

Session Title: #232: Fundamentals of Clinical Trial Design and Methodology

Session Type: Extended Education Session

Date: Friday, June 4

Location: S100a

Time: 1:00 PM - 3:15 PM

- Overview and Introduction of Speakers
Michael Paul Link, MD
 - Clinical Trials Issues and Design
James L. Abbruzzese, MD
 - Statistical Principles in Clinical Trials
Susan G. Hilsenbeck, PhD
 - Ethics in Cancer Clinical Trials
Steven Joffe, MD, MPH
 - Practical Considerations in Clinical Trial Design
Ian Tannock, MD, PhD
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Session Title: #233: Grant Writing Workshop I: Basic Grant Writing

Session Type: Extended Education Session

Date: Friday, June 4

Location: S106a

Time: 1:00 PM - 3:30 PM

- NCI Training and Career Development Grants
Jonathan S. Wiest, PhD
- The ASCO Cancer Foundation Grants Program
Jennifer C. King, PhD
- Choosing a Mentor and Obtaining Letters of Support
Merrill J. Egorin, MD
- Developing Hypothesis and Stating Aims
Charles M. Rudin, MD, PhD

- Statistical Considerations

Donna S. Neuberg, ScD

- R21 Grants, Perseverance, and Resubmission

William G. Blum, MD

- Grant Writing Pearls

Mary L. (Nora) Disis, MD

Session Title: #231: Advanced Concepts in Clinical Trial Design and Methodology

Session Type: Extended Education Session

Date: Friday, June 4

Location: S100a

Time: 3:45 PM - 6:00 PM

- New Designs for Phase III Clinical Trials

Richard Simon, DSc

- Innovative Designs: Randomized Phase II Trials

Mark J. Ratain, MD

- Advanced Statistical Considerations: Things you think you can do, but□

Yu Shyr, PhD

Session Title: #234: Grant Writing Workshop II: Improving Your Grant Writing Skills (Small Group Discussions)

Session Type: Extended Education Session

Date: Friday, June 4

Location: S106a

Time: 4:00 PM - 6:00 PM

- Small Group Roundtable Discussion

Bruce E. Johnson, MD

- Small Group Roundtable Discussion

Jennifer C. King, PhD

- Small Group Roundtable Discussion

Merrill J. Egorin, MD

- Small Group Roundtable Discussion

Charles M. Rudin, MD, PhD

- Small Group Roundtable Discussion
Donna S. Neuberg, ScD
 - Small Group Roundtable Discussion
William G. Blum, MD
 - Small Group Roundtable Discussion
Mary L. (Nora) Disis, MD
 - Small Group Roundtable Discussion
Dawn L. Hershman, MD
 - Small Group Roundtable Discussion
Alex A. Adjei, MD, PhD
 - Small Group Roundtable Discussion
Eric Jay Small, MD
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Session Title: #137: Talking with Your Patients About Clinical Trials

Session Type: Clinical Problems in Oncology Session

Date: Friday, June 4

Location: E451a

Time: 4:45 PM - 6:00 PM

- Academic Perspective
Afshin Dowlati, MD
 - Community Perspective
Stephen S. Grubbs, MD
 - Patient Advocacy Perspective
Mary Lou Smith, JD, MBA
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Session Title: #24: Clinical Trials in Survivorship Populations: Emerging Concepts and Barriers to Application

Session Type: Education Session

Date: Saturday, June 5

Location: S100a

Time: 8:00 AM - 9:15 AM

- Promoting Health During and Beyond Cancer Therapy
Melissa M. Hudson, MD

- Conducting Clinical Trials of Physical Activity in Cancer Survivors
Melinda L. Irwin, PhD, MPH
 - Clinical Trials in Cancer Survivors with Chemotherapy-related Cognitive Impairment
Janette L. Vardy, MD, PhD
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Session Title: #268: Opening Session with Presidential Address, NCI Director's Address, David A. Karnofsky Memorial Award Lecture, and The ASCO Cancer Foundation Donor Recognition Awards

Session Type: Special Session

Date: Saturday, June 5

Location: N Hall B1

Time: 9:30 AM - 12:00 PM

- Opening Session with Presidential Address, NCI Director's Address, David A. Karnofsky Memorial Award Lecture, and The ASCO Cancer Foundation Donor Recognition Awards

Daniel D. Von Hoff, MD

Session Title: #59: Implementing Clinical Trials: Risks, Benefits, Marketing, and Paying for It All

Session Type: Education Session

Date: Saturday, June 5

Location: E353

Time: 1:15 PM - 2:30 PM

- Structuring / Marketing a program for success
Robin Zon, MD, FACP
- The critical role of creating a research team
Gary Irvin Cohen, MD
- Negotiating a contract - Knowing Cost to effectively budget for pharma trials.

Dee Anna Smith

Session Title: #60: Improving Access to Clinical Trials

Session Type: Education Session

Date: Saturday, June 5

Location: S100a

Time: 1:15 PM - 2:30 PM

- Overcoming barriers to access to cancer care and cancer trial enrollment in minority populations

Derek Raghavan, MD, PhD

- Overcoming barriers to clinical trials: Increasing accrual through partnership with community oncologists

J. Phillip Kuebler, MD, PhD

- Overcoming barriers to clinical trial accrual in elderly population and patients with co-morbidities

Hyman Bernard Muss, MD

Session Title: #64: International Collaboration in Clinical Trials: Special Emphasis on Ethics and Regulatory Issues

Session Type: Education Session

Date: Saturday, June 5

Location: S100a

Time: 3:00 PM - 4:15 PM

- Overview of International collaboration in cancer clinical trials

Robert Leo Comis, MD

- European perspective on international collaborative clinical trials

Denis A. Lacombe, MD

- Review NCI symposium on implementation of international collaborative clinical trials in cancer therapies

Edward Lloyd Trimble, MD

Session Title: #107: Update on Gastrointestinal Noncolorectal Malignancies: What's New since the 2009 ASCO Annual Meeting?

Session Type: Education Session

Date: Saturday, June 5

Location: N Hall B1

Time: 3:00 PM - 4:15 PM

- Progress in the Treatment of Esophageal and Gastric Cancers: What's New Since ASCO 2009

Albert C. Lockhart, MD

- Hepatobiliary and pancreatic cancers since ASCO 2009: steady steps forward and a long way to go

Anthony B. El-Khoueiry, MD

Session Title: #167: Highlights of the Day I including Clinical Trials Participation Awards

Session Type: Highlights of the Day

Date: Sunday, June 6

Location: E Hall D1

Time: 7:30 AM - 9:00 AM

- Highlights of the Day I including Clinical Trials Participation Awards

Everett E. Vokes, MD

- Clinical Trials Participation Awards

Douglas W. Blayney, MD

- Discussion: Lymphoma and Plasma Cell Disorders

Bruce D. Cheson, MD

- Discussion: Lung Cancer - Local/Regional and Adjuvant Therapy

Alan B Sandler, MD

- Discussion: Patient and Survivor Care

Gretchen Genevieve Kimmick, MD

- Discussion: Melanoma/Skin Cancers

F. Stephen Hodi, MD

Session Title: #143: Plenary Session including Science of Oncology Award and Lecture

Session Type: Plenary Session

Date: Sunday, June 6

Location: N Hall B1

Time: 1:00 PM - 4:00 PM

- Plenary Session including Science of Oncology Award and Lecture

Douglas W. Blayney, MD

- Plenary Session including Science of Oncology Award and Lecture
Daniel F. Hayes, MD
- Plenary Session including Science of Oncology Award and Lecture
Frank McCormick, PhD, FRS
- #LBA1-Phase III trial of bevacizumab (BEV) in the primary treatment of advanced epithelial ovarian cancer (EOC), primary peritoneal cancer (PPC), or Fallopian tube cancer (FTC): A Gynecologic Oncology Group study.

Robert A Burger

- Discussion
Elizabeth A. Eisenhauer, MD
- #2-Weekly paclitaxel combined with monthly carboplatin versus single-agent therapy in patients age 70 to 89: IFCT-0501 randomized phase III study in advanced non-small cell lung cancer (NSCLC).
Elisabeth A. Quoix
- #3-Clinical activity of the oral ALK inhibitor, PF-02341066, in ALK-positive patients with non-small cell lung cancer (NSCLC).

Yung-Jue Bang

- Discussion
Martin J. Edelman, MD
- #4-A phase III, randomized, double-blind, multicenter study comparing monotherapy with ipilimumab or gp100 peptide vaccine and the combination in patients with previously treated, unresectable stage III or IV melanoma.

Steven O'Day, MD

- Discussion: Ipilimumab: The light at the end of the tunnel?

Vernon K Sondak, MD

Session Title: #168: Highlights of the Day II including Partners in Progress Award

Session Type: Highlights of the Day

Date: Monday, June 7

Location: E Hall D1

Time: 7:30 AM - 9:00 AM

- Highlights of the Day II including Partners in Progress Award

Kim Allyson Margolin, MD

- Highlights of the Day II including Partners in Progress Award
Douglas W. Blayney, MD
 - Partners in Progress Award Recipient
Ellen V. Sigal, PhD
 - Discussion: Genitourinary (Prostate) Cancer
Nicholas J. Vogelzang, MD
 - Discussion: Gastrointestinal (Colorectal) Cancer
Howard S. Hochster, MD
 - Discussion: Gynecologic Cancer
Claire F. Verschraegen, MD
 - Discussion: Myeloma
Jean L. Harousseau, MD
 - Discussion: Cancer Prevention/Epidemiology
Scott Michael Lippman, MD
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Session Title: #58: Impact of Health Literacy on Health Care, Decision Making and Consent

Session Type: Education Session

Date: Monday, June 7

Location: E353

Time: 8:00 AM - 9:15 AM

- Impact of limited health literacy; assessing literacy and overcoming barriers to limited literacy in delivering health care
Terry C Davis, PhD
- overcoming literacy issues in obtaining informed consent
Cathy A. Coyne, PhD
- Decision making in breast and prostate cancer
Angela Fagerlin, PhD

Session Title: #77: Neoadjuvant versus Adjuvant Chemotherapy and Radiation for Esophagogastric Cancers: Do the Results of Recent Trials Give Us a Direction?

Session Type: Education Session

Date: Monday, June 7

Location: E Hall D2

Time: 9:45 AM - 11:00 AM

- (Neo)adjuvant chemotherapy in the management of localized esophagogastric carcinoma.

Peter C. Enzinger, MD

- Neoadjuvant chemoradiation in the management of localized esophagogastric carcinoma.

Mohan Suntharalingam, MD

- Implications for surgery following chemotherapy or chemoradiation.

Cliff P. Connery, MD

Session Title: #102: Improving the Value of Cancer Clinical Trials: Recommendations from the Institute of Medicine and the NCI's Clinical Trials and Translational Research Advisory Committee

Session Type: Education Session

Date: Monday, June 7

Location: S100a

Time: 9:45 AM - 11:30 AM

- Obstacles to clinical trial development and implementation

David M. Dilts, PhD, MBA

- Streamlining the extramural clinical trials system

James H. Doroshow, MD

- Recommendations by the IOM on Reinvigorating Cooperative Group Clinical Trials

John Mendelsohn, MD

- The Role of Cooperative Groups in Comparative Effectiveness Research

Richard L. Schilsky, MD

Session Title: #113: Clinical Research Mentorships: How to Find a Mentor, How to Be a Mentor

- Clinical Research Mentorships: How to Find a Mentor, How to Be a Mentor

Evanthia Galanis, MD

Session Title: #14: Are We Asking Too Much? The Challenges of Mandatory Research Biopsies within Clinical Trials

Session Type: Education Session

Date: Monday, June 7

Location: S100b

Time: 11:30 AM - 12:45 PM

- **WHAT CAN WE LEARN?:** The scientific justification for consideration of mandatory research biopsy within some clinical trials. What questions can research biopsies address? Are they safe? What have we learned from such studies? What is at stake if make all correlative science components optional?

Eric P. Winer, MD

- **ARE WE ASKING TOO MUCH?:** Ethical Concerns over Mandatory Research Biopsy: Concerns over coercion. Need to separate therapeutic trials from correlative studies. Perspectives of a Patient Advocate within a National Cancer Institute Cooperative Group.

Michael Katz

- **THE ETHICAL FRAMEWORK:** Can we pursue mandatory research biopsy under select circumstances? Ethical arguments for mandatory research biopsy, ways to promote protection of research subjects and pursue important research. A proposed framework for consideration of mandatory research biopsy and clarification of the assumptions underlying different positions on this issue.

Jeffrey M. Peppercorn, MD, MPH

Session Title: #75: NCI Community Cancer Centers Program (NCCCP): A New Paradigm for Clinical Trials in the Community Setting

Session Type: Education Session

Date: Monday, June 7

Location: S404

Time: 1:15 PM - 2:30 PM

- Describe the vision of the NCCCP and its potential impact on community cancer care in the future.

John E. Niederhuber, MD

- Multidisciplinary cancer care as the paradigm for prospective case management and clinical trial accrual in the community setting

Mark Krasna, MD

- Disparities and community outreach in the NCCCP

Nicholas J. Petrelli, MD

Session Title: #169: Highlights of the Day III

Session Type: Highlights of the Day

Date: Tuesday, June 8

Location: E Hall D1

Time: 7:30 AM - 9:00 AM

- Highlights of the Day III

Kathy Miller, MD

- Discussion: Breast Cancer - Local/Regional and Adjuvant Therapy

Kathy Miller, MD

- Discussion: Lung Cancer - Metastatic

Charles M. Rudin, MD, PhD

- Discussion: Sarcoma

Gary K. Schwartz, MD

- Discussion: Gastrointestinal (Noncolorectal) Cancer

C. D. Blanke, MD

- Discussion: Head and Neck Cancer

Everett E. Vokes, MD

Session Title: #40: Developing Drugs in Special Populations: Organ Dysfunction Studies

Session Type: Education Session

Date: Tuesday, June 8

Location: E354b

Time: 8:00 AM - 9:15 AM

- Renal dysfunction studies

Daniel Mulkerin, MD

- Liver dysfunction studies

Ghassan K. Abou-Alfa, MD

- Regulatory considerations for organ dysfunction studies

Shiew-Mei Huang, PhD

Session Title: #92: Selection of Endpoints in Clinical Trials: From Bench to Trials to Practice

Session Type: Education Session

Date: Tuesday, June 8

Location: S100b

Time: 8:00 AM - 9:15 AM

- Use of molecular markers as surrogate endpoints in clinical trials

Carlos Cordon-Cardo, MD, PhD

- Design of Clinical Trials to Achieve Meaningful Results

Mary W Redman, PhD

- Translating Clinical Trial Results into Societal Benefit: The Role of Population-based Outcome Studies

Christopher M. Booth, MD