

Clinical Pharmacology Subcommittee
Meeting Agenda for Nov 3-4, 2004
(Draft on 9/30)

Day 1

8:00 Call to order and opening remarks

8:15 Tribute to Dr. Lew Sheiner

8:30 Update on previous meeting discussions,
Introduction to the topics of this meeting

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

9:00 Introduction

9:15 Scientific perspectives

9:45 Additional scientific and clinical perspectives

10:15 Break

10:45 Clinical perspectives: utility of genotyping

11:00 Committee discussion

12:00 Lunch

1:00 Public Hearing

Topic 2: Drug-Drug Interaction Concept Paper: Issues Related to CYP/Transporter- and Induction-Based Interactions and Multiple-Inhibitor Drug Interaction Studies

1:30 Relevant principles of drug interaction
concept paper

2:15 Industry perspective

2:45 Induction-based interactions

3:15 Multiple inhibitor Studies

3:30 Break
4:00 Committee discussion
5:30 Wrap-up of Day 1
5:45 Adjourn

Day 2

8:00 Call to order and opening remarks

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

8:05 Introduction to the topic, background and project plan
8:20 Framing the issues, what needs to be done and how?
9:05 What are industry's expectations of the project and process?
9:50 Opportunities, challenges and some ways forward – how can academia-industry-government collaborations facilitate the development of biomarkers and surrogates?
10:20 Break
10:50 Committee discussion
12:00 Summary of recommendations
12:30 Public Hearing
1:00 Adjourn