Faculty's Biosketches

Robert L. Becker, Jr., MD, PhD
Robert Becker is Chief Medical Officer for the Office of In Vitro Diagnostic Devices Evaluation and Safety (OIVD), Center for Devices and Radiological Health (CDRH), FDA, with special attention to inter-office coordination on regulation of newly emerging genetic/genomic IVD's. Dr. Becker previously served as Director, Division of Hematology and Immunology Devices, in OIVD. He is experienced in regulation of IVD's aimed at cell- and tissue-based specimens (e.g. classical hematology, flow cytometry, cytology, histopathology), plus blood coagulation tests, and immunoserologic tests.
Dr. Becker earned his MD and PhD in Immunology at Duke University, and he is board certified in anatomic and clinical pathology. He served in the United States Air Force as a pathologist at the Armed Forces Institute of Pathology, Washington, DC from 1983 to 2004, specializing in urologic pathology and with research and clinical service applying image analysis and flow cytometry to diagnostic pathology.

Clara D. Bloomfield, MD
Clara D. Bloomfield is Distinguished University Professor at Ohio State University (OSU), William Greenville Pace III Endowed Chair in Cancer Research, OSU Cancer Scholar & Senior Advisor OSU Comprehensive Cancer Center (CCC) & James Cancer Hospital. Prior major academic administration includes Chair Depart Medicine Roswell Park Cancer Institute, Chief Div Oncology State Univ of NY at Buffalo, Director Div Hematology/Oncology OSU & Director OSUCCC. Internationally known for groundbreaking research on adult leukemia/lymphoma, she changed thinking and therapy (Rx) of these diseases. She pioneered use of biologic features of cancer cells for choosing best curative Rx for individual patients (pts). She 1st showed adults with acute leukemia, including the elderly, could be cured by chemotherapy & that certain leukemia pts, defined by leukemia genetics, needed intensive Rx for cure, while others needed only standard Rx. Her study of leukemia/lymphoma chromosomes has enormously impacted finding genes involved in origin of these disorders & application of this information for best Rx for individual pts. She discovered now classic chromosome changes in leukemia/lymphoma (e.g. Philadelphia chromosome in ALL & 16q22 in AML). The driving force in identifying novel molecular prognostic markers in AML, she helped initiate the 1st use of gene array analysis of transcription to classify leukemias & continues pioneering work in gene & microRNA expression profiling. Her work has resulted in the current WHO classification of hematologic malignancies & use of genetics for individualized Rx in leukemia in the main cancer clinical guidelines (ie NCCN & European LeukemiaNet). She has contributed extensively to major professional organizations, serving on the BODs of ASCO, AACR & NCCN & chairing the NCI Div of Cancer Treatment's Board of Scientific Counselors. She chaired the last 2 WHO Clinical Advisory Committees for hematologic malignancies. She was President of the Association for Patient Oriented Research & of the International Association for Comparative Research in Leukemia & Related Diseases. The recipient of many prestigious honors, she is a member of the Institute of Medicine of the National Academy of Sciences & the American Academy of Arts & Sciences, & received the AACR Joseph H. Burchenal Clinical Research Award, the ASCO Distinguished Service Award for Scientific Achievement, the ASH Henry M. Stratton Medal, & the ASCO David A. Karnofsky Memorial Award.

Jan Bogaerts, ScD
Jan Bogaerts earned his degree in mathematics (1986) and his PhD in mathematics (1993) at the Free University of Brussels (Belgium). In 1988 he also earned a degree in management at the Free University in Brussels.
From 1986 to 1993 he worked as an assistant in mathematics and statistics at the faculties of Economic, Social and Political Sciences and of Science at Free University of Brussels.
In 1993 he joined BMS as statistician, and was later promoted Associate Director Statistics. In this position he worked on the development of several drugs in oncology, including several FDA and EMEA submissions.
In 2004 he joined the EORTC as statistician of the EORTC Breast Cancer Group. In 2004 he was appointed senior statistician and in 2010 Head of the Statistics department. He was a contributor to the development of version 1.1 of RECIST and is on the RECIST Steering Committee. He represents EORTC as course

director of the Flims workshop. Another key role is as the statistician of the MINDACT trial EORTC 0041–BIG 3-04 (Microarray In Node-negative and 1 to 3 positive lymph node Disease may Avoid ChemoTherapy: A prospective, randomized study comparing the 70-gene signature with the common clinicalpathological criteria in selecting patients for adjuvant chemotherapy in breast cancer with 0 to 3 positive nodes) which recently closed accrual.

Current statistical interests include the use of and methodological issues around Progression Free Survival, alternative ways to use changes in tumor measurements as predictive markers, and the correct evaluation of the contribution of new markers to existing prognostic risk evaluation.

Robert G. Bristow, MD, PhD, FRCPC

Dr. Bristow is a Clinician-Scientist and Professor within the Departments of Radiation Oncology and Medical Biophysics at the University of Toronto. He is a Senior Scientist at the Ontario Cancer Institute and a Radiation Oncologist in genitourinary cancers at the Princess Margaret Hospital (University Health Network). He received his MD and PhD (Supervisor – Dr Richard Hill) from the University of Toronto (1992; 1997) and completed his RCPSC Board exam in Radiation Oncology in 1996. He completed post-graduate training at the UT MD Anderson Cancer Center (Dr Bill Brock), Massachusetts General Hospital–Harvard (Dr Herman Suit) and Erasmus University, Rotterdam (Drs. D Van Gent/Jan Hoeijmakers). His current translational research interests include DNA damage response and repair, tumour hypoxia, and predictive genomics ss relates to radiotherapy and chemotherapy treatment response.

Dr Bristow is currently Co-Director of the STTARR Innovation Imaging Facility at the University of Toronto (MaRS Complex) and Head of the PMH-Campbell Family Research Institute Prostate Cancer Research Program. He co-leads the Terry Fox Foundation Project Program Hypoxia Team Grant at the Princess Margaret Hospital. He is Lead for the Canadian BRCA1/2 Prostate Cancer Network and the Canadian Prostate Cancer Genome Sequencing Project (CPC-GENE). The latter is an International Cancer Genome Consortium project for which Dr Bristow serves on the International Steering Committee.

He has also championed translational radiobiology as Chair of the Radiation and Cancer Biology Committee of the American Society of Therapeutic Radiation Oncology (ASTRO) and past Chair of the Translational Biology Advisory Group for Canadian Association of Radiation Oncology (CARO).

As an educator, Dr Bristow has directly supervised more than 50 basic science undergraduate, graduate and post-doctoral trainees and 25 clinical residents or post-graduate fellows. In 2009, he was awarded the Post-Graduate Medical Education Excellence Award in Teaching in the Faculty of Medicine, University of Toronto. He has over 200 published papers, abstracts and book chapters and has been an Invited Speaker or Visiting Professor on more than 100 occasions. He was made a Canadian Cancer Society Career Research Scientist in 2004 and is twice an Awardee of the Canadian Foundation of Innovation (CFI).

Carlos Caldas MD, FACP, FRCP, FRCPath FMedSci

Professor Caldas holds the Chair of Cancer Medicine at the University of Cambridge since 2002. He heads the Breast Cancer Functional Genomics Laboratory at the Cancer Research UK Cambridge Research Institute. He is an Honorary Consultant Medical Oncologist at Addenbrooke's Hospital, Lead of the Cambridge Experimental Cancer Medicine Centre and Director of the Cambridge Breast Cancer Research Unit which opened at Addenbrooke's Hospital in 2008. He is Fellow of the American College of Physicians, the Royal College of Physicians and the Royal College of Pathologists. He was elected a Fellow of the Academy of the Medical Sciences in 2004. He was elected a Fellow of the European Academy of Cancer Sciences in 2010.

Professor Carlos Caldas is a graduate from the University of Lisbon Medical School and trained in Internal Medicine at UT Southwestern, Dallas and Medical Oncology at Johns Hopkins Hospital, Baltimore. He then completed a research fellowship at the Institute of Cancer Research in London. In 1996 he moved to Cambridge where he has directed a research group working on the genetic alterations underlying human epithelial malignancies, with a particular focus on breast cancer.

His current research focus is in the functional genomics of breast cancer and its biological and clinical implications. He has also a research program on the genetics of gastric cancer. His main clinical interest is in breast cancer chemotherapy and novel molecularly targeted therapies. He has published 185 peer-reviewed papers including in Nature Genetics, Nature Medicine, Nature, Cell, Cancer Cell, New England Journal of Medicine, Science Translational Medicine, PNAS, Cancer Research, Clinical Cancer Research, Journal of Clinical Oncology, Genome Biology, PLoS Biology, PLoS Medicine, Lancet Oncology, Breast Cancer Research and Oncogene.

Barbara A. Conley MD

Barbara A. Conley, MD, is the Associate Director of the Cancer Diagnosis Program (CDP), National Cancer Institute. Her previous positions at NCI include Senior Investigator in the Clinical Investigation Branch,

Chief of the CDP Diagnostics Research Branch, and Head, Aerodigestive Diseases in the intramural Medicine Branch. Immediately prior to her current appointment, she served as Chief, Division of Hematology/Oncology at Michigan State University (MSU). At MSU and the University of Maryland (1987-1997), Dr. Conley was the principal investigator on several NCI grants or contracts. Dr. Conley holds a BS from the University of Michigan and received her MD degree 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 is on the editorial board of several professional publications.

Maria Grazia Daidone, Biol Sci D, PhD

Maria Grazia Daidone received her degree in Biological Sciences from Università degli Studi, Milan, Italy, where also she got a PhD in Medical Statistics and Biometrics at the University Medical School. She completed her training in cell biology at the Department of Experimental Oncology of Istituto Nazionale Tumori of Milan. In her current position, she is the Director of the Department of Experimental Oncology and Molecular Medicine of the Fondazione IRCCS Istituto Nazionale Tumori, in Milan, and the head of the research unit on Biomarkers.

She serves as an officer for European Organization for Research and Treatment of Cancer (EORTC) as the chairperson of the PathoBiology Group. In addition, Maria Grazia Daidone is a member of the editorial boards of several journals including Cell Proliferation and BMC Cancer.

Maria Grazia Daidone is an active and dedicated pre-clinical researcher, whose main scientific interests include bio-molecular characterization of human solid cancers and pre-neoplastic lesions, translational studies in breast, ovarian, head and neck, colorectal cancers, melanoma, and soft tissue sarcomas (with special reference to investigation on proliferation-related markers and on cell survival mechanisms), and pre-clinical studies on the activity of chemical and physical agents, and on the proposition of innovative treatment approaches, even using tumor-initiating cells as model systems. She has been also involved in promoting quality control programs for biomarker determination, methodologies for translational research in oncology and the proposition of guidelines for the clinical use of biomarkers. She is currently in charge of the organization of the biorepositories at Istituto Nazionale Tumori of Milan, with the Director of the Pathology Department.

Maria Grazia Daidone co-authored more than 170 publications on Journals referenced in the SCI Journal Citation Reports, to date, and 35 book chapters. She has been convener and member of the Scientific Committee of several national and international meetings.

Maria Debiec-Rychter, MD, PhD

Dr. Maria Debiec-Rychter gained her medical degree in 1978 from Medical University of Lodz, Poland, obtaining training in pediatrics and clinical genetics. She holds a doctoral degree in somatic genetics from the same University. In periods 1984-1984 and 1988-1992, she had been working as a post-doctoral fellow in the Wayne State University, Detroit, MI, and later (1998-1999) in the Armed Forces Institute of Pathology, Washington, DC. Since 1999, she works as a senior staff member at the Department of Human Genetics, Catholic University of Leuven (Belgium), appointed currently as a professor. Dr. Debiec-Rychter's research interests are related to development and application of molecular genetic techniques towards identification of causative genes and understanding of pathogenesis of sarcomas. She has published over 200 papers related to the cytogenetic and molecular characterization of solid tumors and cancer targeted therapy.

Ronald A. DePinho, MD

Ronald A. DePinho, MD, is President-Designate of The University of Texas MD Anderson Cancer Center. His research program has focused on the molecular underpinnings of cancer, aging and degenerative disorders and the translation of such knowledge into clinical advances. His independent scientific career began at the Albert Einstein College of Medicine, where he was the Feinberg Senior Scholar in Cancer Research. He then joined the Department of Medical Oncology at the Dana-Farber Cancer Institute and Department of Medicine and Genetics at the Harvard Medical School. At Harvard, he was the founding Director of the Belfer Institute for Applied Cancer Science at the Dana-Farber Cancer Institute and was a Professor of Medicine and Genetics at Harvard Medical School. Dr. DePinho is a former member the Board of Directors of the American Association for Cancer Research, and has served on numerous advisory boards in the public and private sectors including co-chair of advisory boards for the NCI Mouse Models of Human Cancer Consortium and for the Human Cancer Genome Altas Project. Dr. DePinho studied biology at Fordham University, where he graduated class salutatorian, and received his MD degree with distinction in microbiology and immunology from the Albert Einstein College of Medicine. For his fundamental contributions to cancer and aging, he has received numerous honors and awards including the March of Dimes Basil O'Connor Award, James S. McDonnell Scholar Award, the Cancer Research Institute Scholar Award, the Melini Award for Biomedical

Excellence, the Irma T. Hirschl Award, the Kirsch Foundation Investigator Award, and the Richard and Claire Morse Scholar Award. He is the 2002 recipient of the American Society for Clinical Investigation Award, the 2003 AACR Clowes Award, the 2007 Helsinki Medal, the 2007 Harvey Lectureship and the 2009 Albert Szent-Gyorgyi Prize. He is a member of the Institute of Medicine of the National Academy of Sciences. In 2010, Dr. DePinho was elected to membership in the American Academy of Arts and Sciences. He is a founder of Aveo Pharmaceuticals and a number of biopharmaceutical companies focused on cancer therapy and diagnostics.

Christian Dittrich, MD

Christian Dittrich, MD, Professor of Medicine at the Vienna University School of Medicine, is head of the 3rd Medical Department – Centre for Oncology and Hematology at the Kaiser Franz Josef-Spital in Vienna and director of the Ludwig Boltzmann Institute for Applied Cancer Research (LBI-ACR VIEnna) – LB Cluster for Translational Oncology. He is board-certified in internal medicine as well as in oncology and hematology. He passed the European Certification in Medical Oncology established by the European Society for Medical Oncology (ESMO). He also earned a degree in hospital management at the Vienna University School of Economy.

He was and is active member of several preclinical and clinical groups of the European Organisation for Research and Treatment of Cancer (EORTC). Actually, he serves as member of the Protocol Review Committee (PRC) and Scientific Audit Committee (SAC) of the EORTC. Furthermore, he is the Austrian representative of the EORTC Network of Core Institutions (NOCI). He was chairman of the Fellowship and Award Committee of the ESMO and representative of the ESMO in the Board and Council of the Federation of European Cancer Societies (FECS) as well as ESMO-national representative of Austria. Actually, he serves as a member of the board of the Michelangelo Foundation concerning his dedication to breast cancer studies. He is member of several editorial boards and serves as reviewer for various oncology journals.

Christian Dittrich has research interest in clinical trials' methodology as well as in new drug development and translational research, focused on solid tumors such as breast, ovarian and gastrointestinal cancers. He has been acting as principal or co-investigator in numerous clinical trials from phase I (first in man) to phase III.

S. Gail Eckhardt, MD

S. Gail Eckhardt, MD is a tenured Professor and Head of the Division of Medical Oncology at the University of Colorado at Denver and Health Sciences Center where she also holds the Stapp/Harlow Endowed Chair for Cancer Research and is the Senior Associate Director for Translational and Collaborative Research at the University of Colorado Comprehensive Cancer Center.

Dr. Eckhardt received her medical degree from the University of Texas Medical Branch in Galveston followed by an internship and residency at the University of Virginia Medical Center. After a post-doctoral fellowship at the Scripps Research Foundation, she completed her training in medical oncology at the University of California at San Diego. Following fellowship, Dr. Eckhardt joined the faculty of the Cancer Therapy and Research Center, Institute for Drug Development in San Antonio, Texas where she held the position of Associate Director of Clinical Research. In 1999, Dr. Eckhardt joined the faculty of the University of Colorado to set up a Phase I program, and in 2004 became the Director of the Developmental Therapeutics Program in the Cancer Center.

Dr. Eckhardt has served on numerous committees/study sections, including the ASCO Molecular Oncology Task Force, the ASCO Board of Directors, the FDA Oncology Drugs Advisory Committee, the NCI Developmental Therapeutics Study Section, and the NCI Cancer Centers Study Section. She is also a member of the NCI Colon Cancer Task Force. In addition, Dr. Eckhardt has been an Associate Editor of Clinical Cancer Research, the Journal of Clinical Oncology, and Investigational New Drugs.

Research: Dr. Eckhardt is the Principal Investigator on grants involving early clinical trials and colorectal cancer research and has conducted numerous phase I and II clinical trials. She has published over 126 manuscripts and serves on numerous advisory boards. Her area of interest is in the preclinical and clinical development of combinations of molecularly targeted compounds, with a laboratory focus on colorectal cancer and melanoma.

Francisco J. Esteva, MD

Dr. Esteva is a Professor in the Departments of Breast Medical Oncology and Molecular & Cellular Oncology at MD Anderson Cancer Center (Houston, Texas).

Dr. Esteva received MD and PhD degrees from the University of Zaragoza in Spain. After receiving his medical degree Dr. Esteva moved to Camden, New Jersey where he completed an internship and residency in internal medicine at Cooper Hospital/University Medical Center. He continued on to Georgetown University Medical Center (Washington, DC) for a clinical fellowship in medical oncology at the Vincent T. Lombardi Cancer Center. In 1997 Dr. Esteva was recruited by The University of Texas M.D. Anderson Cancer Center, where he rose to the rank of Professor. Dr. Esteva is board certified in medical oncology, and a Fellow of the American College of Physicians. In 2010 Dr. Esteva was inducted as a member of the American Society of Clinical Investigation.

In 1999 Dr. Esteva received the K23 patient-oriented research career development award from the NCI for his research on antisense therapy for solid tumors. Dr. Esteva's clinical research activities are currently centered on the development of targeted therapies for breast cancer, with a focus on the identification and validation of molecular prognostic and predictive markers. His laboratory identified several mechanisms of resistance to trastuzumab monoclonal antibody therapy, and he implemented clinical trials to overcome resistance in breast cancer patients. He is an active member of the American Society of Clinical Oncology and the Southwest Oncology Group. He is an author of more than 100 publications in the area of breast cancer research and treatment.
Dr. Esteva is a respected academic speaker, with invited presentations at universities, research institutions, and meetings nationally and internationally.

David R. Gandara, MD
David R. Gandara, MD, Professor of Medicine at the University of California, Davis School of Medicine, is the Director of the Thoracic Oncology Program at the University of California at Davis Cancer Center. He is a diplomat of the American Board of Internal Medicine specializing in Medical Oncology. He is currently principal investigator for a number of research projects in lung cancer, pharmacology trials at various phases, and Southwest Oncology Group (SWOG) trials. He is the principal investigator for a National Cancer Institute award to the California Cancer Consortium for Early Therapeutic Trials of New Anti-Cancer Agents. He is chair of the SWOG Lung Committee, and a member and prior co-chair of the NCI-directed Investigational Drug Steering Committee (IDSC). He has written over 300 articles, book chapters, abstracts and editorials. He is editor-in-chief of the journal Clinical Lung Cancer, serves on the editorial board of four oncology journals, and is a manuscript reviewer for eight additional journals. He has served as president of International Association for the Study of Lung Cancer (IASLC) from 2009 to 2011. He serves on the board of directors of IASLC and is a prior board member and secretary-treasurer of the American Society for Clinical Oncology (ASCO). He also is chair of the NCI-directed Lung Correlative Science Committee.
After receiving his medical degree from the University of Texas Medical Branch in Galveston. Dr. Gandara was an intern and resident at the Madigan Army Medical Center in Tacoma and a fellow at the Letterman Army Medical Center Presidio of San Francisco.

Jacqueline A. Hall, PhD
Jacqueline A Hall, PhD is a bioinformatician and translational research scientist who joined the EORTC headquaters (Belgium) as Head of theTranslational Research Unit in May 2009 after 8 years of research and training in multidisciplinary environments.
Her interest in bioinformatics began with an internship in computational chemsitry and quantitatve structure activity relationship modelling in the genetic toxicology department of GSK (Ware, UK) focussing on predicitive toxicology for streamlining the drug development process.
She completed a prioitiy area bioinformatics PhD at Glasgow University in 2006 where she worked alongside companies such as Epigenomics AG (Berlin) and Orion Genomics Inc (St Louis) investigating DNA methylation markers for the discovery of diagnostic, prognostic and predictive markers of response to therapy in ovarian cancer. After completing her PhD she joined McGill University (Montreal) for a two year post-doc working in breast cancer jointly with the McGill Center for Bioinformatics and the Molecular Oncology Group at the Rosalind and Morris Goodman Cancer Centre. Here her interests focused on understanding the molecular heterogeneity of breast cancer through dissecting gene expression signatures and the development of new methods for assessing pathway activation.
As the Head of the Translational Research Unit at the EORTC she now focuses on infrastructure development and integration of translational research activities into EORTC clinical studies. This involves the implementation of quality assurance programs for human biological material collection and biobanking, developing and implementing quality assurance principles for biomarker assays that form part of clinical studies as well as managing processes for review and implementation of translational research in EORTC clinical trials. Dr Hall also has a keen interest in how bioinformatics may be used to support biomarker translation to the clinic, including data sharing and data exchange.
In addition she is a member of the EORTC PathoBiology Group (PBG) and EORTC Pharmacology and Molecular Mechanisms Group (PAMM), she is also currently a member of the New York Academy of Sciences (NYAS) and the International Society of Computational Biology (ISCB).

Nadia Harbeck, MD
Professor Nadia Harbeck heads the breast center at the University of Cologne, Germany, the Oncological Therapy and Clinical Trials Unit at the University Dept. of OB&GYN in Cologne. She received her Medical Degree from the University of Munich (LMU). Until 2009, she was Associate Professor and head of Conservative Senology at the Technical University of Munich, where she also obtained a specialist degree in Obstetrics and Gynecology in 1998. Professor Harbeck is a member

of the expert panel issuing the yearly updated evidence-based AGO Guidelines for breast cancer therapy in Germany (www.ago-online.org). She is executive board member of the EORTC, steering committee member of the EORTC PathoBiology Group, and member of numerous other professional organisations, including ASCO, ESMO, and AACR. Professor Harbeck is co-chair of the West German Study Group (WSG, a BIG member) – one of the largest breast cancer study groups in Germany. She is principal investigator or steering committee member of numerous national and international breast cancer trials, with a recent focus on novel targeted compounds. She is also member of the international TransHERA as well as co-chair of the TransALTTO committee. Her translational research focuses on prognostic and predictive factors in breast cancer and other solid tumors, in particular on using biomarkers for therapy decisions within clinical trials. Professor Harbeck has authored more than 260 papers in peer-reviewed journals (cumulative impact factor >1000) and, in addition to serving on editorial boards (e.g. Journal of Clinical Oncology) or as a reviewer (e.g. Annals of Oncology) for several scientific journals and grant-giving agencies (e.g. German Cancer Aid), she is coordinating Editor-in-Chief of Breast Care. She also serves on the organizing committee for numerous national and international clinical and translational cancer meetings. For her clinical translational research, she has received numerous awards, including a 2001 AACR award, the 2001 ASCO Fellowship Merit Award for the highest ranking submitted abstract and the 2002 AGO Schmidt-Matthiesen Award. In honour of her scientific achievements, Prof. Harbeck was invited to give the Emmanuel van der Schueren Lecture at the European Breast Cancer Conference (EBCC) 6 in Berlin 2008 and the Opening Lecture at IBCM-2 in Sarajevo 2009. In 2011, she was co-chair of the 3rd IMPAKT meeting in Brussels.

Susan Galloway Hilsenbeck, PhD

Susan G. Hilsenbeck, PhD, has a PhD in Applied Statistics. She spent many years in cancer centers in Miami and San Antonio, TX as part of the San Antonio Breast Cancer Research Group. She moved with the group in 1999 to join Baylor College of Medicine (Houston, TX) as a founding member of the Smith Breast Center and is a Professor of Medicine (Tenured). In recognition of her contributions in teaching and as a collaborating statistician, she was elected as a Fellow of the American Statistical Association in 2011.

Dr. Hilsenbeck leads the Biostatistics and Informatics Group in the Breast Center and the Biostatistics and Informatics Shared Resource in the Dan L. Duncan Cancer Center. She is a Vice Chair of the Baylor College of Medicine Institutional Review Board, and has served on numerous NIH grant review panels, including the Cancer Biomarkers Study Section. She collaborates as the biostatistician on a number of clinical trials and is the leader of statistical shared resources for several multi-project grants. She has research interests in the identification and validation of prognostic and predictive factors in breast and other cancers, and in trials of targeted therapy and the design and analysis of trials for predictive markers, and she has authored or coauthored more than 225 publications.

Fred R. Hirsch, MD, PhD, *University of Colorado Cancer Center, USA.*

Dr. Fred R. Hirsch graduated from the University of Copenhagen, Denmark in 1977. He has clinical training in medical oncology and pathology from various university hospitals in Denmark and in 1980 was a research fellow at the US National Cancer Institute, Medical Oncology Branch.

Dr. Hirsch's research interest has mainly been lung cancer, and his studies have focused on the biological, pathological and clinical aspects of lung cancer. He moved to the University of Colorado Cancer Center in 1999 and became Professor of Medicine in 2001 and in Pathology in 2004. At the University of Colorado, Dr Hirsch has focused on translational research, especially development and validation of biomarkers for early detection of lung cancer and for prediction of response to new molecular targeted therapies in lung cancer.

Dr. Hirsch is currently on the Board of Directors of the International Association for the Study of Lung Cancer (IASLC), and he has served on several committees in the American Society of Clinical Oncology (ASCO). He is on several Editorial Boards, including Lancet Oncology and Clinical Cancer Research, and is Associate Editor for the Journal of Thoracic Oncology.

Dr. Hirsch has published more than 200 scientific articles about lung cancer, 30 book chapters, and is Editor of 10 international books on lung cancer including an international Textbook on Prevention and Early Detection of Lung Cancer.

Paula M. Jacobs, PhD

Paula M. Jacobs, PhD is Acting Associate Director, Division of Cancer Treatment and Diagnostics at the National Cancer Institute. Her responsibilities in the Cancer Imaging Program include oversight of an extramural grant program in cancer imaging and research in molecular imaging for elucidating cancer biology, as well as clinical investigations of imaging to stratify patients to treatments and evaluate patient response to therapy. Part of her effort is focused on lowering the logistical

and regulatory barriers to investigational use of PET radiopharmaceuticals for therapeutic drug development by facilitating access to IND filings and by research to develop labeled drugs for clinical and pre-clinical use. Another major effort is developing publicly available image archive collections with associate clinical metadata for imaging–genomic correlations and for computer-aided diagnosis software development. Standardization of imaging techniques and quantitative image methods for use in clinical trials is a third area of intense focus.

Dr. Jacobs serves on three NCI Experimental Therapeutics (NExT) committees to review and manage the projects chosen for development in this new NCI program. She also directs a radiochemistry facility that prepares pre-clinical and early clinical radiopharmaceuticals in support of therapeutic drug development.

Dr. Jacobs received her undergraduate degree in chemistry at the Massachusetts Institute of Technology and graduate degrees at Tufts University and Northeastern University. Her post-doctoral training was at Northeastern University, Massachusetts Institute of Technology, and Peter Bent Brigham Hospital/Harvard Medical School.

She joined the NCI after 30 years of diverse experience in the pharmaceutical and medical device industries. Her most recent industrial position was Vice President of Development at Advanced Magnetics where she was a key developer of ultrasmall superparamagnetic iron oxide nanoparticles as magnetic resonance imaging agents and iron replacement therapeutics.

She has published in the areas of organic chemistry, inorganic chemistry, magnetic resonance imaging, regulatory affairs, neuro-oncology and nephrology.

Edward S. Kim, MD

Edward S. Kim, MD is an associate professor of medicine in the Department of Thoracic/Head and Neck Medical Oncology at The University of Texas MD Anderson Cancer Center in Houston, Texas. He also holds the position of Chief, Section of Head and Neck Medical Oncology and serves as the Director of Clinical Research Operations in the department.

Dr Kim received his bachelor of science and medical degrees from the Honors Program in Medical Education (HPME) at Northwestern University in Chicago, Illinois, 1996. Dr Kim completed an internship and residency in internal medicine at the Baylor College of Medicine in Houston, Texas, 1996-1999, and his fellowship in medical oncology at The University of Texas MD Anderson Cancer Center, 1999-2001.

Dr Kim serves as principal investigator on numerous clinical studies including the Department of Defense Biomarker-based Approaches of Targeted Therapy for Lung Cancer Elimination (BATTLE) or personalized medicine program in lung cancer. Dr Kim studies novel targeted agents in the treatment and prevention settings and has expertise in lung, head and neck, as well as thymic cancers.

Dr Kim serves on the editorial boards of Journal of Clinical Oncology and Clinical Cancer Research and is a member of numerous associations and societies, including ASCO, AACR, SWOG, IASLC and the Texas Medical Society. Dr Kim is also the recipient of several awards including the ASCO Young Investigators Award and the AACR Scholar in Training Award. He also serves as the principal investigator of the MD Anderson SWOG U10 institutional grant and is the recipient of a V Foundation Grant.

Dr Kim is the author or coauthor of more than 100 published articles, book chapters, reviews, and abstracts in journals such as Lancet, Journal of Clinical Oncology, Cancer Discovery, Cancer, and Cancer Prevention Research, involving cancer therapeutics and prevention with chemotherapy and novel targeted agents, with particular emphasis on lung cancer and head and neck cancer.

Thomas Lion, MD, PhD

Prof. Lion received his degree in medicine at the University of Vienna (1984). He worked as a postdoctoral research fellow at the University of Chicago und the University of Illinois, USA (1986-1988). Following his training in biology and genetics at different institutions in the USA and Austria, he received his PhD at the Charles University, Prague, Czech Republic (1995). After his residency and fellowship in pediatrics and pediatric oncology at St. Anna Children's Hospital, Vienna, Austria, and training in laboratory medicine at the Department of Medicine, University of Vienna, Austria, he became certified specialist in laboratory medicine (1993), in pediatrics with focus on hemato-oncology (1996), and in human genetics (1997).

He is head of the Division for Molecular Microbiology and Development of Genetic Diagnostics at the Children's Cancer Research Institute (CCRI), Vienna, Austria (since 1989), and professor at the University of Vienna, Austria (since 1997). He is also Medical Director of LabDia Labordiagnostik GmbH, Vienna, Austria, a non-profit SME focusing on the development and performance of genetic diagnostics in cancer and infectious diseases (since 2006).

T. Lion serves as Chairman of the Scientific Board of the Austrian Society of Pediatrics, and as head of a reference laboratory for molecular genetic diagnostics providing services for different national and international hemato-oncological treatment protocols including e.g. the ENEST1st CML trial, the ALL-BFM and AML-BFM trials, and the multicenter stem cell transplantation study ALL-BFM-SCT. He is member of the Scientific Board of the Austrian CML Platform, and various national and

international scientific societies. He has been serving for many years as Section Editor in LEUKEMIA (Nature Publishing Group) and as Editorial board member in other journals. He is author of more than 250 publications in peer reviewed journals, abstracts and book chapters, recipient of 16 national and international research awards, and owner of different patents on molecular diagnostic techniques.

Richard F. Little, MD, MPH

Dr. Little is a medical oncologist and is Head of the therapeutics section for Hematologic and AIDS-related Cancers and Hematopoietic Stem Cell for the Cancer Therapy Evaluation Program (CTEP) of the US National Cancer Institute. Dr. Little received his MD degree from the University of South Carolina, in 1989. After completing Residency Training in Internal Medicine at the Boston City Hospital, he completed a combined medical oncology and hematology fellowship in 1994, at the National Heart Lung and Blood Institute and the National Cancer Institute. Following his medical training, Dr. Little went on to complete two years of research fellowship in the Laboratory of Tumor Cell Biology at NCI. He then served as Clinical Director of the HIV and AIDS Malignancy Branch, and in 2001, Dr. Little was also named Head – AIDS Malignancy Section for the Medical Oncology Clinical Research Unit at NCI.

His research interests have focused on immune suppression-related neoplastic disease; investigation of viral targets for oncolytic therapy and immunotherapy, and antiangiogenesis. In his role as a clinical investigator in the NCI Intramural Research Program, Dr. Little developed clinical trials in AIDS-related lymphoma, primary central nervous system lymphoma, Kaposi's sarcoma, and multicentric Castleman disease. Dr. Little was recognized as an outstanding teacher and mentor in 2005 when he was nominated for the Distinguished NIH Teacher award. As Therapeutic Disease Head at CTEP, Dr. Little has worked to coordinate large randomized phase 2 and 3 trials in lymphoid malignancies and leukemia, and to expand access to cancer clinical trials for individuals with HIV infection.

Tracy Lively

Dr. Tracy Lively joined the NIH in 1996 as a program director in the Cancer Diagnosis Program of the National Cancer Institute. Prior to coming to the NIH she had been an assistant professor in the Division of Biomedical Sciences at the University of California, Riverside, and had completed post-doctoral fellowships in cancer biology and human genetics. As a program director, and later as Associate Chief of the Diagnostics Research Branch of the Cancer Diagnosis Program, Dr. Lively has been responsible for the scientific oversight of a portfolio of investigator-initiated research grants. She has also developed and implemented targeted research initiatives for exploratory research, for technology development and for patient-oriented research in cancer diagnostics. She reviews the correlative science aspects of protocols for NCI's clinical trials program. She also organizes scientific meetings and working groups with investigators outside the NIH.

Irina A. Lubensky, MD

Dr. Lubensky is a surgical pathologist and translational researcher. In the last 5 years she works as Chief of the Resources Development Branch in the Cancer Diagnosis Program, Division of Cancer Treatment and Diagnosis (DCTD) at the National Cancer Institute (NCI), National Institutes of Health (NIH). The Branch supports the development and infrastructure of biospecimen resources needed for discovery, translational and clinical research including validation of biomarkers for diagnosis and response to therapy. Dr. Lubensky manages large NCI cooperative biospecimen programs: Cooperative Oncology Group Banks and Cooperative Human Tissue Network.

Dr. Lubensky received a B.A. at University of Pennsylvania and an MD at Temple University School of Medicine in Philadelphia, PA. She completed her residency training in Anatomic and Clinical Pathology and Surgical Pathology Fellowship in the Department of Pathology and Laboratory Medicine, Hospital of the University of Pennsylvania, Philadelphia, PA.

Dr. Lubensky has been at NIH for most of her career. She served as Attending Staff Pathologist in Surgical Pathology (Gastrointestinal, Genitourinary and Endocrine Pathology Subspecialties) and as Chief of the Hereditary Cancer Syndromes Unit in Laboratory of Pathology, NCI. She also worked at the Molecular Pathogenesis Unit, Surgical Neurology Branch, NINDS. The main focus of her translational research is molecular biology of hereditary cancer syndromes: Multiple Endocrine Neoplasia 1 (MEN1), von Hippel–Lindau disease (VHL), papillary renal cell carcinoma. Dr. Lubensky is an author of 120 scientific papers.

John W.M. Martens, PhD

John W.M. Martens received his PhD (1994) in Molecular Biology at Wageningen University (NL). After being a post-doc in Molecular Endocrinology at the Erasmus MC, Rotterdam (NL) (1994-1998) and at UCSF (1998-2001), he began his career in 2001 in translational breast cancer research at his current department where he is now Associate Professor heading the laboratory of Genomics and Proteomics of Breast Cancer. He currently is chair-elect of EORTC-Pathobiology group, member of the Steering Committee of the Center for Personalised Cancer

Treatment and is a member of BCAC and various national translational research advisory committees.

The major aim of his research is to determine which biological factors are associated with clinical relevant biological differences among breast cancer. To this end, he applies a multitude of state-of-the-art high-throughput technologies (genomics and proteomics) to identify in appropriate clinical patient cohorts tumor profiles [i.e. sets of differentially expressed biological factors (gains or losses, rearrangements, mutations, epi-tags, mRNAs, microRNAs or proteins)] which are associated with disease progression and/or the development of resistance to therapies. The generated tumor profiles pinpoint biological pathways that drive tumor aggressiveness and/or therapy resistance which he functionally studies to understand their molecular basis and to come to novel therapeutic approaches for those patients who currently cannot be cured. He is an inventor/owner of a dozen of patents on clinical significant biomarkers in breast cancer. A few selected papers relevant to his talk and other translational research are listed:

1. Smid M, et al. Genes associated with breast cancer metastatic to bone. JCO 24 (2006): 2261-7.
2. Foekens JA, et al. MicroRNAs associated with aggressiveness of hormone receptor-positive human breast cancer. PNAS (2008) 105: 13021-6.
3. Sieuwerts AM, et al. EpCAM does not detect normal-like circulating breast tumor cells. JNCI 101(2009): 61-6.
4. Umar A, et al. Identification of a putative protein profile associated with tamoxifen therapy resistance in breast cancer. MCP (2009) 1278-94.
5. Stephens PJ, et al. Complex landscapes of somatic rearrangement in human breast cancer genomes. Nature (2009) 462: 1005-10.
6. Rodríguez-González FG, et al. MicroRNA-30c expression level is an independent predictor of clinical benefit of endocrine therapy in advanced estrogen receptor positive breast cancer. BRCT 2010.

William Matsui, MD

William Matsui joined the faculty of the Department of Oncology at the Johns Hopkins University School of Medicine in 2001 and is currently an Associate Professor in the Division of Hematologic Malignancies. He received his undergraduate degree in biochemistry from Harvard College in 1989 and his medical degree from the University of California at San Francisco in 1995. He completed his residency training in internal medicine at the University of Washington in Seattle and his clinical training in Medical Oncology at Johns Hopkins. The primary focus of Dr. Matsui's laboratory is examining the role of cancer stem cells in hematologic malignancies. More recently, his laboratory has expanded these studies to pancreatic adenocarcinoma and the development of novel strategies targeting cancer stem cells in the clinical setting.

David Mauro, MD, PhD

David Mauro MD, PhD has over 14 years of industry experience in oncology drug development and molecular diagnostics. Since 2008 he has served as Executive Director in the Department of Oncology Clinical Research at Merck & Co. (MSD) based in Upper Gwyned, Pennsylvania, U.S.A. In his role at MSD, he oversees multiple programs within the oncology portfolio focused primarily on signal transduction pathway inhibitors. Dr. Mauro also serves a clinical lead for the Sylatron program which recently received FDA approval for the adjuvant treatment of melanoma. Dr. Mauro is actively involved in the development of MSD's program on predictive biomarkes in oncology.

Prior to joining MSD, Dr. Mauro worked for 9 years at Bristol-Myers Squibb (BMS) as Director in oncology. While at BMS, he had mutliple responsibilities from early development through life-cycle management and was involved in several successful primary and supplemental regulatory filings for oncology compounds. Dr. Mauro, in collaboration with his colleague, Dr. Khambatta-Ford, helped lead the effort towards the discovery of the association of KRAS and the EGFR ligands to Erbitux response. In addition, he helped in the discovery of predictive markers of Erbitux-associted hypersensitivity reactions.

Dr. Mauro started his career in industry at Becton Dickinson (BD) as a Medical Director working on the discovery and development of novel biomarkers used in the early detection and prognosis of cancer. After spending several years at BD, he moved to the oncology drug development function at Bristol-Myers Squibb (BMS).

David received his medical and doctoral degrees from Temple University School of Medicine in Philadelphia, Pennsylvania. While at Temple, he received numerous awards including the Temple University President's Award in Biomedical Sciences. After finishing medical school, he moved to the National Institutes of Health/National Cancer Institute in Bethesda, Maryland where he completed a residency in Anatomic Pathology and also served as a Lieutenant Commander in the United States Public Health Service. Dr. Mauro received his undergraduate degree in Biochemistry from Cornell University.

Ultan McDermott, PhD, FRCP

Ultan McDermott is a Group Leader in the Cancer Genome Project and a practising medical oncologist at Addenbrooke's Hospital in Cambridge. He joined the Institute in 2009 to work with Mike Stratton,

Andy Futreal and Peter Campbell and establish a high-throughput screen of human cancer cell lines with pre-clinical and clinical compounds.
Ultan qualified in medicine – with distinctions in Medicine and Surgery – in 1994, trained as a medical oncologist and obtained a PhD in cancer biology at Queen's University, Belfast. He was accepted for a post-doctoral research position in Jeff Settleman's lab at Harvard Medical School/Massachusetts General Hospital in 2005.
In Jeff's lab Ultan helped establish a high-throughput platform to screen cancer cell lines with pre-clinical and clinical compounds in order to detect genetic characteristics that could be used in the clinic to stratify patients for treatment. Subsequent publications confirmed the power of this approach in identifying the biological dependence of certain cancer subsets on specific genomic alterations. Ultan's research interests are in the area of predictive biomarkers to cancer therapeutics and in vitro models of drug resistance in human cancers.
Ultan joined the Sanger Institute in 2009 as a clinical research fellow and was appointed to the faculty as a CDF Group Leader in 2010 with the award of a Cancer Research UK Clinician Scientist Fellowship. He is a member of the Royal College of Physicians.

Lisa M. McShane, PhD
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 PhD 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 regular 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.

Soheil Meshinchi, MD, PhD
Dr. Soheil Meshinchi is an Associate Member at Fred Hutchinson Cancer Research Center and Associate Professor at the University of Washington, Seattle, Washington. He is the Chairman of the Children's Oncology Group's (COG) AML Disease Biology Committee and the Vice Chair of COG Myeloid Disease Committee. His research focuses on the biologic and clinical implications of genomic alterations in AML. His work has led to identification of several disease-associated mutations in AML and has established their role in risk allocation and therapeutic target identification in AML. In directing the COG efforts to identify specific risk groups in childhood AML, he has established FLT3 as well as several other mutations as viable prognostic markers and therapeutic targets. He also leads efforts in using novel molecular and flow cytometric methodologies to assess early response to therapy and monitor patients for early emergence of disease for pre-emptive therapy prior to morphologic relapse. These efforts are aimed at identification of high risk disease at the time of diagnosis and early detection of relapse during and after therapy in order to alter therapeutic approach based on novel biomarkers to improve outcome in AML.

Stefan Michiels, PhD
Stefan Michiels works at the Breast Cancer Translational Research Laboratory of the Institut Jules Bordet in Brussels. His areas of expertise are statistical analysis of biomarker data, prognostic models, clinical trials, Independent Data Monitoring Committees and meta-analyses in oncology.
Stefan holds a PhD in Biostatistics from the School of Public Health at the Paris XI University and Master Degrees in Statistics and in Applied Mathematics from the University of Leuven. His previous positions include the Institut Gustave Roussy (France), the National Cancer Institute (France) and the University of Leuven. He has authored about 60 peer-reviewed publications in journals such as Lancet, JAMA, Lancet Oncology, NEJM, Journal of Clinical Oncology, Journal of Clinical Epidemiology, Statistics in Medicine, Bioinformatics and Statistical Methods in Medical Research. He is a member of

the Translational Research Advisory Committee of the EORTC, of the editorial board of Biometrics and Cancer Prevention Research and does regular statistical reviews for The Lancet journals.

Dr. Luis Paz-Ares

Dr Paz-Ares is currently Chair of the Oncology Department at the Hospital Universitario Virgen del Rocío, Seville, Spain. He obtained his medical degree in 1986 from the Universidad Autonoma, where he also completed his studies for a PhD in Oncological Medicine in 1993. In 1995 he obtained his MSc in Clinical Pharmacology from the University of Glasgow, UK, and in 2003 he was awarded a Master degree in Clinical Units Management from the Universidad UNED, Madrid.

Dr Paz-Ares originally trained in Medical Oncology and in 1993 he took up a post as a European Society for Medical Oncology (ESMO) Fellow in New Drug Development at the CRC Department of Medical Oncology in Glasgow. In 1995 he moved to the Doce de Octubre University Hospital, Madrid and was Head of the Lung and GU Tumours and Drug Development Units. His main research interests include the testing and development of novel therapies, particularly in lung and genitourinary tumours. He is the author of more than 110 papers in peer-reviewed journals, as well as many book chapters. He is an active member of various scientific societies (including ASCO, ESMO, IASLC and other) and collaborative groups (European Organisation for Research and Treatment of Cancer [EORTC], the Spanish Lung Cancer Group and the International Germ Cell Cancer Collaborative Group).

John Quackenbush, PhD

John Quackenbush received his PhD in 1990 in theoretical physics from UCLA working on string theory models. Following two years as a postdoctoral fellow in physics, Dr. Quackenbush applied for and received a Special Emphasis Research Career Award from the National Center for Human Genome Research to work on the Human Genome Project. He spent two years at the Salk Institute working on developing physical maps of human chromosome 11 and two years at Stanford University working on new laboratory and computational strategies for sequencing the Human Genome. In 1997 he joined the faculty of The Institute for Genomic Research (TIGR) where his focus began to shift to post-genomic applications with an emphasis on microarray analysis. Using a combination of laboratory and computational approaches, Dr. Quackenbush and his group developed analytical methods based on integration of data across domains to learn biological meaning from high-dimensional data. In 2005, he was appointed Professor of Biostatistics and Computational Biology and Professor of Cancer Biology at the Dana-Farber Cancer Institute (DFCI) and Professor of Computational Biology and Bioinformatics at the Harvard School of Public Health. Since that time, his work has increasingly focused on the analysis of human cancer using systems-based approaches to understanding and modeling biological problems. In 2009 he launched the Center for Cancer Computational Biology (CCCB) at the DFCI which provides broad-based bioinformatics support to the local research community using a collaborative consulting model.

Roberto Salgado, MD, PhD

Roberto Salgado is board certified in Anatomic Pathology since 2006, has obtained his medical training at the University Hospital of Antwerp (Belgium) and the University Hospital in Leiden (The Netherlands). A PhD-thesis was obtained working with the Translational Cancer Research Group of the AZ Sint-Augustinus Hospital/Antwerp and at the Department of Pathology at the University Hospital of Antwerp; studying the interactions of haemostasis and angiogenesis in breast cancer. His training in Anatomic Pathology and Molecular Pathology took place at the University Hospital Antwerp, the University Hospital Leuven and at the Jules Bordet Institute. Currently he works partly at the Department of Pathology of the Jules Bordet Institute, partly at the Department of Pathology/Translational Cancer Research Group/AZ Sint-Augustinus Hospital in Antwerp. At the Jules Bordet Institute he is currently the quality manager responsible for QA/QC in Molecular Pathology, with a major focus on (1) the implementation of innovative molecular diagnostic techniques, like deep sequencing methodologies in a routine diagnostic and accredited setting; (2) the development of a central digital pathology platform and (3) the enhancement of the integration of the Tumorbank and new Molecular Pathology techniques in innovative clinical trials of the Jules Bordet Institute. He works in close collaboration with the EORTC, of which he is an active member of the Pathobiology Group. He is also an auditor on Molecular Pathology/Genetic laboratories for the Federal Belgian Government and is also an international auditor for the OECI (Organization of European Cancer Institutes).

Aldo Scarpa, MD, PhD

Aldo Scarpa is the Director of the ARC-NET Research Center for the Applied Research on Cancer and has the Chair of the Department of Pathology and Diagnostics at the University and Hospital Trust of Verona.

Dr. Scarpa received his MD from the University of Padua and his PhD in Human Oncology and Molecular

Pathology from the University of Verona. Early in his medical career Dr. Scarpa worked as a family practitioner and served as deputy director of the Clinical Pathology Laboratory of the Military Hospital of Verona before completing his residency in Pathology at the University of Parma.

His current research interest includes molecular pathology, pancreatic cancer and molecular marker discovery in oncology. His work has been published in over 250 peer reviewed publications. Dr. Scarpa has also participated in the creation of facilities addressing cancer research needs such as biobanks (creation/standardization of processes for cancer/normal biological materials and data sets), cancer models (creation of primary human cancer xenografting facility) and molecular diagnostic (development, standardization and automation).

Dr Scarpa was instrumental to the foundation in the early 2000 of the Laboratory of Molecular Diagnostics at the Cancer Center in Cuenca, Ecuador (http://www.institutodelcancer.med.ec/), fully implemented through formation of local people incuding the ability to write projects to raise funds. He received the honorary citizenship of Cuenca, Ecuador.

Dr. Scarpa's recent achievements include the design, financing and development of a research center for the identification and clinical validation of diagnostic/prognostic markers and therapeutic targets in oncology (ARC-NET; www.arc-net.it). He is also responsible for the Italian initiative within the International Cancer Genome Consortium (ICGC) sequencing rare pancreas tumours and collaborates with Australia on pancreas ductal carcinoma.

Lalitha K. Shankar, MD, PhD

Lalitha K. Shankar, MD, PhD is at the Cancer Imaging Program at the National Cancer Institute, at the National Institutes of Health in Bethesda, MD. Since joining NCI in 2002, she has served as an Advisor to the Associate Director of the Division of Cancer Treatment and Diagnosis and is the Chief of the Clinical Trials Branch in the Cancer Imaging Program. The Clinical Trials Branch oversees all aspects of trials evaluating imaging and image-guided interventions from the Phase 0–Phase III trials. The branch activities include programs such as The American College of Radiology Imaging Network (ACRIN) – the imaging cooperative group the Phase I and II Clinical Trials Contract, provision of imaging expertise for ongoing trials of cancer therapeutics sponsored by NCI, trial related informatics and development of guidelines for all trial activities under the Cancer Imaging Program.

Her research interests involve the role of both functional and molecular imaging in the diagnosis and treatment of cancer, as well as evaluating the performance characteristics of imaging modalities for optimal use in the management of the cancer patient. Her work involves establishment of and monitoring of clinical trials to evaluate imaging tracers and techniques, which aim to improve the prevention, diagnosis and treatment of cancer.

Dr. Lalitha K. Shankar received her medical degree in Bangalore University, India and received her MS and PhD in Radiation Sciences at Hahnemann University, Philadelphia. She then trained in clinical Nuclear Medicine and completed fellowships in Positron Emission Tomography and Radio-immunodiagnosis and radio-immunotherapy at the University of Pennsylvania in Philadelphia. Prior to joining the National Cancer Institute, she was a faculty member in the Department of Radiology at Georgetown University and at the Lombardi Cancer Center and also worked in the Division of Nuclear Medicine at Washington Hospital Center.

Sreenath V. Sharma, PhD

Sreenath Sharma is currently a Senior Research Investigator in Oncology Drug Discovery at the Novartis Institutes for Biomedical Research in Cambridge, USA. Prior to joining Novartis, he was Assistant Professor of Medicine at Harvard Medical School, USA, and Assistant Geneticist at Massachusetts General Hospital (MGH) Cancer Center, USA where he was also Assistant Director of the Center for Molecular Therapeutics from 2007 to 2009. Prior to joining MGH in 2005 he was Director of the cDNA Center at the Guthrie Foundation for Education and Research, USA, from 2002 to 2004, Scientific Consultant and Senior Researcher at Kyowa Hakko Kogyo Pharmaceuticals, Japan, from 1999 to 2002 and Assistant Professor of Microbiology and Immunology at the University of Tennessee, USA, from 1988 to 1999. He obtained his PhD in 1986 from the State University of New York at Stony Brook, USA, and did his doctoral dissertation and postdoctoral research training at Cold Spring Harbor Laboratory, USA. His current research is focused on molecularly targeted therapeutics in cancer.

David Sidransky, MD, *Director, Head and Neck Cancer Research Center, Professor of Otolaryngology, Oncology, Pathology, Urology and Cellular and Molecular Medicine, The Johns Hopkins University School of Medicine, The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins*

David Sidransky, MD is a leading expert and pioneer in the molecular genetic detection of cancer. He is the Director of Head and Neck Cancer Research in the Department of Otolaryngology–Head and Neck Surgery at Johns Hopkins University. David Sidransky MD is best

known for his research in biomarkers for early detection and therapy. Currently, his research is concentrating on identifying new genetic changes on smoking-associated tumors, including lung cancer, head and neck cancer and bladder cancer. His laboratory group is also investigating the molecular epidemiology of smoking induced cancers and the link between tobacco smoke and mutations of critical oncogenes (genes that when altered, can cause cancer).

Sidransky received his medical degree from Baylor College of Medicine in 1984, where he also completed a residency in internal medicine. He came to Johns Hopkins in 1988, where he completed a clinical and research fellowship in oncology. Sidransky joined the Hopkins faculty in 1992. He has over 400 peer-reviewed publications, has contributed more than 60 cancer reviews and chapters and also has numerous issued biotechnology that detects genetic biomarkers for cancer in many bodily fluids. The test, which is being studied in bladder, lung, and head and neck cancers, detects malignant cells in a very early stage, before they can be identified by conventional pathology and cytology methods. These same biomarkers have been instrumental in differentiating normal tissue from malignant tissue in head and neck cancer surgery.

He has been the recipient of many awards and honors, including the 1997 Sarstedt International prize from the German society of clinical Chemistry, the 1998 Alton Ochsner Award Relating Smoking and Health by the American College of Chest Physicians and the Richard and Hinda Rosenthal Foundation Award of the American Association of Cancer Research (AACR) for this work.

Jeffrey A. Sosman, MD, *Professor of Medicine, Division of Hematology/Oncology, Ingram Professor for Cancer Research, Mary Hendrickson-Johnson ACS Melanoma Professor, Melanoma Program Director, Cell Proliferation & Signal Transduction Program Co-Leader, Vanderbilt Ingram Cancer Center*

Dr. Sosman leads the Vanderbilt Melanoma Program. He has been an active and well-recognized clinical investigator vested in the therapy of melanoma and renal cancer over the years. He has directed numerous clinical trials studying non-chemotherapy based treatment of cancer. The trials have always included a strong translational component frequently centered on immunotherapy, anti-angiogenic therapy and more recently targeted therapy aimed at mutated or overexpressed oncogenes. At Vanderbilt, Dr. Sosman directs one of the first programs in the nation to offer melanoma patients routine genotyping of their tumors to help identify and treat based on their genetic mutations. He has been a very active researcher, while still providing outstanding clinical care as a physician; putting him among a small group of individuals who can drive science developments in this field into treatments potentially impacting on patient care.

Gabriella Sozzi, PhD

Gabriella Sozzi graduated with full marks in Biological Sciences from the the University of Milan in 1980. Dr. Sozzi had a board certification with full marks and honours in Human Cytogenetics at the University of Pavia in 1991.

In 1980 she became Associate Researcher in the Division of Experimental Oncology A of the Istituto Nazionale Tumori, Milan, Italy. She was Visiting Research Fellow at the Memorial Sloan Kettering Cancer Center, New York, in 1988 (AIRC fellowship) and at the M.D. Anderson Cancer Center, Houston in 1993. In 1986 she was nominated Assistant Professor at the Division of Experimental Oncology A of the Istituto Nazionale Tumori in Milan. In 1996 she worked in the laboratories of Prof. C. Croce at the Kimmel Cancer Center, Thomas Jefferson University, Philadelphia, USA. From 1998 to August 2009 she led the Research Unit "Cytogenetics and Molecular Cytogenetics" and from August 2009 to date she is head of the Research Unit "Cancer Genomics" in Department of Experimental Oncology and Molecular Medicine, Fondazione IRCCS Istituto Nazionale per lo Studio e la Cura dei Tumori, Milano. She also serves as Teaching Professor at the PhD School of Oncology, University of Ferrara and at Master School in Oncology, University of Torino, Italy. She is consultant for Clinical Cytogenetics in the Laboratory of Diagnostic Molecular Pathology, Fondazione IRCCS Istituto Nazionale Tumori of Milan.

Dr. Sozzi has published 170 original articles in peer-reviewed International Journals and has authored several chapters of books.

Her researches are sponsored by Italian Ministry of Health, European Community, Regione Lombardia, AIRC (Associazione Italiana Ricerca Cancro), Fondazione Ermenegildo Zegna.

Paul T. Spellman, PhD

Paul received his training in Biology and Genetics from MIT and Stanford University School of Medicine, where he received SB and PhD respectively. During his PhD Paul was mentored by Drs. David Botstein and Patrick O. Brown; where he worked on a diversity of topics examining the production and analysis of microarray data. After continued training at UC Berkeley with Dr. Gerald M. Rubin, Paul joined Lawrence Berkeley National Laboratory in 2003, where he formed close collaborations with numerous other investigators in the cancer, genomics, and computational biology areas,

particularly, Joe W. Gray. Over the past 8 years, Paul has built a substantial research program focusing on the use of genetics, systems biology, and bioinformatics to understand the causes and identify therapeutic approaches for cancer. For six months in early 2011 Paul was a Special Assistant to the Deputy Director of the NCI, where he advised Dr. Doug Lowy on the application of genomics technology to cancer. In July 2011, Paul joined the faculty of Oregon Health and Sciences University as an associate professor in the department of Molecular and Medical Genetics, a member of the Knight Cancer Center, and the Oregon Center for Spatial Systems Biomedicine. Paul's current research is supported by grants from NCI (PI of a Genome Data Analysis Center for The Cancer Genome Atlas, a core director for the Bay Area Breast SPORE, and a project leader on a large scale systems biology program), DoD where he is coPI with Drs. Peter Lee and Jill Slansky of Stanford and Nationwide Jewish, respectively, Stand Up 2 Cancer, and the Knight Cancer Center.

Fred C.G.J. Sweep, PhD, *Radboud University Nijmegen Medical Centre, Nijmegen, The Netherlands*

Fred C.G.J. Sweep (1959) is full professor of Chemical Endocrinology and head of the department of Laboratory Medicine (300 fte, 30 M€) at the Radboud University Nijmegen Medical Centre (RUNMC). He is board certified in Clinical Chemistry and Endocrinology by the Netherlands Society for Clinical Chemistry and Laboratory Medicine, and registered as a European Clinical Chemist. He studied Medical Biology at the University of Utrecht (1979-1985), where he also obtained his PhD degree (1989) in Pharmacology. He had his training as a clinical chemist at the RUNMC (1991-1995), where he also completed his training in Endocrinology (1998).

Fred Sweep is a reviewer of many journals, member of Editorial boards and has published over 340 papers in peer-reviewed journals (PubMed search code: fred sweep or sweep c or sweep f).

Fred Sweep is an active member of many different national and international societies devoted to cancer biomarkers. He is immediate past secretary of the PathoBiology Group of the European Organisation for Research and Treatment of Cancer (EORTC) and chairman of the Quality Assurance committee within this group. He also was chairman of the Translation Research Advisory Committee of the EORTC and EORTC Executive Committee member (2006-2009). In 2006 he chaired the 4th International NCI–EORTC Meeting on Molecular Markers in Cancer, in Atlanta, USA. Presently, Sweep is president of the Stichting Kwaliteitsbewaking Medische Laboratoriumdiagnostiek (SKML). Fred Sweep's department has developed international Quality Assurance programs for steroid hormone receptors and other biomarkers since 1975. In the early 1990s more than 160 laboratories worldwide participated in these programs. Presently, QA programs are running for large multicentre prospective clinical trials on biomarkers in Europe. His current research interests are focused on development of new antibody based assays for biomarkers in oncology with emphasis on proteases and angiogenesis. Within the field of Endocrinology Sweep's department has a long-standing expertise in thyroid and steroid hormones within special interest in the hypothalamus–pituitary–adrenal/gonadal axis and free hormones. The department of Laboratory Medicine harbours all up-to-date laboratory facilities for Clinical Chemistry, Endocrinology, Haematology, Immunology, Paediatrics and Neurology.

Josep Tabernero, MD, *Head, Medical Oncology Department, Vall d'Hebron University Hospital, Barcelona, Spain*

Josep Tabernero received his medical degree from the Universitat Autònoma de Barcelona, Spain. Afterwards, he completed his specialist training in medical oncology and has had appointments in Barcelona.

Dr. Tabernero is currently the Head of the Medical Oncology Department at the Vall d'Hebron University Hospital in Barcelona, Spain. He is also the head of the Gastrointestinal Tumors and Phase I Unit and is actively involved in translational research and pharmacodynamic phase I studies with molecular targeted therapies and related translational research, with a special focus on EGFR-family inhibitors and IGFR–PI3K–Akt–mTOR pathway inhibitors, and also in phase II and III studies with new chemotherapy agents in gastrointestinal tumors.

In addition, Dr. Tabernero is a member of the European Society for Medical Oncology (ESMO) and the American Society of Clinical Oncology (ASCO), and different Editorial Boards including the Journal of Clinical Oncology, Clinical Cancer Research, Clinical Colorectal Cancer and Annals of Oncology. He has (co)authored approximately 150 peer-reviewed papers. He has also been member of the Educational and Scientific Committees of the ESMO, ECCO, ASCO, AACR/NCI/EORTC, ASCO Gastrointestinal, and WCGIC meetings.

Sheila E. Taube, PhD

Sheila E. Taube received her B.A. in Biology from Brandeis University and her PhD in Microbiology from the University of Pittsburgh School of Medicine. She joined the faculty of the University of Connecticut Medical School following postdoctoral work at Yale University.

In 1983 Dr. Taube joined the Cancer Diagnosis Branch at the National Cancer Institute (NCI) and became Chief of the Branch in 1986. She became Associate

Division Director, Director of the Cancer Diagnosis Program (CDP) in 1997. This Program is responsible for developing initiatives to capitalize on the explosion of new information from the human genome program and the emergence of powerful new technologies to examine cancer cells. The Program is also responsible for creating an infrastructure of resources to facilitate research; this includes development of specimen resources for research.

In September 2000, Dr. Taube and the CDP launched the Program for the Assessment of Clinical Cancer Tests (PACCT). This program is designed to ensure efficient and effective translation of new diagnostic knowledge and technology into clinical practice. The first prospective trial using a molecular signature for risk of recurrence in early stage breast cancer, the TAILORx trial, was developed as part of PACCT.

Dr. Taube serves on the American Society of Clinical Oncology's Expert Panel to develop practice guidelines for the use of tumor markers for breast and colorectal cancer. She co-edited a special issue of Seminars in Oncology (2002) devoted to development of tumor markers. Dr. Taube co-authored the guidelines for reporting studies of prognostic markers (REMARK) published in the JNCI (and 5 other journals simultaneously). Dr. Taube collaborated with the EORTC to launch the "Molecular Markers for Cancer: From Discovery to Clinical Practice" series of international meetings. In 2004, she and colleagues developed the syllabus for the current Tutorial. Dr. Taube served on the FDA Immunology Devices Advisory Panel for over five years. She currently serves as a reviewer on the Special Evaluation Panel for NCI's Clinical Assay Development Program.

Dr. Taube retired from the National Cancer Institute in 2008 and established ST-Consulting.

Lyubomir Vassilev, PhD

Dr. Lyubomir Vassilev is a Distinguished Research Leader in the Oncology Division of Roche, Nutley, New Jersey. He has 18 years of experience in leading small-molecule drug discovery efforts in Oncology. Dr. Vassilev's expertise covers the whole spectrum of activities involved in the discovery and development of cancer therapeutics: discovery and validation of molecular targets, assay development and high throughput screening, identification and optimization of drug leads. His primary research interests include mechanisms of signal transduction and cell cycle control and their deregulation in cancer. Dr. Vassilev received his PhD degree in Molecular Biology from the Institute of Molecular Biology, Bulgarian Academy of Sciences where he worked on the structure and function of chromatin. He did his post-doctoral training at the Brookdale Center for Molecular Biology, Mount Sinai School of Medicine, New York, NY, and the Roche Institute of Molecular Biology, Nutley, NJ, working on the mechanisms of mammalian DNA replication.

Mariusz A. Wasik, MD, *Professor, Department of Pathology and Laboratory Medicine, University of Pennsylvania, Philadelphia, USA*

Dr. Wasik received his MD degree in Wroclaw Poland and trained in immunology and pathology at several institutions including Harvard Medical School. He frequently serves as a member of grant review committees for the National Institute of Health and other funding organizations. He authored over 130 publications with the main focus on cell signal transduction and epigenetic gene silencing in cancer cells. The three key areas of his current research are:

1. Mechanisms of malignant cell transformation by the chimeric ALK kinase. He and his colleagues found that pathways involving STAT3, PI3K/AKT, MEK/ERK, mTORC1 and STAT5b but not STAT5a are constitutively activated by one of the chimeric forms of ALK, NPM/ALK. This aberrant signaling triggered by NPM/ALK affects proteins on the immune evasion and epigenetic gene silencing of tumor suppressor genes.
2. mTOR signaling in cancer. Studies by his team indicate that rapamycin-related mTORC1 inhibitors have strong inhibitory effect on the whole spectrum of B- and T-cell lymphomas. The mechanism of mTORC1 activation is lymphoma-type dependent and involves the key oncogenic signals as well as PI3K/AKT, MEK/ERK, and other signaling pathways upstream of mTORC1. The current efforts focus on further characterization of the mechanisms of mTORC1 activation, methods of in vivo visualization of mTORC1 inhibition, combination of mTORC1 inhibitor with other inhibitors, and analysis of the mTORC2 pathway.
3. Signaling of IL-2R-type receptors in malignant transformation of T lymphocytes. The studies indicate that cutaneous T-cell lymphoma displays activation of IL-2R-associated Jak/STAT signal transduction pathway that is transient in the early stage and constitutive in the late stage of the lymphoma. The constitutive Jak/STAT activation is due, at least in part, to the lack of expression of SHP-1 phosphatase, which normally down-regulates signaling by receptors for antigens, cytokines, and other ligands. SHP-1 gene is silenced due to CpG methylation of its promoter. STAT3 as well as at least two members of the epigenetic gene silencing machinery – DNA methyltransferase (DNMT1) and histone deacetylase (HDAC1) – are involved in silencing of the SHP-1 gene. STAT3 acts by both fostering the silencing at the SHP-1 gene promoter level and inducing DNMT1 expression.

Lodewyk F.A. Wessels, PhD

After obtaining a PhD in Electronic Engineering he joined Delft University of Technology. In 2006 he became a faculty member and head of the Bioinformatics and Statistics group at the Netherlands Cancer Institute (NKI-AVL) in Amsterdam, The Netherlands. His research mainly focuses on developing novel computational approaches to exploit a wide variety of data sources to expand our understanding of the biology underlying oncogenesis and to improve cancer diagnostics and treatment. More specifically building predictors based on multiple types of molecular data to predict outcome and response to therapy and extracting oncogenic networks from hight throughput data sources. Dr Wessels is co-director of the Cancer Systems Biology Center at the NKI-AVL. The goal of this center is to build in silico models of signaling pathways in (breast) cancer to enable improved diagnosis and therapy selection.

D. Lawrence Wickerham, MD

Dr. Wickerham is the Associate Chairman of the National Surgical Adjuvant Breast and Bowel Project (NSABP), which has its Operations and Biostatistical Centers located in Pittsburgh, PA, but has participating sites throughout the USA, Canada, Puerto Rico, Ireland, Australia, New Zeland, and Korea. Dr. Wickerham is also the Protocol Officer for the NSABP chemoprevention trials and an Associate Professor of Human Oncology at the Pittsburgh Campus of Drexel University School of Medicine and the Chief of Cancer Genetics and Prevention at Allegheny General Hospital in Pittsburgh, PA. He is a graduate of the University of Pittsburgh School of Medicine and Washington and Jefferson College in Washington, PA.