



An AACR/ASCO Educational Workshop

Methods in Clinical Cancer Research

July 23-29, 2016 | Vail, CO

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

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



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9:15 *Novel Statistical Designs in Phase I Studies*
Thomas Braun

Lecture Session 2*

Salons EF

10:15 am-12:00 pm

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

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

4:00 pm-5:30 pm

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*



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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, H, 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



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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. Doroshov, 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

Salons EF Foyer

7:00 am-8:00 am

Faculty Meeting (faculty only)

Colorado Ballroom

Meeting Chairperson: Yu Shyr

7:00 am-8:00 am

Lecture Session 5

Salons EF

8:00 am-9:15 am

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*



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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



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ASSIGNMENT DUE: Protocol Drafts

8:30 pm

WEDNESDAY, JULY 27

Chairperson of the Day: Jyoti D. Patel

Continental Breakfast

Salons EF Foyer

7:00 am-8:00 am

Lecture Session 6

Salons EF

8:00 am-10:00 am

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

Salons EF

10:15 am-11:15 am

10:15 *Special Populations in Clinical Trials*

Everett E. Dodson, Stuart M. Lichtman, and Franklin O. Smith, III

Biostatistician Faculty Meeting (biostatistician faculty only)

Salon D

10:15 am-11:15 am

Special Lecture 2

Salons EF

11:15 am-12:15 pm

11:15 *Should We Change Your Firmicutes? Pointers for Young Investigators*

Daniel D. Von Hoff

Protocol Development Group Session 5 / Lunch

Salon A, B, C, D, G, H, I, J, Blue Sky, Eagle Bahn,
Game Creek, Sun Up

12:15 pm-1:45 pm

Office Hours 3: Any Topic:

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)

2:00 pm-3:15 pm

Independent Study Time / Dinner on Own

3:15 pm-8:00 pm



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



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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

1:15 pm-3:15 pm

Susan N. Perkins

(similar to Office Hours, 15 minute time slots)

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