American Association for Cancer Research

ASCO
American Society of Clinical Oncology

2014 AACR/ASCO Workshop

Methods in Clinical Cancer Research

July 26-August 1, 2014 • Vail Marriott • Vail, Colorado

Workshop Co-Directors:
Neal J. Meropol, M.D.
Jamie H. Von Roenn, M.D.
Yu Shyr, Ph.D.

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 supporters

For those protocols using agents from a pharmaceutical company that are not FDA approved for the disease under study, the final application requires a letter of commitment from the collaborating company stating that the drug will be supplied for the proposed trial or a copy of the correspondence with the company suggesting their likely support of the trial. 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).

2013 Workshop Students and Faculty

Application Deadline:
March 17, 2014

WWW.VAILWORKSHOP.ORG

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Faculty Members

Faculty subject to change, additional faculty to be announced.

Stacey L. Berg, M.D.
Texas Children's Cancer Center/Dan L. Duncan Cancer Center, Baylor College of Medicine
Houston, TX

Thomas Braun, Ph.D., M.S.
University of Michigan School of Public Health
Ann Arbor, MI

Richard J. Chappell, Ph.D.
University of Wisconsin
Madison, WI

Angelo M. DeMarzo, M.D., Ph.D.
Johns Hopkins University Sidney Kimmel Comprehensive Cancer Center
Baltimore, MD

Everett Dodson
Lombardi Comprehensive Cancer Center
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Afshin Dowlati, M.D.
Case Western Reserve University
Cleveland, OH

S. Gail Eckhardt, M.D.
University of Colorado Cancer Center
Aurora, CO

Lawrence H. Fong, M.D.
University of California
San Francisco, CA

Margaret Foti, Ph.D., M.D. (h.c.)
American Association for Cancer Research
Philadelphia, PA

Elizabeth S. Garrett-Mayer, Ph.D.
Medical University of South Carolina, Hollings Cancer Center
Charleston, SC

Stuart A. Grossman, M.D.
Johns Hopkins University Sidney Kimmel Comprehensive Cancer Center
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Lyndsay N. Harris, M.D.
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Genentech, Inc.
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Los Angeles, CA

Brenda F. Kurland, Ph.D.
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Pittsburgh, PA

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Baltimore, MD

Barbara K. LeStage, M.H.P.
Wrentham, MA

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Boston, MA

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Pittsburgh, PA

Neal J. Meropol, M.D.
Case Western Reserve University
Cleveland, OH

Vicki A. Morrison, M.D.
University of Minnesota, VA Medical Center
Minneapolis, MN

Katherine S. Panageas, Dr. P.H.
Memorial Sloan-Kettering Cancer Center
New York, NY

Jyoti D. Patel, M.D.
Northwestern University
Evanston, IL

Edith A. Perez, M.D.
Mayo Clinic College of Medicine
Jacksonville, FL

Alfred W. Rademaker, Ph.D.
Northwestern University
Chicago, IL

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

Brian I. Rini, M.D., FACP
Cleveland Clinic Lerner College of Medicine/Case Western Reserve University
Cleveland, OH

Karl L. Schwartz, M.F.A.
Patients Against Lymphoma
Riegelsville, PA

Mary J. Scroggins, M.A.
In My Sister's Care
Washington, DC

Yu Shyr, Ph.D.
Vanderbilt-Ingram Cancer Center
Nashville, TN

George W. Sledge, Jr., M.D.
Stanford University School of Medicine
Stanford, CA

Franklin O. Smith, III, M.D.
University of Cincinnati College of Medicine/ Cincinnati Children's Hospital Medical Center
Cincinnati, OH

Anil K. Sood, M.D.
University of Texas MD Anderson Cancer Center
Houston, TX

Lisa L. Taylor
Packers Falls Group
Durham, NH

Andrea B. Troxel, Sc.D.
University of Pennsylvania
Philadelphia, PA

Jamie H. Von Roenn, M.D.
American Society of Clinical Oncology
Alexandria, VA

Nu Viet Vu, Ph.D.
University of Geneva
Geneva, Switzerland

Vivian K. Weinberg, Ph.D.
UCSF Helen Diller Family Comprehensive Cancer Center
San Francisco, CA

Christopher G. Willett, M.D.
Duke University Medical Center
Durham, NC

Terence Z. Wong, M.D.
Duke University School of Medicine
Durham, NC

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. AACR and ASCO 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 that investigators can use to proceed to the next level of research.
- 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 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.

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 and on the submissions 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 26, 2014)

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 complimentary airline tickets (limits and instructions will be provided to those accepted), hotel accommodations at the Workshop hotel for the nights of July 26 through July 31 (inclusive), and most meals throughout the Workshop. Those selected will be required to share a hotel room with another Workshop participant.

Fellows selected to participate will be required to pay a $650 registration fee to offset some of the costs of the Workshop.

Clinical Researchers/Junior Faculty
(Those who have completed their fellowships between April 30, 2009 and July 26, 2014)

The Workshop faculty will also select approximately 25 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, 2009.

The 25 clinical researchers/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.

Clincal Researchers/Junior Faculty selected to participate will be required to pay a $650 registration fee to offset some of the costs of the Workshop.

General Information

Workshop Materials

Faculty members will contribute material to the electronic 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 AACR/ASCO Methods in Clinical Cancer Research Workshop will take place at the Vail Marriott, Vail, Colorado. All participants must stay at the Vail Marriott. 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 2½ hour ride) for Workshop participants between the Denver International Airport and the Vail Marriott on Saturday mid-day, July 26 and again on Friday morning, August 1. All participants will receive the shuttle bus schedule, which are the only buses on which transportation will be provided.

Accommodations

All participants of the Workshop must stay at the Vail Marriott 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 26, through Thursday, July 31, inclusive. Fellows requesting a room of their own (or shared with a non-attendee) at the Vail Marriott will be responsible for the amount that AACR and ASCO would have been charged for the complimentary accommodations offered as part of the package (approximately $115 per night).

Clinical Researcher/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. Clinical Researcher/Junior Faculty may have the option of sharing hotel rooms with other participants.

Scientific 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. 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 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.

Tentative Daily 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 must arrive at the Vail Marriott no later than 3:00 p.m. on Saturday, July 26. The Workshop will begin with a mandatory pretest at 4:00 p.m. A closing reception and banquet will be held on Thursday evening, July 31, after the last Workshop assignment is due. The Workshop will adjourn after breakfast on Friday, August 1. Session topics and schedule are subject to change, please visit www.vailworkshop.org for updates.

Saturday, July 26

- Registration
- Administration of Pretest
- Protocol Development Group Session
- Dinner

Sunday, July 27

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

Monday, July 28

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

Tuesday, July 29

- Continental Breakfast
- Lecture Session 4
- Break/Group Photo
- Protocol Development Group Session 4
- Buffet Lunch
- Small Group Discussion Sessions 5-7
- Office Hours 2: Protocol-Related Questions
- Independent Study Time/Dinner on Own
- ASSIGNMENT DUE

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Tentative Daily Program

Wednesday, July 30

- Continental Breakfast
- Lecture Session 5
- Protocol Development Group Session 5
- Boxed Lunch
- Lecture Session 6
- Special Interest Group and Career Sessions
- Office Hours 3: Any Question Topics (protocol, career, etc.)
- Independent Study Time/Dinner on Own
- ASSIGNMENT DUE

Thursday, July 31

- Continental Breakfast
- Lecture Session 7
- Protocol Development Group Session 6
- Lunch/Buffet
- Administration of Posttest
- Independent Study Time
- ASSIGNMENT DUE
- Reception/Banquet/Dance

Friday, August 1

- Continental Breakfast
- Adjournment and Departure

Some comments from last year's participants . . .

"This one week will probably teach me more than I can ever gain from my 3 years fellowship; everything I will need from job hunt to getting grants/writing research protocols."

"This workshop has been a career defining moment in my life. It has provided me with valuable collaborative opportunities amongst peers, mentorship opportunities amongst faculty members and – my curiosity in clinical trials."

"Outstanding opportunity. I felt like the faculty were personally invested in my success."

"The workshop has cemented my interest in an academic career. It was an amazing mentorship program to us and made me overall excited about my research."

"This course should be required for every fellow. The highlight of my fellowship so far. The faculty was inspiring (as were the participants)."

"(The faculty) went above and beyond any expectation in mentoring me during this workshop. Their passion for teaching mentoring and development for therapeutics is infectious and pushes me to take things to the next level."

Online Application Procedure

To apply for the AACR/ASCO 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 Monday, March 17.

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

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, the final application requires a letter of commitment from the collaborating company stating that the drug will be supplied for the proposed trial or a copy of the correspondence with the company suggesting their likely support of the trial. 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:

The AACR and ASCO conduct thorough short- and long-term evaluations of the Workshop to assure that it meets its objectives and provides the attendees with the skills they need to be effective clinical investigators. Some of the highlights from past evaluations demonstrate the many benefits of attendance:

- Participants of the last 10 workshops have recognized that the Workshop is a "must attend" event for the advancement of their careers and research training – with 99% of them indicating that they would recommend this Workshop to someone whose training was similar to theirs.
- More than three-fourths of the students who attended the 2012 Workshop applied based upon the recommendation of a colleague.
- Participants have rated highly the daily small protocol development group sessions that constitute the core of the Workshop. Participants indicated that they received constructive feedback from the faculty in their protocol development group sessions and 82% of the participants departed the Workshop with a completed protocol in hand, ready to submit to their IRB for approval.
- 88% of the attendees indicated that the organization of the Workshop and scheduling of activities were excellent and that they had many opportunities to interact and network with the faculty.
- Long-term evaluations of the Workshop demonstrate the continuing productivity of the graduates. Three years after the Workshop, the main focus of three-fourths or more of the attendees is patient-oriented or translational research/more than half of attendees spend substantial time in patient-oriented or translational research, and have designed and/or participated in designing three or more protocols which were approved by an IRB and implemented.

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Full Program Details and Application Procedures Inside

Convenient Online Application Process

Designed for Individuals in Any Clinical Research Specialty Area and Radiology

Scholarship Assistance for All Successful Applicants

- 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
- 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 17, 2014

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