**SATURDAY, JULY 23**  
_Chairperson of the Day: Patricia M. LoRusso_  

**Shuttles from Denver International Airport to Marriott**  
Depart from Main Terminal, West side, Door 510  
11:30 am-2:00 pm  
12:30 pm-3:00 pm  
1:15 pm-3:45 pm  

**Registration**  
Salons CD Foyer  
12:00 pm-5:00 pm  

**Administration of Pre-test**  
Salons EF  
5:00 pm-6:00 pm  

**Faculty Meeting** (faculty only)  
Colorado Ballroom  
Meeting Chairperson: Patricia M. LoRusso  
5:00 pm-6:00 pm  

**Welcome and Workshop Overview**  
Salons EF  
6:00 pm-6:30 pm  
Patricia M. LoRusso  
Jyoti D. Patel  
Yu Shyr  

**Protocol Development Group Session 1 / Dinner**  
Salon A, B, C, D, G, H, I, J, Blue Sky, Eagle Bahn,  
Game Creek, Sun Up  
6:30 pm-9:30 pm  

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**SUNDAY, JULY 24**  
_Chairperson of the Day: Jyoti D. Patel_  

**Continental Breakfast**  
Salons EF Foyer  
7:00 am-8:00 am  

**Lecture Session 1**  
Salons EF  
8:00 am-10:00 am  
8:00 _Statistical Considerations in Protocol Development: From Hypothesis to Analysis_  
Meredith M. Regan  
8:45 _Design and Analysis of Phase I Clinical Trials in Cancer Therapy_  
S. Percy Ivy
9:15  Novel Statistical Designs in Phase I Studies  
Thomas Braun

Lecture Session 2*  
Salons EF  
10:15  Principles of Clinical Pharmacology  
Edward Chu  
10:45  Phase II Trials  
Michael A. Carducci  
11:10  Novel Phase II Designs  
Yu Shyr

Lunch  
Lower Pool Deck  
12:00 pm-1:00 pm

Protocol Development Group Session 2  
Salon A, B, C, D, G, H, I, J, Blue Sky, Eagle Bahn, Game Creek, Sun Up  
1:00 pm-2:30 pm

Office Hours 1: Protocol Related Questions  
Salon A- J, Blue Sky, Eagle Bahn, Game Creek, Sun Up  
4:00 pm-5:30 pm

Biostatisticians will only see those in their PDG during Office Hours 1.

Independent Study Time  
5:30 pm-7:30 pm

ASSIGNMENT DUE: PROTOCOL SYNOPSIS SHEETS  
7:30 pm

Dinner  
Colorado Ballroom  
7:30 pm-9:30 pm

MONDAY, JULY 25  
Chairperson of the Day: Yu Shyr

Continental Breakfast  
Salons EF Foyer  
7:00 am-8:00 am

Lecture Session 3  
Salons EF  
8:00 am-10:00 am

8:00  Incorporation of Biological Correlative Studies into Early Clinical Trials
James H. Doroshow

8:30 Feasibility and Reproducibility in Biomarker Studies
David L. Rimm

9:00 Statistical Aspects of Correlative Studies
Wendy B. London

9:30 ‘Omics’ Platform Considerations in Clinical Trials
Lyndsay N. Harris

Lecture Session 4 10:15 am-11:40 am
Salons EF

10:15 Imaging in the Era of Targeted Therapy and Immunotherapy
Terence Z. Wong

10:40 Special Considerations in the Design of Immunotherapy Studies
Michael T. Lotze

11:20 Panel Discussion / Q&A
Michael T. Lotze, Mary L. Disis, Roy S. Herbst, Daniel A. Laheru

Protocol Development Group Session 3 11:45 am-1:45 pm
Salon A, B, C, D, G, I, J, Blue Sky, Eagle Bahn, Game Creek, Sun Up

Lunch 1:45 pm-2:30 pm
Lower Pool Deck

Small Group Discussion Sessions 1-2 2:35 pm-3:35 pm

Choosing Appropriate Clinical Endpoints
Salons A-D
Daniel A. Laheru and Andrea B. Troxel

Imaging Endpoints
Salons G-J
Brenda F. Kurland and Terence Z. Wong

Small Group Discussion Sessions 3-4 3:40 pm-4:40 pm

Inflammatory and Immunologic Biomarkers
Salons A-D
Mary L. Disis and Katherine Panageas
Laboratory Correlates
Salons G-J
David L. Rimm, Lyndsay N. Harris, S. Percy Ivy, and Motomi Mori

Independent Study Time / Dinner on Own  4:40 pm-9:00 pm

Optional Career Sessions  4:45 pm-5:30 pm

Careers in Industry
Chris H. Takimoto and Stuart G. Lutzker
Salons A-D

Careers in the Government
James H. Doroshow, S. Percy Ivy and Tatiana M. Prowell
Salons G-J

The Patient Advocate as a Career Resource
Everett Dodson, Kay Kays, Susan Krivacic, Barbara LeStage, Pamela Moffitt, Virgil H. Simons
SunUp Room

ASSIGNMENT DUE: STATISTICAL SECTION  9:00 pm

TUESDAY, JULY 26
Chairperson of the Day: Patricia M. LoRusso

Continental Breakfast  7:00 am-8:00 am
Salons EF Foyer

Faculty Meeting (faculty only)  7:00 am-8:00 am
Colorado Ballroom
Meeting Chairperson: Yu Shyr

Lecture Session 5  8:00 am-9:15 am
Salons EF

  8:00  Navigating the National Clinical Trials Network
         Neal J. Meropol

  8:25  Patient-Reported Outcomes
         David F. Penson

  8:50  Barriers to Accrual and How to Overcome Them
Barbara K. LeStage and Neal J. Meropol

Small Group Discussion Sessions 5-7 9:20 am-10:20 am

First in Human Trials: Understanding the Regulatory Process
Salons EF
Tatiana M. Prowell and Chris H. Takimoto

Written and Oral Research Presentations That Audiences Remember
Salons A-D
Roy S. Herbst and George W. Sledge, Jr.

Work-Life Balance (for both men and women)
Salons G-J
Jyoti D. Patel and Neal J. Meropol

Break / Group Photo 10:20 am-10:40 am
Lower Pool Deck

Protocol Development Group Session 4 10:40 am-12:40 pm
Salon A, B, C, D, G, H, I, J, Blue Sky, Eagle Bahn, Game Creek, Sun Up

Lunch 12:40 pm-1:30 pm
Lower Pool Deck

Office Hours 2: Protocol Related Questions 1:30 pm-2:45 pm
Salon A-J, Blue Sky, Eagle Bahn, Game Creek, Sun Up

Independent Study Time / Dinner on Own 2:45 pm-8:30 pm

Optional Career Session 3:00 pm-3:45 pm

Careers in Surgical Oncology
Michael T. Lotze and David F. Penson
Salon A

Careers in Radiation Oncology
Christopher G. Willett and Karyn A. Goodman
Salon B

Careers in Hematological Malignancies
Roy B. Jones and Franklin O. Smith, III
Salon D
ASSIGNMENT DUE: Protocol Drafts 8:30 pm

WEDNESDAY, JULY 27
Chairperson of the Day: Jyoti D. Patel

Continental Breakfast 7:00 am-8:00 am
Salons EF Foyer

Lecture Session 6 8:00 am-10:00 am
Salons EF

8:00   *Everything You Need to Know About Clinical Trial Ethics and Informed Consent: A Case Study*
Jyoti D. Patel, George W. Sledge, Jr., Kay F. Kays, and Susan Krivacic

9:25   *You’re In Charge: Investigator Responsibilities*
Alex A. Adjei

Lecture Session 7 10:15 am-11:15 am
Salons EF

10:15   *Special Populations in Clinical Trials*
Everett E. Dodson, Stuart M. Lichtman, and Franklin O. Smith, III

Biostatistician Faculty Meeting (biostatistician faculty only) 10:15 am-11:15 am
Salon D

Special Lecture 2 11:15 am-12:15 pm
Salons EF

11:15   *Should We Change Your Firmicutes? Pointers for Young Investigators*
Daniel D. Von Hoff

Protocol Development Group Session 5 / Lunch 12:15 pm-1:45 pm
Salon A, B, C, D, G, H, I, J, Blue Sky, Eagle Bahn, Game Creek, Sun Up

Office Hours 3: Any Topic: 2:00 pm-3:15 pm
Funding, mentoring, publishing, careers, etc.
Salon A-J, Blue Sky, Eagle Bahn, Game Creek, Sun Up
(Susan Perkins will hold Office Hours from 2:00 pm - 4:00 pm)

Independent Study Time / Dinner on Own 3:15 pm-8:00 pm
Optional Networking Session: Women in Academia 5:30 pm-6:30 pm
Salons A-D

Patricia M. LoRusso, Jyoti D. Patel, and additional faculty to be announced

Faculty Reception (faculty only) 6:45 pm-8:30 pm
Arrabelle (offsite)

ASSIGNMENT DUE: Informed Consent Documents 8:00 pm

THURSDAY, JULY 28
Chairperson of the Day: Yu Shyr

Continental Breakfast 7:00 am-8:00 am
Salons EF Foyer

Special Interest Sessions 1-3 8:00 am-9:00 am

Taking Your Product to Clinic
Salons A-D
Stuart G. Lutzker

Dose Selection for Oncology Drug Development
Salons EF
Tatiana M. Prowell and Chris H. Takimoto

Cost-Effectiveness Analyses
Salons G-J
David F. Penson

Lecture Session 8 9:05 am-10:20 am
Salons EF

9:05 Career Development Opportunities: The Government Can Help
Susan N. Perkins

9:45 Successful Grantsmanship
Mary L. Disis

Protocol Development Group Session 6 10:30 am-12:00 pm
Salon A, B, C, D, G, H, I, J, Blue Sky, Eagle Bahn, Game Creek, Sun Up

Administration of Post-test 12:00 pm-1:00 pm
Salons EF

**Faculty Meeting**  
Colorado Ballroom  
Meeting Chairperson: Jyoti D. Patel  
12:00 pm-1:00 pm

**One-on-One with the Deputy Branch Chief, NCI-CCT**  
Sun Up  
Susan N. Perkins  
*(similar to Office Hours, 15 minute time slots)*  
1:15 pm-3:15 pm

**Independent Study Time / Lunch**  
Lunch available in Salons EF Foyer  
1:00 pm-7:00 pm

**ASSIGNMENT DUE:**  
Final Protocols and Informed Consent Forms  
7:00 pm

**Closing Reception / Banquet / Dance**  
Salons EF  
7:00 pm-11:00 pm

**FRIDAY, JULY 29**  
Continental Breakfast  
Sun Up  
5:00 am-8:00 am

Departure