



American Society of Clinical Oncology



American Association
for Cancer Research

FINDING CURES TOGETHERSM

2015 ASCO/AACR Workshop

Methods in Clinical Cancer Research

July 25-31, 2015 • Vail Marriott Mountain Resort • Vail, Colorado

Workshop Co-Directors:

S. Gail Eckhardt, MD
Neal J. Meropol, MD
Yu Shyr, PhD

An Intensive Workshop in the Essentials of Effective Clinical Trial Design of Therapeutic Interventions in the Treatment of Cancer for Clinical Fellow and Junior Faculty Clinical Researchers in All Oncology Subspecialties, including Radiation and Surgical Oncology and Radiology

Supported by a Generous Grant from the National Cancer Institute and Educational Grants from Corporate Sponsors

For those protocols using agents from a pharmaceutical company that are not FDA approved for the disease under study, a letter of commitment from the collaborating company or a copy of the correspondence with the company suggesting their likely support of the trial is strongly encouraged. Priority will be given to applicants that have a clear letter of support that is uploaded with the application (preferably a letter of commitment, but at minimum, a letter of intent).



2014 Workshop Students and Faculty

Application Deadline:
March 20, 2015

VailWorkshop.org

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Goals of the Workshop

Clinical trials provide the evidence base for advances in oncology. Errors made in the design and conduct of a clinical trial can make it impossible for the trial to provide a definitive answer about the effectiveness of a new approach. Poor design can lead to the abandonment of promising avenues of research that are based on sound basic scientific work as well as to delays in the introduction of new treatments into the practice of oncology. ASCO and AACR have designed this intensive Workshop to increase the reliability and effectiveness of clinical trials by:

- Introducing clinical fellows and junior faculty in any oncology subspecialty to the principles of good clinical trial design. This Workshop will give them the tools they need to conduct clinical trials that will yield clear results and have the potential to impact the care of our patients.
- Exposing early-career clinical scientists to the full spectrum of challenges in clinical research – from surgery, radiotherapy, conventional and investigational antineoplastic agents, and multidisciplinary treatment regimens to gene therapy, biologic therapy, multimodality and combination treatments, and the integration of biomarkers and behavioral/psychosocial endpoints in clinical trials. Workshop faculty seek to inspire participants to devote all or a portion of their future careers to some aspect of clinical research.
- Developing a cadre of well-trained, experienced clinical researchers whose expertise will foster better clinical trial design. Such expertise will thereby hasten the introduction of improved approaches for cancer therapy and prevention into everyday medical practice and patient care.

Session Formats

The scientific program for the Workshop consists of five educational formats to serve a variety of didactic needs:

- **Protocol development group sessions** during which each participant develops a concept sheet for a clinical trial protocol and, through extensive mentoring, designs and completes the writing of the protocol before the end of the Workshop. These sessions constitute the core activity of the Workshop and allow students to apply the lessons being learned in the Workshop to their own programs and receive detailed critiques of their protocols from experienced scientists.
- **Lectures** on specific topics presented by experts in the field. These talks give participants an essential overview of the field and of the principles of design and conduct of high-quality clinical trials. Lectures provide a comprehensive overview of clinical research, including statistical methodologies, informed consent, genomics, immunologic endpoints, patient-reported outcomes, and investigator responsibilities. Some lectures are followed by panel discussions or case studies so students and faculty can explore issues in greater depth.
- **Small group discussion sessions** on special topics such as laboratory correlates, cancer genomics, imaging endpoints in clinical trials, and measuring immunologic outcomes. These sessions treat topics that are either essential to the success of many different kinds of clinical trials or offer an opportunity for in-depth discussion on topics of special interest to clinical investigators. Attendance at each session will be limited to maximize dialogue and to facilitate the educational experience.
- **Office hours** provide time for individual counseling and advice on protocol and career development.
- **Special interest group and career sessions** provide a networking, mentoring, and career advice forum for individuals with topics such as surgical oncology, pediatric oncology, radiation oncology, and becoming a Phase I investigator.





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Tentative Program

(Please note: Applicants selected to attend the Workshop must attend the entire program. If you are unable to participate over the dates of the Workshop as outlined below, please consider applying next year.)

Participants should plan to arrive at the Vail Marriott no later than 4:00 p.m. on Saturday, July 25. The Workshop will begin with a mandatory pretest at 5:00 p.m. A closing reception and banquet will be held on Thursday evening, July 30, after the last Workshop assignment is due. The Workshop will adjourn after breakfast on Friday, July 31.

Session topics and schedule are subject to change; please visit www.VailWorkshop.org for updates.

Saturday, July 25

- Registration
- Administration of Pretest
- Welcome and Workshop Overview
- Protocol Development Group Session 1/Dinner

Sunday, July 26

- Continental Breakfast
- Lecture Session 1
- Lecture Session 2
- Lunch
- Protocol Development Group Session 2
- Office Hours 1: Protocol-Related Questions
- Independent Study Time
- **ASSIGNMENT DUE**
- Reception/Buffer Dinner

Monday, July 27

- Continental Breakfast
- Lecture Session 3
- Lecture Session 4
- Protocol Development Group Session 3
- Lunch
- Small Group Discussion Sessions 1-2
- Small Group Discussion Sessions 3-4
- Independent Study Time/Dinner on Own
- **ASSIGNMENT DUE**

Tuesday, July 28

- Continental Breakfast
- Lecture Session 5
- Small Group Discussion Sessions 5-7
- Group Photo

- Protocol Development Group Session 4
- Lunch
- Office Hours 2: Protocol-Related Questions
- Independent Study Time/Dinner on Own
- **ASSIGNMENT DUE**

Wednesday, July 29

- Continental Breakfast
- Lecture Session 6
- Lecture Session 7
- Forum
- Lunch
- Protocol Development Group Session 5
- Office Hours 3: Any Topic (protocol, career, etc.)
- Independent Study Time/Dinner on Own
- Optional Networking Session – Women in Academia
- **ASSIGNMENT DUE**

Thursday, July 30

- Continental Breakfast
- Lecture Session 8
- Special Interest Sessions
- Protocol Development Group Session 6
- Administration of Posttest
- Lunch
- Independent Study Time
- **ASSIGNMENT DUE**
- Reception/Banquet/Dance

Friday, July 31

- Continental Breakfast
- Departure

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Faculty

Faculty listed below are from 2014 Workshop. Please visit www.VailWorkshop.org for updates on faculty members for the 2015 Workshop.

Stacey L. Berg, MD, Texas Children's Cancer Center

Thomas Braun, PhD, MS, University of Michigan School of Public Health

Rick J. Chappell, PhD, University of Wisconsin-Madison

Edward Chu, MD, University of Pittsburgh Cancer Institute

Angelo M. De Marzo, MD, PhD, Johns Hopkins University School of Medicine

Everett E. Dodson, Georgetown Lombardi Comprehensive Cancer Center

Afshin Dowlati, MD, Case Western Reserve University

S. Gail Eckhardt, MD, University of Colorado Cancer Center

Lawrence H. Fong, MD, University of California San Francisco

Margaret Foti, PhD, MD (hc), American Association for Cancer Research

Elizabeth S. Garrett-Mayer, PhD, Medical University of South Carolina Hollings Cancer Center

Stuart A. Grossman, MD, Johns Hopkins University School of Medicine

Lyndsay N. Harris, MD, Case Western Reserve University

S. Percy Ivy, MD, National Cancer Institute - DCTD

Roy B. Jones, MD, The University of Texas MD Anderson Cancer Center

Kay F. Kays, Sun City, Arizona

Mark Krailo, PhD, Children's Oncology Group

Brenda F. Kurland, PhD, University of Pittsburgh

Daniel A. Laheru, MD, Johns Hopkins University School of Medicine

Barbara K. LeStage, MPH

Wendy B. London, PhD, Boston Children's Hospital

Michael T. Lotze, MD, University of Pittsburgh

Neal J. Meropol, MD, Case Western Reserve University

Vicki A. Morrison, MD, University of Minnesota VA Medical Center

Katherine Panageas, DrPH, Memorial Sloan Kettering Cancer Center

Jyoti Patel, MD, Northwestern University Feinberg School of Medicine

Edith A. Perez, MD, Mayo Clinic

Tatiana M. Prowell, MD, U.S. Food and Drug Administration

Alfred W. Rademaker, PhD, Northwestern University

Meredith M. Regan, ScD, Dana-Farber Cancer Institute

Brian I. Rini, MD, FACP, The Cleveland Clinic Taussig Cancer Institute

Karl Schwartz, MFA, Patients Against Lymphoma

Mary J. Scroggins, MA, In My Sister's Care

Yu Shyr, PhD, Vanderbilt-Ingram Cancer Center

George W. Sledge, Jr., MD, Stanford University School of Medicine

Franklin O. Smith, III, MD, University of Cincinnati Cancer Institute

Anil K. Sood, MD, The University of Texas MD Anderson Cancer Center

Chris H. Takimoto, MD, Janssen R&D

Lisa L. Taylor, MBA, Pacheco Falls Group, Inc.

Andrea B. Troxel, ScD, University of Pennsylvania School of Medicine

Daniel D. Von Hoff, MD, TGen

Jamie H. Von Roenn, MD, American Society of Clinical Oncology

Nu Viet Vu, PhD, University of Geneva Medical School

Vivian Weinberg, PhD, UCSF Helen Diller Family Comprehensive Cancer Center

Jonathan S. Wiest, PhD, National Cancer Institute-CCT

Christopher G. Willett, MD, Duke University Medical Center

Terence Z. Wong, MD, University of North Carolina School of Medicine



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General Information

Selection of Participants

The faculty will review and accept applications from clinical fellows and junior faculty as described below. The faculty will base their decisions in large part on the quality of the proposed protocol, including feasibility, and on the supporting documents provided by the applicant and the sponsor (Program Supervisor or Department Head or mentor). These documents will be scrutinized both for the information they supply about the candidate and the assurances they provide about the participation of the candidate and sponsor in the long-term evaluation of the Workshop.

The Workshop organizers have set a priority on increasing the participation of students from racial/ethnic minority groups (as identified by the NCI) that are traditionally underrepresented in cancer and biomedical research. Individuals from these groups are strongly encouraged to submit applications. Note that selection of Workshop applicants is conducted on a competitive basis with fewer than half of the applicants accepted each year due to limited space. Unsuccessful applicants are encouraged to reapply the following year. Applicants will be notified of their status in late May.

Fellows

(Those who will complete their fellowships after July 25, 2015)

The Workshop faculty will select approximately 75 clinical fellows from any oncology subspecialty or radiology who have made outstanding progress in their medical training, who have displayed an interest and competence in clinical cancer research, and who come from a diverse group of training institutions and personal backgrounds.

The 75 fellows selected will be provided with hotel accommodations at the Workshop hotel for the nights of July 25 through July 30 (inclusive), and most meals throughout the Workshop. Those selected will be required to share a hotel room with another Workshop participant and will be responsible for their own air travel. The Workshop will provide transportation to and from the Denver International Airport.

Fellows selected to participate will be required to pay a \$1,500 registration fee to offset some of the costs of the Workshop.

Junior Faculty

(Those who have completed their fellowships between April 30, 2010 and July 25, 2015)

The Workshop faculty will also select approximately 25 junior faculty – i.e., clinical researchers in training who have already embarked on academic careers; who hold an appointment at the level of Assistant Professor, Instructor, or Lecturer; and who completed their fellowships after April 30, 2010.

The 25 junior faculty selected will be provided with most meals throughout the Workshop. Those selected will be responsible for their own travel and hotel accommodations at the Vail Marriott (required), but may have an opportunity to share a hotel room with another Workshop participant.

Clinical Researchers/Junior Faculty selected to participate will be required to pay a \$2,000 registration fee to offset some of the costs of the Workshop.

Workshop Materials

Faculty members will contribute material to the Workshop syllabus that will be available electronically to all participants. For every lecture and small group discussion session, the syllabus will contain the instructional objectives for the presentation, an outline of the topics to be covered, and a research bibliography of relevant articles and texts.

Workshop Site

The ASCO/AACR Methods in Clinical Cancer Research Workshop will take place at the Vail Marriott Mountain Resort in Vail, Colorado. While particularly famous for its outstanding winter skiing, Vail offers a full complement of summer recreational activities – including hiking, golfing, fishing, mountain climbing, horseback riding, and swimming – just a short distance from the hotel.

Transportation from the Airport

Arrangements will be made for shuttle bus transport (a 2-3 hour ride) for Workshop participants between the Denver International Airport and the Vail Marriott on Saturday midday, July 25, and again on Friday morning, July 31. All participants will receive the shuttle bus schedule, which are the only buses on which transportation will be provided.

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Accommodations

All participants of the Workshop must stay at the Vail Marriott Mountain Resort for the duration of the Workshop and participate in all group meals. Fellows will receive the following complimentary accommodations at the resort: a hotel room to be shared with one other Workshop participant for the nights of Saturday, July 25, through Thursday, July 30, inclusive. Fellows requesting a room of their own (or shared with a nonattendee) at the Vail Marriott will be responsible for the amount that ASCO and AACR would have been charged for the complimentary accommodations offered as part of the package (approximately \$115 per night).

Junior faculty participants will be offered lodge rooms at the Vail Marriott for \$226 per night. This price, per room per night, is based on single or double occupancy and includes local and state taxes. Junior faculty participants may have the option of sharing hotel rooms with other participants.

Application Procedure

To apply for the ASCO/AACR Workshop on Methods in Clinical Cancer Research, simply visit the Workshop website, **www.VailWorkshop.org**, and follow the onscreen instructions.

In summary, the online application procedure requires the following five items:

1. A completed online application.
2. A one- to two-page description of the clinical trial protocol you intend to write during the Workshop and its feasibility (protocols that are largely written before the Workshop are not acceptable).
3. Your personal C.V. (electronic version).
4. A statement explaining why you wish to participate in this Workshop.
5. A letter of support and feasibility questionnaire from your Program Supervisor or Department Head or mentor in support of your application for this Workshop, submitted online separately.

Detailed instructions for each of these items can be found on the online application. Applications will not be accepted unless they contain all FIVE elements described above. The deadline for receipt of online applications is Friday, March 20.

For questions about the application process, contact Natalie Konrad at **natalie.konrad@aacr.org** or 215-440-9300.

Some comments from previous participants

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"One of the best experiences of my fellowship years. I have grown substantially professionally through this experience."

"Wonderful workshop on every level. Would recommend to all Fellows interested in clinical trials..."

"This was an incredible experience. I learned a ton, appreciated the enthusiasm of colleagues and faculty, and would recommend it strongly to all."

"This is an excellent workshop. My learning curve was being swept away with outstanding faculty. All Fellows who want to stay in academia should attend this workshop."

"I might now apply for a K-08 or R01 because of this."

"One of the best networking experiences of my career (actually the best networking experience)!"

"I couldn't have asked for a better group – they were all outstanding mentors. They really dedicated themselves to us and our trial and they genuinely want us to succeed. I will definitely keep in touch with all of them."



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Workshop Preparation

Those accepted for the Workshop should come prepared to develop the clinical research concept submitted with their application into a complete clinical trial protocol during the course of the Workshop. Participants should bring their institution's protocol and informed consent templates, as well as a background literature review. Participants must bring a laptop computer to the Workshop to facilitate their completion of the daily assignments.

For those protocols using agents from a pharmaceutical company that are not FDA approved for the disease under study, a letter of commitment from the collaborating company or a copy of the correspondence with the company suggesting their likely support of the trial is strongly encouraged. Priority will be given to applicants that have a clear letter of support that is uploaded with the application (preferably a letter of commitment, but at minimum, a letter of intent).

Benefits of Attendance

ASCO and AACR conduct thorough short- and long-term evaluations of the Workshop to ensure that it meets its objectives and provides the attendees with the skills they need to be effective clinical investigators.

Of the 100 participants at the 2014 Workshop, 96% indicated that they have an increased understanding of and interest in conducting cancer clinical trials.

Nearly all participants (99%) noted that they were provided with the tools to conduct clinical trials.





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- Learn from the experts how to design an effective clinical trial of a therapeutic intervention in the treatment of cancer in any oncologic research subfield
- Therapeutic studies involving drugs, devices, and behavioral interventions are welcome
- Apply basic therapeutic clinical trial design concepts to any clinical research specialty, including radiation and surgical oncology and radiology
- Avoid costly and embarrassing mistakes in clinical trial design and implementation
- Understand advanced clinical trial design principles involving multimodality trials
- Enhance the validity and reliability of clinical trials
- Individuals from racial/ethnic minority groups (as identified by the NCI) that are traditionally underrepresented in cancer and biomedical research are especially encouraged to apply

Application Deadline:
March 20, 2015



VailWorkshop.org