



**Implementing a National Cancer Clinical Trials System
for the 21st Century, Workshop #2**

Hosted by the **American Society of Clinical Oncology** and
the **Institute of Medicine’s National Cancer Policy Forum**

AGENDA

An ad hoc committee will plan and conduct a public workshop to identify and examine ongoing activities to implement the recommendations put forth in the IOM consensus report, *A National Cancer Clinical Trials System for the 21st Century*.

The goals of the workshop include:

- summarizing current progress;
- identifying remaining gaps; and
- identifying opportunities for closing those gaps within a national clinical trial system.

February 11, 2013

7:30 am	Breakfast and Registration
8:15 am	<p>Welcome from the IOM’s National Cancer Policy Forum</p> <ul style="list-style-type: none"> • John Mendelsohn, MD Anderson Cancer Center Chair, National Cancer Policy Forum <p>Introduction to Workshop</p> <ul style="list-style-type: none"> • Monica Bertagnolli, Alliance for Clinical Trials In Oncology and Dana-Farber Cancer Institute, Workshop Planning Committee Chair
8:25 am	<p>Session 1: Updates from NCI and NCTN Components: Progress To Date <i>Moderator: James Doroshov, NCI</i></p> <p>NCI Updates</p> <ul style="list-style-type: none"> • James Doroshov, NCI Division of Cancer Treatment and Diagnosis <p>Updates from the Cooperative Groups</p> <ul style="list-style-type: none"> • Robert Comis, ECOG-ACRIN Cancer Research Group <p>Updates on CCOPs/NCCCP/NCORP</p> <ul style="list-style-type: none"> • Wortia McCaskill-Stevens, NCI Division of Cancer Prevention <p>Panel Discussion</p> <p>Speakers above plus representatives of community practices in the NCORP:</p> <ul style="list-style-type: none"> • Stephen Grubbs, Helen F. Graham Cancer Center and Christiana Care CCOP • Robin Zon, Michiana Hematology Oncology, PC and Northern Indiana Cancer Research Consortium CCOP
10:00	Break

10:15 am	<p>Session 2: Funding for Cancer Clinical Trials <i>Moderator: John Mendelsohn, MD Anderson Cancer Center</i></p> <p>Metrics on Technical Risks, Clinical Development Times and Approval Times for Cancer Drugs</p> <ul style="list-style-type: none"> • Joseph DiMasi, Tufts Center for the Study of Drug Development <p>Funding Clinical Trials in the Academic and Community Research Environment</p> <ul style="list-style-type: none"> • Marc Sabatine, Thrombolysis in Myocardial Infarction Study Group <p>Foundation Perspective</p> <ul style="list-style-type: none"> • Margaret Anderson, FasterCures <p>Panel Discussion</p>
11:45 pm	Lunch
12:30 pm	<p>Session 3: Prioritization of Cancer Trials in a Changing Environment <i>Moderator: George Sledge, Stanford University School of Medicine</i></p> <p>Status Report from the CTAC Strategic Planning Subcommittee</p> <ul style="list-style-type: none"> • George Sledge, Stanford University School of Medicine • Robert Diasio, Mayo Clinic Cancer Center <p>An International Perspective from the UK Network on Prioritization of Trials:</p> <ul style="list-style-type: none"> • Richard Kaplan, UK National Cancer Research Network & Medical Research Council <p>Panel Discussion</p>
1:45 pm	<p>Session 4: The NCTN as a Platform to Implement Precision Medicine <i>Moderator: Barbara Conley, NCI Division of Cancer Treatment and Diagnosis</i></p> <p>Resources Needed for a Trial Employing Genomic Profiling for Eligibility</p> <ul style="list-style-type: none"> • Levi Garraway, Dana-Farber Cancer Institute <p>Information from “Exceptional Responders” and the Implementation of Basket Trials</p> <ul style="list-style-type: none"> • David Solit, Memorial Sloan-Kettering Cancer Center <p>Challenges in Real World Implementation of Genomic Profiling for Eligibility in Broad, National Clinical Trials</p> <ul style="list-style-type: none"> • Vincent Miller, Foundation Medicine <p>IDE Requirements for Diagnostic Tests used in Clinical Trials</p> <ul style="list-style-type: none"> • John Jessup, NCI Center for Cancer Research <p>Panel Discussion</p>
3:45 pm	Break

4:00 pm	<p>Panel Discussion (to include questions from the whole day) <i>Moderator: Michael Caligiuri, Ohio State University Comprehensive Cancer Center</i></p> <p>Panelists:</p> <p><u>Cooperative Group Chairs</u></p> <ul style="list-style-type: none"> • Charles Blanke, SWOG • Robert Comis, ECOG-ACRIN • Peter Adamson, Children’s Oncology Group • Walter Curran, NRG Oncology Group <p><u>NCI</u></p> <ul style="list-style-type: none"> • James Doroshow, NCI Division of Cancer Treatment and Diagnosis <p><u>FDA</u></p> <ul style="list-style-type: none"> • Richard Pazdur, FDA Office of Hematology and Oncology Products <p><u>Advocates</u></p> <ul style="list-style-type: none"> • Nancy Roach, Fight Colorectal Cancer • Patrick Gavin, Patrick Gavin R.Ph. Consulting LLC
5:30 pm	Wrap up Day 1 and Adjourn
February 12, 2013	
7:30 am	Breakfast and Registration
8:00 am	<p>Session 5: Accelerating Innovation Through Effective Partnerships <i>Moderator: Monica Bertagnoli, Alliance and DFCI</i></p> <p>Comprehensive Cancer Center Perspectives</p> <ul style="list-style-type: none"> • Edward Benz, Dana-Farber Cancer Institute <p>Industry Perspective</p> <ul style="list-style-type: none"> • Renaud Capdeville, Novartis Oncology <p>International Perspective: NEWDIGS Initiative, MIT Center for Biomedical Innovation</p> <ul style="list-style-type: none"> • Hans-Georg Eichler, European Medicines Agency <p>Accelerating Innovation in Statistical Design</p> <ul style="list-style-type: none"> • Lisa McShane, NCI Division of Cancer Treatment and Diagnosis <p>Partnering with Advocates</p> <ul style="list-style-type: none"> • Patrick Gavin, Patrick Gavin R.Ph. Consulting LLC <p>Panel Discussion</p>
10:45 am	Break – Box lunches available

11:00 am	<p>Session 6: Regulatory Issues <i>Moderator: Richard L. Schilsky, American Society of Clinical Oncology</i></p> <p>Optimizing Safety Data Collection in Cancer Clinical Trials</p> <ul style="list-style-type: none"> • Richard L. Schilsky, ASCO <p>FDA Perspective on Data Quality Issues</p> <ul style="list-style-type: none"> • Rachel Sherman, FDA Office of Medical Policy <p>The Role of CTEP/NCI in Registration Trials</p> <ul style="list-style-type: none"> • Jeffrey Abrams, NCI Division of Cancer Treatment and Diagnosis <p>FDA/NCI collaboration – Independent Radiologic Review</p> <ul style="list-style-type: none"> • Lori Dodd, NCI Biostatistics Research Branch <p>Pharmaceutical Industry</p> <ul style="list-style-type: none"> • Sandra Horning, Genentech <p>EMA-FDA Harmonization</p> <ul style="list-style-type: none"> • Francesco Pignatti, European Medicines Agency <p>Panel Discussion Speakers plus:</p> <ul style="list-style-type: none"> • Robert Iannone, Merck Research Laboratories • Debasish Roychowdhury, Sanofi Oncology
1:45 pm	Workshop Wrap Up
2:00 pm	Adjourn



Workshop Notes

- Please identify your name and affiliation prior to asking questions at the microphone.
- We will be filming a live webcast of the meeting. A link to the webcast feed is available at: <http://www.iom.edu/Home/Activities/Disease/NCPF/2013-FEB-11/Webcast.aspx>
- Please use hashtag **#IOMncpf** to tweet about the workshop.
- An archive of the video webcast, speaker and moderator bios, and presentation slides will be available at: <http://www.iom.edu/Activities/Disease/NCPF/2013-FEB-11.aspx>
- A summary of the workshop will be published following Institute of Medicine procedures. Rapporteurs will compose the summary from the workshop transcript, and external reviewers will examine the summary to make sure it accurately reflects workshop discussions and conforms to institutional policies.
- Interested in receiving IOM and National Cancer Policy Forum Email Updates?
Sign up at: <http://www.iom.edu/Global/Media%20Room/Updates.aspx>
- Like the IOM on Facebook: www.facebook.com/theIOM
- Follow the IOM on Twitter: @theIOM
- Follow the IOM on LinkedIn: <http://www.linkedin.com/company/institute-of-medicine>



American Society of Clinical Oncology

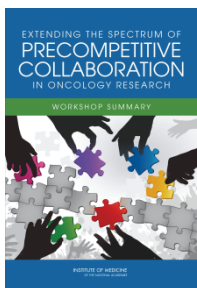
Making a world of difference in cancer care

The American Society of Clinical Oncology is a proud sponsor of the National Cancer Policy Forum and the workshop, *Implementing a National Cancer Clinical Trials System for the 21st Century*

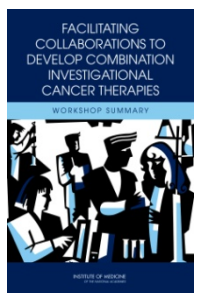
About ASCO

The American Society of Clinical Oncology is a non-profit organization founded in 1964 with the overarching goals of improving cancer care and prevention. ASCO has nearly 30,000 members worldwide. Its membership is comprised of clinical oncologists from all oncology disciplines and sub-specialties; physicians and health care professionals participating in approved oncology training programs; oncology nurses; and other health care practitioners with a predominant interest in oncology.

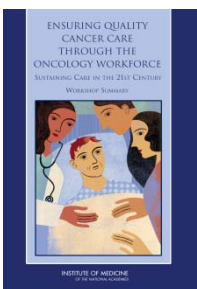
The National Cancer Policy Forum



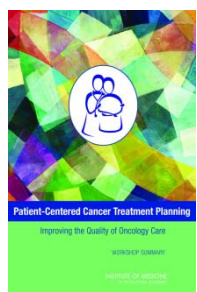
The National Cancer Policy Forum (NCPF) provides a continuous focus on cancer policy at the Institute of Medicine (IOM). IOM forums are designed to allow government, industry, academic, and other representatives to meet, confer, and plan on subject areas of mutual interest. The objectives of the NCPF are to identify emerging high priority policy issues in the nation's effort to combat cancer and to examine those issues through convening activities that promote discussion about potential opportunities for action. These activities inform stakeholders about critical policy issues through published reports, and often provide input for planning formal IOM consensus committee studies.



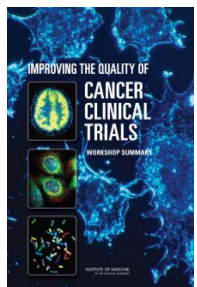
The IOM established the NCPF on May 1, 2005, to succeed the National Cancer Policy Board (1997-2005, the Board). The Board brought together leaders from the cancer community to identify and conduct studies and other activities contributing to cancer research, prevention, treatment, and public awareness. The combination of multi-disciplinary expertise (basic, clinical, and public health scientists, consumers, and advocates) and resources (grants from the National Cancer Institute (NCI) and Centers for Disease Control and Prevention (CDC), as well as smaller contributions from private sector organizations) allowed the Board to produce a remarkably original and diverse body of work contributing to improvements in knowledge and public policy.

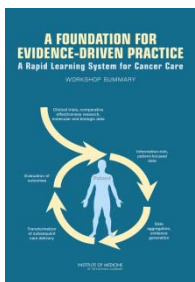


The NCPF continues to provide a focus within the National Academies for the consideration of issues in science, clinical medicine, public health, and public policy relevant to the goals of preventing, palliating, and curing cancer. The NCPF builds upon the work of the Board and enjoys a closer working relationship with its federal and non-federal sponsors. As a forum rather than a board, sponsors are full members with the academic, consumer, and policy community members. They bring ideas and requests to the deliberations and have the advantage of playing an active part in the discussions. Governmental sponsors represented on the NCPF include the NCI and CDC, and non-governmental sponsors include the American Association for Cancer Research, the American Cancer Society, the American Society of Clinical Oncology, the Association of American Cancer Institutes, Bristol-Myers Squibb, C-Change, the CEO Roundtable on Cancer, GlaxoSmithKline Oncology, Novartis, the Oncology Nursing Society, and Sanofi Oncology. Additional distinguished experts from the cancer community are also appointed as members to serve three-year terms. The NCPF operates under the aegis of the IOM Board on Health Care Services.



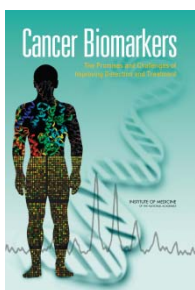
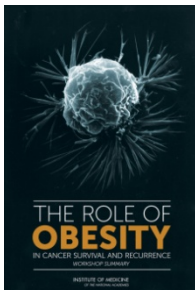
The NCPF enables all members to be full participants in identifying and debating critical policy issues in cancer care and research, and in examining potential opportunities for actions. These convening activities result in published reports that are available to the public and may provide input to planning formal IOM consensus committee studies. Ideas for committee studies that emerge from the NCPF's deliberations are handed off to an appropriate ad hoc committee appointed by IOM. The studies are conducted by NCPF staff and the committees often include one or more members of the NCPF. Forum sponsors often actively pursue activities to facilitate the implementation of recommendations made in these consensus reports, as well as suggestions put forth in NCPF workshops.





National Cancer Policy Forum Reports:

Developing Biomarker-based Tools for Cancer Screening, Diagnosis and Therapy (2006), *Effect of the HIPAA Privacy Rule on Health Research* (2006), *Implementing Cancer Survivorship Care Planning* (2007), *Cancer in Elderly People* (2007), *Cancer-Related Genetic Counseling and Testing* (2007), *Improving the Quality of Cancer Clinical Trials* (2008), *Implementing Colorectal Cancer Screening* (2008), *Multi-center Phase III Clinical Trials and the NCI Cooperative Group Program* (2009), *Ensuring Quality Cancer Care through the Oncology Workforce* (2009), *Assessing and Improving Value in Cancer Care* (2009), *Policy Issues in the Development of Personalized Medicine in Oncology* (2010), *A Foundation for Evidence-Driven Practice: A Rapid Learning System for Cancer Care* (2010), *Extending the Spectrum of Precompetitive Collaboration in Oncology Research* (2010), *Direct to Consumer Genetic Testing* (with the NRC, 2010), *Policy Issues in Nanotechnology and Oncology* (2011), *National Cancer Policy Summit: Opportunities and Challenges in Cancer Research and Care* (2011), *Patient-Centered Cancer Treatment Planning: Improving the Quality of Oncology Care* (2011), *Implementing a National Cancer Clinical Trials System for the 21st Century* (2011), *Facilitating Collaborations to Develop Combination Investigational Cancer Therapies* (2011), *The Role of Obesity in Cancer Survival and Recurrence* (2012), *Informatics Needs and Challenges in Cancer Research* (2012), *Reducing Tobacco-Related Cancer Incidence and Mortality, Delivering Affordable Cancer Care in the 21st Century* (2013)



Spin-off IOM consensus committee reports:

Cancer Biomarkers: The Promises and Challenges of Improving Detection and Treatment (2007), *Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health through Research* (2009), *Evaluation of Biomarkers and Surrogate Endpoints in Chronic Disease* (2010), *A National Cancer Clinical Trials System for the 21st Century* (2010), *Evolution of Translational Omics* (2012), *Ensuring the Quality of Cancer Care in an Aging Population* (In preparation)

Membership of the Forum:

Chair - John Mendelsohn, MD, President, MD Anderson Cancer Center

Vice Chair - Patricia Ganz, MD, Distinguished Professor, UCLA Fielding School of Public Health

Amy Abernethy, MD, Director, Center for Learning Health Care, Duke Clinical Research Institute

Rafael Amado, MD, Senior Vice President and Head of GlaxoSmithKline Oncology R&D

Fred Appelbaum, MD, Director, Clinical Research, Fred Hutchinson Cancer Research Center

Peter Bach, MD, MAPP, Attending Physician & Member, Memorial Sloan-Kettering Cancer Center

Edward Benz, MD, Director, Harvard Cancer Center and President, Dana-Farber Cancer Institute

Monica Bertagnolli, MD, Professor of Surgery, Harvard University Medical School

Otis Brawley, MD, Chief Medical Officer and Executive Vice President, American Cancer Society

Michael Caligiuri, MD, Director, Ohio State University Cancer Center, past President, AACI

Renzo Canetta, MD, Vice President, Oncology Global Clinical Research, Bristol-Myers Squibb

Michaele Chamblee Christian, MD, Retired

William Dalton, PhD, MD, CEO, M2Gen, H. Lee Moffitt Cancer Center

Wendy Demark-Wahnefried, PhD, RD, Professor and Chair, University of Alabama, Birmingham

Robert Erwin, MS, President, Marti Nelson Cancer Foundation

Roy Herbst, MD, PhD, Chief of Medical Oncology, Yale Cancer Center

Thomas Kean, MPH, President and CEO, C-Change

Michelle LeBeau, PhD, Director, Comprehensive Cancer Center, University of Chicago

Douglas Lowy, MD, Deputy Director, Division of Basic Science, NCI

Daniel R. Masys, MD, Affiliate Professor, Biomedical Informatics, University of Washington

Martin Murphy, PhD, DMedSc, Chief Executive Officer, CEO Roundtable on Cancer

Brenda Nevidjon, RN, MSN, Professor, Duke University School of Nursing, past President, ONS

Steven Piantadosi, MD, PhD, Director, Samuel Oschin Comprehensive Cancer Institute

Lisa Richardson, MD, MPH, Associate Director, Division of Cancer Prevention and Control, CDC

Debasish Roychowdhury, MD, Senior Vice President, Global Oncology, Sanofi

Ya-Chen Tina Shih, PhD, Director, Program in the Economics of Cancer, University of Chicago

Ellen Sigal, PhD, Chairperson and Founder, Friends of Cancer Research

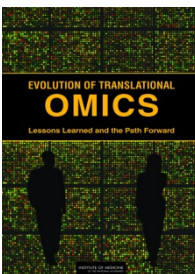
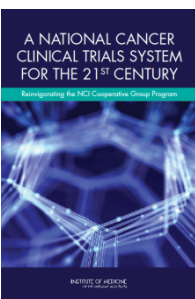
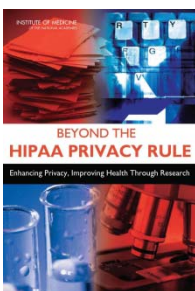
Steven Stein, MD, Senior Vice President, US Clinical Development & Medical Affairs, Novartis

John Wagner, MD, PhD, Vice President, Clinical Pharmacology, Merck Research Laboratories

Ralph Weichselbaum, MD, Chairman, Radiation and Cellular Oncology, University of Chicago

Janet Woodcock, MD, Director, Center for Drug Evaluation and Research, FDA

Forum Director: Sharyl Nass, PhD





INSTITUTE OF MEDICINE

OF THE NATIONAL ACADEMIES

Implementing a National Cancer Clinical Trials System for the 21st Century, Workshop #2

A Workshop hosted by the American Society of Clinical Oncology and the Institute of Medicine's National Cancer Policy Forum

Statement of Task

An ad hoc committee will plan and conduct two public workshops whose agendas will identify and examine ongoing activities to implement the recommendations put forth in the IOM consensus report, A National Cancer Clinical Trials System for the 21st Century. The first workshop was held in early 2011 and invited all stakeholders charged with making changes to the system (e.g., National Cancer Institute (NCI), Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), Centers for Medicare and Medicaid Services (CMS), NCI Cooperative Group Chairs, drug/biotech/device industry, patient advocates, investigators at academic and community sites, and private payers) to discuss what changes they planned to implement in response to the IOM recommendations. The second workshop to be held in early 2013 will reconvene key stakeholders to discuss progress made to date and to identify additional actions to take. Individually-authored summaries of the workshops will subsequently be prepared by a designated rapporteur.

Planning Committee Roster

Chair

Monica Marie Bertagnolli, M.D.

Professor of Surgery
Harvard University Medical School
Associate Surgeon
Dana-Farber Cancer Institute
Group Chair, Cancer and Leukemia Group B
Brigham and Women's Hospital

Amy P. Abernethy, M.D.

Associate Professor of Medicine
Division of Medical Oncology
Department of Medicine
Duke University School of Medicine
Director, Duke Cancer Care Research Program
Duke University Medical Center

Michael A. Caligiuri, M.D.

Director, Comprehensive Cancer Center
CEO, James Cancer Hospital & Solove Research Institute
Foundation Professor of Cancer Research
The Ohio State University

Renzo Canetta, M.D.

Vice President
Oncology Global Clinical Research
Bristol-Myers Squibb Company

Michaele Chamblee Christian, M.D.

Retired
(Former Director, CTEP, NCI)

James H. Doroshov, M.D.

Deputy Director for Clinical and Translational Research
National Cancer Institute

Patrick Gavin

President
Patrick Gavin R.Ph. Consulting LLC

Gregory H. Reaman, M.D.

Associate Director
Office of Hematology and Oncology Products, OND
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

George W. Sledge, Jr., M.D.

Professor of Medicine and Pathology and Distinguished
Professor
Indiana University Simone Cancer Center

Ralph R. Weichselbaum, M.D.

Daniel K. Ludwig Professor
Chairman
Department of Radiation and Cellular Oncology
Director
Ludwig Center for Metastasis Research
The University of Chicago Medical Center

Robin Zon, M.D., FACP

MHO Partner/VP
NICRC-CCOP Principal Investigator

NCPF Staff: Sharyl Nass, Pam Lighter

ASCO Staff: Suanna Bruinooge



Speakers, Panelists, and Moderators Roster

Jeffrey Abrams, MD

Associate Director
Cancer Therapy Evaluation Program
Division of Cancer Treatment and Diagnosis
National Cancer Institute

Peter C. Adamson, MD

Chair, Children's Oncology Group
Chief, Division of Clinical Pharmacology &
Therapeutics
The Children's Hospital of Philadelphia

Margaret Anderson

Executive Director
The Center for Accelerating Medical Solutions
FasterCures

Edward J. Benz, Jr., MD

Director, Harvard Cancer Center
Harvard School of Medicine
President, Dana-Farber Cancer Institute

Monica M. Bertagnolli, MD

Professor of Surgery,
Harvard University Medical School
Associate Surgeon, Dana-Farber Cancer Institute
Group Chair, Cancer and Leukemia Group B
Brigham and Women's Hospital

Charles D. Blanke, MD, FACP, FASCO, FRCPC

Chair-elect, SWOG
Knight Cancer Institute, OHSU
Professor of Medicine
Oregon Health & Science University

Renaud Capdeville, MD

Global Program Head Panobinostat,
Ruxolitinib & Midostaurin
Vice-President, Oncology Global Development
Novartis Pharma AG

Robert L. Comis, MD

President and Chairman, Coalition of Cancer
Cooperative Groups
Group Chair, Eastern Cooperative Oncology
Group; Professor of Medicine/Director,
Drexel University Clinical Trials Research Center

Barbara Conley, MD

Associate Director
Cancer Diagnosis Program
DCTD, NCI

Walter J. Curran, Jr., MD

NRG Group
Executive Director
Winship Cancer Institute of Emory University
Professor and Chair
Department of Radiation Oncology
Emory University School of Medicine

Robert B. Diasio, MD

William J. and Charles H. Mayo Professor
Director
Mayo Clinic Cancer Center

Joseph A. DiMasi, PhD

Director of Economic Analysis
Tufts Center for the Study of Drug Development
Tufts University, Boston, MA

Lori E. Dodd, PhD

Biostatistics Research Branch
National Institute of Allergies and
Infectious Diseases

James H. Doroshow, MD, FACP

Deputy Director for Clinical & Translational
Research
National Cancer Institute

Hans-Georg Eichler, MD, MSc

Senior Medical Officer
European Medicines Agency

Levi A. Garraway, MD, PhD

Principal Investigator
Associate Physician
Brigham and Women's Hospital
Assistant Professor of Medicine
Department of Medical Oncology
Dana-Farber Cancer Institute

Patrick Gavin, RPh

Chair, Patient Advocate Committee
Alliance for Clinical Trials in Oncology

Steven S. Grubbs, MD

Principal Investigator
Delaware Community Clinical Oncology Program
Medical Oncology Hematology Consultants, PA
Helen F. Graham Cancer Center

Sandra J. Horning, MD

Senior Vice President
Global Head of Clinical Development
for Hematology/Oncology Product Development
Genentech, Inc.

Robert Iannone, MD, MSCE

Executive Director, Section Head,
Clinical Oncology Research
Merck Research Laboratories

J. Milburn Jessup, MD

Chief, Diagnostics Evaluation Branch
National Cancer Institute

Richard Kaplan, MD

MRC Clinical Trials Unit, London
University College London Hospital
& NCRN Coordinating Centre
NIHR Cancer Research Network, Leeds

Worta McCaskill-Stevens, MD, MS

Chief, Community Oncology and Prevention Trials
Research Group
Head, Breast Cancer Prevention
Head, Minority-Based Community Clinical
Oncology Program
Division of Cancer Prevention
National Cancer Institute

Lisa M. McShane, PhD

National Cancer Institute
Biometric Research Branch, DCTD

John Mendelsohn, MD

Director, The Khalifa Institute
for Personalized Cancer Therapy
The University of Texas
MD Anderson Cancer Center

Vincent A. Miller, MD

Senior Vice President, Clinical Development
Foundation Medicine, Inc.

Richard Pazdur, MD

Office of Medical Products and Tobacco
Food and Drug Administration

Francesco Pignatti, MD

Head of Oncology, Hematology, Diagnostics
Safety and Efficacy Sector
European Medicines Agency

Nancy Roach

Fight Colorectal Cancer

Marc S. Sabatine, MD, MPH

Chairman, Thrombolysis in Myocardial Infarction
(TIMI) Study Group
Associate Professor of Medicine
Harvard Medical School
Associate Physician, Cardiovascular Medicine
Brigham and Women's Hospital

Richard L. Schilsky, MD, FASCO

Chief Medical Officer
American Society of Clinical Oncology

Rachel Sherman

Program Specialist
CDER/Office of Medical Policy
Food & Drug Administration

George W. Sledge, Jr., MD

Chief of Oncology
Department of Medicine
Stanford University

David B. Solit, MD

Associate Professor
Human Oncology and Pathogenesis Program
Department of Medicine
Memorial Sloan-Kettering Cancer Center

Robin Zon, MD, FACP

P.I., Northern Indiana CCOP
Michiana Hematology-Oncology, P.C.
Advanced Center for Cancer Care



Jeffrey S. Abrams, MD

Associate Director
Cancer Therapy Evaluation Program
Division of Cancer Treatment and Diagnosis
National Cancer Institute

In June 2007, Jeffrey S. Abrams, M.D., was selected to lead the Cancer Therapy Evaluation Program (CTEP) as acting associate director, following the retirement of Dr. Michaele Christian who had directed the program for 10 years. Dr. Abrams has been a member of CTEP since 1993, when he joined as a clinical research scientist to oversee the breast cancer treatment trials portfolio and participate in clinical trials at the Clinical Center and the National Naval Medical Center.

In 2004, Dr. Abrams was appointed chief of the Clinical Investigations Branch and in this position was responsible for the direction of the NCI Clinical Trials Cooperative Group program. This program performs nearly all the phase III cancer treatment trials sponsored by NCI and is the Institute's primary vehicle for conducting definitive, practice-changing clinical trials. He pioneered the Cancer Trials Support Unit, which has established a national network of physicians to participate in NCI-sponsored Phase III treatment trials.

As CTEP acting AD, Dr. Abrams supervises a staff that collectively oversees, reviews, and coordinates several hundred phase 1-3 cancer treatment trials in all varieties of cancer. Dr. Abrams' achievements have been recognized by five NIH Merit Awards and several Performance Awards. He is the author of over 70 original publications in the field of breast cancer and clinical trials, eight book chapters, and nine monographs. He is often called upon to speak at national and international meetings on breast cancer treatment and prevention as well as methods to enhance the performance of large clinical trials.

Dr. Abrams graduated from the medical school of Catholic University of Louvain, Belgium, in 1979. In 1982, he completed an internal medicine residency at St. Agnes Hospital in Baltimore, MD, and an oncology fellowship at the University of Maryland in 1984. A Fulbright scholarship took him to the Jules Bordet Institute in Belgium for a clinical research fellowship in oncology from 1984 to 1985. From 1985 to 1992, Dr. Abrams returned to the University of Maryland where he directed the Breast Cancer Evaluation Program and was Associate Professor of Medicine and Oncology.

Peter C. Adamson, MD

The Children's Hospital of Philadelphia

Dr. Peter C. Adamson is Chair of the Children's Oncology Group (COG), a National Cancer Institute (NCI) supported international consortium of more than 220 childhood centers that conducts clinical-translational research, including large-scale clinical trials, in children with cancer. He is Professor of Pediatrics and Pharmacology at the University of Pennsylvania School of Medicine and Chief of the Division of Clinical Pharmacology and Therapeutics at The Children's Hospital of Philadelphia. Dr. Adamson is Board Certified in Pediatric Hematology/Oncology and in Clinical Pharmacology. He is an internationally recognized leader in pediatric cancer drug development, having served until 2008 as Chair of the COG's Developmental Therapeutics Program. Prior to becoming Chair of the COG, Dr. Adamson served as Director for Clinical and Translational Research at The Children's Hospital of Philadelphia. His laboratory focuses on the clinical pharmacology of new drugs for childhood cancer.





Margaret Anderson

FasterCures

Margaret Anderson is executive director of *FasterCures/The Center for Accelerating Medical Solutions*, defining the organization's strategic priorities and positions on key issues, developing its programmatic portfolio, and managing its operations. Prior to her appointment as executive director, she was *FasterCures'* chief operating officer for five years. She has extensive experience in managing biomedical and public health initiatives and facilitating multi-sector collaborations.

She joined *FasterCures* after five years at the Academy for Educational Development (AED) in Washington. At AED, she was the deputy director and a team leader in the Center on AIDS & Community Health. Her responsibilities included financial and budget oversight; management of a team, projects, and staff; and strategic planning. She managed a portfolio that consisted of

grants and contracts from the Centers for Disease Control and Prevention, the Ford Foundation, and the Annie E. Casey Foundation.

Between 1995 and 1998, Anderson was program director for the Society for Women's Health Research. At the society, she managed grant-funded programs, including the startup planning for the multi-year campaign *Some Things Only a Woman Can Do* to increase women's awareness of and participation in clinical trials, the *Get Real: Straight Talk About Women's Health* campaign for college campuses to improve young women's health, the *Vive La Difference* video and facilitator's guide to provide information about sex-based biology, and the annual Scientific Advisory Meeting.

Prior to joining the society, Anderson was a health science analyst at the American Public Health Association (APHA) from 1992 to 1995, where she managed a programmatic portfolio on HIV/AIDS and other sexually transmitted diseases, infectious diseases, women's health, and public health infrastructure issues. At APHA, she staffed the AIDS Working Group, the Science Board, and the Long Term Care Task Force, and wrote a series of reports on emerging HIV/AIDS issues.

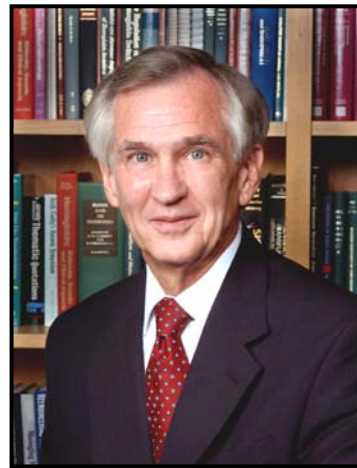
From 1987 to 1991, Anderson was an analyst and project director at the Congressional Office of Technology Assessment. As a staff member in the Biological Applications Program, she contributed to studies on the societal implications of genetic testing. She directed reports on genetic and medical testing in the workplace and contributed to reports on forensic uses of DNA testing, cystic fibrosis screening, and U.S. investment in biotechnology.

In 2011, the Clinical Research Forum recognized her with an award for leadership in public advocacy, a testament to the positive impact of her leadership and *FasterCures'* vital role in improving the medical research system. She is president of the Alliance for a Stronger FDA, co-chairs the eHealth Initiative's Council on Data and Research, and is a member of the National Center for Advancing Translational Sciences Advisory Council, the Cures Acceleration Network Review Board, the Prostate Cancer Foundation Government Affairs Committee, and the Institute of Medicine's Forum on Drug Discovery, Development and Translation. She served as a board member of the Council for American Medical Innovation and the Coalition for the Advancement of Medical Research.

Anderson holds a bachelor's degree from the University of Maryland and a master's degree in science, technology, and public policy from George Washington University's Elliott School of International Affairs.

Edward J. Benz, Jr., MD
Dana-Farber Cancer Institute

Dr. Benz is a pioneering academic hematologist whose early work, showed that messenger RNA defects caused a common congenital anemia, thalassemia. This was the first demonstration that molecular biology could be applied to the study of human diseases. He has subsequently achieved international renown for his research in the area of human red cell disorders, gene regulation, and membrane biology. He remains an active NIH funded investigator and clinician.



As an educator, Benz has been an active and teacher, mentor and throughout his career. He has trained over 50 mentees in his laboratory, many of whom now hold senior faculty or leadership positions in academia, industry or private practice. In recognition of his contributions as a mentor, he was named winner of the 2007 American Society of Hematology Mentoring Award in Basic Science.

Benz also has had an impact as a national leader, having served as president of the prestigious American Society of Clinical Investigation, past president of the American Society of Hematology as well as past president of the Association of American Cancer Institutes. He has co-edited the top-rated textbook in the field of hematology, and educated an entire generation about the application of molecular biology to clinical medicine through his lectures, review articles and book chapters. In November of 2000, Dr. Benz was appointed President of Dana-Farber Cancer Institute. He holds the Richard and Susan Smith Professorship in Medicine and is a Professor of Pediatrics and a Professor of Pathology at Harvard Medical School.



Monica M. Bertagnolli, MD
Dan-Farber Cancer Institute

Dr. Monica Bertagnolli is a Professor of Surgery at Harvard University Medical School, and an Associate Surgeon at Dana Farber Cancer Institute (DFCI) and Brigham and Women's Hospital (BWH). She is presently the Chief of the Division of Surgical Oncology at Dana Farber/Brigham and Women's Cancer Center (DF/BWCC). She is also a member of the Gastrointestinal Cancer and Sarcoma Disease Centers at DF/BWCC, where she collaborates with colleagues in

medical oncology, radiation oncology, and pathology to treat cancer patients in a tertiary care setting.

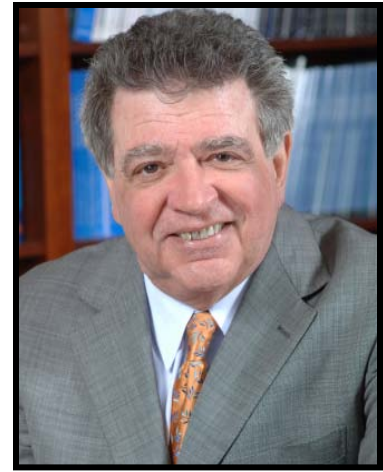
Dr. Bertagnolli maintains an active research laboratory whose work focuses upon understanding the role of the inflammatory response in epithelial tumor formation. In 1999, she extended her basic laboratory observations to the clinical trials setting as the lead Principal Investigator of the Adenoma Prevention with Celecoxib Trial. This pivotal study, reported in 2006, demonstrated dramatic suppression of colorectal adenomas with selective cyclooxygenase-2 inhibition, but also uncovered unanticipated cardiovascular toxicity with these agents. Dr. Bertagnolli was one of the organizing members of gastrointestinal correlative science initiatives within the NCI-funded Cancer Cooperative Groups, where she facilitated integration of tumor-specific molecular markers of treatment outcome into nation-wide clinical cancer treatment protocols. She has had numerous leadership roles in multi-institutional cancer clinical research consortia, and from 2010-2010 served as Group Chair of Cancer and Leukemia Group B (CALGB). Dr. Bertagnolli was recently elected to lead the Alliance for Clinical Trials in Oncology, a new NCI-funded cooperative group formed by merger of CALGB, the North Central Cancer Treatment Group, and the American College of Surgeons Oncology Group.



Renaud Capdeville, MD
Novartis Pharma AG

Renaud Capdeville is a French and Swiss national. He is currently working as Global Project Head, Vice-President of Oncology Global Development at Novartis Oncology (Basel, Switzerland). He is a pediatric hematologist graduated from the Lyon University Medical School (France), where he acted as head of the pediatric hematology outpatient clinic, with interest in bone marrow transplantation, acute leukemias and hemoglobinopathies. He moved in 1992 to Hoffmann-La Roche where he worked on the clinical development of interferon- α , rituximab and a pegylated G-CSF. He joined Novartis Oncology in 1997 where he first led the clinical development of

several compounds in phase 1. Thereafter, he took several positions in oncology clinical research dealing with several programs in oncology and hematology, including in particular the leadership of the team, which successfully developed and registered the Bcr-Abl tyrosine kinase inhibitor Glivec®/Gleevec® (imatinib) in chronic myeloid leukemia and gastro-intestinal stromal tumors. He is now focusing on hematologic malignancies, leading teams managing the development of a histone deacetylase inhibitor, a JAK2 inhibitor and a FLT3 inhibitor. He has been awarded the 2005 award for drug discovery from the Society for Medicines Research. He is a member of the French Society of Hematology, American Society of Hematology and American Society of Clinical Oncology.



Robert L. Comis, MD

President and Chairman, Coalition of Cancer Cooperative Groups;
Group Chair, Eastern Cooperative Oncology Group; and
Professor of Medicine/Director,
Drexel University Clinical Trials Research Center

A leader in international clinical trials research since 1977, Dr. Comis is a champion for patient access to cancer clinical trials, spearheading multiple initiatives to raise awareness about the pivotal role of cancer clinical trials in cancer prevention, detection and treatment. Dr. Comis also serves as President of the ECOG Research and Education Foundation; President of Alpha Oncology, a Coalition clinical research division; and Chairman, ITA Partners, an independent company that develops risk management strategies to improve medical and financial outcomes in catastrophic diseases.

Dr. Comis is a member, Board of Directors, of C-Change and the National Coalition for Cancer Research. He has served on the editorial boards of the *Journal of Clinical Oncology*, *Cancer Research* and *Clinical Cancer Research*. His previous board positions include the American Radium Society and the American Society of Clinical Oncology, where he served the society in a variety of other capacities including the Executive Committee, Chair of the Program, Nominating and Audit committees, and Steering Committee for the Clinical Trials Workshop. As Chair of the Group Chairs for the National Cancer Institute-funded Cooperative Group Program, he raised the international profile of the program and initiated efforts to strengthen and reposition it for the future. Today, his leadership in clinical research continues through frequent appearances as a subject expert to the United States Congress, Institute of Medicine, President's Cancer Panel, National Cancer Advisory Board and many other national and international organizations.

A graduate of Fordham University in New York City, Dr. Comis received his medical degree from SUNY Health Science Center School of Medicine in Syracuse, NY, where he also completed his medical internship and medical residency. He served as a Staff Associate at the National Cancer Institute, Bethesda, Maryland and completed a Medical Oncology Fellowship at The Sidney Farber Cancer Center at Harvard Medical School in Boston, MA. Dr. Comis is a Diplomat of the American Board of Internal Medicine, and a member of the American College of Physicians-American Society of Internal Medicine.

A leader in clinical research who, since 1977, Dr. Comis has championed clinical trials in the area of cancer treatment. Member, Board of Directors, C-Change and National Coalition for Cancer Research. Other board service: American Radium Society and the American Society of Clinical Oncology (served on Executive Committee and as Chair, Program, Nominating and Audit committees. Editorial boards: *Journal of Clinical Oncology*, *Cancer Research* and *Clinical Cancer Research*. Has authored 140+ articles, contributed to 20+ scientific and medical textbooks on cancer. Education and Professional: Fordham University; SUNY Syracuse (medical degree and residency); medical oncology fellow, Harvard Medical School. Staff Associate, NCI; various clinical practice/research leadership at Thomas Jefferson University Hospital, Temple University School of Medicine, Fox Chase Cancer Center, Allegheny Cancer Center. Diplomat, American Board of Internal Medicine.

Barbara A. Conley, MD

Associate Director, Cancer Diagnosis Program
Division of Cancer Treatment and Diagnosis
National Cancer Institute

Barbara A. Conley, MD, is Associate Director of the Cancer Diagnosis Program (CDP) in the Division of Cancer Treatment and Diagnosis (DCTD), National Cancer Institute. She is also a member of the Division's experimental therapeutics clinic. Her previous positions at the Institute included Chief of the Cancer Diagnosis Program Diagnostics Research Branch, Senior Investigator in the Cancer Therapy and Evaluation Program Clinical Investigations Branch, and Head, Aerodigestive Diseases in the intramural medicine branch. Immediately prior to her current appointment at DCTD, she was Chief of the Cancer Diagnosis Program Diagnostics Research Branch was Chief of the Division of Hematology/Oncology at Michigan State University (MSU). She was a member of the faculty at the University of Maryland from 1987-1997. Dr. Conley has been the principal investigator on several NCI grants or contracts.



Dr. Conley holds an undergraduate degree from the University of Michigan and received her MD from Michigan State University. She is board-certified in Internal Medicine and Medical Oncology, and has research interests in diagnostic markers, drug development, and cancers of the aerodigestive tract. She has published extensively in many journals, and serves on the editorial board of several professional publications.

Walter J Curran, Jr. MD

Group Chairman, Radiation Therapy Oncology Group
Executive Director, Winship Cancer Institute of Emory University
Lawrence W. Davis Professor and Chairman of Radiation
Oncology



Walter J. Curran serves as Executive Director of the Winship Cancer Institute of Emory University and the Lawrence W. Davis Professor and Chair of Emory's Department of Radiation Oncology. He also serves as Group Chairman and Principal Investigator of the Radiation Therapy Oncology Group (RTOG), a National Cancer Institute (NCI)-funded cooperative group, a position he has held since 1997. Beginning in 2014, he will serve as one of three inaugural Group Chairs and Principal Investigators of NRG Oncology, an NCI-supported cancer cooperative group.

Dr. Curran is a Georgia Cancer Coalition Distinguished Cancer Scholar and has been a principal investigator on over a dozen NCI-supported grants. He is considered an international expert in the management of patients with locally advanced lung cancer and malignant brain tumors. He has led several landmark clinical and translational trials in both areas and is responsible for defining a universally adopted staging system for patients with malignant glioma. He has authored or co-authored more than five hundred abstracts and scholarly papers. He has been chairman or co-chairman of more than 40 clinical trials and a reviewer for twelve national/international journals. He serves as the Founding Secretary/Treasurer of the Coalition of Cancer Cooperative Groups and a Board Member of the Georgia Center for Oncology Research and Education (Georgia CORE). Dr. Curran is the only individual currently serving as director of an NCI-designated cancer center and as group chairman of an NCI-supported cancer cooperative group.

Dr. Curran is a Fellow in the American College of Radiology and has been awarded honorary memberships in the European Society of Therapeutic Radiology and Oncology and the Canadian Association of Radiation Oncology.

Dr. Curran graduated cum laude from Dartmouth College, received his MD degree from the Medical College of Georgia, and is a Board Certified Radiation Oncologist. He completed his residency in the Department of Radiation Therapy at the University of Pennsylvania Medical Center and his internship in internal medicine at Presbyterian University of Pennsylvania Medical Center in Philadelphia.

Robert B. Diasio, M.D.

Dr. Diasio became the Director of the Mayo Clinic Cancer Center on September 1, 2006. At Mayo Clinic he also holds the position of William J. and Charles H. Mayo Professor, as well as Consultant and Professor of Molecular Pharmacology & Experimental Therapeutics and Oncology. Dr. Diasio received his undergraduate degree from the University of Rochester and subsequently the M.D. degree from Yale University School of Medicine in 1971. Following training in internal medicine at Strong Memorial Hospital in Rochester, NY, Dr. Diasio was a Fellow on the Medicine Branch at the National Cancer Institute in Medical Oncology and later in Clinical Pharmacology. From 1976 until 1984, Dr. Diasio served initially as an Assistant Professor and then subsequently as an Associate Professor in both the Departments of Medicine and Pharmacology at the Medical College of Virginia. In 1984, he moved to Birmingham, AL, where he was appointed Professor in the Departments of Medicine and Pharmacology, as well as Newman H. Waters Chair and Director of the Division of Clinical Pharmacology at the University of Alabama School of Medicine. In 1989, he was appointed Chair of the Department of Pharmacology and Toxicology and in 1997 Associate Director for Basic Sciences of the UAB Comprehensive Cancer Center.



Dr. Diasio is the author of more than two hundred manuscripts and invited reviews. He has authored chapters in several major medical textbooks including the 19th, 20th, 21st, 22nd, 23rd, and 24th editions of the Cecil Textbook of Medicine, 9th edition of Goodman & Gilman's Textbook of Pharmacology - The Pharmacological Basis of Therapeutics, and the 6th and 7th editions of Holland and Frei Cancer Medicine. He has been an invited speaker at numerous national and international meetings on cancer pharmacology/oncology and was the principal organizer and chair of the 2005 AACR-NCI-EORTC Molecular Targets and Cancer Therapeutics Meeting. Dr. Diasio has been the recipient of continuous R01 funding from the National Cancer Institute since 1978, and is the recipient of the highly competitive NCI MERIT award. He has served in the past on several editorial boards, including Cancer Research, Journal of Clinical Oncology, Clinical Cancer Research, and Clinical Colorectal Cancer. He has also been an associate editor of Clinical Pharmacology and Therapeutics. Dr. Diasio has been a member of the NIH Experimental Therapeutics I Study Section and the NCI Cancer Center Support Group Study Section (Subcommittee A), which he chaired for two years. In 2008, he was appointed to the Board of Scientific Advisors of the NCI, which advises the NCI Director on all aspects of the extramural programs, including present and future scientific directions. In 2009, he was elected to the Board of Directors of the Association of American Cancer Institutes. He is an active member of several academic societies, including the American Society of Clinical Oncology, the American Association for Cancer Research, and the American Society for Clinical Pharmacology and Therapeutics. In 1989, he was elected as a member of the American Society for Clinical Investigation and in 1998 he was elected to the American Association of Physicians - two of the nation's oldest and most respected medical honor societies. In 2009, he was elected a Fellow of the American Association for the Advancement of Science. His clinical interest continues to be in the area of gastrointestinal oncology, with particular interest in the predictive and prognostic role of genomic biomarkers. His basic research interest has focused mainly on the area of cancer pharmacogenetics/pharmacogenomics. Dr. Diasio has made important contributions in initially characterizing the pharmacogenetic syndrome of dihydropyrimidine dehydrogenase (DPD) deficiency and subsequently developing genomic tests to predict DPD deficiency.

Robert B. Diasio, M.D.
William J. and Charles H. Mayo Professor
Director, Mayo Clinic Cancer Center
Consultant and Professor of Molecular Pharmacology
& Experimental Therapeutics and Oncology

PHONE: 507-266-4997
FAX: 507-538-6290
EMAIL: diasio.robert@mayo.edu
Mayo Clinic, 200 First Street SW
Rochester, MN 55905

Joseph A. DiMasi, PhD
Tufts University, Boston, MA

Dr. DiMasi is Director of Economic Analysis at the Tufts Center for the Study of Drug Development. The Center is an independent non-profit multidisciplinary research organization affiliated with Tufts University that is committed to the exploration of scientific, economic, legal, and public policy issues related to pharmaceutical and biotechnology research, development, and regulation throughout the world. Dr. DiMasi has served on the editorial boards of the *Drug Information Journal*, the *Journal of Research in Pharmaceutical Economics*, and the *Journal of Pharmaceutical Finance, Economics & Policy*.

He has published in a wide variety of economic, medical, and scientific journals, and has presented his research at numerous professional and industry conferences. Dr. DiMasi testified before the United States Congress in hearings leading up to the FDA Modernization Act of 1997 and reauthorization of the Prescription Drug User Fee Act.



James H. Doroshow, MD, FACP
National Cancer Institute

Dr. James H. Doroshow became the Deputy Director for Clinical and Translational Research of the National Cancer Institute in 2011, where he served as the Director of the Division of Cancer Treatment and Diagnosis from 2004 to 2011. He continues to pursue his own research program as a Senior Investigator in the Laboratory of Molecular Pharmacology of the NCI's intramural Center for Cancer Research. From 1983 to 2004, Dr. Doroshow was the Chairman of the City of Hope Comprehensive Cancer Center's Department of Medical Oncology and Therapeutics Research. From the time of his first research grant in 1980, Dr. Doroshow was continuously funded by the NCI until he moved to the NIH in 2004.



He is the author of over 350 full-length publications in the areas of anthracycline antibiotic molecular pharmacology, the role of oxidant stress in tumor cell signal transduction, and novel therapeutic approaches to solid tumors. Dr. Doroshow served from 1990-1992 as Chairman of the National Institutes of Health Experimental Therapeutics II Study Section, from 1995-2001 as a member of the Subspecialty Board on Medical Oncology of the American Board of Internal Medicine, from 1999-2000 as Chairman of NCI's Scientific Review Group A-Cancer Centers, and from 2004-2007 as a member of the FDA's Oncologic Drugs Advisory Committee. Dr. Doroshow chaired the NCI's Clinical Trials Working Group from 2004-2005 that developed a comprehensive set of initiatives to restructure the national cancer clinical trials enterprise; he also chaired the NCI's Operational Efficiency Working Group from 2008-2010 that developed standards to significantly shorten the timeline for cancer clinical trial implementation across all of NCI's clinical trials platforms. He is currently a member of the Forum on Drug Discovery, Development, and Translation of the Institute of Medicine of the National Academies of Science.

Dr. Doroshow received his bachelor's degree, magna cum laude, from Harvard College in 1969 and his medical degree alpha omega alpha from Harvard Medical School in 1973. After completing an internship and residency in Internal Medicine at the Massachusetts General Hospital in Boston, he spent three years (1975-78) performing his fellowship in Medical Oncology in the Medicine and Clinical Pharmacology Branches of the NCI.

Email: doroshoj@mail.nih.gov



Hans-Georg Eichler, MD, MSc
European Medicines Agency

Hans-Georg Eichler, M.D., M.Sc., is the Senior Medical Officer at the European Medicines Agency in London, United Kingdom, where he is responsible for coordinating activities between the Agency's scientific committees and giving advice on scientific and public health issues. From January until December 2011, Dr. Eichler was the Robert E. Wilhelm fellow at the Massachusetts Institute of Technology's Center for International Studies, participating in a joint research project under the MIT's NEWDIGS initiative. He divided his time between the MIT and the EMA in London.

Prior to joining the European Medicines Agency, Dr. Eichler was at the Medical University of Vienna in Austria for 15 years. He was vice-rector for Research and International Relations since 2003, and professor and chair of the Department of Clinical Pharmacology since 1992. His other previous positions include president of the Vienna School of Clinical Research and co-chair of the Committee on Reimbursement of Drugs of the Austrian Social Security Association. His industry experience includes time spent at Ciba-Geigy Research Labs, U.K., and Outcomes Research at Merck & Co., in New Jersey.

Dr. Eichler graduated with an M.D. from Vienna University Medical School and a Master of Science degree in Toxicology from the University of Surrey in Guildford, U.K. He trained in internal medicine and clinical pharmacology at the Vienna University Hospital as well as at Stanford University.

Levi Garraway, MD, PhD
Dana-Farber Cancer Institute



Dr. Levi Garraway is an Associate Professor of Medicine in the Department of Medical Oncology at the Dana-Farber Cancer Institute, Harvard Medical School and a Senior Associate Member of the Broad Institute. Dr. Garraway received his A.B. in Biochemical Sciences from Harvard College in 1990, and his M.D. and Ph.D. degrees from Harvard Medical School in 1999. Thereafter, he completed his internship and residency in Internal Medicine at the Massachusetts General Hospital, where he also served as Medical Chief Resident in 2003. He received fellowship training in Medical Oncology at the Dana-Farber Cancer Institute. He leads an investigative team in cancer genomics at Dana-Farber and the Broad Institute, and is Co-Leader of the Cancer Genetics Program at the Dana-Farber/Harvard Cancer Center.

Dr. Garraway has made seminal research contributions in cancer genomics, drug resistance, and genomics-driven (or “personalized”) cancer medicine. He published the first genome sequencing studies of aggressive primary prostate cancer, and has led other major sequencing initiatives in prostate cancer, melanoma and head/neck cancers. This work identified multiple new cancer genes and uncovered mechanisms by which complex rearrangements arise. At the Broad Institute, he also leads the Cancer Cell Line Encyclopedia, a collaboration with Novartis that involves a genomic and pharmacological study of ~1000 human cancer cell lines to characterize sensitivity and resistance to anticancer agents.

Dr. Garraway also described the first high-throughput adaptation of genomics technology to profile human tumors for hundreds of “actionable” cancer gene mutations. This provided a basis for tumor mutation profiling as a possible means to stratify cancer patients for clinical trial enrollment and optimal therapeutic choices. He also demonstrated the promise of massively parallel sequencing as a clinical tumor genomic profiling approach. This research has inspired personalized medicine initiatives at many cancer centers worldwide.

Dr. Garraway’s scholarly work has consistently been published in the world’s top scientific journals. He has been the recipient of several awards and honors, including the Minority Scholar Award from the American Association of Cancer Research, the Partners in Excellence Award, and the Career Award in the Biomedical Sciences from the Burroughs-Wellcome Fund. In the fall of 2007, Dr. Garraway was awarded one of the first prestigious New Innovator Awards from the National Institutes of Health. In 2009, Dr. Garraway was inducted into the American Society for Clinical Investigation.



Patrick Gavin, RPh
Chair, Patient Advocate Committee
Alliance for Clinical Trials in Oncology

Pat is a cancer survivor. In 2007, Pat was diagnosed with stage 4 pharyngeal cancer and was not given a very promising prognosis for survival. His oncologist recommended that a cancer clinical trial be incorporated into his treatment. Pat was the recipient of a miracle and was declared cancer-free in December 2007. In December 2008, Pat was diagnosed with malignant melanoma, which was successfully treated with surgery.

Pat is Chair of the Patient Advocate Committee for the Alliance for Clinical Trials in Oncology. He is Co-chair of the Patient Advocate Committee for the Midwest Melanoma Partnership. He is Chair of the Patient Advocate Committee and member of the Executive Board for the Grand Rapids Clinical Oncology program. He is a member of the FDA Patient Representative Program. Pat serves as a Program Mentor working with newly diagnosed cancer patients at Gilda's Club of Grand Rapids. Pat is enjoying his retirement with his wife of 42 years (Mary). They have four adult daughters and seven grandchildren.

Stephen S. Grubbs, MD
Helen F Graham Cancer Center

Dr. Grubbs has been for the past twenty nine years a private practicing Medical Oncologist in Newark, Delaware at the Helen F Graham Cancer Center. He is a graduate of the Thomas Jefferson University Medical School with post graduate training in Internal Medicine at the Medical Center of Delaware and Hematology/Oncology at the Dartmouth Hitchcock Medical Center. He serves as Principal Investigator of the Delaware Christiana Care CCOP, Board member and executive committee member of the Alliance Cooperative research group, and State of Delaware Cancer Consortium Council member and Early Detection and Prevention Committee Chair. He served as a member of the Institute of Medicine's Committee on Cancer Clinical Trials and the National Cancer Institute (NCI) Cooperative Group System. He also served on the American Society of Clinical Oncology (ASCO) Clinical Trials Committee, Exemplary Trials Site Subcommittee, and Clinical Trials Workshop. He currently is a member of the ASCO Government Relations Committee and the ASCO Board of Directors. He is on the faculty of Thomas Jefferson Medical School as a Clinical Assistant Professor of Medicine. Dr Grubbs is a past member of the NCI Clinical Trials Advisory Committee and is past co-chair of the Clinical Trials Subcommittee of the NCI Community Cancer Centers Program (NCCCP). He is the recipient of the 2007 Association of Community Cancer Centers David King Community Clinical Scientist Award. His practice, Medical Oncology Hematology Consultants, PA, was honored as a recipient of the 2008 ASCO Clinical Trials Participation Award.





Sandra Horning, MD

Senior Vice President
Global Head of Clinical Development
for Hematology/Oncology Product Development
Genentech

Dr. Sandra Horning is responsible for leading the medical and scientific strategies for the global clinical development portfolio in oncology and leading and managing the global team of oncology clinical scientists. Since Dr. Horning joined Genentech/Roche in late 2009, *Zelboraf*, *Erivedge* and *Perjeta* have received new marketing approvals and extensions to additional indications were approved for *Rituxan*, *Herceptin*, and *Avastin*. Dr. Horning is an internationally recognized oncologist who has made significant

contributions to the classification, understanding and treatment of lymphoma. She is a tenured Emeritus Professor of Medicine (Oncology) at Stanford University School of Medicine and joined Genentech/Roche after more than 25 years as a practicing oncologist, investigator and professor at Stanford University. Dr. Horning has also held many significant leadership roles within the oncology community, most notably as President of ASCO in 2005-2006.

Robert Iannone, MD, MSCE

Executive Director, Section Head,
Clinical Oncology Research
Merck Research Laboratories



I received a BS degree in Biology from The Catholic University of America in 1989 with Summa Cum Laude and Phi Beta Kappa honors and subsequently graduated from Yale University School of Medicine in 1994, where I was elected to Alpha Omega Alpha. My MD thesis work was on human T cell leukemia virus under the mentorship of Dr. Clarence J. Gibbs (NINDS, NIH). After internship and residency in Pediatrics at Johns Hopkins Hospital, where I also spent an additional year as Chief Resident, I completed a fellowship in Pediatric Hematology and Oncology in 2001 and currently maintain board certification in Pediatrics and Pediatric Hematology-Oncology. My research during fellowship was under Dr. Ephraim Fuchs in the Division of Cancer Immunology and Hematopoiesis at Kimmel Cancer Center at Johns Hopkins. This research on immune tolerance in bone marrow transplantation led to a novel clinical bone marrow transplant trial in patients with sickle cell disease.

I was appointed to the standing faculty of the University of Pennsylvania Medical School in 2001 at the rank of Assistant Professor. While on faculty, I was an attending physician in Pediatric Oncology with an emphasis in pediatric bone marrow transplantation at Children's Hospital of Philadelphia (CHOP). My NIH-funded research interest involved translational clinical trials in bone marrow transplantation related to sickle cell disease, inborn errors of metabolism and hematologic malignancies. During that time, I enrolled in the Master's Program in Clinical Epidemiology (MSCE) at the Center for Clinical Epidemiology and Biostatistics at the University of Pennsylvania Medical School. I am currently an Adjunct Assistant Professor of Pediatrics and regularly attend Pediatric Oncology Clinic.

I was recruited to Merck Clinical Pharmacology in December 2004 as an Associate Director and was promoted to Director in November, 2006. While in Clinical Pharmacology, I was directly involved in a number of drug development programs across several of therapeutic areas, including neuroscience, oncology, hematology, biologics, respiratory and cardiovascular. I was the program chair for two of these teams and, during that time, completed more than 20 phase I clinical trials, including 2 phase Ib proof-of-concept and 3 PET imaging studies. I also contributed to phase II studies and supported numerous regulatory interactions.

In April of 2008 I was promoted to Senior Director and Site Head for Experimental Medicine in Upper Gwynedd, where I oversaw the research groups for Experimental Medicine Oncology, Neuroscience and RNA Therapeutics. This involved direct oversight for clinical translational research protocol development and clinical trial execution. During 2010, I lead the integration effort in Early Stage Development after the merger with Schering-Plough.

As of March 1, 2011 I was appointed Section Head in Clinical Oncology with responsibility for early and translational clinical development, including cancer immunotherapies. I continue to serve as co-Chair for the Pediatric Development Committee.



J. Milburn Jessup, MD

Chief, Diagnostics Evaluation Branch
National Cancer Institute

Dr. J. Milburn Jessup is a surgical oncologist who joined the Cancer Diagnosis Program and NCI as Chief of the Diagnostics Evaluation Branch. This branch facilitates the development of discovery-based markers into in vitro diagnostics that are used in clinical research and trials. He works with the FDA to standardize assays as well as to assist investigators in navigating the requirements for Investigational Device Exemption. In 25 years of practice he

focused on the multidisciplinary treatment of GI and breast cancer as well as melanoma and soft tissue and skeletal sarcomas in several different academic settings. Concurrently he led a research effort studying the mechanisms that underpin hepatic metastasis by human colorectal carcinoma and identified two distinct roles for the marker Carcinoembryonic Antigen in modulating inflammatory responses and promoting metastasis. He is also an Adjunct Investigator in the Laboratory of Experimental Carcinogenesis where his research targets a novel embryonic retrogene that drives cancer stem cells in metastatic human colorectal carcinoma.



Wortia McCaskill-Stevens, MD
NCI Division of Cancer Prevention

Dr. Wortia McCaskill-Stevens is a medical oncologist and Chief of the Community Clinical Oncology Program and program director for the Minority-Based Community Clinical Oncology Program at the National Cancer Institute's Division of Cancer Prevention. After attending Washington University in St. Louis and the American College of Switzerland as an undergraduate, she completed medical school and an internal medicine residency at Georgetown University Medical School followed by a medical oncology fellowship at the Mayo Clinic (Rochester, MN). In 1991, she joined the faculty of

Indiana University Cancer Center as Co- Director of the Breast Care and Research Center at Indiana University's Cancer Center.

After arriving at the NCI in 1998, she became the program director for the "The Study of Tamoxifen and Raloxifene (STAR)," and assumed responsibilities for breast cancer prevention with the Community Oncology and Prevention Trials Research Group. She chaired the September 2009 NIH State-of-the-Science Conference on DCIC and is a member of the Early Breast Cancer Clinical Trialist Group (Oxford, UK); the NCI Premalignancy Research Program Steering Committee which oversees the Breast Cancer Research Stamp Funds; and the NCI Breast Cancer Steering Committee. She is currently the chair of the Women in Cancer Research Council of the American Association of Cancer Research. She has served on the NCCCP Advisory Committee since 2007. Her honors and awards include: Sarah Stewart Award for Leadership in Medicine, 1985; Kaiser Family Fund Award for Excellence in Academic Achievement and Leadership in Medicine; a member of the Omega Alpha Medical Honor Society; the NIH Director's Award for Clinical Trials in the NCI Community Cancer Centers Program; and, the NCI Merit Award for breast cancer prevention.

Prior to medical school, Dr. McCaskill-Stevens was a medical editor for Marcel Dekker and the Alan Guttmacher Institute in New York City.

Lisa M. McShane, PhD
National Cancer Institute

Dr. McShane is a senior Mathematical Statistician in the Biometric Research Branch in the Division of Cancer Treatment and Diagnosis (DCTD) at the National Cancer Institute (NCI). She earned her Ph.D. in Statistics from Cornell University. Since 1996 Dr. McShane has worked closely with the NCI Cancer Diagnosis Program and Cancer Therapy Evaluation Program on statistical matters relating to development and use of tumor markers for prognosis, prediction, and disease-monitoring. She is a member of the NCI Program for the Assessment of Clinical Cancer Tests (PACCT) Strategy Group.



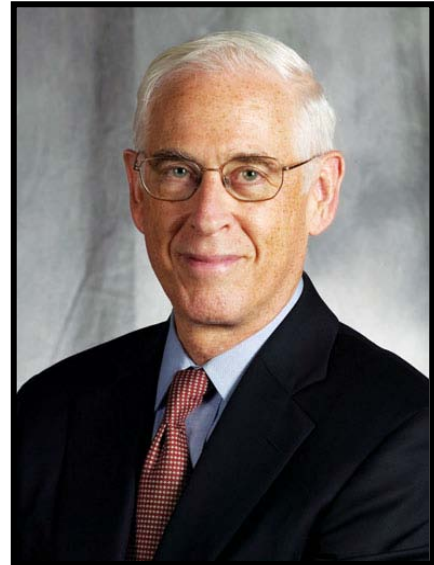
Dr. McShane's statistical interests and publications have covered a diverse set of topics including statistical methods for the analysis of high-dimensional genomic data, multiple comparisons methods, surrogate endpoints, measurement error adjustment methods, laboratory quality control and assay reproducibility assessment, and spatial statistics. She has also been statistical coauthor on many biomedical papers covering topics including genomic studies in breast, colon, and lung cancer, colorectal epithelial cell proliferation, serum markers in prostate cancer, molecular characterization of ovarian tumors, Parkinson's disease, motor control disorders, stroke, and Creutzfeldt-Jakob disease. She is a co-author of the book *Design and Analysis of DNA Microarray Investigations*.

Dr. McShane is a frequent speaker at national and international statistics meetings and oncology meetings. She has presented numerous statistical lectures, didactic lectures, and discussions on the design and analysis of biomarker studies, including gene expression microarray studies. In 2008, Dr. McShane was awarded a prestigious NIH Director's Award in recognition of her work on trial designs to assess predictive biomarkers for their utility in therapeutic decision making for cancer patients.

John Mendelsohn, MD

Khalifa Institute for Personalized Cancer Therapy
The University of Texas MD Anderson Cancer Center
Chair, National Cancer Policy Forum

John Mendelsohn, MD, was president of The University of Texas MD Anderson Cancer Center in Houston from 1996 until 2011. Under his direction, MD Anderson assumed a leadership role in translational and clinical cancer research, and was named the top cancer hospital in the United States eight of the past ten years in U.S. News & World Report's "America's Best Hospitals" survey. Currently, Dr. Mendelsohn is the director of the Khalifa Institute for Personalized Cancer Therapy at MD Anderson. Previously, he chaired the Department of Medicine at Memorial Sloan-Kettering Cancer Center, and he began his career at UCSD in La Jolla, where he was founding director of its cancer center. Dr. Mendelsohn and his collaborators pioneered the concept of therapy targeting the products of genes that cause cancer. His team's innovative research on inhibition of the EGF receptor tyrosine kinase led to production and investigation of monoclonal antibody C225 (Erbix), which is FDA-approved for colon cancer and head and neck cancer. He served as founding editor-in-chief of Clinical Cancer Research, has published over 250 articles and reviews, and has received many prizes and awards. Dr. Mendelsohn is chair of the Institute of Medicine's National Cancer Policy Forum. He has directed postdoctoral programs which trained many dozens of medical oncologists and scientists. He is an active board member of several Houston-area organizations, including Houston Grand Opera, the BioHouston and the Center for Houston's Future.





Vincent A. Miller, MD

Senior Vice President, Clinical Development
Foundation Medicine

Dr. Miller joined Foundation Medicine in October 2011 after nearly 20 years at Memorial Sloan-Kettering Cancer Center where he served as an Attending Physician. His work in clinical and translational research in lung cancer culminated in observations and collaborative efforts critical to identification of EGFR sensitizing and resistance mutations. He is considered a world's expert in lung cancer and clinical trial design and interpretation. Dr. Miller has authored and co-authored numerous abstracts, reviews, and peer-reviewed articles, which have appeared in such journals as Proceedings of the National Academy of Science USA, Cancer Research, Clinical Cancer Research and the Journal of Clinical Oncology.

Dr. Miller has received the prestigious American Cancer Society Clinical Oncology Career Development Award and the Louise and Allston Boyer Award, and was most recently recognized by the Bonnie J. Addario Lung Cancer Foundation with the 2011 Thierry Jahan "A Breath Away from the Cure" award for his efforts and contributions to lung cancer research. He is a Fellow of the American College of Physicians and a Member of the American Association for Cancer Research, the American Society of Clinical Oncology, and the International Association for the Study of Lung Cancer.

Dr. Miller, a National Merit Scholar, received a BA in mathematics at the University of Pennsylvania, where he was honored as a Benjamin Franklin Scholar, and an MD at the University of Medicine and Dentistry of New Jersey in Newark. He completed an internship and residency, and then served as Chief Medical Resident in Internal Medicine at Thomas Jefferson University Hospital in Philadelphia, and subsequently a fellowship in Medical Oncology at Memorial Sloan-Kettering Cancer Center.



Francesco Pignatti, MD
European Medicines Agency

Francesco Pignatti graduated as medical doctor at the University of Rome La Sapienza.

In 1995 he became research fellow at the EORTC Data Center, Brussels, Belgium, where he was involved in numerous activities including clinical trial design, conduct, analysis, and reporting. In 1997 he became Medical Advisor for the Gastrointestinal Tract Cancer Cooperative Group, and Brain Tumor Cooperative Group.

In 1997 he obtained a Master of Science degree in Biostatistics from the University of Limbourg, Belgium.

In 1999 he joined the European Medicines Agency (EMA) in London. Since 2009 he holds the position of Head of Oncology, Haematology and Diagnostics in the Unit for Human Medicines Development and Evaluation.

RICHARD L. SCHILSKY, M.D., FASCO
Chief Medical Officer
American Society of Clinical Oncology
Professor Emeritus
University of Chicago



Dr. Schilsky earned his M.D. at the University of Chicago Pritzker School of Medicine in 1975. Following a residency in Internal Medicine at the University of Texas Southwestern Medical Center and Parkland Memorial Hospital, he received training in Medical Oncology and Clinical Pharmacology at the National Cancer Institute from 1977 to 1981. He then served as Assistant Professor of Medicine at the University of Missouri-Columbia School of Medicine from 1981-1984 when he returned to the University of Chicago. At the University of Chicago, Dr. Schilsky rose to the rank of Professor of Medicine (tenured) and served as Director of the University of Chicago Cancer Research Center (1991-99), as Associate Dean for Clinical Research (1999-2007) and as Chief of the Section of Hematology-Oncology (2009-2012). From 1995-2010, Dr. Schilsky also served as Chairman of the Cancer and Leukemia Group B, an NCI-sponsored national cancer clinical trials group.

An international expert in gastrointestinal malignancies and cancer pharmacology, he has served on a number of peer review and advisory committees for the NCI including as a member and chair of the NCI Board of Scientific Advisors and as a member of the Clinical and Translational Research Advisory Committee. Dr. Schilsky also served as a member and chair of the Oncologic Drugs Advisory Committee of the Food and Drug Administration. Dr. Schilsky has served as a member of the Board of Directors of the American Society of Clinical Oncology (ASCO) and of the Conquer Cancer Foundation of ASCO and as ASCO President 2008-2009. Effective February 28, 2013, Dr. Schilsky will begin his tenure as Chief Medical Officer of ASCO.



Nancy Roach

Fight Colorectal Cancer

Nancy Roach founded Fight Colorectal Cancer (Fight CRC) in 2005, nine years after her mother-in-law was diagnosed with colorectal cancer. Recognizing the need for an advocacy organization, she established Fight CRC to provide focus, infrastructure and support for colorectal cancer survivors, caregivers and those touched by the disease. Since then, Ms. Roach has played a vital role in championing the need for a cure for colon and rectal cancer, through screening, awareness and research.

Her efforts as an advocate have supported education and support for patients as well as the research community. Her leadership and passion has fostered a community of advocates supporting state and federal policies that have led to increased colorectal cancer research opportunities across the country.

Over the last four years, Fight Colorectal Cancer has directed more than \$250,000 in research funding to young investigators. Ms. Roach currently serves as the chair of the Board of Directors and serves on the National Cancer Institute (NCI) Board of Scientific Counselors and the Clinical Trial and Translational Research Advisory Committee. She is on the Executive Committee on the Clinical Trials Transformation Initiative, an FDA-Duke public-private partnership, and is a past chair of its finance committee. She has been involved with cooperative groups and SPORES, and currently serves on the NCI Colon Task force. She served on the Department of Defense Congressionally Directed Medical Research Program Integration Panel in 2010, the first year the colorectal cancer research was funded by the program. She is a past chair of the NCI Patient Advocate Steering Committee, and received the NCI Director's Service Award when she stepped down. She has also received the Preventing Colorectal Cancer Champion Award and the Colon Cancer Alliance Sapphire Visionary Award in recognition of her efforts on behalf of patients. She has spoken on behalf of patients at meetings such as the American Association for Cancer Research, the Friends of Cancer Research/Brookings Institute Conference on Clinical Research, and the Oxford University-Duke University-McMaster University Sensible Guidelines for Clinical Trials.

Marc S. Sabatine, MD, MPH
Brigham and Women's Hospital

Marc S. Sabatine, MD, MPH is the Chairman of the Thrombolysis in Myocardial Infarction (TIMI) Study Group, an Associate Physician in Cardiovascular Medicine at Brigham and Women's Hospital (BWH), and an Associate Professor of Medicine at Harvard Medical School (HMS).

Dr. Sabatine graduated *magna cum laude* from Harvard College and received his medical degree *magna cum laude* from HMS. He did his Internal Medicine residency, Chief Residency, and Cardiology clinical fellowship at the Massachusetts General Hospital (MGH). He received a Master of Public Health degree from the Harvard School of Public Health. Dr. Sabatine is board certified in Internal Medicine and Cardiology and attends in the coronary care units at both BWH & MGH. He is a Fellow of the American Heart Association, the American College of Cardiology, and the European Society of Cardiology.



As Chairman of the TIMI Study Group, Dr. Sabatine leads an Academic Research Organization that includes over a dozen staff cardiologists and whose mission statement is to advance the knowledge and care of patients suffering from cardiovascular disease and its risk factors by performing clinical trials. To that end, Dr. Sabatine has led several large-scale, international, randomized controlled trials of novel pharmacotherapies. He was a pioneer in the multimarker approach to risk stratification and has several NIH grants supporting the application of proteomics and metabolomics for discovery of novel biomarkers. He has a long-standing interest in pharmacogenetics and has made seminal observations on the impact of genetic polymorphisms on the pharmacologic and clinical response to antiplatelet therapy.

Dr. Sabatine has authored over 130 original research, peer-reviewed articles including in the *New England Journal of Medicine*, *JAMA*, and the *Lancet*. Dr. Sabatine has given Cardiology or Medical Grand Rounds at the top academic centers around the world and has authored numerous review articles and book chapters. He is the recipient of multiple honors and awards including the ACC Zipes Distinguished Young Scientist Award and has been inducted into the American Society of Clinical Investigation. He is a member of the Writing Committee for the 2013 ACCF/AHA Guideline for the Management of Patients with Unstable Angina/Non-ST-Elevation Myocardial Infarction.

Rachel E. Sherman, MD, MPH
Food and Drug Administration

Rachel E. Sherman is the Associate Director for Medical Policy, Center for Drug Evaluation and Research, U.S. Food and Drug Administration. She is responsible for developing, implementing, and coordinating medical policy programs and strategic initiatives, including regulation of prescription drug promotion and advertising through the Center's Division of Drug Marketing, Advertising, and Communications. Dr. Sherman provides leadership and scientific guidance and advice in clinical trial implementation and facilitates the development and implementation of Agency policy related to human subject protection and good clinical practices through the development of regulations, guidance documents, and procedures related to medical policy issues. Key activities involve leveraging resources and expertise from within FDA and from industry, academia, and other federal agencies to achieve Agency goals. Dr. Sherman is leading the Agency's implementation of the Sentinel Initiative and the development and implementation of biosimilars policy.



Dr. Sherman began her career with FDA in the Division of Antiviral Drug Products in CDER in 1989. During her tenure there, both as a medical reviewer and team leader, she played a pivotal role in the rapid development of new agents to treat HIV and other viral diseases. Since 1998, she has held a series of senior management positions in the Agency, including Deputy Office Director for the Office of Drug Evaluation I, Deputy Office Director of the Office of Medical Policy in CDER, and Associate Commissioner for Clinical Programs. From 2003 until her return to CDER in 2009, Dr. Sherman directed the Office of Critical Path Programs in the Office of the Commissioner, leading FDA's Critical Path Initiative, an Agency initiative to spur innovation and foster efforts to modernize the way FDA-regulated products are developed, evaluated, manufactured, and used.

Dr. Sherman is a board certified internist and infectious disease subspecialist. She received her A.B in mathematics from Washington University, her M.D. from Mt. Sinai School of Medicine, and her M.P.H. from The Johns Hopkins School of Hygiene and Public Health.



George W. Sledge, Jr., MD

Stanford University School of Medicine

Dr. George Sledge is the Oncology Chief at Stanford University School of Medicine where he is currently a Professor of Medicine. He specializes in the study and treatment of breast cancer and directed the first large, nationwide study on the use of paclitaxel to treat advanced breast cancer. His recent research focuses on novel biologic treatments for breast cancer. He has published over 250 articles in medical journals about breast cancer and chaired several nationwide clinical trials involving new breast cancer treatments. His work spans both laboratory and clinic.

Dr Sledge serves as Editor-in-Chief of the journal *Clinical Breast Cancer*, and Past President of the American Society of Clinical Oncology. He served as chairman of the Breast Committee of the Eastern Cooperative Oncology Group from 2002 – 2009, where he played an important role in the development of several nationwide clinical trials. He has also served as chair of ASCO's Education Committee, as a member of the Department of Defense Breast Cancer Research Program's Integration Panel, as a member of the Food and Drug Administration's Oncology Drug Advisory Committee (ODAC), and currently as a member of the External Advisory Committee for The Cancer Genome Atlas (TCGA) project.

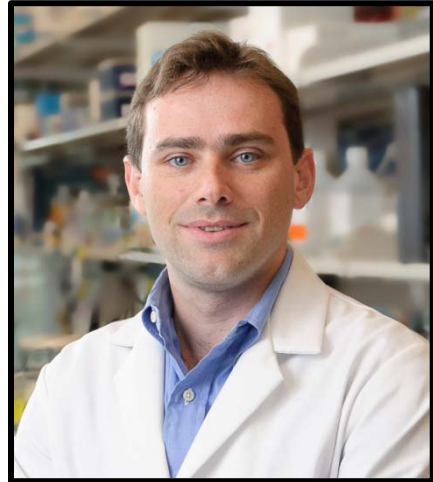
Dr. Sledge was the recipient of the 2006 Komen Foundation Brinker Award for Scientific Distinction, the 2007 Breast Cancer Research Foundation's Jill Rose Award and was the 2010 recipient of the William L. McGuire Award from the San Antonio Breast Cancer Symposium.

David B. Solit, MD

Memorial Sloan-Kettering Cancer Center

Dr. David Solit is a practicing Medical Oncologist and laboratory investigator with a joint appointment in the Department of Medicine and the Human Oncology and Pathogenesis Program. The goal of his research is the development of cancer therapies that target pathways responsible for tumor initiation and progression. He is particularly interested in the study of cancers in which the growth of the tumor depends upon alterations in kinase and steroid receptor signaling. The underlying hypothesis is that the consequences of inhibiting an oncogenic pathway

will vary as a function of cell lineage and the complement of mutations within the tumor. Therefore, in order to design rational therapeutic studies, one must understand not only which genetic changes are commonly found within particular tumor types but the mechanisms whereby these genetic alterations support tumor growth, survival, metastasis or other hallmarks of the cancer phenotype. Dr. Solit's recent laboratory work has focused on the identification of mutational events that co-occur with and cooperate with mutant BRAF in melanomagenesis and abrogate BRAF-addiction and thus response to selective RAF inhibitors. His research group has also been active in the development of novel methods to genetically profile formalin fixed, paraffin embedded tissues for somatic mutations and copy number alterations.



Robin Zon, MD, FACP

Northern Indiana Cancer Research Consortium
Michiana Hematology Oncology, PC

Dr. Robin Zon graduated Magna Cum Laude with a B.S. in Chemistry from the University of Detroit. Prior to medical school, she worked as a pharmaceutical research investigator and manager of medical diagnostic product research and development. After earning her medical degree from Indiana University School of Medicine, Dr. Zon completed her residency at St. Vincent Hospital and Health Care Center in Indianapolis, and a fellowship in medical oncology and hematology at Indiana University Cancer Center.



Dr. Zon maintains an active certification in medical oncology. Currently, Dr. Zon is Medical Director of Research at Memorial Hospital and is the Principal Investigator for the Northern Indiana Cancer Research Consortium, the only National Cancer Institute-designated Community Cancer Oncology Program in the state of Indiana. Dr. Zon also volunteers as a leader for the American Society of Clinical Oncology (ASCO), the world's premier global oncology professional organization, currently serving on the Board of Directors (2010-2013) along with many other ASCO related responsibilities. Her past volunteer activities included being Vice-Chair of the Hoosier Oncology Group, and past Board member of RiverBend Cancer Services and the Center for Hospice and Palliative Care.