

**58th Meeting of the National Cancer Institute (NCI)
Director's Consumer Liaison Group (DCLG)**

Speaker Biographies

James Abbruzzese, MD
Department Chair, Gastrointestinal Medical Oncology and Digestive Diseases
Division of Cancer Medicine
The University of Texas MD Anderson Cancer Center

Dr. Abbruzzese is a member of a number of numerous scientific advisory boards including the external scientific advisory board for the University of Massachusetts, The Arizona Cancer Center, The University of Colorado, and The Lustgarten Foundation for Pancreatic Cancer Research. Dr. Abbruzzese has published over 350 peer-reviewed articles, numerous chapters and reviews. In 2004, he co-edited a book entitled *Gastrointestinal Oncology*, published by Oxford University Press. His research group has been awarded a SPORE in pancreatic cancer and U54 grant on angiogenesis. In 2001 Dr. Abbruzzese served as a co-chair for the American Association for Cancer Research Program Committee and he was the Program Chairman for the ASCO Annual Meeting in 2007. He has recently served as a member of the AACR Board of Directors. He is a past member of the AACR Research Fellowships Committee, the ASCO Grant Awards and Nominating Committees, and currently serves as the Chair of the NCI Clinical Trials and Translational Research Advisory Committee. He is a Deputy Editor of *Clinical Cancer Research*, and member of several other editorial boards including past service for the *Journal of Clinical Oncology*. His scholarly interests center on clinical and translational research for pancreatic cancer.

Donald Berry, PhD
Professor, Department of Biostatistics
The University of Texas MD Anderson Cancer Center

Donald Berry is a professor in the Department of Biostatistics of the University of Texas MD Anderson Cancer Center. He was founding Chair of this department in 1999. Dr. Berry received his PhD in statistics from Yale University and previously served on the faculty at the University of Minnesota and at Duke University. He has held endowed faculty positions at Duke University and MD Anderson. Since 1990 he has served as a faculty statistician on the Breast Cancer Committee of the Cancer and Leukemia Group B (CALGB), a national oncology group. In this role he has designed and supervised the conduct of many large US intergroup trials in breast cancer. Through Berry Consultants, LLC, he has designed many innovative designs of clinical trials for pharmaceutical and medical device companies and for federally funded collaborations in many different diseases. He is well known as a developer of Bayesian adaptive designs that efficiently use information that accrues over the course of the trial. These trials minimize sample size while increasing the likelihood of detecting drug activity. Under his direction, the Department of Biostatistics at MD Anderson designed over 300 clinical trials that take a Bayesian approach. He is co-developer (with Giovanni Parmigiani) of BRCAPRO, a widely used program that provides individuals' probabilities of carrying mutations of breast/ovarian cancer susceptibility genes BRCA1

and BRCA2. Dr. Berry is the author of several books on biostatistics and over 300 published articles, including first-authored articles in the *New England Journal of Medicine*, the *Journal of the American Medical Association*, and *Nature*. Dr. Berry has been the principal investigator for numerous research grants from the National Institutes of Health and the National Science Foundation. He is a Fellow of the American Statistical Association and of the Institute of Mathematical Statistics.

Helen Chen, MD
Senior Investigator, Investigational Drug Branch
Cancer Therapy Evaluation Program
Division of Cancer Treatment and Diagnosis
National Cancer Institute

Helen Chen is associate chief and senior investigator at the Investigational Drug Branch of the Cancer Therapy Evaluation Program of the National Cancer Institute. She is board certified in Internal Medicine and Medical Oncology by the American Board of Internal Medicine. Chen is responsible for NCI-sponsored clinical development of new cancer therapy involving signal transduction inhibitors, antiangiogenesis therapies, and biological agents at the National Cancer Institute.

Barbara Conley, MD
Acting Chief, Diagnostic Biomarker and Technology Branch
Associate Director, Cancer Diagnosis Program
Division of Cancer Treatment and Diagnosis
National Cancer Institute

Barbara A. Conley, MD became the Associate Director of the Cancer Diagnosis Program (CDP) in the NCI Division of Cancer Treatment and Diagnosis (DCTD) in 2010; however, she is an NCI veteran, having held previous positions at the Institute. From 1997 to 2004, she participated in several key programs within the NCI, including Senior Investigator in Clinical Diagnostics Branch, and Chief of the CDP Diagnostics Research Branch, as well as Head, Aerodigestive Diseases in the intramural medicine branch. Immediately prior to her current appointment at DCTD, she had been Chief, Division of Hematology/Oncology at Michigan State University (MSU) as well as Scientific Director of the MSU Clinical Translational Science Institute. At MSU and the University of Maryland (1987-1997), Dr. Conley was the principal investigator on several NCI grants and an investigator with the National Surgical Adjuvant Breast and Bowel Project.

Board certified in Internal Medicine and Medical Oncology, Dr. Conley has research interests in diagnostic markers, drug development, and cancers of the aerodigestive tract. She has published extensively in many journals, including the *Journal of Clinical Oncology* and *Nature Medicine*, and is on the editorial board of several professional publications.

Dr. Conley holds an undergraduate degree from the University of Michigan and received her MD from Michigan State University.

**Giuseppe Giaccone, MD, PhD
Head, Thoracic Oncology Section
Chief, Medical Oncology Branch
Center for Cancer Research
National Cancer Institute**

Giuseppe Giaccone, MD, PhD is an internationally recognized expert in the field of lung cancer and developmental therapeutics. Dr. Giaccone received his MD cum laude from the University of Torino Medical School in 1980, followed by training in clinical oncology and internal medicine, which he completed at the University of Torino in 1988. He spent the next two years in the NCI's Medical Oncology Branch under the direction of Dr. John Minna. Following his training at the NCI, Dr. Giaccone received his PhD from the Free University Medical Center in Amsterdam, The Netherlands. He then served as a senior medical oncologist at the Medical Center from 1990 to 2000, when he was appointed Professor of Medical Oncology. Dr. Giaccone became Head of the Center's Department of Medical Oncology in 2003.

Dr. Giaccone has published more than 400 peer-reviewed papers and contributed to more than 30 book chapters. He has also played a major role in the European Organization for Research and Treatment of Cancer (EORTC), serving as a member of the EORTC's Lung Cancer Cooperative Group since 1982 and as its Chair from 1993 to 2000. During his leadership of this Group, Dr. Giaccone led several major clinical studies focusing on lung cancer and mesothelioma. Dr. Giaccone joined the Center for Cancer Research in 2007 as Chief of the Medical Oncology Branch.

**Lee J. Helman, MD
Scientific Director for Clinical Research
Center for Cancer Research
National Cancer Institute**

Lee J. Helman received his MD from the University of Maryland School of Medicine magna cum laude in 1980 and was elected to Alpha Omega Alpha. He completed his internship and residency in Internal Medicine at Barnes Hospital/Washington University, also serving as Chief Resident. Dr. Helman began his fellowship training at the National Cancer Institute (NCI) in 1983, where he has remained. He did his post-doctoral training in the Molecular Genetics Section, Pediatric Branch, NCI, and became Head of the Molecular Oncology Section, Pediatric Oncology Branch, NCI, in 1993. He was Chief of the Pediatric Oncology Branch from 1997 to 2007, and in 2007 became Scientific Director for Clinical Research in the Center for Cancer Research, NCI, a position he currently holds.

Dr. Helman is a Professor of Pediatrics and Oncology at the Johns Hopkins University. He was elected to the American Society for Clinical Investigation and the American Association of Physicians and is a founding member and past president of the Connective Tissue Oncology Society. He serves on the board of directors of and is a clinical advisor to The Children's Inn at NIH and is a past member of the board of governors of the Clinical Center at NIH. Dr. Helman is a past member of the board of directors of the American Society of Clinical Oncology (ASCO) and a past chair for its

Bylaws Committee. He has been selected to receive the 2011 ASCO Pediatric Oncology Award and the ASCO Statesman Award. He serves on the Science Education, Publications, and Clinical & Translational Research committees of the American Association for Cancer Research, is chair of its Pediatric Oncology Task Force, and is on the Scientific Program Committee for the 2011 annual meeting. He is on the Scientific Advisory Committee of the Children's Oncology Group. Dr. Helman served as an associate editor for the journal *Cancer Research* and *Clinical Cancer Research* and is currently on the editorial board of the *Journal of Clinical Oncology*.

Dr. Helman's laboratory currently focuses on three major themes related to the biology and treatment of pediatric sarcomas, specifically Ewing's sarcoma, rhabdomyosarcoma, and osteosarcoma: (1) determine the pathophysiologic consequences of IGF signaling; (2) identify the molecular/biochemical determinants of the biology of these sarcomas; and (3) apply preclinical laboratory findings to develop novel clinical studies for these sarcomas.

Patricia Keegan, MD
Director, Division of Oncology Products 2
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research
US Food and Drug Administration

Dr. Keegan is the Director of the Division of Oncology Products 2 (DOP2) in the Office of Hematology and Oncology Products in the Center for Drug Evaluation and Research (CDER) at FDA. DOP2 provides regulatory oversight of pre- and post-market clinical development of investigational drugs and biologic products for the treatment of head and neck, lung, gastrointestinal, CNS, sarcomas, melanomas, pediatric, and rare cancers. Dr. Keegan joined the Center for Biologics Evaluation and Review (CBER), FDA in 1990, serving as Branch Chief for the Oncology Branch within Division of Clinical Trials Design and Analysis (DCTDA) in the Office of Therapeutics Research and Review from 1993 to 1998, then as Deputy Division Director, DCTDA from 1993 to 2003. Since 2003 she has served as a Division Director in CDER responsible initially for biologic products and more recently for biologic and drugs intended for treatment of various cancer.

Prior to joining FDA, Dr. Keegan was on the staff of the Division of Medical Oncology at the University of North Carolina at Chapel Hill (UNC-CH) and Roswell Park Cancer Center (RPCC). In addition to serving on the medical school faculty at the UNC-CH, Dr. Keegan was an active investigator in Cancer and Leukemia Group B (CALGB) and industry-sponsored clinical trials; she also served as a member of the Institutional Review Board at RPCC. Dr. Keegan obtained her MD from the Loyola University Chicago Stritch School of Medicine, in Maywood, IL. Her post-graduate training included an internal medicine residency at Loyola University Medical Center, Maywood, IL and an oncology fellowship at Roswell Park Memorial Institute, Buffalo, NY.

Javed Khan, MD
Head, Oncogenomics Section
Senior Investigator, Pediatric Oncology Branch
Center for Cancer Research
National Cancer Institute

Dr. Khan obtained his bachelor's degree in 1984 and his master's degrees in 1989 in immunology and parasitology at England's University of Cambridge. He subsequently obtained his MD there and the postgraduate degree of MRCP (Membership of the Royal College of Physicians), equivalent to board certification in the United States. After clinical training in internal medicine and specialty pediatrics, Dr. Khan joined the Pediatric Branch, NCI, first as a clinical fellow and subsequently as a tenure track investigator. He was tenured in 2008. The focus of Dr. Khan's research is to apply cutting edge genomics to decipher the biology of aggressive pediatric cancers, identify biomarkers, and to rapidly translate the findings to the clinic. Recently, Dr Khan has led an international collaboration to perform comprehensive analysis of pediatric cancer genomes using next generation sequencing strategies. He is also the principle investigator of two clinical protocols: The first to identify driver mutations in these cancers, and the second to provide personalized therapy using microarray-based gene expression signatures for children with resistant and refractory neuroblastoma.

Shivaani Kummar, MD, FACP
Head, Early Clinical Trials Development
Office of the Director, Division of Cancer Treatment and Diagnosis
National Cancer Institute

Dr. Shivaani Kummar did her fellowship training in Medical Oncology and Hematology at the National Institutes of Health and then joined the faculty at the Yale Cancer Center as an Assistant Professor in Medical Oncology. During her time at Yale, she worked closely with the Yale University Department of Pharmacology to facilitate bringing new agents to clinical trials. She returned to the NCI in 2004 and has since been pursuing her interest in the clinical development of new anticancer agents, with an emphasis on new trials designs and integration of laboratory endpoints into clinical trials. She is Head of the Developmental Therapeutics Clinic, NCI and the principal investigator for over 20 early phase trials.

**Lisa McShane, PhD
Mathematical Statistician
Biometric Research Branch
Division of Cancer Treatment and Diagnosis
National Cancer Institute**

Lisa McShane, PhD, is a statistician with the National Cancer Institute Division of Cancer Treatment and Diagnosis. She works on the development of statistical methods for the evaluation of cancer biomarker assays and their use for prognosis, therapy selection, and disease-monitoring. She is a statistical advisor to the Cancer Diagnosis Program and works closely with the Cancer Therapy Evaluation Program as a reviewer for protocols for studies involving biomarkers. She earned her MS and PhD in statistics from Cornell University. She then worked as a staff fellow for the National Institute of Neurological Disorders and Stroke until 1995. She has worked in her current position as a mathematical statistician at NCI since 1996.

**Jane Perlmutter, PhD, MBA
President
Gemini Group**

Jane was first diagnosed with breast cancer in 1985 at the age of 36 and with no family history. Three years later, breast cancer was diagnosed in her other breast. Since these experiences, Jane has been involved in a number of organizations committed to educating the public about breast cancer, supporting people affected by it, and eradicating the disease.

Jane has a PhD in Cognitive Psychology and Master's Degrees in Educational Psychology, Computer and Information Science, as well as an MBA. She started her career as an experimental cognitive psychologist at the University of Texas in Austin, spent most of her career at Bell Labs, and currently runs her own consulting company—Gemini Group. Her consulting focuses on process improvement for small businesses, not-for-profits, and institutions of higher learning. She has been an examiner for the Baldrige and Lincoln quality award programs. Jane also serves as a scientific review administrator for peer review panels for the Departments of Education and Defense external research programs.

As a volunteer, Jane has run breast health awareness workshops for adults and teens and provided peer counseling to women diagnosed with breast cancer. She has been on boards, volunteered, and consulted to many non-profit groups involved with cancer. She has also been an invited speaker and author on a variety of topics and venues related to cancer research and advocacy and has developed and delivered training to a number of cancer advocate groups. In 2008 she received an American Association of Cancer Researcher's Distinguished Advocate Mentor Award. She is particularly interested in innovative clinical trial design and improving patients' involvement in treatment decisions and their experiences in clinical trials.

In regard to clinical trials, Jane is the lead advocate on the I-SPY 2 clinical trial. She has also been an advocate member of the Clinical Trials Transformation Initiative (CTTI), Clinical Trials Summit's Informed Consent Steering Committee, Cancer and Leukemia Group B (CALGB) Breast Cancer Committee, and the Translational Breast Cancer Research Consortium (TBCRC).

As a seasoned advocate with a background in experimental research and teaching, Jane is often invited not only to participate in advocacy, but also to mentor and train other advocates. She has developed and delivered training for, among other organizations, Susan G. Komen for the Cure's Advocates in Science (AIS) program, Y-ME Peer Counselors, Coalition of Cancer Cooperatives, Colon Cancer Coalition, and SHARE advocates as well as several clinical research assistant groups. She is also called on to train young researcher and has been regular faculty member at the AACR/ASCO Vail Methods in Clinical Research Workshop, the FDA Accelerating Anticancer Agent Development and Validation Workshop, and a number of Clinical Research Assistant groups. She has also written *Understanding Clinical Trial Design: A Tutorial for Research Advocates* with funding from the Research Advocacy Network (RAN), which is used for training advocates in a number of organizations.

Barbara Wold, PhD
Senior Advisor, Center for Cancer Genomics
National Cancer Institute

Dr. Barbara Wold joined NCI as the Director of the Center for Cancer Genomics on September 1, 2011. She is leading this new center for one year while she is on leave from her position as Bren Professor of Molecular Biology and Director of the Beckman Institute at the California Institute of Technology (Caltech). She began working on genome structure and gene regulation during embryo development for her PhD thesis at Caltech, then developed ways to assay gene regulation by transfection during postdoctoral work at Columbia. She then joined the biology faculty at Caltech in 1981 where she and her colleagues have charted the architecture of gene networks that drive cell state transitions. Their recent genome-scale work has included development of modern DNA sequencing-based methods and their use to map the inputs and outputs of gene networks. Over the past two decades, she has played an active external advisory role in genome science at NIH and DOE.