

Bibliography
Advisory Committee for Pharmaceutical Science
November 3-4, 2004

Day 1: Wednesday, November 3, 2004

Topic 1 Pharmacogenetics of Irinotecan: Scientific and Clinical Impact of UGT Polymorphism

1. Background information
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Topic 2: Drug-Drug Interaction Concept Paper: Issues Related to Transporter- and Induction-Based Interactions and Multiple Inhibitor Drug Interaction Studies

1. Concept paper” Drug interaction studies- Study Design, Data Analysis, and Implications for Dosing and Labeling
2. Tucker G, Houston JB, and Huang S-M, Optimizing drug development: strategies to assess drug metabolism/transporter interaction potential- toward a consensus,

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 4. Huang, S-M, Hall, SD, Watkins, P, Love, LA, Serabjit-Singh, C, Betz, et al, Drug Interactions with Herbal Products & Grapefruit Juice: A Conference Report, Clin Pharmacol Ther 2004 Jan;75(1):1-12
 5. Huang, S-M, Lesko, LJ, Drug-drug, drug-dietary supplement and drug-citrus fruit and other food interactions- what have we learned? J Clin Pharmacol 2004 Jun;44(6):559-69

Day 2: Thursday, November 4, 2004

Topic 3 Transition of Biomarkers to Surrogate Endpoints: A New Critical Path Initiative

1. Lesko LJ, Atkinson, AJ, Use Of Biomarkers And Surrogate Endpoints In Drug Development and Regulatory Decision Making, Annu. Rev. Pharmacol. Toxicol. 2001. 41:347-66
2. "Challenge and Opportunity on the Critical Path to New Medical Products". FDA white paper available on the FDA Website:
<http://www.fda.gov/oc/initiatives/criticalpath/>