victor M. Santana, M.D.
2:20	Committee Discussion	
2:45	Break	
3:00	Questions	
4:00	Summary Statements	Peter C. Adamson, M.D. and Wayne Rackoff, M.D.
4:30	Adjourn	