U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES
National Institutes of Health

Coordinating Center for Clinical Trials
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NCI Gynecologic Cancer Steering Committee
2011 Ovarian Cancer Clinical Trials Planning Meeting Agenda
October 28-29, 2011

***** Renaissance Philadelphia Airport, Philadelphia, PA *****

DAY 1: FRIDAY, OCTOBER 28, 2011

8:00 – 8:45 AM **Registration**

8:45 – 9:00 AM **Welcome and Introduction to the NCI Clinical Trials Planning Meeting: What we need to accomplish; How sessions lead into one another**
GCSC Co-Chairs, Jeff Abrams, Michael Bookman, Ken Swenerton, Pat Goldman

9:00 – 12:00 PM **SESSION I: MOLECULAR PATHWAYS, TARGETS, AND DIAGNOSIS**
Chair: Michael Birrer
Rapporteur: David Huntsman

(9:00 – 10:00) **Brief Introductory Talks**
Pathogenesis
Christopher Crum

Cell Types
Blake Gilks

Molecular Pathways
Elise Kohn

(10:00 – 10:15) Break

(10:15 - 12:00) **Panel Discussion**
Panel Members: Michael Birrer, Chris Crum, April Donahue, David Gershenson, Blake Gilks, Pat Goldman, David Huntsman, Elise Kohn, Robert Kurman, Doug Levine, Jeffrey Miecznikowski, Mark O'Connor, Nilsa Ramirez, William Rodgers

12:00 – 1:00 PM **WORKING LUNCH /BREAK**
Session I chair and rapporteur will finish first draft of answers to questions and reproduce as handouts for Session II

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1:00 – 4:00 PM **SESSION II: PROOF-OF-PRINCIPLE TRIALS**
Chair: Carol Aghajanian
Rapporteur: Amit Oza

(1:00 – 1:15) **Introduction to and Goals for Session II, Answers to Questions From Session I**
Carol Aghajanian

(1:15 – 3:00) **Brief Introductory Talks**
"Process" Talk
Carol Aghajanian

Novel Trial Designs
Larry Rubenstein
Donald Berry

Drug Development in Pediatrics
Malcolm Smith

(3:00 – 3:15) Break

(3:15 – 4:00) **Panel Discussion**
Panel Members: Carol Aghajanian, Donald Berry, Michael Bookman, Steve Cannistra, Alice Chen, Helen Chen, Robin Cohen, Sue Friedman, Susanna Lee, Karen Orloff Kaplan, Amit Oza, Larry Rubenstein, Malcolm Smith, Ken Swenerton

(4:00 – 5:00) **Review of Draft Recommendations of Action Items From Sessions I and II**
Chairs and rapporteurs with input from participants

(7:00 – 9:00) **Informal Dinner in Hotel Dining Rooms**

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DAY 2: SATURDAY, OCTOBER 29, 2011

7:30 –8:00 AM **Registration/ Light Refreshments**

8:00 – 8:30 AM **Introduction: Charge for CTPM and second day; What we want to accomplish before departure; Review of recommendations of revised action items from Sessions I and II**
Ken Swenerton, Michael Bookman, Mary Jackson Scroggins

8:30 – 11:30 AM **SESSION III: OPTIMIZING INTERACTION BETWEEN PHARMACEUTICAL AND BIOTECHNOLOGY INDUSTRIES, ACADEMIA, AND NCI; IMPLICATIONS FOR PHASE II AND III CLINICAL TRIAL DESIGNS**
Chair: Michael Bookman
Rapporteur: Jonathan Ledermann

(8:30 – 9:30) **Brief Introductory Talks**
Innovative Trial Design
Michael Bookman & Mark Brady

Discussion of Open Phase III Trials
Christian Marth

(9:30 – 9:45) Break

(9:45 – 11:30) **Panel Discussion**
Panel Members: Michael Bookman, Mark Brady, Jakob Dupont, Keiichi Fujiwara, Mary Jackson Scroggins, Jonathan Ledermann, Christian Marth, Michael Merger, Deborah Miller, Laura Reese, Larry Rubenstein, Christy Schmidt, Michael Seiden, Cara Tenenbaum, Tate Thigpen

11:30 – 12:30 PM **WORKING LUNCH/ BREAK**
Draft recommendation of action items from session III by rapporteur

12:30 – 2:30 PM **SESSION IV: FINALIZATION OF ACTION ITEMS**
What trials do we want to undertake?
How can we complete them most efficiently?
What do we want to accomplish over the next three years
Chairs & rapporteurs from sessions I-III and participants

2:30 PM **Adjourn**