



An ASCO/AACR Workshop on
Methods in Clinical Cancer Research
July 27 - August 2, 2019 | Vail, Colorado

ASCO
AMERICAN SOCIETY OF
CLINICAL ONCOLOGY

AACR
American Association
for Cancer Research

Workshop Codirectors:

Jyoti D. Patel, University of Chicago, Chicago, IL

Manuel Hidalgo, Weill Cornell Medicine, New York Presbyterian Hospital, New York, NY

Meredith M. Regan, Dana-Farber Cancer Institute, Boston, MA

SATURDAY, JULY 27

Workshop Pretest

Completed online between Thursday, July 25 and Saturday, July 27

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

Welcome/Overview

5:45 pm-6:00 pm

Salons EF

Jyoti D. Patel, University of Chicago, Chicago, IL

Protocol Development Group Session 1 / Buffet Dinner

6:00 pm-9:00 pm

Salon A, Salon B, Salon C, Salon D, Salon G, Salon H, Salon I, Salon J, Berry Picker, Lodgepole, Sun Down, Sun Up

(Dinner and drinks will be available in Salons EF Foyer, outside of Sun Down, and outside of Lodgepole)

Faculty Meeting (Faculty Only)

9:00 pm-9:30 pm

Colorado Ballroom



SUNDAY, JULY 28

Breakfast

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

Opening Keynote Lecture

Session Chair: Jyoti D. Patel, University of Chicago, Chicago, IL
Salons EF
8:00 am-8:45 am

The Journey as a Translational Investigator with Excellence in Science and Application to Patients

Thomas F. Gajewski, University of Chicago, Chicago, IL

Lecture Session 1

Session Chair: Jyoti D. Patel, University of Chicago, Chicago, IL
8:50 am-10:40 am
Salons EF

8:50-9:20 *Clinical Trial Design: Asking Important Questions that Impact Our Patients*

Jyoti D. Patel, University of Chicago, Chicago, IL

9:20-9:50 *Answering Important Questions: From Hypothesis to Analysis*
Meredith M. Regan, Dana-Farber Cancer Institute, Boston, MA

9:50-10:10 *Phase I Trial Questions*
Manuel Hidalgo, Weill Cornell Medicine, New York Presbyterian Hospital, New York, NY

10:10-10:40 *Phase I Trial Designs*
Nolan M. Wages, University of Virginia, Charlottesville, VA

Break

10:40 am-11:00 am
Salons EF Foyer



Lecture Session 2

Session Chair: Michael A. Carducci, Johns Hopkins Kimmel Comprehensive Cancer Center, Baltimore, MD

11:00 am-1:10 pm

Salons EF

- 11:00-11:20 *Phase II Trial Questions/Objectives*
Michael A. Carducci, Johns Hopkins Kimmel Comprehensive Cancer Center, Baltimore, MD
- 11:20-11:50 *Phase II Trial Designs*
Mary W. Redman, Fred Hutchinson Cancer Research Center, Seattle, WA
- 11:50-12:30 *Dose Selection for Oncology Drug Development*
Timothy Yap, The University of MD Anderson Cancer Center, Houston, TX
- 12:30-12:50 *Combination Trials*
Stuart G. Lutzker, Genentech, Inc., South San Francisco, CA
- 12:50-1:10 *Multimodality Trials*
Karyn A. Goodman, University of Colorado Anschutz Medical Campus, Aurora, CO

Protocol Development Group 2 / Lunch

1:10 pm-3:45 pm

Salon A, Salon B, Salon C, Salon D, Salon G, Salon H, Salon I, Salon J, Berry Picker, Lodgepole, Sun Down, Sun Up

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

Independent Study Time

3:45 pm-7:30 pm

Office Hours 1 (Biostatisticians Only, prescheduled appointments)

3:45 pm-6:45 pm

Salons EF Foyer

ASSIGNMENT DUE: PROTOCOL TEMPLATE

7:30 pm



Dinner

7:30 pm-9:30 pm
Colorado Ballroom

MONDAY, JULY 29

Breakfast

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

Special Lecture

8:00 am-8:30 am
Salons EF

Career Development Opportunities: The Government Can Help
Susan N. Perkins, National Cancer Institute, Rockville, MD

Lecture Session 3

Session Chair: Wendy B. London, Boston Children's Hospital/Dana-Farber Cancer Institute
Boston, MA

8:30 am-10:30 am
Salons EF

- 8:30-9:00 *Feasibility and Reproducibility in Biomarker Studies*
Kurt A. Schalper, Yale University, New Haven, CT
- 9:00-9:30 *Incorporation of Biological Correlative Studies into Early Clinical Trials*
Timothy A. Yap, The University of Texas MD Anderson Cancer Center,
Houston, TX
- 9:30-10:00 *Statistical Aspects of Correlative Studies*
Wendy B. London, Boston Children's Hospital/Dana-Farber Cancer Institute
Boston, MA
- 10:00-10:30 Panel Discussion
Deborah E. Collyar, PAIR: Patient Advocates In Research, Danville, CA
Wendy B. London
Kurt A. Schalper
Timothy A. Yap



Break

10:30 am-10:45 am
Salons EF Foyer

Lecture Session 4

Session Chair: Ezra Cohen, UCSD Moores Cancer Center, La Jolla, CA

10:45 am-12:15 pm
Salons EF

10:45-11:05 *Imaging in the Era of Targeted Therapy and Immunotherapy*
Thomas E. Yankeelov, The University of Texas, Austin, TX

11:05-11:25 *Special Considerations in the Design of Immunotherapy Studies*
Roy S. Herbst, Yale Cancer Center, New Haven, CT

11:25-11:50 *Inflammatory and Immunologic Biomarkers*
Ezra Cohen, UCSD Moores Cancer Center, La Jolla, CA

11:50-12:15 Panel Discussion
Ezra Cohen
Roy S. Herbst
Josh Mailman, NorCal CarciNET Community, Oakland, CA
Byung S. Park, Oregon Health & Science University, Portland, OR
Thomas E. Yankeelov

Protocol Development Group Session 3 / Lunch

12:15 pm-3:00 pm

Salon A, Salon B, Salon C, Salon D, Salon G, Salon H, Salon I, Salon J, Berry Picker, Lodgepole,
Sun Down, Sun Up

(Box lunches and drinks available in Salons EF Foyer from 12:00 pm-1:30 pm)

Office Hours 2: Protocol Related Questions

3:15 pm-5:15 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

3:15 pm-8:15 pm

(Pizza and salads available from 5:00 pm-7:00 pm)



ASSIGNMENT DUE: STATISTICAL DESIGN

8:15 pm

TUESDAY, JULY 30

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

Challenges of Novel Trial Designs

Salons A-D

Richard Chappell, University of Wisconsin Medical School, Madison, WI
A. Craig Lockhart, University of Miami Sylvester Comprehensive Cancer Center,
Miami, FL
Jane Perlmutter, Gemini Group, Ann Arbor, MI

Palliative Care and Quality of Life

Salons G-J

Dawn L. Hershman, Herbert Irving Comprehensive Cancer Center of Columbia
University, New York, NY
Shing Lee, Columbia University, New York, NY
Laurel Pracht, NRG Oncology, Sun City, AZ



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Small Group Discussion Sessions 3-5

9:10 am-10:10 am

Imaging Endpoints

Salons A-D

Thomas E. Yankeelov, The University of Texas, Austin, TX

Incorporation of Digital Health and PROs

Salons G-J

Adam P. Dicker, Thomas Jefferson University Kimmel Cancer Center,
Philadelphia, PA

Jane Perlmutter, Gemini Group, Ann Arbor, MI

Laboratory Correlates

Salons EF

Elizabeth G. Hill, Hollings Cancer Center at the Medical University of South
Carolina, Charleston, SC

Ruth O'Regan, University of Wisconsin Carbone Cancer Center, Madison, WI

Kurt A. Schalper, Yale University, New Haven, CT

Break / Group Photo

10:10 am-10:30 am

Patio

Small Group Discussion Sessions 6-8

10:30 am-11:30 am

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

Salons A-D

Emily V. Dressler, Wake Forest University School of Medicine, Winston Salem,
NC

Jane Perlmutter, Gemini Group, Ann Arbor, MI

Walter M. Stadler, University of Chicago, Chicago, IL



First in Human Trials: Understanding the Regulatory Process

Salons G-J

Douglas Yee, Masonic Cancer Center, University of Minnesota, Minneapolis, MN

Large-scale Genomic Analysis: Bench to Bedside

Salons EF

Manuel Hidalgo, Weill Cornell Medicine, New York Presbyterian Hospital, New York, NY

Lunch

11:30 am-12:40 pm

Patio

Lecture Session 5

Session Chair: Stuart M. Lichtman, Memorial Sloan-Kettering Cancer Center, New York, NY

12:40 pm-1:55 pm

Salons EF

12:40-1:05 *Navigating the National Clinical Trials Network*

Tracy T. Batchelor, Harvard Medical School, Boston, MA

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

Adam P. Dicker, Thomas Jefferson University Kimmel Cancer Center, Philadelphia, PA

1:30-1:55 *Barriers to Accrual and How to Overcome Them*

Carole L. Baas, NCI Physical Sciences-Oncology Network, Bethesda, MD

Stuart M. Lichtman, Memorial Sloan-Kettering Cancer Center, New York, NY

Protocol Development Group Session 4

2:00 pm-4:00 pm

Salon A, Salon B, Salon C, Salon D, Salon G, Salon H, Salon I, Salon J, Berry Picker, Lodgepole, Sun Down, Sun Up

Independent Study Time/Dinner on Own

4:00 pm-8:00 pm

ASSIGNMENT DUE: PROTOCOL DRAFTS

8:00 pm



WEDNESDAY, JULY 31

Breakfast

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

Lecture Session 6

Session Chair: Jyoti D. Patel, University of Chicago, Chicago, IL
8:00 am-9:40 am
Salons EF

- 8:00-8:20 *You're In Charge: Investigator Responsibilities*
Manish A. Shah, Weill Cornell Medical College, New York, NY
- 8:20-8:40 *Challenges of Multi-Institutional Trials: How Do We Pay For It*
Walter M. Stadler, University of Chicago, Chicago, IL
- 8:40-9:40 *Everything You Need to Know About Clinical Trial Ethics and Informed Consent: A Case Study*
Howard A. Burris, Sarah Cannon Cancer Center, Nashville, TN
Ivy B. Elkins, LUNgevity, Buffalo Grove, IL
Pamela R. Moffitt, Galva, IA

Break

9:40 am-9:55 am
Salons EF Foyer

Lecture Session 7

Session Chair: Mark Krailo, Children's Oncology Group, Arcadia, CA
9:55 am-11:20 am
Salons EF

- 9:55-10:20 *Data Collection: It's All In the Data*
Mark Krailo, Children's Oncology Group, Arcadia, CA
- 10:20-11:20 *Inclusivity in Clinical Trials*
Stacey L. Berg, Texas Children's Hospital, Houston, TX
Stuart M. Lichtman, Memorial Sloan Kettering Cancer Center, New York, NY
Josh Mailman, NorCal CarciNET Community, Oakland, CA



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Biostatistician Faculty Meeting (Faculty Only)

10:30 am-11:30 am

Salon D

Special Lecture from the Workshop Founder

11:30 am-12:15 pm

Enabling the Dreams of Others

Daniel D. Von Hoff, The Translational Genomics Research Institute (TGen),
Phoenix, AZ

Lunch

12:20 pm-1:20 pm

Patio

Protocol Development Group Session 5

1:30 pm-3:00 pm

Salon A, Salon B, Salon C, Salon D, Salon G, Salon H, Salon I, Salon J, Berry Picker, Lodgepole,
Sun Down, Sun Up

Independent Study Time/Dinner on Own

3:00 pm-8:00 pm

Office Hours 3

3:15 pm-4:45 pm

Room locations noted on signup sheets

(Signup sheets will be available in Salons EF Foyer during the morning break.)

Optional Networking Session: Women in Academia

5:00 pm-6:00 pm

Sun Up

DO NOT POST - Faculty Reception

6:30 pm-8:30 pm

Arrabelle

ASSIGNMENT DUE: INFORMED CONSENT DOCUMENTS

8:00 pm



THURSDAY, AUGUST 1

Breakfast

7:00 am-8:00 am

Salons EF Foyer

Optional Career Sessions

7:15 am-8:00 am

Careers in Industry

Salons AB

Maura Dickler, Eli Lilly and Company, Indianapolis, IN
Stuart Lutzker, Genentech, Inc., South San Francisco, CA
Franklin O. Smith, Medpace, Cincinnati, OH

Careers in Radiation Oncology

Salons CD

Jeff Bogart, State University of New York
Adam Dicker, Thomas Jefferson University Kimmel Cancer Center,
Philadelphia, PA
Karyn Goodman, University of Colorado Anschutz Medical Campus,
Aurora, CO

Careers in Surgical Oncology

Salons GH

Tari King, Dana-Farber Cancer Institute/Brigham and Women's Cancer
Center, Boston, MA
Andrew Lowy, University of California, La Jolla, CA



Lecture Session 8

Session Chair: Roy S. Herbst, Yale Cancer Center, New Haven, CT

8:00 am-9:00 am

Salons EF

8:00-8:30

Successful Grantsmanship

Dawn L. Hershman, Herbert Irving Comprehensive Cancer Center of
Columbia University, New York, NY

8:30-9:00

Reporting and Presenting Results

Michael A. Carducci, Johns Hopkins Kimmel Comprehensive Cancer Center,
Baltimore, MD

Sean M. Devlin, Memorial Sloan Kettering Cancer Center, New York, NY

Roy S. Herbst, Yale Cancer Center, New Haven, CT

Break

9:00 am-9:15 am

Salons EF Foyer

Closing Keynote Lecture

9:15 am-10:00 am

Salons EF

Cancer Resolution

Gerard I. Evan, University of Cambridge, Cambridge, England

Protocol Development Group Session 6

10:00 am-12:00 pm

Salon A, Salon B, Salon C, Salon D, Salon G, Salon H, Salon I, Salon J, Berry Picker, Lodgepole,
Sun Down, Sun Up

Administration of Post-test

12:15 pm-1:15 pm

Salons EF

Faculty Meeting (Faculty Only)

12:15 pm-1:15 pm

Colorado Ballroom



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Independent Study Time / Lunch

1:15 pm-7:00 pm

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

Optional Session: Engaging the Advocates

1:30 pm-2:30 pm

Sun Up

Carole L. Baas, Convergent Science Physical Oncology, Irving, TX
Deborah E. Collyar, PAIR: Patient Advocates In Research, Danville, CA
Ivy B. Elkins, LUNGeivity Foundation, Buffalo Grove, IL
Kay F. Kays, Pancreatic Cancer Action Network, Sun City, AZ
Josh Mailman, NorCal CarciNET Community, Oakland, CA
Pamela R. Moffitt, Independent Advocate, Galva, IA
Jane Perlmutter, Gemini Group, Ann Arbor, MI
Laurel Pracht, NRG Oncology, Sun City, AZ

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 2

Continental Breakfast

5:00 am-8:00 am

Sun Up

Departure

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

Hotel Lobby