



An AACR/ASCO Educational Workshop
**Methods in
Clinical Cancer Research**
July 28-Aug. 3, 2018 | Vail, CO [APPLY TODAY!](#)



SATURDAY, JULY 28

Workshop Pretest

Completed online between Thursday, July 26 and Saturday, July 28 (5:30 pm)

Shuttles from Denver International Airport

11:30 am-2:00 pm / 12:30 pm-3:00 pm / 1:15 pm-3:45 pm

Registration

1:30 pm-6:00 pm

Salons CD Foyer

Faculty Meeting (Faculty Only)

4:00 pm-5:00 pm

Colorado Ballroom

Welcome/Overview

5:00 pm-5:30 pm

Salons EF

Protocol Development Group Session 1 / Buffet Dinner

5:30 pm-8:30 pm

Blue Sky, Game Creek, Sun Up, Sun Down, Salons A, B, C, D, G, H, I, J

SUNDAY, JULY 29

Breakfast

7:00 am-8:00 am

Salons EF Foyer

Lecture Session 1

8:00 am-9:50 am

Salons EF

8:00-8:30 *Clinical Trial Design: Asking Important Questions that Impact Our Patients*
Jyoti D. Patel



8:30-9:00 *Answering Important Questions: From Hypothesis to Analysis*
Meredith M. Regan

9:00-9:20 *Phase 1 Trial Questions*
Patricia M. LoRusso

9:20-9:50 *Phase 1 Trial Designs*
Thomas Braun

Break

9:50 am-10:05 am
Salons EF Foyer

Lecture Session 2

10:05 am-12:05 pm
Salons EF

10:05-10:25 *Phase 2 Trial Questions/Objectives*
Michael A. Carducci

10:25-10:55 *Phase 2 Trial Designs*
Mary W. Redman

10:55-11:30 *Dose Selection for Oncology Drug Development*
Tatiana M. Prowell and Chris H. Takimoto

11:30-12:05 *Combination and Multimodality Trials: Many Variables but One Question*
Karyn A. Goodman and Stuart G. Lutzker

Protocol Development Group 2 / Lunch

12:15 pm-3:00 pm
Blue Sky, Game Creek, Sun Up, Sun Down, Salons A, B, C, D, G, H, I, J
(Box lunches and drinks available in Salons EF Foyer)

Independent Study Time

3:00 pm-7:30 pm



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American Association
for Cancer Research*

ASCO
AMERICAN SOCIETY OF
CLINICAL ONCOLOGY

Office Hours 1 (Biostatisticians Only)

3:15 pm-6:15 pm

Salons EF Foyer

Appointments will be pre-scheduled; students will only visit biostatisticians in their PDG for 20 minutes.

ASSIGNMENT DUE: PROTOCOL TEMPLATE

7:30 pm

Dinner

7:30 pm-9:30 pm

Colorado Ballroom

MONDAY, JULY 30

Breakfast

7:00 am-8:00 am

Salons EF Foyer

Special Lecture

7:30 am-8:15 am

Salons EF

7:30-8:15 *Career Development Opportunities: The Government Can Help*
Susan N. Perkins

Lecture Session 3

8:25 am-10:25 am

Salons EF

8:25-8:55 *Feasibility and Reproducibility in Biomarker Studies*
Kurt A. Schalper

8:55-9:25 *Incorporation of Biological Correlative Studies into Early Clinical Trials*
Timothy A. Yap

9:25-9:55 *Statistical Aspects of Correlative Studies*
Wendy B. London



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9:55-10:25 Panel Discussion / Q&A
Deborah E. Collyar, Wendy B. London, Kurt A. Schalper, and Timothy A. Yap

Break

10:25 am-10:40 am
Salons EF Foyer

Lecture Session 4

10:40 am-12:10 pm
Salons EF

10:40-11:00 *Imaging in the Era of Targeted Therapy and Immunotherapy*
Thomas E. Yankeelov

11:00-11:20 *Special Considerations in the Design of Immunotherapy Studies*
Roy S. Herbst

11:20-11:45 *Inflammatory and Immunologic Biomarkers*
Mary L. Disis

11:45-12:10 Panel Discussion / Q&A
Mary L. Disis, Roy S. Herbst, Josh Mailman, Byung S. Park, and Thomas E. Yankeelov

Lunch / Protocol Development Group Session 3

12:15 pm-3:30 pm
Blue Sky, Game Creek, Sun Up, Sun Down, Salons A, B, C, D, G, H, I, J
(Lunch will be available from 12:15 pm-1:45 pm in Salons EF Foyer)

Office Hours 2: Protocol Related Questions

3:40 pm-5:40 pm
Room locations noted on signup sheets
(Biostatisticians will only see those in their PDG during Monday Office Hours. Signup sheets will be available in Salons EF Foyer during the morning break.)

Independent Study Time / Dinner

5:40 pm-8:30 pm
(Pizza, salad, and drinks will be available 6:00 pm-8:00 pm in Salons EF Foyer)



ASSIGNMENT DUE: STATISTICAL DESIGN

8:30 pm

TUESDAY, JULY 31

Faculty Meeting (Faculty Only)

7:00 am-8:00 am
Colorado Ballroom

Breakfast

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

Small Group Discussion Sessions 1-2

8:00 am-9:00 am

First in Human Trials: Understanding the Regulatory Process

Tatiana M. Prowell and Chris H. Takimoto
Salons A-D

Written and Oral Research Presentations That Audiences Remember

Roy S. Herbst, Mary Jackson Scroggins, and Eric P. Winer
Salons G-J

Small Groups Discussion Sessions 3-4

9:15 am-10:15 am

Defining, Identifying, and Knowing Your Trial's Clinical Endpoints

Emily V. Dressler, Jane Perlmutter, and Walter M. Stadler
Salons A-D

Waterfalls, Swimmers, and Who Are Kaplan and Meier Anyway

Michael A. Carducci and Sean M. Devlin
Salons G-J

Break / Group Photo

10:20 am-10:40 am
Patio



Small Group Discussion Sessions 5-7

10:40 am-11:40 am

Imaging Endpoints

Richard J. Chappell and Thomas E. Yankeelov
Salons A-D

Laboratory Correlates

A. Craig Lockhart, Wendy B. London, and Kurt A. Schalper
Salons EF

Challenges of Umbaskets

Edward Chu, Jane Perlmutter, and Mary W. Redman
Salons G-J

Lunch

11:40 am-12:40 pm

Patio

Lecture Session 5

12:40 pm-1:55 pm

Salons EF

12:40-1:05 *Navigating the National Clinical Trials Network*
John C. Byrd

1:05-1:30 *Patient-Reported Outcomes*
Smita Bhatia

1:30-1:55 *Barriers to Accrual and How to Overcome Them*
Carole L. Baas and Stuart M. Lichtman

Protocol Development Group Session 4

2:00 pm-4:00 pm

Blue Sky, Game Creek, Sun Up, Sun Down, Salons A, B, C, D, G, H, I, J

Independent Study Time / Dinner on Own

4:00 pm-8:30 pm



Optional Career Sessions

4:15 pm-5:00 pm

Careers in Government

Richard F. Little and Tatiana M. Prowell

Careers in Industry

Stuart G. Lutzker, Neal J. Meropol, Chris H. Takimoto

Careers in Radiation Oncology

Jeffrey A. Bogart, Adam P. Dicker, and Karyn A. Goodman

Engaging the Advocates

Carole L. Baas, Deborah E. Collyar, Ivy B. Elkins, Josh Mailman, Pamela R. Moffitt, Jane Perlmutter, Laurel Pracht, and Mary Jackson Scroggins

ASSIGNMENT DUE: PROTOCOL DRAFTS

8:30 pm

WEDNESDAY, AUGUST 1

Breakfast

7:00 am-8:00 am

Salons EF Foyer

Lecture Session 6

8:00 am-10:00 am

Salons EF

- 8:00-8:25 *You're In Charge: Investigator Responsibilities*
Alex A. Adjei
- 8:25-9:15 *Everything You Need to Know About Clinical Trial Ethics and Informed Consent: A Case Study*
Ivy B. Elkins, Neal J. Meropol, Pamela R. Moffitt, and Jyoti D. Patel
- 9:15-9:40 *Challenges of multi-institutional trials: How do we pay for it*
Walter M. Stadler



9:40-10:00 *Data Collection: It's All In the Data (when to look at data, how to collect data, real-world data collection situations, how to prevent wrong data)*
Mark Krailo

Break

10:00 am-10:15 am
Salons EF Foyer

Lecture Session 7

10:15 am-11:15 am
Salons EF

Special Populations in Clinical Trials
Rochelle Bagatell, Stuart M. Lichtman, and Josh Mailman

Biostatistician Faculty Meeting (Faculty Only)

10:15 am-11:15 am
Salon D

Protocol Development Group Session 5

11:15 am-12:45 pm
Blue Sky, Game Creek, Sun Up, Sun Down, Salons A, B, C, D, G, H, I, J

Lunch

12:45 pm-1:30 pm
Patio

Office Hours 3

1:30 pm-3:30 pm
Room locations noted on signup sheets
(Signup sheets will be available in Salons EF Foyer during the morning break.)

Independent Study Time/Dinner on own

3:30 pm-8:00 pm

Optional Networking Session: Women in Academia

4:30 pm-5:30 pm
Sun Up

Workshop Codirectors and Faculty



ASSIGNMENT DUE: INFORMED CONSENT DOCUMENTS

8:00 pm

THURSDAY, AUGUST 2

Breakfast

7:00 am-8:00 am

Salons EF Foyer

Special Interest Sessions

8:00 am-9:00 am

Taking Your Product to Clinic

Stuart G. Lutzker and Chris H. Takimoto

Salons AB

Palliative Care and Quality of Life

Stuart M. Lichtman and Laurel Pracht

Salons CD

Lecture Session 8

9:05 am-10:30 am

Salons EF

9:05-9:45 *Successful Grantsmanship*

Mary L. Disis

9:45-10:30 *Your Clinician-Scientist Pail List*

Daniel D. Von Hoff

Protocol Development Group Session 6

10:30 am-12:00 pm

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Administration of Post-test

12:10 pm-1:10 pm

Salons EF



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12:10 pm-1:10 pm
Colorado Ballroom

Independent Study Time / Lunch

1:10 pm-7:00 pm
(Box lunches and drinks will be available from 1:00 pm-2:30 pm in Salons EF Foyer)

ASSIGNMENT DUE: FINAL PROTOCOLS, INFORMED CONSENT FORMS, and ALL WORKSHOP EVALUATIONS

7:00 pm

Closing Reception / Banquet / Dance

7:00 pm-11:00 pm
Salons EF

FRIDAY, AUGUST 3

Continental Breakfast

5:00 am-8:00 am
Colorado Ballroom

Departure

6:00 am-8:30 am / 7:15 am-9:45 am / 10:00 am-12:30 pm
Colorado Ballroom